POLICY ROUNDTABLES

Generic Pharmaceuticals

2009

Introduction

The OECD Competition Committee held a roundtable discussion on Generic Pharmaceuticals in October 2009. This document includes an executive summary and the documents from the meeting: an analytical note by the staff of the United States Federal Trade Commission, written submissions from Canada, the Czech Republic, the European Commission, India, Indonesia, Ireland, Italy, Japan, Korea, Norway, the Russian Federation, South Africa, Spain, Sweden, the United Kingdom, the United States, and BIAC, as well as an aide-memoire.

Overview

Practices that may harm competition in the pharmaceutical sector have emerged as important and controversial issues in recent years. The Committee examined the nature of competition between generic and branded products in the pharmaceutical sector, as well as the effects on competition of agreements to delay the entry of generics on the market. The discussion showed that the pharmaceutical sector is highly regulated, driven by R&D, and very dependent on patent protection. It also revealed that regulation of pharmaceutical prices and other factors has mixed effects, solving or mitigating some problems while creating or worsening others. One lesson was that competition authorities should be involved not only in competition enforcement settings but also in the regulatory regimes that cover this sector (both the branded and generic components).

Related Topics

Competition, Patents and Innovation II (2009)
Competition, Patents and Innovation (2006)
Intellectual Property Rights (2004)
Competition in the Pharmaceutical Industry (2001)

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ROUNDTABLE ON GENERIC PHARMACEUTICALS

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FOREWORD

This document comprises proceedings in the original languages of a roundtable on Generic Pharmaceuticals, held by the Competition Committee in October 2009.

It is published under the responsibility of the Secretary General of the OECD to bring information on this topic to the attention of a wider audience.

This compilation is one of a series of publications entitled "Competition Policy Roundtables".

PRÉFACE

Ce document rassemble la documentation dans la langue d'origine dans laquelle elle a été soumise, relative à une table ronde sur les médicaments génériques dans les marchés publics qui s'est tenue en octobre 2009 dans le cadre du comité de la concurrence.

Il est publié sous la responsabilité du Secrétaire général de l'OCDE, afin de porter à la connaissance d'un large public les éléments d'information qui ont été réunis à cette occasion.

Cette compilation fait partie de la série intitulée "Les tables rondes sur la politique de la concurrence".

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EXECUTIVE SUMMARY

By the Secretariat

(1) Competition from generic drugs is a desirable policy objective as it typically brings substantial savings to pharmaceutical buyers. However, it should be balanced against the incentives brand manufacturers need to invest in developing innovative new products.

Competition between branded and generic pharmaceutical manufacturers can provide consumers with substantial savings. In the US, the first generic competitor typically enters the market at a price that is 20 to 30 percent lower than its brand name counterpart, and savings may reach up to 80 percent in the long run. In Europe, savings are estimated to be around 20 percent in the first year of generic entry, rising to 25 percent after two years.

Branded pharmaceutical manufacturers face very high fixed costs for the production of new drugs and estimates of average R&D costs for successful drugs can reach hundreds of millions of dollars. Initial prices for new drugs entering the market will therefore be high, to allow the branded manufacturer to recover its fixed costs and be adequately compensated for its risk-adjusted investment. Patents awarded to new drug manufacturers do not necessarily confer market power, but they do confer the exclusivity necessary to stimulate innovation. Once the branded firm has recouped its investment, generic producers should then be allowed onto the market. However, consumers benefit not just when existing drugs sell at lower prices, but also when new and more effective drugs reach the market over time. The positive welfare effects from such long term benefits can be much greater than the static benefits from short term price decreases.

(2) The effects of generic drug competition vary across jurisdictions depending on the rules and regulatory regimes in place. However, those effects are positive for consumers across all jurisdictions.

The effects of generic drug competition can vary substantially from country to country depending on a number of factors. If the prices of branded drugs are regulated, generic competition on the market will have less of an effect than if prices are unregulated. Rules that limit the prices that pharmaceutical manufacturers can charge reduce the margins within which generic firms can compete. Regulations may be in place that affect the number of generic entrants able to operate on the market. Differences in the number and types of health insurance providers and the methods by which insurers reimburse drug costs also matter. Research has shown that generic competition has had a significant effect on prices in countries that encourage generics through reference-pricing based reimbursement systems as well as countries that create significant incentive programs for doctors to prescribe generics. By contrast, countries that have stringent price regulation of new product launches and declining prices over time, along with competitive barriers in their pharmacy distribution system, have experienced smaller savings from generic competition. However, while generics can have a variety of effects and may bring different levels of reward, there is no evidence of generic entry having a negative effect on consumers in pharmaceutical markets.

(3) *To encourage generic entry and foster competition, various jurisdictions have adopted incentives and/or taken steps towards legal and regulatory reform in the pharmaceutical market.*

A number of jurisdictions commented on policies (either currently in place or proposed) that are intended to increase competition from generic products in the pharmaceutical sector. Some countries have implemented mandatory generic substitution regimes that oblige pharmacies to provide the generic alternative to the branded drug. Other countries use strong price control regimes to regulate the prices of generic drugs. Legislative intervention has also been used to reduce extensive patent coverage.

The use of incentives is central to encouraging increased generic entry. Doctors should be encouraged to prescribe generic products, and where a prescription is written in general terms, pharmacists should be encouraged to dispense the generic product. In one jurisdiction, proposals have been made for pharmacists to substitute generics even when the branded product is prescribed. Other jurisdictions have increased advocacy efforts to promote competition in the pharmaceutical sector, for example with the establishment of action plans to promote the safe use of generic drugs. Still other countries recommended improving distribution methods for distributing generic pharmaceuticals, such as by using pooling systems, national logistical distribution systems, prescription software systems, and prescription data analysis.

The EU Pharmaceutical Sector Inquiry Final Report makes clear that companies operating in the sector should expect increased antitrust scrutiny by the EU of their patent related conduct and agreements with competitors to the extent they may delay entry of a generic drug or stifle innovation by a competitor. The Report also supports the idea of a community patent and the creation of a specialised and unified patent litigation system in Europe. These changes would avoid unnecessary duplication, contradictory judgments and rising litigation costs.

(4) *To prevent or delay generic entry, branded manufacturers may offer potential generic competitors a 'reverse payment' or 'pay for delay settlement'. This type of payment is a strategy used by branded manufacturers to keep generics from entering the market, and can be one of the most harmful for consumers.*

In a typical 'reverse payment' or 'pay for delay settlement', a branded manufacturer will pay the potential generic entrant an amount of money in exchange for the generic company delaying its entry into the market. In the absence of such agreements, the generic would be expected to enter at an earlier date. These settlements are among the most frequently used strategies to reduce competition on the pharmaceutical market in the US, and are also of substantial concern in Europe. The agreements allow the branded and generic manufacturer to share excess profit which otherwise would go to the consumer. A US Federal Trade Commission study estimated that banning these settlements would result in $3.5 billion in annual savings. The consumer and social welfare losses can be many multiples of the original payment from the branded firm to the generic firm. That is because there is a significant gap between what the branded firm will lose from generic competition and what the generic firm will gain, and therefore a relatively modest payment can preserve a very substantial profit margin.

(5) *Three other emerging strategies are being adopted by brand name manufacturers to prevent generic entry. These are 'authorised generics',' product hopping' and 'biosimilars'.*

There are both competitive and anti-competitive ways for brand name manufacturers to respond to generic competition. Some examples of pro-competitive practices include reducing prices on existing drugs or introducing improved drugs that leave the generic entrant a generation behind.

The range of potentially anti-competitive strategies adopted by branded manufacturers is broader. In addition to pay for delay settlements, newer forms of competition include strategic use of authorised generics and product hopping and the increased use of biosimilars.

'Authorised generics' are generic versions of a branded drug, issued by the brand manufacturer. Brand name companies do not routinely place authorised generics on the market, but their production can be a tactic to deter entry by generics manufacturers. However, evidence indicates that consumers may benefit from authorised generics, even when third party generics are already in the market.

'Product hopping' occurs when brand name companies introduce new patented products that have minor or no substantive improvements as soon as generic entry is imminent. The introduction of these new products is intended to discourage doctors and pharmacies from substituting lower price older generation generic products.

'Biosimilar' drugs are subsequent versions of earlier biologic drugs. Such drugs are more complex and expensive to develop than small-molecule pharmaceutical products. In the US, legislation passed in May 2010 provides the reference biologic drug with a regulatory exclusivity period of 12 years, during which no biosimilar product can be approved for sale. Follow-on biosimilar drug entry by generic companies is therefore delayed.

SYNTHÈSE

Par le Secrétariat

(1) *La concurrence des médicaments génériques est un objectif souhaitable d'une politique de santé dans la mesure où, en général, elle permet aux acheteurs de produits pharmaceutiques de réaliser des économies considérables. Toutefois, cet objectif doit être concilié avec la nécessité d'inciter les fabricants de médicaments de marque à investir dans la mise au point de nouveaux produits innovants.*

La concurrence entre les fabricants de produits pharmaceutiques de marque et les produits génériques peut permettre aux consommateurs de réaliser des économies considérables. Aux États-Unis, le premier concurrent produisant des médicaments génériques accède généralement au marché à un prix inférieur de 20 à 30 % à celui du produit de marque concurrent et les économies réalisées peuvent atteindre jusqu'à 80 % à long terme. En Europe, les économies sont estimées à environ 20 % au cours de la première année de lancement du médicament générique et elles atteindraient 25 % au bout de deux ans.

Les fabricants de produits pharmaceutiques de marque doivent faire face à des coûts fixes très élevés pour la production de nouveaux médicaments et d'après les estimations, les coûts moyens de recherche-développement pour le lancement de médicaments performants pourraient atteindre des centaines de millions de dollars. Les prix initiaux des nouveaux médicaments accédant au marché seront par conséquent élevés, pour permettre au fabricant de produits de marque de récupérer ses coûts fixes et d'être suffisamment rémunéré pour son investissement ajusté en fonction du risque. Les brevets accordés aux fabricants de nouveaux médicaments ne confèrent pas nécessairement un pouvoir de marché mais ils confèrent bien l'exclusivité nécessaire à la stimulation de l'innovation. Une fois que l'entreprise produisant le médicament de marque a récupéré son investissement, les producteurs de médicaments génériques doivent donc être admis sur le marché. Toutefois, les consommateurs ne tirent pas seulement un bénéfice de la vente des médicaments existants à des prix plus bas, mais aussi de la mise sur le marché de nouveaux médicaments plus efficaces au fil du temps. Les effets positifs de ces avantages à long terme sur le bien-être peuvent être beaucoup plus importants que les avantages statiques qui résultent de réduction de prix à court terme.

(2) *Les effets de la concurrence des médicaments génériques varient selon les pays et selon les règles et dispositifs réglementaires en vigueur. Toutefois, ces effets sont positifs pour les consommateurs dans toutes les juridictions.*

Les effets de la concurrence des médicaments génériques peuvent varier sensiblement d'un pays à l'autre en fonction d'un certain nombre de facteurs. Si les prix des médicaments de marque sont réglementés, la concurrence des médicaments génériques sur le marché aura moins d'effet que si les prix sont fixés librement. Les réglementations limitant les prix que les laboratoires pharmaceutiques peuvent pratiquer réduisent les marges à l'intérieur desquelles les fabricants de médicaments génériques peuvent soutenir la concurrence. Il peut exister des réglementations affectant le nombre de nouveaux fabricants de médicaments génériques en mesure d'opérer sur le

marché. Les différences dans le nombre et les catégories de fournisseurs d'assurance maladie et les méthodes par lesquelles les assureurs remboursent le coût des médicaments interviennent également. Des recherches ont montré que la concurrence des médicaments génériques a eu un effet sensible sur les prix dans les pays qui encouragent ce type de produits par des systèmes de remboursement fondés sur des prix de référence ainsi que dans les pays qui ont mis en place des programmes qui incitent fortement les médecins à prescrire des médicaments génériques. En revanche, les pays qui appliquent une réglementation stricte des prix des nouveaux produits lancés et dans lesquels les prix baissent au fil du temps, tandis que le système de distribution de produits pharmaceutiques comporte des obstacles à la concurrence, ont fait apparaître des économies moindres du fait de la concurrence des produits génériques. Toutefois, si ces produits peuvent avoir des effets variables et procurer des avantages différents, il n'est pas prouvé que l'accès de ces produits ait un effet négatif sur les consommateurs de produits pharmaceutiques.

(3) Pour encourager le lancement de produits génériques et favoriser la concurrence, diverses juridictions ont adopté des mesures incitatives et/ou pris des mesures visant à réformer la législation et la réglementation du marché des produits pharmaceutiques.

Un certain nombre de juridictions ont fait part de politiques (déjà en vigueur ou envisagées) ayant pour objet de renforcer la concurrence des produits génériques dans le secteur pharmaceutique. Certains pays ont mis en œuvre des régimes obligatoires de substitution de produits génériques en vertu desquels les pharmacies sont tenues de fournir le substitut générique du médicament de marque. D'autres pays ont recours à des systèmes stricts de contrôle des prix pour réguler les coûts des médicaments génériques. Des mesures législatives ont également été prises pour réduire le champ d'application des brevets.

Le recours aux mesures d'incitation joue un rôle essentiel dans l'accroissement de l'offre de médicaments génériques. Les médecins doivent être encouragés à prescrire des produits génériques et lorsqu'une ordonnance est rédigée en termes généraux, les pharmaciens doivent être incités à fournir le produit générique. Dans une juridiction, des propositions ont été faites pour que les pharmaciens substituent des produits génériques même lorsque le médicament de marque est prescrit. D'autres juridictions ont intensifié les mesures de sensibilisation visant à promouvoir la concurrence dans le secteur pharmaceutique, par exemple, en mettant en place des plans d'action pour favoriser la sécurité d'utilisation de médicaments génériques. D'autres pays encore ont recommandé l'amélioration des méthodes de distribution de produits pharmaceutiques génériques, notamment en ayant recours à des regroupements, à des systèmes logistiques nationaux de distribution, à des systèmes de logiciels de prescription, et à l'analyse des données concernant les prescriptions.

Le rapport final d'enquête de l'Union européenne sur l'industrie pharmaceutique précise que les entreprises qui opèrent dans ce secteur doivent s'attendre à un renforcement de la surveillance par les autorités européennes de contrôle de la concurrence en ce qui concerne leur comportement en matière de brevets et leurs ententes avec des concurrents, dans la mesure où ces pratiques peuvent retarder l'entrée d'un médicament générique sur le marché ou entraver l'innovation d'une entreprise concurrente. Le rapport est par ailleurs favorable à la notion de brevets communautaire et à la création d'un système de contentieux spécialisé et unifié en matière de brevets dans le cadre européen. Ces réformes permettraient d'éviter les doubles emplois, les jugements contradictoires et l'augmentation du coût des procédures judiciaires.

(4) Pour empêcher ou retarder l'entrée de médicaments génériques sur le marché, les fabricants de médicaments de marque peuvent offrir à leurs concurrents potentiels un « paiement inversé » ou un « paiement au titre d'un retard ». Ce type de paiement s'inscrit dans une stratégie utilisée par

les fabricants de médicaments de marque pour empêcher les produits génériques d'accéder au marché et peut constituer l'une des pratiques les plus dommageables pour les consommateurs.

Dans un cas type de « paiement inversé » ou de « paiement au titre d'un retard», un fabricant de médicaments de marque verse à un fournisseur potentiel de produits génériques une somme d'argent en échange de laquelle l'entreprise en question retardera son accès au marché. En l'absence de tels accords, le produit générique devrait accéder au marché plus rapidement. Ces types de règlements font partie des stratégies les plus fréquemment utilisées pour réduire la concurrence sur le marché pharmaceutique aux États-Unis et sont également très préoccupants en Europe. De tels accords permettent aux fabricants de produits de marque et de produits génériques de partager le surprofit qui devrait normalement revenir aux consommateurs. Une étude de la Federal Trade Commission des États-Unis a estimé que l'interdiction de ce type de versements permettrait de réaliser une économie annuelle de 3.5 milliards USD. Les pertes de bien-être pour les consommateurs et pour la collectivité peuvent représenter plusieurs fois le versement initial de l'entreprise qui fabrique le médicament de marque à celle qui fabrique le produit générique. En effet, il existe un écart important entre ce que l'entreprise qui fabrique le médicament de marque perdra du fait de la concurrence des produits génériques et ce que gagnera le fabricant de produits génériques, et par conséquent un versement relativement modéré peut permettre de préserver une marge bénéficiaire considérable.

(5) Trois autres stratégies nouvelles sont adoptées par les fabricants de produits de marque pour empêcher l'entrée de médicaments génériques. Il s'agit des « génériques autorisés », du « saut sur un autre produit » et des « produits biosimilaires ».

Pour les fabricants de médicaments de marque, il existe à la fois des méthodes concurrentielles et anticoncurrentielles pour faire face à la concurrence des médicaments génériques. Parmi les exemples de pratiques favorables à la concurrence, on peut citer la réduction des prix des médicaments existants ou le lancement de médicaments améliorés qui laissent le fournisseur de produits génériques une génération en arrière. L'éventail des stratégies anticoncurrentielles pouvant être adoptées par les fabricants de médicaments de marque est plus large. Outre les versements au titre des retards de mise sur le marché, de nouvelles formes de concurrence comportent l'utilisation stratégique de génériques autorisés, le saut sur un autre produit et l'utilisation accrue de produits biosimilaires.

Les « génériques autorisés » sont des versions génériques d'un médicament de marque produit par le fabricant de ce médicament. En général, les fabricants de médicaments de marque ne mettent pas des génériques autorisés sur le marché mais leur production peut constituer une tactique pour dissuader les fabricants de génériques d'entrer sur le marché. Toutefois, des données disponibles montrent que les consommateurs peuvent bénéficier des génériques autorisés, même lorsque des génériques produits par des tiers sont déjà offerts sur le marché.

Le « saut sur un autre produit » intervient lorsque le laboratoire propriétaire de la marque introduit de nouveaux produits brevetés qui représentent une amélioration mineure ou non significative lorsque l'entrée d'un médicament générique sur le marché est imminente. L'introduction de ces nouveaux produits a pour objet de dissuader les médecins et les pharmaciens de leur substituer des produits génériques moins chers de l'ancienne génération.

Les médicaments « biosimilaires » sont de nouvelles versions de médicaments biologiques plus anciens. Ces médicaments sont plus complexes et plus coûteux à mettre au point que les produits pharmaceutiques à petites molécules. Aux États-Unis, une loi votée en mai 2010 prévoit epour les médicaments biologiques de référence un délai d'exclusivité de 12 ans pendant lequel aucun produit biosimilaire ne peut être autorisé à la vente. Le lancement ultérieur de médicaments biosimilaires par les fabricants de produits génériques se trouvent donc retardé.

BACKGROUND NOTE

by the Secretariat

1. Introduction

This background paper will discuss entry by generic drug manufacturers into pharmaceutical markets and the associated challenges for competition policy. The objective is to provide background on the key policy issues that arise with respect to generic entry and on the factors that influence the consumer welfare effects of generic drug competition.

The pharmaceutical market is generally susceptible to two kinds of competition: competition among different brand-name drugs designed to treat the same condition and competition from generic manufacturers of drugs that are equivalent to branded drugs that have already had success in the marketplace. Both forms of competition benefit society by reducing prices and motivating innovation. This note will focus on the particular issues that arise from generic competition.

Generic entry into pharmaceutical markets raises a number of important questions and challenges for competition policy. As will be discussed below, generic entry can reduce prices and thereby benefit final consumers, insurance providers, and governmental health programs. Yet the desirability of the price reductions pursuant to generic entry must be considered in light of the need to maintain incentives in the pharmaceutical marketplace for development of new drugs and continued investment in the improvement of mature drugs.

This note will examine the benefits of generic entry and discuss how the static price benefits of generic competition relate to the dynamic benefits of research and development (R&D) related to new drugs. It will then examine different modes of generic entry and their potential costs and benefits. The note will then discuss the questions and challenges for competition policy raised by generic entry into pharmaceutical markets.

2. Price effects of generic entry

Pharmaceutical firms usually produce drugs at low cost but sell them at high prices; "high" at least by the economic standard of market price in relation to some measure of incremental production costs like marginal or average variable costs. The high price-cost margins of pharmaceuticals provide a lot of room for generic competitors to cut price while still earning a profit. But drugs are not widgets and there are good reasons for the high margins on drugs, at least for a period of time.

New drugs typically have very high fixed costs of production. Estimates of the average research-and-development (R&D) costs for successful drugs are in the hundreds of millions of dollars.[1] Once a firm develops a drug, brings it through clinical trials, and successfully introduces it to consumers, the drug's retail price will be high. The price will be high both because the fixed costs must be recovered and because, absent competition from other branded drugs treating the same condition, the producer typically has a monopoly protected by intellectual property rights to the drug. Under monopoly, the price may be

[1] Adams CP. Estimating the cost of new drug development: is it really $802 million? *Health Affairs*. 2006;25(2):420–428.

higher than necessary to compensate the innovator for its risk-adjusted investment and, absent market entry, there is usually nothing to stop the incumbent firm from maintaining non-competitive prices long after it has profitably recouped its investment; hence the importance of competition from firms producing generic versions of the incumbent's brand-name drug, even while recognizing the economic necessity of some period of exclusivity and supra-competitive returns for the brand-name innovator.

Competition between branded and generic pharmaceutical manufacturers can provide consumers with substantial savings. While, as we will discuss, the magnitude of savings depends on many regulatory and market factors, in most jurisdictions the competitive effect of generic entry on drug prices is significant. For example, studies of pharmaceutical markets in the United States indicate that the first generic competitor typically enters the market at a price that is 20 to 30 percent lower than that for the brand-name counterpart and gains substantial share from the brand-name product in a short period of time.[2] Subsequent generic entrants may enter at even lower prices – discounted as much as 80 percent or more off the price of the brand-name drug – and prompt the earlier generic entrants to reduce their prices. Thus, as the number of generic versions of a drug increases, prices to consumers go down even further. Because of their lower prices as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture anywhere from 44 to 80 percent of branded sales within the first full year after launch of a lower-priced generic product.[3]

In the European Union, estimates of the consumer benefits from generic drug competition cluster around a 20 percent savings within one year after the first generic firm enters the market and about 25 percent after two years (EU average) off the monopoly brand-name price.[4] One 2006 study examining the pharmaceutical markets of 11 European countries calculated savings from generic substitution for the top ten branded substances by public expenditure in each country, based on data from 2004.[5] The study found that increased generic substitution would bring additional savings of at least 21 percent in each country examined, with higher savings rates estimated at 48 percent for Denmark, 47 percent for Germany, 35 percent for France, 33 percent for the UK and Spain, and 31 percent for Italy.[6]

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2 *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) ("CBO Study"), *available at* http://www.cbo.gov/showdoc.cfm?index=655&sequence=0 (hereinafter "CBO Study"); *see generally* David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87.

3 CBO Study, xiii.

4 European Commission, Pharmaceutical Sector Inquiry Final Report, (July 8, 2009), at 94, *available at* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html (hereinafter: Pharma SI Report). The Pharma SI Report also highlights that in relation to a sample of medicines analyzed in the period 2000 to 2007, estimated savings due to generic entry could have been 20% higher than they actually were, if entry had taken place immediately following loss of exclusivity. According to the in-depth analysis of this sample, the aggregate expenditure amounting to about EUR 50 billion for the period after loss of exclusivity would have been about EUR 15 billion higher without generic entry (evaluated at constant volumes). However, additional savings of some EUR 3 billion could have been attained had entry taken place immediately. Pharma SI Report, at 94.

5 Simoens, S. & De Coster, S. Potential Savings from Increased Substitution of Generic for Originator Medicines in Europe. *J. Generic Med.* 2006**;** 4(1):43-45.

6 *Id.* Potential savings for the other countries participating in the study were 42% for Belgium and Portugal, 41% for the Netherlands, 27% for Austria, and 21% for Poland. The size of potential savings annually reaches EUR 1 billion in Germany.

In Brazil, there is evidence that generic entry saved approximately USD 5 billion for the healthcare system between 2001 and 2007.[7] In Canada, the prescription of generic drugs saved approximately CAD 3 billion in 2008,[8] with estimated further savings of up to CAD 800 million per year if further generic competition could be encouraged.[9]

3. Factors that affect the impact of generic entry

The variation across jurisdictions in the price benefits of generic drug competition is due to a number of factors. If a country regulates the prices of branded drugs, competition will likely have less of an impact than if prices are unregulated. Rules that limit the prices that pharmaceutical manufacturers can charge likely reduce the margins within which generic firms will compete. Regulations that affect the number of generic entrants may also be important determinants of the price effects of generic competition.

A study published in 2000 by Danzon and Chao examined the effects of generic competition on pharmaceutical prices in countries with varying regulatory regimes.[10] The authors used comprehensive data on outpatient drug sales in 1992 for seven countries (Canada, France, Germany, Italy, Japan, the UK, and the US). Those countries represent a range of price regulation regimes and levels of competition. For example, the US has virtually unregulated pricing of prescription drug products. By contrast, France, Italy, and Japan were characterized by strong systems of price regulation on a product-by-product basis (as well as declining trends in overall drug prices). The UK, Canada, and Germany were intermediate cases with considerable discretion to price new drug products, but they were also subject to profit constraints (the UK), price caps adjusted for inflation (Canada), or a reference pricing reimbursement system (Germany).[11]

One key finding of the 2000 study was that the sensitivity of prices to the number of generic competitors was greatest in the US.[12] The authors found that the US had more generic entrants, more generic price competition, and higher returns to later entrants than in the more regulated price environments. Germany, the UK, and Canada also exhibited significant price sensitivities to generic competitors. Germany, in particular, with its reference price system experienced a correlation between price effects and number of entrants that was similar to that of the US.

The study found little relation between drug prices and the number of generic competitors in Japan, France, and Italy. Those countries' price regulation schemes may therefore have diminished the level and impact of marginal generic competitors. In the cases of France and Italy, generic manufacturers typically introduced products at prices well below the prices they could charge in other major pharmaceutical

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7 *See* The Rising Generic Drugs Market in Brazil, *Daniela Putti*, Oct. 20, 2008, *available at* www.frost.com/prod/servlet/market-insight-top.pag?docid=146732330.

8 Generic Drugs Now Fill Majority of Canadian Prescriptions, Canadian Generic Pharmaceutical Association Press Release (March 26, 2009), *available at:* http://www.canadiangenerics.ca/en/news/mar_26_09.asp.

9 Competition Bureau, Benefiting from Generic Drug Competition in Canada: The Way Forward, November 2008, *available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/GenDrugStudy-Report-081125-fin-e.pdf/$FILE/GenDrugStudy-Report-081125-fin-e.pdf, and Major Savings Available on Generic Drug Spending Through More Competition, Competition Bureau Study Finds, Competition Bureau Press Release (Nov. 25, 2008), *available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/02754.html.

10 Danzon, Patricia M & Chao, Li-Wei. "Does Regulation Drive out Competition in Pharmaceutical Markets?," Journal of Law & Economics, University of Chicago Press, vol. 43(2), Oct. 2000 pp. 311-57, October.

11 Reference pricing is the practice of setting a maximum reimbursement price and then requiring patients to pay any excess if the manufacturer sets the retail price above the reference price.

12 *Id.*

markets, limiting the impact of additional entrants. The regulations also limited the possibility for inflation adjustments, so real product prices exhibited a downward spiral over time even with very few generic entrants. Therefore, companies have little or no incentive to introduce drugs already being produced by multiple firms, and when they do, they often choose to introduce new forms of old molecules to obtain a higher regulated price.

Regulation of retail pharmacies has also affected generic competition in France and Italy. In both countries, pharmacists receive a regulated dispensing margin based on product price, and the requirement to price and dispense drugs on a unitary package basis has reduced the potential for volume discounts. In the case of Japan, physicians dispensed drugs directly and were strongly motivated to prescribe drugs with the highest margin between the reimbursed price and the acquisition price; they thus had no incentive to dispense generics based solely on their lower price.

An important question is whether the regulatory pressures on prices over the product life cycle in countries with stringent price regulation like Japan, France, and Italy achieve similar effects to generic competition in less regulated markets like the US, the UK, or Germany. The evidence shows that the net welfare effects differ significantly in the two contexts. Generic competition has had a significant effect on prices in countries that encourage generics through reference-pricing based reimbursement systems (*e.g.*, Germany) as well as countries that create significant incentive programs for physicians to prescribe generically (the UK). By contrast, countries like France and Italy, which have stringent price regulation of new product launches and declining prices over time, along with competitive barriers in their pharmacy distribution system, have experienced smaller savings from generic competition. The lack of a competitive retail pharmacy system in France and Italy means that pharmacists and wholesalers capture part of the potential savings from lower prices in these countries (as do physicians in Japan from dispensing drugs with the highest margins).

One lesson from the 2000 multi-country study is that a reference-based price system can produce powerful incentives for generic firms to compete and reduce drug prices for a particular molecule. In a reference-based price system, products are classified into groups based on criteria such as chemical composition, mode of action, or therapeutic effects. Each product group gets a "reference price" based on the manufacturer price of a low-priced product in the group - for example, the minimum or median price. The reference price is the maximum reimbursement for all products in the group. Manufacturers may then charge a price above the reference price but patients must pay the difference. If the manufacturer's price is less than the reference price, the savings may be shared between the payer and the dispensing pharmacist, depending on system design. This creates an opportunity for generic firms to gain market share from the branded producer by cutting price. The above finding is significant because following Germany's model,[13] several other countries such as Denmark, Norway, and the Netherlands have adopted reference pricing and have experienced rising levels of generic competition in recent periods.

In the case of the UK, the incentives for generic usage have emanated from physicians. In particular, the British National Health Service (NHS) allows general practitioners who underspend their budgets to

[13] German public authorities were the first to institute a reference price policy with the 1989 health care reform (also called the Blüm reform). According to this legislation (§35 *Sozialgesetzbuch* V), reference prices are defined for drugs containing the same substance, for drugs with similar substances, and for drugs with comparable efficacy. Implementation of the policy occurred in three stages. The first stage began with the Blüm reform in 1989 and concerned only drugs containing the same active molecule, i.e. unpatented brand name drugs and their generic forms. In 1992, the reference pricing system was extended to drugs with active substances that were similar but not identical. Finally, since 1993, the reference pricing system has included products with similar therapeutic effects but chemically different active substances.

reinvest the savings in their practice. Baines, Tally, and Whynes (1997) found the main impact of the fund-holding program was to encourage more generic prescribing.[14]

A brief comparison of the historical paths of policy toward generic drugs in France and the UK illustrates how a variety of factors can influence the impact of generic competition.[15] The development of a generic drug market in France was slow. The weak response to generics was partly due to the already low prices of brand-name drugs in France compared with other EU countries. In the 1990s, France adopted legislation extending the period of patent protection, which delayed the development of generics.[16] The French government did not legally define generics and designate them for reimbursement until 1997.

The UK generics market had a different development curve. Regulation governing profits rather than prices of medicines led to high medicine prices and stimulated market entry of generic medicines.[17] A principal factor in stimulating generics use was the fact that medical students have long been taught to prescribe generic medicines and generic prescribing has been a key part of the generics strategy.[18]

In both France and the UK, financial incentives for both physicians and pharmacists have been an important part of developing the generic drug market. In France, until 1999 pharmacists were paid based on the margins on public prices of medicines, thereby restricting the development of a market for lower priced generic drugs. Since 1999, French pharmacists receive the same margin for the generic as they would for the branded drug. In the UK, pharmacists are paid a flat fee per medicine dispensed plus the list price of the drug; therefore, if they are able to purchase the drug below the list price, they are able to retain a higher margin.[19] Although pharmacists in France have had the right to substitute drugs from a defined list, nevertheless physicians in both countries still retain an important role in the process: in France this means a physician can choose whether to block generic substitution, while in the UK the use of generics is entirely dependent on the physician prescribing by the generic name.[20]

Unlike the US, neither the UK nor France had targeted incentives to patients in the use of generics, although media campaigns in France facilitated wider patient acceptance of generic substitution. In 2002, France agreed to pay physicians higher fees on outpatient visits in exchange for their allowing generic

14 Baines, Tally, and Whynes (1997).

15 Monique Mrazek and Richard Frank, "The Off-Patent Pharmaceutical Market," in Elias Mossialos, Monique Mrazek, and Tom Walley (eds.), *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality*, 2004.

16 To compensate for the delay between the date of filing the patent application and the date of marketing authorization of the medicine, patent protection could be extended by up to seven years. This legislation was introduced in France in 1990, three years before the implementation of the EU Supplementary Protection Certificate (SPC) for a maximum period of five years in 1993. For a discussion on the SPC, see para. 35.

17 Regulation of branded drug prices in the UK is governed by the Pharmaceutical Price Regulation Scheme. This voluntary arrangement between the British Pharmaceutical Industry and the Department of Health does not control prices directly. Instead, pharmaceutical companies strike an agreement enabling them to gain a specific return on capital which is set equal to profits from sales to the NHS minus allowable costs. Companies are free to set launch prices of new medicines as long as they do not systematically exceed the target rate of return on capital. This system has led to higher medicine prices in the UK than in other EU countries. Simoens, S. & De Coster, S., *Sustaining Generic Medicines Markets in Europe*, Research Centre for Pharmaceutical Care and Pharmaco-Economics, KU Leuven, April 2006, at 33.

18 *Id.* at 34.

19 Mrazek and Frank note 15, at 254-255.

20 *Id.*

substitution more often unless this was medically unjustified. These policy developments in France, and particularly the agreement with physicians, were an important part of the sudden growth in the use of generics: rates of generic substitution increased from 18% of drugs for which there were generic versions in 2000 (AFSSAPS 2002) to 48.2% by 2002 (CNAMTS 2003a). However, by 2006, generics accounted for only 17% by volume of all reimbursed medicines, compared with 65% in the UK.[21] These numbers in France increased following the implementation of a reference price scheme covering off-patent drugs in 2003.

Differences in the number and types of health insurance providers may also affect drug prices. Similarly, to the extent that health insurance programs or regulations facilitate or mandate substitution of cheaper generic versions of a drug for the branded drug, the generics' market share will be higher and the total consumer savings will be larger.

The methods by which insurers reimburse drug costs also matter. Patients do not pay directly the full costs of prescription medicines, and health systems must organize the reimbursement to patients and/or distributors of relevant costs. This can be done through state agencies, which usually finance reimbursements from taxes. The UK with its NHS is an example for this type of system.[22] Another way to organize the reimbursement is through relatively autonomous social insurers, as in Germany. Typically, such systems are based on contributory social insurance schemes, which are mainly financed through contributions by insured parties that are based on income earned from employment. However, there appears to be a trend for health insurers to negotiate prices and rebates directly with the manufacturers.

The level of reimbursement is often the subject of controversy between health insurers and pharmaceutical companies. High co-payments can discourage some patients from buying certain pharmaceutical products. In order to find a solution to controversial reimbursement decisions, Member States tend to delegate the cost-benefit assessment of medicines to independent experts such as the National Institute for Health and Clinical Excellence (NICE) in the UK and the Institute for quality and Efficiency in Health Care (IQWIG) in Germany. These institutions assess medicinal products or treatments according to two criteria: the effectiveness of a medicine in providing therapeutic benefits; and the effectiveness of a product or treatment in relation to its cost and alternative products, as a measure of the (relative) efficiency of the medicinal product or treatment.[23]

4. Dynamic incentives to develop new drugs and generic entry

As mentioned, an important consideration in deciding policy toward generic competition relates to incentives to invest in developing new drugs. Generic entry typically occurs some years after the introduction of the brand-name drug. It would of course be possible to achieve larger savings over the life cycle of an existing brand-name drug if the generic firms could enter even sooner. Generic entry that does not undermine branded firms' ability to recoup the returns necessary to justify R&D investment can motivate branded firms to innovate. But any policies designed to promote earlier generic entry must take into account the incentive effects on the pharmaceutical companies that undertake the original R&D necessary to introduce new and improved drugs. No commercial enterprise would incur the substantial fixed costs of such R&D only to have the returns on its investment be appropriated by the producer of a generic bio-equivalent. Generic competition is an unambiguous benefit to consumer welfare only to the extent it does not reduce dynamic incentives for firms to innovate and produce new drugs.

"Brand-name" pharmaceutical firms specialize in developing new and innovative products that are marketed under brand names. New drug development is expensive and risky. Not only does the firm have

21 Generic Market Shares in Europe, 2006,

22 Pharma SI Report, at 47.

23 *Id.*

to find a molecule that treats the targeted condition, but it then must demonstrate the safety and efficacy of the product sufficiently to overcome regulatory gateways to the marketplace. In the EU, new medicinal products must pass through the testing and screening procedures established by the European Medicines Agency, a decentralized EU body that coordinates approvals for the marketing of both human and animal drugs.[24] In the United States, in order to gain regulatory approval to market a new brand-name product a manufacturer must file a "New Drug Application" (or "NDA") with the Food and Drug Administration (FDA). In the filing the manufacturer must submit to the FDA sufficient data to demonstrate the safety and efficacy of the product in its intended use. This approval process can take years, and the cost of developing a new brand-name product can be substantial.[25] One study (DiMasi et al., 2003) estimates branded pharmaceutical companies incurred out-of-pocket research and development costs of $403 million (measured in year-2000 dollars) per approved drug.

Despite the risks and costs, competition among firms to develop new drugs is fierce and competition to innovate is a key element of market performance in the pharmaceutical sector. Consumers benefit not just when existing drugs sell at lower prices, but when new and more effective drugs reach the marketplace over time. The positive welfare effects from such long-run benefits can be much greater than the static price benefits from short-run price decreases. This does not mean, of course, that endless monopolies are warranted for existing pharmaceuticals; it does mean that public policy has to balance static and dynamic welfare effects.

Whereas competition enforcement has been one of the main ways that the government ensures that there is price competition in product markets, intellectual property policy and other means of ensuring periods of market exclusivity are the common means of providing dynamic incentives to innovate. By awarding exclusive rights to an invention for a limited time, the patent system promotes innovation in several ways. It encourages invention, the development and commercialization of inventions, and their public disclosure.[26]

In the US system, patents are provided for in the Constitution. Article I, Section 8 of the Constitution authorizes Congress, in an oft-quoted phrase, "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[27] The Patent Act implements this charge by giving patentees the right to exclude others from making, using or selling a patented invention for 20 years from the filing the patent application.[28] By offering protection from appropriation by others, even after the invention becomes public, patent protection leads inventors to make public what they might otherwise keep secret. The public disclosure of scientific and technical information is part of the consideration that the inventor gives the public in exchange for exclusive rights, and that disclosure can stimulate further scientific progress by others who build upon the invention or identify opportunities for collaboration.[29]

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24 See European Medicines Agency, www.emea.europe.eu.

25 See Cockburn and Henderson, "The Economics of Drug Discovery," in *Pharmaceutical Innovation*, Landau, Achilladelis, and Scriabine, eds., 1999; DiMasi, "New Drug Development in the United States from 1963 to 1999," *Clinical Pharmacological Therapy*, 2001, pp. 286-296; DiMasi, Hansen, and Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, 2003, pp. 151-185.

26 F.M. Scherer, Industrial Market Structure and Economic Performance 440 (2d ed. 1980).

27 U.S. Const. art. I, § 8.

28 35 U.S.C. § 154(a)(2). Earlier versions of the Patent Act conferred similar rights. To obtain a patent, an invention (that is, a product, process, machine, or composition of matter) must be novel, nonobvious, and useful. A patent confers a right to exclude others from making, using, or selling in the United States the invention claimed by the patent for twenty years from the date of filing the patent application.

29 Scherer, *supra* note 26, at 442. *See* Report, Ch.2 at 3-7.

A patent enables an inventor to capture returns from investment by preventing others from appropriating the invention and reducing the price of the final product. Without some such form of excludability, innovators may not be able to appropriate sufficient benefits from their innovation to justify their creative effort. The problem is especially acute when the original inventor's efforts entail substantial fixed costs, and imitators can copy the invention cheaply, which are common conditions in the pharmaceutical industry.[30] Representatives of brand-name drug companies therefore argue that patent protection is indispensable in promoting the search for new chemical entities that serve as the active ingredients in new drug products.[31] Cross-industry surveys support the claim that patent protection plays a key role in the pharmaceutical sector.[32]

The US FTC, in its 2003 Report, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," described how innovation in the pharmaceutical industry is highly dependent on patent protection, more so than any other industry.[33] Stand-alone innovation in this industry is costly and unpredictable, requiring significant amounts of pioneering research to discover and test new drug products. By preventing rival firms from free riding on discoveries, patents allow pioneer firms to recoup the substantial capital investments made to discover, test, and obtain regulatory approval of new drug products. Patents also help to attract the capital to fund high-risk investment,[34] and the patent system has a proven record of protecting and stimulating biotechnology and pharmaceutical innovation.[35]

Even outside of the realm of IP law, policymakers have granted exclusivity periods to stimulate innovation. The U.S. Congress has implemented exclusivity periods to encourage the development of new and innovative drug products when the drug molecule is in the public domain, and therefore not

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30 Comments of the Pharmaceutical Research and Manufacturers of America (PhRMA), at 2 (February 10, 2009), available at http://www.ftc.gov/os/comments/iphearings/index.shtm.

31 FTC IP Report, Ch. 3 at 11-12.

32 For evidence that patents are relatively more useful for protecting innovations in the pharmaceutical industry (compared to other industries), see W.M. Cohen, R.R. Nelson and J.P. Walsh, "Protecting their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)," Working Paper 7552, February 2000, National Bureau of Economic Research, Cambridge, Mass., revised 2004; Richard Levin, Alvin Klevorick, Richard Nelson, and Sidney Winter, "Appropriating the Returns from Industrial Research and Development," Brookings Papers on Economic Activity (1987, no. 3), pp. 783-820; Edwin Mansfield, "Patents and Innovation: An Empirical Study," Management Science, (1986, vol. 32, no. 2), pp. 173-181.

33 *See* Federal Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (2003), Ch. 3 at 1 [hereinafter "FTC Patent Report"].

34 *Id*, *see also* Arti K. Rai, *Knowledge Commons: The Cost of the Biopharmaceutical Industry*, First Monday (June 2007) ("Small biotechnology firms rely on patents, often on technology that is far removed from an end product, for purposes of deterring misappropriation when they market their technology. Patents also help small biotechnology firms negotiate vertical R&D alliances with pharmaceutical firms. For their part, pharmaceutical firms rely on patents on end product drugs for purposes of recouping research and development costs. [citations omitted.]"), *available at* http://firstmonday.org/htbin/cgiwrap/ bin /ojs/index.php/fm/article/view/1909/1791.

35 F.M. Scherer & David Ross, Industrial Market Structure and Economic Performance, at 621 (3rd Ed., 1990); *see also Patent Reform: The Future of American Innovation, Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Kathryn L. Biberstein, Senior Vice President, Alkermes) at 2; *Patent Reform Act of 2007: Hearing on H.R. 1908 Before the H. Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on Judiciary*, 110th Cong. 65 (2007) (statement of Kevin Sharer, CEO of Amgen), *available at* http://judiciary.house.gov/hearings/April2007/Sharer070426.pdf., *Stifling or Stimulating - The Role of Gene Patents in Research and Genetic Testing Before the H. Comm. on the Judiciary, Subcomm. on Courts, the Internet, and Intellectual Property*, 110th Cong. (2007) (statement of Jeffrey P. Kushan on Behalf of BIO), *available at:* http://judiciary.house.gov/hearings/pdf/Kushan071030.pdf.

patentable.[36] Similarly, exclusivity periods have been used to incentivize post-FDA approval clinical trials for new uses of existing drug products. For example, the Hatch-Waxman Act provides a five-year exclusivity period to incentivize the development of new chemical entities. It also provides a three-year exclusivity period for new clinical investigations ("NCI") of small-molecule drugs.[37]

In other instances, Congress has implemented an exclusivity period when market-based pricing has not provided sufficient incentives to develop drug products for target populations. For example, six-month periods of marketing exclusivity are awarded upon the showing of safety and effectiveness for children. A seven-year marketing exclusivity period is awarded to manufacturers of drug products that treat diseases affecting fewer than 200,000 persons in the United States.[38] Central to each of these exclusivities is a public policy trade-off: a restriction on competition is provided in return for development of a new drug or of a new use for an existing drug that would be less likely to occur without the heightened economic rewards from the statutory exclusivity.

In the EU, the intellectual property regime is supplemented by data exclusivity rules. To gain approval for a drug to enter the market, an original drug producer is required to conduct studies comprised of reviews stemming from clinical tests and expert opinion. Thus, in addition to patent protection, original producers gain data exclusivity for their products, as generic producers are not given access to the data required for drug approval for a specific period of time. The EU has certain provisions that facilitate patent protection and other provisions that facilitate generic entry of pharmaceutical drugs.

First, the EC regulations permit generic producers to work on their drug approvals even while the original molecule is still patent-protected and without the data relating to the original product. This occurs through Directive 2004/27/EC which prescribes that eight years after the original product is marketed, an applicant is not required to provide the results of preclinical tests and of clinical trials if they can show that the medicine is a generic version of the original patented medicine.[39] However, the original producer is granted a 10-year market exclusivity period and the original drug producer may lengthen the 10 year market exclusivity through the provision of a three-part patent protection period known as "8+2+1". In essence, this protection has the effect of extending the patent protection for a product for one year. The three periods refer to the data exclusivity period (8 years), plus the market exclusivity period (2 years), plus the additional year of protection that may be granted if the original producer has obtained a further

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36 *See* BIO Comment (5/1/09) at 7-9 (Benjamin Roin, *Unpatentable Drugs and the Standards of Patentability* 87 TEX. L. REV. (forthcoming)).

37 *See* Appendix B for a description of the marketing exclusivities for small-molecule drug products.

38 *See* Orphan Drug Act ("ODA"), 21 U.S.C.A. § 360aa *et seq.* (2009), 21 C.F.R. § 316 *et seq.;* FDA, Office of Orphan Products Dev't, Cong. Findings For the ODA ("[B]ecause so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss; there is reason to believe that some promising orphan drugs will not be developed unless changes are made in the applicable Federal laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs."), *available at* http://www.fda.gov/orphan/oda.htm. It is likely that the patents for orphan drugs and not the 7-year ODA exclusivity period provide the greatest incentive to innovators. *See* Robert Rogoyski, *The Orphan Drug Act and the Myth of the Exclusivity Incentive,* 7 Colum. Sci. & Tech. L. Rev 2 (2006), http://www.stlr.org/volumes/volume-vii-2005-2006/rogoyski/. According to one study, the majority of orphan drugs are protected by patents with both a broader scope than the disorder specific ODA, and a longer duration than the 7-year ODA exclusivity period. *Id.* at 18, Figure 1.

39 Art. 10, 10a, 10b, 10c of Directive 2004/27/EC, *available at* http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/dir_2004_27/dir_2004_27_en.pdf. Directive 2004/27/EC amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, became fully effective November 2005.

authorization for use of the drug for a new therapeutic application, which has "significant clinical benefit." The one-year extension may also be obtained if the original product switches from being a prescription to an over-the-counter drug, or if it is shown to have "well-established use."[40]

In addition to this extra year, original producers may apply for a supplementary protection certificate (SPC). The purpose of this certificate is to compensate patent holders for the amount of time required to gain regulatory approval before their products could be placed on the market. The application may be filed with the patent office of a member state of the EU in order to extend the patent duration for medicinal products.[41] The filing requirements as laid down in Article 3 of the regulation stipulate that an SPC shall be granted if the product (a) is protected by a basic patent in force, (b) has obtained a valid marketing authorization according to Directive 65/65/EEC or Directive 81/851/EEC, (c) has not already been the subject of an SPC, and (d) the marketing authorization referred to in (b) is the first to place the product on the market as a medicinal product.[42] According to Article 1(b) the product is defined as "the active ingredient" or "a combination of active ingredients."[43] The maximum period of extension is five years after the general patent expires.[44] However, the duration of the SPC may be extended for a further six months, thus coming to a total of five and a half years, when the SPC relates to a human medicinal product for which data from clinical trials conducted in accordance with an agreed Pediatric Investigation Plan have been submitted.[45]

Because of the substantial costs of development, and the low likelihood that any particular drug product will make it through the approval process, firms must anticipate that they will be able to earn a substantial enough return on those products that are successful to cover the costs of unsuccessful efforts in order to have an incentive to invest the resources in the development of new products. By limiting the intensity of direct price competition, patent and other regulatory exclusivities thus strengthen branded pharmaceutical firms' incentives to undertake research and development projects that result in new products.

There is no direct evidence on the effects of generic entry on dynamic innovation in the pharmaceutical sector. At least one study, however, finds that regulation that lowers retail prices for brand-name drugs may reduce investment in the research and development (R&D) necessary for new drugs. The study found that stringent price regulation in countries such as France, Italy, and Japan have had a deleterious effect on drug innovation incentives in these countries.[46] Because, as the data cited earlier in this paper show, generic entry has the same downward effect on retail prices as regulation can have, the study linking increased price regulation with reduced long-run innovation incentives may be instructive.

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40 *Id.*

41 Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ No L 182 of 2.7.1992, p. 1), *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992R1768:EN:HTML.

42 *Id.* at article 3.

43 *Id.* at article 1(b).

44 *Id.* at article 13.

45 Regulation (EC) No 1901/2006 of The European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 article 36, available at http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2006_1901/reg_2006_1901_en.pdf.

46 Grabowski and Wang (2006).

Generic entry could potentially have a more serious impact on innovation than retail pricing rules have. When competitors rather than regulators determine the timing and magnitude of price decreases from the unregulated monopoly level, the effect on retail prices may be bigger and less predictable. For that reason, pharmaceutical firms that develop new drugs may be even more conservative in their calculations of whether to invest in a project when their returns are determined through anticipated but uncertain market competition rather than by a more predictable regulatory process in which the firm can participate. Regulators are, moreover, likely to have more concern for preserving the dynamic innovation incentives of brand-name firms than will generic manufacturers who take their profits at the expense of brand-name firms.

Despite the benefits of IP protections and related exclusivity regulations for pharmaceutical R&D, the dynamic story should not obscure the importance of competition. It is not only the ability to exclude but pressure from competition that motivates innovation. Moreover, exclusion should ideally not be any greater than what is necessary to provide investment incentives, thus unduly broad or long-lasting patents would be unnecessary for innovation and harmful to both long and short-term consumer welfare.

The optimal level of innovation and, similarly, the optimal length and scope of IP protections are extremely difficult to calculate or achieve with any practical precision. For current purposes, this paper will assume that intellectual property rights are sufficient to protect against inefficiently early generic entry and will therefore proceed on the further assumption that generic competition is beneficial. In making this assumption, we recognize that there is substantial controversy over the strength of intellectual property protections in different countries, with allegations that such rights are too strong or too weak often arising within the same jurisdiction. While IP rights that are too weak can reduce innovation incentives and have implications for the net welfare effects of generic entry into pharmaceutical markets, we believe in the first instance that it should be left to IP policy to correct such flaws rather than to compensate through departures from the core objectives of competition policy. With the assumption that IP rights will motivate investment in innovation, we turn next to generic entry in a world of patent-protected pharmaceutical products.

5. Types of generic competition

Generic competition in markets for patented pharmaceuticals can occur in several ways. The simplest scenario is one in which off-brand manufacturers simply wait for the innovator's patent to expire on the brand-name drug. Generic firms that have obtained the necessary regulatory approvals for their bio-equivalent products are then free of IP barriers to entry into the marketplace.

Waiting until a drug is off patent, however, delays and therefore reduces the benefits of post-expiration reductions in the drug's price. That delay is acceptable where the patent is valid and the generic cannot invent around it. The patent length incorporates an IP policy judgment that the patent's beneficial incentives for innovation of new drugs outweigh its costs with respect to competition in existing drugs. But where a patent is weak or avoidable, waiting for it to expire before entering the market can be costly for consumers.

Post-expiration generic entry can nonetheless bring large welfare benefits where the drugs at issue are widely consumed and have remaining commercial life. For that reason, rules that, consistent with public safety considerations, reduce hurdles for generic entrants can increase consumer welfare. Similarly, competition policies that prevent patentees from prolonging the IP protections on their products beyond the original patent period will be important.

In the EU, generic firms are able to expedite entry through the use of a central application to the European Medicine Evaluation Agency. The benefit of this application is that Community market authorization is obtained at once. After receiving the application, the Agency will send a recommendation

to the European Commission within a period of 270 days and then the European Commission will typically grant market approval.[47]

In the US, the Hatch-Waxman Act[48] governs the regulatory framework under which a generic manufacturer may obtain approval of its drug by the FDA by filing an Abbreviated New Drug Application ("ANDA"). An ANDA must satisfy all of the requirements of the NDA, except it is allowed to rely on the clinical data first submitted by the brand-name drug manufacturer to establish the safety and efficacy of the generic drug if the generic manufacturer can demonstrate bioequivalence with the brand-drug. Consequently, the cost of a successful ANDA application is generally estimated to be dramatically lower than the cost of an NDA, in the range of one million dollars or less.[49]

A second means of entry is for the generic firm to launch its drug even before the branded firm's patent has expired and then to challenge the validity of that patent if the branded firm tries to enforce it. Such a strategy carries risks for the generic firm, but has occurred in cases in which the entrant believed the incumbent's patent to be weak. "At risk" entry by a generic firm that is prepared to challenge the patent if sued for infringement can benefit consumers by bringing to market generic versions of drugs protected by invalid patents. Firms will rightfully hesitate to launch such "at risk" drugs because of the costs of defending an infringement suit and the risk of losing whatever fixed investment they have made in the drug at issue.

One possible policy response is to create incentives for generic firms to enter into competition with patented drugs and risk infringement suits. In the US, to encourage generic entry as soon as warranted, the Hatch-Waxman Act allows a generic drug manufacturer to file a so-called "Paragraph IV" ANDA certifying (a) its generic drug will not infringe patents listed in the FDA's "Orange Book" ("Orange Book patents") in regard to the relevant brand-name drug product, and/or (b) that the relevant Orange Book patents are invalid. Typically, patent litigation then ensues, and the FDA may not approve the generic drug until 30 months after the generic filed notice of the Paragraph IV ANDA to the brand (or after a favourable decision in the litigation, if earlier). At that point the FDA may authorize the marketing of the generic drug under the ANDA application, and the first-filed paragraph IV ANDA applicant becomes entitled to 180 days of marketing exclusivity. The 180 days of marketing exclusivity generally protects one first-filed ANDA applicant from competition by prohibiting FDA approval of additional ANDAs until after the 180-day period. This 180-day period of marketing exclusivity was intended to provide an incentive for ANDA filers to challenge brand-name patents and seek generic entry prior to patent expiration.

Another way that a generic version of the brand-drug can enter the market is for the brand manufacturer to issue a generic version of the drug using the same FDA authorization it received originally through the NDA (thus these are called "authorized generics"). Because the brand manufacturer already has approval, it may place its authorized generic on the market immediately and is not restricted by a 180-day exclusivity period granted to a successful, third-party paragraph IV first filer. Brand-name companies do not routinely place authorized generics on the market unless a generic company is about to enter. Evidence nonetheless shows that there generally can be consumer benefit from entry by authorized generics even when third-party generics are already in the market. In an Interim Report on Authorized

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47 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:EN:PDF.

48 Drug Price Competition and Patent Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified as amended at 21 U.S.C. § 355.

49 Reiffen, D. and M Ward. Generic Drug Industry Dynamics. *The Review of Economics and Statistics.* 2005; 87(1): 37–49.

Generics, issued in June of 2009, the FTC reported that generic drug prices during 180-day exclusivity periods were as much as 8% lower when an authorized generic competed with an ANDA generic.[50] Furthermore, because the authorized generic enters via the NDA, these benefits are obtained without an additional company needing to sink the entry costs associated with obtaining an ANDA.

However, one concern often voiced is that the incentives of generic companies to pursue paragraph IV challenges can be substantially affected by the presence or absence of authorized generics. A potential ANDA filer will recognize that the entry of an authorized generic would make the difference between the ANDA filer's being the only generic manufacturer on the market or one of two generic competitors, potentially substantially affecting the ANDA filer's expected profits. The FTC's report drew no conclusions about the overall effect of authorized generics on potential paragraph IV challenges, but did report that the estimated revenues of successful paragraph IV first-filers was reduced by 50% during the 180-day exclusivity period when an authorized generic entered the market. If these reductions occur with no entry deterrence, then they are beneficial for consumers. If the reduction in estimated revenues does deter entry, the case is ambiguous.

Finally, the brand-name pharmaceutical firm can use the prospects of authorized generic entry to induce potential ANDA filers to agree to stay out of the market. Paragraph IV disputes are frequently settled with an agreement between the brand company and the generic challenger. These settlements often include a negotiated date on which the generic entrant would be allowed to enter the market, but can also include a variety of other features, including promises by the brand not to launch an authorized generic. The independent generic firm then has the choice of entering now but having its profits reduced by the authorized generic, or giving the branded firm an additional period of monopoly but being allowed to enter later (but still before patent expiration) without competition from an authorized generic. Consequently, there is the potential for promises not to launch an authorized generic to be used as a form of compensation in "pay-for-delay" settlements (discussed below).[51]

6. Competition policy concerns

Makers of brand-name drugs have a lot to lose from generic entry. Their market shares and profits drop, often substantially. As a result, they have strong incentives to prevent generic entry and the success of those generic firms that do enter. There are both competitive and anticompetitive ways for the brand-name firms to respond. On the procompetitive side, they can cut prices and/or introduce improved drugs that leave the generic entrant a generation behind.

The range of potential strategies that may be anticompetitive is broader. Consider the following, non-exhaustive list of strategies that have been observed, each of which will be discussed in more depth below: so called "reverse-payment" or "pay-for-delay" settlements; "product hopping," which involves the brand-name firm's withdrawal of a product just before generic entry and replacing it with a trivially reformulated version of the same product in a way that can set back generic entrants' ability to enter and gain market share; filing multiple patents on a single drug to complicate challenges by new entrants and to extend the life of IP protections on a drug; and strategic use of the brand-name manufacturer's own "authorized generic" to fend off or negotiate away competition from unaffiliated generic firms. Not all of these strategies involve the same level or likelihood of anticompetitive harm, but all pose risks and challenges for competition policy.

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50 Federal Trade Commission. *Authorized Generics: An Interim Report.* June 2009 available at http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf.

51 Ibid.

Some of the strategies for blocking or evading generic competition fall within the realm of intellectual property and regulatory law and policy. For example, "product hopping" involves questions relating to the standards for patentability, regulatory exclusivity, and generic substitution. Stacking of multiple patents on a single drug similarly raises questions that may invite answers more from IP than from antitrust policy.

Other strategies, however, fall squarely in the realm of competition enforcement. Most obviously, collusive agreements on price, output, or entry among branded pharmaceutical manufacturers and generic firms should be vigorously policed under conventional anti-cartel principles.

More complex questions arise in the case of pay-for-delay settlements, among the most frequently used strategies in the US and also of substantial concern in Europe. In a typical pay for delay settlement, the branded manufacturer will pay the potential generic entrant some amount of money. In exchange, the generic company will delay its entry into the market. In the absence of such an exclusion payment, the generic could be expected to enter at an earlier date. Thus, by making an exclusion payment, the branded pharmaceutical company has paid for delayed entry by the generic. In light of court decisions adverse to plaintiffs in antitrust suits challenging pay-for-delay settlements in the US, the debate over these settlements has spread to the U.S. Congress even while the court battles continue. Congress currently has pending a number of bills outlawing or restricting pay-for-delay agreements.

In the EU, the publication of the Pharmaceutical Sector Inquiry Final Report expressed that companies operating in the sector should expect increased antitrust scrutiny by the Commission of their patent-related conduct and agreements with competitors to the extent they may delay entry of a generic drug or stifle innovation by a competitor. As a clear and timely illustration of its enforcement intentions, the Commission confirmed that it opened a formal antitrust investigation against Les Laboratoires Servier for suspected breaches of the EC Treaty's rules on restrictive business practices (Art. 81) and on abuse of a dominant market position (Art. 82).[52] The Commission specifically identified as the focus of this investigation forming patent clusters, pursuing litigation against generic companies, and entering into anticompetitive patent settlement with generic companies. The decision to open proceedings also concerns a number of generic companies with regard to a number of individual, possibly restrictive, agreements between each of them and Servier, including pay-for-delay settlements.[53] The opening of formal proceedings followed unannounced inspections carried out by the Commission in November 2008 in several Member States.[54] The ongoing Commission proceedings concern conduct that may have the object or effect of hindering entry on to the market of generic perindopril, a cardiovascular medicine.

7. Conclusion

Competitive entry by generic drug manufacturers into pharmaceutical markets can bring substantial benefits to consumers and reduce costs throughout healthcare systems. The benefits of generic entry will differ among jurisdictions, with the welfare effects depending on a number of policy variables. These include retail regulation of pharmaceutical products, reimbursement schemes for physicians and pharmacists, the structure of health insurance programs, and approval processes for new and generic drugs. Although these variables may affect the degree to which generic entry improves consumer welfare, the

52 EC Press Release: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies, July 8, 2009, available at: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/322&format=HTML&aged=0&language=EN&guiLanguage=en.

53 *Id.*

54 EC Press Release: Commission confirms unannounced inspections at pharmaceutical companies, Nov. 24, 2008, available at: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/08/734&format=HTML&aged=0&language=EN&guiLanguage=en.

evidence is compelling that competition from generic manufacturers is a desirable policy objective. Price reductions from such competition have been shown to range from 20 to 80 percent across a variety of jurisdictions.

Despite the benefits of generic competition, the static price reductions and their associated consumer benefits must be balanced against the important dynamic benefits of continued investment in the development of new drugs. The balance between short and long term benefits in pharmaceutical markets is largely accomplished by the intellectual property system. Within the constraints of the exclusivity afforded by legitimate patents, however, competition policy should ensure that anticompetitive strategies do not further prevent generic drug manufacturers from entering pharmaceutical markets.

NOTE DE RÉFÉRENCE

par le Secrétariat

1. Introduction

Le présent document traite de l'entrée des médicaments génériques sur les marchés pharmaceutiques et des problèmes que cela pose pour la politique de la concurrence. Il dégage les principales questions que soulève concrètement l'ouverture du marché aux génériques et passe en revue les facteurs susceptibles de faire varier les effets de la concurrence des génériques sur le bien-être du consommateur.

Le marché pharmaceutique est en règle générale caractérisé par deux types de concurrence : la concurrence entre plusieurs médicaments de marque, ou principes, conçus pour traiter la même pathologie, et la concurrence de produits génériques équivalents à des médicaments de marque qui sont déjà vendus avec succès sur le marché. Ces deux formes de concurrence sont avantageuses pour la collectivité dans la mesure où elles font baisser les prix tout en stimulant l'innovation. On s'intéressera essentiellement ici au problème particulier de la concurrence exercée par les génériques.

L'entrée des médicaments génériques sur le marché soulève un certain nombre de questions et de problèmes non négligeables pour la politique de la concurrence. Comme il est indiqué ci-après, l'arrivée des génériques peut faire baisser les prix, au profit des consommateurs, des assureurs et des programmes de santé publics. Cela étant, l'intérêt des baisses de prix entraînées par l'arrivée des génériques doit être mis en balance avec la nécessité de maintenir des incitations sur le marché pharmaceutique pour le développement de nouveaux médicaments et la poursuite de l'investissement dans l'amélioration des médicaments matures.

Cette note se propose d'étudier les avantages de l'arrivée des génériques en commençant par comparer leurs avantages économiques statiques avec les avantages dynamiques des activités de recherche et développement (R-D) consacrées à la conception de nouveaux médicaments. Elle s'intéresse ensuite aux différents modes d'entrée des génériques, ainsi qu'à leurs coûts et avantages potentiels. Sont abordés pour finir les questions et les défis que pose l'arrivée des génériques sur les marchés pharmaceutiques du point de vue de la politique de la concurrence.

2. Impact des médicaments génériques sur les prix

Les laboratoires pharmaceutiques produisent en règle générale des médicaments pour un faible coût, mais les vendent à un prix élevé, au moins au sens économique du terme, c'est-à-dire au regard du rapport entre le prix du marché et un coût de production différentiel qui peut être le coût marginal ou le coût variable moyen. Le taux de marge élevé des médicaments permet aux producteurs de génériques de réduire les prix tout en faisant un bénéfice. Les médicaments ne sont pas des produits comme les autres, c'est ce qui justifie l'importance des marges dont ils bénéficient, du moins pendant un certain temps.

Les coûts fixes de production des nouveaux médicaments sont en général très élevés. On estime à plusieurs centaines de millions USD en moyenne les coûts de R-D nécessaires à la mise au point d'un

médicament[1]. Lorsqu'un laboratoire crée un médicament, le soumet à des essais cliniques et obtient une réaction positive des consommateurs, il le vend généralement cher sur le marché, et cela pour deux raisons : premièrement, pour amortir ses coûts fixes, et deuxièmement, parce qu'en l'absence de concurrence d'autres médicaments de marque traitant la même pathologie, le fabricant jouit ordinairement d'un monopole garanti par les droits de propriété intellectuelle qui protègent son produit. En cas de monopole, le prix peut être supérieur au niveau nécessaire pour compenser l'investissement corrigé des risques réalisé par l'innovateur et, si aucun produit concurrent n'est mis sur le marché, rien n'empêche en général le fabricant en place de maintenir des prix non concurrentiels longtemps après avoir rentabilisé son investissement. C'est pour cela que la concurrence des génériques est importante, même s'il convient de reconnaître la nécessité économique d'une période d'exclusivité commerciale et de taux de rendement supraconcurrentiels pour la marque innovante.

La concurrence entre les fabricants de médicaments de marque et de génériques peut permettre aux consommateurs de réaliser des économies substantielles. Si, comme on le verra, l'ampleur de ces économies dépend de nombreux facteurs d'ordre réglementaire et commercial, dans la plupart des pays, l'effet concurrentiel de l'arrivée de génériques sur le prix des médicaments est important. Ainsi, des études sur le marché des médicaments aux États-Unis indiquent que le premier concurrent générique pénètre en général le marché avec un prix 20 à 30 % plus bas que celui du médicament de marque, et qu'il gagne en peu de temps une importante part de marché de celui-ci[2]. Les autres génériques commercialisés par la suite peuvent être vendus à des prix encore plus bas, avec une décote pouvant aller jusqu'à 80 %, voire plus, par rapport au prix du médicament de marque, et pousser les fabricants des premiers génériques mis sur le marché à revoir leurs tarifs à la baisse. Ainsi, plus le nombre de versions génériques augmente, plus les prix diminuent. Grâce à leurs prix attractifs, à la promotion dont ils bénéficient de la part des pouvoirs publics et des assureurs maladie et aux législations nationales qui les encouragent, les médicaments génériques parviennent en général à capter entre 44 et 80 % des ventes du princeps dans les 12 mois qui suivent le lancement du premier générique bon marché[3].

Dans l'Union européenne, on estime que la concurrence des médicaments génériques se traduit par une économie d'environ 20 % un an après l'entrée du premier générique sur le marché et d'environ 25 % au bout de deux années (en moyenne), par rapport au prix de la marque en situation de monopole[4]. Une étude de 2006 portant sur le marché des médicaments de 11 pays européens a calculé pour chacun d'eux le montant des économies réalisées sur les dépenses publiques grâce à la substitution des dix médicaments de

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1 Adams CP, "Estimating the cost of new drug development: is it really $802 million?", *Health Affairs*, 2006 ; 25(2), p. 420-428.

2 Voir Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (juillet 1998) (« Étude CBO »), consultable à l'adresse http://www.cbo.gov/showdoc.cfm?index=655&sequence=0 (ci-après dénommé « étude CBO ») ; voir de manière générale David Reiffen et Michael R. Ward, *Generic Drug Industry Dynamics*, p.87.

3 Étude CBO, xiii.

4 Commission européenne, Rapport d'enquête final sur le secteur pharmaceutique (8 juillet 2009), p. 94, consultable à l'adresse *:* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html (ci-après dénommé : rapport Pharma). Le rapport Pharma estime également que pour un échantillon de médicaments étudiés pendant la période 2000-2007, les économies réalisées grâce à la mise sur le marché de médicaments génériques auraient pu être de 20 % supérieures à ce qu'elles ont effectivement été, si cette mise sur le marché était intervenue immédiatement après la fin de l'exclusivité. D'après l'étude approfondie de cet échantillon, le montant global des dépenses sur la période qui a suivi la perte de l'exclusivité (environ 50 milliards EUR) aurait été supérieure d'environ 15 milliards EUR si les médicaments génériques n'étaient pas apparus (évaluation en volume constant). Toutefois, une économie supplémentaire de 3 milliards EUR environ aurait été possible si la mise sur le marché du médicament générique était intervenue immédiatement. Rapport Pharma, p. 94.

marque les plus répandus par des génériques, à partir des chiffres publiés pour l'année 2004[5]. Elle conclut qu'un recours plus large aux génériques, à la place des princeps, permettrait des économies supplémentaires d'au moins 21 % dans chaque pays étudié, avec des estimations encore plus élevées pour le Danemark (48 %), l'Allemagne (47 %), la France (35 %), le Royaume-Uni et l'Espagne (33 %) et l'Italie (31 %)[6].

Au Brésil, les données disponibles montrent que la mise sur le marché de médicaments génériques a permis au système de santé d'économiser environ 5 milliards USD entre 2001 et 2007[7]. Au Canada, la prescription de génériques a permis une économie de l'ordre de 3 milliards CAD en 2008[8], et il serait possible d'économiser encore jusqu'à 800 millions CAD par an, d'après les estimations, si la concurrence des génériques était encouragée[9].

3. Facteurs influant sur l'impact des médicaments génériques

Les différences constatées d'un pays à l'autre concernant l'impact des médicaments génériques sur les prix s'expliquent par un certain nombre de facteurs. Lorsque le prix des médicaments de marque est réglementé, par exemple, la concurrence des génériques a sans doute un impact moindre que dans la situation inverse, puisque les plafonds imposés sur les prix des fabricants réduisent la marge à l'intérieur de laquelle la concurrence peut s'exercer. De même, les règles qui limitent le nombre de nouveaux génériques pouvant être mis sur le marché peuvent être déterminantes pour les effets de la concurrence des génériques sur les prix.

Une étude de 2000 réalisée par Danzon et Chao examine les effets de la concurrence des génériques sur les prix des médicaments dans des pays dotés de régimes réglementaires différents[10]. Les auteurs se fondent sur un ensemble très complet de données concernant les ventes de médicaments aux malades non hospitalisés en 1992 dans sept pays (Allemagne, Canada, États-Unis, France, Italie, Japon et Royaume-Uni). Cet échantillon se caractérise par divers niveaux de concurrence et de réglementation des prix. Par exemple, aux États-Unis, le prix des médicaments délivrés sur ordonnance est quasiment libre, alors qu'en France, en Italie et au Japon, il est au contraire très réglementé, produit par produit (et a globalement tendance à baisser). Le Royaume-Uni, le Canada et l'Allemagne se situent quant à eux dans une position

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5 Simoens, S. et De Coster, S., "Potential Savings from Increased Substitution of Generic for Originator Medicines in Europe", *J. Generic Med.* 2006 **;** 4(1) , p. 43- 45.

6 *Idem.* Les économies potentielles pour les autres pays participant à l'étude atteignaient 42 % pour la Belgique et le Portugal, 41 % pour les Pays-Bas, 27 % pour l'Autriche et 21 % pour la Pologne. Le montant annuel des économies potentielles s'établit à 1 milliard EUR en Allemagne.

7 Voir "The Rising Generic Drugs Market in Brazil", Daniela Putti, 20 octobre 2008, disponible à l'adresse http://www.frost.com/prod/servlet/market-insight-top.pag?docid=146732330.

8 Association canadienne du médicament générique, "Les médicaments génériques utilisés pour remplir la majorité des prescriptions au Canada", communiqué (26 mars 2009), consultable à l'adresse : http://www.canadiangenerics.ca/fr/news/mar_26_09.asp.

9 Bureau de la concurrence, Pour une concurrence avantageuse des médicaments génériques au Canada : Préparons l'avenir, novembre 2008, *disponible à l'adresse* http://www.cb-bc.gc.ca/eic/site/cb-bc.nsf/vwapj/GenDrugStudy-Report-081125-fin-f.pdf/$FILE/GenDrugStudy-Report-081125-fin-f.pdf, et De grandes économies réalisables sur les dépenses en médicaments génériques grâce à une concurrence accrue, Annonces, Centre des médias, Bureau de la concurrence (25 nov. 2008), disponible à l'adresse http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/fra/02754.html.

10 Danzon, Patricia M et Chao, Li-Wei. « Does Regulation Drive out Competition in Pharmaceutical Markets? », Journal of Law & Economics, University of Chicago Press, vol. 43(2), oct. 2000, p. 311-57, octobre.

intermédiaire, avec une grande liberté des prix pour les nouveaux médicaments, mais également des limites sur les bénéfices (Royaume-Uni), des prix-plafonds ajustés en fonction de l'inflation (Canada) et un système de remboursement sur la base d'un prix de référence (Allemagne)[11].

D'après les conclusions de l'étude de 2000, c'est aux États-Unis que les prix sont le plus sensibles au nombre de concurrents génériques[12]. C'est là que l'on compte le plus grand nombre de nouveaux génériques, que les génériques ont le plus d'effet sur les prix et que la rentabilité de ceux qui entrent après les autres sur le marché est la plus élevée par rapport à des environnements où les prix sont davantage encadrés. L'Allemagne, le Royaume-Uni et le Canada se caractérisent également par une grande sensibilité des prix à la concurrence des génériques. L'Allemagne, en particulier, avec son système de prix de référence, affiche une corrélation comparable à celle constatée pour les États-Unis entre le nombre de produits entrants et les effets sur les prix.

Au Japon, en France et en Italie, en revanche, le nombre de concurrents génériques et les prix des médicaments ne semblent guère être liés. Il se peut donc que le système de réglementation des prix de ces pays ait pour effet de diminuer le nombre et l'impact des concurrents génériques marginaux. En France et en Italie, les fabricants de génériques vendent en règle générale leurs produits à des prix très inférieurs à ceux qu'ils pourraient pratiquer sur d'autres grands marchés pharmaceutiques, limitant ainsi l'impact de tout nouvel arrivant. En outre, les réglementations en vigueur restreignent les possibilités d'ajustement des prix par rapport à l'inflation, de sorte que le prix réel des médicaments suit une spirale descendante au fil du temps malgré l'entrée sur le marché d'un très petit nombre de nouveaux génériques. Par conséquent, les fabricants ne sont guère incités à lancer sur le marché des médicaments déjà fabriqués par d'autres et quand ils le font, ils préfèrent souvent proposer d'anciennes molécules sous des formes nouvelles, afin que le prix réglementé appliqué au départ soit plus élevé.

La réglementation des officines de pharmacie affecte également la concurrence des génériques en France et en Italie. Dans ces deux pays, les pharmaciens perçoivent une marge de distribution réglementée calculée sur la base du prix du produit, tandis que l'obligation de facturer et de dispenser les médicaments sous forme de conditionnements individuels réduit la possibilité de pratiquer des tarifs dégressifs. Dans le cas du Japon, les médecins délivrent eux-mêmes les médicaments et sont fortement incités à prescrire ceux qui présentent la plus forte marge entre le prix d'achat et le prix remboursé ; le prix compétitif des génériques n'est donc pas pour eux une raison suffisante de dispenser ces médicaments.

Il est important de se demander si les pressions réglementaires exercées sur les prix pendant le cycle de vie d'un produit dans les pays dotés d'une réglementation rigoureuse en la matière, comme le Japon, la France et l'Italie, aboutissent aux mêmes effets que la concurrence des génériques dans les marchés moins réglementés tels ceux des États-Unis, du Royaume-Uni ou de l'Allemagne. Les faits montrent que les effets nets en termes de bien-être varient considérablement entre ces deux situations. La concurrence des génériques a un effet sensible sur les prix dans les pays qui favorisent ces médicaments via des systèmes de remboursement basés sur des prix de référence (l'Allemagne, par exemple), ou qui incitent fortement les médecins à prescrire des génériques (Royaume-Uni). À l'inverse, les pays tels que la France et l'Italie, qui réglementent strictement les prix des nouveaux produits, où les prix baissent au fil du temps et dont le système de distribution pharmaceutique comporte des barrières à la concurrence, ne profitent pas autant de la concurrence des génériques. L'absence de concurrence dans le système de distribution pharmaceutique en France et en Italie signifie que les officines et les grossistes retiennent une partie des économies que pourraient permettre des prix plus bas (comme le font les médecins au Japon en délivrant les médicaments dont la marge est la plus élevée).

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11 Le système de prix de référence consiste à fixer un montant maximal remboursé et à faire supporter aux patients tout supplément si le fabricant fixe son prix de vente au-dessus du prix de référence.

12 *Idem.*

L'une des leçons de l'étude multinationale de 2000 est qu'un système fondé sur des prix de référence peut inciter fortement les fabricants de génériques à se faire concurrence et conduire ainsi à une baisse des prix pour une molécule donnée. Dans un système fondé sur des prix de référence, les produits sont répartis en différentes classes sur la base de critères tels que la composition chimique, le mode d'action ou encore les effets thérapeutiques. À chaque classe de produits est associé un « prix de référence » calculé en fonction du prix fabricant d'un produit bon marché de cette classe – par exemple le prix minimum ou le prix médian. Le prix de référence est le montant maximal du remboursement pour tous les produits de la classe. Les fabricants peuvent alors fixer un prix supérieur au prix de référence, mais les patients devront acquitter la différence. Si le prix du fabricant est inférieur au prix de référence, les économies ainsi réalisées peuvent être partagées entre l'acheteur et l'officine ayant délivré le produit, selon le système en place. Cela offre aux fabricants de génériques la possibilité de prendre des parts de marché au producteur du princeps en abaissant leur prix. Cette conclusion a son importance. En effet, à l'instar de l'Allemagne[13], plusieurs pays tels que le Danemark, la Norvège et les Pays-Bas ont adopté un système de prix de référence et ont récemment observé une concurrence accrue de la part des génériques.

Dans le cas du Royaume-Uni, les incitations à l'usage des génériques sont venues des médecins. Plus précisément, le système de santé national britannique (*British National Health Service - NHS*) permet aux médecins généralistes qui ne dépensent pas la totalité de leur budget de réinvestir les économies ainsi réalisées dans leur cabinet. D'après Baines, Tally, et Whynes (1997), le principal effet de la réforme ayant consisté à allouer un budget aux médecins a été d'encourager la prescription de génériques[14].

Une brève comparaison des politiques menées au fil du temps en France et au Royaume-Uni à l'égard des médicaments génériques montre que toute une série de facteurs peut influencer leurs effets que ces médicaments peuvent avoir sur le plan de la concurrence[15]. L'émergence d'un marché de médicaments génériques en France a été lente. Ce manque de réactivité face aux génériques s'explique en partie par le niveau des prix des médicaments de marque déjà peu élevé en France en comparaison avec d'autres pays de l'Union européenne. Dans les années 90, la France a adopté une législation allongeant la durée de validité des brevets, ce qui a retardé l'essor des génériques[16]. Les autorités françaises ont attendu 1997 avant de donner un cadre légal aux génériques et de les inscrire sur la liste des médicaments remboursés.

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13 Les pouvoirs publics allemands ont été les premiers à instaurer une politique de prix de référence dans le cadre de la réforme du système de santé de 1989 (également appelée réforme Blüm). Aux termes de cette législation (§35 *Sozialgesetzbuch* V), des prix de référence sont déterminés pour des médicaments contenant la même substance, des substances similaires ou d'une efficacité comparable. La mise en œuvre de cette politique s'est faite en trois étapes. La première a commencé avec la réforme Blüm en 1989 et a concerné uniquement les médicaments contenant le même principe actif, c'est-à-dire les médicaments de marque non brevetés et leurs formes génériques. En 1992, le système de prix de référence a été élargi aux médicaments contenant des substances actives similaires mais non identiques. Enfin, depuis 1993, le système de prix de référence inclut les produits dont les effets thérapeutiques sont similaires mais qui utilisent des substances chimiques actives différentes.

14 Baines, Tally et Whynes (1997).

15 Monique Mrazek et Richard Frank, « The Off-Patent Pharmaceutical Market », dans Elias Mossialos, Monique Mrazek et Tom Walley (dir. publ.), *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality*, 2004.

16 Afin de compenser le délai entre la date de dépôt d'une demande de brevet et celle de l'autorisation de mise sur le marché du médicament, la durée du brevet pouvait être prolongée au maximum pour sept ans. Cette législation a été introduite en France en 1990, trois ans avant la mise en œuvre du certificat complémentaire de protection (CCP) de l'Union européenne, en 1993, qui permet quant à lui d'étendre la période de protection pour un maximum de cinq ans. Pour en savoir plus sur le CCP, voir le paragraphe 35.

Le marché britannique des génériques a connu une évolution différente. La réglementation du médicament étant axée sur les profits et non sur les prix, ceux-ci ont atteint des niveaux élevés et cela a stimulé l'arrivée sur le marché de médicaments génériques[17]. L'un des principaux facteurs qui ont favorisé le recours aux génériques a été le fait d'avoir enseigné depuis longtemps aux étudiants en médecine l'usage de ces médicaments, dont la prescription est un élément-clé de la stratégie menée dans ce domaine[18].

En France comme au Royaume-Uni, les incitations financières destinées aux médecins et aux pharmaciens ont joué un rôle important dans le développement du marché des médicaments génériques. En France, jusqu'en 1999, les pharmaciens étaient payés sur la base d'une marge ajoutée aux prix publics des médicaments, ce qui restreignait le développement d'un marché de génériques à prix réduits. Depuis 1999, les pharmaciens français reçoivent pour les génériques la même marge que pour leurs équivalents d'origine. Au Royaume-Uni, les pharmaciens perçoivent un montant forfaitaire par médicament délivré, plus le prix référencé du médicament. Par conséquent, s'ils achètent le médicament à un prix inférieur au prix référencé, leur marge est plus grande[19]. Bien que les pharmaciens français aient le droit de remplacer les médicaments prescrits par des génériques figurant dans un répertoire officiel, les médecins de ces deux pays conservent un rôle important : en France, le médecin peut s'opposer à la substitution, et au Royaume-Uni, c'est de lui que dépend entièrement l'usage des génériques puisqu'il les prescrit lui-même directement[20].

Contrairement aux États-Unis, ni le Royaume-Uni ni la France n'ont opté pour des mesures d'incitation dirigées vers les patients, même si les campagnes de sensibilisation organisées dans les médias français ont favorisé l'acceptation par les patients du principe de substitution au profit des génériques. En 2002, les autorités françaises ont augmenté les tarifs de consultation des médecins en échange d'une augmentation des prescriptions de génériques, sauf contre-indication médicalement justifiée. Ces évolutions de l'action publique menée en France, et plus particulièrement l'accord conclu avec les médecins, ont été pour beaucoup dans la soudaine augmentation du recours aux génériques : le taux de substitution par des génériques est passé de 18 % des médicaments ayant un équivalent générique disponible en 2000 (AFSSAPS, 2002) à 48.2 % en 2002 (CNAMTS, 2003a). Cela étant, en 2006, les génériques représentaient seulement 17 % du volume total des médicaments remboursés, contre 65 % au Royaume-Uni[21]. Ces chiffres ont augmenté en France suite à la mise en œuvre en 2003 d'un système de prix de référence couvrant les médicaments tombés dans le domaine public.

Le nombre et le type de prestataires d'assurance maladie peuvent aussi avoir une incidence sur les prix des médicaments. De même, si des programmes d'assurance maladie ou des réglementations dans ce domaine facilitent ou imposent le remplacement de médicaments de marque par des équivalents génériques moins coûteux, la part de marché des génériques va augmenter, et l'économie globale pour le consommateur, également.

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17 La réglementation des prix des médicaments de marque au Royaume-Uni est régie par le Pharmaceutical Price Regulation Scheme. Cet accord volontaire entre l'industrie pharmaceutique britannique et le ministère de la Santé n'exerce pas directement un contrôle sur les prix. Il permet aux laboratoires pharmaceutiques d'obtenir un taux de rendement du capital égal aux bénéfices tirés des ventes au NHS, moins les coûts admissibles. Les laboratoires peuvent fixer librement le prix de lancement de leurs nouveaux médicaments dans la mesure où celui-ci ne dépasse pas systématiquement le taux de rendement préalablement fixé. Ce système a pour résultat que le prix des médicaments est plus élevé au Royaume-Uni que dans les autres pays de l'Union européenne. Simoens, S. et De Coster, S., *Sustaining Generic Medicines Markets in Europe*, Research Centre for Pharmaceutical Care and Pharmaco-Economics, Université catholique de Louvain, avril 2006, p. 33.

18 *Idem*, p. 34.

19 Mrazek et Frank, note 15, p. 254-255.

20 *Idem.*

21 Generic Market Shares in Europe, 2006,

Les méthodes de remboursement des dépenses en médicaments ont elles aussi une incidence. Les patients ne paient pas directement l'intégralité du coût des médicaments prescrits, et les systèmes de santé doivent organiser le remboursement de ces frais aux patients et/ou aux distributeurs. Cela peut se faire par l'intermédiaire d'organismes publics, et les remboursements sont alors généralement financés sur les impôts. Le Royaume-Uni, avec son NHS, est un exemple de ce type de système[22]. Mais le remboursement des médicaments peut aussi être géré par des organismes d'assurance maladie relativement autonomes, comme en Allemagne. En règle générale, ces systèmes sont fondés sur des régimes de sécurité sociale contributifs principalement financés par des cotisations assises sur les revenus du travail. Il semble cependant de plus en plus fréquent que les organismes d'assurance maladie négocient eux-mêmes les prix des médicaments, et les éventuels rabais, directement auprès des fabricants.

Le taux de remboursement suscite de nombreux débats entre les organismes d'assurance maladie et les sociétés pharmaceutiques. Si les frais laissés à la charge du patient sont élevés, cela risque de le dissuader d'acheter certains produits pharmaceutiques. Afin de trancher la question épineuse du remboursement, les États membres ont tendance à déléguer l'évaluation coûts-avantages des médicaments à des experts indépendants tels que le *National Institute for Health and Clinical Excellence (NICE)* au Royaume-Uni ou l'Institut pour la qualité et l'efficience des soins de santé (IQWIG) en Allemagne. Ces institutions évaluent les produits ou traitements médicamenteux selon deux critères : l'efficacité au regard des effets thérapeutiques et l'efficacité par rapport au coût et en comparaison avec d'autres produits, autrement dit l'efficience (relative)[23].

4. Incitations dynamiques au développement de nouveaux médicaments et à la mise sur le marché de médicaments génériques

Comme il a déjà été indiqué, on ne peut pas concevoir une politique en faveur des génériques sans tenir compte de ses implications pour l'investissement dans la conception de nouveaux médicaments. La mise sur le marché d'un générique intervient généralement plusieurs années après le lancement du médicament d'origine. Logiquement, de plus grandes économies pourraient donc être réalisées au cours du cycle de vie d'un médicament de marque si les fabricants de génériques pouvaient accéder plus tôt au marché. L'arrivée des génériques, lorsqu'elle n'empêche pas les laboratoires fabriquant les médicaments d'origine d'amortir leurs coûts de R-D, peut pousser ces derniers à innover. Cela étant, toute politique visant à favoriser une entrée plus rapide des génériques sur le marché doit obligatoirement tenir compte de ses retombées potentielles pour les laboratoires pharmaceutiques qui réalisent l'investissement initial nécessaire en R-D pour mettre au point de nouveaux médicaments ou des médicaments améliorés. Aucune société commerciale n'accepterait de supporter des coûts fixes considérables que suppose cet effort de R-D uniquement pour voir le fabricant d'un générique bio-équivalent s'en approprier le fruit. La concurrence des génériques ne peut procurer un avantage incontestable pour le bien-être du consommateur que si elle ne réduit pas les incitations dynamiques qui poussent les entreprises à innover et à produire de nouveaux médicaments.

Les fabricants de princeps se font ont pour spécialité de concevoir des produits nouveaux et innovants qui sont commercialisés sous des noms de marque. Le développement de nouveaux médicaments coûte cher et comporte des risques. Non seulement le laboratoire doit trouver une molécule capable de traiter la pathologie visée, mais il doit ensuite apporter des preuves suffisantes de la sécurité et de l'efficacité de son produit pour franchir les étapes réglementaires qui conduisent au marché. Dans l'Union européenne, les nouveaux médicaments sont soumis aux procédures de criblage et d'essai instaurées par l'Agence européenne des médicaments (EMEA), un organe décentralisé de l'UE qui centralise les demandes

22 Rapport Pharma, p. 47.

23 *Idem.*

d'autorisation de mise sur le marché de médicaments à usage humain et vétérinaire[24]. Aux États-Unis, c'est auprès de la Food and Drug Administration (FDA), l'administration chargée du contrôle des produits pharmaceutiques et alimentaires, que le fabricant doit déposer une demande, dite "NDA" (New Drug Application), pour obtenir l'autorisation de mettre sur le marché un nouveau médicament. Dans le dossier qu'il soumet à la FDA, le fabricant doit fournir toutes les données nécessaires pour prouver la sécurité et l'efficacité du produit compte tenu de son usage prévu. Le processus d'approbation peut prendre plusieurs années, et le coût de développement d'un nouveau médicament princeps peut être considérable[25]. D'après une étude (DiMasi *et al.*, 2003), les coûts de recherche et développement supportés par les fabricants de princeps s'élèveraient à 403 millions USD (en dollars de 2000) par médicament approuvé.

En dépit des risques et des coûts, la concurrence entre les fabricants de princeps innovants est très vive, et elle constitue un élément-clé de la performance du marché dans le secteur pharmaceutique. L'intérêt des consommateurs n'est pas seulement que des médicaments existants puissent se vendre moins cher, mais aussi que des médicaments nouveaux et plus efficaces fassent peu à peu leur apparition sur le marché. En termes de bien-être, ces effets bénéfiques à plus long terme peuvent être beaucoup plus importants que les avantages statiques des baisses de prix à court terme. Cela ne signifie pas bien entendu que les médicaments existants doivent pouvoir jouir indéfiniment d'une protection exclusive ; cela signifie que l'action publique doit trouver un équilibre entre les effets statiques et les effets dynamiques de la concurrence sur le bien-être.

Si l'application du droit de la concurrence est l'un des principaux moyens de garantir l'exercice de la concurrence par les prix sur les marchés de produits, les droits de propriété intellectuelle et autres moyens d'assurer une exclusivité commerciale temporaire à certains produits sont les instruments les plus courants pour mettre en place des incitations dynamiques à l'innovation. En octroyant des droits exclusifs à une invention pour une durée limitée, le système des brevets stimule l'innovation de plusieurs façons. Il encourage l'invention, le développement et la commercialisation d'inventions, ainsi que leur diffusion auprès du public[26].

Aux États-Unis, le système des brevets s'appuie sur la Constitution. Un passage fréquemment cité de l'article Ier, section 8 de la Constitution autorise le Congrès « [à] promouvoir le progrès de la science et des techniques en assurant, pour un temps limité, aux auteurs et inventeurs le droit exclusif à leurs écrits et découvertes respectifs »[27]. La loi sur les brevets (*Patent Act*) met en œuvre cette disposition en octroyant aux détenteurs de brevets le droit d'interdire à quiconque de fabriquer, d'utiliser ou de vendre une invention protégée par un brevet pendant 20 ans à compter de la date de dépôt de la demande[28]. En offrant une protection face à toute appropriation par autrui, même après que l'invention est tombée dans le domaine public, le brevet amène les inventeurs à rendre public ce qu'ils pourraient sinon garder secret.

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24 Voir Agence européenne des médicaments, www.emea.europe.eu.

25 Voir Cockburn et Henderson, « The Economics of Drug Discovery », dans *Pharmaceutical Innovation*, Landau, Achilladelis, et Scriabine, dir. publ., 1999 ; DiMasi, « New Drug Development in the United States from 1963 to 1999 », *Clinical Pharmacological Therapy*, 2001, p. 286-296 ; DiMasi, Hansen, et Grabowski, « The Price of Innovation: New Estimates of Drug Development Costs », *Journal of Health Economics*, 2003, p. 151-185.

26 F.M. Scherer, Industrial Market Structure and Economic Performance, 440 (2ème éd., 1980).

27 Constitution des États-Unis, art. I, § 8.

28 Constitution des États-Unis, art. 35, § 154(a)(2). Les versions antérieures de la loi sur les brevets prévoyaient des droits similaires. Pour bénéficier d'un brevet, une invention (c'est-à-dire un produit, un processus, une machine ou une composition d'éléments) doit être inédite, non évidente et utile. Un brevet confère le droit d'interdire à quiconque de fabriquer, d'utiliser ou de vendre aux États-Unis l'invention revendiquée par le brevet pendant 20 ans à compter de la date de dépôt de la demande dudit brevet.

La diffusion au public d'informations scientifiques et techniques est une partie de ce que l'inventeur cède en échange de droits d'exclusivité, et cette diffusion peut stimuler à son tour l'avancée de la science, car d'autres inventeurs peuvent tirer parti d'une invention brevetée ou détecter des possibilités de collaboration[29].

Un brevet permet à un inventeur de rentabiliser son investissement en empêchant autrui de s'approprier son invention et de faire baisser le prix du produit qui en découle. S'il ne dispose d'aucune forme d'exclusivité, il risque de ne pas pouvoir rémunérer suffisamment le fruit de son effort créatif pour que celui-ci en vaille la peine. Le problème est encore plus aigu lorsque les efforts de l'inventeur entraînent des coûts fixes importants et que les imitateurs peuvent copier l'invention à moindres frais, ce qui arrive souvent dans l'industrie pharmaceutique[30]. Les représentants des fabricants de princeps font donc valoir que la protection conférée par les brevets est indispensable pour promouvoir la recherche de nouvelles entités chimiques qui serviront d'ingrédients actifs à de nouveaux médicaments[31]. Les études menées dans plusieurs secteurs confirment que le brevet joue un rôle capital dans l'industrie pharmaceutique[32].

Dans son rapport de 2003 intitulé « *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* » (Comment promouvoir l'innovation : le juste équilibre entre concurrence et droit et politique des brevets), la Commission fédérale du commerce (FTC) des États-Unis explique de quelle façon l'innovation dans le secteur pharmaceutique, plus que dans n'importe quel autre secteur, dépend fortement de la protection par brevet[33]. Innover seul dans ce secteur est très coûteux, imprévisible et nécessite beaucoup de recherches exploratoires pour mettre au point et tester de nouveaux médicaments. En empêchant les entreprises rivales d'exploiter librement les découvertes, les brevets permettent aux entreprises pionnières de récupérer les investissements considérables qu'elles ont effectués pour découvrir, tester et faire autoriser leurs nouveaux médicaments. Les brevets contribuent aussi à attirer les capitaux indispensables au financement des investissements à haut risque[34], et le

29 Scherer, *supra*, note 26, p. 442. Voir Report, ch. 2, p. 3-7.

30 Comments of the Pharmaceutical Research and Manufacturers of America (PhRMA), p. 2 (10 février 2009), consultable à l'adresse http://www.ftc.gov/os/comments/iphearings/index.shtm.

31 FTC IP Report, ch. 3, p. 11-12.

32 Pour des données démontrant que les brevets sont comparativement plus utiles à la protection des innovations dans l'industrie pharmaceutique que dans d'autres secteurs d'activité, voir W.M. Cohen, R.R. Nelson et J.P. Walsh, « Protecting their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not) », Working Paper 7552, février 2000, National Bureau of Economic Research, Cambridge, Mass., révisé en 2004 ; Richard Levin, Alvin Klevorick, Richard Nelson et Sidney Winter, « Appropriating the Returns from Industrial Research and Development », Brookings Papers on Economic Activity (1987, n° 3), p. 783-820 ; Edwin Mansfield, « Patents and Innovation: An Empirical Study », Management Science, (1986, vol. 32, n° 2), p. 173- 181.

33 Voir Federal Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (2003), ch. 3, p. 1 [ci-après dénommé « rapport de la FTC sur les brevets »].

34 *Idem*, voir également Arti K. Rai, *Knowledge Commons: The Cost of the Biopharmaceutical Industry*, First Monday (juin 2007) (« Les petites entreprises du secteur de la biotechnologie ont recours aux brevets, souvent pour des technologies très éloignées d'un éventuel produit final, afin de dissuader toute appropriation abusive au moment où elles mettent leur technologie sur le marché. Les brevets aident aussi les petites entreprises de biotechnologie à négocier des alliances verticales en R-D avec des laboratoires pharmaceutiques. De leur côté, les laboratoires pharmaceutiques qui fabriquent les médicaments mis sur l marché comptent sur les brevets pour récupérer leurs frais de recherche et développement [références non précisées] »), consultable à l'adresse http://firstmonday.org/htbin/cgiwrap/bin/ojs/index.php/fm/article/ view/1909/1791.

système des brevets a prouvé qu'il était capable de protéger et de stimuler l'innovation dans les secteurs pharmaceutique et de la biotechnologie[35].

Même en dehors du champ de la propriété intellectuelle, les dirigeants ont accordé des périodes d'exclusivité pour stimuler l'innovation. Le Congrès américain l'a fait pour encourager le développement de médicaments nouveaux et innovants lorsque la molécule de base appartient au domaine public et qu'elle n'est donc pas brevetable[36]. De la même manière, l'octroi de périodes d'exclusivité commerciale a servi d'incitation à la réalisation d'essais cliniques pour le développement de nouvelles utilisations de médicaments existants après approbation par la FDA. Ainsi, la loi Hatch-Waxman prévoit une exclusivité de cinq ans pour inciter au développement de nouvelles entités chimiques, et une exclusivité de trois ans pour de nouvelles études cliniques sur des médicaments à petites molécules[37].

Dans d'autres circonstances, le Congrès des États-Unis a instauré une période d'exclusivité lorsque le prix déterminé par le marché n'était pas suffisamment incitatif pour le développement de médicaments destinés à certaines populations cibles. Par exemple, une période d'exclusivité commerciale de six mois est accordée au fabricant s'il est en mesure d'apporter la preuve de la sécurité et de l'efficacité d'un médicament pour les enfants. Une période d'exclusivité de sept ans est accordée aux fabricants de médicaments destinés à traiter des maladies affectant moins de 200 000 personnes aux États-Unis[38]. Chacune de ces exclusivités est le fruit d'un compromis : on restreint la concurrence, mais c'est pour permettre le développement d'un nouveau médicament ou d'une nouvelle application d'un médicament

35 F.M. Scherer et David Ross, Industrial Market Structure and Economic Performance, p. 621 (3ème éd., 1990) ; voir également *Patent Reform: The Future of American Innovation, Hearing Before the S. Comm. on the Judiciary*, 110ème Congrès (2007) (déposition de Kathryn L. Biberstein, premier vice-président, Alkermes) p. 2 ; *Patent Reform Act of 2007: Hearing on H.R. 1908 Before the H. Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on Judiciary*, 110ème Congrès 65 (2007) (déposition de Kevin Sharer, PDG d'Amgen), consultable à l'adresse http://judiciary.house.gov/hearings/April2007/Sharer070426.pdf., *Stifling or Stimulating - The Role of Gene Patents in Research and Genetic Testing Before the H. Comm. on the Judiciary, Subcomm. on Courts, the Internet, and Intellectual Property*, 110ème Cong. (2007) (déposition de Jeffrey P. Kushan pour le compte de BIO), consultable à l'adresse *:* http://judiciary.house.gov/hearings/pdf/Kushan071030.pdf.

36 Voir le commentaire de BIO (5/1/09), p. 7-9 (Benjamin Roin, *Unpatentable Drugs and the Standards of Patentability* 87 Tex. L. Rev. (à paraître).

37 Voir l'annexe B pour la description des exclusivités relatives à la commercialisation de médicaments à petites molécules.

38 Voir la loi sur les médicaments orphelins (Orphan Drug Act - ODA), 21 U.S.C.A. § 360aa et suivants (2009), 21 C.F.R. § 316 et suivants *;* FDA, Office of Orphan Products Dev't (Bureau pour le développement des médicaments orphelins), conclusions du Congrès concernant l'ODA (« [D]u fait que très peu de personnes sont atteintes par telle ou telle maladie ou pathologie rare, une entreprise pharmaceutique qui met au point un médicament orphelin peut raisonnablement s'attendre à ce que le médicament génère relativement peu de ventes en comparaison avec ses coûts de développement, et entraîne, par conséquent, une perte financière ; il y a lieu de croire que certains médicaments orphelins prometteurs ne seront pas développés à moins que des modifications ne soient apportées aux lois fédérales applicables afin de réduire le coût de leur mise au point et de proposer des incitations financières à leur développement ».), consultable à l'adresse http://www.fda.gov/orphan/oda.htm. Pour les fabricants de médicaments orphelins, toutefois, le brevet constitue sans doute une plus grande incitation que l'exclusivité de sept ans prévue par la loi ODA. Voir à ce sujet Robert Rogoyski, *The Orphan Drug Act and the Myth of the Exclusivity Incentive*, 7 Colum. Sci. & Tech. L. Rev 2 (2006), http://www.stlr.org/volumes/volume-vii-2005-2006/rogoyski/. D'après une étude, la plupart des médicaments orphelins sont en fait protégés par des brevets, qui ont d'une part une portée est plus large que celle de l'ODA, réservée à certaines pathologies, et d'autre part une durée de validité plus longue que la période d'exclusivité de sept ans accordée par l'ODA. *Idem*. p. 18, figure 1.

existant qui aurait plus de mal à voir le jour sans la forte récompense économique que représente l'exclusivité légale.

Dans l'Union européenne, le régime de la propriété intellectuelle est complété par des règles d'exclusivité des données. Pour obtenir l'autorisation de mise sur le marché d'un médicament, un fabricant de princeps est tenu de réaliser des études comprenant des rapports étayés par des tests cliniques et des avis d'experts. Par conséquent, en plus de la protection conférée par le brevet, les fabricants de princeps obtiennent l'exclusivité des données relatives à leurs produits, données auxquelles les fabricants de génériques ne peuvent donc pas avoir accès, pendant une période déterminée, pour faire approuver des copies des médicaments d'origine. L'Union européenne est dotée de certaines dispositions qui facilitent la protection par brevet et d'autres en faveur de la mise sur le marché des médicaments génériques.

Tout d'abord, la réglementation de l'Union européenne autorise les producteurs de génériques à préparer leurs demandes d'autorisation de mise sur le marché, alors même que la molécule originale est encore protégée par un brevet, et sans devoir fournir les données d'évaluation du produit original. En effet, aux termes de la directive 2004/27/CE, huit ans après la mise sur le marché du médicament d'origine, un demandeur n'est pas tenu de fournir les résultats des essais précliniques et cliniques d'un produit s'il est en mesure de prouver qu'il s'agit d'une version générique du médicament original breveté[39]. Cela étant, le producteur original se voit octroyer une période d'exclusivité commerciale de 10 ans qu'il peut prolonger s'il le souhaite selon la formule communément appelée « 8+2+1 ». En substance, il s'agit de trois étapes consécutives qui ont pour effet d'étendre d'une année la durée de la protection conférée par le brevet. Il y a tout d'abord la période d'exclusivité des données (8 ans), puis la période d'exclusivité commerciale (2 ans) et enfin une année de protection supplémentaire qui peut être accordée en cas d'autorisation du médicament d'origine pour une nouvelle application thérapeutique présentant un « avantage clinique significatif ». L'extension d'une année peut également être obtenue si le produit original sort du domaine des médicaments délivrés sur ordonnance pour être mis en vente libre, ou encore s'il est démontré qu'il est « d'un usage médical bien établi »[40].

Outre cette année supplémentaire, les producteurs de princeps peuvent demander un certificat complémentaire de protection (CCP), qui a pour objet de compenser le délai requis pour obtenir l'autorisation légale de mise sur le marché. La demande peut être déposée auprès de l'office des brevets de l'un des États membres de l'Union européenne[41]. Les conditions à remplir sont visées à l'article 3 du règlement communautaire correspondant ; elles stipulent qu'un certificat complémentaire de protection sera accordé si le produit a) est protégé par un brevet de base en cours de validité, b) a obtenu une autorisation de mise sur le marché en cours de validité conformément à la directive 65/65/CEE ou à la directive 81/851/CEE selon le cas, c) n'a pas déjà fait l'objet d'un certificat, et d) si l'autorisation mentionnée au point b) est la première autorisation de mise sur le marché du produit, en tant que médicament[42]. Aux termes de l'article 1 b), le produit est défini comme étant « le principe actif » ou « la composition de principes actifs »[43]. La période d'extension maximale est de cinq ans à compter de la date

39 Art. 10, 10a, 10b, 10c de la directive 2004/27/CE, consultable à l'adresse http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/dir_2004_27/dir_2004_27_fr.pdf. La directive 2004/27/CE modifiant la directive 2001/83/CE instituant un code communautaire relatif aux médicaments à usage humain, est entrée en vigueur en novembre 2005.

40 *Idem.*

41 Règlement CEE n° 1768/92 du Conseil du 18 juin 1992 concernant la création d'un certificat complémentaire de protection pour les médicaments (JO n° L 182 du 2.7.1992, p. 1), consultable à l'adresse http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992R1768:FR:HTML.

42 *Idem*, article 3.

43 *Idem*, article 1 b).

d'expiration du brevet de base[44]. Néanmoins, la durée du certificat complémentaire de protection peut être encore prolongée de six mois, ce qui fait cinq ans et demi au total, si le produit est un médicament à usage humain pour lequel ont été fournies des données obtenues à partir d'essais cliniques réalisés conformément à un plan de recherche pédiatrique approuvé[45].

Compte tenu des coûts de développement considérables des médicaments et de la faible probabilité de voir un nouveau produit atteindre le marché, il faut que les profits dégagés en cas de réussite compensent suffisamment les pertes subies en cas d'échec pour que les entreprises continuent d'investir dans le développement de nouveaux produits. En limitant la concurrence directe sur les prix, le brevet et les autres exclusivités réglementaires renforcent donc les incitations des fabricants de médicaments princeps à entreprendre les projets de recherche et développement grâce auxquels de nouveaux produits pourront voir le jour.

Il n'existe aucune observation directe de l'incidence des génériques sur l'innovation dynamique dans le secteur pharmaceutique. Une étude au moins indique cependant qu'une réglementation de nature à faire baisser les prix au détail des médicaments de marque peut entraîner une diminution de l'investissement en R-D nécessaire à la conception de nouveaux médicaments. Ses auteurs parviennent à la conclusion que des réglementations rigoureuses en matière de prix, telles qu'on en trouve en France, en Italie et au Japon, ont eu dans ces pays des effets néfastes sur les incitations à l'innovation dans le domaine des médicaments[46]. Si, comme le montrent les données mentionnées précédemment, l'arrivée sur le marché des génériques exerce la même pression à la baisse sur les prix de détail que la réglementation, il peut être instructif de s'intéresser au lien qu'établit cette étude entre la sévérité de la réglementation des prix et la diminution des incitations à l'innovation sur le long terme.

L'ouverture du marché aux génériques pourrait avoir sur l'innovation un impact plus marqué encore que l'encadrement des prix de vente. Si ce sont les concurrents qui déterminent le moment et l'ampleur des baisses de prix par rapport au prix de monopole non réglementé, il en résultera peut-être des effets plus importants et moins prévisibles que lorsque les prix au détail sont fixés par la réglementation. De ce fait, les laboratoires qui développent de nouveaux médicaments risquent de se montrer encore plus prudents dans leurs décisions d'investissement : face à l'incertitude que représente la concurrence du marché, la réglementation leur apparaîtra comme un processus plus prévisible auquel ils peuvent participer. De plus, les autorités de régulation se soucient sans doute davantage de préserver les incitations dynamiques à l'innovation que les fabricants de génériques qui réalisent leurs profits au détriment des producteurs de princeps.

Malgré les avantages des droits de propriété intellectuelle et autres règles d'exclusivité qui protègent les activités de recherche et développement dans l'industrie pharmaceutique, l'aspect dynamique de la question ne devrait pas occulter l'importance de la concurrence. Ce n'est pas seulement la capacité d'exclure les concurrents qui motive l'innovation, c'est aussi la pression qu'exerce la concurrence elle-même. Dans l'idéal, en outre, l'exclusion ne devrait pas être plus importante qu'il n'est nécessaire pour stimuler l'investissement, ce qui signifie que des brevets d'une portée ou d'une durée excessive ne seraient pas nécessaires à l'innovation et porteraient préjudice au bien-être du consommateur à court comme à long terme.

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44 *Idem*, article 13.

45 Règlement (CE) n° 1901/2006 du Parlement européen et du Conseil du 12 décembre 2006 relatif aux médicaments à usage pédiatrique, modifiant le règlement (CEE) n° 1768/92, les directives 2001/20/CE et 2001/83/CE ainsi que le règlement (CE) n° 726/2004 article 36, consultable à l'adresse http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2006_1901/reg_2006_1901_fr.pdf.

46 Grabowski et Wang (2006).

Le niveau optimal de l'innovation et, de la même façon, la durée et la portée optimales des protections conférées par le système de propriété intellectuelle sont extrêmement difficiles à déterminer avec une quelconque précision pratique. Pour la question qui nous intéresse, le présent document part du principe que les droits de propriété intellectuelle sont suffisants pour protéger contre une arrivée trop précoce des génériques sur le marché, et admet par conséquent que la concurrence des génériques est bénéfique. En partant de ce postulat, nous reconnaissons que la question du degré de protection conféré par les droits de propriété intellectuelle est très controversée dans différents pays, et que, dans bien des cas, une même situation peut être jugée trop sévère pour certains et pas assez pour d'autres. Si des droits de propriété intellectuelle trop faiblement protecteurs peuvent réduire les incitations à l'innovation et amoindrir les effets nets des génériques sur le bien-être des consommateurs, nous estimons avant tout que c'est à la politique de la propriété intellectuelle qu'il incombe de corriger ces défauts, plutôt que d'y remédier en s'écartant des objectifs essentiels du droit de la concurrence. En faisant l'hypothèse que les droits de propriété intellectuelle stimuleront l'investissement dans l'innovation, nous nous intéresserons maintenant à la mise sur le marché des génériques dans un environnement où les produits pharmaceutiques sont protégés par des brevets.

5. Modes d'entrée des génériques sur le marché

La concurrence des génériques sur le marché des médicaments brevetés peut prendre diverses formes. Le scénario le plus simple est celui où les fabricants attendent tout simplement l'expiration du brevet protégeant le médicament princeps. Lorsqu'ils ont obtenu les approbations réglementaires nécessaires pour leurs produits bio-équivalents, rien ne les empêche plus alors d'entrer sur le marché.

Cependant, attendre qu'un médicament soit tombé dans le domaine public retarde et, par conséquent, réduit les avantages liés à la baisse des prix consécutive à l'expiration du brevet. Un tel retard est acceptable lorsque le brevet est valable et que le générique ne peut apporter aucune innovation à partir de ce dernier. La durée du brevet reflète l'idée que les avantages de la protection en termes d'incitation à l'innovation et au développement de nouveaux médicaments compensent ses coûts en termes d'absence de concurrence entre médicaments existants. Mais lorsqu'un brevet peut être remis en cause ou contourné, attendre son expiration avant de pouvoir accéder au marché peut s'avérer coûteux pour les consommateurs.

La mise sur le marché de génériques après l'expiration d'un brevet peut néanmoins apporter des avantages non négligeables en termes de -être lorsque les médicaments concernés sont des produits très populaires et que leur vie commerciale n'est pas terminée. Les règles qui réduisent les barrières à l'entrée des génériques, tout en tenant compte des considérations de sécurité publique, peuvent ainsi accroître le bien-être du consommateur. Il en va de même pour les mesures qui interdisent de prolonger la validité des brevets au-delà de leur durée initiale.

Dans l'Union européenne, les fabricants de génériques peuvent accélérer la mise sur le marché de leurs produits en déposant une demande centralisée auprès de l'Agence européenne des médicaments. L'avantage de cette procédure est qu'elle débouche sur une autorisation unique pour l'ensemble du marché communautaire. Après avoir reçu la demande, l'Agence dispose d'un délai de 270 jours pour soumettre une recommandation à la Commission européenne, laquelle accorde généralement ensuite l'autorisation de commercialisation[47].

[47] Règlement (CE) n° 726/2004 du Parlement européen et du Conseil du 31 mars 2004 établissant des procédures communautaires pour l'autorisation et la surveillance en ce qui concerne les médicaments à usage humain et à usage vétérinaire, et instituant une Agence européenne des médicaments, consultable à l'adresse http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:FR:PDF.

Aux États-Unis, la loi Hatch-Waxman[48] définit le cadre réglementaire dans lequel un fabricant de génériques peut obtenir l'approbation de son médicament par la FDA en soumettant une demande ANDA (*Abbreviated New Drug Application*). Une ANDA doit satisfaire à toutes les exigences de la NDA, à ceci près qu'elle peut reprendre les données cliniques initialement fournies pour établir la sécurité et l'efficacité du princeps à condition que la bio-équivalence du générique soit démontrée. C'est pourquoi le coût d'une ANDA approuvée est généralement considéré comme nettement moins élevé que celui d'une NDA, de l'ordre d'un million de dollars ou moins[49].

Une deuxième possibilité consiste à lancer le médicament générique sans attendre l'expiration du brevet protégeant le princeps, puis à contester la validité de ce brevet si son titulaire cherche à faire appliquer ses droits. Une telle stratégie comporte des risques pour le fabricant de génériques, mais elle a été mise en œuvre dans des situations où le nouvel entrant estimait que le brevet du laboratoire en place n'était pas valable. Les lancements « risqués » de génériques par des fabricants prêts à contester des brevets en cas d'accusation de contrefaçon peuvent servir les intérêts des consommateurs dans la mesure où ils permettent l'entrée sur le marché de versions génériques de médicaments protégés par des brevets susceptibles d'être remis en cause. Mais les fabricants hésiteront à juste titre à courir de tels risques vu les frais à débourser en cas d'action en contrefaçon et la perte éventuelle des investissements fixes déjà réalisés.

L'une des réponses possibles consiste pour les pouvoirs publics à adopter des mesures pour inciter les fabricants de génériques à concurrencer les médicaments brevetés malgré les risques de poursuites pour contrefaçon. Aux États-Unis, par exemple, pour encourager la mise sur le marché des génériques aussi vite que possible, la loi Hatch-Waxman donne la possibilité au fabricant de déposer une demande d'autorisation dite "ANDA au titre du paragraphe IV", par laquelle il certifie : a) que son médicament générique ne portera atteinte à aucun des brevets du princeps répertoriés dans le « Livre orange » ("*Orange Book*") de la FDA, et/ou b) que les brevets concernés du Livre orange ne sont pas valables. En règle générale, il s'ensuit un litige autour du ou des brevets en question, et la FDA peut différer l'autorisation pendant une période pouvant aller jusqu'à 30 mois à compter de la notification au fabricant du princeps du dépôt de l'ANDA au titre du paragraphe IV (à moins qu'une décision favorable n'intervienne plus tôt dans le règlement du litige). À ce stade, la FDA peut autoriser la mise sur le marché du médicament générique, et le premier fabricant à avoir déposé la demande ANDA au titre du paragraphe IV se voit conférer une exclusivité de commercialisation de 180 jours. L'exclusivité de commercialisation ne protège en général de la concurrence qu'un seul fabricant de génériques, le premier qui a déposé l'ANDA, car elle interdit à la FDA d'approuver toute autre ANDA visant le même médicament avant le terme de la période de 180 jours. Cette mesure a pour but d'encourager les fabricants de génériques à contester les brevets sur les médicaments de marque pour essayer d'avoir accès au marché avant l'expiration de ces brevets.

L'arrivée d'un générique sur le marché peut aussi être le fait du fabricant du princeps lui-même, qui décide dans ce cas de lancer une copie de son médicament d'origine en utilisant l'autorisation qu'il a reçue initialement de la FDA après le dépôt d'une NDA (ces médicaments sont alors appelés « génériques autorisés »). Puisque le fabricant du princeps dispose déjà d'une approbation, il peut mettre son générique autorisé immédiatement sur le marché et n'est pas concerné par la période d'exclusivité de 180 jours accordée au premier tiers qui dépose avec succès une demande ANDA au titre du paragraphe IV. Les fabricants de princeps n'ont pas pour habitude d'introduire eux-mêmes des génériques autorisés sur le marché, mais ils le font parfois lorsqu'ils sont directement menacés par un projet de générique. Les faits

48 Loi Hatch-Waxman relative au rétablissement de la durée des brevets et à la concurrence sur le prix des médicaments (Drug Price Competition and Patent Restoration (Hatch-Waxman) Act) de 1984, Pub. L. n° 98-417, 98 Stat. 1585 (1984), codifiée sous sa forme amendée à l'art. 21 U.S.C. § 355.

49 Reiffen, D. et M. Ward, Generic Drug Industry Dynamics, *The Review of Economics and Statistics*, 2005 ; 87(1), p. 37-49.

montrent néanmoins que les consommateurs bénéficient généralement de l'arrivée de génériques autorisés sur le marché, même lorsque des génériques de fabricants tiers sont déjà en vente. Dans un rapport provisoire publié en juin 2009 sur les génériques autorisés, la FTC constate que durant les 180 jours d'exclusivité les prix des médicaments génériques baissent de 8 % lorsqu'un générique autorisé est en concurrence avec un générique lancé via la procédure ANDA[50]. De plus, comme les génériques autorisés sont mis sur le marché dans le cadre d'une NDA, ces avantages peuvent être obtenus sans que personne n'ait à récupérer les coûts d'entrée inhérents à l'octroi d'une ANDA.

Cela étant, on estime souvent que l'incitation que peuvent avoir les fabricants de génériques à contester des brevets au titre du paragraphe IV peut être sensiblement réduite du fait de la présence ou de l'absence de génériques autorisés. Celui qui voudrait déposer une demande ANDA tiendra compte du fait qu'avec l'arrivée d'un générique autorisé il ne sera plus le seul fabricant de génériques sur le marché et que la concurrence risque de peser lourdement sur les bénéfices escomptés. Le rapport de la FTC ne tire aucune conclusion quant à l'impact global des génériques autorisés sur les contestations potentielles de brevets fondées sur le paragraphe IV, mais il constate que les recettes du premier bénéficiaire d'une autorisation demandée au titre du paragraphe IV baissent d'environ 50 % pendant la période d'exclusivité commerciale de 180 jours lorsqu'un générique autorisé est mis sur le marché. Si cette baisse ne décourage pas l'entrée sur le marché, elle est alors bénéfique pour le consommateur. Dans le cas contraire, la question n'est pas tranchée.

Enfin, un fabricant de médicaments princeps peut miser sur la commercialisation d'un générique autorisé pour convaincre les demandeurs potentiels d'autorisation ANDA de rester en dehors du marché. Les litiges fondés sur le paragraphe IV se règlent souvent par un accord entre le fabricant du princeps et son rival sur la date d'entrée du générique sur le marché, mais d'autres conditions peuvent aussi être négociées, par exemple la promesse du laboratoire du médicament de marque de ne pas lancer de générique autorisé. Le fabricant indépendant de génériques a le choix entre mettre immédiatement son médicament sur le marché, sachant que ses bénéfices seront diminués par la présence du générique autorisé, ou accorder au fabricant du médicament de marque une période additionnelle de monopole en échange d'un accès ultérieur au marché (avant l'expiration du brevet) sans la concurrence d'un générique autorisé. Ainsi, l'engagement de ne pas lancer de générique autorisé peut être une sorte de compensation dans le cadre de règlements amiables dits de « *pay-for-delay* » qui consistent à payer un concurrent pour qu'il retarde son entrée sur le marché (voir ci-après)[51].

6. Questions relevant de la politique de la concurrence

Les fabricants de médicaments de marque ont beaucoup à perdre avec l'arrivée de génériques sur le marché puisqu'ils voient leurs parts de marché et leurs bénéfices diminuer, et souvent dans de fortes proportions. Ils sont donc très désireux d'empêcher à la fois l'arrivée de génériques sur le marché et le succès des fabricants de génériques qui parviennent à s'implanter. Deux possibilités s'offrent à eux selon qu'ils décident ou non de jouer le jeu de la concurrence. Dans le premier cas, ils peuvent abaisseur leurs prix et/ou proposer des médicaments améliorés en avance d'une génération sur les génériques nouvellement entrés sur le marché.

Dans le second cas, les stratégies anticoncurrentielles possibles sont très variées. Plusieurs d'entre elles sont énumérées ci-après et seront commentées dans les paragraphes qui suivent : les paiements aux fabricants de génériques dits « *pay-for-delay* » ou « *reverse payments* » ; le changement de produit ou « *product hopping* », qui consiste pour un fabricant de médicaments de marque à retirer un produit juste

50 Commission fédérale du commerce, *Authorized Generics: An Interim Report*, juin 2009, consultable à l'adresse http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf.

51 *Ibid*.

avant l'arrivée d'un générique sur le marché et à le remplacer par une version légèrement modifiée de manière à retarder l'entrée des nouveaux génériques et à les empêcher de gagner des parts de marché ; le dépôt d'un grand nombre de brevets pour un même médicament, afin de rendre difficiles les contestations et d'allonger la durée de la protection conférée par les droits de propriété intellectuelle ; et l'utilisation à des fins stratégiques par les fabricants de princeps de leurs propres « génériques autorisés » pour écarter la concurrence des génériqueurs ou passer des accords avec eux. Ces stratégies n'ont pas toutes le même potentiel de nuisance pour la concurrence, mais toutes constituent à la fois un risque et un enjeu pour la politique de la concurrence.

Certaines stratégies visant à bloquer ou à éviter la concurrence des génériques relèvent du droit de la propriété intellectuelle et de la politique réglementaire dans ce domaine. Par exemple, le « *product hopping* » soulève des questions concernant la brevetabilité, les règles d'exclusivité et le principe de substitution par les génériques. De même, la multiplication des brevets pour un seul médicament pose des problèmes qui concernent davantage le droit de la propriété intellectuelle que le droit de la concurrence.

D'autres stratégies, en revanche, relèvent clairement de l'application du droit de la concurrence. Les plus évidentes, à savoir les ententes entre fabricants de médicaments de marque et fabricants de génériques portant sur les prix, la production ou l'accès au marché, devraient être surveillées de près et soumises aux règles ordinaires de la législation antitrust.

Les règlements du type « *pay-for-delay* », une stratégie très répandue aux États-Unis et qui suscite aussi de nombreuses préoccupations en Europe, soulèvent des questions plus complexes. Le principe consiste à payer le fabricant d'un concurrent générique potentiel pour qu'il retarde son entrée sur le marché, autrement dit à négocier financièrement son exclusion du marché pendant un certain délai. À la lumière des décisions de justices rendues à l'encontre des plaignants dans le cadre de procédures pour infraction au droit de la concurrence impliquant des règlements de *pay-for-delay* aux États-Unis, le débat sur la question a gagné le Congrès des États-Unis, alors que les batailles judiciaires se poursuivent. Un certain nombre de projets de lois prévoyant l'interdiction ou la limitation des accords de type *pay-for-delay* sont actuellement à l'étude au Congrès.

Dans l'Union européenne, le rapport d'enquête final sur le secteur pharmaceutique indique que les entreprises du secteur doivent s'attendre à une intensification de la surveillance exercée par la Commission dans le cadre de la lutte contre les pratiques anticoncurrentielles, notamment en ce qui concerne les comportement en matière de brevets et les accords entre concurrents, dans la mesure où ces derniers visent à retarder l'entrée d'un médicament générique sur le marché ou à freiner l'innovation chez un concurrent. Dans le droit fil de cette mise en garde, la Commission a confirmé avoir ouvert une procédure formelle d'examen contre Les Laboratoires Servier pour infractions présumées aux règles du traité CE relatives aux pratiques commerciales restrictives (art. 81) et aux abus de position dominante sur le marché (art. 82)[52]. Sont visés en particulier dans le cadre de cette procédure le dépôt de grappes de brevets, les litiges et actions en justice contre des fabricants de génériques et les règlements amiables anticoncurrentiels avec des fabricants de génériques concernant des brevets. La décision d'entamer des poursuites concerne également plusieurs fabricants de génériques et porte sur certains accords individuels, potentiellement anticoncurrentiels, passés entre chacun d'eux et Servier, y compris des règlements dits de *pay-for-delay*[53]. L'ouverture d'une procédure formelle fait suite aux inspections-surprises menées par la Commission en

52 Communiqué de presse de la Commission européenne – Ententes et abus de position dominante : la Commission ouvre une procédure formelle d'examen contre Les Laboratoires Servier et plusieurs fabricants de génériques, 8 juillet 2009, consultable à l'adresse: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/322&format=HTML&aged=0&language=FR&guiLanguage=fr.

53 *Idem.*

novembre 2008 dans différents États membres[54]. L'enquête en cours porte sur des comportements susceptibles d'avoir pour objet ou pour effet d'entraver l'entrée sur le marché du perindopril générique, un médicament cardio-vasculaire.

7. Conclusion

L'arrivée de médicaments génériques sur les marchés pharmaceutiques peut comporter des avantages considérables pour les consommateurs et réduire les dépenses des systèmes de santé. Ces avantages varient toutefois d'un pays à l'autre et leur incidence en termes de bien-être dépend d'un certain nombre de facteurs institutionnels, tels que la réglementation afférente à la distribution des produits pharmaceutiques, les systèmes de remboursement applicables aux médecins et pharmaciens, la structure des régimes d'assurance maladie et les procédures d'autorisation des nouveaux médicaments et des médicaments génériques. Cependant, même si ces facteurs font varier l'ampleur des effets positifs de l'entrée des génériques sur le bien-être du consommateur, l'ouverture du marché à la concurrence des génériques devrait être un objectif de l'action publique : les données montrent qu'elle peut faire baisser les prix dans une proportion de l'ordre de 20 à 80 % dans un certain nombre de pays.

Malgré les avantages que présente la concurrence des génériques, les baisses de prix statiques et le bénéfice qui en découle pour le consommateur doivent être mis en balance avec les avantages dynamiques importants que représente l'investissement continu dans la mise au point de nouveaux médicaments. Sur les marchés pharmaceutiques, l'équilibre entre les avantages à court et à long terme est largement assuré à l'heure actuelle par le système des droits de propriété intellectuelle. La politique de la concurrence devrait néanmoins veiller à ce que les contraintes de l'exclusivité accordée aux brevets légitimes ne laissent aucune place à des stratégies anticoncurrentielles qui renforceraient encore davantage les barrières à l'entrée des fabricants de médicaments génériques sur les marchés pharmaceutiques.

[54] Communiqué de presse de la Commission européenne : La Commission confirme avoir mené des inspections-surprises auprès d'entreprises pharmaceutiques, 25 novembre 2008, consultable à l'adresse : http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/08/734&format=HTML&aged=0&language=FR&guiLanguage=fr.

CANADA

One of the important roles of Canada's Competition Bureau (the "Bureau") is to advocate in favour of greater reliance on market forces, to federal and provincial regulators and other decision-makers. In recent years, the Bureau has focused much of its advocacy effort on health-related markets, as they are crucial to the welfare of Canadians. Canada's publicly funded health sector comprises and depends on many markets, and it is important to the Bureau to ensure they remain effective so they can deliver the benefits of competition.

Since 2006, the Bureau has made pharmaceuticals one of its key health-related advocacy priorities, reflecting the magnitude of the sector and its important role in treating patients. Prescription pharmaceuticals represent the second largest health care cost in Canada, totaling over $Cnd21.4-billion in 2008.[1] The Bureau has specifically focused its attention on prescribed generic pharmaceuticals. Generic drugs play an important role in creating competition in the supply of pharmaceuticals after the period of patent protection has ended. Generics currently account for over 50 per cent of all prescriptions filled in Canada annually.

There has been widespread concern over the last few years that generic drugs have not provided the benefits to the Canadian health care system that they should. A number of studies have found prices paid by Canadians for generic drugs to be high in relation to other developed countries. The studies prompted the Bureau to conduct an extensive generic drug study to deepen its knowledge of the sector and explore potential causes for high prices with the goal of identifying areas where changes in the market framework might secure greater benefits through competition.

The first phase of the study, completed with the release of the *Generic Drug Sector Study* in October 2007, examined the competitive framework for generic drugs in Canada, from the supply of active ingredients through to the dispensing and reimbursement of generic drugs.[2] The study found that a high level of competition exists for many generic drugs in Canada, but the benefits of this competition are not being passed on to payers (public drug plans, private plan sponsors and persons paying out-of-pocket) in the form of lower prices. The principal reason for this finding was the design of public and private drug plans in Canada that provided limited incentive to either manufacturers or pharmacies to provide generics to payers at the competitive prices established at the pharmacy level. The second phase of the Bureau's study, leading to the release of *Benefiting from Generic Drug Competition in Canada: The Way Forward*, suggested ways to make the generic drug market work better for consumers, businesses and governments in order to get the most value for Canadian's health-care dollars. [3]

This submission provides a description of Canada's generic pharmaceutical sector and outlines the findings and impact of the Bureau's recent work on generic drugs.

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1 IMS Health Canada *News Release*, March 26, 2009, available at: http://www.imshealthcanada.com/web/content/0,3148,77303623_63872702_77770096_84335036,00.html.

2 Competition Bureau Canada (October 2007) "Canadian Generic Drug Sector Study" available online: http://competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/02495.html.

3 Competition Bureau Canada (November 2008) "Benefiting from Generic Drug Competition in Canada: The Way Forward" available online: http://competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03026.html.

1. Canada's generic pharmaceutical sector

1.1 Competition among branded pharmaceuticals that are potential therapeutic substitutes

In Canada, there has traditionally been limited price competition among branded pharmaceuticals that are potential therapeutic substitutes. Physicians normally choose which brand to prescribe based upon their knowledge of the drugs within the therapeutic class, preferences and assessment of the drug's efficacy. Unlike the case of generic drugs, discussed below, once a particular brand pharmaceutical within a therapeutic class is prescribed, the pharmacist cannot switch the patient to another brand product. Therefore, the main channel through which brand manufacturers of therapeutic substitutes compete is the promotion of their products to physicians.

Hospital purchasing of brand drugs is a notable exception to this situation. Canadian hospitals are responsible for prescribing and supplying new drugs to patients while they are in the hospital's care. They commonly put out tenders for the supply of brand drugs within therapeutic classes to meet their needs, or negotiate prices with the manufacturers of these drugs. After leaving the hospital, patients tend to remain on the brand drug dispensed by hospital. They obtain the drug from retail pharmacies, normally at their list price plus fees and mark-ups. Accordingly, offering reduced prices to hospitals provides a way for brand manufacturers to compete to increase their share of sales at list prices outside of the hospital.

In addition, a limited amount of therapeutic substitution takes place at the drug plan level. For example, the provincial drug benefit plan in British Columbia applies reference-based pricing to drugs within five therapeutic classes. Under the scheme, the maximum amount that will normally be reimbursed to the patient is based on the lowest cost alternative within the therapeutic class on the provincial drug formulary.[4]

1.2 Competition between a branded pharmaceutical and its corresponding generic substitute

Brand manufacturers may use various strategies to prevent the loss of drug sales to generic manufacturers. The addition of further patents on a chemical to create a new drug listing can allow the brand manufacturer to limit erosion of its market share for the active chemical. These patents may be for the purposes of, for example, allowing more than one treatment to be combined in a dose, or improving the delivery of the active chemical in the bloodstream. Patients prescribed these new drugs by physicians normally cannot be switched by pharmacies to a generic product.

Brand manufacturers may also attempt to retain a share of markets for their drugs after they lose patent protection by licensing a generic company to supply the brand version. For the cooperating generics, this avoids the costs of developing and obtaining approval for its own generic product.

In the past, brand manufacturers did not engage in price competition with generics to protect their market shares. More recently, there have been increased instances of brand companies either lowering the price of their drugs after generic entry or, more frequently, providing off-list price rebates to private or public drug plans to obtain exclusive or preferential listing on the plans' respective formularies. The fact that major drugs brought to market in the 1990's are losing their patent protection and that fewer new

[4] Exceptions are permitted where warranted to protect patients. In 1995, B.C. PharmaCare implemented therapeutic reference-based pricing to three drug classes, nitrate drugs, histamine-2 blockers, and non-steroidal inflammatory drugs (NSAIDs). Two additional classes were added in 1997, angiotensin-converting enzyme (ACE) inhibitors and calcium-channel blockers. For discussion of the B.C. policy, see Morgan, S., M. McMahon, and D. Greyson (2004) "Outcomes-Based Drug Coverage in British Columbia," *Health Affairs*, Millwood, Vol 23(3), pp. 269-76.

blockbuster drugs are anticipated in the near future may account for the increased interest by brand companies to maximize their returns on existing drugs after they lose patent protection.

Efforts by brand companies to maintain market share by discounting prices to plans are being resisted by pharmacies. In a contrasting approach, generic manufacturers, as discussed further below, provide large rebates and allowances to pharmacies for stocking.

1.3 Competition among generic drug producers

The principal means by which generic drug companies have competed in Canada has been to provide discounts or rebates off-list prices to pharmacies on sales of their products. As indicated in the *Generic Drug Sector Study*, the design of public and private drug plans in Canada has traditionally provided limited incentive for generic manufacturers or pharmacies to offer low generic drug prices to payers. As a consequence, prices paid by public plans, private plans and persons paying out-of-pocket, are normally equal to the drug's list price or any applicable maximum price.

As pharmacies only need to stock one generic product, where multiple generics exist, their suppliers compete by offering higher discounts or allowances off-list prices to pharmacies. The price paid to the pharmacy, net of these rebates or allowances, may be but a small fraction of the price charged to payers.

Some other important elements of competition among generic manufacturers include:

- *Patent challenge strategies:* Being the first to enter the market can provide a major competitive advantage. Companies that are aggressive in challenging drug patents may obtain a competitive advantage by being first to enter the market, while ones that are more passive may be able to avoid litigation-related entry costs.

- *Breadth of product line*: Pharmacies can generally keep costs lower by dealing with fewer generic suppliers. Therefore, having a broader product line can constitute a competitive advantage.

- *Promotion to pharmacies:* Generic manufacturers actively sell and promote their products to pharmacies. This activity can be particularly important for sales to independent stores or small chains.

1.4 Pricing of branded and generic drugs

1.4.1 Branded drugs

Patented drugs in Canada are subject to maximum prices set by the Patented Medicine Prices Review Board (PMPRB). The PMPRB is an independent, quasi-judicial body. It sets maximum prices for patented drugs based on a range of factors, including the circumstances, the price of other drugs in the same therapeutic class or prices in international comparator countries.[5] When drugs lose patent protection, they are no longer subject to PMPRB regulation.

As indicated above, there is limited price competition among brand drugs within the same therapeutic class. Accordingly, maximum prices allowed by the PMPRB also tend to be the prices at which patented drugs are sold to pharmacies and charged to payers subject to additional prescription fees and mark-ups.

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5 The PMPRBs Compendium of Guidelines, Policies and Procedures was published in June 2009 and it is available at: http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1034.

1.4.2 Generic drugs

For generic drugs, it is essential to distinguish between the setting of prices to pharmacies versus payers, drug plans and persons paying out-of-pocket.

Prices to pharmacies have traditionally been determined by competition among generic manufacturers to have their products stocked by pharmacies. Until recently, this competition took the form of off-list price rebates paid to pharmacies by generic manufacturers. The net pharmacy price of generic drugs to pharmacies is based on competition among generic manufacturers who offer rebates from invoice prices to secure their generic version as the one stocked by the pharmacy.

The Bureau's first generic drug study found that competition by generic manufacturers to offer lower prices, through rebates, to pharmacies had not been reflected in prices paid by either public or private plans, or people paying out-of-pocket. Instead, prices paid for generic drugs across Canada tended to reflect the maximum generic drug prices allowed under the province of Ontario's drug plan.[6] Prior to 2006, the Ontario Drug Benefit Plan (ODB) used to set a cap on retail prices of most generic drugs at 63 per cent of the brand name equivalent. The Bureau's study found that the main reason for the high prices to be reimbursed by payers was the design of private and public drug plans that did not provide incentives for either pharmacies to pass on rebates to payers, or manufacturers to structure their prices so as to offer competitive prices to payers.

The traditional generic pricing framework changed in 2006 when Ontario introduced the *Transparent Drug System for Patients Act*. The Act reduced the maximum that the province would pay for generic drugs to 50 per cent of the brand-name product price. These lower prices apply only to Ontario public drug plans and not to private drug plans. The province of Quebec received the benefit of the lower Ontario prices owing to its policy to pay no more than the lowest price available to other public drug plans. The reduced Quebec prices apply to both public and private payers in the province.

For private payers outside of Quebec and public drug plans outside of Quebec and Ontario, the price of generic drugs has increased. For them, the list price for new generics coming on the market has increased to 70 per cent or more of the interchangeable brand product price.[7]

In 2006, both Ontario and Quebec passed legislation and regulations prohibiting the granting of rebates to pharmacies on generic drugs. However, both provinces allow generic manufacturers to provide allowances to pharmacies in support of designated patient care services. In the case of Ontario, the allowances are capped at 20 per cent of generic drug costs for public plans only.[8] In Quebec, allowances are also capped at 20 per cent but for both private and public generic drug sales.

1.5 Regulatory approval process for generic products

All drugs marketed in Canada are subject to the *Food and Drugs Act* and *Food and Drug Regulations* administered by Health Canada. In order to market a generic drug in Canada, a company must first obtain a Notice of Compliance (NOC) from Health Canada. The NOC process addresses two key matters, the

6 Ontario is Canada's most populous province and the largest drug plan payer in Canada.

7 For example, the province of B.C. has negotiated an interim agreement with pharmacists under which the maximum price to the province's public drug plans for generics coming on to the market starting January 2009 will be 50 % of the interchangeable brand product price.

8 It should be noted that irregularities in the reporting of allowances, the increase of drug prices to private payers, observance of high levels of allowances and other concerns have led the province to fundamentally review its generic drug policies.

bio-equivalence of the generic drug in relation to the corresponding brand drug, and whether the generic infringes any existing patents on the corresponding brand drug.[9]

To establish the bio-equivalence of a product, generic manufacturers must submit data and analysis indicating that the product contains the same active chemical as the brand drug and has comparable therapeutic effects with respect to such factors as the timing and amount of the delivery of the active chemical in the bloodstream. While substantial, the requirement to establish bio-equivalence is generally much less demanding to meet than are requirements for bringing new drugs to market.[10] This is because generic companies do not have to develop information on the safety and efficacy of the relevant molecule. Rather, subject to a minimum data protection period, generic companies can rely on the safety and efficacy information filed by the drug originator. The data protection period is 8 years from the date of approval of the patented drug by Health Canada for marketing in Canada with an additional period of 6 months being allowed for drugs used to treat children.

The NOC process is also the link between the *Patent Act* and the review process under the *Food and Drugs Act* and *Regulations*. When a generic manufacturer seeks approval of a drug in Canada based on a previously approved drug, it must address all patents currently listed on the patent register concerning that drug. After a generic manufacturer files an application to Health Canada on a drug covered by a patent on the register, and while the safety and efficacy are being reviewed, the applicant must either: advise Health Canada that it will accept that the NOC will not be issued until the patent expires; file a statement claiming that the person who filed the patent list is not the patent owner (or acting with the owner's consent); or file a statement that the patent has either expired, is not valid, or is not infringed (a Notice of Allegation, or NOA).

The NOA must be served on the person who submitted the patent list (generally the holder of the original NOC). That person then may, within 45 days, apply for a court order prohibiting Health Canada from issuing a NOC for the second entry (generic) product. If it receives notice of such a court application, Health Canada cannot issue a NOC for 24 months, or until the patent expires or the court makes a determination regarding the allegations in the NOA, whichever comes first. The court may shorten the 24-month period or extend it if the parties consent, or if the court finds that one or both of the parties has failed to reasonably cooperate in expediting the application.

If the patentee wins the case, the NOC cannot be issued until the final patent expires. If the generic wins, a NOC can be issued as soon as Health Canada has completed its review for safety and efficacy. Where a patent has been successfully challenged under the NOC process, the generic company is not given immunity under the *Patent Act*. In these cases, while the generic company can market its product upon receipt of a NOC, it is not uncommon for them to also be challenged under the *Patent Act*.

9 A detailed description of the generic drug approval process in Canada is provided in the Generic Drug Sector Study.

10 An application typically involves between 10 to 20 binders of data that include scientific information on the generic product's performance compared with the brand-name product and provide details on the production of the generic drug, its packaging and labelling. The significance of the hurdle created by the bio-equivalence standard can be higher, for example, for topical creams where extensive clinical trials may be required. Once the original submission is complete, the generic product enters a formal review process that takes a minimum of 180 days. Three reviews are performed: chemistry and manufacturing, safety and efficacy and product information.

1.6 National, provincial and local regulations

All Canadian provinces have adopted interchangeability laws providing a legal basis for substituting generics for branded pharmaceuticals. The laws apply to all interchangeable products, whether they are dispensed under public or private plans or paid for out-of-pocket. The laws allow pharmacists to interchange bio-equivalent products and provide protection for the dispenser of the interchanged drugs against related legal proceedings. Interchangeability laws can be obligatory, requiring that the lowest cost interchangeable products be dispensed, or voluntary, permitting pharmacists to interchange products.

In conjunction with these laws, provincial and private drug plans commonly provide a financial incentive for patients to purchase generics through maximum allowable cost, or least cost alternative policies. These policies base the maximum amount that patients will be reimbursed for a drug on the lowest priced interchangeable product on the plan's drug formulary. If a higher cost brand or generic product is dispensed, the patient or the pharmacy must pay the difference.

A further important factor influencing the take up of generics in Canada has been the financial incentives provided by rebates and allowances for pharmacies to switch patients to generics.

1.6.1 Discounts for generic drugs and corresponding branded pharmaceuticals

Prior to the amendments to Ontario's generic drug policies in 2006, the discount to payers for generic drugs off of the corresponding brand drug price was typically 37 per cent. This discount does not include off-list rebates received by pharmacies that were not passed on to payers. These rebates were 40 per cent or more of the list price paid to pharmacies.

Since 2006, Ontario public drug plans and Quebec public and private payers have received standard price discounts of 50 per cent. However, for other payers, the standard discount on generic drugs coming onto the market since 2006 has fallen to 30 per cent or less.

While the share of all prescriptions filled by generics in Canada is in excess of 50 per cent, the fraction of drug sales that shifts from branded products to generics when the latter are introduced can vary widely from case to case. The Bureau has not systematically examined the factors explaining these variations.

The increasing willingness of brand companies to discount prices or provide rebates to payers to protect market share after they lose patent protection is a new dynamic in the generic marketplace. While it is too early to tell what its full effects will be, the trend toward greater price discounting and rebating by brand companies may lead to them maintaining significantly higher market shares than has tended to be the case in the past.

2. Competition bureau experience in the generic drug sector

The Bureau's market study into generic drug pricing was initiated in an effort to ensure that competitive factors are taken into consideration by federal and provincial government decision-makers. The purpose of the market study was to provide a market analysis of the generic drug sector, with a focus on regulatory and market structure matters.

2.1 Generic drug sector study

The first phase of the study was completed in October 2007 and consisted of a detailed examination of each level of the Canadian generic drug sector, starting from the acquisition of ingredients for manufacturing generics and proceeding through their production, approval process, distribution and wholesaling, dispensing and reimbursement or payment by public and private drug plans, and persons paying out-of-pocket. To perform the study, the Bureau acquired and analyzed data, retained outside experts and conducted extensive interviews with participants and interested parties at all levels of the sector. Before finalizing the paper, a draft of the report was circulated to over 100 sector participants and interested parties for fact-checking purposes.

The final report found that more than ten generic drug manufacturers were competing for shelf space in Canadian pharmacies by offering rebates to pharmacies averaging 40 per cent or more of the retail price; however, the benefits of this competition were not being passed on to provincial drug plans, consumers or private payers. The most important factor contributing to this finding is the design of drug plans, which provide limited incentive for manufacturers to compete to offer competitive prices to end payers, or pharmacies to pass on rebates on to payers.

The second phase of the study looked at ways to free up the benefits from generic competition taking place at the pharmacy level. *Benefiting from Generic Drug Competition in Canada: The Way Forward*, released in November 2008, recommended a number of ways to make the generic drug market work better for Canadian governments, businesses and consumers. These included designing methods, such as a competitive tendering process, to reveal to end payers the actual competitive prices being paid for generic drugs by pharmacies. The Bureau also recommended that provinces set up a framework to reimburse pharmacists directly for services they provide, in addition to dispensing drugs. Provinces were also encouraged to remove any unnecessary limits on advertising or other restrictions on competition between pharmacies. Finally, the report encouraged the provinces to coordinate generic procurement, pricing and reimbursement policies to avoid or at best minimize unintended anticompetitive consequences.

The 2008 report also suggested different strategies that private payers could consider to achieve the benefits from generic competition. These include, for example, the development of preferred pharmacy networks, where private payers would get a negotiated discount on the price of drugs from a pharmacy network in return for encouraging patients to purchase drugs there. It was noted that provinces can also play a role in helping private payers attain generic drug savings by ensuring that their legislation, regulations and drug plan policies do not create unnecessary barriers to private payer actions to achieve the benefits from competition.

The Bureau estimated that up to $Cnd800 million a year could be available to be reinvested in Canada's health-care system or passed on to taxpayers, consumers and businesses, if generic drugs were sold in a more competitive market. This amount could be used to allow drug plans to maintain or expand their coverage, reduce premiums or fund some pharmacist services.

2.2 Impact of the generic drug sector study

While the full effects of the Bureau's work on generic drugs are yet to be determined, it has been influential in shaping both public debate and practice in the Canadian generic drug sector. The market study has been instrumental in demonstrating the importance of generic drug issues across the country. By clarifying the underlying competitive framework for generic drugs, the Bureau has focused public and private attention on the key issue to be addressed in getting the benefits from generic drug competition in Canada; namely, the design of provincial and private drug plans.

The Bureau's work is beginning to be reflected in the development of public and private sector policies to capture the benefits from generic drug competition. One province, Manitoba, has amended its drug plan policies according to the Bureau's generic drug sector findings. The Bureau's work in this area is also factoring prominently in reviews being conducted of generic drug policies in a number of other provinces. In the private sector, the report has increased interest and activity in actions to attain the benefits from generic drug competition.

The Bureau is continuing to advocate the findings and recommendations to public and private sector interests.

CZECH REPUBLIC

1. Introduction

The submission of the Office for the Protection of the Competition of the Czech Republic (hereinafter referred to as "the Office") to the Roundtable on Generic Pharmaceuticals analyses national legal framework of this area in the introduction. It particularly focuses on the issue of entry of new original pharmaceutics and generics to the market, as well as on clarifying the system for stipulating the price of generics and the amount of reimbursement of pharmaceuticals from public health insurance of the Czech Republic. The submission also deals with other relevant questions from the scope of competition on the market, for example the possibility of changing original pharmaceuticals by generics in pharmacy, advertisement of pharmaceuticals in general, as well as patent protection of the original generics.

The objective of the submission is not only to describe the system of placing pharmaceuticals on the market in the Czech Republic and how prices shall be stipulated and refunded within the scope of public health insurance. In its submission, the Office also describes the main differences in the placement of original pharmaceuticals and generics on the market in the Czech Republic, and mainly evaluates the impact of the legal framework on the market with pharmaceuticals, or more precisely the impact of the laws on the functioning of the competition on the market of pharmaceuticals in the Czech Republic.

2. Regulatory framework and authorities

The pharmaceutical system in the Czech Republic is based on two main acts:

- The Act on pharmaceuticals (Act No. 378/2007 Coll.) designates the legal framework for production, distribution, control and authorization of pharmaceuticals as well as their prescription, dispensing and post-marketing surveillance.

- Act on public health insurance (Act No. 48/1997 Coll.) is the legislative framework for pricing and reimbursement of pharmaceuticals.

- Besides these two acts there are many supplementary provisions and decrees concerning health insurance, prescription and dispensing of medicines or evaluation of pharmaceuticals.

The State Institute for Drug Control (Státní ústav pro kontrolu léčiv, SUKL) is the Czech medical agency, responsible for vesting marketing authorizations, regulation and supervision over clinical trials, production, distribution, dispensing and post-marketing surveillance of pharmaceuticals. Newly since the beginning of 2008 it is also responsible for pricing and reimbursement of pharmaceuticals. SUKL is a state institution answering to the Ministry of Health. The Ministry of Health is the superior body responsible for legal framework and strategic decisions.

2.1 Conclusion

It can be summed up that basic legislative conditions on the placement of pharmaceuticals on the market are identical for producers of original pharmaceutics as well as for producers of generics. The area

of the trading with pharmaceutics is governed by extensive state regulation and control with the aim to protect the public health of humans and limit drawn down of public health insurance resources.

3. Entry to the market - Pharmaceutical registration/Approval process

Only authorized human medicinal products (both original and generic) may be prescribed, placed on the market, and used in the delivery of health care in accordance with Act No. 48/1997 Coll. The marketing authorization of human medicinal products may only be issued by SUKL. A medicinal product may not be placed on the market in the Czech Republic, unless it has been authorized by SUKL, or authorized by a procedure compliant with a directly applicable Community regulation (see. point 12.).[1]

The application for marketing authorization of generic products shall not been given until 8 years after the original medicinal product has been registered and before the expiration of 10 years from the first marketing authorization of the reference product in any of the Member States or in the Community. This period shall be extended to a maximum of 11 years, if the marketing authorization holder of the reference product obtains a marketing authorization for one or more new therapeutic indications during the first eight years of the said 10 years, which must be scientifically rated as a significant clinical benefit compared to the existing therapeutic procedures prior to marketing authorization..

In the event of an application for marketing authorization of a new indication of a human medicinal product containing a well established substance where significant preclinical tests and clinical trials related to this new indication have been conducted, SUKL must not take the results of these studies into account when considering an application lodged by another applicant for marketing authorization for the period of one year of granting the marketing authorization for another medicinal product with the given indication. For the purposes of assessing applications concerning different medicinal products with the same qualitative and quantitative composition in terms of active substances and identical pharmaceutical form, the marketing authorization holder may approve the use of pharmaceutical, preclinical and clinical source materials contained in the marketing authorization dossier of the medicinal product after the marketing authorization is granted.

SUKL's authorization procedure has several stages. In the first stage, SUKL assesses the completeness of the application. Within 30 days of the delivery of the application, SUKL notifies the applicant for marketing authorization of the outcome of such assessment. In the event that SUKL identifies shortcomings in the application, it will request the applicant for marketing authorization to supplement the submitted data and documentation.

Where the application has been found by SUKL to be complete, SUKL shall make a decision on the application no later than:

- Within 150 days of the date when the applicant for marketing authorization was informed that his or her application was found to be complete, in the case of generic products;
- Within 210 days of the date when the applicant for marketing authorization was informed that his or her application was found to be complete, in the case of other medicinal products.

[1] See Regulation (EC) No 726/2004 of the European Parliament and of the Council, which establishes Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishes a European Medicines Agency. The arrangement of the conditions of the registration the medicinal products strictly come from EU Acts, which lead to implement the same conditions for registration in Member States of the EU with the objective to create a single market of medicinal products.

Marketing authorization shall be valid for five years of becoming legally effective. The application for renewal is possible only once, whereby it shall be effective for an unlimited period of time. On the date 1.4.2009 SUKL had 57 218 marketing authorizations of a variety of medical products.

When the Czech Republic became a member of the EU, it also entered the system of mutual recognition of marketing authorisations with other Member States of the EHP. For these purposes there are three procedures in the recognition phase: procedure of mutual recognition, decentralised procedure and centralised procedure. After completion of these procedures, the individual national registrations are conducted within a period of 30 days.

3.1 Conclusion

The legal framework in the Czech Republic requires a registration granted by SUKL to the producers of original pharmaceutics and generics for any new product entering the market. When registering generics, producers are much farther ahead, because they can use pharmaceutical, preclinical and clinical source materials contained in the marketing authorization dossier of the medicinal product, if producers of the original pharmaceuticals grant approval. The period of the approval procedure of generics is shorter than the approval procedure of other pharmaceuticals, which facilitates entry to the market. Entry to the market of generics in the Czech Republic is possible after the registration period of original pharmaceutics has elapsed. The deadline is determined by the act, this period is identical with the period stipulated in community law.

4. Pricing and reimbursement

Till the end of 2007 it used to be Ministry of Health who decided on the maximum ex-factory prices. The level and conditions of reimbursement were issued by ministerial decree and were revised four times a year by a categorization committee. There were no statutory guidelines for assessing pharmaceuticals during the decision-making process about reimbursement. Since January 2008, SUKL has been responsible both for setting the maximum ex-factory price and for decisions on reimbursement. This responsibility is based on Act No. 48/1997 Coll.

Until the beginning of June 2008 there were only 2 groups of pharmaceuticals from the aspect of price regulation. Reimbursable pharmaceuticals were regulated by the maximum ex-factory price and regressive mark-up scheme. Prices of non-reimbursable pharmaceuticals were not regulated. Since the beginning of June 2008 a new ministerial regulation has been valid which introduces the category of pharmaceuticals regulated only by the mark-up scheme and some hospital pharmaceuticals whose prices are not regulated at all.

Thus in the Czech Republic there is statutory pricing for almost all reimbursable pharmaceuticals. Prices of pharmaceuticals are set at ex-factory level or are regulated by statutory prices (these are prepared medicinal products, prepared radiopharmaceutics and transfusion products made in the facilities of the transfusion service). The maximum pharmacy retail price can be defined based on fixed wholesale and pharmacy margins. Ex-factory prices as well as margins of non-reimbursable pharmaceuticals can be set freely.

The Ministry of Health issued a Decree on the list of reference groups. The decree determines about 300 groups of pharmaceuticals based on therapeutic indications. Pharmaceuticals included in the same reference groups have similar efficacy, safety profile and clinical use, and are considered to be therapeutically interchangeable.

Terms of admission of the application for setting the maximum price and amount and conditions of reimbursement differ for the applicant of generic and original medicinal products. Besides conditions set

by Act. No. 48/1997 Coll., likewise for the applicant of generic and original drugs, the applicant must corroborate other documentations on setting the maximum price and amount and conditions of reimbursement of original and generic drugs, e.g. quantified and evaluated foreseeable results and reasons of pharmacotherapy that will be achieved by including the drugs in the system of reimbursement from health insurance, the results of the available clinical rating etc. The applicant of setting the maximum price and amount and conditions of reimbursement for the generic drugs shall not provide this data, if it applies only for changing current amount and conditions of the reimbursement. Setting the price and reimbursement for small-molecule drug products and biological drug products is the same.

Companies are obliged to pay the fee for their application (application for new active substances, new combination of a substance, new indications, new pharmaceutical form for new indications – CZK 20 000, application for new pharmaceutical form without assignment for new indication, new strength – CZK 10 000, generic or new size of packaging – CZK 8 000, in other cases – CZK 10 000). Pricing procedure runs on the basis of individual administrative proceedings with fixed terms and conditions. The company (both original and generic) has to apply (fill the form) and the decision is made within 75 days (165 respectively for joint application of price and reimbursement). The appeal authority against decisions made by SUKL is the Ministry of Health. There is no space for negotiating between the competent authority and the companies independently on the nature of the company, nature of the product and the market conditions.

The ex-factory price of a certain pharmaceutical is set as the average ex-factory price of this pharmaceutical found in 8 EU member states (reference basket states - Estonia, France, Italy, Greece, Spain, Hungary, Lithuania and Portugal). If the pharmaceutical (with the exception of highly innovative drugs) is not on the market in at least three reference basket states, prices of the cheapest generic can be used in the evaluation, if the manufacturer agrees. If the pharmaceutical is not marketed in reference basket states or the price of the generic cannot be used, the average of the three lowest prices in any EU member state is used in establishing the ex-factory price. If none of the above mentioned procedures is applicable, the price is set as the maximum ex-factory price of the closest therapeutically comparable pharmaceutical available in the Czech Republic. For highly innovative drugs it is possible to set the ex-factory price as the average manufacturer's price found in at least 2 reference basket states or if the pharmaceutical is available only in one reference basket state the price will be equal to the manufacturer's price found in this state.

According to Act No. 48/1997 Coll., the pricing rules are indifferent to prescription restrictions (OTC - Over-the-Counter/POM - Prescription-only Medicines). There is no special rule for HOM (Hospital-only Medicines) or original/generic or any other pharmaceutical types. The only criterion is whether it is reimbursable or not.

According to Act No. 48/1997 Coll., when calculating the maximum ex-factory price for the first (First in the reference group that is the group of active substances with similar effect) generic pharmaceutical, the price limit is at 80% of the price for the original pharmaceutical.

Act No. 48/1997 Coll. sets the legal framework for the calculation of the maximum ex-factory drugs prices and also establishes the methods for reimbursing pharmaceuticals. Generally only pharmaceuticals with regulated prices (maximum ex-factory price and/or regressive mark-up scheme) are eligible for reimbursement.

Medical products containing active substances from groups of medicinal products listed in supplement no.. 2 of Act No. 48/1997 Coll., are reimbursed from health insurance if SUKL makes a decision on its amount of reimbursement. Reimbursement prices of generics are usually set at 55% of the manufacturer's price of the original pharmaceutical (the level of reimbursement has to be at least 20 %

lower than the reimbursement of the originator). In each group of medicinal products listed in supplement no. 2 of Act No. 48/1997 Coll., at least one of the medicinal products is fully reimbursed from health insurance.

In general, the cheapest out of a defined group of pharmaceuticals (in most cases a generic, often a locally manufactured one) is fully reimbursed. All other pharmaceuticals are partly or fully paid for by patients: sickness funds only reimburse up to the price of the generic equivalent, i.e. the reference price.

Half of the medicinal products reimbursed from public health insurance are regulated by the maximum price. Manufacturers can decide to supply pharmaceuticals for lower prices than the stipulated maximum ex-factory price, in order to reduce or fully eliminate the difference between the price and the reimbursement paid by the patient and thus increase the sale of its product.

In the case the medicinal product is not regulated by a maximum price, it relies on the price policy of the holder. Medicinal products which are not regulated that way undermine the market competition (there are at least four holders of marketing authorization); we can expect a higher effort to compete on the market by charging the minimum or no additional payments to patients.

POM and most of the OTC drugs can be dispensed only by pharmacies or drug dispensaries. There is a small group of drugs called restricted pharmaceuticals which can also be dispensed outside pharmacies (drug stores, gas stations etc.). All restricted pharmaceuticals belong among OTC drugs.

Wholesalers and pharmacists are remunerated by a regressive mark-up scheme. This scheme is issued by the Ministry of Health in a ministerial regulation and is valid for all reimbursable pharmaceuticals. The margins are common for both wholesaler and pharmacy. It means that the lesser margin is kept by the wholesaler, and the greater margin can be applied by the pharmacy. The estimated share of wholesaler margin is 5-7%. Discounts are possible both for wholesalers and for pharmacies. Maximum mark-ups are not always applied and thus prices of pharmaceuticals can vary throughout the country.

In general, the maximum mark-up is not fully used, which leads to different prices for the same pharmaceuticals (especially in the OTC segment) in pharmacies. Therefore patients have the possibility to shop around for the cheapest pharmaceutical.

Patients pay a co-payment which is the difference between the actual price of a drug and the reimbursement. Prices of drugs may vary throughout the country due to the fact that maximum mark-ups are not always applied. In addition to the co-payment there is a fixed regulatory fee of CZK 30 for each item on the prescription (only two items are allowed on one prescription form). The price of a pharmaceutical is reduced by the specific sum (which should compensate the regulatory fee) if a pharmaceutical is reimbursed.

4.1 Conclusion

As the procedural rules concerning the amount and conditions of reimbursement of pharmaceuticals was not being published in the past (it was decided by Ministry of Health), the reimbursement process was - compared to other EU Member States - rather in-transparent. The change of the legal rules as of 1 January 2008 therefore seems to be crucial, because since then on this issue has been tackled by SUKL on the grounds of conditions stipulated by Administrative Code. This increased transparency of the entire procedure and improved the competition on the market.

The prices of pharmaceuticals are regulated by the state only if subsidised from the system of public health insurance, no matter if the pharmaceuticals are original or generic. Pharmaceuticals (both original and generic), which are not even partly reimbursed from the public health insurance, are subject to free

price competition. The generics are sometimes favoured when the maximum amount of price or reimbursement is being set. First of all, their maximum price and amount of reimbursement is always set up to 80 % of the maximum price or amount of reimbursement of the original drug. The price of generics is thus always lower than price of original pharmaceutics, i.e. generics are a cheaper alternative for consumers. The lower reimbursement should motivate doctors for prescription of cheaper generics. Also the rules for submission of applications on price setting and amount of reimbursement should be beneficial for producers of generics under the condition they only apply for the change of current amount and conditions of the reimbursement. After the expiration of the patent protection of original pharmaceutical and the entry of generics substitute on the market, the generics are in fact prioritized as a result of the reimbursement policy. Due to the lower reimbursement of generics in comparison with originals, the cheapest generic in each pharmacotherapeutic group is always fully reimbursed from the public health insurance (only in the case the group does not consist any generic, the original is fully reimbursed). This could again lead to more frequent prescription of cheaper generics. On the contrary the principle of joint margin of pharmaceutists and distributors and rules of drug prescription do not give any preference to originals or generics.

5. Generic substitution

Since 2008, generic substitution has been possible according to Act No. 48/1997 Coll. Generic substitution was possible before but only in the case the prescribed pharmaceutical was not available at the pharmacy. The substitution has been introduced to offer quality and effective pharmaceuticals at lower prices to patients.

Act No. 48/1997 Coll. as amended, introduced several changes in field of generic substitution. Generic substitution is possible if certain conditions are met. Substitution is seen more as an option and is not mandatory. Czech legislation does not provide specific adjustments for parallel imports in the case of generic substitution.

The substitution is possible only if the patient agrees and the prescribing doctor does not object. According to legislation the pharmacist has the right to offer a substitution; it is not an obligation but an option. The substitute must be the same active substance, dosage, strength and pharmaceutical form. It is also possible to substitute for different (but equivalent) active substance but only after consultation with the prescribing doctor and only if the pharmaceutical is urgently needed.

Due to the specific nature of the reimbursement system in the Czech Republic, generic substitution is considered more as a tool for patients (lowering their co-payment) than a tool for rationalising health care system expenditures (insurance companies costs). The reimbursement amount is equal to the lowest price of the pharmaceutical in the reference group - that is the common price of a generic pharmaceutical so there is no difference in reimbursement among originals and generics, except in situations when actual market prices are lower than the (fixed) reimbursement amount but the original is still higher than the generic.

The value of generic sales in the Czech Republic is about 60 %. There has been a long tradition of generic manufacturing companies in the Czech Republic. The size of the generic market is also due to the introduction of the reference price system, which encourages the use of low cost, fully reimbursed generic pharmaceuticals.

5.1 Conclusion

Generic substitution was implemented in the Czech Republic with the aim of decreasing the cost of public health insurance and above all decreasing the expenditures of the end consumer in the form of

charge for medicine. It is yet another measure which has a more favourable effect on the market – if the motive of generic substitution is cost savings for patients, this leads to replacing more expensive original pharmaceutics prescribed by the doctor by cheaper generics with the same active substance or equivalent effect, especially if it is fully paid by public health insurance. Existing limitation of generic substitution is considered by the Office as adequate protection of patient's health.

6. Generic promotion

Since January 2008, generic substitution has been in the centre of publicity in connection with the amendment of Act No. 48/1997 Coll. This Act introduced a possibility for the pharmacist to give a generic pharmaceutical to the customer instead of the prescribed original. Latest information shows that this option has not been sufficiently utilized. A lack of promoting activities may be one of the reasons. Even if people know about this possibility many of them still do not fully trust generics. There is a general apprehension among patients that original pharmaceuticals are more effective and generics have lower or adverse effect. The generic substitution has been introduced to offer quality pharmaceuticals at a lower price (lower co-payment) to the patients. The majority of local manufacturers is producing generic pharmaceuticals.

There is no special Essential Drug Policy in the Czech Republic. The combination of price regulation and system of private pharmacies is considered competent to provide essential pharmaceuticals in satisfactory amounts. The reimbursement amount for a specific product is fixed on a national level and it is not possible to obtain a different (higher) reimbursement amount for the same product for any reason. Remission of the prescription fee is possible in some special cases though (Act No. 48/1997 Coll).

6.1 Conclusion

Although the possibility of replacement of original pharmaceutics by generics has been implemented in the Czech Republic (see above), it is not fully exploited by patients. The Office assumes that it caused by an insufficient promotion of the potential interchangeability, as well as the patient's continuous trust in doctors´ recommendations. Patients hesitate to use totally identical generics instead of medicine, which was prescribed by the doctor, who provides the patients with the long term health care and who "knows the patient's health condition best".

7. Advertising in general

In early 2006, the Czech advertising law was brought into line with EU standards – see the amendment of Act No. 40/1995 Coll., on the regulation of advertisement and on the amendment of Act No. 468/1991 Coll., on the radio and TV broadcasting (amended by Act No. 40/1995 Coll.). Advertising for medical staff is restricted to the product's name and must carry no endorsements. The public may only be informed of the disease which a product is able to treat and the fact that it is licensed.

Under the new law, manufacturers may not send drug distributors, such as pharmacies, samples of medicine. Only prescribing doctors may receive samples and there are now limits as to the quantity and frequency of samples. Pharmaceutical manufacturers may supply nurses with comparative advertising information, training and invitations to conferences, provided they are not merely promotional meetings for prescription medicines. Nurses are not permitted to supply or prescribe drugs.

There are no obligations or financial incentives for doctors to prescribe or pharmacists to dispense cheaper products.

The behaviour of original manufacturers and their generic competitors in advertisement for medicinal products is different only quantitatively, not qualitatively. Generally, the manufacturers of original drugs

invest larger financial amounts into advertising activities focused on promoting original medicinal products, compared to competitors producing generic drugs, which is clear from the behaviour on market.

During the promotion of generic drugs some manufacturers are successful on the market and receive new clients from the list of doctors and pharmacists, especially financial gifts, or even by promotions of so-called Off-label indications. This behaviour is forbidden by Act No. 40/1995 Coll. SUKL examines such cases and in the case of proven infringement of Act No. 40/1995, it imposes sanctions to liable subjects. It is not possible to state that generic manufacturers breach Act. No. 40/1995 more often than manufacturers of original medicinal products in present times. These infringements of Act. No 40/1995 are rare and punished subjects rarely repeat the offence.

7.1 Conclusion

The Czech legal framework makes no distinction between the original products and generics in terms of advertisement. The experience, however, shows that the producers of medicines (no matter if they produce originals or generics) in an effort to be successful on the market use practices that are in conflict with the advertisement rules. The Office supports a wide range of advertisement in the area of off-prescription medicine, because advertising is considered one of the legitimate tools of competition, which enables new competitors to enter the market.

8. Patent protection & Intellectual property rights

International patents were not recognized in Czechoslovakia prior to 1991. A patent law was introduced at the beginning of 1991 (Act No. 527/1990 Coll.) which provides a patent term of 20 years for product claims and pipeline protection. The law is not retroactive, so patented drugs that were copied before 1991 are often still produced locally. In April 2000, the Czech parliament adopted the local Supplementary Protection Certificate (SPC), reflecting extraordinary time consuming research and development of new medicinal products. The possibility to get an additional protective certificate increases the patent's protection of the medicinal product for up to five years (depending on the time between submitting an application of the basic patent and the day of the first registration of the medicinal product in the EU).

Altogether, drugs manufacturers have a very sophisticated strategy for presentating drugs to the market and their subsequent life cycle. Processing these basic questions is routine for marketing departments and development departments of individual drugs. These departments of the manufacturers of generic drugs systematically monitor the happenings on the market with medicinal products in particular countries mainly through data provided by the company IMS Health and also with regard to the expiration of the patent rights of the original drugs. With consideration to these situations, the departments conduct thorough analyses of the market and establish which drugs and when they shall be introduced to the market in particular countries, together with the aspect of production and commercial possibilities of the production plants. These detailed plans are always drawn up several years in advance. Mostly the decision under what conditions the individual generic products appear on the market is up to the management of the company.

The main factors which influence the decision are financial turnover in the pharmacotherapeutic group, the actual amount of reimbursement from public health insurance; respective medicinal product groups, number of competitors in the relevant pharmacotherapeutic group, possible increase in the number of patients with the respective disease etc. As a result the pharmacotherapeutic groups with a high selling potential (which currently have large turnover or which anticipate an increase of the number of patients) have the highest degree of competition, because all the manufacturers use a similar decision-making pattern. It is common that when the patent of an original drug expires, a number of its generic competitors

enter the market, however, with different success depending on the quality and intensity of advertising activities. Whereas, manufacturers of original drugs influence the market with their support of the current pharmacotherapeutic group by new medicinal products, which are more or less different from current ones in character. Manufacturers of generic drugs influence the market mainly by emphasising the price of drugs and by pricing; they very often sell the drugs for a lower price than the reimbursement of current drugs from resources of public health insurance, thereby attracting new customers.

One example of litigation concerning patent protection and intellectual property rights is the case between Zentiva and Pfizer, regarding the distribution of Atorvastatin. In April 2005, Zentiva launched a generic version of Pfizer's cholesterol-reducing drug, whose patent had just expired. Pfizer filed an application to prevent Zentiva from using a specific marketing campaign and to halt the distribution of high-dosage samples. The courts granted Pfizer's request but the decision was later overturned, as EC legislation only places limits on the pack size of samples, not the dosage size. Pfizer fought back by writing to doctors, claiming that authorization for Zentiva's Atorvastatin drug had been issued in breach of Czech and EU laws. An injunction was then placed against Pfizer, preventing further circulation of these letters. A lawsuit against Pfizer required the company to make a public apology to Zentiva and an apology to all physicians who had received the letter. The court then lifted its earlier ban on the distribution of Atorvastatin samples by Zentiva, under the guidance of SUKL.

8.1 Conclusion

The patent protection of producers of original medicines in the Czech Republic has been fully harmonized with community law since year 2000. The protection of producers of original medicines from producers of generics is ensured with the objective to gain returns of high investments expended into research and development of original medicines. The generic producers in the Czech Republic deliberate their entry to the market similarity as the producers in other EU countries.

9. Discounts and rebates

There is no mandatory/statutory system of discounts or rebates applied to the pharmaceutical industry, wholesalers or pharmacies in the Czech Republic. However, the General Health Insurance (VZP) negotiates the subject of discounts on the prices of pharmaceuticals with individual manufacturers to either lower or eliminate co-payment for patients. These so-called "agreed prices" are valid for all pharmacies in the Czech Republic, although the participation of companies is voluntary. Willingness to conclude arrangements on agreed maximum prices for the end consumer is higher among the manufacturers of generic drugs than manufacturers of original drugs. In terms of hospitals, it is common to write up the selective procedure on the delivery of the drugs, which not only leads to obtaining a lower price for the exporter, but also lower distributor margins. In hospitals there often exists a positive list of drugs, which compete at a lower price and which are preferably used. Additionally, individual community pharmacies also negotiate discounts with individual pharmaceutical companies.

9.1 Conclusion

From the abovementioned, it is clear that negotiations between a particular producer of original or generics medicines and health insurance companies or associations of pharmaceuticals lead to decreasing regulated prices of medicines for end consumers and decreasing reimbursement from sources of public health insurance. From practice it is clear that the producers of generics are more interested in such negotiation, as their objective is to try and succeed with lower prices of medicines.

10. Domestic production

The Czech Republic is rather an import country. There are several local manufacturers of pharmaceuticals. The most important of them is Sanofi-Aventis (formerly Zentiva, previously Leciva, plus Slovakofarma), the leading generic pharmaceutical company in the Czech Republic, Slovak Republic, Romania and Turkey. The other pharmaceutical companies with significant presence in the market are Teva (formerly IVAX ČR, previously Galena) and Pliva-Lachema. The industry is now fully privatized, and much of it is now in foreign ownership, usually involving major US/European generic companies.

10.1 Conclusion

Although the Czech Republic is a county with long standing traditions in generics production, there has been a number of acquisitions in the past few years which changed the character of domestic producers into companies focusing production on original pharmaceuticals.

11. Specific issues tackled by the Czech NCA

In connection with establishing the reimbursement of drugs, where according to Act No. 48/1997 Coll. the lowest price of drugs in foreign countries is considered, SUKL pointed out the problems to Czech NCA, which could lead to infringement of the competition.

If the price of a drug in foreign countries decreases e.g. due to time-limited or product-targeted discounts (e.g. in Denmark the prices can be changed once per 14 days, in Sweden the prices are changed once per month), SUKL takes account of the discounted price when setting the price of the drug or the amount of reimbursement of the drug in the Czech Republic. Price or the reimbursement of the drugs is thus set on unusually low level. In the opinion of SUKL, the result of the "reduced" price, especially the reimbursements of drugs could lead to deformation of the competition by reducing the interest of drug manufacturers to enter the market. This decrease in interest results from the economic disadvantage of introducing the drug to the Czech market, as none of the manufacturers of the drug would be able to secure sufficient supply of the drug to the Czech market at this unusually low price.

Similarly these „action" prices of drugs in foreign countries influenced the pricing and reimbursement of the drugs in the Czech Republic to that manufacturers, whose application was decided during the time of the action discounts. If the price was influenced by the foreign lower price during the time when the manufacturers application for pricing and amount of the reimbursement were assessed, there were set the different amount or reimbursement of the drug substitutable with other about which price or reimbursement was decided at the time when in foreign countries there were no price and/or other actions which influenced the price of that drug.

Although the abovementioned procedures are stipulated in Act No. 48/1997 Coll., the Czech NCA has the same opinion as SUKL that the lowest prices in foreign countries influenced by discounts could lead to favouring one subject against its competitors or other negative influence to the competition. At least barriers of entry can be set for other competitors on the market and that can lead to deformation of the competition. Therefore the Czech NCA promised the SUKL that it will favour the SUKL in any proceedings by establishing conditions of the maximum price and reimbursement of drugs ensuring the competition on the drugs market will not be distorted.

Another question is the repetition of legislative efforts in implementing single prices of medicines. The effort on price fixation results from the fact that prices of the same medicines in pharmacies are in some cases considerably different (it is in virtue of the fact that the pharmacy decides not to draw from its charge when stipulating the final price of medicine, respectively when the distributor or the producer of the medicine provides the pharmacy with some quantity discount).

The price fixation is called for by the patients forced to "run round" pharmacies and search for one offering the cheapest product, as well as by the pharmacists. These, according to numerous opinions, feel like a "greengrocer on the market" as they are obliged to explain the high prices of their medicines to patients, although they consider their profession as distribution of necessary medicines together with provision of professional guidance to the patients, i.e. provision of pharmaceutical care that is part of health care.

Regarding the situation, the Office holds the consistent view that the implementation of price regulation is an outstanding tool applied in situations when natural regulation failed – in other words where the market failed. However, in such cases the market did not fail because competitive mechanisms are enforced, which develop a space for price reaction of pharmacies to consumer demand. Relatively significant competition exists, which brings indisputable benefits to the end consumer.

From all of the mentioned reasons, the Office considered all the efforts on the implementation of a single price of medicines as unreasonable. The situation on the market shows evidence that it is not the government's interventions, but free competition that brings benefits to consumers in the form of a wide selection of medicines for favourable prices.

11.1 Conclusion

The Office monitors all changes concerning setting the prices of medicines in the Czech Republic and is ready to intervene in the case, when the possible negative influence of competition occurs on the market. The significant partner in this area is SUKL, with whom the Office cooperates closely.

12. Conclusion

The legal framework in the Czech Republic stipulating the conditions for the manufacturers of generic and/or original drugs does not contribute to making distinctive barriers for the entry of the new drugs (in other words for later entry of the new generic to the market).

Since 2004, legislative conditions have been adapted to the conditions in the EU area, when relevant regulations and EU directives have been transposed to national Acts. The Czech NCA has not had to deal with any competition concerns of manufacturers of generic or the original drugs or other market players. The Czech NCA is not aware of any other practices investigated by the Commission which would concern delayed entry of the generics on the market or reduced innovation of the drugs.

This is given by the fact that there are traditionally well-established manufacturers of the generics drugs in the Czech Republic, likewise in other Member States of the former "Eastern block". Their well-established brand-names of products, same as their time-proved effectiveness contribute to a better perception from patients and doctors, who prescribe their drugs. What is also indispensable is the fact that the drugs made by manufacturers of generics are cheaper than original drugs and are mostly fully reimbursed from public health insurance.

As mentioned in detail above (Chapter V), the Czech legal framework has been adopted for the benefit of patients, with the aim to decrease the costs for patients on purchases of medicines, i.e. support the consumption of generics, the prices of which are always lower than the prices of originals (Chapter IV).

Regarding the specific system of medicine reimbursement from public health insurance, it is clear that the choice or particular medicine is extremely dependent on the doctor, who makes the prescription. The doctor's prescription is not regulated by the law or motivated by the effort to recommend and prescribe cheaper medicines to their patients. The fact that the doctor has no motivation to prescribe cheaper

medicines to patients can lead to increasing costs of medical treatment to patients, as well as to public health insurance in general.

The Czech legislation created a leverage in the form of possible substitution of original medicines by generics in pharmacy (chapter V), however, it is not largely exploited in reality. Not only because the patients are not aware of such possibility, but also because the pharmaceutists are not empowered to such substitution and are thus not motivated to sell medicines with lower reimbursement. This is caused by the patient's high confidence in and loyalty to the decision of their doctor, and on the other hand by an unreasonable doubt of some people in the effectiveness of generics.

Generally, the practices of pharmaceutical companies, which try to motivate doctors to prescribe medicines produced by the company in the form of intangible gifts, refunds to seminars abroad etc. are also known. However, by doing so other competitive products are in fact blocked, which could otherwise be more favourable from the aspect of the consumers and system of public health insurance. It is necessary to stress that the practice, which is not illegal, is alleged both by producers of originals and generics, thereby it does not cause continual aggravation of the position of generics producers.

Currently the Office is not dealing with any particular case of breach of Czech or community competition law in this area. Regarding the sensitivity of the market, the Office continuously monitors the market. In the case any problems arise, the Czech NCA closely cooperates with SUKL. Also, the Czech NCA is one of the authorities of the Czech administration which makes statements on draft legislative bills in the area of pharmaceuticals.

IRELAND

1. Introduction

In Ireland, generic medicines are sold in low volumes. In fact, the European Commission recently found that Ireland has the lowest penetration of generic medicines in the Member States surveyed, with a market share of just 12%[1]. The Department of Health and Children in Ireland supports the increased use of generics where this is appropriate and achievable in the market.

There are in excess of 140 pharmaceutical companies operating in a manufacturing capacity and/or marketing capacity in Ireland[2]. Many of the major manufacturers in the World have a base here. The genuine generic medicines in Ireland are typically manufactured by small indigenous manufacturers. In 2003, out of the top 20 pharmaceutical companies, 4 were generic manufacturers, but 2 of these also produced branded products[3].

There is a high degree of concentration of market share in the top number of companies, however, when assessing the market as a whole, it does not appear to be overly concentrated[4]. The combined market share of the largest 4 (out of over 140) companies in the market was found to be 39% in 2003. The top ten companies accounted for 57% of total expenditure from the General Medical Services ('GMS') scheme[5] in 2003.

2. Regulation

2.1 Setting the price

The cost or 'trade price'[6] of prescription medicines in Ireland (branded and generic) is set by means of two agreements between the State and the Irish Pharmaceutical Healthcare Association ('IPHA') and the Association of Pharmaceutical Manufacturers of Ireland ('APMI'). The IPHA represents branded pharmaceutical manufacturers and the APMI represents generic manufacturers. The agreements cover all medicines prescribable and reimbursable under the state drug schemes, as well as all medicines supplied to hospitals.

The manufacturer is not permitted to deviate from the trade price set for the prescription medicine. The current agreements were negotiated in September 2006. Ireland links its drug price by formula to those

1 The European Commission Pharmaceutical Sector Inquiry Final Report, 8th of July, 2009, page 88.

2 'Review of Pharmacy Wholesale Margins' by Indecon, 26th of October, 2007, 'Aspects of the Pharmaceutical Market', page 4.

3 Ibid, table 2.1, page 5.

4 Ibid, page 6.

5 The largest state drug scheme for those who are unable, without undue hardship, to arrange general practitioner and surgical services for themselves and their dependants.

6 This is the price paid by the State to the manufacturers in respect of drugs dispensed.

of 9 other Member States of the European Community. The 2006 agreement allows the State to request and use evidence of the cost effectiveness of a new drug.

A consequence of the current pricing structure means that there is little difference between the price of the proprietary drug and the available generic in certain therapeutic areas[7]. This is reflected in a study, conducted in 2006, by the National Centre for Pharmacoeconomics, which investigated the cost effectiveness of statin therapy for the primary prevention of coronary heart disease in the Irish healthcare setting. The study found that under the GMS scheme, the most cost effective statins were not the generic statins[8]. This was, in part, related to the pricing of such products on the Irish market. Nonetheless, an important component of the supply agreements with the manufacturers in 2006 was that a phased cut of 35% was agreed for branded drugs where the patent has already expired[9].

2.2 Licensing the drug and the wholesaler

Every medicine sold at retail level in the State must have a licence from the Irish Medicines Board or the European Commission. To obtain a licence, a medicine must be tested for safety, quality and efficacy. The licence also dictates the information to be provided on the packaging, the size of package and the classification (e.g. prescription only). Also, pharmaceutical wholesalers in the State must obtain a licence to wholesale prescription medicine to pharmacy retailers.

2.3 Restriction on dispensing

The use of a branded or generic equivalent medicine in Ireland is a matter for the prescriber in consultation with the patient, the idea being that the medicine chosen best meets the patient's needs and delivers best value for money. Pursuant to the terms of the 2006 agreements, pharmacy retailers in Ireland are obliged to dispense the product as written on the prescription. In 2008, 25 and 27% of prescription items were dispensed as proprietary preparations when a generic equivalent was available on the GMS and DP/LTI (Drug Payments/Long Term Illness)[10] schemes respectively[11]. Only 18% of prescription drugs were dispensed generically (branded generics (15.9%) and non-branded generics (2.4%)) on the GMS scheme in that year[12].

3. Reforms

The European Commission has encouraged Member States, in its Sector inquiry, to provide an automatic/immediate pricing and reimbursement status for generic medicines that are equivalent to the original products. Also, the Commission recommends that legislation be introduced in Member States to facilitate generic uptake, such as prescription by substance rather than brands. There are signs that the Irish State is taking note of these suggestions. A scheme for reference pricing for off-patent (generic) medicines

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7 '*Economics in Drug Usage in the Irish Healthcare Setting*', published by the Department of Health and Children, 2009, page 24, at http://www.dohc.ie/publications/economies_drug_usage.html.

8 Walsh V, Nash A, Barry M, 'The cost effectiveness of statin therapy for the primary prevention of coronary heart disease in the Irish healthcare setting', Irish Medical Journal 2006; 100(3): 144-145.

9 See press release of 28 February 2007 '*HSE to save over €250m in drug costs*', at http://www.hse.ie/eng/newsmedia/2007 Archive/ February 2007/HSE to save over €250m in drug costs.html

10 These are two more of the most popular types of state drug schemes.

11 '*Generic Drug Utilisation in Ireland in 2008*', published by the National Centre for Pharmacoeconomics, April 2009; at www.ncpe.ie

12 Ibid.

is being proposed by the Irish Minister for Health and Children for the coming year. It is proposed that the State would pay one price for any medicine that is off-patent, whether manufactured and sold as a generic or a branded medicine[13]. Also, one of the recommendations of a Department of Health publication this year is that 'Generic prescribing by general practitioners should be encouraged and facilitated by the provision of prescription software systems; prescription data analysis and professional prescribing advice and support'[14].

The State has acknowledged that consideration should be given to the introduction of a fixed ex-manufacturer price for generic medicines in the region of 20% to 30% below current prices[15].

4. Conclusion

In summary, the generic and branded medicines industry in Ireland is highly regulated. This occurs at all levels of the distribution chain. Manufacturers are obliged to comply with licensing requirements and are obliged to adhere to the agreement with the State. Wholesalers also must adhere to the licensing requirements and their wholesale margin is calculated with reference to the trade price set in the manufacturers' agreements. Retailers are similarly restricted and there is the added, restrictive, effect that prescribers have on the role of retailers. In short, competition does not work in the normal way in this market.

Recently, on 4 September, one of the largest generic pharmaceutical manufacturers in the World, Teva Pharmaceuticals (formerly known as IVAX pharmaceuticals), announced that it was cutting 300 jobs in Ireland, thereby phasing out its oral solid dose (tablet manufacturing). Teva Pharmaceuticals used to be ranked 18th in the Irish market in 2003[16], therefore, the presence of generic manufacturing in Ireland has been negatively effected.

Although the prescribing of newer, more expensive medication is essential for crucial treatments, it is appreciated that enhanced generic prescribing (with appropriate pricing) has the potential to produce significant savings. In this regard, it is likely that the State will seek an increased use in generic medicines in return for a reduction in the price of these medicines in the next series of agreements, which will last from 2010 until 2015.

13 See press release of 6 August 2009 '*Statement by the Minister for Health and Children, Mary Harney TD re pharmacy service*' at http://www.dohc.ie/press/releases/2009/20090806.html

14 Refer to footnote 7, page 25.

15 Refer to footnote 7, page 25.

16 Refer to footnote 3.

ITALY

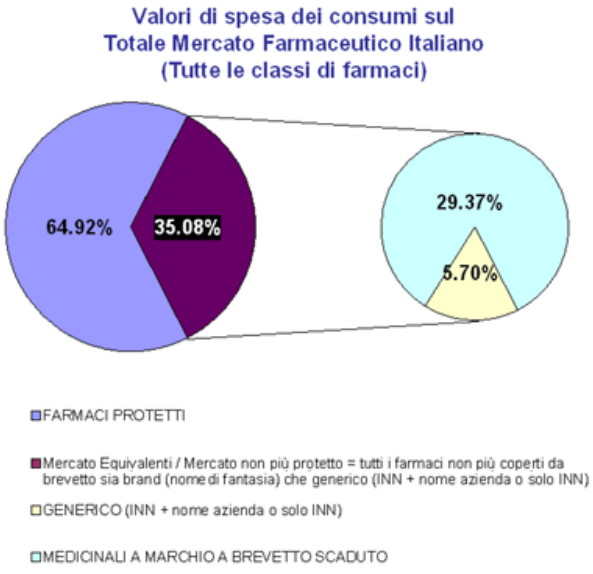
1. Introduction

The generic market in Italy is comparatively small, with respect to other European countries. Generic pharmaceuticals represent no more than 6-7% of the market for pharmaceuticals. Historical reasons, associated to the patent regulation system, provide some explanation for the delay in the introduction of generic drugs. Other factors, such as regulation of pharmaceutical distribution creating a disincentive to the distribution of lower price drugs, also contributed in the creation of obstacles to generics entry. More generally, the Italian pharmaceutical market's price level, which is lower than in other European countries as a result of health policy cost containment interventions, has made the Italian market less attractive to generic producers.

2. The market of generics in Italy

An important characteristic of the Italian off patent system is the contemporary presence of both generics and copies (copies are drugs of the same active substance marketed, with their own brand name, often by the originator itself). Two reasons explain this phenomenon: first, Italy lacked patent protection until 1978, when the Italian High Court included pharmaceutical among products on which patent rights could be applied. Copies (sometimes referred to as "equivalent" to generics) marketed before 1978 were allowed to stay in the market even after patent introduction. Moreover, in Italy co-promotion (the same brand sold by different companies) is forbidden. However co-marketing, the practice of marketing the same active compound as different brands under the originator license has been a common practice, increasing the number of copies even after patent introduction.

Thus while the percentage of total off patent pharmaceuticals represented, in 2008, about 35% of the value of the Italian pharmaceutical market, generics only accounted for 5.7% of the market (Source: Assogenerici, the national association of generic industry).



Prices of pharmaceuticals in Italy, in general, are lower when compared to the US or other European countries. This is the result of the many cost containment interventions in the health care sector. Taking into account all pharmaceutical drugs prices in Italy were in 2005, on average, 45% lower than in the US and 5% lower than in EU 15. However, generic prices showed prices about 27% higher than in the US and 17% higher than in EU 15[1].

Regulation of retail pharmacies has also affected generic competition: the margins that the pharmacists receive on reimbursable drugs are established by law and are a fixed percentage of the product price, thus creating an incentive for the pharmacists to dispense the drugs at higher prices.

3. Regulatory framework

In Italy the regulation of the national health system and of the pharmaceutical sector is complex. The national health system, introduced in 1978, is a public system funded by general taxation which provides universal coverage and comprehensive health care. In the last decade the national health system has been extensively reformed, increasing regional autonomy. The first important reform in the pharmaceutical sector was in 1993, and since then pricing schemes and reimbursement rules have continuously changed, and the pharmaceutical market has experienced several cost containment interventions in the health care sector[2].

Some of the features of the Italian regulatory regime have affected the diffusion of generic drugs. In particular, three areas of the regulatory framework seem crucial in determining competitive conditions for generic drugs: legislation governing patents, marketing authorisation procedures and pricing and reimbursement provisions.

3.1 Legislation governing patents

In addition to patent coverage for a period of 20 years, the Italian Complementary Certificate of Protection was introduced in 1991 (just before approval of the European Supplementary Protection Certificate - SPC) extending patent protection for up to 18 years. The supplementary term of protection is calculated as the number of years that have elapsed from the date of filing the patent application to the date of the initial marketing authorisation. This extension of patent coverage was granted to around 400 active substances. Despite all attempts to abolish it, the only compromise reached with Law 112/02 was a gradual reduction, starting in 2004, of six months every two years until Italy is aligned with the other European countries[3].

The term "generic drug" was first introduced in the Italian legislation in 1996 (Law n.323/96). A generic drug has to be marketed under the International Non-Proprietary Name (INN) followed by the manufacturer's name at a price at least 20% lower than the originator drug. The definition of generic was extended in 2003 to cover all off-patent drugs, including copies.

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1 See Pammoli F., Bonassi, C., Riccaboni M., Salerno N.C., *Regolazione, innovazione e ciclo di vita dei prodotti*, CERM Quaderno 2/2007, February 2007.

2 For an extensive description of the Italian health system regulatory framework and its evolution see Ghislandi S., Krulichova I., Garattini L., *Pharmaceutical policy in Italy: towards a structural change?* in Health Policy 72 (2005) 53-63.

3 In a previous version of the norm, contained in Legislative Decree n. 63 of April 15 2002, the gradual reduction was to start in 2003, and to be of one year every two years, but this version was abandoned when the Decree was converted into Law 112/02, notwithstanding the report of the Italian Competition Authority (AS239, see below).

3.2 Marketing authorisation procedures and pricing

The regulatory authority in Italy is the Ministry of Health. Pharmaceutical products registration and marketing authorisation are undertaken by the Ministry's pharmaceutical agency, AIFA. The agency has the following responsibilities: marketing authorisation procedures, including bio-equivalence assessment for generic drugs, vigilance on pharmaceutical usage, reimbursement, clinical trials and provisions for special use, monitoring pharmaceutical information and promotion.

Pharmaceuticals have been classified for pricing and reimbursement purposes as follows: essential or life-saving pharmaceuticals, that require a prescription and are fully reimbursable (Class A); pharmaceuticals which require a prescription but are not reimbursable (Class C); pharmaceuticals which do note require a prescription and over the counter drugs; hospital use only pharmaceuticals (Class H). Innovative products are initially given non-reimbursement status (Class C) or hospital-use only status (Class H), before their final classification is decided[4].

The prices of the reimbursed drugs (Class A) are set through negotiation between the government (through AIFA) and the industry, while prices of non reimbursed drugs (Class C) have been liberalised since 1998. Even after liberalisation regulation required, until 2007, that the price of each drug was the same all over the country. Besides, in the last years, cost containment measures by the government often affected all categories of pharmaceuticals[5].

3.3 Reimbursement' provisions and distribution margins

Regulation also affects distribution margins. For pharmaceutical products in Class A, Law 662/96 has established wholesalers and pharmacies margins over medicines' fixed price, equal to 6,65% and 26,7%, respectively, of the industry price.

There is no correlation between the distribution prices and the costs actually faced by the distributors for selling the drugs, and the mechanism creates a clear incentive to sell higher price drugs. In order to partially correct this phenomenon and introducing some regression on distribution margins mandatory discounts to the National Health System for reimbursable drugs were introduced in 1997, with higher discounts rates applying to higher price ranges (discounts range from 3.75% for prices less than 25.82 Euros to 19% for prices greater than 154.94% in 2003). This correction, however, had a marginal impact on the financial disincentive to dispense the cheaper generic drugs[6].

Notwithstanding these measures generics manufacturers have faced difficulties in placing their products since the regulation still provides an incentive for pharmacists to dispense higher price products. Although not expressly allowed by the law, generic producers have offered high discounts to pharmacies (therefore reducing their margins from the level fixed by law) in order to promote the sale of generics by

4 Originally there was also a Class B, non-essential pharmaceuticals which met primary therapeutic requirements that were restricted to prescription-only and reimbursable up to 50%. This category has been eliminated with Law n. 388 of 2000.

5 The Italian Competition Authority in an advocacy report (AS 3300, see below) criticized the introduction of restrictions on the prices of pharmaceutical products, in the form of a maximum price, which had previously been liberalized arguing that they would result in elements of rigidity in business practices and that the maximum price could become a benchmark referred to by undertakings to establish collusive practices.

6 An explanation is that about 85% of the sales of pharmaceuticals concerns products that fall into the lowest price range where the discount to the NHS is only 3.75%.

pharmacies. At the same time generic producers were less willing to reduce the final prices in the negotiation with the regulator in order to use the discount leverage with the pharmacists.

In order to curb this industry practice the legislator intervened, in April 2009, with a norm that reduced by 12% the price of generic drugs, at the same time allowing an increase of 8% to the margins of the distributors for the same products. The norm forbids any form of negotiation between pharmacies and generics producers (not originators) introducing sanctions in the case of non observance of the margins established by law[7].

Starting from 2001 reimbursable off patent products have been subject to a reference pricing system: if a drug price is higher than the reference limit, the patient is expected to pay the difference (the reference limit is the lowest price among equivalent products available in the regional distribution network). The introduction of reference pricing was clearly aimed at containing demand for highly priced products by cutting down reimbursement pricing. Pharmacists are obliged to dispense the lowest price drug if the patient accepts the substitution and provided that the physician has not declared on the prescription that a higher price drug cannot be substituted.

4. The interventions by the Italian competition authority

4.1 Advocacy interventions

4.1.1 Report on the duration of supplementary patent coverage for pharmaceuticals[8]

In May 2002 the Authority reported on the potential competition-distorting effects of a bill that extended the duration of the supplementary patent coverage for several hundred pharmaceuticals. In the report the Authority pointed out that the proposed extension of the supplementary patent coverage would distort competition in three main ways: *i*) by preventing the development of the market for generic drugs in Italy, that was already much smaller than in the other European countries; *ii*) by keeping prices higher because of the lack of a competition caused by the existence, in Italy alone, of a system of patent coverage for a large number of products; *iii*) by restricting the growth of the basic chemical industry since the patent extension would not allow firms to manufacture patented molecules even for export to countries where the patent had expired.

4.1.2 Report on urgent measures for pricing pharmaceuticals not reimbursed by the National Health Service[9]

In June 2005 the Authority sent a report to Parliament and the Government under Article 21 of Law 287/1990 regarding the possible anticompetitive effects of a decree law introducing: *i*) a maximum price for non-prescription and self-medication pharmaceutical products, to be fixed by the undertaking that introduces the products onto the market and indicated on the package; and *ii*) the possibility for pharmacists to apply price discounts of up to a maximum of 20%. In its report the Authority criticized the introduction of restrictions on the prices of pharmaceutical products which had previously been liberalized. Such limits, it argued, would result in elements of rigidity in business practices. Moreover, the maximum price could become a benchmark referred to by undertakings to establish collusive practices. As regards

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7 The Italian Competition Authority in a report pointed out that the application of fixed margins, in percentage of the product's final price, creates an incentive for the pharmacists to dispense higher price drugs. The Authority proposed a new remuneration system based on a lump-sum *fee for service.*

8 Italian Competition Authority, report AS239 of 30 May 2002, published in Bulletin n. 21/2002.

9 Italian Competition Authority, report AS300 of 1 June 2005, published in Bulletin n. 22/2005.

the prospect of pharmacists applying price discounts of up to a maximum of 20%, the Authority observed that imposing limits on the discounted price introduced de facto minimum prices for pharmaceuticals that had no economic justification whatsoever. On the contrary, this would only hinder the achievement of fully competitive conditions with negative effects for the general public. The Authority therefore called for the removal of this limit and for pharmacies to be left entirely free to set prices.

4.1.3 Budget law provisions on health expenditure[10]

In October 2007 the Authority sent a report to Parliament and the Government under Article 21 of Law 287/1990 concerning measures on health spending introduced with the budget decree. The Authority pointed out that these measures risked holding back the competitive dynamic amongst innovative manufacturers of pharmaceuticals and not encouraging the development of manufacturers of generic pharmaceuticals. In its report the Authority argued that regulation throughout the pharmaceutical supply chain must motivate companies to carry out adequate research and development, offer an incentive for parallel imports of lower-cost pharmaceuticals and at the same time promote competition amongst pharmaceuticals that are not covered by patents so as to encourage the entry of manufacturers of generic drugs. Article 5 of the decree accompanying the 2008 budget, by modifying the mechanisms for reimbursement of pharmaceuticals by the National Health System, fostered instead a market structure that in large measure preserved the relative positions of suppliers causing a slowing down of the market dynamic amongst competitors. The Authority advocated the adoption of criteria that create incentives for companies that invest in research and development while the percentage of incremental resources the decree set aside for reimbursing the expenditure of the most innovative companies was too small for this purpose. The Authority therefore suggested to increase it, reducing instead the percentage of resources assigned to the generality of companies on the basis of 'historical quotas'. In its report the Authority also suggested to include mechanisms that, by modifying the rules for prescribing medicines and attributing margins to pharmacies, would promote price competition from generics companies and parallel importers whose positive effects for consumers and the National Health System were still extremely limited in Italy compared with most other European countries.

4.1.4 Report on design of public tenders for pharmaceuticals[11]

In January 2008 the Authority sent a report to Parliament and the Government under Article 21 of Law 287/1990 concerning the design of public tenders for pharmaceuticals. In its report the Authority pointed out that the tenders' design, allowing pharmaceutical firms to make offers grouping different products (both patented and off patent) and offering discounts not only for the single products but also for the bundle, might result in a barrier to entry for generics.

4.1.5 Report on remuneration mechanism for reimbursable pharmaceuticals[12]

In May 2009 the Authority sent a report to Parliament and the Government under Article 21 of Law 287/1990 concerning the remuneration mechanism set for distribution of reimbursable pharmaceuticals. The Authority pointed out that the application of fixed margins, in percentage of the product's final price, has no correlation to the costs actually faced by distributors for selling the drugs and that this mechanism creates an incentive for the pharmacists to dispense higher price drugs. The Authority proposed a new remuneration system based on a lump-sum *fee for service.*

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10 Italian Competition Authority, report AS 421 of 25 October 2007, published in Bulletin n. 38/2007.

11 Italian Competition Authority, report AS440 of 8 January 2008, published in Bulletin n. 48/2007.

12 Italian Competition Authority, report AS 523 of 15 May 2009 , published in Bulletin n. 18/2009.

5. Enforcement

In recent years the Italian Competition authority investigated conduct of pharmaceutical companies delaying entry of generic competitors. In particular, the Authority assessed Merck's and Glaxo's refusal to grant licences to chemical companies for the production of API's (Imipenem Cilastatin and Sumatriptan Succinate) to be supplied to generic companies in European countries where any patent on those products had already expired.

5.1 Glaxo - Active ingredients[13]

In February 2006 an investigation into the pharmaceutical group Glaxo concluded with the finding of abusive practices in violation of Article 82 of the EC Treaty. Glaxo refused to grant Fabbrica Sintetici Italiana (FIS), a chemical-pharmaceutical undertaking, a licence to produce an active drug ingredient known as Sumatriptan Succinato, covered in Italy by a supplementary protection certificate, for use in other Member States (in which Glaxo no longer held any patent-rights) in the production of generic drugs known as triptans for the treatment of migraines. The Authority found that Glaxo, in addition to holding a quasi-monopoly on the production of Sumatriptan Succinato worldwide, occupied a dominant position in the Spanish and Italian markets for the production and marketing of triptans sold through hospitals. In these markets Glaxo held a particularly high market-share, equal to about 96% in Italy and 58% in Spain. As for the possibility of access for potential competitors, all the products sold in the markets concerned were found to be covered by industrial patent-rights, which were due to lapse between 2008 and 2012, with the exception of Sumatriptan Succinato which was not covered by any patent in the Spanish market. Based on the investigation's findings, the Authority deemed that Glaxo's refusal to grant the requested licence constituted an abuse of dominant position in violation of Article 82 of the EC Treaty, since its refusal hindered the production of an active ingredient needed by producers of generic drugs, potential competitors of Glaxo, to access national markets where Glaxo did not have any exclusive rights. The Authority considered this conduct had no objective justification. Despite having ascertained the abusive nature of the conduct, the Authority did not impose any fine on the group because well before the end of the investigation, Glaxo had not only granted the licences originally requested by FIS but had also set conditions allowing that company to save the time required to research and test an efficient production process for obtaining Sumatriptan Succinato. As a result, well before the conclusion of the proceedings, a producer of generic drugs based on this active ingredient had succeeded in entering the Spanish market.

5.2 Merck-active ingredients[14]

In March 2007 the Authority concluded an investigation under Article 82 of the EC Treaty into the company Merck & CO. Inc. and its subsidiary Merck Sharp & Dohme (Italia) Spa, accepting the company's commitments under Article 14-ter, paragraph 1 of Law no. 287/1990, and closing the proceedings without establishing an infringement. The investigation was launched to examine alleged abusive practices consisting in refusals to grant licenses requested by chemical-pharmaceutical firms for the manufacture of two active ingredients, Imipenem Cilastatina and Finasteride, both covered by a Supplementary Protection Certificate (SPC) to be sold in other European countries in which Merck was no longer enjoying intellectual property rights. In order to ensure that, pending the outcome of the investigation, Merck's behaviour would not continue to cause serious and irreparable harm in the markets concerned, in June 2005 the Authority adopted interim measures obliging the company to issue without delay – and at least for stockpiling purposes – licences authorising the production in Italy of Imipenem

13 Italian Competition Authority's case A363 Glaxo-Principi attivi, decision n. 15175 of 8 February 2006, published in Bulletin n. 6/2006.

14 Italian Competition Authority's case A364 Merck-Principi attivi, decision n. 16597 of 21 March 2007, published in Bulletin n. 11/2007.

Cilastatina. In accordance with this ruling, in August 2005 Merck issued a license to the chemical firm Dobfar to manufacture this active ingredient, whose Supplementary Protection Certificate expired in January 2006.

In November 2006 Merck presented a commitment under Article 14-ter of Law no. 287/1990, (later to be amended), offering free licenses to manufacture and sell the active ingredient Finasteride and related generic drugs, even though the Supplementary Protection Certificate does not expire until 2009. The Authority deemed that this commitment was likely to result in the permanent removal of any anticompetitive effects flowing from Merck's former refusals to grant licences. More specifically, the Authority considered that this commitment would remove an obstacle to the manufacturing of Finasteride in Italy and increase its sales and that of the related generic drug, both in Italy and in various European countries, generating a reduction in prices to the benefit of consumers and the National Health Service.

6. Conclusion

Generics' producers have faced several difficulties in entering the Italian pharmaceutical market. The marketing of copies in the period covered by the patent and the prolongation of patent coverage delayed the onset of generic competition. Cost containment measures aimed at short run effects on health expenditures have led to a low price level affecting competitive conditions on the market that have not fostered entry by generic producers and rules concerning distribution margins have created further distortions that have affected generic drugs.

Several advocacy interventions by the Italian Competition Authorities have pointed out the elements of the current regulation creating restrictions to generic entry, suggesting regulatory reforms that might facilitate the diffusion of generic pharmaceuticals and foster competition in the pharmaceutical industry. Moreover, the Authority enforced competition rules in the sector detecting exclusionary conducts by pharmaceutical companies holding licenses for active principles aimed at delaying entry of generic firms.

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JAPAN

1. Introduction

Generic drugs are approved to be manufactured and sold as the therapeutic equivalent of their corresponding approved drugs. Their drug prices are cheaper than those of the originator drugs because their R&D costs are generally inexpensive.

For this reason, the prevalence of generic drugs will contribute to alleviate the burden of patients and to improve the finances of the health insurance system. On the other hand, it is pointed out that currently, generic drugs are not necessarily popular in Japan as shown by their lower share in quantity compared to that of Europe and the U.S.

Based on these points, this contribution paper explains the procedure and the costs, as well as the periods required, for the entry of generic drugs and introduces a fact finding survey of the Japan Fair Trade Commission (JFTC) as well as an Action Programme of the Ministry of Health, Labour and Welfare, as activities related to the use and promotion of generic drugs.

2. Approval of generic drugs

Generic drugs means pharmaceutical products equivalent to corresponding approved drugs in terms of active ingredients, dosage and indications except those products produced by the same manufacturers of the approved drugs. The requirements for marketing authorisation are as follows:

- The applicant has a license for manufacturing and marketing
- The factory has a license or accreditation for manufacturing the item
- The name, ingredients, quantity, dosage and indications of the item are appropriate
- The item fulfils the requirement for compliance with the GMP[1]

The firms producing generic drugs also need to fulfil the requirements above. However, some of the requirements for 3) above are waived for the application of a drug that has been filed after the re-evaluation period of the originator drug expires. This means the generic firm can rely on the safety, equivalence, and efficacy data from the originator's application to receive approval. To apply for approval of this type of generic drug, submission of information on the process of manufacturing, standard and specifications with the testing procedure, stability tests, and bioequivalence tests is basically required.

Generic products for approved biologic drug products are required to submit the application with the data of efficacy, repeated dose toxicity tests, clinical pharmacokinetics tests, and pharmacodynamics tests, as well as the tests required for chemical generic drugs except for the bioequivalence tests. The data on the

[1] "GMP" refers to "Good Manufacturing Practice."

quality, safety and efficacy of these products should be developed in accordance with the government guidelines in line with ICH[2] guidelines.

The re-evaluation period for new pharmaceuticals is normally four to ten years and the marketing authorization holder must track the usage record to confirm the product's safety and efficacy during that period. If it is still in this re-evaluation period, any drugs, even if they are proved identical to the originator drug, are required to submit the equivalent or more documents for approval. In addition, the substance patent period or the process patent period need to be considered as well as the above mentioned re-evaluation period.

A manufacturer can submit an application of a generic drug while waiving some of the requirements mentioned above after the re-evaluation period of the originator drug. The standard processing time is one year after the acceptance of the application to the Minister of Health, Labour and Welfare. The standard processing time does not include time for the modification of deficiencies in the documents and time to answer reviewers' questions etc. by the applicants.

The application fee for the approval for manufacturing and marketing is 654,200 yen for generic drugs with onsite GCP[3] conformity assessment, 440,200 yen for generic drugs without onsite GCP conformity assessment, and 30,881,500 yen for follow-on biologics. In addition, fees for licensing the factory or for GMP inspection may apply.

3. Work related to the use and promotion of generic pharmaceuticals by the competition agency and the regulatory agency

In September 2006, the JFTC published "The Report of the Fact Finding Survey on the Distribution of Pharmaceuticals," which reveals the trade practices related to generic pharmaceuticals and evaluates them from the viewpoint of competition policy.

In addition, the Ministry of Health, Labour and Welfare has set numerical targets to boost the share of generic drugs to over 30% in volume (double the current share) by FY 2012 and established the "Action Programme for Promoting the Safe Use of Generic Drugs" in October 2007 to promote the use of generic pharmaceuticals.

3.1 Report of the fact finding survey on the distribution of pharmaceuticals (Overview)

3.1.1 Survey purpose and method

Japan's national health care expenditure has exceeded 32 trillion yen in recent years, creating an urgent need to reduce skyrocketing medical expenses. It is also essential to reduce the cost of medicine, which accounts for more than 20% of medical expenses.

The JFTC conducted a survey to specify the facts about the distribution of pharmaceuticals, such as the trade in generic medicine, that are thought to help reduce medical expenses, and to make suggestions from the standpoint of competition policy. Thereby, the JFTC published a survey report on September 27, 2006.

The report is based on the results of questionnaires for pharmaceutical manufacturers, wholesalers and medical institutions and interviews with them. The following is the overview of the results in relation to generic drugs.

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2 "ICH" refers to "The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use."

3 "GCP" refers to "Good Clinical Practice."

3.1.2 Overview of the results

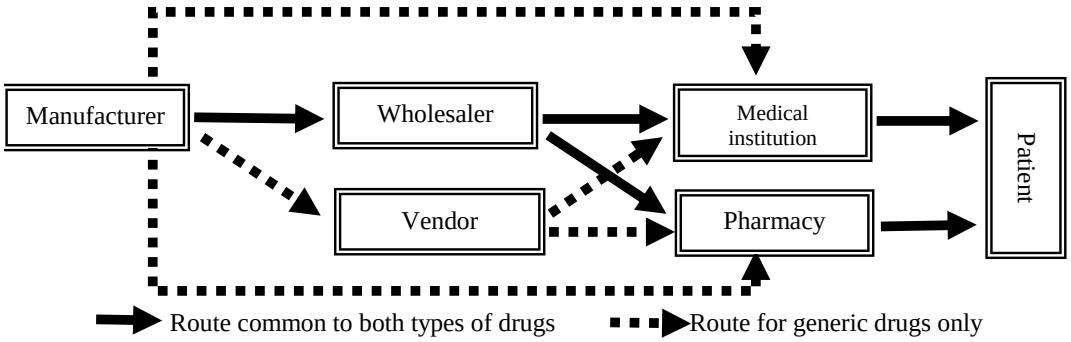
Structure of the prescription pharmaceutical industry

(1) Market scale

- The market scale of prescription pharmaceuticals in Japan is estimated at 6,737.7 billion yen (shipment amount in FY 2004)
- Generic drugs represent a lower share (17% in quantity) in the whole transaction amount of prescription pharmaceuticals than their share in European countries and the U.S. (United Kingdom: 55%, United States: 53%, Germany: 46%)

(2) Distribution route

- Originator drug manufacturers sell products to medical institutions, etc. via wholesalers. Generic drug manufacturers sometimes sell products through vendors specializing in generic drugs.



(3) Manufacturers provide information about the quality, effectiveness and safety of the drugs to medical institutions via their Medical Representatives (MR).

Trade practices for prescription pharmaceuticals concerning generic drugs and their evaluation from the perspective of competition policies

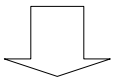
(1) Attitude of medical institutions towards the use of generic drugs

Almost all medical institutions use generic drugs. When the JFTC asked medical institutions about concerns they had before using generic drugs, medical institutions answered as follows. The top response was "Anxious about safety, stable supply or amount of information about generic drugs" (84.6%). There were other responses such as "Patients may have a feeling of anxiety" (31.3%), "Patients may suppose that the quality of medical treatment is lowered" (27.8%) and "Explaining the safety of generic drugs to patients is troublesome" (22.3%), etc.

"Evaluation from the Perspective of Competition Policies"
It is desirable for the Ministry of Health, Labour and Welfare to continue its efforts to encourage the use of generic drugs and for generic drug manufacturers to strive to eliminate the anxiety that medical institutions harbor about the stable supply of generic drugs, information provision and quality assurance and to win their confidence in these aspects.

(2) Explanations about generic drugs by originator drug manufacturers

Some originator drug manufacturers provided inaccurate information about prescription examples of generic drugs and explained information about manufacturing defects of a particular generic drug as if it were about generic drugs in general.

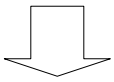


"Evaluation from the Perspective of Competition Policies"
If originator drug manufacturers interfere with the sales activities of generic drug manufacturers, it will be in violation of the Antimonopoly Act (Interference with a Competitor's Transactions). Originator drug manufacturers should not, when providing information about pharmaceuticals to medical institutions, provide inaccurate information about prescription examples of generic drugs, or explain information about manufacturing defects of a particular generic drug as if it were about generic drugs in general, for example.

(3) Consumers' choice of pharmaceuticals

The results of the questionnaire of consumer monitors indicate that when generic drugs or originator drugs are available, 31.3% of consumers always select the generic drug and 65.4% of consumers select the generic drug depending on the case.

In addition, among the consumers who answered that they would select the generic drug depending on the case, 78.1% of consumers answered that they would select the generic drug if they are persuaded by the explanation about the safety and effect of generic drugs from the doctor or pharmacist even if they feel anxiety about the safety or effect of the drugs.



"Evaluation from the Perspective of Competition Policies"
- The consumer should be able to select medications (originator drugs or generic drugs) as much as possible.
- It is desirable for medical doctors or pharmacists, when prescribing or preparing generic drugs, to explain that generic drugs are comparable to originator drugs in terms of safety and efficacy.

3.2 Outline of the action programme for the promotion of the safe use of generic drugs

The Action Programme has laid out actions which should be taken by the government and relevant players in terms of 1) Stable supply, 2) Quality control, 3) Information provision from the generic drug manufacturers, 4) Platform arrangements for promoting their use, and 5) Institutional arrangements in the Health Insurance System in order to achieve the national target to "Boost the share of generic drugs to over 30% in volume by FY 2012".

3.2.1 Stable supply

There are complaints from medical practices that the time from order to delivery is long. Therefore, the government set a target to give straightforward instruction for stable supply. And the target set for manufacturers was to deliver every product to the distributor by the day after the order (by FY 2007) and to make same-day delivery available for 75% of the delivery when the distributor has no stock (by FY 2008).

3.2.2 Quality control

There are voices from medical practices saying that the hemolyzing property and blood levels of generic drugs may be different from their corresponding approved drugs. Therefore, the government set a target to implement tests and announce the results if there is doubt about the products' quality. And the target set for manufacturers was to implement product testing for each lot (by FY 2007).

3.3.3 Information provision from generic drug manufacturers

There are voices from medical practices saying that generic manufacturers rely too much on the originator drug manufacturers for information on their products and do not visit to explain, etc., or simply say "Please ask the originator drug manufacturer". Therefore, the target set by the government was to give instructions to the generic drug manufacturers to provide more explanation documents and information. And the target set for manufacturers was to provide information on test data and the adverse effects through their HP, etc, and to reply promptly to information requests (by FY 2007).

3.3.4 Platform arrangement for promoting the use of generic pharmaceuticals

The government will establish prefectural councils to design acceleration plans and spread understanding of generic drugs at prefectural levels, and diffuse information by posters and booklets. The manufacturers will disseminate information through "Generic drug Q&A" for medical institutions and newspaper advertisements.

3.3.5 Institutional arrangements in the Health Insurance System

The Central Social Insurance Medical Care Council will discuss and set effective plans for accelerating the use of generic drugs, including changes to the prescription form or evaluation of the cost to pharmacies for stock control.

The implementation of the Action Programme is monitored and published once a year.

KOREA

1. Introduction

The Korea Fair Trade Commission (KFTC) began comprehensive investigation into the pharmaceutical market in 2006 as part of its efforts to promote competition in regulated industries. As a result, in late 1997 and early 2009, the KFTC imposed corrective orders and 40.3 billion won of surcharges on 17 pharmaceutical companies for their act of providing rebates to doctors and medical institutions and of maintaining resale prices. Moreover, in 2008, the KFTC selected the pharmaceutical and health care related industries as areas for focused monitoring, intensifying surveillance over these industries.

In addition, currently, the introduction of an approval-patent linkage system gains a lot of interest in Korea. As the Korea-US FTA requires Korea to adopt the approval-patent linkage system, there is much concern over potential anti-competitive behaviors exploiting intellectual property rights.

To date, in its review for drug approval, the Korea Food and Drug Administration (KFDA) has not considered whether the drug under review has infringed on the patents of existing drugs or would have chances to do, which often leads to patent lawsuits after its approval. However, with the approval-patent linkage, when a company applies for the KFDA's approval of its marketing a generic drug, it is required to notify the matter to the concerned patent holder. And in case the patent holder challenges it, the government is not to approve the marketing to the generic drug for a set time period. This might increase incentives for patent holders to engage in anti-competitive conduct taking advantage of intellectual property rights, for instance by filing frivolous lawsuits to delay or obstruct the generic drug's market entry.

As a matter of fact, discussions had not been active with respect to competition issues concerning generic drugs in Korea. Since, in particular, pharmaceutical companies' act of unfairly lobbying hospitals through rebate has been a social issue for quite some time, how original drug manufacturers might exploit their intellectual property rights like obstructing generic drugs' entry have relatively not been highlighted, with little research and law enforcement experience. Going forward, the KFTC thinks that the pharmaceutical market has high probability of intellectual property rights-related unfair trade practices, and thus is keen on studying the market and revamping related regulations as well as monitoring the market.

2. Current status of the pharmaceutical market

2.1 Distribution structure of the pharmaceutical market

The distribution of the domestic pharmaceutical industry is structured as followed: 24.3% of the manufactured pharmaceutical drugs are over-the-counter ones sold at pharmacies to consumers (patients), 29.8% directly sold to hospitals or clinics with 100 beds or less and 48.9% sold to general hospitals via wholesalers. As for OTC drugs, pharmacists or end-user consumers can choose one as they see fit. But in case of prescription drugs, a final say lies in doctors.

However, as to be explained below, pharmaceutical companies often offer illegal rebates to doctors to encourage them to prescribe certain drugs. For example, some generic producers don't go for fair price competition, but instead, just set the maximum price guaranteed by the government and induce doctors to

adopt and prescribe their own drugs. They offer economic benefits to hospitals and doctors under the pretext of meal treatment, participation in academic seminars or post-marketing surveillance (PMS). Unlike ordinary rebate, this one distorts the pharmaceutical market in a way that would deprive consumers of price discounts, just confining the benefits to doctors or medical institutions only.

A close look at their acts shows that they offered economic benefits repetitively to hospitals and doctors through various methods including treating meals, bearing expenses for local and international seminar participation and office goods or service and giving financial support under the pretext of PMS.

2.2 Approval process of generic drugs

Generic drugs refer to drug products produced after original drugs' patent and reexamination period expire with the same efficacy and quality as that of an original drug as it is produced with the formula and ingredients disclosed by the patent holder.

For a generic drug to get an approval, it should undergo a preparation stage, ingredient study, pilot production, preparation for plan of bio-equivalence test, pilot drug production, bio-equivalence testing and finally gets an approval. In particular, in the preparation stage, the generic drug manufacturer gets confirmation on whether the original drug's patent and reexamination periods (usually 4~6 years) have expired or not. In case the patent has expired, but the reexamination period has yet to pass, the generic drug cannot get an approval.

Meanwhile, whereas the notion of generic drugs has so far been applied to just small-molecule drugs, the KFDA in July 2009 revised the Notification for the Item Approval and Examination Regulation of Bio-Agents to introduce the institutional ground and regulations concerning biosimilars. According to the amendment, biopharmaceuticals are defined as "medicines whose ingredients are derived from humans or other living organisms and that require special care in terms of health and hygiene" and biosimilars are defined as "medicines whose quality and clinical & non-clinical equivalence with pharmaceutical products that are already approved for manufacturing, marketing and importing have been proven valid."

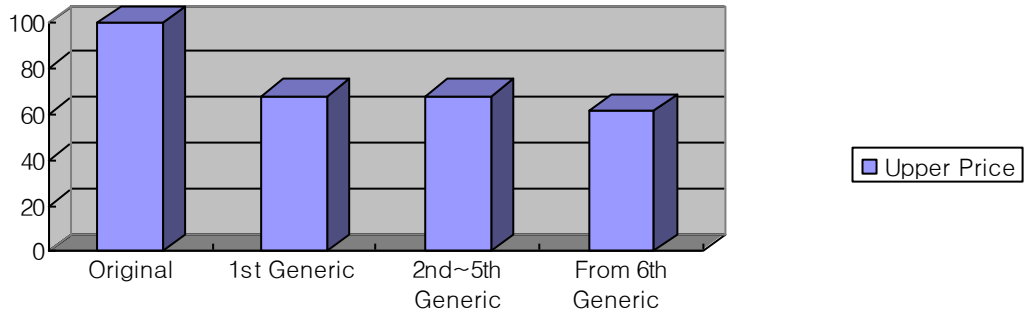
In producing generic versions of small-molecule pharmaceutical drugs, most of the clinical trials can be skipped. However, to develop and get an approval of biosimilars, companies should go through the entire pre-clinical stage and clinical trials just like for original drugs. In other words, it takes longer time and more investment to develop biosimilars.

2.3 Drug pricing

It is required for all Koreans to buy health insurance run by the government. Also almost every drugs are covered by the insurance, thus a price cap or standard price to be borne by the insurance is virtually set as the market price. When a drug company submits an application, the determination of standard prices is made, and then a committee under the Ministry for Health, Welfare and Family Affairs (MIHWAF) assesses the application, and the MIHWAF announces the result.

The current generic drug pricing system in Korea is very unique like the following graph. In case of an original drug to be first on the insurance-covered drugs list (hereinafter the "list"), its standard price is to be decided in consideration of related costs and the average price of other countries. Then for the generic drugs to be on the list, the standard prices are determined at certain levels below the standard price of the original drug. Currently the price of the 1st generic is capped at 68% of the original drug price, and the 2nd through 5th generic drugs are priced at a lower one between the lowest price cap on the list and the price 85% of the highest price cap on the list. The 6th and the later generics are priced at a lower one between the price 90% of the lowest price cap on the list and the price 85% of the highest price cap on the list.

Graph 1: Generic Drug Pricing System



3. KFTC's law enforcement in the pharmaceutical market

3.1 Investigation into pharmaceutical companies' unfair trade practices

For some 2 years from 2006, the KFTC conducted comprehensive investigations into the pharmaceutical industry. Most of the law violations detected were pharmaceutical companies' unfair practices of providing rebates to doctors and hospitals aiming to lure them to choose and prescribe their drugs. Such practice as a sort of rent-seeking behavior would do greater harm to society than usual forms of mono- or oligopoly. Even worse, unlike other customary rebates, these rebates do not benefit consumers through cheaper drug prices, but rather the prices would go up due to the cost of this shady practice. It only serves doctors and medical institutions on the receiving end and undermine consumer welfare.

3.2 Law enforcement against unfair trade practices of obstructing generics' market entry

The case involves the abuse of Korea's drug pricing regime. Company D, a leading pharmaceutical company of Korea, sold dementia treatment drugs in the Korean market that were manufactured out of an ingredient exclusively supplied by an Italian company which held a patent to the ingredient. The product patent already expired, with process patent only valid at that time, but the patented process was too complex for any generic drugs to be produced. Then in 2005, as another foreign company succeeded in manufacturing the drug, 8 other Korean pharmaceutical companies geared up for production of the generic drug.

In response, Company D decided to block the entry of its competitors, so it proposed an outsourcing contract to 5 other Korean companies on manufacturing the generic drug. The 5 companies accepted the offer and got approval from the KFDA concerning the item, finalized listing on insurance of the generic drug and applied for the drug price. This application came faster than the 8 companies preparing generic drug production, preoccupying the drug price application slots for a higher price. That is, the 5 companies applied for the drug price at 780 won, about 80% at maximum applicable of the original drug price of Company D (986 won) according to the then Notification clause. Company D then suggested to Company W, one of the 5 companies, re-bidding for price at 585 won, a price much lower than the other 4 companies'. Adding to the suggestion, Company D also promised to Company W that for the re-bidding at 585 won, it would make up for the loss incurred by the lower drug price, which Company W accepted. Likewise, the 5 companies ended with application procedure, but the another group of 8 companies that had been preparing production of the generic drug could not make it within the 5th application, which forced them to apply for price at 90% of the lowest price listed thus far, 585 won. But at price below 585 won, production of drugs virtually became unprofitable, rendering the companies' entry into the market impossible.

Company D, who has enjoyed the monopolistic benefic from patent right, committed the illegal act in an attempt to avoid competition inevitably happens after the patent's expiration. Since this case was resolved without a problem as Company W cancelled application of listing its drug, the KFTC only imposed a corrective order. As the first law enforcement case of the KFTC related to IPR, this case alerted people to the possible unfair practices in the pharmaceutical market as well as abuse of IPRS.

3.3 Reform of anti-competitive regulations

The KFTC explored anti-competitive laws and regulations concerning pharmaceuticals, and requested competent authorities such as the MIHWAF and the KFDA to improve the regulations found problematic. For instance, in 2007, the KFTC requested the MIHWAF to improve its supervision of post-marketing surveillance (PMS). PMS refers to the practice of monitoring a pharmaceutical drug after its release on the market in order to see the drug's efficacy and safety so as to confirm the drug's status. Although PMS is supposed to assess drugs' safety and efficacy, the KFTC found out that it had been reduced to a means to give illicit rebates or promote drugs. So the KFTC asked the MIHWAF to disclose the operation of PMS on the Internet, and recommended it to obligate all PMS to be reported to the KFDA as well as to strengthen the standards and obligations of PMA operators. In response, the MIHWAF established a program for disclosing PMS operation activities at the KFDA homepage in April 2008 and to this end, amended the relevant Notification.

Moreover, an amendment bill of the Medical Services Act has been introduced that newly instituted a provision to suspend for less than a year a license of doctors who receive illegal rebates. Likewise, the MIHWAF revised the Enforcement Rule of the Pharmaceutical Affairs Act in December 2008 to newly institute a provision to suspend or revoke a pharmacist license for receiving illegal rebates, and in January 2009, amended the National Health Insurance Reimbursement Standard and Regulations to newly institute a provision that would cut down on reimbursement prices of drugs for which illegal rebates are found to be offered.

3.4 Study on other competition issues in the pharmaceutical market

In a bid to analyze anti-competitive behaviors concerning intellectual property rights in the pharmaceutical sector, the KFTC outsourced research on that matter in May 2009. Through analyzing cases in foreign jurisdictions and possible remedies, it would help the KFTC for effective law enforcement in this sector.

Also, in September 2009, the KFTC analyzed market structure of the sector and published the Competition Policy Report containing related antitrust issues after collecting opinions from relevant authorities including the MIHWAF, the KFDA and the Korean Intellectual Property Office.

Moreover, the KFTC revised the Guideline for Review of Abuse of Market Dominance in September 2009 to clearly state the act of abusing intellectual property rights as one of the abuses. Before the revision, it was vaguely stated as "an act of filing a patent suit against other enterprise in order to undermine the enterprise's competitiveness in spite of knowing that the enterprise's behavior does not violate its patent," which was so vague that actual application of the provision was not available. Now it is clarified as "an act of unduly using the legal and administrative procedure concerning the act of abusing intellectual property rights."

4. Future law enforcement direction

The health care and pharmaceutical sector was selected as one of the areas for focused monitoring in 2008. Thus the KFTC intensified monitoring over the pharmaceutical market, imposing corrective orders

and surcharges against unfair trade practices. Moreover, in the wake of the conclusion of the Korea-US FTA, the KFTC has analyzed cases overseas and is trying to reflect the analysis results on the Korean competition law and to improve and study related laws and regulations.

Yet, as Korea has not dealt with many cases involving abuse of intellectual property rights in the pharmaceutical market, to accumulate actual law enforcement cases and experiences in this area would be an urgent priority for Korea.

NORWAY

1. Introduction

The Norwegian pharmaceutical market is small and only accounts for approximately 1 % of the European pharmaceutical market. The Norwegian production of pharmaceuticals is also relatively small, and the country imports far more than it exports. In 2007, import of pharmaceuticals amounted to NOK 10 billion, whereas export amounted to NOK 4 billion (nominal values). In total, 4630 persons were employed in the Norwegian pharmaceutical industry in 2008. Only nine pharmaceutical firms had production of pharmaceuticals with marketing permit the same year.

The Norwegian Competition Authority (the NCA hereafter) has not had any specific competition issues relating to generics and the pharmaceutical industry yet. However, the Norwegian experience relating to regulation of and competition in the generics retail market might be of interest to a wider audience. Regulation of the generics retail market and the degree of competition therein will be the focus of the Norwegian contribution to the Roundtable on Generic pharmaceuticals.

2. Development and main features of the Norwegian pharmaceutical market

The deregulation of the Norwegian pharmaceutical market started with the termination of the state-owned wholesale monopoly Norsk Medisinaldepot AS (NMD) in 1995, as a preparation to the introduction of the EEA-agreement. The termination of the wholesale monopoly resulted in two new wholesalers entering the market. It should be noted that all wholesalers are obliged to stock all drugs with marketing permit in Norway, i.e. they are all full-line wholesalers. The next major change came with new pharmacy legislation in 2001, effectively deregulating the sector. With the enactment of this law, restrictions on ownership to pharmacies were abolished. However, the law still requires that manufacturers and doctors cannot own pharmacies and that the pharmacy must be managed by a trained pharmacist. One result of the new pharmacy act was a significant increase in retail outlets - mainly in urban areas. However, the retail market is today dominated by three vertically integrated chains, and the market is highly concentrated at both the retail and wholesale level.

At the producer level, all the major international pharmaceutical companies are represented in Norway through subsidiaries.

Concerning the regulatory regime, it is common to distinguish between regulation of price and the regulation of structure and conduct. Regarding the latter, there are no significant restrictions on establishing new pharmacies. There are some measures to preserve the presence of pharmacies in rural areas. So far there have been certain restrictions on advertising, implying among other things that the retail firm could not advertise price. These restrictions were removed with recent changes in the Norwegian pharmacy law. However, the law and its regulations still restrict the possibility to ship pharmaceuticals outside the pharmacy's natural geographic district. The background for this restriction has been considerations relating to customer counselling and preservation of local pharmacists in rural areas. These limitations are currently under consideration.

Another important feature is that it is permitted to sell certain non-prescription drugs outside pharmacies. The arrangement encompasses certain approved non-prescription drugs (mostly medicines for

pain relief, cold and allergies). With regards to this, there are certain requirements that must be fulfilled. Among other things, the pharmaceuticals must have marketing permit and be on an approval list, there is a minimum range requirement and the sale must be under control. In the regulations it is stated that the pharmaceuticals must be "behind counter, closed cabinet or physically unavailable for customers".

The price regulation of prescription medicines are based on maximum prices. For pharmaceuticals still under patent protection, the pharmacy's maximum purchase price (i.e. the price of the pharmaceutical charged by the wholesaler to the pharmacy/retailer – "AIP") is based on an average of the three lowest prices in a sample of nine European countries. Since the pharmacy margin is regulated, this effectively determines the pharmacy's maximum price at the counter. For pharmaceuticals with generic competition, the prices are determined according to the so called "stepped price model" ("Trinnprismodellen"). Features and experiences with this model will be explored in somewhat more detail below. Prices for non-prescription drugs are unregulated.

3. The patent situation in Norway

In Norway, for patent applications submitted before 1992 it was not possible to grant a patent on the actual medicine, a so-called product patent. The only available patent protection for medicines was a protection of the manufacturing method regarding the synthesis of the finished product. Such a manufacturing method patent does not provide protection against competition from products with an identical active substance as long as it is manufactured according to a process sufficiently different from the protected product. The right to achieve patent protection was thus more restricted for medicines before 1992 than for other products.

The restriction on the right to protect medicines via patents that applied up to 1992 was a conscious choice on the part of the legislator to ensure more competition and lower prices on medicines in general. For many of the larger products on the global medicines market today, research and development had started before 1992. These products are thus not protected by product patents in Norway.

As the technological development has accelerated and the government has put more emphasis on stimulating the use of generic alternatives, the incentives for challenging the manufacturing method patents have grown. This has led to several legal proceedings, some ending with settlements and others going to the courts with varying outcomes for the innovative and generics manufacturers respectively.

There are currently negotiations between manufacturers of patented medicines and the government to prevent medicines from being entered on the list of interchangeable medicines where legal proceedings have been initiated to stop a generic medicine from being marketed.

4. Regulations on generics substitution

With the new Pharmacy Act in 2001 and the establishment of a market structure with three large pharmacy chains there has been a shift in market power from the manufacturers to the distributors. This shift is particularly visible in the non-patented market due to the introduction of generic substitution in pharmacies.

The Pharmacy Act gives the pharmacy an opportunity to switch the prescribed medicine for a generic equivalent if the products have been approved as interchangeable by the Norwegian Medicines Agency. The pharmacies are not obliged to substitute and even though it may seem obvious that a switch is made to a cheaper medicine, the legal base does not contain such a requirement. This gives the pharmacies great leverage with regard to which medicine is actually dispensed to the patient.

The list of interchangeable medicines is made by the Norwegian Medicines Agency and most of the products on the list have been entered because they have been approved by a simplified registration procedure for generics, whereby the necessary documentation of safety and efficacy is replaced by a requirement to document that the product is essentially similar to a product approved on the EEA market under a full application. Pursuant to the EEA-agreement, approval of medicines in Norway follows the same procedures as those in the member states of the European Union.

One consequence of this system in a market with three pharmacy chains is that there is fierce competition amongst the generic manufacturers to become one of the chains' preferred supplier of generics. If a generic manufacturer is not able to become one of the pharmacy chains' preferred supplier in one or more therapeutic areas it will be difficult for the generic manufacturer to enter the Norwegian market as there are few customers left.

The stepped price model: for pharmaceuticals with generic competition, the maximum (refund) prices are reduced in steps, starting with the maximum pharmacy sales price (i.e. price of the pharmaceutical charged by the pharmacy/retailer to the user "AUP") on the date stable competition from generics can be established. The model was introduced in 2005, and presupposes generic substitution (introduced in 2003) and an obligation to secure the capacity to deliver at least one pharmaceutical product at a retail price equal to the stepped price. A table presenting the cuts and the price of prescription pharmaceuticals with generic competition is presented below.

Table 1. Stepped prices for pharmaceuticals with generic competition

Turnover AUP last 12 months before generic competition		< 100 MNOK	> 100 MNOK	
	Cut - point in time			
1st. cut	When generic competition	30 %	30 %	
2nd cut	6 months after generic competition	55 %	75 %	
Turnover AUP at least 12 months after last cut		> 15 MNOK	>30 MNOK and < 100 MNOK	> 100 MNOK
	Cut - point in time			
3rd cut	At the earliest 12 months after last ordinary cut	65 %	80 %	85 %

Since the cuts start on the date when stable generic competition can be established, the model is obviously vulnerable to any attempts from producers to delay this date. This is an issue covered by the European Commission in its pharmaceutical sector inquiry. Furthermore, it must be profitable for the generics producer to introduce the product in the market. Thus, for some marginally profitable generics, the stepped price model may not be applied since the generic alternatives have not been introduced into the market.

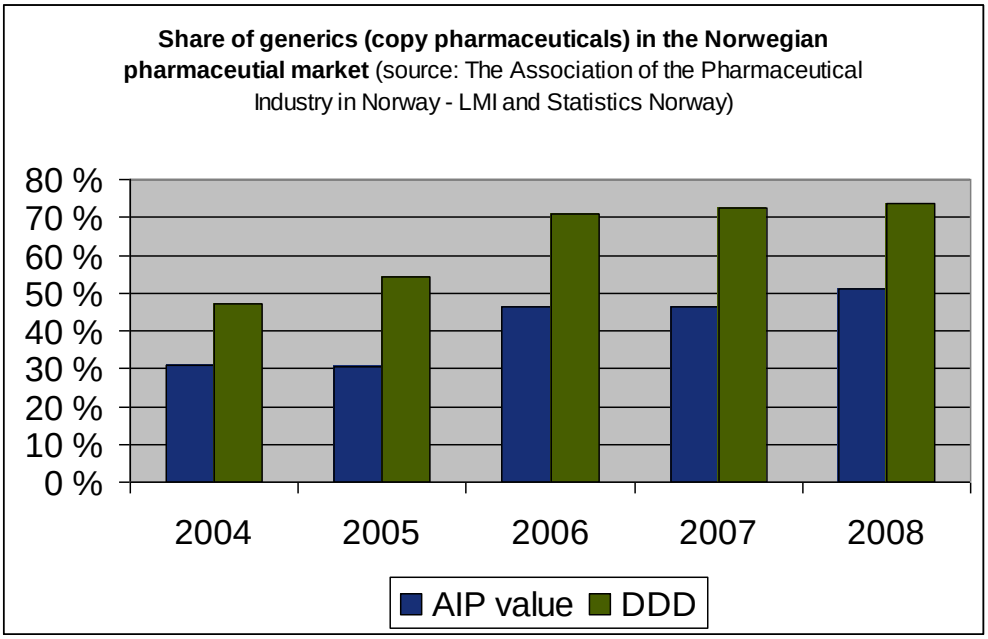
The Norwegian Medicines Agency presented an assessment of the stepped price model in 2006, concluding that the practical and administrative sides of the model had worked well, although the savings for the state were somewhat lower than assumed when the model was introduced. Later, sharper cuts have been introduced, implying higher savings.

Some statistics for prices and generics penetration in Norway will be presented below.

The figure below presents generic penetration in the Norwegian market. Measured in Daily defined doses (DDD), the penetration was almost 74 percent in 2008 (parallel imported pharmaceuticals excluded),

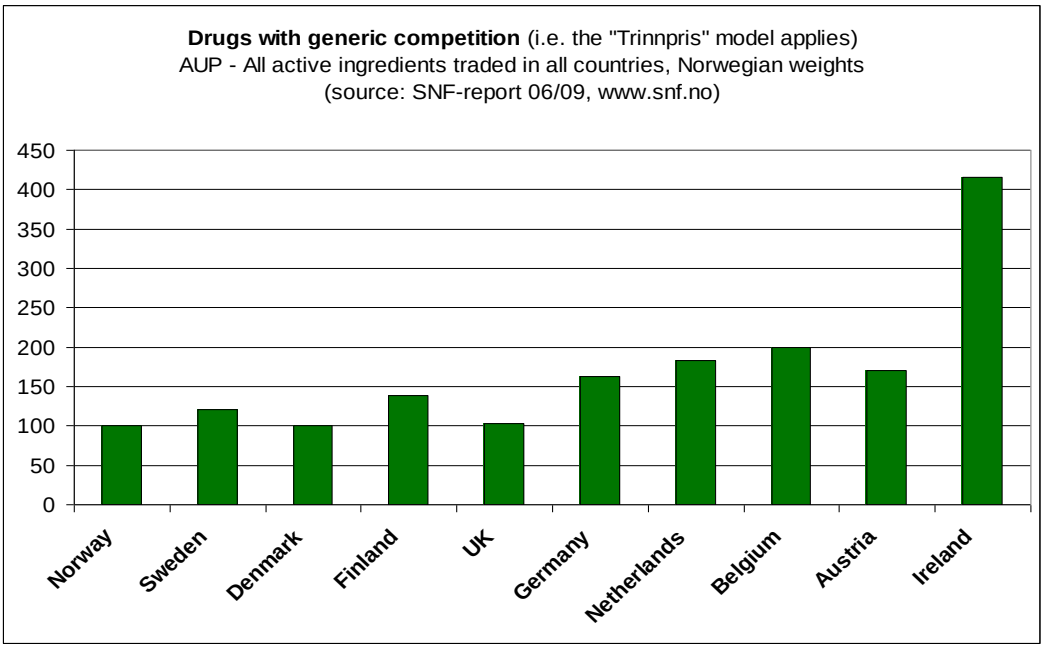
and measured in value, the penetration was 51 per cent. This difference can be explained by the relatively high prices of the original product.

Graph 1. Share of generics



The next figure presents price indices for drugs with generic competition in a sample of nine countries. The figures are based on a report from the Foundation for research in economics and business administration ("SNF") prepared for the Norwegian Pharmacy Association in 2009, and is an update of an analysis made for the Norwegian Ministry for Health and Care Services the previous year. The figure indicates that the ladder price model has been fairly successful in keeping prices relatively low in Norway.

Graph 2. Price indices



5. Ownership regulations and competition in the generics market

Under the Norwegian Pharmacy Act section 2-3, a manufacturer of medicines may not be the owner of a pharmacy. The rationale of this restriction is to prevent the dispensing of medicines being motivated by other interests than a patient's medical need for a particular medicine. It is also argued that a fully integrated chain from manufacturer to retailer would potentially weaken the competition amongst generic manufacturers.

Of the three pharmacy chains currently operating in Norway, one of them is owned by an undertaking that is also the owner of a larger generic manufacturer. The Norwegian Medicines Agency which is in charge of the administration of the Pharmacy Act has experienced difficulties trying to get full insight into the relations between the undertakings. This has made them hesitant to conclude with regard to the question of whether the pharmacy chain is in breach of the pharmacy act. Sales statistics show that the generic manufacturer has considerably higher sales through the pharmacy chain with the same owner than any larger generic manufacturer in the other two pharmacy chains.

The Norwegian Medicines Agency has proposed to the Ministry of health and care services to remove the current limitations on ownership and to allow the introduction of private labels for medicines.

With the oligopolistic structure in the Norwegian market for distribution and retail sales of medicines there are high entry barriers for generic manufacturers that would like to access the market. The Norwegian competition authority is concerned that removing the limitations on ownership to pharmacies could raise the entry barriers for generic manufacturers further and thereby weaken the competition in the non-patented segment of the medicines market.

6. Concluding comments

The Norwegian pharmaceutical market is a highly concentrated market with three vertically integrated main actors on wholesale and retail level.

The NCA has on different occasions raised concerns from a competition point of view relating to the wholesale/retail part of the market. The highly concentrated market structure by itself is a concern. Moreover, the full range requirement for wholesalers implies extremely high barriers to entry. In addition, there are concerns relating to presumably negative effects on competition of marketing and advertising restrictions as well as the regulations effectively restricting the development of internet trade.

Experience seems to indicate that allowing certain drugs to be sold outside pharmacies has resulted in lower growth in prices on those pharmaceuticals encompassed by this scheme than those outside. However, the regulations stipulating that the sale of the products must be "behind counter, closed cabinet or physically unavailable for customers", limits the potential of this scheme from a competition point of view.

On the other hand, the experience with the stepped price model seems to be good, and has led to relatively high penetration of generics, relatively low prices of generic pharmaceuticals and consequently substantial savings in private and state refund expenditures for pharmaceuticals.

SPAIN

1. Introduction

The Spanish Pharmaceutical sector is a highly regulated market where both prices and margins are fixed by Law in certain cases, in particular, in reimbursable prescription-only pharmaceuticals dispensed in Spain.

The Spanish pharmaceutical market has been traditionally characterised by the great influence of brand medicines with scarce competition between brand and generic medicines. However, in the last years, and mainly due to an increase in sanitary expenditure, new legislative initiatives have been adopted to promote the entry of generic medicines and thus increasing competition between brand and generic medicines.

The purpose of this paper is to put forward the key elements of the Spanish pharmaceutical sector both from the regulatory framework and from the competition enforcement angles, focusing on some interesting antitrust cases which the Spanish Competition Authority has dealt with in the last years.

2. Regulatory framework of the Spanish pharmaceutical sector

2.1 Authorities

The Spanish Health system is regulated under Act 29/2006 of Guarantees and the Rational Use of Medicines and Health Products.

In relation with the sanitary authorities, the main players in the pharmaceutical system, according to current legislation, are the following:

- The Directorate General of Pharmacy and Health Products of the Ministry of Health, which controls the pricing and reimbursement process.

- The Interministerial Commission on Pharmaceutical Prices which imposes the price of reimbursable prescription-only pharmaceuticals dispensed in Spain and decides on final pricing.

- The Spanish Medicine Agency (Ministry of Health), which is responsible for the evaluation, authorisation, inspection, surveillance and control of pharmaceuticals.

- The general practitioners, who play a fundamental role in the demand for prescription pharmaceuticals, being responsible for the prescription itself of these medicines.

- The pharmacists that, according to Act 29/2006, are obliged to dispense generic medicines, if any, for a certain prescription; and ,within the generic medicines, those with the lowest price.

2.2 Health legislation

In 1986, the General Health Act established a National Health System (NHS) in Spain. It is a highly decentralised system, with universal coverage and financed through general taxation. There are 17 Autonomous Communities which have full powers regarding public health and healthcare services planning. The health system financing remains centralised and it is distributed between the Autonomous Communities according to a capitalisation scheme. Under the NHS, healthcare is provided free of charge except for pharmaceuticals.

Pharmaceuticals are classified in Spain into the flowing groups:

- Prescription-only pharmaceuticals, which are all reimbursed.
- Non-prescription reimbursable pharmaceuticals, which can be prescribed by a medical doctor (and, thus, reimbursed by the NHS) or not prescribed (and not reimbursed).
- Over the counter (OTC) pharmaceuticals, which are not reimbursed.
- Other non-prescription, non-reimbursable pharmaceuticals, which are not OTC.

In 2006, a new law on "Guarantees and the Rational Use of Medicines and Health Products" was adopted[1]. This new act introduced a new reference pricing system. The pricing of reimbursable prescription-only pharmaceuticals dispensed in Spain is carried out by the Interministerial Commission on Pharmaceutical Prices within the Ministry of Health.

Furthermore, in 2007, a Royal Decree[2] was adopted in order to regulate the procedure of authorisation, register and dispense conditions of medicines for human use.

3. Competition in the Spanish pharmaceutical sector

3.1 Competition among branded pharmaceuticals.

Competition among branded pharmaceuticals depends on the therapeutic group to which they belong, and, more specifically, depending on the ATC3 or ATC4. In Spain, there are markets for certain therapeutic groups which are highly competitive, but also others where competition does not exist due to the fact that just a very little number of medicines are commercialised for certain diseases.

According to Act 29/2006, prices of branded pharmaceuticals are fixed by the Ministry of Health taking into account the prices of the three EU Member States where the medicine is commercialised at a lower price. In case the medicine is not commercialised in any EU Member State, the Ministry of Health, when fixing the medicine´s price, carries out an investigation of the trade-off effectiveness-cost in which different factors are taken into account, such as the R&D cost, the investment made by the company and the therapeutic action of the medicine.

3.2 Competition between branded pharmaceuticals and its corresponding generics

Competition between branded pharmaceuticals and its corresponding generics depends once again on the therapeutic group to which they belong and, therefore, on the ATC3 or ATC4. Prices play in these

1 Act 29/2006 of Guarantees and the Rational Use of Medicines and Health Products.

2 Royal Decree 1345/2007.

cases a key role. Yet, again, there are markets with a high degree of competition between brand and generic medicines but there are still many markets where no generics are commercialised.[3]

Under Act 29/2006, and aiming at the promotion of competition between brand and generic medicines, the practitioner is recommended to prescribe according to active ingredients and not according to a particular brand. At the same time, in the case of reimbursable pharmaceuticals, pharmacists are obliged to dispense the medicine with the lowest price in case brand and generic medicines exist for the same treatment and in case the lowest price medicine are both the generic and the branded medicine.

As far as patents are concerned, Royal Decree 1345/2007 establishes two exclusivity periods: an exclusivity period of 11 years for brand medicines data and an exclusivity period of 20 years for the patent itself .

Moreover, the first generic medicine that is commercialised usually has a discount between 10-35% of the brand medicine regarding the same treatment. Nevertheless, subsequently commercialised generics do not have a regulated price or discount, being fixed by the generic medicines companies, and, therefore, exists the possibility of fixing lower prices than the reference prices established each year by the Government.

According to a recent report issued by the European Commission on the pharmaceutical sector inquiry, Spain is one of the EU Member States with greater delays in the generic medicines entry. On average, the delay stands up to 13 months from the original medicine patent expiration date.

However, this does not necessarily mean the existence of competition concerns between brand and generic medicines in Spain. In fact, typical initial problems for generic entry have not been detected in this sense, given that pharmaceutical companies have reacted by applying 3 different commercial policies:

- They have tried to develop their own generic medicine;
- They have decreased the price of their brand medicine, or
- They have stop promoting their brand medicine.

Therefore, as far as the Spanish Competition Commission is concerned, so far the delay in Spain regarding generic medicines entry in the market has been caused by existing problems regarding authorisation, register and marketing procedures of generic medicines by sanitary authorities.

3.3 Competition among generic pharmaceuticals

Competition among generic pharmaceuticals obviously depends again on the therapeutic group to which they belong and more specifically they are analyzed depending on the ATC3 or ATC4. In Spain, there are markets highly competitive in this sense but also markets for certain therapeutic where only one generic is active, especially in the case of markets characterised by a low demand.

4. Competition enforcement in the Spanish pharmaceutical sector

In recent years, The Spanish Competition Authority has dealt with two important cases in the pharmaceutical sector.

[3] For example, in the paracetamol market there is only one brand pharmaceutical and several generics whilst in the levetiracetam market (an antiepilepsy pharmaceutical) there are no generics yet.

The first one (the URIACH Case) is related to predatory prices of a branded pharmaceutical company as a result of the entrance of a generics one.

The second case (PHAMACY ASSOCIATIONS), and probably the most important one given the sanction imposed for the declared infringement, is related to a recommendation made by several associations of pharmacists to cause a boycott to a generic company which had announced the commercialisation of its products at lower prices than the regulated reference ones.

4.1 The URIACH Case

This case was originated by a complaint issued by GES GENERICO (a Spanish company devoted to the production and marketing of generics) in 2005 against GRUPO URIACH for an alleged abuse of a dominant position consisting of selling under cost its medicine *Venofer* (a medicine for hospital use to treat the lack of iron), aiming at the elimination of its competitors.

In Spain, medicines for hospital use are only dispensed at the pharmaceutical service area in each hospital. Therefore, it can only be sold to hospitals, generally through tenders.

URIACH was marketing its medicine *Venofer* at a maximun authorised price (PVL) of 59,02€/pack of 5 ampoules (11,8€/ampoule) until the generic *Feriv* was launched, marketed by GES GENÉRICOS on the 1st July of 2005, at a price of 29€/pack (5,80€/ampoule). Since then, URIACH started marketing its medicine to the Sanitary Services and to private hospitals at a price of 13,50€/pack (2,70€/ampoule).

As a result of the investigation the former Servicio de Defensa de la Competencia (now Investigations Division of the CNC) issued a report to the Council concluding the existence of an abuse of dominant position in the market for trivalent iron, through predatory pricing by URIACH of its medicine *Venofer*. However, the Council decided to file the case as they considered that URIACH had just reacted to the entry of a new competitor and, hence, they started a price war among them.

4.2 The pharmacy associations case

The special interest of this case lays on the fact that the entry by a generics company was hampered by several pharmacy associations and not by its direct competitors, the brand medicine producers.

In fact, this case reflects the present situation in the Spanish market where the main competition concerns are not between brand and generic pharmaceuticals but between distributors and pharmaceutical producers of generic pharmaceuticals on the one hand and between the pharmacies and pharmaceutical producers on the other.

Focusing on this particular case, it was originated in 2007 by a complaint from Laboratorios DAVUR (a Spanish company which produces and commercializes generic pharmaceuticals) against four Pharmacy Associations alleging restrictive practices. These practices consisting on a collective boycott against DAVUR products through a collective recommendation of these associations to their associates (pharmacies).

In March 2007, Laboratorios DAVUR decided to decrease the price of twelve of its generic pharmaceuticals below the reference prices set by the Health Ministry. The following were, among others, the main marketed pharmaceuticals of the company: Omeprazole, Simvastatin, Paroxetine and Fluoxetine.

After this decision, several Pharmacy Associations made recommendations to almost all the pharmacies in Spain (22.360 e-mails were sent) in order to stop the commercialisation of DAVUR medicines on the basis that, from their point of view, pharmacists were not obliged to dispense the cheapest

medicine but the medicine that is included in the Ministry Order imposing reference prices of generic medicines. The e-mails and letters sent also recognised the fear that DAVUR lower prices could significantly affect the annual price revision made by the Health Ministry, leading to lower reference prices of generic medicines on the following year and, therefore, a decrease in their future revenues.

As a result, many Spanish pharmacists decided not to deal with Laboratorios DAVUR avoiding the entry of its products in their pharmacies.

During the investigation proceedings, Laboratorios DAVUR came to an agreement with the main claimed associations and withdrew its complaint. Nevertheless, the Investigations Division decided to continue with the investigation *ex-officio* . Finally, on the 24th March 2009, the Spanish Competition Commission Council solved to declare the existence of infringement of article 1 of the Spanish Competition Act, qualified as a collective recommendation to homogenize the pharmacies behaviour against Laboratorios DAVUR in the market for generic medicines subject to medical prescription.

The Spanish Competition Commission Council imposed a total fine of EUR 1 million to these associations.

5. Final remarks

Due to its nature, the pharmaceutical market is a highly regulated market in Spain where even several margins, discounts and prices are fixed by the Public Administration. As far as generics are concerned, from a competition point of view, barriers of entry to generics companies still persist originated by the existing legal procedures to obtain the binding authorisations and registrations.

In this respect, so far, competition problems concerns have arisen rather more from concerns between distributors and pharmaceutical producers of generic pharmaceuticals or between pharmacies and pharmaceutical producers, than between brand and generic pharmaceuticals.

Nevertheless, the Spanish Competition Authority has been especially active to ensure a successful entry of generics in the Spanish pharmaceutical sector, tackling both legal barriers of entry through its reports on legislative initiatives as well as other competition concerns that may be detected such as the DAVUR boycott which was sanctioned early this year.

SWEDEN

The Swedish Competition Authority (SCA) focuses in this contribution primarily on the following suggested issues:

- Competition between different branded drugs
- Competition between branded and generic drugs
- Competition between different generic drugs
- Factors that influence demand
- Effects of generic competition

Conclusions

In Sweden, price competition is weak between branded drugs which are therapeutic substitutes. Mainly due to low out-of-pocket costs for the patients and the resulting price insensitivity of demand, the companies have incentives to try to maximize the price that the regulator allows the companies to set. Some aspects of the way drug prices are regulated in Sweden make these incentives even stronger than in many other countries.

Concerning price competition between branded and generic drugs, the pressure to cut prices is also low on branded drugs on patent which compete with generic drugs containing other active ingredients. The consequence of a drug's patent expiring and the accompanying launch of cheap generics, is that competing drugs still on patent – containing other active ingredients but still therapeutic substitutes – might become cost-ineffective. But usually physicians keep on prescribing these formerly cost-effective drugs, giving the drug companies no reason to cut prices.

More frequent evaluations of the cost-effectiveness of existing drugs by the authority responsible for drug price regulation, might lead to lower prices. When companies are faced with the consequence of having their drugs excluded from reimbursement, they may choose to cut prices to avoid the exclusion.

If physicians were better informed on the therapeutic similarity of different drugs containing different active ingredients, this could make physicians more aware of price differences when prescribing drugs, which would improve price competition between branded drugs as well as between branded and generic drugs.

Price competition between different generic drugs is rather stiff in Sweden since the introduction in 2002 of mandatory substitution to the cheapest available generic at the pharmacy. During the ongoing regulatory reform process of the Swedish pharmacy retail market, a much discussed issue has been how to keep the price competition on generics as stiff in the future, although privately owned pharmacies may have incentives not to substitute to the cheapest generic available.

Concerning factors that influence demand, an important aspect is that an absolute majority of Swedish physicians are publicly employed and on salary and have therefore no financial incentives to prescribe expensive drugs.

The effect of generic competition on prices and sold quantities depends very much on the sales of the drug that loses its patent. If the patent of a large selling drug expires the price drops steeply and it has been observed that in Sweden the brand name drug will be able to keep only a small market share.

1. Competition between branded drugs

The prices of patented drugs are regulated in Sweden, as in almost all other European countries. The prices are set by the Dental and Pharmaceutical Benefits Agency (TLV).

Prices are regulated for all prescription drugs which are included in the reimbursement system. If producers do not wish to have a drug included – which is rare – they are free to set whatever price they want.

The basic principle for the price regulation is that the price cannot be higher than the requirement for cost-effectiveness allows. This means that a drug can be priced up to the point where it is just barely cost-effective, and still be reimbursed. Cost-effectiveness implies that higher quality drugs (drugs which improve life expectancy or quality of life the most) are allowed higher prices than lower quality drugs. This is believed to strengthen the pharmaceutical industry's incentives to develop drugs which have a large potential to improve life expectancy or quality of life, rather than drugs with very small advantages over existing drugs.

Drugs which are found to be cost-effective at the price the producer wish to set are approved reimbursement. For the last 7 years, the reimbursement authority has not used its bargaining power, to bid down prices further – below the cost-effective price – in direct negotiations. However, this will probably change since the Swedish government now have provided TLV with new guidelines on how to set prices, with more focus on cost containment.

TLV does not make any cross-country price comparisons when setting prices, which is a common practice in many other European countries.

A patented drug often belongs to a certain class of drugs. Even though these drugs contain different active ingredients they are still considered to be therapeutic substitutes. Examples of classes of drugs are beta-blockers for hypertension, statins for high cholesterol, and proton pump inhibitors (PPIs) for ulcers and dyspepsia. While, the producers of these drugs are in close competition, there is rarely any price competition between the drugs belonging to the same class, if all of them happen to still be on patent. This is the case in Sweden, and probably in most other countries.

Conversely, producers of patented drugs often try to get the highest price possible approved when applying for reimbursement. A main reason for this is that third party financing makes demand insensitive to price. However, another reason may be that a high price signals high quality – so that demand actually increases in price. Physicians are often lack information about evidence on the treatment effects of a particular drug – it is simply impossible for a physician to be perfectly informed about details in all clinical trials. But physicians are aware that the reimbursement authority only allows a higher price for a new drug – relative to the existing drugs – if the new drug is better than the already existing ones. Therefore, physicians may use the regulated price as a signal of high quality – if they trust the reimbursement authority to do a good job. According to this logic it would be rational for originator companies to try to get the highest possible price approved.

This mechanism could be a contributing factor for the observed absence of price competition between patented drugs. And we believe this mechanism is more pronounced in Sweden than in other countries due to the importance the Swedish price regulator puts on cost-effectiveness, rather than cost containment. TLV only regulates prices for drugs used in outpatient care, and not drugs used in inpatient care. However,

it is rather common that companies that launch drugs which only will be used in inpatient care still wish TLV to approve the price, because TLV's decisions provide a seal of approval for using the drug, i.e. that the drug is cost-effective.

2. Competition between branded and generic drugs

Patented drugs belonging to a certain class of drugs rarely lose their patents at the same time. Therefore, at a particular point in time, branded drugs on patent will compete with – usually – much cheaper generics containing other active ingredients.

The consequence of a patent expiring, and the price decrease that follows, is that competing drugs which earlier was cost-effective no longer are cost-effective, since a close substitute has become much cheaper. Thus, patients no longer should be prescribed the more expensive drugs. However, patients usually "migrate" very slowly from one drug to another, even though the difference in price can be large.

In Sweden, the reimbursement authority TLV has conducted reviews of different therapeutic groups, trying to weed out drugs that no longer are cost-effective. But this is a slow process, and in the meantime – usually for several years – former cost-effective drugs can go on being reimbursed and heavily prescribed, costing tax payers large sums.

3. Competition between different generic drugs

Sweden introduced mandatory generic substitution in 2002. The pharmacies are now obliged to substitute the prescribed drug to the cheapest available drug that the Medical Products Agency (MPA) has listed as substitutable. If a patient still prefers the prescribed drug, the patient has to pay the difference in cost direct out-of-pocket.

The reform is considered to be a success. Prices of generics have come down and the market share of generics, expressed in terms of defined daily doses (DDDs), has increased substantially. Sweden now has low prices on off-patent drugs compared with many other countries.

At the moment, the Swedish pharmacy retail market is going through a regulatory reform process. Until the 1st of June 2009 the state owned company Apoteket AB had a statutory monopoly on pharmaceutical retail sale. Following the reform, the monopoly has now been abolished and it is possible for other actors to enter the pharmacy market. Any companies who wish to open a pharmacy are allowed to do so, provided they live up to the regulatory frameworks. Thus, there will be no supply restrictions.

Sweden has low price on generics, which is a result of voluntary price cuts. Since the former monopolist Apoteket AB has been - reasonably - efficient in substituting to the cheapest available generic, the generic producers have found it worthwhile to compete to become the cheapest generic available and thereby gain a large market share. A lot of the discussions concerning the reform have focused on how to maintain the stiff price competition on off-patent drugs that has been established during the last years.

In order to make the system work also in a liberalised market, it is essential that all pharmacies try their best in ordering and dispensing the cheapest available drug. Otherwise the generic producer setting the lowest price will not gain a large market share, and thus there will be no incentive to set a low price in the first place.

Therefore, there has been much discussion concerning how to get privately owned pharmacies to be as efficient as the former monopolist in substituting the prescribed drug to the cheapest available drug. To get all pharmacies to try their best, one could either rely on regulation (mandating pharmacies to always substitute, and possibly impose sanctions if pharmacies do not comply) or monetary incentives (for

instance paying pharmacies a bonus in proportion to how often they succeed in dispensing the cheapest generic available).

In the end, the Government opted for regulation rather than incentives. So each pharmacy is obliged to substitute to the cheapest available alternative, and it will be closely monitored by the authorities that they actually do so. Since the system has not been in place for more than two months – and since no competitors to the former monopolist have yet entered the market – it is too soon to tell whether the generic competition will be as efficient in the future as it has been in the past.

Biologicals may prove to be a problem, since the current – and future – system relies to such a large extent on pharmacies substituting expensive drugs to cheaper drugs. Although there are generic biologicals, so called bio-similars, they will not be defined as substitutable by the Swedish Medical Products Agency, since they never will be identical to the brand name drug. A fear then is that prices of bio-similars, will neither decrease as much as ordinary generics, nor be able to capture a very large market share.

4. Factors that influence demand

The Swedish health care system resembles for instance the British NHS to the extent that all citizens are covered in the public health insurance program and most hospitals are publicly owned, i.e. both financing and production are taken care of by the public sector. A small share of the population is also covered by private add-on insurance that guarantees faster access to health care at private clinics.

An absolute majority of Swedish physicians are publicly employed and are on salary. Thus, they have no financial incentives to prescribe expensive drugs. The physician is free to prescribe any drug she wants to. However, not all drugs are reimbursed, which usually make them unattractive to patients. Hospitals also provide prescription guidelines to physicians.

The average share of drug expenditure paid out of pocket is roughly 20 percent.

5. Effects of generics competition

The magnitude of the discount that a generic firm offers, compared to the price of the branded drug, varies a lot. The larger the volume of sales of the drug, the more intense is the price competition between different generic manufacturers. For drugs which are rarely prescribed, the price drops hardly at all when the patent expires. However, if the patent of a large volume drug expires the price can drop 90-95 percent following the entry of generics. The table below, from a report by TLV in 2006 on the effects of generics competition, illustrates the drop in average price paid for five large selling substances a couple of years after patent expiration.

Table 1: Changes in average price paid for five large selling substances

Substance	Brand name	Therapeutic area	Date of patent expiry	Price change* %
Citalopram	Cipramil	Depression	June 2002	-83
Felodipin	Plendil	High bloodpressure	Feb 2003	-61
Omeprazol	Losec	Ulcers	March 2003	-65
Sertralin	Zoloft	Depression	Oct 2005	-62
Simvastatin	Zocord	High cholesterol	Feb 2003	-92

*From the month the patent expired until December 2005. Source: ”Kraftig prispress på läkemedel efter introduktion av generiskt utbyte.”, Läkemedelsförmånsnämnden 2006. http://www.tlv.se/Upload/Pressmeddelanden/PM_060629_rapport_generiskt_utbyte.pdf

UNITED KINGDOM

Box 1. Summary of key points

This paper covers the following:

- A description of how competition works in the UK market for pharmaceuticals and the benefits provided by generic medicines
- The key competition problems in the generic sector by reference to the OFT's past work in this area and the recent Pharma sector inquiry published by the European Commission ('the Inquiry')
- The OFT's experience in the sector and its assessment of the related issues and their significance to effective generic competition
- Questions to other members

1. Background

The pharmaceutical sector is one of the UK's most dynamic industries, and of key importance to the UK economy. According to the UK Department of Health ('DH') figures 73,000 people were directly employed in the UK pharmaceutical industry in 2004. The industry invested about £3.2 billion in UK-based research and development ('R&D') in that same year. Drug costs form a significant proportion of total healthcare expenditure. It is estimated that the state-run National Health Service ('NHS') in England spent around £11 billion on medicines in 2006.

Against this background, it is easy to understand why, as for the European Commission and the U.S. Federal Trade Commission, the pharmaceutical sector is and has been an OFT priority area for a number of years. The sector has raised both competition and consumer issues. In the last 8 years or so, the OFT has completed a number of healthcare sector investigations and studies, including reaching two infringement decisions involving abuse of a dominant position under Chapter II of the Competition Act 1998.

Given the mainly informative and discussion purposes of this roundtable, section one of this paper provides an overview of the distinguishing features of competition within markets for pharmaceuticals in the UK. Section two then outlines the OFT's views on the key competition issues relating to generic medicines that it has considered over the past 10 years.

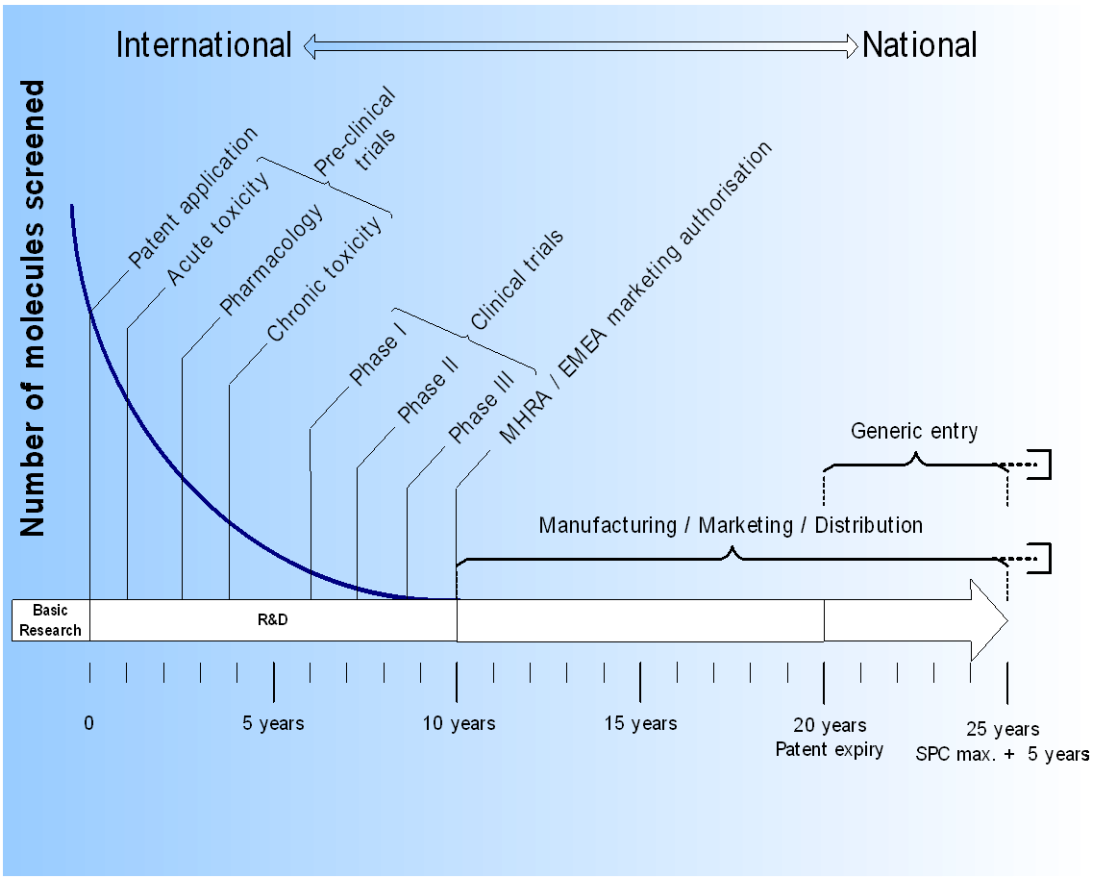
2. The supply of UK pharmaceuticals

2.1 The life cycle of a medicine

The life cycle of a new medicine is described in detail in the European Commission Pharma Sector Inquiry ('the Inquiry') of 8 July 2009. Therefore we will not provide a detailed description here, other than the summary chart below. This is drawn from the OFT market study on 'The Pharmaceutical Price

Regulation Scheme'[1] and it presents a schematic overview of the drug production process, from basic discovery to generic entry after patent expiry.

Figure 1: Stages in the life cycle of a medicine



As shown by the chart, there are three distinct phases to the life cycle of a new medicine: 1) the R&D phase up to market launch; 2) the period between launch and loss of exclusivity (LoE) due to patent expiry; and 3) the period following the LoE, when generic products can enter the market. For the purposes of the discussions at this OECD roundtable relating to originator-generic competition, it is worth highlighting that in every phase, patent protection plays a key role in the business strategies of originator companies. This is because patent protection enables originator companies to maximise the revenue streams from a given product as well as recover the often huge R&D investments, while also determining the extent to which these companies will be able to further develop their inventions in the future.

Patent applications are already filed during the phase of basic research for a new medicine and can continue to be filed throughout its entire life cycle. The time between filing an application for the first patent (patent for the active molecule or 'primary patents') to the launch of the product varies significantly, depending on the obstacles encountered. It can take between two to ten years, with an average of 5 years[2]. As a reaction to this significant delay, mechanisms were introduced by the legislature to provide additional

1 OFT market study on 'The Pharmaceutical Price Regulation Scheme', February 2007, figure 3.3 at page 40.

2 'Pharmaceutical Pricing Policies in a Global Market', OECD 2008.

patent-like protection in the form of Supplementary Protection Certificates (SPC)[3] and rules on data exclusivity. The purpose is to give medicinal products an effectively extended period of protected or exclusive marketing during the second phase of the lifecycle of a medicine.

This second phase is particularly crucial for originator companies as it is the phase during which they market the medicines they have developed, with a view to recouping upfront investments and making a profit. In this context, effective patent protection is vital to sustain this business model, which, as noted earlier, also ensures that incentives for further innovation are preserved and promoted. After patent expiry, generic companies will be able to enter the market, leading typically to falling prices and decreasing volumes for the originator companies. In this respect, it is interesting to note that, based on data from the Inquiry, the effective protection period counted from first launch to first generic entry increased by approximately 3.5 years in the period 2000-2007[4]. This is indeed consistent with the finding by the Inquiry that in anticipation of the declining turnover following patent expiry, originator companies tend to employ so- called life cycle management strategies aimed at 1) extending the time of their market exclusivity without generic competition; and 2) maintaining or widening the market that the product covers during its exclusivity period. The main ones are: measures enhancing product loyalty, reformulation and second-generation launch, patent clusters, settlements with generic companies, putting into question the efficacy or quality of generic products, etc. The Inquiry provides a detailed description of how these and other similar practices are used to try and extend the marketing exclusivity of the originator product beyond LoE.

Following LoE, generic medicines can enter the market. Their entry typically has a major impact on the sales price (which tends to decrease) and the volume of the medicine sold. The Inquiry[5] found that it took more than seven months, on a weighted average basis, for generic entry to occur once originator medicines lost exclusivity. Also, two years after entry, prices of generic medicines were on average 40% below the originator price. In addition, the prices of originator products appear to drop following generic entry. This shows the significant cost/revenue impact that delays have in this context.

The share of generic medicines varies significantly between Member States. The latest market figures on the generic medicines industry in Europe from July 2007 show that generic penetration goes from less than 20% by value in Belgium, Finland, France, Greece, Ireland, Italy and Spain, to between 20% and 40% in Austria, Denmark, the Netherlands, Sweden, Hungary and the UK, and to over 40% in Poland[6]. The level of generic penetration in the EU is largely influenced by the different public policy choices made by the Member States.

2.2 The UK National Health Service

In the UK, the state-run NHS[7] is divided into primary (or community) care and secondary (or hospital) care segments. The process of supplying pharmaceuticals to patients differs between these two segments.

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3 SPC was introduced by Council Regulation (EEC) N 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ L 182, 2.7.1992, pp1-5. SPC provides for a kind of extension of the patent right for a maximum of five years.

4 Paragraph 164, page 59, of the EC Pharma Sector Inquiry, July 2009.

5 EC Pharma Sector Inquiry, pages 64-94.

6 Paragraph 170, page 61, of the EC Pharma Sector Inquiry, July 2009.

7 The National Health Service (NHS) is the name commonly used to refer to the four publicly funded healthcare systems of the United Kingdom, collectively or individually, although only the health service in England uses the name 'National Health Service' without further qualification. Each system operates

In brief, in primary care, general practitioners (the 'GPs') write prescriptions for pharmaceuticals, which a patient takes to a pharmacy, which, in turn, dispenses the pharmaceutical in question, often for free.[8] Pharmacies are responsible for the purchase of the pharmaceuticals either directly from manufacturers or through wholesalers. They are then reimbursed by the NHS for the cost of these drugs.

In secondary care, a hospital clinician will prescribe a pharmaceutical, which is then dispensed by the hospital pharmacy. Hospitals are responsible for purchasing the pharmaceuticals they dispense, but – unlike primary care pharmacies- they are not reimbursed directly for doing so. They must draw on the overall NHS budget they are given to treat patients. Patients do not pay for pharmaceuticals supplied in hospitals.

2.2.1 Pricing – the Pharmaceutical Price Regulation Scheme (PPRS)

In both primary and secondary care, the price that the NHS pays for pharmaceuticals/medicines is the subject of the PPRS.

The PPRS is one of the main instruments by which the UK Government, through the Department of Health ('DH'), tries to control NHS expenditure on branded drugs. The PPRS is not a formal regulatory system or binding contract, nor does it control prices directly. Rather, it is a voluntary arrangement that is agreed periodically between the DH and the Association of the British Pharmaceutical Industry.

By way of illustration, the 2009 PPRS[9] became effective on 1 January 2009 with a duration of not less than five years. Its aim is to strike a balance to ensure that the interests of patients, the NHS, industry and the taxpayer are promoted for each other's mutual benefit. Its objectives are to:

- Deliver value for money for the NHS by securing the provision of safe and effective pharmaceuticals at reasonable prices, and encouraging the efficient development and competitive supply of medicines;

- Promote a strong and profitable pharmaceutical industry that is both capable and willing to invest in sustained R&D to encourage the future availability of new and improved medicines for the benefit of patients and industry in the UK;

- Increase uptake and patient access for new clinically and cost-effective medicines in the NHS in a sustainable manner; and

- Help the NHS and industry develop sustainable financial and investment strategies, the UK must remain a stable and predictable market that does not place unforeseen burdens on either party over the coming years.

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independently, and is funded by, and politically accountable to the relevant devolved government of Scotland, Wales, and Northern Ireland and to the UK government for England.

8 The majority of community prescriptions do not attract the prescription charge which is collected in the community by pharmacies, due to exemptions (e.g. pregnant women, children, senior citizens and patients who require regular medication, unemployed). According to the OFT 'The Pharmaceutical Price Regulation Scheme' report of February 2007, page 14, the part of the community medicines bill that was paid for by prescription charges in 2004 was 5.6% in England, 3.2% in Wales, 4.6% in Scotland and 3.6% in Northern Ireland.

9 See http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_091825.

The scheme comprises two key components which relate to the entire portfolio of branded, licensed medicines (both in- and out-of-patent) sold by a manufacturer to the NHS:

- A profit cap: In the 2009 PPRS this is 21% return on capital per year with a margin of tolerance of 140% of that target. This applies to all the branded products sold by a company to the NHS and associated features (e.g. cost allowances for certain types of expenditure such as R&D expenditure). There are allowances for R&D, marketing and information costs.
- A range of price controls: There is freedom to set the initial price of new active substances (NAS). In the context of that freedom of pricing, there are restrictions on subsequent increases to the list price; controls on the pricing of non-NAS; and the one-off price cuts periodically agreed at the time of scheme renegotiations.

2.2.2 Competition to supply medicines

As shown in some detail below, demand for pharmaceuticals within the NHS– notably in primary care– is characterised by a complex set of principal-agent relationships, in which: i) the person who uses the product (the patient) neither decides nor, in most cases pays; (ii) the person who decides which products should be used (the prescribing GP) neither pays nor consumes; (iii) the institution that pays for the products (the NHS/UK Government) neither consumes nor decides.

2.2.3 Primary care

In the primary care sector, it is important to distinguish between competition to influence GPs when they write a prescription, and competition to supply pharmacies when they dispense a prescription written by a GP.

Competition to influence GPs: In the UK the delivery of frontline healthcare, including pharmaceuticals, is centred on primary care organisations (PCOs). PCOs receive the NHS funds and individually they manage the delivery of most healthcare to populations of 100,000 to 300,000. PCOs manage GPs under the terms of a UK-wide General Medical Services (GMS) contract. PCOs' main aim is to encourage GPs to prescribe cost-effectively through local incentive schemes and other arrangements.

However, GPs' interests are not always closely aligned with those of PCOs. The latter are more strongly motivated to control expenditure on drugs. GPs, instead, tend to take many varied incentives and considerations into account when deciding how to prescribe. This leads to clear principal-agent issues, since essentially GPs make decisions that PCOs fund.

In their prescribing, GPs tend to be influenced by the following:

- Guidance from national bodies such as the National Institute for Clinical Excellence ('NICE');
- The GMS contract which determines GPs' working conditions and provides a framework for their remuneration across the UK;
- Local measures implemented by PCOs, including local formularies, prescribing incentive schemes;
- Peer pressure, informed by prescribing trend information and the practice of hospital consultants;
- Marketing activities of pharmaceutical manufacturers;
- Their own independent assessment of clinical evidence; and
- Pressure from patients who may have attachment to a particular brand.

As noted earlier, GPs make decisions on how to treat a particular condition and can then issue a prescription. At this point, competition is from all therapeutically similar treatments that the GP could prescribe in the specific circumstances, hence it is primarily between branded pharmaceutical manufacturers who will try to persuade GPs of the benefits of their products. Given drugs' imperfect substitutability for one another and a low awareness of price among GPs, their prescribing tends not to be price-sensitive and price competition at this level is weak. In contrast, there is vigorous non-price competition between manufacturers marketing in-patent pharmaceuticals to GPs.

Competition to supply pharmacies: Once the GP has written the prescription, there are two types of downstream markets in which suppliers compete to supply pharmacies to dispense the relevant drugs. These differ depending on whether the prescription written by the GP is for a branded pharmaceutical, or whether it is written generically (that is by chemical name) and also on whether generic versions of the pharmaceutical in question are available. Also, reimbursement arrangements mean that pharmacies have a strong incentive to negotiate competitive prices with suppliers. Competition depends to some extent on how the pharmaceutical is reimbursed.

If reimbursed as a brand (as is the case for reimbursement of on-patent pharmaceuticals with no generic substitute or for branded pharmaceuticals where no generic can be dispensed even if one exists), competition is between the branded manufacturer and parallel importers (i.e. those trading across national borders into the UK) to supply the pharmacy. The NHS reimburses pharmacies at the manufacturer's list price (which is constrained by the PPRS price control) less 'clawback' (which refers to an amount that the UK Government periodically recovers from pharmacies to ensure that, as a population, their profitability is at a pre-determined level as set out in the 'pharmacy contract' agreed between the DH and the sector). A pharmacy's reimbursement price is not affected by what it actually pays for the product, so pharmacies are motivated to buy from the cheapest supplier.

If reimbursed as a generic (that is, where a prescription is written in generic terms and a generic exists), competition is primarily between generic manufacturers through a distinct reimbursement instrument known as Category M[10] (but may also come from branded suppliers, for example through brand equalisation deals ('BE'). These involve the incumbent brand manufacturer offering a pharmacy a single blended price for the supply of the branded pharmaceutical to be dispensed against both branded and generic prescriptions. The blended price may provide the pharmacy with a bigger margin than stocking both branded and generic products. It should be noted that because the PPRS and Category M schemes are based on very different principles, the two schemes may result in widely varying prices for off-patent brands (set under PPRS) and bioequivalent generics (set through Category M), in other words in major differences in reimbursement prices and margins earned on brands and generics.

2.2.4 Secondary care

Hospitals have more control of prescribing, as doctors have to adhere to formularies. Therefore they are in a position to bargain on price with manufacturers of pharmaceuticals with therapeutic substitutes. It follows that competition on price between manufacturers is likely to be more effective in this sector than in primary care. The extent of such competition depends on the number of therapeutic substitutes available for a certain pharmaceutical. The closeness of therapeutic substitutes has been found to be an important factor in explaining the size of hospital discounts.

[10] Category M.is based on surveys of transaction prices between manufacturers, wholesalers and pharmacies.

2.3 The emergence of generic competition

Once the patent relating to the pharmaceutical product of an originator company (originator pharmaceutical) expires, the generic versions of that drug can be launched onto the market. Based on the findings of the recently published Inquiry (by the European Commission), the average time from patent expiry to generic entry is about 7 months, although for products with the highest sales in the European Commission's dataset, generic entry occurred somewhat more quickly (around 4 months on a weighted average basis). The time taken in the UK is relatively shorter (4 months) in comparison with other EU Member States[11].

The Inquiry also reported that within 3 years following loss of exclusivity by the originator product, the ratio of generic companies to originators is about 6:1 (para 171). Importantly, the Inquiry also noted that any delays in generic entry are costly as the price at which generic companies enter the market has been found to be, on average, 25% lower than the price of the originator products prior to the loss of exclusivity; and that the prices of originator products appear to drop following generic entry, thus indicating that any delay will have a significant impact on costs/revenue[12].

The Inquiry report points to several reasons for delayed market entry of generics, some of which originate from the regulatory framework of the market (namely, lengthy marketing authorisation ('MA') processes, pricing and reimbursement procedures) or patient switching costs (for example if a product is for a chronic condition, hence taken for a long time, patients may be reluctant to change from their existing product), while some others originate from company behaviour.

In this respect, the Inquiry report highlights several specific delaying or blocking strategies originator companies have used to delay entry and protect revenue streams from their pharmaceuticals, including:

- Strategic patenting or 'patent clusters' – a large number of EU-wide patents and pending applications for a single product;

- 'Ever-greening' practices, namely tactics employed by originator companies to effectively extend the patent protection afforded to its product even after expiry of the primary patent;

- Patent litigation and settlements agreements between originator and generic companies aimed at delaying the entry of generic products onto the market– a problem particularly widespread in the US; and

- Life cycle strategies for follow-on products – where originator companies launch follow-on products prior to patent expiry so as to dissuade customers from switching to generic pharmaceutical products.

While the Inquiry does not conclude that the practices referred to above are *per se* anti-competitive under existing antitrust legislation, it sends a clear message to the European pharmaceutical industry that such practices will be subject to careful scrutiny by competition agencies, particularly if there are suggestions that their main or only aim is to exclude competitors, rather than– depending on the circumstances of the individual cases– pursuing innovative efforts or improving on existing products.

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11 Paragraph 194 and Figure16, pages 71-72 of the EC Pharma Sector Inquiry, July 2009.

12 Section 2.1.2 of the EC Pharma Sector Inquiry. See also footnote 5 above.

2.4 Responses to generic competition

Although generic competition has helped to deliver significant savings for the NHS, that success has perhaps provided for heightened incentives for manufacturers to find ways of pre-empting or hindering effective generic competition.

As outlined further below, the UK has seen various allegations of pharmaceutical 'ever-greening' (one of which has progressed to an upheld infringement Decision), whereby manufacturers have sought ways to prolong the benefits of patent protection beyond the period of the relevant patent. The allegations that have been aired in the UK include:

- The use of predatory pricing to hospitals as a means of foreclosing competition in primary care (see the outline of the *Napp* case below);
- The use of minor product changes as a way of inhibiting generic companies' progress in developing and marketing an equivalent product;
- The use of so-called 'dirty tricks' (e.g. misleading medical articles suggesting that generic equivalents are not as effective or not even bio-equivalent, hence not recognised equivalent generic products to the originator products), as branded manufacturers seek to persuade GPs and PCOs that equivalent generic products are in fact clinically inferior; and
- The alleged manipulation of the regulatory processes so as to impede effective generic competition.

The OFT has seen no complaints in relation to the problematic patent settlements considered by the U.S. FTC and the EC in its sector inquiry, though it views this potentially as a very significant area for the application of competition law and one in which a European precedent may be of considerable value.

The following section considers the OFT's approach to dealing with issues that have inhibited effective generic competition in the UK.

3. Parameters necessary to effective generic competition

Generic prescribing has helped to deliver significant savings to the NHS. Perhaps as a consequence of the success of generic competition, the OFT has, since 2000 received a number of complaints relating to the alleged ever-greening of pharmaceutical products[13]. In addition to enforcement actions , the OFT has also undertaken a number of market studies that have considered how the sector's regulation may be affecting competition at all levels of the supply chain.

The OFT's major work in this sector, since 2000, is summarised as follows:

- Competition Act enforcement

  The OFT has pursued two cases in this sector, *Genzyme*[14] and *Napp*[15], both involving abuse of a dominant position. The second considered pharmaceutical 'ever-greening' and is outlined further

13 Not all of these allegations have been pursued, having been closed either for evidential or administrative priority reasons.

14 Case No. 1016/1/1/03 *Genzyme Limited v OFT* [2004] CAT 4

15 *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1 [2002] CompAR [13].

below. The OFT has also conducted other investigations following complaints of ever-greening but these did not result in enforcement action

- Enterprise Act Market Studies[16]

  The OFT has undertaken three studies in this sector, the first on community pharmacy entry regulations, the second on the PPRS[17], and the third on the Distribution of Medicines[18]. The PPRS study is outlined further below.

- Advocacy

  The OFT has a dedicated competition advocacy team that has ongoing dialogue with the DH (as well as other UK Government departments) to consider the competition implications of competition within the sector.

The OFT considers it important to ensure that the right balance is struck between enforcement actions and those that are focused on encouraging regulatory reform. In many cases it may be obvious which approach is likely to be proportionate and to deliver greatest value to consumers, for example, where there is no suggestion that a regulation is being manipulated by relevant undertakings, but is simply creating incentives for parties that do not deliver best value to consumers. There will however be instances where the distinction will be less clear, and there may be a choice between focusing on deterring problematic conduct (such as the mis-use or gaming of a regulatory framework) or on correcting the regulatory framework to remove such opportunities. The factors that we take account of in making such decisions include:

- The political appetite for regulatory reform;

- The practicalities of regulatory reform (for example the costs and resources necessary to execute the reform);

- Whether regulatory reform is likely or can ever in fact prevent a given type of conduct, such that establishing a suitable precedent as a deterrent using competition law enforcement is likely to be a more efficient option;

- Whether competition law enforcement may send a deterrence message more widely than the pharmaceutical sector, where this is considered necessary or desirable as similar agreements, conduct or practices are used elsewhere.

Moving forward, the OFT would propose to make increased use of its advocacy role, to ensure that new regulations within the sector take due account of the possible competition concerns, and that new

16 Market studies involve an analysis of a particular market with the aim of identifying and addressing all aspects of market failure from competition issues to consumer detriment and the effect of government regulations. The OFT conducts its market studies under the Enterprise Act 2002. Possible results of market studies include: enforcement action by the OFT; a reference to the Competition Commission; recommendations for changes in law and regulations; recommendations to regulators, self-regulatory bodies and others to consider changes to their rules; campaigns to promote consumer education and awareness; a clean bill of health.

17 See http://www.oft.gov.uk/advice_and_resources/resource_base/market-studies/completed/price-regulation

18 See http://www.oft.gov.uk/advice_and_resources/resource_base/market-studies/completed/medicines

regulation is both robust to resist 'gaming' of the system as far as possible and creates appropriate incentives for pharmaceutical companies.

This section now sets out some of the learning OFT has accumulated in completing the above work.

3.1 Incentives of manufacturers

3.1.1 Pricing

It is apparent that the pricing and reimbursement system in the UK and elsewhere incentivises manufacturers to seek ways to prolong the benefits of patent protection beyond the period of the patent itself, and to therefore restrict generic entry. We consider that a pricing and reimbursement system that more accurately reflects a pharmaceutical product's value, would help to ensure that manufacturers' incentives are focused on valuable innovation rather than on hindering effective and desirable generic competition, although it would not remove the problem completely.

A common complaint, and one that is outlined at length in the Inquiry, is that originator companies (or branded manufacturers) make peripheral 'secondary' changes to a product, yet manage to secure a new patent for the new product and at a price level that is at a premium to that awarded to the 'primary' innovation. This conduct can deter generic entry as the generic company can only produce the (perceived) 'inferior' original product.

For example, in the UK, a new cancer treatment that was priced at £100 per pack would retain that price until the end of the patent. If the relevant manufacturer chose to launch a new version of that product, which included a very minor yet patented charge, under the UK system one would expect that product to be priced by reference to the original product, and most likely at a premium to it. This new version of the product would then receive patent protection for the following 20 years, and the original product may be withdrawn.

GPs ordinarily identify the relevant prescription by first searching for the known brand in the area. However, in this case a pharmacy that received a prescription for the new version of the branded product would be unable to dispense products that were equivalent to the original products rather than the new version product. This means that the generic entrant's ability to compete effectively is hindered, and the branded manufacturer remains protected from effective generic competition, including its impact on prices and market share.

It is clear that under such a system manufacturers incentives are not always directed to identifying the innovations of most value to consumers; the new peripheral innovation will receive the same reward as that attributed to the original product and will benefit from a further patent at the expense of generic competition and the savings that this brings to the health system.

A value-based pricing model, whereby the UK Government ensured that the true value of an innovation was reflected in the price that was awarded to it, would provide manufacturers with better incentives to invest in medicines of most value. This was the subject of the OFT's market study into the PPRS, which was published in 2007 and is summarised below:

Box 2: The OFT's PPRS report[19]

The PPRS report aimed at improving competition by advising the UK Government on the existing pricing and reimbursement scheme. The study recommended that the current 'profit-cap-and price-cut' scheme be replaced with a patient-focused, value-based pricing scheme, in which the prices that the NHS pays for medicines reflect the therapeutic benefits they bring to patients. This would enable the NHS to obtain greater value for money from its existing drug spend.

The Government's 2009 PPRS scheme incorporates elements of the recommendations outlined in the OFT's PPRS market study, and some aspect of the value-based pricing approach envisaged by the OFT have been incorporated. The fundamentals of the scheme are largely unchanged however.

3.1.2 Deterring the misuse of regulation

While regulatory reform can certainly help to foster effective generic competition, the perfect regulatory environment is likely to remain an aspiration. This means that it is likely to remain necessary to use competition law and enforcement actions as a way of deterring conduct that has an adverse effect on generic competition.

For example, it may never be proportionate for the DH to assess in detail the motivations of every product change, and it may be more efficient for the OFT to seek to establish through enforcement action a suitable deterrent against product changes made only to inhibit effective competition.

The point is illustrated by the OFT's decision in *NAPP Pharmaceuticals*, which is summarised below. In that case, Napp used predatory pricing in secondary care to foreclose the primary care market, where its prices were found to be excessive. Regulatory reform may be impractical in this area, and establishing a suitable deterrent was therefore important.

Box 3: NAPP Pharmaceuticals

Napp was found to have abused its dominant position in the market for the supply of a drug used by cancer patients (sustained release morphine (MST)), to patients in the community at excessively high prices while supplying hospitals at prices that were predatory and below cost. Because the prescribing practices of GPs were found to be strongly influenced by the brands used in hospitals, Napp was able to use predatory pricing in the hospital sector to protect a large share in both the hospital and the community segments. Community prices were typically more than 10 times higher than NAPP's hospital prices and up to six times the export price of MST. During the period concerned, at least one competitor withdrew from the market. On appeal, the UK Competition Appeals Tribunal later upheld the OFT's decision.

3.2 Incentives of pharmacies and GPs

UK pharmacies that receive a prescription that refers to a branded pharmaceutical by its brand name are unable to dispense any existing therapeutically equivalent medicine against that prescription and can only dispense the named brand. Despite being encouraged to write prescriptions using the relevant generic name, many GPs continue to prescribe using brand names and this means that branded manufacturers are guaranteed sales against such prescriptions. As a result, generic competition cannot be fully effective even

19 The 'Pharmaceutical Price Regulation Scheme', an OFT market study, February 2007.

where generic equivalents exist, as branded manufacturers retain an 'assured base' of sales for as long as a body of GPs continue to prescribe using brand names.

This has led to the widespread use of so-called brand equalisation deals, whereby the incumbent brand manufacturer offers a pharmacy a single blended price for the supply of the branded drug to be dispensed against both branded and generic prescriptions. The blended price may provide the pharmacy with a bigger margin than stocking both branded and generic drugs. The use of such deals, which are analogous to fidelity rebates, may in circumstances merit competition scrutiny in the future.

Following the OFT's PPRS market study and the re-evaluation of the framework that it prompted, the new PPRS scheme may soon provide pharmacies with the ability to dispense equivalent generic medicines even against a prescription that records a brand name (this proposal is currently under consultation). This should help to ensure that effective generic competition takes place against a far greater number of prescriptions, and undermines the potential use of brand equalisation deals.

3.3 Questions for other members

- Do other members share our views on ever-greening being a key issue in the sector?
- What experience do other members have of tackling this issue and what examples of ever-greening behaviour have they seen?
- Do other members have views or experience on whether it is preferable to pursue ever-greening issues through enforcement or by changes to the regulatory system to discourage or prevent such behaviour?
- What other agreements, conduct or practices (including those outlined in the Inquiry) affecting generic competition have other members experienced in their work?
- How have other members, whether through promoting changes to health systems or competition enforcement action, ensured effective competition between branded and generic products?
- What experience can members share about the relative merits of enforcement action and advocacy to promote effective competition in this sector generally?

UNITED STATES

This paper discusses the efforts of the United States Government to foster a competitive and innovative pharmaceutical marketplace, principally (but not exclusively) by promoting competition between branded and generic pharmaceuticals. Restrictions on such competition, often accomplished through what the Federal Trade Commission ("FTC") has termed "pay for delay" settlements or "exclusion payments" are among the biggest barriers to competition in the United States, costing consumers an estimated $3.5 billion per year. This note also briefly touches upon policies other than the promotion of competition between branded and generic pharmaceuticals that are aimed at producing a more competitive pharmaceutical marketplace. These policies include efforts to combat restraints on competition that involve agreements or mergers between branded drug producers; agreements or mergers between generic drug producers; and regulatory distortions of competition (including through merger). Finally, the paper briefly describes the competitive potential of "biologic" drugs.

1. Introduction

The patent system is essential to a dynamic and innovative pharmaceutical industry. Patent protection is widely acknowledged to promote innovation in the pharmaceutical industry by allowing companies to recoup the costs of their innovations.[1] In particular, patent rights for pharmaceuticals are essential for brand-name companies to prevent free riding and recoup their significant investments in research and development of pharmaceuticals.[2] Moreover, by disclosing inventions in the patent application process, the patent system encourages generic companies to innovate by designing around brand-name company patents.[3] United States law further encourages generic competition by permitting generic applicants to rely on the brand-name company's proprietary data demonstrating the safety and efficacy of the brand-name drug product.[4]

Competition between branded and generic pharmaceutical manufacturers provides consumers enormous savings. Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a price that is 70 to 80 percent of the brand-name counterpart, and gains substantial share from the brand-name product in a short period of time.[5] Subsequent generic entrants may

1 Several commentators have argued that patents are particularly important to stimulating innovation in the pharmaceutical industry. *See* W.M. Cohen, R.R. Nelson and J.P. Walsh, *Protecting their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, National Bureau of Economic Research, Working Paper 7552 (Feb. 2000, rev. 2004); Richard Levin, Alvin Klevorick, Richard Nelson, and Sidney Winter, *Appropriating the Returns from Industrial Research and Development*, Brookings Papers on Economic Activity 783-820 (1987, no. 3); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Management Science, 173–181 (1986).

2 Federal Trade Commission, *To Promote Innovation:The Proper Balance Of Competition And Policy* (Oct. 2003) ("IP Report"), Ch. 3, *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

3 IP Report, Ch. 3, at 9.

4 *Id.*, Ch. 3, at 9-10.

5 *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) ("CBO Study"), *available at*

enter at even lower prices – discounted 80 percent or more off the price of the brand-name drug – and prompt the earlier generic entrants to reduce their prices. Thus, as the number of generics increase, prices to consumers decrease even further. As a result of price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture from 44 to 80 percent of branded sales within the first full year after launch of a lower-priced generic product.[6]

Generic substitution laws in most states within the United States contribute significantly to the reduction of drug costs and the use of generic drugs instead of the branded equivalent.[7] This, too, benefits consumers. Generic substitution is the dispensing of a generic bioequivalent drug product that contains the same active ingredients(s) as the brand name drug.[8] In the United States, generic substitution generally occurs when a consumer presents a prescription for a branded drug. All states allow pharmacists to fill a prescription written for a branded drug with its bioequivalent generic equivalent. These laws generally lead to rapid substitution (or uptake) of generic drugs instead of the branded equivalent.[9] In addition, because generic drugs are substantially less expensive than their brand name counterparts, generics offer substantial discounts to pharmacies and health plans and health plans, HMOs, and federal and state government provide substantial incentives for patients to use generic versions of drugs. The combination of these incentives means that generic substitution significantly lowers prescription drug costs.[10]

In recognition of the importance of preserving incentives for innovation that would continue to bring new drugs to market, as well as the important competition that generic drugs can provide, Congress enacted the Hatch-Waxman Act in 1984. Congress intended that the Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims.[11] The Act sets up a process that was intended to give generic pharmaceutical makers both an incentive to enter the market for a particular drug market and to challenge any applicable patents on that drug to test their validity and application.

A brand-name drug manufacturer seeking to market a new drug product must first obtain approval from the Food and Drug Administration ("FDA") by filing a New Drug Application ("NDA") that, among

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<http://www.cbo.gov/showdoc.cfm?index=655&sequence=0> (hereinafter "CBO Study").; *see generally* David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87.

6 CBO Study, xiii.

7 *See* Federal Trade Commission, Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies 12-13 (Aug. 2005), *available at* http://www.ftc.gov/reports/pharm benefit05/050906pharmbenefitrpt.pdf.; Alison Masson and Robert L. Steiner, FTC Bureau of Economics Report, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (Sept. 1985).

8 There are additional requirements that the generic is, among other things, chemically identical to the brand product in strength, concentration, dosage form, and route of administration.

9 By comparison, switching between branded drugs requires a change of prescription from a physician, the time, cost, and effort of which reduces price competition between branded drugs.

10 *See* John Dicken, Assistant Director for Health Care Issues, U.S. Gen. Accounting Office, Remarks at the Federal Trade Commission and Department of Justice Hearings on Health Care and Competition Law and Policy 32 (June 26, 2003). As of 2005, there were approximately 10,000 brand drugs on the United States market, and approximately 8,000 generic equivalents. *See* Food and Drug Admin., Approved Drug Products with Therapeutic Equivalence.

Evaluations (25th ed. 2005), *available at* http://www.fda.gov/cder/orange/obannual.pdf (commonly known as the "Orange Book"). Generic drugs account for nearly 50% of all prescriptions dispensed in the United States. Pharmacy Benefit Managers Report, *supra* note 7, at 13.

11 H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2661.

other things, demonstrates the drug product's safety and efficacy. When it files the NDA, the NDA filer also must provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA.[12] Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled "Approved Drug Products with Therapeutic Equivalence," commonly known as the "Orange Book."[13]

The Hatch-Waxman Act also allows for accelerated FDA approval of a drug through an Abbreviated New Drug Application ("ANDA"), upon showing, among other things, that the new drug is "bioequivalent" to an approved drug.[14] This is of particular importance to generic drug manufacturers, who may use the ANDA process to secure approval of its generic version of the drug.

The Hatch-Waxman Act establishes certain rights and procedures in situations where a company seeks FDA approval to market a generic product prior to the expiration of a patent or patents relating to a brand-name drug upon which the generic is based. In such cases, the applicant must: (1) certify to the FDA that the patent is invalid or is not infringed by the generic product (known as a "Paragraph IV certification");[15] and (2) notify the patent holder of the filing of the certification. If the holder of patent rights files a patent infringement suit within 45 days, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed.

To encourage generic drug manufacturers to challenge questionable patents, the Hatch-Waxman Act provides that the first generic manufacturer to file an ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA may not approve a potential competitor's ANDA.[16] Although a first-filer can forfeit its exclusivity under certain conditions,[17] ordinarily it will be entitled to 180 days of exclusivity beginning on the date of the first commercial marketing of the generic drug product.[18] Even if the first filer substantially delays marketing its product, under the prevailing interpretation of the Hatch-Waxman Act, a later ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired.[19]

Against this regulatory backdrop, the FTC has taken numerous steps to preserve or enhance competition in the pharmaceutical sector. These efforts are described in this note, which is divided into six parts, including this introductory section. Part 2 of this note focuses on efforts by the FTC and private parties designed to combat anticompetitive agreements between branded and generic producers aimed at delaying generic entry into the market. Although these efforts have resulted in litigation, the FTC recently has supported legislative proposals that would ban such anticompetitive agreements. Part 3 of this note focuses on FTC actions that have prevented anticompetitive agreements between generic pharmaceutical companies. Part 4 describes the anticompetitive potential of "product hopping," whereby a branded pharmaceutical company might seek to introduce new patented pharmaceutical products that provide no real benefits but are designed to forestall generic competition. Recent litigation aimed at blocking alleged

12 21 U.S.C. § 355(b)(1).

13 *Id.* § 355(j)(7)(A).

14 21 U.S.C. § 355(j).

15 *Id.* § 355(j)(2)(A)(vii)(IV).

16 *Id.* § 355(j)(5)(B)(iv).

17 *Id.* § 355(j)(5)(D).

18 *Id.*

19 *See id*. § 355(j)(5)(B)(iv).

product hopping is summarized. Part 5 surveys FTC merger enforcement designed to promote competition in pharmaceutical markets. Finally, part 6 briefly describes ongoing FTC efforts to study emerging pharmaceutical competition policy issues, including the treatment of "biologic" drugs (protein-based drugs derived from living matter) and "authorized generic" drugs (generic drugs introduced by brand name pharmaceutical producers).

2. Reverse payments litigation under the Hatch-Waxman Act

Competition by generic drugs against branded pharmaceuticals has the potential for substantial consumer savings. Such competition can arise most rapidly when a generic entrant challenges the patent held by the branded pharmaceutical manufacturer, either on the ground that the patent is not valid or that the generic does not infringe the patent. A successful challenge means that there will be nearly immediate competition between the branded drug and the generic equivalent. An unsuccessful challenge, however, means that meaningful competition may be delayed for many years, until the expiration of the patent. The consumer savings can be significant. Generic competition following successful patent challenges involving just four major brand-name drugs is estimated to have saved consumers more than $9 billion.[20]

This Section describes first the economic incentives facing branded and generic pharmaceutical manufacturers to limit competition between each other. It then describes the consumer harm created by settlements of patent litigation that limit competition between the two, known as "pay for delay" settlements, or "exclusion payments." It proceeds to describe the investigatory efforts the FTC has taken as well as the challenges the FTC has brought regarding such settlements. The following subsections describe the FTC's concerns with recent judicial rulings regarding pay for delay settlements, continued litigation efforts by the FTC, and legislative initiatives that would make pay for delay settlements unlawful.

2.1 The economic incentives for and consumer harm from pay for delay settlements

The competitive dynamic between brand-name drugs and their generic equivalents creates an incentive for brand and generic manufacturers to conspire to avoid competition and share the resulting profits. In a typical pay for delay settlement, the branded manufacturer will pay the potential generic entrant some amount of money. In exchange, the generic company will delay its entry into the market. In the absence of such an exclusion payment, the generic could be expected to enter at an earlier date. Thus, by making an exclusion payment, the branded pharmaceutical company has paid for delayed entry by the generic. The Hatch-Waxman Act regulatory regime, described in Section 1, makes such agreements easily possible.

The reason for such agreements is simple: in nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the amount of profit the brand-name drug company stands to lose from the same sales. This is because the generic firm sells at a significant discount off the price of the brand-name product. The difference between the brand's loss and the generic's gain is the money consumers save. Consequently, it will typically be more profitable for both companies if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and agree to defer entry.[21]

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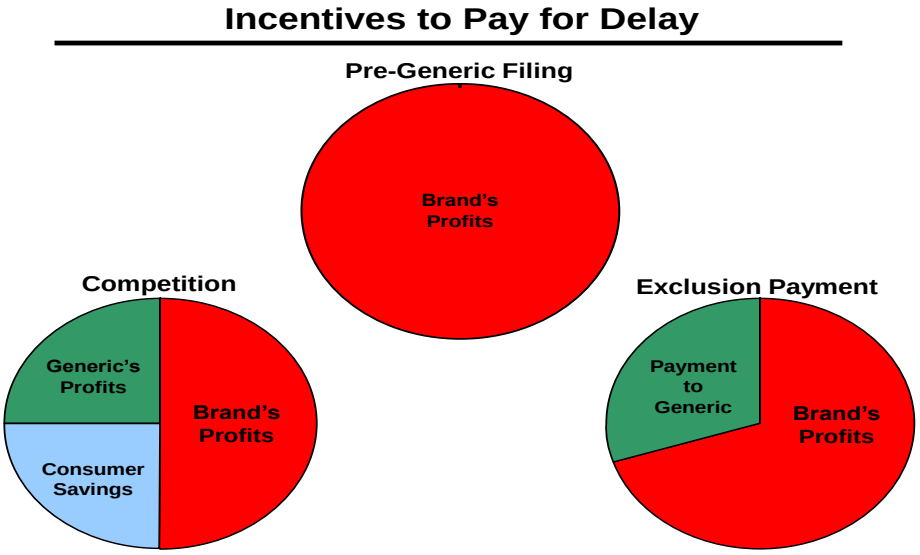
20 *Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm.*, 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, *available at* http://commerce.senate.gov/hearings/042302jaeger.pdf.

21 *See generally* Michael Salinger et al., *Economics at the FTC: Pharmaceutical Patent Dispute Settlements and Behavioral Economics*, 31 Review of Industrial Organization 85–105 (2007); Jeremy Bulow, "The Gaming of Pharmaceutical Patents," in *Innovation Policy and the Economy, Volume 4*, 145–87 (Adam B. Jaffe et al. eds 2004); Carl Shapiro, *Antitrust Limits To Patent Settlements*, 34 Rand Journal of Economics 391 (2003).

By eliminating the potential for competition, the parties can share the consumer savings that would result if they were to compete. In other words, these settlements are harmful because the parties are resolving their dispute at the expense of consumers. Although both the brand-name companies and generic firms are better off with such settlements, consumers lose the possibility of earlier generic entry, which may occur either because the generic company would have prevailed in the lawsuit (significantly, a 2002 FTC study found that generic challengers enjoyed a success rate in excess of 70 percent),[22] or because the parties would have negotiated a settlement with an earlier entry date absent the payment.[23] Instead, consumers pay higher prices because such early generic entry is delayed, as illustrated in the following chart.

Figure 1: Incentives to Pay for Delay



Consumer harm from pay for delay settlements is significant. An FTC study has estimated that under relatively conservative assumptions, the annual savings to purchasers of drugs that would result from a ban on such settlements would be approximately $3.5 billion. This calculation takes into account four factors: (1) the consumer savings that result from generic competition in any given month; (2) the likelihood that a generic manufacturer and brand-name manufacturer will reach a settlement that delays entry in return for compensation; (3) the length of entry delay resulting from such settlement; and (4) the combined sales volume of drugs for which settlements are likely.[24] Overall, the calculation determines how much delay of entry such settlements create, and how much each month of delay costs consumers in the form of higher prices during the period of delay when there is no generic competition.

22 Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration (July 2002) ("Generic Drug Study"), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

23 For example, for a hypothetical patent infringement claim with a 50% chance of success, with 10 years remaining in the patent term, continued litigation between the parties affords consumers an overall expected value of 5 years of competition, taking into account the likelihood of the two possible outcomes. If the parties instead reach a settlement in which the patent holder makes a payment to the challenger, and the challenger agrees to enter only one year prior to the expiration date, consumers are worse off, on average, than had the litigation gone forward. The appellate courts' approach, by contrast, would automatically endorse such a settlement because it is within the outer, nominal bounds of the patentee's claims.

24 *See* Jon Leibowitz, Speech at Center For American Progress, "Pay-for-Delay Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution)" (June 23, 2009), at 12, *available at* http://ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf ("Pay for Delay Speech").

The FTC calculated the $3.5 billion estimate in the following way. First, on average, consumers save 77% in a mature market in which generic drugs exist relative to pre-generic price levels.[25] Next, the FTC determined that agreements with delay payments on average delay entry for 17 months (1.4 years) longer than agreements without payments. Thus, for that 17-month period, consumers do not benefit from generic competition and the lower prices it brings. Third, approximately $90 billion of branded drug sales are subject to patent litigation.[26] Accordingly, $90 billion is the total value of sales that pay for delay settlements could affect. Based on historical averages, roughly 15% of these challenges will end in settlement, and 24% of settlements include an exclusion payment.[27] This means that the total value of drug sales affected by pay for delay settlements is about $3.2 billion per year.[28] Thus consumers lose savings of 77% on that amount each year, for 17 months, leading to an annual cost to consumers of $3.5 billion.[29]

2.2 Litigation by FTC against pay for delay settlements

Because of the potentially significant anticompetitive effects of settlements between branded pharmaceutical companies and potential generic drug entrants, the FTC has over the past decade sought to use antitrust enforcement to stop pay for delay settlements. These are settlements of patent litigation in which the brand-name drug firm pays its potential generic competitor to abandon a patent challenge and delay entering the market with a lower cost, generic product. Such settlements effectively buy more protection from competition than the assertion of the patent alone provides. And they do so at the expense of consumers, whose access to lower priced, generic drugs is delayed, sometimes for many years.

In the late 1990s, the Commission began to bring antitrust challenges to some settlements reached under this patent challenge process that Hatch-Waxman established. The FTC brought two cases that resulted in consent decrees involving a payment from a branded-drug manufacturer to a potential generic entrant as part of a settlement of patent claims.[30] In addition, the FTC reached a consent decree in another matter involving a related strategy of listing patents in the FDA's Orange Book in order to prevent the entry of generic competition for two anti-cancer drugs and an anti-anxiety agent.[31]

After bringing these initial cases, the FTC sought additional information about the prevalence of such settlements and related practices by branded pharmaceutical companies to limit timely generic entry. The FTC, pursuant to its statutory authority, issued subpoenas to over 70 branded and generic drug

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25 Pay for Delay Speech, at 13. This figure derives from a combination of the average 85% savings of a generic drug in lieu of the branded equivalent multiplied by the typical 90% of market share that the generic obtains.

26 *Id.* at 13. The figures are based on industry health data and FDA listings of drugs subject to challenge under Hatch-Waxman.

27 *Id.* at 14.

28 $90B X 15% X 24%.

29 Pay for Delay Speech, at 14. The Bureau of Economics also calculated savings under differing assumptions of lower and higher settlement rates and different length of delay. Under the most conservative assumption of lower settlement rates and shorter delays for generic entry pursuant to settlement, the consumer costs of settlements was $.7 billion per year. Under the most liberal assumptions, with lengthier delays and higher settlement rates, the cost to consumers was $7.5 billion per year.

30 *See* Abbott Laboratories, No. C-3945 (May 22, 2000) (consent order), *available at* http://www.ftc.gov/os/2000/03/abbott.do.htm; Hoechst Marion Roussel, Inc., No. 9293 (May 8, 2001) (consent order), *available at* http://www.ftc.gov/os/2001/05/hoechstdo.pdf.

31 Bristol-Myers Squibb Co., No. C-4076 (April 18, 2003), *available at* http://www.ftc.gov/os/2003/04/bristolmyerssquibbdo.pdf.

manufacturers requesting information about patent settlements. The information received in response to this subpoena was described in the FTC's 2002 study on generic drugs.[32] Among the central findings was that such settlements had occurred, but declined significantly shortly after FTC actions challenging such settlements as anticompetitive became public. The study made several recommendations regarding the Hatch-Waxman framework, including one that called for companies that enter into settlements to report them to the FTC. Congress enacted a requirement that all such settlements be filed with the FTC and the Department of Justice in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA Act"), giving the FTC access to this information. This filing requirement enables FTC staff to review all settlements of patent cases brought under the Hatch-Waxman Act.

The first fully litigated case brought by the FTC was against Schering-Plough Corporation ("Schering").[33] Schering, the manufacturer of a brand-name drug called "K-Dur 20," settled patent litigation with two manufacturers of generic counterparts, Upsher-Smith Laboratories, Inc. ("Upsher") and American Home Products Corporation ("AHP"). The two generic manufacturers agreed to forbear marketing their generic drugs until specified dates in exchange for guaranteed cash payments totaling $60 million to Upsher and $5 million to AHP.[34] A full trial was held before an administrative law judge, and the Commission reviewed the entire record *de novo*. The Commission concluded that in each settlement, Schering had paid its generic competitors to accept the settlement and that the settlements provided Schering with more protection from competition than a settlement without a payment. This was the result either because a settlement with an earlier entry date might have been reached, or because continuation of the litigation without settlement would yield a greater prospect of competition at an earlier date. The Commission found that, as a result of these agreements, Schering continued to enjoy supracompetitive profits from K-Dur 20 for several more years, at the expense of consumers.

The court of appeals set aside the Commission's decision in *Schering*.[35] The court assessed whether the agreement exceeded the exclusionary potential of Schering's patent. The court relied on the supposition that the patent provided Schering with "the legal right to exclude Upsher and [AHP] from the market until they proved either that the…patent was invalid or that their products…did not infringe Schering's patent,"[36] and noted that there was no allegation that the patent claim was a "sham."[37] In particular, the court ruled that a payment by the patent holder, accompanied by an agreement by the challenger to defer entry, could not support an inference that the challenger agreed to a later entry date in return for such payment, even if there was no other plausible explanation for the payment.[38]

Despite the court's decision in *Schering*, the Commission has continued to pursue its legal arguments in other cases involving reverse payments. In one recent case, brought by private parties but in which the FTC participated as an *amicus curiae*, another United States court of appeals also issued a decision that effectively immunized reverse payment patent settlements. In the *Tamoxifen* case, the plaintiff alleged that Zeneca (the brand) paid Barr (the generic) $21 million to keep its generic off the market until patent

32 Generic Drug Study, note 22, *supra*.

33 *In the Matter of Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp*., Docket No. 9297, Opinion of the Commission (Dec. 18, 2003), *available at* http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf., *vacated*, 402 F.3d 1056 (11 Cir. 2005), *cert. denied,* 126 S. Ct. 2929 (2006).

34 The agreement further provided an additional $10 million to AHP if its product received FDA approval.

35 *Schering*, 402 F.3d, at 1058.

36 *Id.* at 1066-67.

37 *Id.* at 1068.

38 *Id.* at 1076.

expiration. The Second Circuit, in a 2-1 decision, affirmed the district court's dismissal of the complaint. Like the Eleventh Circuit opinion in *Schering*, the majority would allow payments of any size to be made, except where the generic agrees not to market beyond the brand's patent term or where the infringement suit is a sham.[39] Third, the FTC participated as an *amicus curiae* in a pay for delay case appealed to the Federal Circuit. In that matter, the Federal Circuit held that using exclusion payments to exclude a competitor until patent expiration is *per se* legal.[40]

In contrast to these cases, the Sixth Circuit ruled in a private case that a pay for delay settlement was a *per se* violation of the U.S. antitrust laws, explaining that: "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market."[41]

In 2008, the FTC charged that Cephalon, Inc. engaged in illegal conduct to prevent competition for its branded drug, Provigil, by paying four firms to refrain from selling generic versions of the drug until 2012. Provigil is used to treat excessive sleepiness in patients with sleep apnea, narcolepsy, and shiftwork sleep disorder. The four companies had applied to the Food and Drug Administration for approval to market a generic formulation. In the ensuing patent case, the generic companies argued that their products did not infringe the only remaining patent on Provigil, the formulation patent related to the size of the particles used in the drug, and challenged the validity of the patent. Cephalon entered into agreements with these companies, paying more than $200 million in exchange for agreements not to sell a generic version of Provigil until 2012. No other generic company could enter the market until all four "first filers" relinquished their marketing exclusivity or 180 days had elapsed after one of them entered the market. By these agreements, Cephalon effectively prevented any generic from entering the market until at least 2012. The FTC's complaint before the federal district court alleges that Cephalon's conduct in entering into patent litigation settlement agreements that included payments designed to prevent generic competition constituted an abuse of monopoly power that is unlawful under section 5 of the FTC Act. The case remains pending in the federal district court in Philadelphia.

Most recently, the FTC sued Solvay Pharmaceuticals, Inc., as well as two generic drug makers. Solvay manufactures a testosterone-replacement drug, AndroGel, a prescription pharmaceutical with annual sales of more than $400 million. In May 2003, Watson and Paddock, which partnered with Par, each filed applications for FDA approval to market generic versions of AndroGel. Solvay's patent on Androgel had been issued in January 2003, with an expiration date of August 2020. By early 2006, Watson had received final approval to market its generic product. According to the complaint, it was well known that if Watson or Par were to enter with cheaper generic versions of AndroGel, Solvay's AndroGel sales would plummet and consumers would benefit from the lower prices. The complaint alleges that Solvay, realizing the devastating effect generic entry would have on its AndroGel franchise, acted unlawfully to eliminate this threat: Solvay paid Watson and Par a share of its AndroGel profits to abandon their patent challenges and agree to delay generic entry until 2015. As a result, the complaint states that the defendants are cooperating on the sale of AndroGel and sharing the monopoly profits, rather than competing. The case is pending in federal court in Georgia.

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39 *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).

40 *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 577 U.S. /(U.S. June 22, 2009) (No. 08-1194).

41 *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

2.3 Current status of reverse payment jurisprudence

The prospects for effective antitrust enforcement against anticompetitive agreements between branded and generic pharmaceutical manufacturers are substantially less encouraging today than they were in 2001. Four U.S. circuit courts have examined the competitive effects of settlements featuring exclusion payments from the patent holder of a branded drug to a potential generic entrant (or entrants) that agreed not to enter the market until a later date. One circuit found an agreement *per se* illegal in which the generic manufacturer received payments and agreed not to compete during the pendency of the litigation using the product at issue or any non-infringing product.[42] Three other circuits have not found antitrust liability.[43] However, recently, as *amicus curiae* in a case before the United States Court of Appeals for the Second Circuit, the United States Department of Justice took the position that a settlement that involves a payment from a branded to a generic firm in exchange for an agreement not to compete and to withdraw a patent validity challenge in the context of the Hatch-Waxman Act is presumptively anticompetitive. If the plaintiff shows that the generic manufacturer withdrew its challenge to the patent's validity; that money (or other consideration serving the same purpose) flowed from the patent holder to the generic drug firm; and that the payment accompanied the agreement to withdraw the validity challenge, it has established a prima facie case.[44]

2.4 The Decisions by courts have resulted in continued use of pay for delay settlements

These judicial rulings on reverse payments have had a noticeable effect on the settlements occurring in such patent cases. Based on data obtained through the MMA Act, settlements with payments to the generic patent challenger had essentially stopped by 2004. In that year, of the 14 settlements reported to the FTC, not one involved a payment to generic. [45] In 2005, most of which occurred before the decision in *Schering*, only 3 out of 11 settlements involved a payment to the generic company. However, by 2006 half of the settlements reported (14 of 28) involved a payment to the generic. And in 2007, 14 out of 33 involved a payment. The staff's analysis of settlements filed during the fiscal year ending in September 2006 found that half of all of the final patent settlements (14 of 28) involved compensation to the generic patent challenger and an agreement by the generic firm to refrain from launching its product for some period of time. Overall, since 2005, 69 percent (22 of 32) of the settlements with first generic filers

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42 *In re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003).*

43 In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d. 187 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *Valley Drug Co., Inc. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003).

44 *See* Brief for the United States as *amicus curiae* in response to the Court's invitation in *In re: Ciprofloxacin Hydrochloride Antitrust Litigation* (2d Cir. July 6, 2009), *available at* http://www.usdoj.gov/atr/cases/f247700/247708.htm.

45 Bureau of Competition Report, Federal Trade Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007: A Report by the Bureau of Competition, 7 fig. 3 (May 2008), available at http://www.ftc.gov/os/2008/05/mmaact.pdf ("2008 MMA Report"); Bureau of Competition Report, Federal Trade Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006: A Report by the Bureau of Competition (Apr. 2007), available at http://www.ftc.gov/reports/mmact/MMAreport2006.pdf; Bureau of Competition Report, Federal Trade Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition (Apr. 2006), available at http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

involved a payment to the generic challenger and a restriction on generic entry.[46] Given this burgeoning activity, the U.S. antitrust agencies are increasingly concerned about the consumer harm caused by such agreements. When a patent holder makes a payment to a challenger to induce it to agree to a later entry than would otherwise occur, consumers are harmed – either because a settlement with an earlier entry date might have been reached, or because continuation of the litigation without settlement would yield a greater prospect of competition.

Moreover, there are several other ways that a brand can compensate a generic to delay its entry. For example, as explained above, generally, the first generic does not face competition from other generic for the first six months after it is launched. For example, the FTC has encountered settlements in which the generic is licensed to promote or sell the branded product instead of entering with its own generic. Other settlements may involve overpayment for an unrelated patent, ingredient supplies, or other products instead of a direct cash payment for delay. And branded companies have also entered into co-development deals with generics that appear to provide the generic with more than fair value with respect to the generic's share.

A particularly important method of paying for delay that has recently arisen is through the use of authorized generic rights. The 180-day exclusivity provision for the first generic entrant does not prevent the brand from launching its own generic (known as an "authorized generic"). In other words, while a generic entrant has exclusivity vis-à-vis third-party generic entrants, the branded pharmaceutical manufacturer is not limited under the Hatch-Waxman Act from producing and selling its own generic version of the branded drug. Recently, it has become common for the generic to agree to delay its entry as part of the patent settlement and, in exchange, the brand agrees that during that first 180 days, it will not compete with an authorized generic. Such a promise by the brand can substantially increase the generic's revenues when it does enter.

A recent FTC study determined that over the past five years, branded companies have frequently used a promise not to compete with the generic through use of an authorized generic, as part of a patent settlement agreement.[47] During the period 2004-2008, 38 drug patent settlements were reported to the FTC under the MMA Act in which authorized generics were limited by the terms of the agreement. Of those 38 settlements, 20 included a provision explicitly barring the branded drug manufacturer from creating an authorized generic to compete with the entering generic during the period of marketing exclusivity.[48] Another 10 settlements involved similar provisions that either barred an authorized generic or provided

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46 Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007: A Report by the Bureau of Competition (May 2008)*, *available at* http://www.ftc.gov/os/2008/05/mmaact.pdf; Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006: A Report by the Bureau of Competition* (Apr. 2007), *available at* http://www.ftc.gov/reports/mmact/MMAreport2006.pdf; Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), *available at* http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

47 Federal Trade Commission, Authorized Generics: An Interim Report (June 2009), *available at* http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf ("*Authorized Generics Report*"). As discussed in part 6 of this note, however, authorized generics do have a precompetitive potential, when not misused as part of a restrictive agreement to defer generic entry by generic pharmaceutical firms.

48 Authorized Generics Report, Ch. 2, at 6-9.

strong disincentives to the branded company to introducing an authorized generic.[49] The remaining 8 settlements used authorized generic rights in other ways that provided benefits to the entering generic.[50]

2.5 Legislative activity

In June 2009, the FTC testified in favor of proposed legislation (H.R. 1706) that would ban anticompetitive pay for delay patent settlements.[51] In its testimony, the FTC described the harm to consumers and to the health care system resulting from pay for delay settlements, and concluded that congressional action to prohibit these settlements is both appropriate and timely. The FTC concluded that legislation is likely to be swifter and more comprehensive than litigation in preventing anticompetitive settlements, and the arguments made by some supporters of pay for delay settlements are "contradicted by experience in the market." The testimony concluded that the provisions of H.R. 1706 – legislation introduced by House Committee on Energy and Commerce Waxman and other to bar pay for delay settlement – "offers a straightforward means to quickly combat anticompetitive conduct that is pervasive and costly to consumers, while also providing flexibility to protect procompetitive arrangements." The prospects for the passage of such legislation are uncertain and remain in the hands of Congress. This testimony built on several previous testimonies by the Commission regarding this legislative proposal and other similar ones in recent years.[52]

In July 2009, the House Commerce and Energy Committee approved H.R. 1706 and incorporated into its Health Care Reform Bill. A companion bill awaits action in the Senate Judiciary Committee.

3. Anticompetitive agreements involving competing generic pharmaceutical producers

The benefits of generic entry, outlined above, may be severely curtailed if pharmaceutical companies agree to limit competition among their generic products. The FTC has been vigilant in combatting anticompetitive arrangements of this sort. Generic manufacturers may avoid direct competition through manipulation of the Hatch-Waxman Act, because its framework facilitates anticompetitive agreements. In these cases, two generics, each entitled to 180-day exclusivity on their generic variants of a branded drug, may agree to limit competition between them. The possibility arises because the two different dosage levels each were entitled to separate 180-day exclusivity periods.

In 2002, the FTC charged that Biovail Corporation and Elan Corporation agreed to unreasonably reduce competition in the market for a generic hypertension drug, Adalat CC.[53] Elan was the first to file with the FDA an Abbreviated New Drug Application (ANDA) on the 30 mg Adalat dosage, and Biovail was the first to file an ANDA on the 60 mg dosage. Pursuant to the Hatch-Waxman Act, Elan qualified for

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49 *Id.*, Ch. 2, at 9-10.

50 *Id.*, Ch. 2, at 10.

51 *Anticompetitive Pay for Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs* (June 3, 2009) (prepared statement of the Federal Trade Commission presented by Director of Bureau of Competition Richard Feinstein), *available at* http://www.ftc.gov/os/2009/06/P859910payfordelay.pdf.

52 *See, e.g., How Pay for Delay Settlements Make Consumers and the Federal Government Pay More For Much Needed Drugs,* Statement Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce, 111 Cong. (2009) (prepared statement of the Fed. Trade Comm'n presented by Comm'r J. Thomas Rosch,), *available at* http://www.ftc.gov/os/2009/03/P859910payfordelay.pdf.

53 *In the matter of Biovail Corporation and Elan Corporation, PLC,* Docket No. C-4057, Complaint (Aug. 15, 2002), *available at* http://www.ftc.gov/os/2002/08/biovalcmp.pdf.

180 days of exclusivity for the 30 mg product upon receiving final FDA approval, and Biovail qualified for 180 days of exclusivity on the 60 mg product upon receiving final FDA approval. Each was the second firm to file an ANDA on the dosage for which the other was the first filer. The two companies entered into agreement which, among other things, provided that Elan would appoint Biovail as the exclusive distributor of Elan's 30 mg and 60 mg generic Adalat products and allow Biovail to profit from the sale of both products. The FTC found that this agreement provided the companies substantial incentives not to compete against each other in the market for the 30 mg and 60 mg dosage forms of Adalat. Consistent with this finding, the two companies maintained separate monopolies in the two dosage categories and shared profits, rather than competing against each other in each category. Biovail and Elan agreed to a consent decree with the FTC under which the companies terminated their agreement and agreed not to enter into similar agreements in the future.

In 2004, the generic drug manufacturers Alpharma, Inc. and Perrigo Company agreed to give up $6.25 million in illegal profits to settle FTC charges that their agreement to limit competition for over-the-counter (OTC) store-brand children's liquid ibuprofen drove up prices and violated federal law.[54] According to the FTC's complaint in Federal District Court for the District of Columbia, Perrigo paid Alpharma – the only other manufacturer of OTC store-brand children's liquid ibuprofen approved by the U.S. Food and Drug Administration (FDA) – to eliminate Alpharma as a competing supplier. Although Alpharma was the first filer, and entitled to 180 days of exclusivity, it instead agreed to waive those exclusivity rights so that Perrigo, which was next in line as a generic entrant, would secure the 180-day exclusivity period. In exchange, Alpharma agreed not to compete for seven years with Perrigo and received a share of Perrigo's profits. Thus, Alpharma took itself out of competition with Perrigo in exchange for a share of Perrigo's revenue. The settlements called for Perrigo to pay $3.75 million and Alpharma to pay $2.5 million to the FTC. In addition, the companies were required to pay state attorneys general $1.5 million to resolve their claim challenging the same agreement. The FTC's settlements barred the companies from entering into agreements not to compete when either party is the first filer of an abbreviated new drug application (ANDA) with the FDA. The settlements also required the companies to notify the FTC of agreements that fall within four narrow exceptions to the general prohibition.

4. "Product Hopping"

According to some commentators, brand name pharmaceutical firms may seek to forestall competition by introducing new patented products that have minor or no substantive improvements but prevent pharmacies (and thus consumers) from substituting lower-priced generic products for the old branded product.[55] Such "product hopping" may occur when generic entry is (or is expected to be) imminent.[56] A brief review of a few litigated matters involving "product hopping" is set forth below. This case law is very limited; judicial analysis of this topic is at an early stage.

Issues related to product hopping arose in the FTC's investigation of the Warner Chilcott pharmaceutical company's attempt to stifle generic competition for the prescription birth control drug

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54 *FTC v. Perrigo Company and Alpharma Inc.*, Civil Action No. 1: 04CV01397 (RMC), Complaint (D.D.C. Aug. 12, 2004), *available at* http://www.ftc.gov/os/caselist/0210197/040812comp0210197.pdf.

55 *See, e.g.*, Mark A. Lemley, *Ignoring Patents*, 2008 Mich. State L. Rev. 19, 30 (product hopping involves "[p]atent holders . . . changing the product they sell and restarting the regulatory clock once their patent on the existing product expires or is invalidated"), *citing* 1 Herbert Hovenkamp Et Al., Ip and Antitrust § 12.5 (perm. ed. & Supp. 2008).

56 Product hopping raises sensitive policy questions as to whether the new product represents a welfare-increasing innovation or is merely used to delay significantly generic competition and thereby harm consumer welfare.

Ovcon.[57] According to an FTC complaint filed in 2005, the pharmaceutical company Barr planned to launch a generic version of Ovcon as soon it received regulatory approval from the U.S. Food and Drug Administration (FDA). A 2005 FTC complaint alleged that Warner Chilcott entered into a March 2004 agreement with Barr to forestall generic entry. Under this agreement, Warner Chilcott would have an option to pay Barr $20 million to secure Barr's agreement not to bring its generic version of the drug to market for five years. Barr also agreed that it would be available as a supplier of Ovcon to Warner Chilcott if Warner Chilcott so requested. In April 2004, Barr received FDA approval to make and sell its generic version of Ovcon. Several weeks later, Warner Chilcott paid Barr the $20 million required under the agreement, preventing Barr from selling a generic version of Ovcon until May 2009. While the case was pending in court, the FTC learned that Warner Chilcott intended to execute a "switch strategy" related to Ovcon. The plan, according to the Commission, was to launch a new, chewable version of Ovcon, and then to stop selling Ovcon, in order to convert consumers to the new product. Such a strategy could have essentially destroyed the market for generic Ovcon before the resolution of the trial, because if regular Ovcon were unavailable, generic substitution at the pharmacy would be unavailable. As a result, even if the FTC had won at trial, generic entry (the relief sought by the FTC) would have been meaningless.

To prevent this development, on September 25, 2006, the FTC filed for a preliminary injunction that, if granted, would have required Warner Chilcott to continue to make regular Ovcon to allow for the eventual entry of a generic version, until the case could be resolved on the merits. The day that the FTC filed the papers, Warner Chilcott waived the exclusionary provision in its agreement with Barr that prevented Barr from entering with its generic version of Ovcon. The next day, Barr announced its intention to start selling a generic version of the product. The FTC and Warner Chilcott agreed to terms for a permanent injunction. The FTC's action thus prevented the company from taking action that would have frustrated the purpose of generic substitution laws that bring lower prices to consumers.

In *Abbott Labs. v. Teva Pharmaceuticals U.S.A., Inc.*,[58] the generic pharmaceutical company Teva alleged that Abbott had "responded to the threat of generic entry... by changing the formulation of TriCor [a branded drug], not to improve the product, but simply to prevent generic formulations from becoming AB-rated for substitution with TriCor."[59] Abbott had withdrawn TriCor capsules from the market and had substituted them with tablets having different dosage strengths; Abbott sought to bar generic sale of tablets through patent infringement suits. Teva and other generic producers alleged that Abbott's actions amounted to attempted monopolization and monopolization in violation of the Sherman Act. Abbott sought to have the antitrust claims dismissed on the grounds that: (1) the introduction of improved formulations and new products is *per se* legal; (2) generic pharmaceutical producers were not totally foreclosed from the market in question because they could still sell their generic products; and (3) Abbott was under no obligation to help its competitors "free ride" on the TriCor brand. In refusing to dismiss the antitrust case, the reviewing federal district court rejected all three of Abbott's claims. Specifically, the court found that a rule of reason, not a *per se* rule, should apply to this new product introduction (and that plaintiffs need not prove that the new formulations were absolutely no better than the old versions); that the relevant test was whether Abbott's actions "severely restricted the market's ambit," not whether Abbott had completely foreclosed generics from the market; and that plaintiffs had not alleged that Abbott had failed to help them, but, rather, that Abbott suppressed competition by blocking the introduction of a generic product.

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57 The Warner Chilcott matter is described in *Consumers Win as FTC Action Results in Generic Ovcon Launch* (FTC press release), *available at* http://www2.ftc.gov/opa/2006/10/chilcott.shtm.

58 432 F. Supp. 2d 408 (D. Del. 2006).

59 432 F. Supp. 2d at 415.

In *Walgreen Co. v. AstraZeneca Pharmaceuticals*,[60] a federal district court rejected plaintffs' "product hopping" complaint that (unlike the situation in *Abbott Labs. v. Teva*) did not involve actual withdrawal of a product from the market. Plaintiffs alleged that as the branded drug Prilosec (omeprazole) was about to lose patent protection, AstraZeneca introduced Nexium (esomeprazole magnesium), a drug that plaintiffs claimed was "virtually identical" to Prilosec and offered no medical benefit over it. Plaintiffs asserted that defendant's introduction of Nexium and its effort to switch patients from Prilosec to Nexium (through a major advertising campaign) were aimed at impeding generic competition and maintaining AstraZeneca's monopoly in the "omeprazole/esomeprazole" market, in violation of Section 2 of the Sherman Act. AstraZeneca claimed that Nexium had statistically significant clinical benefits over Prilosec. In granting defendant's motion to dismiss, however, the court did not address that point. Rather, it held that plaintiffs had failed to allege "exclusionary behavior" that is a prerequisite for a finding of a Section 2 violation. Specifically, the court stressed that AstraZeneca had not withdrawn any product from the market or otherwise limited consumer choice. Rather, according to the court, AstraZeneca had actually *added* choices by introducing a new drug to compete with already established drugs (both its own and others) and with the generic substitutes for at least one of the established drugs.

5. Pharmaceutical mergers

In pharmaceuticals, as in all other markets, the U.S. antitrust enforcement agencies seek to block only those mergers, or those portions of mergers, that will result in substantial reductions in competition, and in so doing to ensure that firms are not prevented from achieving efficiencies that benefit consumers. Recent pharmaceutical merger enforcement by the FTC (the U.S. antitrust agency primarily responsible for reviewing such mergers) is summarized below.

Through its pharmaceutical merger work, the FTC has protected different types of competition. Early in the pharmaceutical life cycle, competition among branded drugs is based on innovation – with firms competing at the product development stage to be the first to market with a product for treating a particular disease or condition. The winner of that race can (appropriately) earn significant rewards – which provide economic incentives for firms to create new products and bring them to market faster, in turn providing consumers more choice. Non-price competition also produces incentives for firms to expand the use of their existing products by exploring new drug indications or to make other improvements. Later in its life cycle, however, the branded product will likely face direct competition from the first generic equivalent on the market and less competitive interaction with other branded products. In those situations, the FTC will look closely at a merger eliminating the only generic competition with a branded product. Finally, at the latest stages of a drug's life cycle, it is likely that the closest competition will not include the branded product, which often sells at a premium, but the multiple generics that have entered the market.

The FTC has aggressively sought to protect these incentives to develop new drugs and new indications. For example, in its challenge to Sanofi's acquisition of Aventis in 2004,[61] the FTC acted to protect potential competition for branded Factor Xa inhibitors, which are drugs that are used to treat excessive blood clot formation. Aventis's Lovenox product had a 90% marketshare. Sanofi marketed the competing drug, Arixtra, but was also pursuing FDA approval for new indications, which were expected to increase the drug's competitive significance. The Commission challenged the transaction and negotiated a remedy that required Sanofi to divest Arixtra to Glaxo Smith-Kline ("GSK") and to assist GSK in completing key clinical trials in order to preserve the potential benefits of the new indications.

60 534 F. Supp. 2d 146 (D.D.C. 2008).

61 In the Matter of Sanofi-Synthelabo and Aventis, FTC Docket No. C-4112, Complaint (July 28, 2004), *available at* http://www.ftc.gov/os/caselist/0410031/040728cmp0410031.pdf.

Protecting price competition is also a core component of the FTC's merger work in pharmaceutical markets. As previously discussed, the first generic competitor typically enters the market at a price that is 70 to 80 percent of its brand-name counterpart, and quickly gains substantial share from the brand name product.[62] Because this price drop produces obvious and substantial benefits for consumers, the FTC acts when a merger threatens to eliminate this competition. For example, a 2004 transaction between Cephalon and Cima[63] would have combined Cephalon, which had a monopoly in the market for treating cancer pain, and Cima, which was poised to enter that market with its own drug. Cephalon's ownership of both branded products could have allowed it to thwart generic entry by shifting patients from its product to Cima's, which had later expiring patents. The "switch" strategy would have deprived consumers of the full benefits of generic competition. The Commission remedied these potential anticompetitive effects by requiring Cephalon to license its patents, and to transfer all of its technological know-how to a third-party generic drug company, to expedite entry of a lower priced generic version of Cephalon's drug.

In addition, the FTC is concerned about maintaining competition among competing branded pharmaceuticals. In February 2009, the FTC issued a final consent order to settle its charges that King Pharmaceuticals, Inc.'s proposed $1.6 billion acquisition of rival drug-maker Alpharma Inc. would be anticompetitive.[64] The consent order required King to divest the rights to Alpharma's branded oral long-acting opioid (LAO) analgesic drug Kadian to Actavis, restoring the competition between Kadian and King's branded LAO Avinza that would be lost as a result of the acquisition. (Actavis was well-positioned to acquire the Kadian assets, as it had manufactured the drug for King at its plant in Elizabeth, New Jersey.) In 2003, the FTC charged that Pfizer's acquisition of Pharmacia would eliminate competition between two of the three branded makers of combination hormone replacement therapies (HRT).[65] The FTC's consent agreement with the parties restored competition that otherwise would have been lost by requiring Pfizer to divest all of its rights and assets related to its branded HRT product, including its intellectual property. Thus, the FTC preserved competition by maintaining three independent HRT competitors in the market.

The FTC will not hesitate to challenge consummated pharmaceutical mergers that have anticompetitive effects. In December 2008, the FTC filed a complaint in the Federal District Court for the District of Minnesota, challenging Ovation Pharmaceuticals, Inc.'s January 2006 acquisition of the drug NeoProfen.[66] That acquisition eliminated Ovation's only competitor for the treatment of a serious and potentially deadly congenital heart defect affecting more than 30,000 babies born prematurely each year in the United States. When it acquired NeoProfen, Ovation already held the rights to Indocin I.V., the only other drug used to treat this serious condition. After ensuring that it would not face competition from NeoProfen, Ovation promptly raised the price of Indocin nearly 1,300 percent, from $36 to nearly $500 per

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62 See Congressional Budget Office, How Increased Competition from Generic Drugs HasAffected Prices and Returns in the Pharmaceutical Industry (July 1998), available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0> (hereinafter "CBO Study"); see generally David Reiffen & Michael R. Ward, Generic Drug Industry Dynamics, 87 REVIEW OF ECON. & STAT. 37-79 (2005).

63 *Cephalon, Inc./Cima Labs, Inc.*, FTC Docket No. C-4121, Complaint (Sept. 20, 2004), *available at* http://www.ftc.gov/os/caselist/0410025/040924comp0410025.pdf; Decision and Order (Sept. 20, 2004), *available at* http://www.ftc.gov/os/caselist/0410025/040924do0410025.pdf.

64 *In the Matter of King Pharmaceuticals, Inc. and Alpharma Inc.*, FTC Docket No. C-4246, Complaint (Feb. 2, 2009), *available at* http://www.ftc.gov/os/caselist/0810240/090203alpharmacmpt.pdf.

65 *Pfizer, Inc., and Pharmacia Corp.*, No. C-4075 (Apr. 14, 2003), Analysis to Aid Public Comment at 3, *available at* http://www.ftc.gov/os/caselist/c4075.htm.

66 *FTC v. Ovation Pharmaceuticals Inc.*, FTC File No. 0810156, Complaint (Dec. 16, 2008), *available at* http://www.ftc.gov/os/caselist/0810156/081216ovationcmpt.pdf.

vial. When it launched NeoProfen in July 2006, Ovation set a similarly inflated price. The FTC is seeking divestiture of assets related to one of the two treatments, and disgorgement of all unlawfully obtained profits obtained from the sale of these two treatments.

The FTC also has brought merger challenges directed at protecting the aggressive price competition that occurs among generic pharmaceutical manufacturers. As previously noted, generic competition can drive prices as low as 80 percent or more below the price of the brand name drug, and the FTC's work has shown that, up to a point, pricing is heavily influenced by the number of generic firms in the market for a particular drug. Since 2005, the Commission has challenged nine transactions between generic manufacturers, all of which were resolved by divestitures. These challenges were directed at transactions involving: Novartis and Eon;[67] Teva and Ivax;[68] Barr and Pliva;[69] Watson and Andrx;[70] Hospira and Mayne;[71] Actavis and Arbika;[72] Mylan and Merck;[73] Barr and Teva;[74] and Sun Pharmaceutical and Taro.[75] In each case, the Commission identified several markets in which the proposed merger would cause significant anticompetitive harm to consumers by eliminating a current or future generic product.

Pharmaceutical mergers may also harm consumer welfare by allowing firms to manipulate government regulations. A behavioral remedy may sometimes be appropriate in such cases. This is illustrated by the FTC's 2008 action to block an acquisition that would have achieved such an anticompetitive result through a regulatory abuse of the United States Medicare reimbursement program.[76] The FTC challenged Fresenius Medical Care Ag & Co. KGaA's (Fresenius) proposed acquisition of an exclusive sublicense from Luitpold Pharmaceuticals, Inc. (Luitpold), a wholly owned U.S. subsidiary of

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67 *In the Matter of Novartis AG*, FTC Docket No. C-4150, Complaint (September 21, 2005), *available at* http://www.ftc.gov/os/caselist/0510106/0509236comp0510106.pdf.

68 *In the Matter of Teva Pharmaceutical Industries Ltd., and IVAX Corporation*, File No. 051-0214, FTC Docket No. C-4155, Complaint (January 20, 2006), *available at* http://www.ftc.gov/os/caselist/0510214/0510214complaint.pdf.

69 *In the Matter of Barr Pharmaceuticals, Inc.*, File No. 061 0217, FTC Docket No. C-4171, Complaint (October 19, 2006), *available at* http://www.ftc.gov/os/caselist/0610217/0610217barrcomplaint.pdf.

70 *In the Matter of Watson Pharmaceuticals, Inc. and Andrx Corporation*, File No. 061- 0139, FTC Docket No. C-4172, Complaint (Oct. 21, 2006), *available at* http://www.ftc.gov/os/caselist/0610139/0610139complaint.pdf.

71 *In the Matter of Hospira, Inc. and Mayne Pharma Limited*, File No. 071-0002, FTC Docket No. C-4182, Complaint (January 18, 2007), *available at* http://www.ftc.gov/os/caselist/0710002/070118cmp0710002.pdf.

72 *In the Matter of Actavis Group, HF.*, File No. 071-0063, FTC Docket No. C-4182, Complaint (Apr. 16, 2007), *available at* http://www.ftc.gov/os/caselist/0710063/0710063cmp.pdf.

73 *In the matter of Mylan Laboratories Inc. and E. Merck oHG*, FTC Docket No. C-4200, Complaint (Sept. 26, 2007), *available at* http://www.ftc.gov/os/caselist/0710164/070921cmp0710164.pdf.

74 *In the Matter of Teva Pharmaceutical Industries Ltd. and Barr Pharmaceuticals, Inc.*, FTC Docket No. C-4242, Complaint (Dec. 18, 2008), *available at* http://www.ftc.gov/os/caselist/0810224/081219cmp0810224.pdf.

75 *In the Matter of Sun Pharmaceutical Industries Ltd.*, FTC Docket No. C-4230, Complaint (Aug. 12, 2008), *available at* http://www.ftc.gov/os/caselist/0710193/080813sunpharmcmpt.pdf.

76 Although the Medicare Program (which provides medical care for the elderly) is specific to the United States, other countries may have their own regulatory schemes that could be manipulated to an anticompetitive end. Thus, the example discussed in this paragraph may serve as a general cautionary tale about the importance of evaluating the competitive effects of regulatory programs affecting pharmaceuticals.

the Japanese firm Daiichi Sankyo Company, Ltd.[77] Under the sublicense, Fresenius would manufacture and supply the intravenous iron drug Venofer to dialysis clinics in the United States. The FTC's complaint charged that the proposed vertical agreement would provide Fresenius, the largest provider of end-stage renal disease (ESRD) dialysis services in the United States, with the ability to increase Medicare reimbursement payments for Venofer. This is possible because after the transaction, the competitive market will no longer determine the price that Fresenius's clinics will pay for intravenous (IV) iron. That amount will instead become an internal transfer price reported by Fresenius to the United States Government Center for Medicare & Medicaid Services. A consent order settling the FTC's complaint and allowing the companies to consummate the transaction barred Fresenius from reporting intra-company transfer prices higher than certain levels specified in the order. Those levels are derived from current market prices.

The FTC focuses its enforcement work so as not to prevent efficient mergers. One merging firm may have expertise in bringing products to market quickly or gaining market acceptance that will increase the use of a product that the other firm has in development. The Commission credits these efficiencies. The FTC's review of the Genzyme/Ilex merger demonstrates the agency's appreciation of efficiencies that benefit innovation.[78] That case also demonstrates the flexibility that can emerge from an analysis focused on the particular facts rather than rigid structural rules.

The drugs at issue in the Genzyme/Ilex matter provide acute therapy for solid organ transplants by suppressing the immune system during initial organ transplant and during episodes of acute rejection. Genzyme was the leading supplier of such drugs with its product, Thymoglobulin. Ilex sold Campath, which the FDA had approved for the treatment of chronic lymphocytic leukemia, but which doctors also prescribed off-label for transplants. The merger would have lessened competition in the market for acute therapy drugs used in solid organ transplant by eliminating this competition between Genzyme and Ilex. Instead of requiring that the merged firm divest all of its interests in Campath, however, and eliminating efficiencies that would have been produced from the acquisition of Campath by Genzyme, the FTC negotiated a consent decree that required the divestiture to Schering of the firm's contractual rights, including earnings, involving Campath's use for solid organ transplant only. This unique remedy maintained competition in the market for solid organ transplant drugs, while preserving the efficiencies of the transaction.

6. Emerging pharmaceutical competition policy issues

The FTC continues to monitor competition policy developments in the pharmaceutical sector. New business models, technological innovations, and the enactment of federal health care reforms (through legislation or regulation) may affect pharmaceutical competition in ways that cannot currently be predicted. The FTC will respond to these changes through new research, public policy recommendations, and, when appropriate, enforcement actions. The precise nature of these initiatives must await future developments. Special mention should be made, however, of two recent FTC policy-oriented reports, which deal with topics that are expected to loom large in future competition policy deliberations – the treatment of "authorized generics" and of "follow-on biologics."

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77 *In the matter of Fresenius Medical Care AG & Co. KGaA and Daiichi Sankyo Company, Ltd.*, FTC Docket No. C-4236, Decision and Order (Oct. 20, 2008), *available at* http://www2.ftc.gov/os/caselist/0810146/081021freseniusdo.pdf.

78 *In the matter of Genzyme Corp. and Ilex Oncology, Inc.*, FTC Docket No. C-4128, Complaint (December 21, 2004) *available at* http://www.ftc.gov/os/caselist/0410083/041220comp0410083.pdf.

In its June 2009 *Authorized Generics Report*,[79] the FTC examined the short-term effects of authorized generics during the initial period of generic competition (the 180-day marketing exclusivity period). The *Authorized Generics Report* concluded that: (1) during the initial period, both retail and wholesale drug prices are lower when authorized generics are marketed against a single generic drug than when they are not; (2) authorized generic entry during the initial period also substantially reduces the revenues of a first-filer generic firm; and (3) patent litigation settlement agreements that delay the introduction of both independent generics and authorized generics can harm consumers by delaying generic drug entry. The FTC plans to release a report setting forth the long-term competitive effects of authorized generics.

Another emerging policy issue that the FTC has studied is biologic drug competition. Biologic drugs are protein-based drugs that are derived from living matter or manufactured in living shells using recombinant DNA technologies. Biologics are far more complex and much larger than the chemically synthesized, small molecules that form the basis of most pharmaceutical products, and they are also far more expensive. The United States Congress is currently drafting various legislative proposals to provide an abbreviated regulatory pathway for follow-on biologic ("FOB") drugs to encourage FOBs to enter and compete with pioneer biologics once a pioneer drug's patents have expired. In a June 2009 Report ("*Biologics Report*"),[80] the FTC provided an independent analysis of how the legislative proposals would likely affect consumers. The FTC's Biologics Report concluded that: (1) the likely market dynamics of FOB competition will resemble brand-to-brand drug competition, rather than brand-generic drug competition under the Hatch-Waxman Act; (2) the existing United States patent system and market-based pricing are likely to be sufficient to support continued pioneer and FOB biologic drug innovation; and (3) inclusion of entry barriers in the form of additional regulatory exclusivity periods and special patent resolution procedures would likely harm consumers by delaying FOB entry and decreasing the pace of biotech innovation.[81] FTC Commissioner Pamela Jones Harbour presented the findings and recommendations of the *Biologics Report* on behalf of the Commission in a June 11, 2009 testimony before Congress, and answered questions posed by the Committee with Michael S. Wroblewski, Deputy Director Office of Policy Planning, lead author of the Biologics Report.[82] The ultimate decision how to devise an abbreviate FOB regulatory approval pathway rests with Congress.

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79 The *Authorized Generics Report* is discussed in part 2.2 of this note at paragraph 22, *supra.*

80 Fed. Trade Comm'n, Emerging Health Issues: Follow-on Biologic Drug Competition (June 2009), *available at* http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf.

81 *See id.* at iii-x.

82 *FTC Testifies on "Competition Issues and Follow on Biologic Drugs"* (FTC press release describing June 11, 2009 testimony by FTC Commissioner Pamela Jones Harbour before the Subcommittee on Health of the U.S. House of Representatives Committee on Energy and Commerce), *available at* http://www.ftc.gov/opa/2009/06/biologicdrugs.shtm.

EUROPEAN UNION

1. Introduction

On 8 July 2009, the Commission presented its final report on the sector inquiry into pharmaceuticals.[1] The inquiry was initiated in response to information that competition in the pharmaceutical market in the European Union may not be working well as indicated by a decline in innovation[2] and by instances of delayed market entry of generic medicines.

This paper will explain the Commission's insights into the area of generic competition within the pharmaceutical sector. These are mostly based on the results of the above mentioned sector inquiry.

For the in-depth analysis of the inquiry 219 prescription medicines were selected. These medicines were in their majority either blockbusters or well selling medicines facing loss of exclusivity in the period 2000 to 2007 or both. This sample corresponds to approximately 50% of the total prescription market in 2007 in the EU and covers a great variety of products across various therapeutic areas. Also, the 70 respondent companies account for 80% of the total turnover generated with prescription medicines in the EU in 2007.

The report shows that R&D based companies (originator companies) engage in practices that can contribute to a delay of market entry of generic medicines. The report also states that originator companies use patent strategies aimed at blocking or delaying the development of novel medicines by competitors. It furthermore highlighted room for improvement of the regulatory framework within the sector, in particular, it called for the creation of a Community patent and a unified and specialised Community jurisdiction to decide on patent litigation in the EU as well as improvements within marketing and pricing and reimbursement procedures.

2. Market characteristics

The pharmaceutical sector is essential for the health of Europe's citizens who need access to innovative, safe and affordable medicines. On average approximately € 430 was spent on medicines in 2007 for each European citizen and this amount will likely continue to increase as the population in Europe ages. Overall, in 2007, the market for prescription and non-prescription medicines for human use in the EU was worth over € 138 billion ex-factory and € 214 billion at retail prices. The pharmaceutical market thus accounted for close to 2% of annual EU GDP.

2.1 General relationship between originator (branded) pharmaceuticals and generic pharmaceuticals

The pharmaceutical sector is highly regulated and R&D driven. Patents are of crucial importance to protect the innovative efforts. On the supply side, there are two types of companies. Originator companies

1 The full texts of the Commission Communication on the final report as well as the final report as technical annex to the communication are available at the website of DG Competition: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html. See also Press Release IP/09/1098 and MEMO/09/321.

2 As measured by the decreasing number of novel medicines reaching the market each year.

are active in research, development, management of the regulatory process for new products including the clinical trials needed for marketing authorisation, manufacturing, marketing and supply of innovative medicines. Their products are usually subject to patent protection, which, on the one hand, provides a compensation for the often very high costs spent on innovation (including failed projects) and, on the other hand, makes information on inventions public. The protection is limited in time, encouraging the company to bring the innovation to market as quickly as possible and ensuring that the company continues to innovate and brings forward future innovative products. The second category of companies, manufacturers of generic products, can enter the market with medicines that are equivalent to the original medicines, however only upon patent expiry of the existing original products and when the so called data exclusivity period for the originator product expired. Their prices are on average 40% lower than those of the originator products in the EU after two years. This helps containing public health budgets and ultimately benefits consumers. The market share of generic medicines varies significantly between Member States.

Originator companies spend a comparatively large amount (on average 17%) of their turnover from prescription medicines on R&D, but an even higher amount on marketing and promotion (23%). Not all active ingredients for the companies' medicines are discovered and developed by the originator companies marketing them. Nowadays a substantial amount (close to 40% undergoing final approvals in 2007) are acquired or in-licensed, e.g. from SMEs including those in the biotechnology sector. Generic companies have a different cost structure spending most on manufacturing (51%) and less on R&D (7%).

On the demand side, the pharmaceutical sector is unusual in that, for prescription medicines, the ultimate consumer (the patient) is not the decision maker. Decisions are generally made by the prescribing doctors, and in certain Member States, the pharmacist also plays a role. Yet, neither the patient, nor the prescriber or the dispenser directly bear most of the costs, as these are generally covered and/or reimbursed largely, or even wholly, by national health (insurance) schemes. The pharmaceutical sector is also unusual in that prices are most often the result of a regulated decision-making process, involving negotiations between the pharma companies and the administration. Where this is not the case, i.e. in countries with so-called free pricing, prices are dependent on the reimbursement status. Because of this structure, doctors, pharmacists and patients are usually not very price sensitive for prescription medicines, although various mechanisms to control prescription medicine budgets do exist.

As regards concentration of the industry, there is a trend for consolidation in the pharmaceutical sector in human health and in particular, in animal health. Three categories of cases can be identified in the field of human health: Firstly, mergers between different originators whereby the rationale for the acquisition of another originator company particularly seems to lie in a broadening of the R&D activities into further therapeutic areas and in a filling up of the R&D pipeline (like *Pfizer/Wyeth*[3], *Merck/Schering-Plough*[4]); secondly, mergers between generic companies with other generic companies (like *Teva/Barr*[5]), which are leading to very significant players in the generic markets. Thirdly, further mergers between originator and generic drug companies (like *Sanofi-Aventis/Zentiva*[6]) can be expected, whereby originators wish to pursue also the generics business. In the field of animal health, and in particular in the field of vaccines, there is already a high concentration in the markets in Europe.

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3 Commission Decision of 17 July 2009 (Case Comp/M.5477 Pfizer/Wyeth); see press release under: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1161 .

4 Case Comp/M.5502 Merck/Schering-Plough; just notified.

5 Commission Decision of 19 December 2008 (Case Comp/M.5295 Teva/Barr); see press release under: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/2043 .

6 Commission Decision of 4 February 2009 (Case Comp/M.5253 Sanofi-Aventis/Zentiva); see press release under: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/210 .

2.2 Regulatory framework for generics

The pharmaceutical sector constitutes a market which is strongly regulated by different legal frameworks that to a certain degree can affect classic market and competition forces. Thus, rules on patents and data protection, marketing authorisation as well as pricing and reimbursement play an important role.

2.2.1 Patents

In Europe, patent protection can last up to 20 years from the date of a patent application. For the pharmaceutical sector, where the time between filing a patent application and market launch can be significantly longer than in other sectors, supplementary protection certificates (SPCs[7]) can be issued. These extend the effective protection of products already on the market by a maximum of five years. Despite significant efforts, neither a Community patent nor a Community jurisdiction for patent matters exist. The European Patent Office handles centralised patent applications (and opposition and appeal procedures relating to granted patents). However, once granted, the European patent turns into a bundle of national patent rights, which, in court, must be challenged at national level. This can lead to diverging national decisions and is costly and time-consuming for all stakeholders concerned as will be pointed out further below.

2.2.2 Marketing authorisation and data protection expiry

In order to maintain public health standards, marketing authorisation procedures verify that medicines are safe, effective and of good quality. Detailed results of (pre-) clinical tests and clinical trials must be submitted for a new medicine. Generic medicines also require marketing authorisations, but applications need not resubmit detailed tests and trial results, if it is shown that the generic product is bio-equivalent to a medicine previously authorised. However, abridged applications of this kind are only permitted once the originator company's data relating to the pre-clinical tests and clinical trials is no longer protected (so-called data protection). The latter protection period can be up to ten years. The implementation of harmonised rules will only take effect in 2013.

As a consequence, the exclusivity an originator product enjoys for a certain period can either stem from its patent protection or from data protection. The latter will be applicable in the few cases where a patent was filed a long time before the market authorisation for the product concerned was obtained. In such a case the effective patent protection after grant of the marketing authorisation can be shorter than the data exclusivity period.

Marketing authorisation procedures are regulated by EU law. There is a centralised application procedure leading to authorisation for the entire EU or national procedures which result in national authorisations that can benefit from mutual recognition in other Member States. The scope of the centralised procedures has been extended over the years. Since 2005 it also applies to generic products.

7 For further details see: Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, pp. 1-5).

Marketing authorisations are issued on the basis of scientific criteria concerning the quality, safety and efficacy of the medicinal product concerned. While dealing with such applications, the marketing authorisation bodies should disregard all other criteria such as the patent status of the reference medicinal product.[8]

2.2.3 Pricing and reimbursement

In almost all Member States the pricing and reimbursement status of a prescription medicine must be determined before launch if funded under the social security system. The underlying objective is to maintain control over national health budgets. There is only a minimum harmonisation of procedures governing price setting procedures (as required by the Transparency Directive[9]).

In several Member States prices for a medicine are set following negotiations between the companies and the health administration, while others allow the companies to determine them freely. However, in the latter case the level of reimbursement as negotiated with the state will be crucial. Even if in both cases the Member State play an important role in the price setting mechanism it has to be underlined that companies have a certain room of negotiation within these procedures. A new model used by some Member States is that of tendering for rebate contracts, discussed further below.

2.3 Findings on generic entry and impact

As regards the impact of generic entry the sector inquiry found that in markets where generic medicines become available, average savings to the health system (as measured by the development of a weighted price index of originator and generic products) are almost 20% one year after the first generic entry, and about 25% after two years (EU average). In rare instances even price drops of as much as 80 – 90% after generic entry could be observed. Obviously, there are significant differences between different medicines and Member States. For example, in certain Member States the price for the originator product remains largely stable, even after generic entry, whilst in other Member States the prices dropped much sharper than the average, in particular for the generic versions of the product. By comparison, the price of medicines without generic entry stayed stable and even slightly increased.

Based on a sample of medicines used for in-depth investigation that faced loss of exclusivity in the period 2000 – 2007 (representing an aggregate post-expiry expenditure of about € 50 billion over this period in 17 Member States) the sector inquiry report estimates that this expenditure would have been about € 15 billion higher without generic entry. However, the savings from generic entry could have been 20% higher, if generic entry had taken place without delay.

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8 See in particular Article 81 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1 (as last amended by Regulation (EC) No 1394/2007, OJ L 324, 10.12.2007, p. 12) and Article 126 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67 (as last amended by Directive 2008/27/EC, OJ L 81, 20.3.2008, p. 45).

9 See: Directive 89/105/EEC of the Council of 21 December 1989 relating to the transparency of measures regulating the process of medicinal products for human use and their inclusion in the scope of national insurance systems (OJ L 40, 11.2.19689, pp. 8-11).

2.4 Factors that seem to encourage generic uptake

A number of Member States apply policies supporting the sale of generic medicines by combining demand and supply side pricing practices, such as obliging doctors to prescribe the molecule instead of the brand or obliging pharmacists to dispense the cheapest product. In certain Member States health insurers have recently become active in efforts that should lower the prices for generic medicines, e.g. through tender procedures. The latter provides for discounts that the companies winning a tender give to the sickness funds. In exchange the sickness funds will only reimburse their patients for the specific substances that are covered by the contract, thereby bringing down the costs of medicines. Concerns have been voiced in particular by generic firms that these tenders may in the long run reduce competition, where big firms will be able to undercut prices over a longer period in order to drive smaller ones out of the market. Also pharmacists complained as they lost the discounts/rebates granted by the originator company.

2.5 Problematic issues as regards the regulatory framework

2.5.1 Fragmented patent system

The need for a Community patent and a unified and specialised court is now supported by originator and generic companies and their industry associations alike. The need for a Community patent is furthermore fully supported by findings of the sector inquiry namely by the high number of patent litigation cases, in many instances dealing with the same underlying issue across different Member States. Thus 30% of the cases were duplicates of parallel cases in other Member States and in 11% of the cases conflicting judgements were rendered, putting legal certainty into question. Last but not least, the total costs of the patent litigation analysed in the report amount to € 420m.

In addition, generic companies and some originator companies also called upon the patent offices and most prominently the EPO, to which most applications go, to ensure a high quality of patents granted and effectively counter strategies that may cause unnecessary delays such as divisionals.

2.5.2 Marketing authorisation issues

With respect to procedures governing marketing authorisations, companies, industry associations and national agencies reported most prominently about bottlenecks that can lead to obstacles and delays of market entry.

Some originator companies also said that they would favour further international harmonisation of marketing authorisation procedures, in particular between the EU and the US. First steps are under way to achieve this.

Furthermore, the inquiry revealed that originator companies intervene in marketing authorisation procedures of generic products claiming the latter to be less safe, less efficient than or not equivalent to the corresponding originator product or even violating their patent rights.

2.5.3 Issues of pricing and reimbursement

With respect to pricing and reimbursement procedures, originator companies complained in particular about the delays and uncertainties created by the national procedures. The delays would reduce the time during which originator companies can reap the benefits of their innovation. Whilst additional efforts to speed up procedures should be undertaken, it should also be noted that the effective protection period of originator products increased from 10.5 years in 2000 to more than 14 years in 2007 (effective protection is measured from product launch of the originator product to the first product launch of an independent generic product).

Generic companies voiced concerns about delays in the pricing and reimbursement procedures as a result of the additional requirements introduced by some Member States. They pointed in particular to the fact that some Member States request evidence that the patents of the originator companies are not violated. The latter was often based on interventions by originator companies. They also called for immediate pricing and reimbursement status for their product.

Generic companies also called for measures facilitating generic uptake after loss of exclusivity.

2.6 Recommendations by the commission on regulatory framework

As far as the regulatory framework is concerned, the Commission reaffirmed the urgent need for the establishment of a Community patent and of a unified specialised patent litigation system in Europe, which pursuant to the sector inquiry has received increased support from the pharmaceutical sector. With respect to patent law the sector inquiry also fully confirmed the relevance of the recent initiatives of the European Patent Office to ensure a high quality standard of patents granted and to accelerate procedures ("raising the bar") as well as the limitation of the period during which voluntary divisionals may be applied for.

With respect to marketing authorisation the Commission announced that it will focus on the full implementation and effective enforcement of the regulatory framework, e.g. regarding patent linkage or the respect of deadlines in the approval procedures. The Commission recalls that third party submissions and even less so formal interventions during the assessment of an application for a marketing authorisation are not foreseen in Community pharmaceutical legislation. It calls upon marketing authorisation bodies to ensure that submissions by third parties that cannot be excluded are well documented and made transparent towards the applicant, and to make all necessary efforts that submissions do not necessarily lead to delays for the applicants.

Concerning pricing and reimbursement the Commission invites Member States to consider (the introduction of) provisions that would grant pricing and reimbursement status to generic products automatically/immediately where the corresponding originator product already benefits from such a status. Moreover, Member States should disregard third party submissions raising patent, bioequivalence or safety issues. Member States should ensure that submissions by a third party at pricing and reimbursement bodies that cannot be disregarded are well documented, made transparent towards the applicant and should make all necessary efforts that the intervention does not lead to unnecessary delays for the applicant. Finally, the Commission invites Member States to the extent not yet done to consider policies facilitating rapid generic uptake and/or generic competition. It will facilitate cooperation between Member States and the exchange of best practices on generic policies. Ultimately the Commission will examine the potential need for a review of existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC). Furthermore, a Joint Action on Health Technology Assessment has just been submitted for funding under the Health Programme 2009. Its aim is to reduce the duplication and risk of contradictions of scientific assessments of medicinal products in order to evaluate their "added value".

3. Practices of originator companies vis-à-vis generic products

Apart from regulatory issues the sector inquiry examined strategies originator companies used in response to (imminent) generic market entry: Originator companies design and implement a variety of strategies in order to ensure continued revenue streams from their medicines. The successful implementation of the strategies of this "tool box"[10] of instruments may have the effect of delaying or blocking generic entry. The preliminary and final reports underline, however, that company behaviour may not be the only cause for the delay of generic entry on the market.

[10] The term "tool box" is a term commonly used by originator companies in their strategy documents.

3.1 Importance of IP and patents for this sector

Patents are key for the pharmaceutical industry, as they allow companies to recoup investment and to be rewarded for innovative efforts. The sector inquiry report does not put into question the need for strong intellectual property rights. Patents are essential for innovation, in particular for the pharmaceutical industry with its long R&D phase and long lifecycle of products. Patents are necessary to recoup investments that have been put into research. At the same time, this does not mean that EC competition law does not need to be respected.

3.2 Patent strategies

The sector inquiry looked in detail at patent strategies of originator companies. The aim of the sector inquiry was to help understand whether originator companies develop and employ strategies with the purpose of blocking or delaying generics.

The sector inquiry found that originator companies aimed to extend the breadth and duration of protection of a product by filing numerous patents for the same molecule, forming so-called "patent clusters".

Patent clusters in this context describe a situation, where, in order to protect its medicine, an originator company holds in addition to some fundamental patents, often called "primary patents", as they protect the main active compound, a multitude of additional patents often referred to as "secondary patents", covering all kinds of secondary aspects of the medicine, e.g. formulations, processes or non-formulation products such as salts or hydrates. In some cases, individual blockbuster medicines are protected by up to 90 patent families translating into 1300 national and EPO patents and pending patent applications across the EU Member States. This creates a dense web of patents around the originator company's blockbuster product which can lead to uncertainty for generic companies as to which of these patents they will possibly have to face. From a commercial perspective a generic company that wants to enter the national markets has to confront the sum of all patents in these member states.

Quotes from strategy documents and e-mails gathered during the course of the inquiry, in particular during the inspections confirmed the intention of companies to delay generic entry through the filing of secondary patents such as the following two:

> *"I suppose we have all had conversations around "how can we block generic manufacturers" […]. Don't play games in patenting new salt forms too late, the generics are starting earlier and earlier. Get claims on key intermediates that cover a number of routes […] Process patents are not the biggest block but can put generics off if a superior chemistry job is done."*
>
> *"Secondary patents will not stop generic competition indefinitely but may delay generics for a number of years, at best protecting [the originator's] revenue for a period of time."*

Furthermore, the increased filing of divisional patent applications, in particular before the EPO, has been an object of complaint by the generic industry as a potential instrument to prevent or delay generic entry.

A divisional patent application is created where the applicant, either voluntarily or at the request of the examining office, divides out from a patent application ("parent patent application") one or several (narrower) patent applications ("divisionals"). Such a division must be undertaken as long as the parent patent application is still pending. However, once created, a divisional has a life of its own, i.e. even if the parent patent application is refused or revoked, the divisional would still be pending. The divisional will

have the same priority and application date as the parent patent application. In other words, if granted, a divisional will, in principle, provide the same duration of patent protection as the parent application. Also, the divisional application cannot go beyond the scope of the parent application.

However, applicants can use this procedure to "reset the clock" and gain more time for patent examination, thus extending the period where applications are pending. As each divisional application has to be assessed individually, a successful challenge of a parent application will not create legal certainty for the challenger, as long as several other divisional applications are still pending. In such cases, generic companies pointed out, it is virtually impossible for them to predict when which divisional application will possibly be granted. As a consequence they are unsure as to what they can reproduce without infringing any patents, even if the parent patent application has been refused or revoked.[11]

On the basis of observations of patent filings for the top 20 best-selling medicines the sector inquiry found a clear continuity on average, i.e. that originator companies keep on filing new patent applications for their blockbusters. Hence, there is a steady increase in the number of patent applications over the whole lifetime of the primary patent, often only after product launch. This is due to the fact, that amongst the top-selling medicines there is an important number of medicines, where filings increase rapidly just in the years prior to expiry.

3.3 Patent disputes and litigation

The patent strategies mentioned above may eventually lead to non-litigious patent disputes as well as litigation. In this respect it needs to be underlined that enforcing patent rights is a fundamental right which is not put into question by the sector inquiry.

The sector inquiry found almost 460 patent disputes outside legal proceedings on the sample of 219 medicines alone. Interestingly, almost all of these patent disputes between originator and generic companies - 91% - were initiated by an originator company.

As regards litigation, the inquiry found that, in the period 2000 to 2007, originator companies engaged in nearly 700 cases of patent litigation with generic companies concerning the sample of products investigated. Here, 54% of the cases were initiated by an originator company. Secondary patents accounted for nearly two thirds of all litigated patents (64%). Primary patents made up the remaining 36%. It is noteworthy that of all cases where a final judgment was taken (149) generic companies won 62%. However, on average, it took 2.8 years for a final judgment to be reached by court.

Moreover, in about half of all cases where an originator company requested an interim injunction ordering the generic not to sell, such an injunction was granted. This happened in 112 cases of the sample. On average, an interim injunction lasted for 18 months. When analysing the final outcome of cases in which interim injunctions were granted, it would appear that almost 50 % of them were favourable to the generic companies (including favourable settlements).

Furthermore there are issues of duplication and contradictory judgements already mentioned above.[12]

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[11] In reaction to such complaints the EPO recently changed its rules on voluntary divisional patent applications limiting the filing period.

[12] See above para. 21.

3.4 Patent opposition procedures

The sector inquiry also examined opposition procedures including appeals before the European Patent Office (EPO), involving generic companies as opponents against the patents of originator companies. Opposition procedures, in this particular context, allow generic companies to request a review by the European Patent Office of whether the conditions for granting the patent are met. Thus these procedures can serve as an important tool for opponents, such as generic companies, in order to ensure patent quality and to remove patents that do not meet the agreed standard.

In opposition procedures, a European patent can be either maintained, or rejected or amended.

Counting only rejections as a success the sector inquiry found that in the majority (60%) of opposition procedures in which a final decision was reached, generic companies were successful. In a further 15% the scope of the patent was reduced. While, in theory, opposition procedures could represent an efficient legal remedy for generic companies to challenge invalid patents, they unfortunately do not bring clarity and legal certainty in a timely manner. Almost 80% of procedures took more than 2 years before a final decision was reached. For some extreme cases, it took up to 9 years.

3.5 Patent settlements

Patent settlements are agreements between originator and generic companies to resolve patent-related disputes and litigation. Occasionally, these settlements are also concluded in the context of opposition procedures. Whilst the sector inquiry recognises that settlements can be an efficient way to solve disputes it also found instances where patent settlements can have a restricting effect on generic entry.

For the period 2000 to 2007, companies reported more than 200 settlement agreements relating to the EU markets and covering almost 50 medicines. Out of these 200 settlements, a bit more than half did not limit generic entry. The other half imposed a limitation on generic entry.

Within this latter category the sector inquiry found that 54 agreements did not foresee any value transfer from the originator to the generic. These are typically cases where the generic company accepts that the originator company had a valid patent that needs to be respected.

However, in the remaining 45 agreements one could observe a value transfer from the originator company to the generic company. The value transfer can take different forms, e.g. it can consist of a distribution agreement, a license agreement or an agreement with direct payments.

In 22 patent settlements in which generic entry was limited in some form or other there was a direct payment made from the originator company to the generic company. In these cases more than € 200m were transferred to the generic companies.

3.6 Interventions before regulatory bodies

Originator companies also intervened before national marketing authorisation and pricing and reimbursement authorities to call into question the quality or safety of generic products or to claim that the commercialisation of these products would violate their patent rights.

In this respect it is interesting to note that marketing authorisation bodies are not entitled under EU law to verify the patent status of the generic product.[13]

The sector inquiry found that - where an initial intervention before the authority does not lead to the desired result - originator companies may take the national authorities to court. The vast majority of court cases brought against national authorities by originator companies, however, were lost by the latter. In fact, originator companies won only 2% of cases launched against marketing authorisation bodies where patent infringement or safety issues were raised. Likewise, originator companies were only successful in 19% of cases against marketing authorisation bodies regarding data exclusivity.

Even where generic companies can ultimately enter the market, the interventions can have significant consequences. When comparing the duration of approval procedures in which an intervention took place with procedures in which no such intervention took place the former lasted on average 4 months longer. In the inspection material one originator company reported about significant additional revenues obtained through such interventions.

3.7 Life cycle strategies

Incremental research is important as it can lead to small but important steps in innovation and thus can lead to second generation products that address unmet patient needs. The generic industry is however more critical towards second generation products, and speaks about so called ever-greening strategies. Generic companies argue that second generation products are often based on first generation products and have little or no added value for patients.

For the sample of 219 molecules originator and generic companies reported that approximately 40 % of all medicines were either a first or a second generation product. For the narrower sample of medicines that faced expiry in the period 2000 to 2007 the percentage figures increased even to 53%. Obviously, there were significant discrepancies between the reports of generic and originator companies.

Originator companies confirmed that they launch second generation products on average 1 year and five months prior to the loss of exclusivity of the first generation product. Timing is crucial when switches occur and significant marketing and promotion efforts are undertaken when the switches are envisaged.

Originator companies confirmed that the switch to the next generation must take place before the generic version of the first generation product is launched as was also illustrated by quotes from strategy documents. Generic companies on the other hand submitted that they have difficulties to enter the market when a second generation product was launched successfully by the originator company and the patient base was switched.

3.8 Cumulative use of instruments

In many instances, originator companies used two or more instruments from the "tool-box" in parallel and/or successively in order to protect the revenue streams from their (best-selling) medicines which can lead to cumulative delays.

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[13] Article 81 of Regulation (EC) 726/2004 and Article 126 of Directive (EC) 2001/83 provide that an authorisation to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in the Regulation and the Directive. Considering that patent status is not included in the grounds set out in the Regulation and the Directive, it cannot be used as an argument to refuse, suspend or revoke a marketing authorisation.

3.9 Problematic issues

Many of the practices examined in the report may be completely unproblematic. An evaluation of their compatibility with competition law will have to be carried out on a case-by-case basis taking into account individual circumstances. However, as mentioned in the Commission decision[14] launching the sector inquiry certain practices may cause market distortion when they unduly fence off incumbent suppliers of drugs from generic competition, for example, due to *de facto* extended patent protection through unilateral conduct or agreements. Such practices may limit consumer choice; reduce economic incentives to invest in research and development of new products and damage public and private health budgets.

Such practices may include the filing of patent applications or the exercise of patent rights which may not serve to protect innovation but to block generic competition; litigation, which may be vexatious, and agreements, which may be collusive, such as patent settlements that restrict generic market entry and contain a value transfer from the originator company to the generic company.

3.9.1 Patent thickets and divisionals

The increased use of patent applications and the creation of patent clusters by originator companies in the pharmaceutical sector seem to lead to uncertainty for generic competitors as regards how they can enter with a generic product after the primary patent has expired without infringing any secondary patents as explained above.[15] In a similar manner the use of divisional applications by originator companies create such a legal uncertainty.[16]

Thus, in the course of the sector inquiry several generic manufacturers complained that originator companies filed numerous patent applications for secondary aspects of a medicine, using also a great number of divisionals in this context. Generic companies maintained that originator companies obtain "weak patents" since in their opinion novelty and inventive step requirements, in particular for secondary patent applications, were too easily considered to be met by the EPO, an argument which was also reiterated during the public consultation. In this context it needs to be pointed out that certain types of prior art may be "unsearchable" and thus not easy to detect for the EPO. Furthermore, examination by the EPO does not include any experiments to verify applicant allegations.

Given that a significant number of patents that have been challenged in litigation or opposition have been later annulled, questions as to the quality of these patents could be raised. Depending on the circumstances of the case the filing of a multitude of patents protecting the same medicine as well as the use of divisionals may be problematic under company law.

3.9.2 Disputes and Litigation, opposition procedures: may deter generic entry, litigation length, possibly weak patents

Access to courts is guaranteed as a fundamental right in Article 6 of the European Convention of Human Rights. This as well as the judicial enforcement of patent rights constitutes a self-evident guarantee which is not questioned by the Final Report of the Sector Inquiry.

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14 See: Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No 1/2003, available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/decision_en.pdf .

15 See above para. 37.

16 See above para. 41.

It is noteworthy, though, that in the majority of opposition and appeal procedures against originator company's patents examined in this report the final outcome was a revocation of the disputed patent. These procedures almost exclusively concerned secondary patents. Furthermore in 55 % of the patent litigation cases between originator and generic companies that involved a question of the disputed patent's validity and that reached a final judgement, the patents were annulled (43 of 78 cases). This could, again, be an indication for a lesser quality of the patents involved.

The judicial enforcement of such patents with the aim of sending out signals to generic companies, or the intentional creating financial barriers in form of multiple costly and lengthy patent litigation procedures in order to deter generic competitors from entering the market, may constitute a problem in individual cases depending on its circumstances.

3.9.3 Settlements: pay for delay deals

As already pointed out patent settlements may have restrictive effects on market entry of generic medicines. Cases run by the US FTC show that certain patent settlements, in particular those including a so-called reverse payment from the originator to the generic company have the main purpose to keep generic products from entering the market where they might have had good chances to do so due to a significant probability of their winning patent litigation.

The sector inquiry has found a substantial number of patent settlements that contained a value transfer in one form or another from the originator company to the generic company and entailing a restriction of generic market entry. Though the litigating parties may have found an understanding in these cases this may be problematic: Consumers, e.g. sickness funds and partly patients were not included in negotiations and will have to continue paying higher prices as generic market entry usually resulting in price drops is restricted.

3.9.4 Interventions: patent linkage and interventions with sole aim of delaying

Regulatory procedures like the one aimed at marketing authorisation are in principle bilateral ones. Thus interventions from third parties are not foreseen in the process. On the other hand marketing authorisation bodies have to take into account all indications or hints made by third parties that suggest safety or efficacy concerns. Where such interventions are not founded and systematically run by third parties with the primary aim of preventing a generic competitor to enter the market this may well raise competition law concerns.

Patent linkage, i.e. considering potential patent infringements in a marketing authorisation procedure, is clearly forbidden by EU law. Where a third party continuously claims such patent infringements before marketing authorisation bodies and in particular challenges their decisions on this ground in order to avoid that pricing and reimbursement status is granted to the generic product, the originator company might succeed in delaying the procedure, which could trigger competition concerns.

3.9.5 Life cycle strategies

Second generation products often constitute an improvement of a previous product. They may have fewer side effects, may be easier to administer or may significantly enhance patient compliance, e.g. because they only have to be taken once a week instead of each day. This may serve a patient need.

However, the launch of a second generation product can be a scenario in which an originator company might want to make use of instruments that delay the market entry of generic products corresponding to the first generation product. Thus they could prevent a consumer choice between a second generation and a

(generic) first generation product. The companies have an incentive to do so in order to avoid generic exposure for the second generation product. Therefore they have to ensure that a substantial part of the patient base is "switched" to the second generation product before generic versions of the first generation product are on the market. If generic companies enter the market before the patients are switched, originator companies may have difficulties in convincing doctors to prescribe their second generation product or in obtaining a high price for the second generation product.

In this context the *AstraZeneca*[17] case has to be mentioned where the Commission came to the conclusion that *AstraZeneca* had abused government procedures (e.g. submitting misleading information to obtain longer SPC periods) in order to delay generic entry of generic omeprazole. In the specific circumstances of the case this was held to amount to an abuse of a dominant position, in other words a violation of Article 82 of the EC Treaty. One underlying aim was to facilitate the launch of AstraZeneca's second generation product on the market. Thus it is not the launching of a second generation product but another form of behaviour, namely the tactics of an exclusionary bridging strategy to keep out generic competition during the crucial "switching phase" that may be problematic under competition law rules.

3.9.6 Accumulation of practices

The sector inquiry showed that originator companies often use several of the above mentioned strategies, sometimes even all of them. The cumulative use of such tactics may be an indication for an anticompetitive strategy aimed at preventing the market entry of generic products. This will, however, always depend on the circumstances of the individual case. It certainly not a *per-se* infringement of competition law rules and the combination of various legal means does not necessarily render their combination illegal.

3.10 Recommendations: Competition law scrutiny

The possible use of specific instruments and strategies by originator companies in order to delay generic entry will be subject to competition scrutiny if used in an anti-competitive way, which may constitute an infringement under Article 81 or 82 of the EC Treaty. In particular patent settlements with reverse payments and interventions before regulatory bodies will be closely monitored by the Commission.

The Commission has already started investigations in a few cases such as *Servier*[18] examining potential anti-competitive agreements. Furthermore the Commission has already concluded a case involving the abuse of a dominant position and the abuse of government procedures in the context of supplementary protection certificates (*AstraZeneca*).[19]

This will inevitably touch upon the intersection of competition and IP law. In this context it has to be underlined that both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof.[20] If the existence and exercise of an industrial property right is

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17 Commission Decision of 15 June 2005 (Case COMP/A. 37.507/F3 - AstraZeneca); currently under appeal currently pending before the Court of First Instance (T-321/05).

18 COMP/39.612 - Perindopril (Servier) ; see press release under: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/322&format=HTML&aged=0&language=EN&guiLanguage=en .

19 Commission Decision of 15 June 2005 (Case COMP/A. 37.507/F3 - AstraZeneca); currently under appeal currently pending before the Court of First Instance (T-321/05).

20 Commission Notice – Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, OJ C 101 of 27 April 2004, p. 2-42.

not of itself incompatible with competition law, they are not immune from competition law intervention.[21] However, certain practices can only be an infringement in exceptional circumstances.[22]

Thus, where appropriate, the Commission will make full use of its powers under antitrust rules (Articles 81, 82 and 86 of the EC-Treaty), but also merger control (Regulation (EC) No 139/2004)[23] and State aid control (Articles 87 and 88 of the EC-Treaty). The Commission, in close cooperation with the National Competition Authorities, will pursue any antitrust infringement in the sector, wherever required by the Community interest. Action can also be taken at national level and in areas which were not the primary focus of the inquiry or are outside its scope. The Commission will in particular continuously monitor patent settlements.

21 See Commission Notice – Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, OJ C 101 of 27 April 2004, p. 2-42. See also Judgment of the Court of 27 September 1988, Case 65/86 (Bayer v. Süllhöfer), [1988] ECR, p. 05249.

22 See, for instance: Joined cases C-241/91 P and C-242/91 Radio Telefis Eireann (RTE) and Independents Television Publications (ITP) v Commission (Magill) [1995] ECR I-743, para. 50; case C-418/01 IMS Health v NDC Health [2004] ECR I-5039; case T-201/04 Microsoft v Commission [2007] ECR II-3601, in particular paras. 688 et seq. Commission Communication of 16 July 2008 on an Industrial Property Rights Strategy for Europe, COM(2008)465 final.

23 Council Regulation (EC) No 139/2004 of 20 January 2004, OJ L 24 of 29.1.2004, p. 1-22.

INDIA*

1. Introduction

The pharmaceutical industry of India has matured over the years into a major producer of bulk drugs, rated among the top five in the world. The industry is largely concentrated in the production of 'generics' on account of the Process Patent Law introduced in the seventies (repealed under the recent TRIPS Agreement). India has since been able to establish technological capability for manufacture and supplying of generic drugs. This 'generics capability' of India has attracted worldwide attention. A noticeable surge in mergers and acquisitions with either a foreign company seeking a stake in an Indian counterpart or vice versa reflects the attractiveness of what has been called as the 'platform of capabilities'[1] . Indian companies seek to expand and consolidate their platform of capabilities in their endeavor to either develop indigenous branded generics or to acquire established branded generics. Today the Indian pharmaceutical industry has become a prominent provider of healthcare. It meets 95% of the country's medical needs and constitutes about 1.3% of the world market in value terms and 8% in volume terms represented by 250 large pharmaceutical manufacturers (5 of these are in the public sector) and about 8000 small scale units. The generics pharmaceuticals sector in India have come of age, their future sustainable growth depends on ensuring competitive markets and the Competition Commission is sensitive to the differing perspectives that are inevitable to an industry so critical to life itself.

2. Brief sketch of industry pharmaceuticals

The Indian Pharmaceutical Industry is among top five producers of bulk drugs in the world. Pharmaceuticals market can be roughly classified into Bulk drugs (20% of the market) registering growth rates of 20% and formulations (80% of the market) with an annual growth rate of 15%.

There are about 8174 bulk drug manufacturing units and 2389 formulations units spread across the country. Pharmaceutical Companies Operating in India is a pool representing about 250 large Pharmaceuticals manufacturers and suppliers and about 8000 Small Scale Pharmaceutical & Drug Units including 5 Central Public Sector Units. At the time of independence, the bulk drug industry in India was in the infancy stage. Most of the bulk drugs and formulations were imported. Since then, the Indian pharmaceuticals industry has evolved through the opportunities arising within the regulated environment. The Indian Patents Act (1970) and establishment of large public sector companies for the manufacture of bulk drugs enabled the development of the pharmaceuticals industry in India.

The Indian pharmaceutical industry from being a pure reverse engineering industry focused on the domestic market, the industry is becoming research driven, export oriented and globally becoming competitive. The industry is dependent on its presence in the therapeutic segment and new categories, viz. cardiovascular, central nervous system and anti diabetic are expanding at double digit growth rates.

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* Note by Geeta Gouri. Member Competition Commission of India. The views expressed are personal and not to be taken as the views of the Commission. Any errors or omissions are entirely of the author.

1 Chris Viehbacher, CEO. Sanofi-Aventis, *Business World*., September 2009.

The generic drug companies in India have broad technological and diversified market capabilities. As more and more patents expire, the generic portion of the pharmaceutical market is expected to continue to have increased sales. Indian companies are attempting to tap the generic drug markets of the developed countries. The technological capability for manufacturing and supplying generic drugs of these companies make them major players in the international generics market. With the WTO commitment in Jan 1, 2005, to recognize foreign product patents outsourcing in the fields of R&D, contract manufacturing and co-marketing alliances have been identified by industry federations[2] as an opportunity for Indian companies. India has the best chemistry skills and low cost advantages in research and manufacturing and skilled manpower, which will attract foreign investors, apartment from encouraging basic research and drug discovery.

3. Branded Competition v/s Generic Competition

It is interesting to observe the responses of a matured generics player to competition, where large numbers of patents are expected to expire in a few years time. Few cases reported by media and newspapers, given below, provide glimpses of how Indian companies have taken legal measures to refute claims of multinational drug majors for extension of their patents.

- A case that attracted a lot of attention in India is that of the Swiss drug company Novartis. Novartis had challenged Section 3(d) [3]of the Indian Patents Act claiming immunity for their drug Gleevic , a major drug for leukemia on the pleas that the new Gleevic was a major improvement over a older version whose patent was over. This was disputed by Indian companies such as Natco Pharmaceuticals. The plea of Novartis was rejected consequently enabling manufacture by Indian generic companies. Cost estimates of the new generic drug place it at one tenth the price of Gleevic.

- In a similar case the Delhi Court rejected the petition of Bayer Healthcare, a German drug major from preventing the Drug Controller General of India giving marketing approval to Indian company Cipla for the generic version of the cancer drug Nexavar. The ruling however had a caveat namely, that if the Indian drug company is found guilty of patent infringement damages will have to be compensated by payment to Bayers.

- Cipla in another case won the right to manufacture and market the generic version of the anti-cancer drug Tarceva originally patented by the Swiss pharma company Hoffman La Roche both in Delhi Court and the Supreme Court.[4]

- Recently, Aurobindo Pharma an Indian drug pharma received USFDA approval for Risperidone Oral Solution a drug used in the treatment of mental and emotional problems. Indian companies are becoming increasingly active in the US market. In the first quarter of 2009 Indian companies had achieved 50 ANDA approvals.[5]

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2 Report of Federation of Indian Chambers of Commerce & Industries (FICCI) "Competitiveness of the Indian pharmaceutical industries in the new Product Patent Regime" in India., March 2005.

3 Section 3(d) of the Indian Patent Act forbids the patenting of derivative forms of known substances unless they are substantially more effective than the known substance. See Jayati Ghosh in her regular column 'Economic Currents'., *Deccan Chronicle.,* and also *Economic Times,* 29 August, 2009.

4 Reported in *Financial Express*., 5th September,2009 and *Economic Times*.,19th August, 2009. The price difference for example, in the case of Cipla v/s Roche, Roche sells Tarceva for Rs.4500 per tablet while Cipla's generic is sold at Rs.1500 per tablet.

5 See report on "The Indian Pharmaceutical Industry 2009"., Espicom Business Intelligence, May 2009

The European Commission investigation into the case of 'patent pooling' a commonly used tactics for prolonging the life of a patent has attracted a lot of attention in India. EU is probing into the anti-trust violations indulged by Lupin, Matrix Laboratories and Unichem Laboratories for 'knowingly delaying' the generic launch of a cardiovascular drug, Perinaopril by teaming with the innovator of the drug, Laboratories Servier.

4. History of Regulation in Pharmaceuticals

In this section we shall briefly outline the regulatory framework. The regulatory framework operates at two levels: i) licensing and ii) pricing. Licensing entails the need for manufacturers to get approval from Drug Regulatory Commissions at state-level. The Drugs and Cosmetics Act, 1940, governs the import, manufacture, distribution and sale of drugs, in India. The Drug Controller General of India (DCGI), an authority established under the Drugs and Cosmetics Act, 1940, oversees the conduct of clinical trials and is also responsible for the approval and registration of drugs, and issues manufacturing and marketing licenses for the same.

Essential drugs pricing is fixed by the Central Government. On a regular basis the list of drugs whose prices are controlled and the methodology of fixing prices is issued referred to as the Drug Price Control Order (DPCO). In the last few years only a few essential drug prices are regulated and the implementing authority as of now is the National Pharmaceutical Pricing Authority.

The Indian Patents Act (IPA), and the Drug Prices Control Order (DPCO) were both passed in 1970. Under the IPA, substances used in foods and pharmaceuticals could not be granted product patents. Only process patents were allowed for a period of five years from the date of the grant of patent, or seven years from the date of filing for patent, whichever was earlier. The introduction of the IPA provided a major thrust to growth of the Indian generics pharmaceuticals industry; and Indian companies, who through the process of reverse engineering and synthesis, began to produce bulk drugs and formulations at lower costs.

The DPCO is an order issued by the Government, under Section 3 of the Essential Commodities Act, l955, empowering it to fix and regulate the prices of essential bulk drugs and their formulations. The order incorporates a list of bulk drugs whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention, and various other guidelines and directions. The order is subject to the guidelines of Drug Policy and supposedly aims to ensure equitable distribution, increased supply, and cheap availability of bulk drugs and played a vital role in directing the pharmaceutical industry's fortunes.

The first DPCO was issued in 1970, revised in 1979, 1987 and 1995. In its introductory form, DPCO was a direct control on the profitability of a pharmaceutical business, and only an indirect control on the prices of pharmaceuticals. It stipulated that a company's pre-tax profit from its pharma business should not exceed 15 per cent of its pharma sales (net of excise duty and sales tax). In case profits exceeded this sum, the surplus was deposited with the Government. So, a pharma company had the freedom to decide the prices of its products. Product-wise margins were also flexible, so long as the overall margin did not exceed the stipulated norm. Since individual product prices did not require approval from the Government, bureaucratic hurdles were low. DPCO (1970) effectively put a ceiling on prices of all mass-usage bulk drugs and their formulations. Its primary objective was to protect the interests of consumers, and ensure a restricted but reasonable return to producers. The order was a landmark regulation and has had several implications in shaping the Indian pharmaceuticals industry.

In 1974, the Government of India (Gol) appointed a committee under the chairmanship of Rajya Sabha MP, Mr. Jaisukhlal Hathi, to inquire into the conditions prevailing in the sphere of pharmaceuticals in the country. DPCO 1979 was loosely based on the recommendations of the Hathi Committee. The revised DPCO stipulated ceiling prices for controlled categories of bulk drugs and their formulations. The

retail prices of controlled formulations were decided by applying the concept of MAPE (Maximum Allowable Post- manufacturing Expenses).[6]

DPCO 1979 put 370 drugs under price control. These drugs were segregated into three categories, having different MAPEs. The most important drugs, including life-saving drugs were put in Category I, which had the least MAPE. Through this DPCO, around 80 per cent of the Indian pharma industry (in value terms) was brought under strict price control. However, 13 Transnational Corporations (TNCs) challenged the order and succeeded in obtaining a stay on the DPCO, 1979, from High Courts and ignored the prices fixed under this. Ultimately the Government of India had to appeal to the Supreme Court, which upheld the validity of its action and directed the Government to assess and recover the amounts.[7]

In 1984, the Government constituted another expert committee to look into the issue of drug pricing known as the Kelkar Committee. The Committee recommended the exclusion of a number of drugs from the purview of price control. Various suggestions were made for determining the criteria for inclusion and exclusion.

DPCO, 1987, was based on the Drug Policy of 1986, and the Kelkar Committee Report. In DPCO, 1987, the number of bulk drugs under price control was significantly reduced from 370 to 142. In addition, the categories of control were reduced to two, and higher MAPE was provided for each category of controlled drugs (75 per cent and 100 per cent respectively). However, around 75 per cent of the pharmaceutical industry was still under price control.

In September 1994, the New Drug Policy was announced. The New Drug Policy liberalized the criteria for selecting bulk drugs, or formulations, for price control. In addition, industrial licensing was abolished for all bulk drugs. All hindrances to capacity expansions were removed, and it was expected that, as a result, supply would rise, resulting in higher competitive pressures. Foreign investment up to 51 per cent was also permitted in the case of all bulk drugs, their intermediates and formulations. FDI above 51 per cent could also be considered on a case-to-case basis. Nevertheless, five bulk drugs; Vitamin B1, Vitamin B2, Folic Acid, Tetracycline and Oxy-tetracycline were reserved for the public sector till 1998.

The latest Drug Price Control Order was passed in 1995. The basic structure of this DPCO is the same as that of the earlier orders, except that a uniform MAPE of 100 per cent was granted to all controlled formulations. Nevertheless, the span of price control, under DPCO 1995, was liberalized considerably from 142 drugs to just 76. It was under the New Drug Policy, National Pharmaceutical Pricing Authority (NPPA**)** was appointed to implement and enforce the provisions of the Drugs (Prices Control) Order 1995 in accordance with the powers delegated to it.

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6 The pricing formula was retail price = (MC+CC+PM+PC) x (1+MAPE7100) + excise duty. MC was the material cost, including cost of bulk drugs/recipients; CC was the conversion cost as per the dosage form; PM was the cost of packing material suitable to dosage form; and PC was the packaging charge calculated in accordance with established costing procedures.

7 In its judgment on April 10, 1987, the Supreme Court made a revealing observation. It discovered that Hoechst India Ltd. had fraudulently priced Earalgan Ketone, a non-essential drug. Hoechst applied for a price level of Rs. 3,500 per kg but was charging Rs.24,735.38 per kg. The Government, after analyzing the cost, fixed it as 1,810.20 per kg. Before the DPCO, Hoechst was charging a price of Rs. 24,735.38 per kg. But instead of reducing it to Rs. 1,810.20 per kg., or even Rs. 3,500 per kg., as requested of them, they continued to sell the drug for Rs. 24,735.38 per kg., under the protection of the High Court's stay order. The angered Supreme Court observed thus: *"We see that the price, of Rs. 24,735 per kg; at which the manufacturer was previously selling the drug, and at which he continues to market the drug to this day because of the quashing of the order fixing the price, by the high court; is so unconscionably high, even compared with the price claimed by itself, that it appears to justify the charge that some manufacturers do indulge in 'profiteering".*

Thus, the objective of the Government was to decontrol in order to induce increased competition and to make essential drugs affordable to the weaker sections of society.

5. Competition in the domestic market: Generics and the healthcare system

How does the 'generic capability' of Indian companies emerging as major players in the world market affect competition in the domestic market? The domestic market is very competitive with a large number of players and is characterized by several market segments. There are pure generics; branded generics, formulations, with varying degrees of combinations and permutations among large players and small players. Surprisingly despite the comparative advantage in generics the Indian market remains largely untapped with one estimate on penetration of modern medicine placing it as less than 30%. [8] This applies to the healthcare segment. The basis for competition exists. While the objective of the government to decontrol in order to increase competition the concern of the Commission is on ensuring competition and on this aspect it is worthwhile to glimpse briefly at the the dynamics of the Indian pharmaceutical sector and also the health care segment.

While the number of drugs decontrolled has increased, the maturing of the pharmaceutical industry can be seen in the wide range of drugs ranging from pure generics to branded generics enabling the consumer to exercise choice. Studies have shown that a generic controlled by DPCO required to be sold at an MRP of Rs. 7/- per strip can be marketed separately as a branded drug at Rs. 15/- per strip i.e. at double the price, often on account of variations in the chemical combinations of the branded generic as compared to the generic drug. This suggests developing universal classification systems, but there are limitations to such universality.

The choice of patients to either buy generics or branded drugs to some extent may be influenced by whether they seek to avail of the public health system or go to a private hospital and within the two systems there are again several again options. Access to drugs and healthcare is an important dimension of ensuring competition between branded generics and generics. Similarly, information available in the public domain on common drugs can also have a contributing role towards competition.

While there is range of choice open to consumers, the exercise of choice is determined by several factors but the critical factor is on the availability of information. In brief, competition as always depends on ensuring smooth and free flow of information. Towards this end the suggestions are:

Strengthening the existing regulatory system especially for enabling more detailed and universal classification of drugs and chemicals between branded generic and generic

- Strengthening the public information system where simple drugs are known to consumers
- Strengthening the public procurement process of drugs by public health system.

[8] "Indian Pharma Industry: SWOT Analysis: internet report., June ,2009

INDONESIA

Indonesia is the Country with large number of inhabitants (around 250 million people), while the public awareness to secure the availability of their own personal medicine was quite low. Compared with other countries, their expenditure for their medicine needs was around US$ 5/capita/year, lower compared to Malaysia (US$ 12/capita/year) or Singapore (US$ 40/capita/year). This condition showed that Indonesia was a potential market for pharmaceutical industrial development. However, this massive potency is not yet to be optimal facing several social-economic factors.

There was an anomaly in the pharmaceutical industrial structure in Indonesia. This shown by increased number of sales (amount of Rp. 23.6 trillion) with decreasing industrial growth (in 2000 the industry grew for 32%, while in 2005 it declined into 13.2%). At this condition, demand on drugs is also declining. The main factor of the situation was high inflation rate in Indonesia, causing significant increase in the price of raw material, logistic cost, price of production factors, and operational cost.

There were several obstacles in developing the pharmaceutical industry in Indonesia. The living standard of most Indonesian was low (low economic level), thus the fulfillment of medicines was influenced mostly by the price. Moreover, most of Indonesia people consumed the medicine as response of illness, not as preventive actions to maintain their health. In Indonesia, doctor had the authority in determining the type of medicine for the patients, but some of them were absent in providing clear information of the prescription. The consumer (patients) did not have any options but redeemed the prescription. The lack of knowledge and health awareness (which determined by economic factor) made the Indonesian tends to ignore their medicine need and consumed the medicine in inexact manner.

From the economical price point of view, the drugs price in Indonesia was expensive and the price structure was not yet transparent. The WHO research showed that the price of certain drugs with different brand and same content had significant selling price differentiation. There was also insufficient information on the determination of the drugs price.

Therefore, in ways to overcome obstacle in drug's supply, the government (Ministry of Health) issued several regulations on generic drugs and ceiling price for over the counter drugs. In this regards, the government tries to make the drugs available for the society at reasonable price.

1. Patent and generic drugs

Generally, available drugs are categorized into type and formula contain in the medicine. In Indonesia, we acknowledge two types of drugs, namely patent drugs and generic drugs. Patent drugs are medicines with certain trademark produced by the pharmacist based on newest research and latest invention in pharmaceutical. For further development, producer obtain royalty fee as result of their innovation. This exclusive right often uses to finance the follow-up research. In Indonesia, the patent right is applicable for twenty years before its expiration.

Generic drugs are medicines produce as mass production using expired patent drugs (off-patent drugs) and could be produced by any pharmacist. In Indonesia, the off-patent drugs are often found still owned by the pharmacist who is invented the drugs. Furthermore, Indonesia also acknowledge term of "branded

generic", an off-patent drug with additional chemical (such vitamin and such), other than common generic drugs which printed its chemical name or its international nonproprietary name.

2. Drugs price formulation

As one of the industrial commodity, the formulation of drugs price is similar to other commodity. They also determined by its operational cost, material cost, labour cost, taxes, marketing cost, and other relevant costs. Distribution or marketing cost plays important rule in fixing the drugs price in Indonesia. Therefore, to avoid consumer exploitation behaviour, the government (by the Minister Decree) always determined specific price for generic drugs price in Indonesia and evaluating them for every two years. Example of price structure for branded generic drugs in Indonesia is as follows:

Table 1

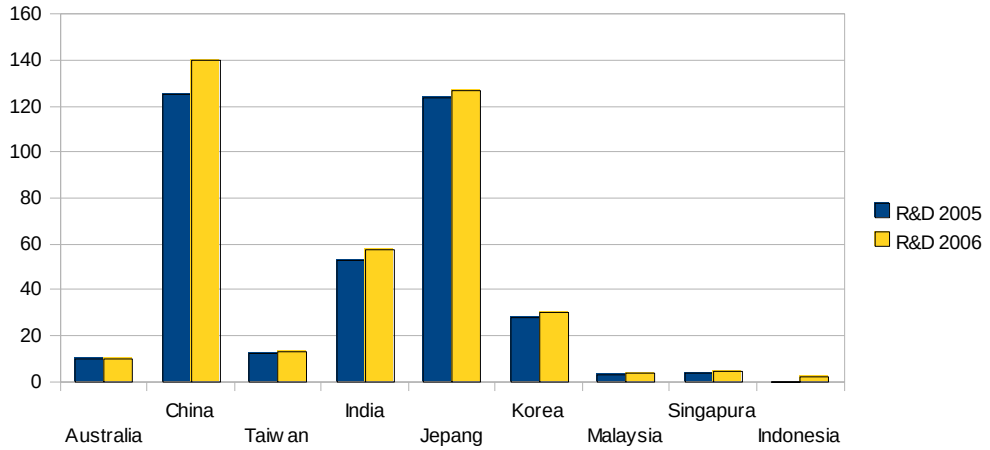
Cost Component	Percentage from Production Cost
Cost for import	
Material cost	40.73
Import tax	2.04
Price before VAT	42.77
VAT	4.28
Logistic cost	2.04
Total cost for import	49.08
Production cost	20.37
Processing cost	8.15
Additional material cost	6.11
Packaging cost	16.29
Marketing cost	100
Total production cost	
Producer's price (30% margin)	130.02
Retailer's price (75% margin)	227.54

Source: YPKKI, 2006

For patent drugs price, the price is affected by overall production and distribution value. However, due to unique feature of patent drugs, the government provides incentive in term of patent right and exclusive right to determined its owned price. Thus, therefore the patent price is relatively high to compensate their research and development cost. However, there is also a tendency showed that research and development cost in Indonesia is lower compare to other countries.

Generic price drugs are determined by industrial mechanism as patent drugs. However, due to the generic drugs are merely off-patent drugs, therefore there is no compensation for their research and development. Generic drugs price also fix by the government to ensure its availability for consumer, especially low and middle society, at the lowest price. Moreover, in the determination of drugs price, compensation for R&D cost also allocated, thus could create higher price. However, compare with international samples, Indonesian allocated cost for R&D is relatively low. This condition is shown by chart beneath.

Table 2



Source: GP Farmasi, 2006

This could be observed that that pharmaceutical industry is an industry with intense technology and capital industry that require huge financing for their development. However in Indonesia, research and development cost in pharmacy for 2005 and 2006 just at 0.1 – 1.89% from the GDP. It shows that Indonesia's pharmaceutical companies tend to import off-patent drugs and add some new substance to change the content changed, and thus registered as a new drug.

Moreover the competition in the Indonesia's pharmaceutical industry tend be monopolistic, where 20 largest companies controlled around 54% of the market, while 60 largest companies controlled around 84% market, Other 139 companies contested approximately 10% of the available market. The market share of the biggest business actor is relatively small with less than 11%. Cost spent for R&D also quite low compare with other foreign company. Most of their costs are allocated for their marketing, through detailing system to doctor, pharmacist, seminars, workshops, and several direct selling events to attract consumer.

3. The marketing method for medicines in Indonesia

Both patent and generic drugs are available in Indonesian market. Patent drugs are distributed through structured line of distribution to the pharmacy. Detailing system also favorable in the drugs, especially when it prove to be effective to capture certain consumer. Branded generic also develops by the pharmaceutical company, hoping when the patent license is expired and become a generic drug. The company will constantly obtain consumer loyalty through existing brand building.

Branded generic drugs are distributed using conventional marketing system through pharmacist and convenience store. In order to success with the system, the producer shall create intensive promotional strategy to build the brand image of their medicine. As for the generic drugs, direct sales mechanism through Society Health Center (Puskesmas) is more favorable. In this system, effective marketing and direct selling system with clear target market will reduce marketing cost, and consequently will increase firm's profit. However, in conventional marketing, besides high cost in promotion, it also involves distribution chain from producers to consumer. In which the wide range of selling chain of generic medicine from producer, distributor up to pharmacy shop could cause high cost on marketing.

4. Problems in developing generic medicine

From aforementioned, even though Indonesia has large population and majority is at low to medium economic level, it should be a potential market opportunity for developing generic drugs that focuses on low price. In fact, the development of generic drugs faces many obstacles. The main problem is inflation causing materials price also increase significantly. Moreover, the inflation factor encourages production cost, labor and other related factors. Producer of generic drugs cannot adjust the price based on market condition.

There are several factors which producer "can not" adjust their drugs price with inflation rate. Producer of generic drugs produces medicine with market segment addressed to certain price rate. Thus, when general price for generic drugs will adjusted with the market condition, it makes the producer for facing condition on potential switched consumer correspondence to their new price that beyond the customer threshold.

There is also regulation from the Ministry of Health that regulates the ceiling retailer price for generic drugs in market. Under this regulation, the pharmaceutical company could not easily adopt its new price on inflation rate and market condition. In this context, sustainability of pharmaceutical industry is limited, where the increase of production and operational cost in industry is insignificantly followed by the increase sales value. If this condition keeps continually, the sustainability of the pharmaceutical industry will be in critical situation.

Moreover, the marketing system of generic drugs that utilizes the conventional marketing method by relying on the network of the Society Health Centre (Puskesmas) or branded generic drugs that sold freely in retail shops, also made generic drugs to be only could cover certain consumer, without involving doctor to decide the type of medicine. This mechanism make the distribution of generic drugs is not well developed. Moreover, in promoting generic drugs to the consumer, the generic drugs also could use other promotional method through the media, which need high promotional cost. Patent drugs are distributed through complex distribution system involving pharmacy and detailer. Generally, the patent's owner due to their ability to generate its own price and strategy to win the market and executes the detailing system.

The next challenge is the low consumer knowledge in health and medicine, which could be abused by doctors or hospitals in determining certain medicine to patient. The code of ethic in health industry obliges doctor to provide generic name in its prescription. However, some doctors or hospitals having cooperation with certain business actor could prioritize the use of the producer's product for their own future benefit. There is also condition in which the pharmacy is not having authority in amending the prescription and suggesting other medicine with similar chemical contents. Ethical drugs are commonly placed in the pharmacist office, not in the counter. This could limit consumer's ability to compare medicines and strict to prescription determined by their doctor or hospital.

In this regard, the flow of distribution is relatively high due to the ability of pharmacy to conduct transaction analysis on their inventory. In contrary, the distribution of generic drug will be stable or declining. Due to its limited consumer with fixed price, the pharmacy did not have flexibility in distributing unfavorable generic drugs.

5. Solution for further development in generic drugs

Generic drug is one of solution by lower income society for their health assurance. However, some challenges in producing the medicine will lessen incentive for producer to make the medicine. This in the end could diminish choices for the society for a cheaper medicine. Therefore, several steps need to be made in saving the Indonesia's generic industry.

The existing government regulation on ceiling price for generic drugs will ensure supply for society needs period. However, in contrary, this will unfavorable to producer when facing high inflation rate. Therefore, some incentives (such taxes deduction) from the government are need to encourage business actor to enter the generic drugs industry. Distribution will entirely depends on demand and supply in the market, thus adjustment in this regard is less favorable. Some changes might need in facilitating pooling system for generic drugs prior to its distribution. This massive distribution center surely will create more efficient distribution system for the generic drugs.

The producer and hospital could abuse low awareness of society through detailing system. This could be avoided with a government regulation on pharmacy's authority to suggest amendment for prescription with other relevant generic drugs. This surely will also increase the capacity of pharmacist.

It expected that, the generic and patent drugs industry will inline with its respective relevant market without limiting the distribution channel of patent drugs. The final goals is to provide easiness for the business actor and provide achievable drugs price in supporting the livelihood of society at large.

RUSSIAN FEDERATION

According to the experts estimates the share of generic pharmaceuticals on the whole Russian pharmaceutical market varied from 61% to 78-95% during 2007-2008.

The generic pharmaceuticals promote competition development on the pharmaceutical market through price reduction, development of innovation products which would be protected against competition with generic pharmaceuticals during validity of the patent, improvement of branded products which were already registered. It can be mentioned that extension of the range of pharmaceuticals is mainly caused by entry of new products with new pharmaceutical form (effervescent tablets, sanative band aids, etc.) or with new strength (for example, "No-Shpa forte", etc.).

The proportion between the branded and generic pharmaceuticals in Russia decreases due to reduction of share of the non-branded generic pharmaceutials. The generic pharmaceuticals accounts for 50% of manufacturer total sales, among these manufacturers are such large companies as "Pharmstandard", "National medicines", "Verofarm", "Sintez AKO", "BIOTEK" and "Nizhfarm". The share of the branded generic pharmaceuticals in portfolios of these companies is growing.

In order to develop competition to provide Russian citizens with qualitative, modern and available pharmaceuticals the FAS Russia undertakes measures of legal control over pharmaceutical market including generic pharmaceuticals segment.

Nowadays the FAS Russia has prepared proposals and observations for the draft of the Federal Law "On medicaments turnover". Thus, according to the FAS Russia's proposal the legal provision which assumed to implement the mechanism on protection of data of preclinical and clinical studies of pharmaceuticals during six years after the moment of its public registration, was excluded. The FAS Russia considers that realization of this legal provision will favour maintenance of the monopolistic position by producers of pharmaceuticals over the rather long term which could lead to restriction of competition and considerably reduce number of rather cheaper generic pharmaceuticals on the Russian market as the protection of data of preclinical and clinical studies will not allow to use the procedure of rapid registration.

Moreover the FAS Russia takes a stand against the legal provision which prohibits the public registration of single pharmaceutical (duration of patent of which was over) under different trade marks which will have a negative impact on competition development on the relevant product markets and on the price reduction.

In accordance with its competence the FAS Russia takes active part in the preparation of the Concept of development of public healthcare in the Russian Federation up to 2020 (hereinafter – the Concept) which also contains the topics related to the development of the pharmaceutical market.

Nowadays, in particular, the FAS Russia believes that the procedure of registration of pharmaceuticals and medical products contains the administrative barriers (unreasonable duration, nontransparency in the performance of documentation expertise; absence of preferences for rarely applicable pharmaceuticals) that restrict competition. According to the FAS Russia's opinion the main reason for non-observance of term

for registration of pharmaceuticals lies in artificial division of registration function and pre-registry expertise of pharmaceuticals.

The FAS Russia supports introduction of obligatory medicinal insurance alongside with strengthening of doctor's responsibility for unfounded prescription of medicines through introduction of joint liability of doctor and respective preventive treatment agency in order to eliminate corrupted selection mechanism of prescription of products produced by the certain lobbied pharmaceutical company.

At present time the Draft Strategy of development of pharmaceutical industry in Russia for the period up to 2020 (hereinafter – the Draft Srategy) is under consideration together with the pharmaceuticals producers and interested auhtorities. The Draft Strategy is based on the economic assessment that takes into account the long-term changes both on the local and global pharmaceutical markets and assumes the creation of terms for rather active participation of domestic companies on the generic market at the first stage and development of new medicine. The next step is realization of accumulated experience for production of owned innovation products. As a result of implementation of the Strategy up to 2020 it is expected to increase the share of domestic products up to 50% in value terms in general amount of consumption on local level.

Also the Draft specifies modification of manufacture range of pharmaceuticals made in Russia including the increase of share of innovation products up to 75% in value terms in the portfolios of local producers.

SOUTH AFRICA

1. Introduction

The Competition Committee of the OECD invited contributions for the roundtable discussion on competition issues involving generic pharmaceuticals. This paper provides a background to the regulation of generic pharmaceuticals in South Africa and discusses two cases (an enforcement case and a merger case) where South Africa's Competition Commission ("Commission") required firms to extend licences to generic firms.

2. Background

2.1 The National Drug Policy for South Africa

Section 27 of the Constitution of the Republic of South Africa (Act 108 of 1996) recognizes that all South Africans have a right to healthcare services and imposes the duty on the state to take reasonable legislative and other measures to realise this right.

In line with this, South Africa's National Drug Policy ("NDP") was published in 1996. The NDP was government's way of "ensuring an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa and the rational use of drugs by prescribers, dispensers and consumers". In order to promote the availability of safe and effective drugs at the lowest possible costs, the NDP recommended that the legislation governing the manufacture, distribution, sale, and marketing of medicines in South Africa, namely the Medicines and Related Substances Control Act, (Act 101 of 1965) be strengthened by amendment; a Pricing Committee[1] be established within the Ministry of Health to monitor and regulate drug prices; and also recommended the use of generic drugs.

2.2 Definition of generic drugs

Act 101 of 1965 was subsequently amended by the Medicines and Related Substance Control Amendment Act 90 of 1997 ("Medicines Control Act"). Section 22F of the Medicines Control Act refers to "generics" as interchangeable multi-source medicines ("IMSM"). IMSM is defined in the Medicines Control Act as "medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards which comply with the requirements for therapeutic equivalence as prescribed".

2.3 The Pharmaceutical Manufacturer's Association case against the South African government

The amended Medicines Control Act was intended to make medicines more affordable with provisions that compelled pharmacists to implement generic substitution, allowed for parallel importation, allowed for government to issue compulsory licences under certain conditions to local producers of generics of patented medicines, and introduced a transparent pricing mechanism to ensure that pharmaceutical companies were able to justify the prices they charged.

[1] The Pricing Committee was only established in terms of section 22G of the Medicines and Related Substances Control Amendment Act 90 of 1997 on 2 May 2003.

However, in 1998, the Pharmaceutical Manufacturer's Association, along with about 38 pharmaceutical manufacturing companies, brought an application in the High Court of South Africa against the South African government to prevent certain provisions in the Medicines Control Act from coming into effect. Most significantly, the pharmaceutical manufacturers objected to section 15C of the Medicines Control Act which permitted parallel importation and compulsory licensing. The pharmaceutical manufacturers contested the constitutionality of section 15C arguing that it gave the Minister of Health the power to override South Africa's Patents Act by an administrative act. The Patent Act grants a patent term of 20 years from date of application for a patent. The pharmaceutical manufacturers also contended that section 15C was contrary to article 28 of the Agreement on Trade-Related aspects of Intellectual Property Rights ("TRIPS"). TRIPS obliges all World Trade Organization members states (which includes South Africa), to amongst others, grant patents for a minimum of 20 years for pharmaceutical products. The South African government in contesting the application relied on article 8 of TRIPS which allows members to adopt measures to protect public health.

This case drew international and local attention with widespread condemnation of the actions of the pharmaceutical companies who were seen as preventing access to cheaper and essential medicines. There was extensive lobbying against the application of the pharmaceutical firms. A non-profit organization, the Treatment Action Campaign ("TAC") which advocates for access to cheaper medicines for people living with HIV and AIDS, joined the High Court application as *amicus curiae*.

The TAC was active in lobbying for generic competition in order to reduce the costs of medicines. To illustrate the huge discrepancies in the pricing between the cost of original and generic drugs, the then leader of the TAC, Mr Zackie Achmat, smuggled 5000 Biozole tablets in South Africa. Biozole is a generic medicine used to treat opportunistic infections from HIV such as oral thrush. It is a generic version of fluonazole, sold in South Africa as Diflucan and manufactured by Pfizer. At that time, fluconazole was patented and a single tablet was selling as R124 (U$16) in South African pharmacies whilst government was paying R28.57 (U$3.71) per tablet. Mr Achmat bough the generic tablets from Thailand at a cost of R1.78 (U$0.23) each. [2]

In 2001, the pharmaceutical firms withdrew the application after facilitation from the Secretary General of the United Nations Kofi Anan and President Nelson Mandela. In a joint statement of understanding the firms and government agreed to co-operate to accelerate access to care and treatment of diseases the affect the health of the South African population. The parties committed to work together and consequently the Minister of Health agreed to a working party from the pharmaceutical industry to consult on provisions of the Medicines Control Act, in particular section 15C. The government also reiterated its commitment to honour its international obligations including those under the TRIPS agreement. The return, the pharmaceutical industry recognized that government may enact national laws or adopt measures necessary to protect public health and broaden access to medicines in accordance with the Constitution and TRIPS.

2.4 The promotion of generic substitution

The Medicines Control Act subsequently introduced generic substitution as law in 2003. In terms of section 22F of the Medicines Control Act, a pharmacist must inform all members of the public who visit his who visit his or her pharmacy with a prescription for dispensing, of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine; and dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so. A

[2] Kahn,R. 2008. A sick state – access to medicine in South Africa. Available from http://icommon.org/articles/a-sick-state-access-to-medicine-in-south-africa. Accessed on 5 October 2009.

pharmacist shall not sell an interchangeable multi-source medicine if the person prescribing the medicine has written in his or her own hand on the prescription the words 'no substitution' next to the item prescribed; if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or where the product has been declared not substitutable by the Medicines Control Council ("MCC"). The MCC is a statutory body established in terms of the Medicines Control Act to oversee the regulation of medicines in South Africa, to safeguard and protect the public through ensuring that all medicines that are sold and used in South Africa are safe, therapeutically effective and consistently meet acceptable standards of quality.[3]

2.5 Price regulation

In 2004, in striving to ensure transparency in medicine pricing and following the discovery of excessive secret rebates passing between manufacturers and private hospitals, the South African government introduced a single exit price ("SEP") for generic and branded medicines and put a stop to discounts and additional levies on medicines. The medicine pricing regulations provided only for the addition of a dispensing fee to the SEP. In terms of the SEP pricing regulations, pharmaceutical manufacturers must annually submit applications for price increases to the Minister of Health. The Department of Health ("DoH") must then approve these price increases within 30 days of receipt of an application by the manufacturer.

According to the DoH, the introduction of the SEP resulted in an average reduction in medicine prices of 19% in South Africa. The SA Health Review of 2007, published by the Health Systems Trust, stated that before 1994 medicines were the single largest category of medical aid expenditure at nearly 32% and now account for only 16%.

3. Cases

This section discusses two key cases to illustrate how the competition authorities have imposed conditions to promote generic competition in the market.

In the 2002 enforcement case of Hazel Tau and others v Glaxosmithkline South Africa (Pty) Ltd ("GSK") and Boehringer Ingelheim ("BI"), the Commission found that the manufacturers of branded ARV medicines (innovators) were unjustifiably impeding competition in the market and required them to licence their drugs to generic manufacturers. The pharmaceutical companies concluded a settlement agreement with the Commission before the matter was referred for adjudication.

In the 2009 merger between GSK and Aspen Pharmacare Holdings Ltd ("Aspen"), the Commission found that the merger posed a threat to generic competition in the treatment of HIV/AIDS. Despite this, the merger passed other legal tests for approval. The Commission was nevertheless able to impose a condition that GSK grant a licence to a number of generic manufacturers to manufacture the drug *Abacavir* and in that way ensure better access to life saving treatment.

3.1 The Hazel Tau case

In 2002 Hazel Tau, a person living with HIV, and others filed a complaint alleging that GSK and BI had contravened the Competition Act by charging excessive prices for their patented ARV medicines used to treat HIV/AIDS. GSK held patents in South Africa on AZT (branded as Retrovir), Lamivudine (branded as 3TC) and AZT/Lamivudine (branded as Combivir). BI held patents in South Africa on Nevirapine (NVP) (branded as Viramune). At that time both GSK and BI had refused to grant voluntary licences to

[3] www.mccza.com.

generic manufacturers, despite numerous applications. The complainants sought to compel the respondents to license these ARV medicines to generic manufacturers.

Following an investigation, the Commission developed a case that both GSK and BI had contravened the Competition Act by (1) charging excessive prices; (2) refusing to grant a competitor access to an essential facility; and (3) engaging in exclusionary conduct. Before the Commission could refer the case to the Competition Tribunal for prosecution, GSK and BI decided to settle the case and agreed to:

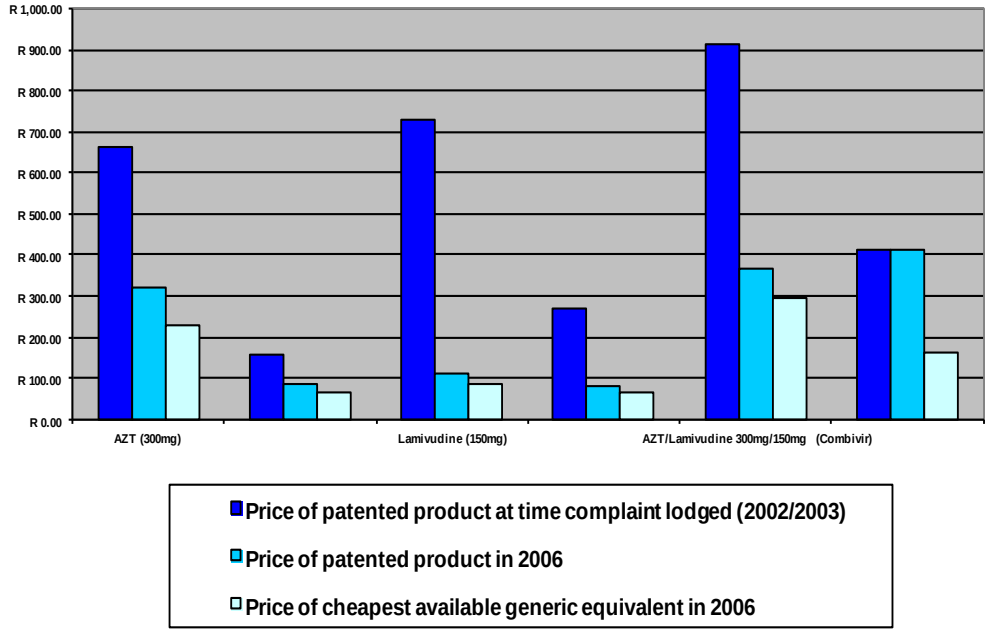
- Grant licences to generic manufacturers;
- Permit the licensee's to export the relevant ARV medicines to sub-Saharan African countries;
- Where the licensee did not have manufacturing capability in South Africa, permit the importation of the ARV medicines for distribution in South Africa only, provided all the regulatory approvals were obtained;
- Permit licensees to combine the relevant ARV's with other ARV medicines; and
- Not require royalties in excess of 5% of the net sales of the relevant ARV's.

Both GSK and BI settled subject to an undertaking that the Commission would not insist on an admission of guilt or an administrative penalty of any sort. As a consequence of the settlement, GSK concluded 8 licence agreements of which 6 directly related to the South African market and BI concluded 3 licence agreements in total.

A study conducted by the Treatment Action Campaign (TAC), a HIV/AIDS activist group, in 2006 demonstrated the impact of the above settlement in the market for ARVs.

Figure 1 below compares the prices of patented ARV's at the time of the complaint (2002) with the 2006 price of the patent ARV's and the cheapest available generic equivalent at that time.

Figure 1: Price comparisons (excluding South Africa's value-added tax)



Source: TAC study on ARV prices, 2006

3.2 The GSK / Aspen merger

During 2009 the Competition Commission had to consider the transaction between Aspen and GSK. In terms of the transaction filed in South Africa (which formed part of a broader international transaction) Aspen, a generic pharmaceutical company, acquired control over the pharmaceutical business of GSK in South Africa. In return GSK became the single largest shareholder in Aspen holding 16% of the entire issued share capital of Aspen. The Commission considered the likely effects of this merger under current market conditions as well as on potential competition in the future.

3.2.1 Analysis of the merger under current market conditions

The Commission analysed the existing product portfolio of the parties in order to determine whether the transaction would likely substantially prevent or lessen competition in any of the markets in which they currently compete. The Commission identified product overlaps within sixteen ATC3 categories and found that, even though the combined market shares in some of these products are high, there is sufficient competition in these markets to satisfy its concerns that there would be a substantial lessening of competition.

The Commission was however concerned about the market for an ARV, *Abacavir*, for which GSK held a patent and Aspen was granted an exclusive licence. *Abacavir* is used for the treatment of children with HIV. At the time of the merger, GSK was the only supplier of this product in South Africa. The Commission raised a concern with the merging parties in relation to their expressed commitment to licence *Abacavir* to Aspen and the uncertainty in relation to other generic firms obtaining this licence on the same terms as Aspen.

3.2.2 Analysis of potential competition in the future

GSK has about 20 patented products that will be coming off patent within the next five years. When this happens GSK will face competition from generic manufacturers for their expired patented drugs. The Commission had to consider whether Aspen's removal as a competitor would have an effect on the competition that GSK was going to face from generic manufacturers at the expiry of these patents.

The Commission took note of a recent trend of mergers globally in the pharmaceutical manufacturing sector. There have been several mergers between originator companies (Pfizer & Wyeth and Schering Plough & Merck) and the originator and generic companies (Sanofi Aventis & Zentiva). The Commission also noted from the EC Pharmaceutical Sector Inquiry Report, published in July 2009[4], that *"many larger originator companies are investing in the growing generic market by taking over generic players"*. Originator companies are undergoing a phase of transition with their high revenue generating products expiring, R&D costs increasing, and novel medicines declining. These trends have reduced profits, and as a result, some originator companies have acquired generic companies to, "*diversify their risk structure and…create opportunities to enter into new geographic markets*". The EC Report also makes reference to exclusive agreements entered into between originator and generic companies for the sale/distribution of generic medicines that were concluded before the originator companies lost exclusivity, possibly in anticipation of *"generic competition or to react to the presence of a generic company".*

The Commission considered whether the merger would have substantially prevented or reduced potential competition between Aspen's pipeline products and GSK's products coming off patent, within the next five years. In each of the ATC categories coming off patent in the next five years, the Commission found that there was likely to be sufficient competition from other generic manufacturers both in South

[4] European Commission, *Pharmaceutical Sector Inquiry: Final Report*, 8 July 2009.

Africa and internationally. This would prevent the merged entity from substantially lessening competition in the future.

In addition, of the GSK patented products, only 9 (5%) will be included in the 166 pipeline products of Aspen. It is therefore unlikely that the overall generic strategy of Aspen will be affected by the merger, with respect to the majority of non-GSK products. Aspen will continue to manufacture and compete for other originator companies' off patent products.

3.2.3 The Commission's decision

To address the Commission's concerns regarding *Abacavir*, GSK subsequently decided to extend the voluntary licences to Adcock Ingram, Cipla Medpro, Ranbaxy, Biotech Laboratories and Feza Pharmaceuticals and provided the Commission with signed copies (by GSK) of the licensing agreements on 27 August 2009. The Commission was of the view that the undertakings and licensing offers made by GSK to the various generic firms would sufficiently address the potential competition concerns arising from this merger in relation to *Abacavir* and subsequently approved the merger subject to the condition that GSK licence *Abacavir* to the identified firms and other interested parties on terms no less favourable than those offered to Aspen.

4. Conclusion

The promotion of generic competition is important in ensuring that South Africans have access to low cost and affordable medicines. The Commission's assessments did not view intellectual property rights as being beyond competition scrutiny. Rather, the exploitation of these rights is assessed against competition principles and the benefits they provide to end-consumers. Where the conduct of manufacturers of innovator drugs results in abuse of patent rights (such as in the Hazel Tau case) or potentially threatens access to treatment (for example in the GSK/Aspen merger), the Commission imposed remedies that required originator companies to out-licence their patented products to generic manufacturers.

BIAC

1. Introduction

The research-based pharmaceutical industry is one of the leading global high technology industries spending more on research and development (R&D) than any other industry.[1] It is a strategically important sector in terms of public health, economic growth, and employment. The industry in Europe directly employs about 635,000 people, of which 117,000 work in R&D. Direct employment in the US is over 686,000 with an estimated 3.2 million jobs indirectly tied to the sector.

The generic industry also plays an important role: increased competition on prices when products lose exclusivity enables sustainable treatment of more patients with less resources, and creates financial headroom for the funding of speedier patient access to innovative medicines. BIAC supports swift generic entry on originators' loss of exclusivity and policies that facilitate generic uptake and effective competition among generic producers.

BIAC welcomes the broad scope of the Roundtable agenda and the opportunity to provide its views on the functioning of competition in the pharmaceuticals sector, and as it relates to generic pharmaceuticals in particular. It is only through taking a holistic view of the need for coherent public policies that recognize the importance of R&D incentives, strong and effective intellectual property rights, and swift patient access to life-saving drugs, that the pharmaceutical sector will thrive and be in a position to continue to contribute effectively to the health and wealth of citizens in Europe and beyond.

This paper focuses on the following key issues:

- The importance of intellectual property rights for dynamic competition in the pharmaceutical sector;
- The highly regulated nature of pharmaceutical markets and the impact on competition;
- The functioning of off-patent markets and the factors that influence generic market entry; and
- The rationale for settlement agreements in disputes between originator and generic pharmaceutical companies.

[1] European Commission 2007 EU Industrial R&D Investment Scoreboard, October 2007, p. 12. The scoreboard considers the world's top 1,400 companies with R&D spend over a minimum threshold comprising the top 400 EU and 1,000 non-EU companies. In Europe, the industry spends about 18% of sales on R&D. A 2006 Congressional Budget Office report similarly found that the US biopharmaceutical industry leads the nation in terms of R&D spend (Congressional Budget Office Research and Development in the Pharmaceutical Industry (Washington, D.C. CBO, October 2006)). In 2008, 20.3% of sales by biopharmaceutical companies was invested in domestic R&D (Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 2009 (Washington, DC: PhRMA, April 2009)).

2. The importance of intellectual property rights for dynamic competition in the pharmaceutical sector

The costs of developing and launching a new pharmaceutical product are extraordinarily high and are estimated to have increased almost ten-fold between 1975 (USD 138m) and 2006 (USD 1.318bn).[2] It is widely recognised that strong intellectual property protection is the cornerstone of pharmaceutical innovation.[3] Without sufficient patent protection, innovators will not create the new drugs which generics, in due time, will copy. Patent protection also creates the incentives that drive the race by innovators to be the first to develop products to exploit a scientific discovery, knowing that their rivals may be pursuing parallel research.[4]

Patent portfolios are established over time and reflect new compounds studied and the technical hurdles overcome in the course of the 10 to 15 year drug development process. A variety of patentable new formulations, combinations, forms or uses may be developed during this time. These later patents reflect the continuous innovative process and are common in any high technology industry. It is axiomatic that there can be no double patenting of the same invention: once the protection of the originally marketed product expires, the system facilitates generics' copying of the medicine.

R&D funding – in a sector where development costs are extraordinary and only two out of 10 new molecular entities reaching the market are commercially successful – requires the ability to obtain, enforce and defend a patent.[5] Under prevailing regulatory systems, patents are properly granted only after expert scrutiny and the patent system provides ample legal remedies to seek to oppose, revoke or obtain declaratory judgment in respect of a patent. Patent rights are intangible and are of no value if the right holder cannot enforce them by seeking effective protection in the courts: the Commission's sector inquiry report recognises that patent enforcement through the courts is a fundamental right guaranteed by the European Convention of Human Rights.[6]

The sector inquiry report also acknowledges the fundamental importance of patent protection to encourage high-risk R&D investment and the importance of dynamic efficiencies – the gains that result from technological change and new breakthrough products; in other words, the competition for innovation.[7] Against this background, BIAC welcomes the Commission's statement that it will abide by existing case law according to which the exercise of intellectual property rights can only be a competition law infringement in exceptional circumstances.[8]

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2 The Cost of Biopharmaceutical R&D: Is Biotech Different? J.A. Di Masi and H.G. Grabowski, Managerial and Decision Economics 28 (2007): pp.469-479 (calculated in year 2005).

3 Competition, Patents and Innovation, OECD 2 January 2008, page 209 ("[F]or certain sectors like the pharmaceutical sector, patents are recognised as being very important for the appropriation of the revenues from innovation"). The European Commission's sector inquiry final report of 8 July 2009 notes that the window of exclusivity increased by 3.5 years from an average of 10.5 years in 2000 to 14 years in 2007. Even if this period of exclusivity is maintained, which is open to doubt, it is still shorter than the period intended by the legislature of 15 years of effective protection.

4 The Economics of Follow on Drug Research and Development: Trends in Entry Rates and Timing of Development, Joseph DiMasi and Cherie Paquette, (2004) Pharmacoeconomics, v. 22, supp. 2, pp. 1-14 (Referring to a "development race for drugs in a new therapeutic class.").

5 Vernon, J., Golec, JH., and DiMasi, J. Health Economics Letters: Drug Development Costs When Financial Risk Is Measured Using The Fama–French Three-Factor Model. *Health Economics*; June 2009. www.interscience.wiley.com.

6 Sector inquiry Communication, section 3.2.2 on patent-related exchanges and litigation.

7 Sector inquiry Communication, p. 2 on the key role of innovation.

8 Final report of 8 July 2009, paragraph 1568.

3. The highly regulated nature of pharmaceutical markets and the impact on competition

In Europe and in many other countries, competition in pharmaceutical markets must be assessed against the backdrop of state controls operating on both the supply side (to control prices[9] or volumes) and demand side (to control demand from physicians' prescribing budgets or patients' co-payment incentives).[10] The fragmented and complex nature of these price, supply and expenditure controls have long been a cause for concern in relation to innovation and competition. They tend to under-reward innovators whilst failing to reap the benefits of an efficient generics market: year on year price cuts, price freezes and paybacks signal that healthcare buyers are not prepared to fund new medicines or to create a climate for such investment. A World Health Organisation report has observed that this "unpredictable lottery" of price controls in Europe "has a direct effect on which medicines are produced by innovator companies."[11]

In particular, the grouping of new innovative products together with less effective rivals, including unpatented or generic products within a therapeutic reference class for reimbursement purposes, signals to innovators that the advantages of the patented drug (suitability for patient groups resistant to other drugs, better safety or efficacy profile or reduced side effects) are not valued. Therapeutic reference pricing, coupled with the use of cost effectiveness assessments as a tool for rationing, pricing and reimbursement, are perhaps the biggest threat to new investments in novel treatments.

The competitive impact of these state controls is felt not only by innovators, but also, at a later stage, by generics. If price controls are set at a level that undervalues the patented drug, there will be insufficient margin to encourage generics companies to enter the market. In the long run, the efficiencies of a competitive off-patent market are replaced by less efficient state regulation of prices. Moreover, the use of reference pricing tends to set a floor rather than a ceiling since generic entrants tend to price at the top of the state reference price[12] suggesting that the normal interplay of market forces would be more likely to result in significant price reductions and more effective cost containment.

Striking the right balance between the desire for cost containment and the need to ensure incentives for continued innovation is not easy but must be achieved if innovation is to thrive. The industry is working with governments around the world and with the EC institutions at many levels (inter alia, the G10, the High Level Pharmaceutical Forum and IMI) to establish a clear roadmap for creating a climate for innovation and addressing the inefficiencies caused by state controls. BIAC welcomes the OECD's engagement in this complex debate.

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9 Simply the process of pricing and reimbursement decision-making can delay market entry for both originator and generic products for as long as 18 months in some countries, to be contrasted with those countries where no formal bar to accessing the market exists (e.g., the US, Germany and the UK).

10 Report for the DG Competition: Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States, Österreichisches Bundesinstitut für Gesundheitswesen ("ÖBIG Report"), July 2006; Report for DG Enterprise: Analysis of Differences and Commonalities in Pricing and Reimbursement Systems In Europe, Andalusian School of Public Health, June 2007 ("ASPH Report").

11 Priority Medicines for Europe and the World, World Health Organisation, November 2004, p. 104. The distorting effects of state controls are also amplified where price controls that undervalue the innovative medicine have extraterritorial effect: (i) by means of wholesaler arbitrage in potentially all higher priced countries where the vast majority of the price differences are kept by intermediaries; and/or (ii) in potentially any state, whether in the EU or elsewhere, which uses international price referencing.

12 International Prices and Availability of Pharmaceuticals in 2005, Patricia Danzon and Michael Furukawa, Health Affairs, Vol. 27, No. 1 (2008), pp. 230-231. These findings are corroborated by the econometric analysis carried out by the Commission as part of its sector inquiry (final report, paragraphs 1477-1480).

4. How off-patent markets function and the factors that influence generic market entry

The innovator model of pharmaceutical competition is characterized by costly upfront investments, limited prospects of products reaching the market and producing a return, strict price controls imposed by state buyers, and reimbursement policies that significantly delay market access and diminish the value of intellectual property. Generic entry requires access to limited capital, but little or no investment in invention or innovation although, increasingly, generics are developing new formulations, dosage forms and delivery methods since such products are more likely to receive rapid regulatory approval and have the potential for higher reimbursement rates. Generic companies also pursue patent strategies to protect their products.[13]

Generic entry is actively facilitated by the legal framework once the innovator's exclusivity period expires. Because the patent discloses the invention in a way that enables copying and the exclusivity period provides a body of experience, extensive pre-clinical and clinical trials are not required. Marketing authorisation can be obtained on the basis of an abridged data package demonstrating that the copy is accurate (with the same qualitative and quantitative composition in active substances and same pharmaceutical form) and bioequivalent to the reference product. There are other measures to facilitate speedy generic approvals: generics can usually refer to and rely on the innovator's safety and efficacy trials data; generics are permitted to conduct bioequivalence studies or trials necessary to obtain market authorisation even prior to patent expiry,[14] etc.

The consequence is that generic companies can enter the market very swiftly after the originator's exclusivity expires. Looking at the medicines which lost exclusivity protection in 2000-2007, the data show that products representing approximately 85% of the value of pre-expiry sales in the main five European markets are subject to generic competition. Of these, approximately 70% faced entry within three to four months.[15] In 2007, generics represented 67% of prescriptions filled in the United States, up from 19% in 1984.[16] In the U.S., when a generic version of a medicine becomes available for the first time, it can capture as much as 86 to 97% of the market within the first month.[17]

The data show that the speed of entry has accelerated over time in response to different public policy choices, in some countries dramatically so. Generics are attracted to commercial opportunities, swiftly copying innovative products with high annual sales prior to exclusivity. Conversely, commercial and regulatory factors such as limited market value, safety, liability risk, complex manufacturing processes, specialised delivery devices, existing generic or other competitors, patient monitoring, as well as certain national pricing systems, can deter rapid generic entry in some cases.

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13 Sector inquiry report, paragraphs 93 and 94.

14 Article 10, Directive 2001/83 on the Community code relating to medicinal products for human use (as amended) [2004] OJ L 311/67).

15 See Factors Affecting Generics in Europe, CRA International, appended to EFPIA submission of 13 June 2008 to the European Commission in relation to the pharmaceutical sector, at page 23. These estimates were largely confirmed by the European Commission's subsequent findings in the final report at paragraphs 177 *et seq*.

16 PhRMA tabulation of 1984-2000 data: IMS Health Inc., National Prescription Audit Plus™; IMS Health News Release, IMS Health Reports U.S. Prescription Sales Grew 3.8 Percent in 2007 to $286.5 Billion (Mar. 12, 2008), available at http://www.imshealth.com.

17 Medco, 2008 Drug Trend Report (2008) at 9, available at http://medco.mediaroom.com/file.php/162/2008+DRUG+TREND+REPORT.pdf.

Many national health systems fail to fully exploit the full potential of competitive off-patent markets and this has been confirmed by a regression analysis carried out as part of the Commission's sector inquiry. The econometric analysis illustrates that price caps and mandatory discounts correlate with a lower number of entrants and, in the longer run, lead to higher prices in comparison with non-cap schemes. For this reason, open-price competition seems to be the policy option that maximizes long run consumer welfare.[18]

BIAC welcomes the commitment made by the Commission, in concluding the sector inquiry, to facilitate Member State cooperation and the exchange of best practices on generic policies that create headroom for innovation.

5. The rationale for settlement agreements in disputes between originator and generic pharmaceutical companies

Settlement agreements to resolve a reasonably asserted patent infringement claim should be regarded as pro-competitive, allowing the parties to focus investments on those areas where they may legally compete without infringing the other's rights and without the need for litigation. Patent litigation cases are fact-intensive, legally complex and unpredictable in outcome. By definition, a settlement will be made in circumstances where no final adjudication has occurred. A settlement should therefore be legitimate where the parties settle a claim in circumstances where, as the European Commission has said, both parties believe "they have … good and valid reasons to believe that a blocking position exists".[19]

The terms of the settlement will be as highly fact-specific as the underlying dispute. As the European Court of Justice has noted, such agreements are to be assessed under the antitrust rules in the same manner as any other agreement.[20] Any per se or other stricter approach would be untenable.

A settlement is a negotiated position that will reflect the parties' evaluation of the respective merits based on perceived probabilities, imperfect information, an assessment of risk and the level of costs incurred and anticipated, their exposure to damages claims, legal costs incurred and likely to be incurred, and the risks of a judgment in one jurisdiction being influential for other jurisdictions where the patent is at issue. It will, therefore, not necessarily involve a decisive outcome in the sense that the generic concedes that it cannot enter a market or that the patent holder concedes that it may. Rather, a negotiated position could involve one or more of the following: (i) an agreement to respect the patent term or some shorter duration; (ii) value transfers from one party to another (or from each to the other); or (iii) a distribution or licensing arrangement for the products in dispute or other products.

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18 Sector inquiry final report, paragraphs 1478 – 1480.

19 The competitive gains that may be made from settlements are recognised in the Guidelines on the Technology Transfer Block Exemption: "[L]icensing … in the context of settlement agreements … is not as such restrictive of competition since it allows the parties to exploit their technologies post agreement … Licensing in the context of settlement agreements is treated like other license agreements". The same Guidelines recognise that if the parties' own technologies are in a 'one-way' or 'two-way' blocking position, they are considered not to be competitors on that technology market. A generic and innovator will be in a one-way blocking position to the extent that the innovator's patent blocks the generic's access to the market which means that an agreement between them does not restrict competition. (OJ 2004 C 101/2).

20 Case 65/86 *Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Süllhöfer* [1988] ECR 5249.

The policy statements of the US Federal Trade Commission with respect to settlements in the US system must be evaluated in the context of the incentives created by the Hatch-Waxman Act.[21] By virtue of this statute, litigation prior to generic entry is actively encouraged by the US market authorization process and tends to focus on the first generic applicant who is eligible for a 180 day period of exclusivity against subsequent filers. Thus, there are specific features of the US system that provoke litigation and, in due course, settlement.

Given the system of incentives created by the Hatch-Waxman Act, the FTC has taken the policy position that so-called "reverse payments" are presumptively unlawful,[22] and that ancillary business transactions that might accompany settlement of the patent case are often a disguised payment for delayed generic entry.

BIAC notes that the policy position of the agencies is not the prevailing view of US jurisprudence. Most US courts have held that the mere inclusion of a "reverse payment" is not a sufficient basis for finding a settlement unlawful. Instead, they have focused on a range of important considerations, including the public policy favouring settlements, full consideration of the counterfactual of generic exclusion and the need for a case-by-case assessment of settlement agreements and side arrangements.[23]

Box 1:

"[T]he size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement."

"[W]e fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and in an ancillary transaction, pays for other products licensed by the generic. Such a result does not represent the confluence of patent and antitrust law."

Schering-Plough Corp. v. Federal Trade Commission, 402 F.3d 1056, 1075 and 1076 (11th Cir. 2005)

While courts have articulated somewhat different tests, the weight of US judicial authority holds that settlements are lawful for as long as (i) the underlying litigation was not a sham, (ii) the patent was not procured by fraud, and (iii) the exclusion of generic competition is no greater than would have been occasioned by the patent in any event. In other words, the settlement is not anti-competitive if it goes no

21 See the White Paper on Certain Aspects of US Pharmaceuticals and Antitrust Law, WilmerHale, 12 June 2008 ("White Paper on Certain Aspects of US Pharmaceuticals and Antitrust Law"), pp. 4-7.

22 Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to Anticompetitive Patent Settlements in the Pharmaceutical Industry: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce, 110th Cong. 19 (2007).

23 This approach also finds support in economic literature which recognizes that settlements can be pro-competitive since they lower costs and uncertainty. A ban on some potentially pro-competitive settlements would narrow the available patent protection and, on the margin, lower incentives to innovate. It would also increase the cost and risk of bringing a generic drug to market and, on the margin, lower the incentives of generic manufacturers to challenge patents in the first place. ("*An Economic Assessment of Patent Settlements in the Pharmaceutical Industry"*, Dickey, Orszag, Tyson, March 2009).

further than the protection conferred by the underlying patent.[24] Liability would only arise for conduct seeking to extend the exclusive rights conferred by the patent.[25]

In BIAC's submission, an automatic prohibition of specific settlement terms would not be appropriate. There is no indication that such settlements should be deemed as "always or almost always" unlawful, as normally is required to justify such per se treatment, especially in light of the legally and factually complicated nature of such arrangements. This is reflected in the weight of U.S. jurisprudence. The European Commission has recognised this in its sector inquiry report which correctly states that any assessment of a particular settlement requires an in-depth analysis of the individual agreement, taking into account the factual economic and legal background.[26]

[24] See *Tamoxifen*, 466 F.3d at 212-23 (upholding dismissal of private challenges to Hatch-Waxman settlement, and stating that "[w]e generally agree …that 'simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law,' unless the 'exclusionary effects of the agreement' exceed the scope of the patent's protection'"), *amending* 429 F.3d 396 (2d Cir. 2005); *Schering-Plough*, 402 F.3d at 1076 (reversing FTC decision that had invalidated Hatch-Waxman settlements including "reverse payments" because restrictions were "no more broad than the patent's own exclusionary power"); *Valley Drug*, 344 F.3d at 1312 ("reverse payment" settlement subject to antitrust scrutiny only if "found to have effects beyond the exclusionary effects of [defendant's] patent"); *Cipro III*, 363 F. Supp. 2d at 535 (granting defendants' motions for summary judgment where Hatch-Waxman settlement restrained "competition… only within the scope of the patent").

[25] *See United States v. Line Material Co.*, 333 U.S. 287, 304 (1948) ("Within the limits of the patentee's rights under his patent, monopoly of the process or product by him is authorized by the patent statutes."); *see also United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) ("[T]he possession of a valid patent … does not give the patentee any exemption from the provisions of the Sherman Act *beyond the limits of the patent monopoly.*"); *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) ("The owner of a patent cannot *extend* his statutory grant by contract or agreement.") (emphasis added); *Tamoxifen*, 466 F.3d at 302 (citing *Singer*); *Schering-Plough*, 402 F.2d at 1067 (same); *Valley Drug*, 344 F.3d at 1312 (citing *Masonite*); *Cipro III*, 261 F. Supp. 2d at 248 (citing *Singer*).

[26] Sector inquiry report, paragraph 763.

SUMMARY OF DISCUSSION

By the Secretariat

The Chairman set out the five main topics of the roundtable; (1) the importance of intellectual property ("IP") for dynamic competition, (2) the restrictions on competition and consumer welfare in the generic pharmaceutical industry, (3) current competition investigations, (4) legal and regulatory reforms to promote generic competition, (5) new forms of competition in generic pharmaceuticals markets.

A delegate from the US briefly summarised some of the key issues raised in the background paper, which was prepared by the US Federal Trade Commission (FTC). Generic drug competition typically brings substantial price benefits to pharmaceutical marketplaces. A recent FTC study found that discounts in the US could be as high as 80% in 'mature generic drug markets', i.e. markets that have seen repeated generic entry over a couple of years. An EU study found average price reductions of around 20% from generic entry. While generic entry is a desirable policy objective, it should not be promoted to the extent that it compromises incentives to conduct expensive and valuable initial innovation in pharmaceutical markets. However, once there has been a sufficient recoupment period (e.g. the life of a patent), or when a drug is not, or should not be protected by a patent, generic competition is valuable and should be strongly promoted.

The effects of generic drug competition can vary substantially. If doctors have no incentives to prescribe generics, and pharmacists have no incentives to dispense generics, then generic entry will have a rather limited impact. There may also be regulation on branded drugs, meaning the retail price is relatively low compared to the unconstrained monopoly level, and therefore the generic drug prices will not lead to the usual level of reduction. Generic entry has different effects in different jurisdictions, although as yet there has been no evidence of a jurisdiction in which the effects of generic entry are not positive. Focusing on generic entry also encourages thinking about a variety of related policies, for example the rules related to generic drug dispensing. In the US many insurance companies and government health plans require that, where possible, generic drugs should be dispensed in preference to branded drugs to save costs. However, in those jurisdictions where pharmacists share in the drug profit margins they may have the opposite incentive. Therefore generic drug entry is a policy objective intricately linked to a variety of other healthcare sector and health insurance policies, in addition to requiring a balancing act against the preservation of innovation in the pharmaceutical industry.

1. The importance of IP for dynamic competition

A delegate from BIAC referred to the EU's pharmaceutical sector enquiry and the question of the impact of competition policy on static versus dynamic efficiency. Start up investment costs in life sciences have now reached on average around $140 million, with full development including opportunity costs reaching $1.3 billion. This is due to the rising demands from regulatory authorities and the increasing number of patients involved in clinical trials. In 1990 one out of five medicines which reached clinical trials with patients (the point at which it becomes much more costly) made it to the market. Now only one out of twelve reach the market and only two out of ten products which reach the market are commercial successes. While there is a notion that life cycle management continues the protection of patents for too long, an analysis of blockbuster drugs as part of the EU sector enquiry found that for every drug making more than €1 billion in sales a year, generic market entry occurred at the time the first patent lapsed.

When liberal market forces are allowed to drive down prices, the savings potential of generics can be better exploited than when mandated or regulated discounts are imposed. In countries where regulated discounts for off-patent drugs reach up to 50%, generics may be unable to compete. Regulation can therefore prevent or deter generic drugs from entering the market. Likewise, regulation can also reduce branded drug producers' incentives to engage in R&D. The World Health Organisation (WHO) stated in a recent report that while branded drug producers risk failure and incur the time and cost of market development for new drugs, there is no guarantee of financial return and there are substantial regulatory hurdles to be overcome. Overly regulated drug markets can stifle innovation. More liberal rules in this area to encourage both generic entry and increased R&D would therefore be welcome.

The Chairman commented that patents do not necessarily confer market power, but they confer exclusivity and this exclusivity is necessary to have a sufficient level of innovation. There are two relevant issues here: (i) the relationship between exclusivity and the incentive for innovation and (ii) the relationship between market power and innovation. When patent holders try to delay the entry of generic products, this is negative in a static sense. However, making the original patent holders more profitable might lead to more innovation.

A delegate from the US responded that while the US government vigorously supports antitrust enforcement in the pharmaceutical sector, this should not be viewed as detracting from the importance of giving strong incentives for pharmaceutical innovation. Vibrant innovation by the pharmaceutical sector is a key part of achieving the medical breakthroughs of the future. Strong patent rights are indispensable in fostering the incentives to innovate, and they drive pharmacological improvements. Ensuring strong returns on successful drugs is essential to make up for losses incurred on unsuccessful research efforts and to incentivise future R&D. However, competition law enforcement is not aimed at undermining legitimate pharmaceutical patent rights; it is designed to prevent anticompetitive abuses of patents that go beyond legitimate patent exploitation and harm consumers. For example, an important question is whether delay settlements create incentives or disincentives for innovation. When companies pay generic competitors to stay out of the market, this will generally protect weak patents (those that are likely invalid or not infringed). Therefore, the exclusionary power of this type of patent seems unlikely to promote innovation. It should be emphasised that competition is also a powerful source of innovation and the threat of generic competition spurs companies to develop new products.

Pharmaceutical prices in the US are not regulated in the same way as in other countries, and the belief is that competition is the best approach for innovation and to save consumers money. Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a price that is 20% to 30% of the brand name counterpart and then gains a substantial market share in a short time. After six months other generic companies can enter, meaning a discounted price of about 80% of the price of a brand name drug, with generic sellers capturing 50-90% of the market. In 1984 Congress enacted the Hatch-Waxman Act to create a pathway for generic drugs to enter the market. The Act was intended to make more low cost drugs available while fully protecting legitimate patent claims. Under this law a potential generic competitor can obtain approval to introduce its drug through an Abbreviated New Drug Application (ANDA) upon showing that the new drug is a bio equivalent to the approved drug.

In a typical pay for delay settlement, the branded manufacturer will pay the potential generic entrant an amount of money, in exchange for the generic company delaying its entry into the market. In the absence of an exclusionary reverse payment or a pay for delay settlement, the generic could be expected to enter at an earlier date. In effect, these agreements allow the brand name company and the generic firm to share the excess profit that should have gone to consumers. An FTC study estimated that a ban on these settlements would result in approximately $3.5 billion per year in annual savings to American consumers or to the drug purchasers. The FTC is therefore pursuing reverse settlement casesand currently is litigating two in the courts. There is also proposed legislation that would restrict such anticompetitive agreements.

A delegate from New Zealand commented on the fact that competition authorities focus on the behaviour after patents have been granted, rather than questioning the granting of monopoly rights through allowing the patent in the first place. A less competitively distortive means of incentivising innovation could be the use of innovation prizes, where large sums of money are offered for certain types of discoveries, e.g. a cure for neglected diseases.

A delegate from the US agreed that innovation should not be inexorably tied to IP rights, and a significant amount of valuable innovation is never patented. There are other means of incentivising innovation, e.g. through the trade secret regime or contractual protections, and in some cases technology moves too quickly for patenting to be worthwhile. However, in terms of prizes or government funding, research suggests that these methods are not as effective as IP rights. Given the substantial amount of investment necessary in pharmaceuticals, the prize fund would have to match this. The prizes would also become distortive and drive innovation towards the prize regime, rather than more valuable goals.

The Chairman commented that this may be an issue in the pharmaceutical sector due to the ease with which products can be duplicated once they are on the market, making the alternatives to patents not so effective.

A delegate from BIAC commented that different situations exist in the EU and the US due to a variety of rules and regulations. The EU sector investigation highlighted twenty-two settlement agreements over eight years across the EU, with payments totalling €200 million. However, given the size of the European market, this is not a hugely significant figure. The EU statement that settlement agreements need closer scrutiny was welcomed by BIAC. The US rules incentivise generic companies to launch a product, but there are risks attached. It is intriguing that under EU rules challenging a patent due to patent linkage is deemed illegal, but under US rules challenging a patent in the orange book[1] allows an exclusivity period of 180 days. In one case this 180 day period allowed a generic manufacturer to benefit from a $2 billion windfall because other generic competitors were prevented from entering the market. Incentivising to launch at risk results in uncertainty on both sides. Under the US rule of reason case law a patent settlement will be deemed appropriate and pro-competitive unless it is clearly a sham, i.e. there is no valid patent behind it, or exclusivity is extended beyond the scope of the patent term. This case by case analysis does work, and given that generic manufacturers are incentivised to adopt 'launch at risk' strategies, i.e. launching a generic version of a drug that still has patent protection because of the potential windfall and the reasonably high chance of winning any ensuing patent dispute, it is sensible to allow court settlements.

A delegate from the US responded that not all US courts deal with these types of settlements in the same way, with some treating the agreements as per se illegal and others adopting a rule of reason approach. A rule that permits all settlement agreements under which payments are made in exchange for promises not to compete unless there is proof that either the underlying infringement claim is a sham or the agreement restricts competition beyond the term of the patent, is extremely permissive. Companies can take advantage of permissive rules and pay until the end of the patent, as this enables the sharing of monopoly profits until patent expiration, even if the generic company could design around the patent or was not infringing. This is a very complicated area, with varying frameworks across countries for the intersection of patents and antitrust. The US marketplace differs from others because of the dramatically lower prices offered by generics, and this needs to be balanced against the importance of innovation.

2. Restrictions on competition and consumer welfare in the generic pharmaceutical industry

The Chairman invited Norway to take the floor and discuss the restrictions in place there on the ownership of pharmacies.

[1] Contains a list of approved drug products with therapeutic equivalence evaluations.

A delegate from Norway explained the historical context concerning the ownership restrictions which prevented doctors and manufacturers of pharmaceutical products from owning pharmacies. The Norwegian Medicine Agency proposed to remove these ownership restrictions as they were difficult to enforce and were not contributing to the purposes of the Pharmacy Act. In 2003 generic substitution was introduced, and by 2005 the maximum prices were cut by 30%, ultimately cutting prices up to 86% over time. By 2008 generics had a market share of 70%. Norway, in line with Denmark, now has the lowest prices for non-patented prescription drugs. One of the reasons for success in the generics market is the ownership restriction that limits the possibility of full vertical integration from producer to retailer. The producers of generics compete both to enter the market as the preferred supplier to wholesalers, and to enter at retail level. Therefore, removing the restriction on full vertical integration will increase barriers to entry and restrict competition in the non-patented prescription drug market in Norway.

The Chairman next asked Canada to elaborate on its recent study, which showed that large rebates offered by generics to pharmacies were not passed on to consumers.

A delegate from Canada briefly set out the evolution of the Canadian pharmaceutical market and the four elements making it unique including (i) the historical compulsory licensing regime (ii) the division of customers by federal, provincial and territorial drug plants, (iii) the influence of two to three large pharmaceutical chains with limited advertising due to self imposed restrictions and (iv) the principal agent problem. Today the generic industry makes up about 20% of total pharmaceutical sales (approx $100 billion) and over 50% of all prescriptions. The public drug programs essentially set the rules for reimbursement. Ontario is the largest public plan and it sets the reimbursement prices for all provincial drug programs and many private plants. Reimbursement prices for generics were set at 63% of the brand name price, and these prices were publicly available. The pharmacies, and in particular the larger ones, were able to extract large rebates of around 40% or more from generic manufacturers in order to stock the products. However there was very little incentive for buyers to demand lower prices as the provincial drug plants were funded by the tax payer, and therefore if the drug bill increased by 20%, the buyers could simply request more money from the government. This resulted in a principal agent problem.

In order to motivate change, the Competition Bureau carried out advocacy work and commissioned studies which showed that over a billion dollars could be saved in the generic market alone through the use of mitigation and removing unintended rebates. Private plans should prefer pharmacy networks, providing patients with a greater incentive to carry out comparison shopping, rather than relying on a developed relationship with a pharmacist. In terms of provincial plans, a way of separating pharmacy services from drug costs is needed. It is also important to remove unnecessary restrictions on pharmacies to compete and use advertisements to increase customer awareness. Ontario dramatically changed its approach, making rebates up to a certain point illegal and reducing the price to 50%.

3. Current competition investigations

A delegate from the EC provided a summary of the Astra Zeneca case, which concerned the misuse of the patent system and the procedures for marketing authorisations within the context of an Article 82 dominance case. Astra Zeneca adopted two strategies with the intention of blocking or delaying market entry for generic competitors of its ulcer drug Losec. First, it gave misleading information to several national patent offices in order to gain the SPC (supplementary protection certificate) which provides extended patent protection. Second, it deregistered the market authorisation for Losec capsules, which was necessary in order for firms to produce the generic drug. Astra Zeneca was fined €60 million by the European Commission in June 2005. The decision was appealed before the CFI and judgment is expected

this year.[2] It should be noted that following a change in legislation, it is no longer possible to adopt the strategy employed by Astra Zeneca.

Regarding life cycle strategies, the EC recognises the importance of IP rights in this sector and that incremental research can lead to important steps in innovation, i.e. second generation products. The launching of a second generation product is not in itself a competition concern, because if the product does not show any incremental innovation then it will simply not succeed in the market. However, issues may arise if, as in the Astra Zeneca case, the company aims not only to delay generic entry, but also attempts to secure an extra period of exclusivity in order to switch the patient base to the second generation product. Fewer patent settlements are observed in the EU compared to, for example, the US so there is no general 'per se' approach and each individual situation will be considered on a case-by-case basis. Particular focus will be given to sham patents and any patent settlements that go beyond the scope of the disputed patent. The EU is also particularly interested in those patent settlements where a generic product is restricted from entering the market at the same time there is a value transfer from the original company to the generic company.

The Chairman then handed the floor to Korea to provide details on the relevant case law there.

A delegate from Korea first explained that in Korea almost all drugs are covered by the public health insurance system. The Daewoong pharmaceuticals case concerned an abuse of the standard pricing system used to establish generic drug prices. Daewoong was the leading pharmaceutical company in Korea with a monopoly on the market for the essential ingredient used in a drug to treat dementia. When the patent for this drug expired, pharmaceutical companies attempted to import the generic version of the drug. In an effort to block this market entry Daewoong entered into an outsourcing contract with five Korean generic drug manufacturing companies. Daewoong asked one of the outsourcing companies (Company W) to price much lower than the other four companies and promised to compensate any losses it might suffer. The other generic manufacturers would therefore have to set their prices even lower to compete, rendering the generic drug production unprofitable. The KTFC (Korean Fair Trade Commission) rejected the argument that this forced reduction in the price of the drug would be beneficial to consumers. Daewoong was the only importer of the essential ingredient and as only a small amount of this ingredient would be outsourced to Company W, in reality few consumers would benefit from the lower price.

The Chairman then asked Spain to take the floor.

A delegate from Spain explained that the Spanish pharmaceutical sector is highly regulated, and both reference prices and margins are fixed by law. In 2006 a law was passed which was intended to promote the entry of generic drugs. Under this law a new reference pricing system was introduced, in addition to a recommendation that pharmacists dispense generic drugs for certain prescriptions and sell them at the lowest price. As a result there has been some increase in the use of generic drugs, but the new legislation has not produced its full effects yet. Once generic drugs enter the market, branded drug producers react by either: (i) developing their own generic medicines, (ii) reducing the price of the original branded drug or (iii) stopping the promotion of their brand products. However, these actions are not considered anticompetitive by the Spanish competition authority as in many cases they are rational reactions to the introduction of new competitors.

Instead, the competition authority is focusing on practices between the distributors and the producers of generics or between pharmacists and pharmaceutical producers. In the Davur boycott case several pharmaceutical associations were sanctioned with a total fine of €1 million after recommending that pharmacists should not buy medicines from a generic laboratory following a decision by the latter to

[2] Judgment given by the General Court on 1 July 2010, largely dismissing the appeal.

reduce the selling prices of its principal products. As a consequence, the pharmacists' revenues declined and given the regulated system in place, this affected the future reference prices charged for the generic drugs. The competition authority is following the markets closely and there are dramatic differences between regional regulations covering the introduction of generics.

The Chairman next asked South Africa whether it may be proper to impose patent licensing requirements on branded pharmaceutical companies in light of the cases discussed in their contribution.

A delegate from South Africa responded that there have been two cases in which competition problems were addressed with patent licensing conditions. In both instances the companies voluntarily offered to address the competition authority's concerns by licensing certain aspects of their patented products. The first of these cases occurred in 2002 and concerned a complaint regarding the price of anti retroviral drugs used to treat HIV. The competition authority built a case based on the provisions in the Competition Act prohibiting excessive pricing and granting access to an essential facility. However, the case settled before going to the Competition Tribunal for adjudication. At the time there was a certain element of political denial in South Africa surrounding the HIV crisis, and this complicated the situation. It was in this context that GSK and Boerhingher Ingelheim decided to offer voluntary licenses for their drugs, and over a period of four years the price of generics dropped from between 50% to 90%.

The second case concerned a merger between GSK and Aspen, the largest generic manufacturer in South Africa, and one of the beneficiaries of the 2002 licenses granted by GSK. The competition authority analysed this merger both in terms of current market conditions and the future competition taking into account the significant number of GSK patents that were due to expire. However, the competition authority could not sustain an argument of substantial lessoning of competition as the market was in general highly innovative, and there were alternative generic suppliers. There was one product for which GSK held a patent and Aspen had an exclusive license, and a merger would therefore have resulted in the removal of an effective competitor to GSK. However, to rectify this GSK volunteered to extend the voluntary licenses of this product to the five other generic companies in the same terms and conditions as it did to Aspen.

4. Legal and regulatory reforms

The Chairman turned again to the EU and asked them to report in more detail on the sector enquiry in the pharmaceutical market, noting that this report had suggested a number of legal reforms to try to foster competition from generic products.

A delegate from the EU reiterated that the EU is limited to suggestions or recommendations, and the power to make legislative amendments in this area remains largely with the member states. Following the sector enquiry a number of conclusions were drawn. The EU fully supports the idea of a community patent, and the creation of a specialised and unified patent litigation system in Europe. Improvement is needed as the sector enquiry's results indicate that 30% of cases are duplicated, 11% of cases render contradictory judgments and litigation costs reach around €420 million. The EU welcomed the European Patent Office's intended procedural reform, which aims to raise the quality of patent applications and limit voluntary divisional applications. The EU hopes that the sector enquiry findings reopen the negotiations on the community patent and the litigation system. The current EU marketing authorisation procedures are causing delays, and the legal framework should be reinforced to ensure deadlines are kept and discrepancies reduced. Transparency should be increased and the adverse effects of unjustified third party submissions should be limited. The EU encourages immediate and automatic pricing for generics, and a cross border collaboration to assess the added value of new medicines should take place in order to avoid a duplication of these assessments. The EU recommends member states consider the various mechanisms available to facilitate generic entry. The enquiry had received a positive reception within the EU

competition network and individual member states are looking at the report and considering where their national systems can be improved.

A delegate from BIAC commented that there was now a clear move towards a specialised and unified European system, and to more relevant patent litigation with an immediate impact.

The Chairman then asked Italy to comment on its advocacy efforts to promote competition in the pharmaceutical market.

A delegate from Italy commented that the Italian generic market is relatively small and this is in part due to regulation. The problems are concentrated in two areas;

- *Patent coverage* is more extensive in Italy, resulting in a distortive effect on competition. Legislative intervention gradually reduced this supplementary patent coverage by six months every two years until the Italian legislation aligned itself with other European legislation.

- *Incentives* are distorted as pharmacy distribution margins are fixed by law as a percentage of the price of the product, and as a consequence pharmacists have an incentive to sell higher priced drugs. Suggestions for rectifying this include moving to a fee for service remuneration system, or requiring doctors to write the active ingredient on the prescription and not the name of the branded drug.

The Chairman next asked the Czech Republic to comment on the current pricing system in operation there.

A delegate from the Czech Republic explained that in each therapeutic group of pharmaceutical products at least one of the available products is fully reimbursed by the public health insurance. In general this is the cheapest product and in most cases it is therefore the generic product. When calculating the maximum ex-factory price for the first generic product in the therapeutic group the price limit is capped at 80% of the price of the original pharmaceutical. The system, introduced last year, has not yet benefitted from a full impact assessment. However, due to the historically strong position of the domestic producers of generic drugs and the prevalence of their consumption, it is not expected to have a major impact on competition in the pharmaceutical sector. In fact many generic manufacturers charge lower prices to retailers for their products in order to reduce the difference between price and the reimbursement paid by patients and therefore increase sales. The aim of the new pricing and reimbursement policy is to economise within the public health insurance system while at the same time lowering the prices of the original products.

The Chairman next called upon Ireland to discuss the regulatory issues that could explain the lack of generic pharmaceuticals in the Irish market, and the possible introduction of a new pricing system.

A delegate from Ireland confirmed that generic pharmaceuticals have not fully penetrated the Irish market, and that parallels could be drawn with the circumstances set out by the Italian delegation. In Ireland the trade price of both generic and branded prescription medicine is set via an agreement between the state and the drug manufacturer, and manufacturers are obliged to adhere to the prices decided. Doctors decide in consultation with their patient whether to use a branded product or not, and pharmacists are then obliged to dispense the product specified in the prescription; they cannot change the product. There are, however, positive aspects of the trade price agreements. As part of the 2006 agreement a phased cut of 35% of the off-patent branded product was agreed, and this resulted in savings. The state can also, pursuant to the agreement, request and use evidence of the cost effectiveness of a particular medicine.

As for the proposed reforms, a reference pricing system for off-patent medicines is due to be introduced. There will be one price for off-patent medicine whether it is manufactured and sold as a branded or generic medicine, and therefore even if no generic equivalent exits, the price will still be lower. A recent Department of Health study recommended that doctors should be encouraged to prescribe generic products, which up until recently was not the case. Increased prescription of generics could be achieved through the provision of prescription software systems, prescription data analysis and professional prescribing advice to doctors. The study also recommends a reduction in the current price of generics by around 20 – 30%. These proposals are likely to come into force in the next series of agreements, which will operate from 2011 – 2015.

The Chairman next ask Sweden to comment on mandatory generic substitution, which was introduced in 2002, and asked if it had a noticeable effect on competition between generic and branded pharmaceuticals.

The delegation from Sweden confirmed that the introduction of the mandatory generic substitution scheme has reduced the prices of generic pharmaceuticals and increased their market share. The Swedish competition authority financed a research project aimed at quantifying the effects of the mandatory scheme. It was found that after the patent expiry, the average price paid for a substance is 10% lower than before the scheme was in place. This captures both the effect of decreased prices in addition to the effect of a larger generic market share. The figure of 10% may be an underestimate, but the increased sales of products can be confirmed and the average price paid per mg decreased in the range of 60 – 90% for five blockbuster products. This price reduction cannot be wholly attributed to the mandatory scheme, as prices would have dropped after the patent expired. However it would not have been by such a significant amount. The institutional details of this type of scheme are also important because they can ensure the cost savings are not retained at the retail level. Pharmacies should have in stock and dispense the cheapest available generic product on the market. This can be ensured through incentives or regulation, and Sweden has opted for the latter, meaning pharmacies are obliged to provide the generic alternative.

The Chairman then turned to the UK's contribution which set out the reasons for which the market for drugs functions differently including the fact that the person who uses the product neither decides nor in most cases pays for the product, the person who decides on which product to use neither pays for nor consumes the product and finally the institution that pays for the product (the National Health Service or "NHS") neither consumes nor decides what is consumed. These features can be found in a number of other countries. The Chairman asked the UK to elaborate on how the system operates in the context of NHS and how entry from generic pharmaceutical products has affected competitive outcomes.

The delegate from the UK explained that the incentives of patients, doctors and the paying institutions are not always aligned, and in some cases can be entirely misaligned. Patients are most concerned with products that will treat their condition quickly and effectively, with a preference for products they are familiar with. They are generally unaware of the cost of the drugs, or any available substitutes. Doctors are usually well informed about alternative drugs, but not about costs and they primarily prescribe based on their experience with products in practice and on a clinical basis. The paying institutions, such as pharmacies, have limited control over either patient conditions or prescribing habits. This is a classic principle agent problem.

In contrast with other countries which have introduced generic substitution schemes it is important to recall that in the UK the vast majority of public health is completely free at the point of delivery. It is the doctor who decides which product to prescribe and the patient pays nothing. Competition therefore occurs between branded manufacturers promoting their products to doctors and suppliers competing against each other to ensure their products are in the pharmacy. Two major reports have been carried out by the OFT (Office of Fair Trading) in the last couple of years on (i) UK Government Pharmaceutical Price Regulation

and (ii) Medicine Distribution in the UK. Currently if a patient has a prescription specifying a branded product, the pharmacist is obliged to dispense this product only. If the prescription is written in more generic terms then the pharmacist can dispense a generic product, but can also dispense a branded product. If a generic prescription is available then the pharmacist will only be reimbursed on an average price for all the generic products. The pharmacist therefore seeks to buy the generic drug at the most attractive available price.

The approach taken in the UK is that prescribing generics is the key to increasing effective competition in the supply of medicines. The regulatory system has changed significantly over the last ten years and although the prescription of generics has increased, there is still significant expenditure by the NHS on off-patent branded products where generic substitutes are available. Following the market study, the government is now consulting on proposals that will enable pharmacists to generically substitute products even where the branded product is on the prescription.

The Chairman next turned to the contribution from India.

The delegation from India explained that a strict regulated system has helped to develop a platform of capabilities including generics, branded generics and small scale production industries within the central public sector. There is also a strong price control regime. The primary concern in the health system is the low penetration of generic drugs. However, too much information concerning generic drugs in the public domain may not bring the right results, and this is not something the competition authority intends to encourage. Instead the focus is on examining transparency in the public health system and the public procurement of drugs. In some states, such as Tamil Nadu, a model of procurement has been put in place that requires all stakeholders to decide together and agree on which generic drugs should be used. Public participation through NGO work is also being encouraged.

The Chairman then asked the delegation from Indonesia to elaborate on the role of price control to promote the use of generic drugs.

The delegation from Indonesia replied that the supply of generic drugs is aimed at responding to patients with low incomes who need generic drugs at the lowest prices. A regulation exists to control the selling price and the mechanics of generic drug distribution. This aims to ensure producers and suppliers have sufficient generic drugs to respond to the need for low priced drugs in Indonesia. However, in practice the regulation faces a number of obstacles. First, market penetration of generic drugs is very weak and few people are aware that generic drugs have the same functions and quality compared with branded drugs. Second, producers tend to limit the production of generics and prefer instead to produce new patented drugs in order to charge higher prices. Due to high inflation in Indonesia's economy and government regulation it is not always financially feasible for companies to produce generic drugs. If they do produce them, production volume tends to be limited to reduce financial risks. The existing regulation will therefore require some time before it becomes wholly effective. Inflation adjusted tax incentives are also needed to reduce the high production costs in relation to the selling price. To facilitate distribution, pooling systems and a national logistic distribution system for the supply of generic drugs should be created.

The Chairman next asked Japan to elaborate on its goals to increase the market share of generic drugs and the action program to inform consumers about the benefits of generic drugs.

A delegate from Japan explained that prescription drugs can be distributed via doctors in hospitals, but in other cases, patients go to pharmacies with the written prescriptions given to them by their doctors. While it is not considered that distribution via doctors in hospitals is the direct reason why the market share of generic drugs is low, a survey has shown that medical institutions have some concerns regarding delivery, quality and information about generic pharmaceuticals. A consumer survey carried out by the JFTC (Japan Fair Trade Commission) shows that if there is a choice between generic and branded drugs,

one third of consumers would always choose the generic drug and two thirds would choose the generic drug depending on the situation. Of the two thirds, around 80% responded that they would choose the generic drug if they have sufficient information on the product and are persuaded by their doctor. Therefore, in October 2007 the Ministry of Health, Labour and Welfare established "Action Programme for Promoting the Safe Use of Generic Drugs", with the target of boosting the market share of generic drugs to over 30% in volume by 2012. The program consists of five targets:

- *Stable supply*: The government should provide straightforward instruction for stable supply. Manufacturers should deliver the product to the distributors no later than the day after the order and same day delivery should be available for at least 75% of the deliveries when the distributor has no stock.
- *Quality control*: Tests will be carried out by government to ensure that the quality of generic drugs does not differ from that of the corresponding approved drug, and the results will be made public. Manufacturers should implement product testing for each lot.
- *Provision of information*: Generic drug manufacturers will be requested to provide more explanation, including test results and effects, and respond to information requests promptly rather than relying on the original drug manufacturers.
- *Platform arrangements*: The government will establish prefectural councils to design acceleration plans, improve the understanding of generic drugs at the prefecture level and the manufacturers will diffuse information via the media.
- *Institutional arrangements*: The Central Social Insurance Medical Care Council will discuss and establish effective plans for accelerating the use of generic drugs.

The Chairman then asked Russia to describe the changes planned in its legal system to reduce the scope of IP protection.

A delegate from Russia responded that pro-competitive development in the pharmaceutical market has only recently become the priority of the Russian competition authority. A comprehensive analysis of the market was made and a number of changes have been proposed with the aim of reducing the administrative barriers faced by producers of generic pharmaceuticals. The procedure for pharmaceutical registration lacks transparency and contains certain requirements which tend to protect branded products, such as rules on the length of patents. The competition authority has made proposals to the government regarding the elimination of these barriers to entry, with the hope of promoting innovation and lowering prices through increasing the presence of generics on the market. A proposal has also been made to formulate a code of fair practice for doctors. This is to avoid situations where doctors prescribe certain drugs due to the relationship they have with the pharmaceutical company producing them.

5. New forms of competition in the generic pharmaceutical market

A delegate from the US commented that in terms of new forms of competition there are three main types emerging in the US market, but these may also be applicable in other jurisdictions.

- *Authorised generic*: this is the practice of a brand name company issuing its own generic version of a drug that is coming off patent protection. A study carried out by the FTC has led to the findings that (i) during the initial period an authorised generic is on the market, retail and wholesale drug prices are lower, (ii) authorised generics result in the revenues from the first generic being substantially cut, in some cases by up to 50% and (iii) refraining from introducing an authorised generic is a new way of effectuating a reverse payment agreement.

- *Product hopping*: this is the practice of a brand name company introducing new patented products (when generic entry is imminent) that have minor or no substantive improvements, but prevent pharmacies from substituting lower price generic products. Two recent US cases of product hopping occurred (i) in the market for birth control, in which the branded manufacturer planned to switch from a pill to a chewable contraceptive as part of a strategy to prevent a generic manufacturer from entering and (ii) in the market for narcolepsy and 'wakefulness' drugs, in which to maintain its market share, the branded manufacturer released a new generation drug at a lower price, while raising the price of the existing product.
- *Biologic drugs/biosimilars*: this is the practice of creating biologic drugs, which are far more complex and expensive to develop than small-molecule pharmaceutical products. In Europe there is already a pathway to biosimilars, and the US Congress is currently considering various legislative proposals for dealing with follow-on biological drugs. The concern is that entry barriers in the form of additional regulatory exclusivity periods (up to ten to twelve years) and special patent resolution procedures would harm consumers by delaying follow-on biologic drug entry.

In following up on the comments of BIAC, the delegate added that in most cases IP protection is not sector specific and tends to be of the 'one size fits all' nature. However, competition law should not be used to adjust for shortcomings in the IP regime. As regards anticompetitive horizontal restraints, there may be occasions when innovation is at stake and this may affect the anticompetitive assessment. Merger policy in a variety of jurisdictions, including the EU and the US, has come to recognise that potentially anticompetitive transactions bringing together complementary innovative assets may merit less strict treatment under merger law. In terms of reverse payment agreements, it should be emphasised that consumer and social welfare losses can, in fact, be many multiples of the original payment from the branded firm to the generic firm. There is a significant gap between what the branded firm will lose from generic competition and what the generic firm will gain. Therefore a relatively modest payment can preserve a very substantial profit margin.

The Chairman concluded the roundtable by noting that the concern of competition authorities was twofold; (i) the anticompetitive practices and what to do about them and (ii) the kind of regulation that is required to ensure the market will work for the benefit of consumers. While competition is necessary it is not always sufficient, and generic pharmaceuticals provides an excellent example of a market where this is the case.

COMPTE RENDU DE LA DISCUSSION

Par le Secrétariat

Le Président expose les cinq principaux points de la table ronde ; (1) l'importance de la propriété intellectuelle (« PI ») pour une concurrence dynamique, (2) restrictions à la concurrence et bien-être des consommateurs dans l'industrie des médicaments génériques, (3) études en cours sur la concurrence, (4) réformes législatives et réglementaires pour promouvoir la concurrence des produits génériques, (5) les nouvelles formes de concurrence sur les marchés de médicaments génériques.

Un délégué des États-Unis résume brièvement certains des principaux points évoqués dans le document de référence qui a été établi par la Federal Trade Commission des États-Unis. La concurrence des médicaments génériques apporte en général des avantages considérables en termes de prix aux marchés de produits pharmaceutiques. Une étude récente de la Federal Trade Commission a conclu que les baisses de prix aux États-Unis pouvaient atteindre jusqu'à 80 % sur les « marchés de médicaments génériques arrivés à maturité » c'est-à-dire les marchés sur lesquels des produits génériques ont été lancés à plusieurs reprises sur une période de deux ans. Une étude de l'Union européenne a constaté des réductions moyennes de prix d'environ 20 % du fait de l'entrée de médicaments génériques sur les marchés. Si cette entrée est un objectif souhaitable de la politique de santé, elle ne doit pas être encouragée au point de compromettre l'incitation à mener des activités de lancement de produits nouveaux coûteux et de grande valeur sur les marchés de produits pharmaceutiques. Cependant, à partir du moment où la période de récupération de l'investissement a été suffisante (par exemple la durée de validité d'un brevet) ou lorsqu'un médicament n'est pas ou ne doit pas être protégé par un brevet, la concurrence des médicaments génériques est bénéfique et doit être vivement encouragée.

Les effets de la concurrence des médicaments génériques peuvent varier sensiblement. Si les médecins ne sont pas incités à prescrire ces médicaments et si les pharmaciens ne sont pas incités à les fournir, le lancement de ces produits n'aura qu'un impact limité. Il est également possible que des réglementations s'appliquent aux médicaments de marque, ce qui signifie que leurs prix de détail sont relativement faibles par rapport au niveau correspondant à un monopole sans entraves et que, de ce fait, les prix des médicaments génériques n'aboutissent pas à la baisse habituelle. L'entrée des médicaments génériques sur le marché a des effets différents selon les juridictions bien que, jusqu'à présent, on n'ait pas observé de juridictions dans lesquelles les effets de l'entrée de ces médicaments sur le marché ne sont pas positifs. Le fait de mettre l'accent sur le lancement de médicaments génériques encourage par ailleurs les réflexions sur diverses politiques qui y sont liées, par exemple sur les règles de fourniture de ces médicaments. Aux États-Unis, beaucoup de compagnies d'assurances et de programmes publics de santé exigent que, dans la mesure du possible, les médicaments génériques soient fournis de préférence aux médicaments de marque pour réduire les coûts. Cependant, dans les juridictions où les pharmaciens perçoivent une part des marges bénéficiaires concernant les médicaments, leur incitation peut jouer en sens inverse. Par conséquent, l'entrée des médicaments génériques sur le marché est un objectif étroitement lié aux différentes politiques portant sur le secteur des soins de santé et l'assurance maladie, tout en devant rester compatible avec la préservation de l'innovation dans l'industrie pharmaceutique.

1. L'importance de la propriété intellectuelle pour une concurrence dynamique

Un délégué du BIAC mentionne l'enquête de l'Union européenne sur l'industrie pharmaceutique et la question de l'impact de la politique de la concurrence sur l'efficience en termes statiques ou dynamiques. Les coûts des investissements de démarrage dans le domaine des sciences de la vie ont désormais atteint près de 140 millions de dollars en moyenne, tandis que les coûts totaux de développement, y compris les coûts d'opportunité, atteignent 1.3 milliard de dollars. Cela est dû aux exigences croissantes des autorités réglementaires et au nombre de plus en plus élevé de patients faisant l'objet d'essais cliniques. En 1990, un médicament sur cinq ayant atteint le stade des essais cliniques sur les patients (le stade auquel leur coût devient beaucoup plus élevé) était mis sur le marché. À présent, seul un de ces médicaments sur douze est mis sur le marché et parmi ceux-ci, deux sur dix seulement sont des succès commerciaux. S'il semble que la gestion du cycle de vie a pour effet de protéger les brevets pendant une durée trop longue, une analyse des médicaments qui ont connu le plus de succès dans le cadre de l'enquête sectorielle de l'Union européenne a constaté que, pour chaque produit dont le montant des ventes a dépassé un milliard d'euros par an, l'entrée du produit générique sur le marché est intervenue au moment où la période d'application du premier brevet a expiré.

Lorsqu'on laisse jouer librement les mécanismes du marché pour abaisser les prix, il est possible de mieux exploiter les possibilités d'économies offertes par les médicaments génériques que lorsque des rabais obligatoires ou réglementés sont imposés. Dans les pays où les rabais réglementés pour les médicaments ne faisant pas l'objet de brevets atteignent jusqu'à 50 %, les génériques peuvent n'être pas compétitifs. La réglementation peut donc empêcher ou dissuader les médicaments génériques d'accéder aux marchés. De même, la réglementation peut également réduire l'incitation, pour les producteurs de médicaments de marque, à entreprendre des activités de recherche-développement. L'Organisation mondiale de la santé (OMS) a déclaré, dans un récent rapport, que si les producteurs de médicaments de marque risquent l'échec, et subissent les délais et les coûts de la mise sur le marché de nouveaux produits, le rendement financier de leurs activités n'est pas garanti et il leur faut surmonter des obstacles réglementaires considérables. Une réglementation excessive des marchés de médicaments peut étouffer l'innovation. Par conséquent, des règles plus libérales dans ce domaine permettant à la fois d'encourager la mise sur le marché de produits génériques et le renforcement de la recherche-développement seraient souhaitables.

Le Président fait observer que les brevets n'assurent pas nécessairement un pouvoir sur le marché mais qu'ils assurent l'exclusivité et que celle-ci est nécessaire pour que le niveau d'innovation soit suffisant. Deux problèmes se posent à cet égard : (i) la relation entre l'exclusivité et l'incitation à l'innovation et (ii) la relation entre le pouvoir de marché et l'innovation. Lorsque les titulaires de brevets s'efforcent de retarder l'entrée de produits génériques, cette attitude est négative dans une perspective statique. Toutefois, l'amélioration de la rentabilité pour les titulaires du brevet initial peut encourager l'innovation.

Un délégué des États-Unis répond que, si le gouvernement de son pays soutient fermement l'application de la législation antitrust dans le secteur pharmaceutique, cette politique ne doit pas être interprétée comme signifiant qu'il attache moins d'importance à la nécessité d'encourager fortement l'innovation dans le secteur pharmaceutique. Une activité intense d'innovation dans ce secteur constitue un élément essentiel de la réalisation des percées médicales de l'avenir. Des droits bien établis sur les brevets déposés sont indispensables pour inciter à innover et ils suscitent des progrès dans le domaine pharmacologique. Il est essentiel que les médicaments performants procurent des rendements importants pour compenser les pertes subies sur les efforts de recherche infructueux et inciter à poursuivre la recherche-développement. Toutefois, l'application du droit de la concurrence n'a pas pour objet de saper les droits légitimes des titulaires de brevets dans l'industrie pharmaceutique ; elle vise à empêcher l'usage abusif et anticoncurrentiel de brevets allant au-delà de leur exploitation légitime et causant un préjudice

aux consommateurs. Par exemple, l'une des questions importantes est de savoir si les paiements effectués en échange du retardement de la mise sur le marché ont un effet incitatif ou dissuasif sur l'innovation. Lorsque des sociétés paient des concurrents fabriquant des produits génériques pour qu'ils restent en dehors du marché, cela a en général pour effet de protéger des brevets peu contraignants (ceux considérés comme probablement invalides ou n'ayant pas donné lieu à des contrefaçons). Par conséquent, le pouvoir d'exclusion de ce type de brevet ne semble guère susceptible de promouvoir l'innovation. Il faut souligner que la concurrence est également une source d'innovation puissante et que la menace de la concurrence des produits génériques stimule le développement de produits nouveaux par les entreprises.

Aux États-Unis, les prix des produits pharmaceutiques ne sont pas réglementés de la même manière que dans d'autres pays, et l'on estime que la concurrence est la meilleure méthode pour favoriser l'innovation et permettre aux consommateurs de réaliser des économies. Des études de l'industrie pharmaceutique montrent qu'en général le premier concurrent générique pénètre sur le marché à un prix qui représente 20 à 30 % de celui du médicament de marque concurrent puis acquiert une part considérable du marché dans de brefs délais. Après six mois, d'autres fabricants de produits génériques peuvent entrer sur le marché, ce qui se traduit par un rabais d'environ 80 % du prix du médicament de marque, tandis que les fournisseurs de produits génériques s'emparent de 50 à 90 % du marché. En 1984, le Congrès a adopté la loi Hatch-Waxman pour faciliter l'accès des médicaments génériques au marché. L'objet de la loi était de permettre la fourniture d'une plus grande quantité de médicaments à faible coût tout en préservant intégralement les droits légitimes des titulaires de brevets. Selon cette loi, un concurrent potentiel fabricant des produits génériques peut obtenir l'autorisation de mettre son médicament sur le marché au moyen d'une demande simplifiée de lancement d'un nouveau médicament (« *Abbreviated New Drug Application* » - *ANDA)* en démontrant que ce nouveau médicament est équivalent sur le plan biologique à celui qui est déjà autorisé.

Dans un cas type de paiement pour l'obtention de délais, le fabricant d'un médicament de marque verse au fabricant de produits génériques susceptible d'entrer sur le marché une somme en échange de laquelle cette société retarde son entrée. En l'absence d'un paiement inversé d'exclusion ou d'un paiement au titre d'un retard, on pourrait s'attendre à ce que le produit générique entre sur le marché plus rapidement. En fait, ces accords permettent à la société fabricant le médicament de marque et à celle qui fabrique le produit générique de partager le bénéfice excédentaire qui aurait dû revenir au consommateur. Une étude de la Federal Trade Commission a estimé qu'une interdiction de ces paiements se traduirait par une économie annuelle de 3.5 milliards USD pour les consommateurs américains de produits pharmaceutiques. La FTC exerce donc des poursuites dans des affaires de paiements inversés et deux de ces affaires sont actuellement examinées devant les tribunaux. Il existe d'ailleurs une proposition de législation qui limiterait de tels accords anticoncurrentiels.

Un délégué de Nouvelle-Zélande fait observer que les autorités de contrôle de la concurrence mettent l'accent sur le comportement des entreprises après l'octroi de brevets plutôt que de commencer par se demander si l'octroi d'un pouvoir de monopole au moyen de ce brevet est justifié. Un moyen d'inciter à l'innovation tout en provoquant moins de distorsions dans la concurrence pourrait consister à recourir à des prix d'innovation, en vertu desquels des sommes importantes seraient offertes pour certaines catégories de découvertes, par exemple les remèdes aux maladies « orphelines ».

Un délégué des États-Unis convient que l'innovation ne doit pas être inexorablement liée aux droits de propriété intellectuelle et qu'une proportion notable des innovations les plus utiles n'a jamais fait l'objet de brevets. Il y a d'autres moyens d'inciter à l'innovation, par exemple dans le cadre du régime du secret industriel et commercial ou par des protections contractuelles, et dans certains cas la technologie évolue trop rapidement pour qu'il vaille la peine de déposer des brevets. Toutefois, en ce qui concerne les prix ou les financements publics, les recherches effectuées montrent que ces méthodes sont moins efficaces que les droits de propriété intellectuelle. Étant donné le coût considérable des investissements nécessaires dans

l'industrie pharmaceutique, il faudrait que le montant des prix soit du même ordre. Par ailleurs, ces prix risqueraient de donner lieu à des distorsions et d'orienter l'innovation vers les domaines qui font l'objet de prix plutôt que vers des objectifs plus utiles.

Le Président fait observer que cela pourrait poser des problèmes dans l'industrie pharmaceutique en raison de la facilité avec laquelle les médicaments peuvent être reproduits une fois qu'ils sont sur le marché et que, par conséquent, les alternatives aux brevets risquent d'être peu efficaces.

Un délégué du BIAC fait observer que les situations diffèrent dans le cadre de l'Union européenne et aux États-Unis en raison de la diversité des règles et des réglementations en vigueur. L'enquête sectorielle de l'Union européenne a fait apparaître vingt-deux accords sur huit ans dans l'ensemble de l'Union européenne, le montant total des paiements correspondants s'élevant à 200 millions EUR. Toutefois, étant donné la taille du marché européen, ce chiffre n'est pas énorme. Le BIAC se félicite de la déclaration de l'Union européenne selon laquelle ces accords doivent être examinés de plus près. Les réglementations en vigueur aux États-Unis constituent une incitation au lancement de produits par les fabricants de médicaments génériques mais cela comporte des risques. Il est curieux de constater que, selon la réglementation européenne, la contestation d'un brevet en raison de liens avec d'autres brevets est considérée comme illégale, alors que selon les règles en vigueur aux États-Unis, la contestation d'un brevet figurant dans le livre orange[1] autorise à bénéficier d'une période d'exclusivité de 180 jours. Dans un cas, ce délai de 180 jours a permis à un fabricant de produits génériques de bénéficier d'un profit exceptionnel de 2 milliards USD du fait que les autres concurrents fabriquant des produits génériques étaient empêchés d'entrer sur le marché. L'incitation à lancer des produits en prenant des risques aboutit à une incertitude des deux côtés. Selon la règle de raison de la jurisprudence américaine, un dépôt de brevet sera considéré comme approprié et favorable à la concurrence à moins qu'il ne s'agisse de toute évidence d'une fiction, c'est-à-dire qu'il ne corresponde pas à un brevet valable ou que l'exclusivité soit élargie au-delà du délai applicable aux brevets. Cette analyse au cas par cas fonctionne effectivement et étant donné que les fabricants de médicaments génériques sont incités à adopter des stratégies de « lancement risqué », c'est-à-dire de lancement d'une version générique d'un médicament qui est encore protégé par un brevet en raison des bénéfices exceptionnels potentiels qui pourraient en être tirés et des chances relativement élevées de gagner le litige qui en résulterait concernant le brevet, il est raisonnable d'autoriser le recours aux tribunaux.

Un délégué des États-Unis répond que tous les tribunaux américains ne traitent pas ce type de règlement de la même manière, certains jugeant que ces accords sont illégaux en eux-mêmes tandis que d'autres adoptent l'approche de la règle de raison. Une règle qui autoriserait tous les accords selon lesquels des paiements seraient faits en échange de promesse de ne pas se faire concurrence à moins de prouver soit que l'action en contrefaçon est une fiction soit que l'accord limite la concurrence au-delà de ce qui stipule le brevet, est extrêmement permissive. Les entreprises peuvent tirer profit des dispositions permissives et payer jusqu'à l'expiration du brevet car cela permet le partage des profits de monopoles jusqu'à cette échéance, même si le fabricant de produits génériques pouvait contourner le brevet ou ne se livrait pas à une contrefaçon. Il s'agit d'un domaine très complexe, dont les règles varient selon les pays à l'intersection du droit des brevets et du droit de la concurrence. Le marché américain diffère des autres en raison du niveau nettement plus bas des prix des produits génériques et ce fait doit être concilié avec la nécessité de favoriser l'innovation.

[1] Qui contient une liste des produits pharmaceutiques autorisés considérés comme équivalents sur le plan thérapeutique.

2. Restrictions à la concurrence et bien-être des consommateurs dans l'industrie des produits pharmaceutiques génériques

Le Président donne la parole à la Norvège pour exposer les restrictions en vigueur dans ce pays concernant la propriété des pharmacies.

Un délégué de la Norvège expose le contexte historique concernant les restrictions à la propriété qui empêchent les médecins et les fabricants de produits pharmaceutiques d'être propriétaires de pharmacies. L'Agence norvégienne du médicament a proposé de supprimer ces restrictions dans la mesure où elles sont difficiles à appliquer et ne contribuent pas à la réalisation des objectifs de la loi sur la pharmacie. En 2003, la substitution des produits génériques a été instaurée et en 2005 les prix maximums avaient été abaissés de 30 %, ce qui a finalement abouti progressivement à une baisse des prix allant jusqu'à 86 %. En 2008, la part de marché des produits génériques était de 70 %. La Norvège, de même que le Danemark, a désormais les prix les plus bas pour les médicaments non brevetés vendus sur ordonnance. L'une des raisons du succès du marché des produits génériques est l'existence de restrictions en matière de propriété qui limitent les possibilités d'intégration verticale totale du producteur au détaillant. Les producteurs de médicaments génériques se font concurrence aussi bien pour entrer sur le marché en tant que fournisseurs préférés des grossistes que pour y entrer au niveau du détail. Par conséquent, la suppression des restrictions à l'intégration verticale totale aura pour effet d'accroître les barrières à l'entrée et de limiter la concurrence sur le marché des médicaments non brevetés vendus sur ordonnance en Norvège.

Le Président demande ensuite au Canada de donner des précisions sur son étude récente, qui a montré que les importants rabais offerts aux pharmacies par les fournisseurs de médicaments génériques n'étaient pas répercutés sur les consommateurs.

Un délégué du Canada expose brièvement l'évolution du marché des produits pharmaceutiques de son pays et les quatre éléments qui le rendent unique : (i) le régime antérieur de licence obligatoire ; (ii) la répartition des clients entre les laboratoires à l'échelon fédéral, provincial et territorial ; (iii) l'influence de deux à trois grandes chaînes pharmaceutiques limitant leur activité publicitaire à la suite de restrictions qu'elles s'imposent à elles-mêmes et (iv) le problème mandant-mandataire. Actuellement, l'industrie des médicaments génériques représente environ 20 % du total des ventes de produits pharmaceutiques (approximativement 100 milliards de dollars) et plus de 50 % de l'ensemble des prescriptions. Les programmes publics concernant les médicaments fixent essentiellement des règles pour leurs remboursements. Le programme public le plus important est celui de l'Ontario, qui fixe les prix de remboursement pour tous les programmes concernant les médicaments au niveau de la province et de nombreux laboratoires privés. Les prix de remboursement des produits génériques ont été fixés à 63 % du prix du médicament de marque, et ces prix ont été rendus publics. Les pharmacies, et en particulier les plus grandes d'entre elles, ont eu la possibilité d'obtenir des fabricants de produits génériques des rabais importants de l'ordre de 40 % ou plus pour stocker les produits en question. Toutefois, les acheteurs n'étaient guère incités à exiger des prix plus bas, dans la mesure où les laboratoires pharmaceutiques au niveau de la province étaient financés par le contribuable et, par conséquent, si la facture des produits pharmaceutiques augmentait de 20 %, les acheteurs pouvaient tout simplement demander à l'administration d'augmenter ces prestations. Il en résultait un problème mandant-mandataire.

Afin de promouvoir le changement, le Bureau de la concurrence a mis en œuvre des activités de sensibilisation et commandé des études qui ont montré qu'il était possible d'économiser plus d'un milliard de dollars sur le seul marché des produits génériques par le recours à la réduction et à la suppression des rabais non souhaités. Les plans des particuliers devraient donner la préférence aux réseaux pharmaceutiques, qui incitent davantage les patients à effectuer des comparaisons en vue de leurs achats plutôt que de se fier à la relation qu'ils ont nouée avec un pharmacien. En ce qui concerne les programmes au niveau de la province, il est nécessaire de trouver un moyen de séparer les services pharmaceutiques du

coût des médicaments. Il est également important de supprimer les restrictions inutiles à la concurrence entre les pharmacies et d'utiliser la publicité pour améliorer l'information des clients. L'Ontario a modifié son approche d'une manière spectaculaire, en déclarant illégaux les rabais jusqu'à un certain point et en ramenant le prix à 50 %.

3. Études en cours sur la concurrence

Un délégué de la Commission européenne résume l'affaire Astra Zeneca, qui portait sur une mauvaise utilisation du système de brevet et des procédures d'autorisation de mise sur le marché dans le cadre d'une affaire de position dominante au sens de l'article 82. Astra Zeneca a adopté deux stratégies avec l'intention de bloquer ou de retarder l'entrée sur le marché de médicaments génériques concurrents de son produit antiulcéreux Losec. En premier lieu, ce laboratoire a donné des informations fallacieuses à plusieurs offices nationaux de brevets afin d'obtenir le certificat complémentaire de protection (CCP) qui prolonge les droits du propriétaire d'un brevet. En second lieu, il a radié l'autorisation de mise sur le marché des capsules de Losec qui était nécessaire pour permettre aux entreprises de produire le médicament générique. Astra Zeneca a été condamné à une amende de 60 millions EUR par la Commission européenne en juin 2005. La décision a fait l'objet d'un recours devant la CFI et le jugement devrait intervenir cette année[2]. Il y a lieu de noter qu'à la suite d'un changement de législation, il n'est plus possible d'adopter la stratégie utilisée par Astra Zeneca.

En ce qui concerne les stratégies de cycle de vie, la Commission européenne reconnaît l'importance des droits de propriété intellectuelle dans ce secteur et le fait que des recherches additionnelles peuvent permettre des innovations importantes, par exemple en ce qui concerne les produits de la deuxième génération. Le lancement d'un produit de deuxième génération ne pose pas en lui-même un problème de concurrence dans la mesure où, si ce produit n'apporte pas une innovation notable, il ne réussira tout simplement pas sur le marché. Toutefois, des problèmes peuvent se poser si, comme dans l'affaire Astra Zeneca, l'entreprise s'efforce non seulement de retarder l'entrée des médicaments génériques mais aussi de s'assurer une période supplémentaire d'exclusivité afin d'orienter les patients potentiels vers le produit de seconde génération. On observe dans le cadre de l'Union européenne moins de paiements liés aux brevets que, par exemple, aux États-Unis, de sorte qu'il n'existe pas d'approche générale « en soi » et que chaque situation individuelle est examinée au cas par cas. L'accent est mis en particulier sur les brevets fictifs ainsi que sur tous les règlements qui vont au-delà du champ d'application du brevet en question. L'Union européenne s'intéresse plus particulièrement aux paiements liés aux brevets lorsque l'entrée d'un produit générique sur le marché se trouve entravée au moment même où un transfert de valeur est effectué de l'entreprise qui est à l'origine du brevet vers le fabricant de produits génériques.

Le Président donne ensuite la parole à la Corée pour obtenir des précisions sur la jurisprudence en vigueur dans ce pays.

Un délégué de la Corée explique tout d'abord que, dans ce pays, presque tous les médicaments sont couverts par le système public d'assurance maladie. L'affaire des produits pharmaceutiques Daewoong portait sur un usage abusif du système standard de fixation des prix pour déterminer les prix des médicaments génériques. Daewoong est l'entreprise pharmaceutique dominante en Corée et détient un monopole sur le marché d'un élément essentiel utilisé pour la fabrication d'un médicament destiné à traiter la démence. Lorsque le brevet de ce médicament a expiré, les entreprises pharmaceutiques se sont efforcées d'importer sa version générique. Pour tenter de bloquer cette entrée sur le marché, Daewoong a conclu un contrat de sous-traitance avec cinq entreprises fabricantes de médicaments génériques. Daewoong a demandé à l'une de ces entreprises sous-traitantes (la société W) de fixer un prix beaucoup plus bas que les quatre autres entreprises et a promis de l'indemniser pour les pertes qu'elle pourrait subir.

[2] Jugement rendu par le Tribunal général le 1er juillet 2010 qui a, dans une large mesure, rejeté ce recours.

Les autres fabricants de produits génériques auraient donc dû fixer leurs prix encore plus bas pour être compétitifs, ce qui rendait la production de médicaments génériques non rentable. La KFTC (Korean Fair Trade Commission) a rejeté l'argument selon lequel cette réduction forcée du prix du médicament serait bénéfique pour les consommateurs. Daewoong était le seul importateur de l'élément essentiel et comme une faible partie seulement de cet élément serait sous-traitée à la société W, en fait peu de consommateurs bénéficieraient de cette baisse de prix.

Le Président donne ensuite la parole à l'Espagne.

Un délégué de l'Espagne explique que l'industrie pharmaceutique de ce pays est étroitement réglementée et que les prix de référence comme les marges sont fixés par la loi. En 2006, une loi dont l'objet était de promouvoir l'entrée de médicaments génériques sur le marché a été adoptée. En vertu de cette loi, un nouveau système de prix de référence a été instauré, en plus d'une recommandation aux pharmaciens de fournir des médicaments génériques pour certaines prescriptions et de les vendre au prix le plus bas. À la suite de cette réforme, le recours aux médicaments génériques a quelque peu augmenté, mais la nouvelle législation n'a pas encore produit tous ses effets. Une fois que les médicaments génériques entrent sur le marché, les fabricants de médicaments de marque réagissent de l'une des manières suivantes : (i) en développant leurs propres médicaments génériques, (ii) en réduisant le prix du médicament de marque original, ou (iii) en stoppant la promotion de leurs produits de marque. Toutefois, ces actions ne sont pas considérées comme anticoncurrentielles par l'Autorité de contrôle de la concurrence espagnole car, dans de nombreux cas, il s'agit de réactions rationnelles face à l'entrée de nouveaux concurrents sur le marché.

L'Autorité de contrôle de la concurrence met plutôt l'accent sur les pratiques en vigueur entre les distributeurs et les producteurs de médicaments génériques ou entre les pharmaciens et les laboratoires pharmaceutiques. Dans l'affaire du boycott de la société Davur, plusieurs associations pharmaceutiques ont été sanctionnées par une amende totale d'un million EUR après avoir recommandé aux pharmaciens de ne pas acheter de médicaments auprès d'un fabricant de produits génériques à la suite d'une décision prise par ce dernier de réduire les prix de vente de ses principaux produits. De ce fait, les recettes des pharmaciens ont diminué et, étant donné le système réglementé en vigueur, cela a affecté les prix de référence futurs applicables aux médicaments génériques. L'autorité de contrôle de la concurrence suit de près les marchés et il existe des différences considérables entre les réglementations en vigueur dans les différentes régions en ce qui concerne la mise sur le marché de produits génériques.

Le Président demande ensuite à l'Afrique du Sud s'il pourrait être approprié d'imposer aux laboratoires pharmaceutiques fabricant des produits de marque des conditions en matière de concession de brevets à la lumière des affaires examinées dans sa contribution.

Un délégué de l'Afrique du Sud répond qu'il y a eu deux cas dans lesquels des problèmes de droit de la concurrence ont porté sur des conditions de concession de brevets. Dans les deux cas, les entreprises ont volontairement proposé de répondre aux préoccupations de l'Autorité de contrôle de la concurrence en accordant des concessions concernant certains aspects de leurs produits brevetés. La première de ces affaires s'est produite en 2002 et concernait une plainte relative au prix des médicaments antirétroviraux utilisés pour traiter le VIH. L'Autorité de contrôle de la concurrence a présenté un recours sur la base des dispositions du droit de la concurrence interdisant la fixation de prix excessifs et concernant l'octroi de l'accès à une facilité essentielle. Toutefois, l'affaire a été réglée avant d'être soumise au jugement du tribunal de la concurrence. À l'époque, il existait en Afrique du Sud un certain déni politique concernant la crise du VIH et cela a compliqué la situation. C'est dans ce contexte que GSK et Boerhingher Ingelheim ont décidé d'offrir des concessions volontaires concernant leurs médicaments et sur une période de quatre ans le prix des génériques a baissé dans des proportions comprises entre 50 % et 90 %.

La seconde affaire concernait une fusion entre GSK et Aspen, le principal fabricant de médicaments génériques d'Afrique du Sud, et l'un des bénéficiaires des licences accordées en 2002 par GSK. L'Autorité de contrôle de la concurrence a analysé cette fusion aussi bien dans l'optique des conditions en vigueur sur le marché que de la concurrence future compte tenu du nombre important de brevets de GSK dont la validité devait arriver à expiration. Toutefois, l'Autorité de contrôle de la concurrence ne pouvait soutenir l'argument de réduction sensible de la concurrence, dans la mesure où le marché était en général fortement innovant et où il existait des fournisseurs de médicaments génériques de substitution. Il existait un produit pour lequel GSK détenait un brevet et Aspen disposait d'une concession exclusive, et une fusion aurait donc abouti à la disparition d'un concurrent effectif de GSK. Toutefois, pour y remédier, GSK a accepté d'étendre les concessions volontaires concernant ce produit aux cinq autres fabricants de médicaments génériques aux mêmes clauses et conditions qu'elle l'avait fait pour Aspen.

4. Réformes législatives et réglementaires

Le Président se tourne à nouveau vers les représentants de l'Union européenne et leur demande de rendre compte plus en détail de l'enquête sectorielle sur le marché des produits pharmaceutiques, en notant que ce rapport avait suggéré un certain nombre de réformes législatives en vue de s'efforcer d'encourager la concurrence de produits génériques.

Un délégué de l'Union européenne rappelle que les pouvoirs de cette institution se limitent à des suggestions ou recommandations et que dans ce domaine, le pouvoir de procéder à des modifications législatives relève dans une large mesure des États membres. À la suite de l'enquête sectorielle, un certain nombre de conclusions ont été tirées. L'union européenne est tout à fait favorable aux projets de brevets communautaires, et à la création d'un système spécialisé et unifié de contentieux concernant les brevets en Europe. Des améliorations sont nécessaires dans ce domaine, dans la mesure où les résultats de l'enquête sectorielle font apparaître des doubles emplois dans 30 % des cas et des jugements contradictoires dans 11 % des cas tandis que les coûts des litiges atteignent près de 420 millions EUR. L'Union européenne se félicite de la réforme des procédures de l'Office européen des brevets qui est envisagée et qui s'efforce d'améliorer la qualité des demandes de brevets et de limiter les demandes divisionnaires volontaires. L'Union européenne espère que les conclusions de l'enquête sectorielle auront pour effet de rouvrir les négociations sur le brevet et le système contentieux communautaire. Les procédures actuelles d'autorisation de mise sur le marché en vigueur dans le cadre de l'Union européenne donnent lieu à des retards et il y a lieu de renforcer le cadre juridique pour s'assurer que les délais sont respectés et que les distorsions sont réduites. Il y a lieu d'améliorer la transparence et de limiter les effets néfastes des demandes injustifiées formulées par des tiers. L'Union européenne encourage la fixation immédiate et automatique des prix des médicaments génériques et une coopération transfrontalière pour déterminer la valeur ajoutée des nouveaux médicaments devrait intervenir afin d'éviter que ces évaluations ne donnent lieu à des doubles emplois. L'Union européenne recommande aux États membres d'examiner les différents mécanismes disponibles pour faciliter l'accès des médicaments génériques au marché. L'enquête a reçu un accueil favorable dans le cadre du réseau de l'Union européenne concernant la concurrence et les différents États membres examinent le rapport en recherchant les domaines dans lesquels les systèmes nationaux pourraient être améliorés.

Un délégué du BIAC fait observer que l'on s'oriente à présent nettement vers un système européen spécialisé et unifié et vers un règlement plus efficace et ayant un effet immédiat des litiges.

Le Président demande ensuite à l'Italie de faire des commentaires sur ses activités de sensibilisation en vue de promouvoir la concurrence sur le marché des produits pharmaceutiques.

Un délégué de l'Italie fait observer que le marché des produits génériques de son pays est relativement étroit et que cela s'explique en partie par la réglementation. Les problèmes sont concentrés dans deux domaines :

- *La durée d'application des brevets* est plus longue en Italie, ce qui aboutit à des distorsions dans la concurrence. Des mesures législatives ont eu pour effet de réduire progressivement ce délai supplémentaire de six mois tous les deux ans jusqu'à ce que la législation italienne soit alignée avec les autres législations européennes.

- *Les incitations* se trouvent faussées du fait que les marges de la distribution de produits pharmaceutiques sont fixées par la loi en pourcentage du prix du produit et, par conséquent, les pharmaciens sont incités à vendre les médicaments dont le prix est le plus élevé. Les suggestions pour remédier à cet état de choses sont notamment l'évolution vers un système de commissions en rémunération des services rendus ou l'obligation faite aux médecins d'indiquer le principe actif sur l'ordonnance et non la marque du médicament.

Le Président demande ensuite à la République tchèque de présenter ses commentaires sur le système de fixation des prix actuellement en vigueur dans ces pays.

Un délégué de la République tchèque explique que, dans chaque groupe thérapeutique de produits pharmaceutiques, l'un au moins des produits disponibles est intégralement remboursé par l'assurance maladie publique. En général, c'est le produit le moins cher et, dans la plupart des cas, c'est donc le produit générique. Dans le calcul du prix maximum à la sortie de l'usine du premier produit générique du groupe thérapeutique, le prix est plafonné à 80 % du prix du médicament original. Le système, instauré l'an dernier, n'a pas encore fait l'objet d'une évaluation d'impact complète. Toutefois, en raison de la position de force où se trouvent traditionnellement les fabricants nationaux de médicaments génériques et du caractère prédominant de la consommation de ces produits, ce système ne devrait pas avoir une incidence majeure sur la concurrence dans le secteur pharmaceutique. En fait, beaucoup de fabricants de médicaments génériques facturent leurs produits à des prix plus faibles aux détaillants afin de réduire la différence entre le prix et le versement effectué par les patients et d'accroître par conséquent les ventes. L'objet de cette nouvelle politique de fixation des prix et de remboursement est de réaliser des économies dans le cadre du système public d'assurance maladie tout en abaissant en même temps le prix des produits originaux.

Le Président fait ensuite appel à l'Irlande pour qu'elle expose les questions relatives aux réglementations qui pourraient expliquer l'absence de produits pharmaceutiques génériques sur le marché irlandais ainsi que l'instauration éventuelle d'un nouveau système de fixation des prix.

Un délégué de l'Irlande confirme que les médicaments génériques n'ont pas totalement pénétré le marché de son pays et qu'il serait possible d'établir un parallèle avec les circonstances exposées par la délégation italienne. En Irlande, le prix de vente des médicaments génériques comme des médicaments de marque vendus sur ordonnance est fixé dans le cadre d'un accord entre l'État et le laboratoire pharmaceutique et les laboratoires sont tenus d'accepter les prix fixés. Les médecins décident en consultation avec leurs patients s'il y a lieu ou non d'utiliser un médicament de marque et les pharmaciens sont donc tenus de fournir le produit spécifié dans la prescription ; ils ne peuvent changer de produit. Il existe cependant des aspects positifs des accords concernant le prix de vente. Dans le cadre de l'accord de 2006, une réduction progressive de 35 % du produit de marque non couvert par un brevet a été décidée, et cela s'est traduit par des économies. L'État peut également, en vertu de l'accord, demander et utiliser des données attestant l'efficacité en termes de coûts d'un médicament particulier.

Pour ce qui est des réformes proposées, un système de fixation des prix de référence pour les médicaments non brevetés doit être instauré. Il n'existera qu'un seul prix des médicaments non brevetés, qu'ils soient fabriqués et vendus comme produits de marque ou comme produits génériques et, par conséquent, s'il n'existe pas d'équivalent générique, le prix sera encore plus faible. Une étude récente du ministère de la Santé a recommandé que les médecins soient incités à prescrire des médicaments génériques, ce qui n'était pas le cas jusqu'à une date récente. Il serait possible d'accroître les prescriptions de produits génériques par la fourniture de systèmes de logiciels de prescription, l'analyse de données concernant les prescriptions et la fourniture de conseils professionnels aux médecins. L'étude recommande par ailleurs une réduction du prix actuel des médicaments génériques d'environ 20 à 30 %. Ces propositions devraient entrer en vigueur dans le cadre de la prochaine série d'accords, qui s'appliquera de 2011 à 2015.

Le Président demande ensuite à la Suède de donner des précisions sur la substitution obligatoire de médicaments génériques, qui a été instaurée en 2002 et demande si elle a eu un effet notable sur la concurrence entre les médicaments génériques et les médicaments de marque.

La délégation de la Suède confirme que l'instauration du système de substitution obligatoire de produits génériques a réduit les prix de ces médicaments et accru leur part de marché. L'autorité de contrôle de la concurrence suédoise a financé un projet de recherche visant à chiffrer les effets du système obligatoire. Il est apparu qu'après l'expiration du brevet, le prix moyen versé pour une substance fait apparaître une baisse de 10 % depuis l'entrée en vigueur du système. Cela s'explique à la fois par les effets de la baisse des prix et par ceux de l'augmentation de la part de marché des produits génériques. Le chiffre de 10 % pourrait être inférieur à la réalité mais l'augmentation des ventes de produits peut être confirmée et le prix moyen versé par milligramme a diminué dans des proportions comprises entre 60 et 90 % pour cinq produits parmi les plus performants. La réduction de prix ne peut être intégralement attribuée au système obligatoire, car les prix auraient baissé après l'expiration du brevet. Toutefois, ils n'auraient pas baissé dans des proportions aussi importantes. Les détails institutionnels de ce type de dispositifs sont également importants, dans la mesure où ils permettent de faire en sorte que les économies réalisées ne soient pas conservées au niveau des détaillants. Les pharmacies doivent avoir en stock et fournir les produits génériques les moins chers disponibles sur le marché. Ce résultat peut être obtenu par des mesures incitatives ou par une réglementation, et la Suède a opté pour cette dernière solution, ce qui signifie que les pharmacies sont tenues de fournir la version générique du médicament.

Le Président examine ensuite la contribution du Royaume-Uni, qui expose les raisons pour lesquelles le marché des produits pharmaceutiques ne fonctionne pas de la même manière que les autres marchés, et notamment le fait que la personne qui utilise le produit ne décide pas de son choix et ne le paie pas non plus dans la plupart des cas, la personne qui décide du produit à utiliser ne le paie pas et ne le consomme pas non plus et finalement l'institution qui le paie (le National Health Service ou le « NHS ») ne le consomme pas et ne décide pas de son choix. Ces caractéristiques se retrouvent dans un certain nombre d'autres pays. Le Président demande au Royaume-Uni de développer le mode de fonctionnement de ce système dans le contexte du NHS et d'indiquer comment l'accès des produits pharmaceutiques génériques au marché a affecté la situation de la concurrence.

Le délégué du Royaume-Uni indique que les motivations des patients, des médecins et des organismes payeurs ne sont pas toujours concordantes et que, dans certains cas, elles peuvent être tout à fait discordantes. Les patients s'intéressent surtout aux produits qui leur assurent un traitement rapide et efficace, avec une préférence pour ceux qui leur sont familiers. Ils ne sont généralement pas conscients du coût des médicaments ni de celui de leurs substituts disponibles. Les médecins sont généralement bien informés des substituts de ces médicaments mais non de leur coût et ils formulent généralement leurs prescriptions sur la base de l'expérience qu'ils ont des produits existants et selon des critères cliniques. Les organismes payeurs, tels que les pharmacies, ont un contrôle limité sur la situation des patients ou sur les habitudes en matière de prescription. Il s'agit d'un problème classique de mandant-mandataire.

Il est important de rappeler qu'au Royaume-Uni, contrairement à d'autres pays qui ont instauré des systèmes de substitution de produits génériques, la grande majorité des prestations dans le domaine de la santé sont complètement gratuites au stade où elles sont fournies. C'est le médecin qui décide du produit à prescrire et le patient ne paie rien. La concurrence intervient donc entre des fabricants de médicaments de marque qui assurent la promotion de leurs produits auprès des médecins et entre des fournisseurs qui rivalisent entre eux pour s'assurer que leurs produits sont disponibles en pharmacie. Deux rapports majeurs ont été établis par l'OFT (Office of Fair Trading) au cours des deux dernières années : (i) la réglementation des prix des produits pharmaceutiques par le gouvernement du Royaume-Uni et (ii) la distribution des médicaments au Royaume-Uni. Actuellement, si un patient présente une ordonnance qui prescrit un produit de marque, le pharmacien est obligé de ne lui fournir que ce produit. Si l'ordonnance est rédigée dans des termes plus génériques, le pharmacien peut fournir un produit générique mais aussi un produit de marque. En cas de prescription d'un produit générique, le pharmacien ne sera remboursé que sur le prix moyen de l'ensemble des produits génériques. Par conséquent, le pharmacien s'efforce d'acheter le médicament générique au prix le plus avantageux qu'il puisse obtenir.

L'approche adoptée au Royaume-Uni revient à considérer la prescription de produits génériques comme le meilleur moyen de renforcer l'efficacité de la concurrence dans la fourniture de médicaments. Le système réglementaire a été fortement modifié au cours des dix dernières années et, bien que la prescription de produits génériques se soit développée, il existe encore d'importantes dépenses du NHS portant sur des produits de marques non brevetés pour lesquels des substituts génériques sont disponibles. À la suite de l'étude du marché, le gouvernement procède actuellement à des consultations sur les propositions qui permettront aux pharmaciens de substituer des produits génériques aux produits de marque même lorsque ces derniers figurent sur l'ordonnance.

Le Président donne ensuite la parole à l'Inde.

La délégation de l'Inde explique que le système strictement réglementé de son pays a contribué au développement d'une offre de capacités comprenant des médicaments génériques, des génériques de marques et des industries produisant sur une petite échelle au sein du secteur public centralisé. Il existe par ailleurs un régime strict de contrôle des prix. La principale préoccupation dans le cadre du système de santé est la faible pénétration des médicaments génériques. Toutefois, la mise à la disposition du public d'un trop grand nombre d'informations concernant les médicaments génériques pourrait ne pas aboutir aux résultats souhaités et ce n'est pas ce que les autorités de contrôle de la concurrence souhaitent encourager. En revanche, l'accent est mis sur la recherche de la transparence dans le cadre du système public de santé et dans le système de marchés publics de médicaments. Certains États, tels que le Tamil Nadu, ont mis en place un modèle de passation de marchés publics qui oblige toutes les parties prenantes à décider ensemble et d'un commun accord des médicaments génériques à utiliser. La participation du public par le biais des activités des ONG est également encouragée.

Le Président demande ensuite à la délégation de l'Indonésie de donner des précisions sur le rôle du contrôle des prix dans la promotion de l'utilisation des médicaments génériques.

La délégation de l'Indonésie répond que la fourniture de médicaments génériques a pour objet de répondre aux besoins de patients à faibles revenus qui ont besoin de ce type de médicaments au prix le plus bas possible. Il existe une réglementation en vue de contrôler le prix de vente et les mécanismes de distribution des médicaments génériques. L'objet de cette réglementation est de faire en sorte que les producteurs et les fournisseurs disposent de médicaments génériques en quantité suffisante pour répondre aux besoins de produits pharmaceutiques à faible prix en Indonésie. Toutefois, en pratique, la réglementation se heurte à un certain nombre d'obstacles. En premier lieu, la pénétration du marché par les produits génériques est très faible et peu de personnes sont au courant du fait que ces médicaments ont les mêmes fonctions et la même qualité que les médicaments de marque. En second lieu, les producteurs ont tendance à limiter la production de médicaments génériques et préfèrent fabriquer de nouveaux produits

brevetés de manière à pratiquer des prix plus élevés. En raison du taux élevé d'inflation dans l'économie indonésienne et des réglementations appliquées par le gouvernement, les entreprises n'ont pas toujours financièrement la possibilité de produire des médicaments génériques. Si elles le font, le volume de leur production a tendance à rester limité pour réduire les risques financiers. Il faudra donc un certain temps avant que la réglementation en vigueur fasse pleinement sentir ses effets. Des mesures d'incitation fiscale ajustées en fonction de l'inflation sont également nécessaires pour réduire les coûts de production élevés par rapport aux prix de vente. Pour faciliter la distribution, des systèmes de regroupement et un système national de logistique de la distribution de produits génériques devraient être mis en place.

Le Président demande ensuite au Japon de donner des précisions sur ses objectifs d'accroissement de la part de marché des produits génériques et sur son programme d'action en vue d'informer les consommateurs sur les avantages de ces produits.

Un délégué du Japon explique que les médicaments vendus sur ordonnance peuvent être distribués par les médecins dans les hôpitaux mais que, dans certains cas, les patients se rendent dans les pharmacies avec les ordonnances écrites qui leur sont données par leur médecin. Alors qu'il n'est pas considéré que la distribution par les médecins dans les hôpitaux soit la cause directe de la faible part de marché des médicaments génériques, une étude a montré que les institutions médicales sont préoccupées par la fourniture, la qualité et les informations concernant les produits pharmaceutiques génériques. Une étude effectuée auprès des consommateurs par la JFTC (Japan Fair Trade Commission) montre que s'il existe un choix entre des médicaments génériques et des médicaments de marque, un tiers des consommateurs choisissent toujours le médicament générique et les deux tiers le choisissent en fonction de la situation. Sur ces deux tiers, environ 80 % ont répondu qu'ils choisiraient le médicament générique s'ils disposent d'assez d'informations sur le produit et si leur médecin les en persuade. Par conséquent, en octobre 2007, le ministère de la Santé, du Travail et de l'Aide sociale a mis en œuvre un « Programme d'Action pour la Promotion de l'Utilisation Sécurisée des Médicaments Génériques »avec pour objectif de porter la part en volume de ces produits sur le marché à plus de 30 % d'ici 2012. Le programme comporte cinq objectifs :

- *Offre stable :* Afin d'avoir une offre stable, le gouvernement devrait donner des instructions simples. Les fabricants devraient fournir le produit aux distributeurs au plus tard le lendemain de la commande et plus de 75 % des livraisons devraient être effectuées dans la journée lorsque le distributeur n'a pas de stock.
- *Contrôle de la qualité :* des tests seront effectués par le gouvernement pour s'assurer que la qualité des médicaments génériques ne diffère pas de celle du médicament correspondant dont la mise sur le marché a été autorisée, et les résultats seront rendus publics. Les fabricants devraient mettre en ouvre des tests de produit pour chaque lot.
- *Communication d'informations :* les fabricants de médicaments génériques seront tenus de donner davantage d'explications, y compris les résultats et les effets des tests, et de répondre rapidement aux demandes d'information plutôt que de s'en remettre aux fabricants des médicaments originaux.
- *Mise en place de programmes :* le gouvernement mettra en place des conseils de préfecture chargés de concevoir des programmes de développement de ces produits, d'améliorer la compréhension des médicaments génériques au niveau des préfectures et les fabricants diffuseront les informations par l'intermédiaire des médias.
- *Dispositifs institutionnels :* le Conseil Central des Assurances Sociales et des Soins Médicaux se chargera de la discussion et de la mise en place des plans effectifs en vue d'intensifier le recours aux médicaments génériques.

Le Président demande ensuite à la Russie de décrire les changements envisagés dans son système juridique pour réduire le champ d'application de la protection de la propriété intellectuelle.

Un délégué de la Russie répond que le renforcement de la concurrence sur le marché des produits pharmaceutiques n'est devenu que depuis une date récente une priorité pour l'autorité russe de contrôle de la concurrence. Une analyse d'ensemble du marché a été effectuée et un certain nombre de changements ont été proposés en vue de réduire les obstacles administratifs auxquels doivent faire face les producteurs de médicaments génériques. La procédure d'enregistrement des produits pharmaceutiques manque de transparence et comporte certaines conditions qui ont tendance à protéger les produits de marque, tels que les règles relatives à la durée d'application des brevets. L'autorité de contrôle de la concurrence a fait des propositions au gouvernement concernant l'élimination de ces obstacles à l'entrée, avec l'espoir de promouvoir l'innovation et d'abaisser les prix en renforçant la présence de produits génériques sur le marché. Il a également été proposé d'établir un code de bonnes pratiques à l'intention des médecins. Ceci afin d'éviter les cas dans lesquels les médecins prescrivent certains médicaments en raison de la relation qu'ils ont avec le laboratoire pharmaceutique et les produits.

5. Les nouvelles formes de concurrence sur le marché des médicaments génériques

Un délégué des États-Unis fait observer qu'en ce qui concerne les nouvelles formes de concurrence, il existe trois catégories principales qui apparaissent sur le marché des États-Unis, mais qui peuvent également exister dans d'autres juridictions.

- *Les génériques autorisés :* il s'agit de la pratique qui consiste, pour une société fabriquant un médicament de marque, à lancer sur le marché sa propre version générique d'un produit dont la validité du brevet arrive à expiration. Une étude effectuée par la FTC a abouti à la conclusion que (i) au cours de la période initiale de lancement sur le marché d'un générique autorisé, les prix de détail et de gros du médicament sont plus bas ; (ii) le lancement de génériques autorisés a pour effet de réduire sensiblement les recettes du premier générique, cette réduction atteignant dans certains cas 50 % et (iii) s'abstenir de lancer un générique autorisé constitue un nouveau moyen de conclure un accord de paiement inversé.
- *Le saut sur un autre produit :* cette pratique consiste pour une entreprise qui fabrique un médicament de marque à lancer de nouveaux produits brevetés (lorsque l'entrée de produits génériques est imminente) qui apportent des améliorations mineures ou non significatives mais empêchent les pharmacies de les remplacer par des produits génériques à prix plus bas. Deux affaires récentes de sauts sur d'autres produits ont eu lieu aux États-Unis : (i) sur le marché de la contraception, où le fabricant de médicaments de marque a planifié de remplacer une pilule par un contraceptif à mâcher dans le cadre d'une stratégie visant à empêcher le fabricant de produits génériques d'accéder au marché et (ii) sur le marché des narcoleptiques et des médicaments « d'éveil » sur lesquels, afin de maintenir sa part de marché, le fabricant de produits de marque lance des médicaments de nouvelle génération à un prix plus bas tout en relevant le prix des produits existants.
- *Médicaments biologiques/biosimilaires :* cette pratique consiste à créer des médicaments biologiques qui sont beaucoup plus complexes et coûteux à développer que les produits pharmaceutiques à petites molécules. En Europe, il existe déjà une voie vers les biosimilaires et le Congrès des États-Unis examine actuellement diverses propositions législatives pour traiter des produits biologiques de suivi. On craint en effet que les obstacles à l'entrée sous la forme de périodes réglementaires additionnelles d'exclusivité (jusqu'à 10 à 12 ans) et de procédures spécifiques de règlement des litiges sur les brevets ne causent un préjudice aux consommateurs en retardant l'entrée sur le marché des médicaments biologiques de suivi.

Pour faire suite aux commentaires du BIAC, le délégué ajoute que, dans la plupart des cas, la protection de la propriété intellectuelle n'est pas spécifique à un secteur et a tendance à comporter une « taille unique ». Toutefois, le droit de la concurrence ne doit pas être utilisé pour pallier les insuffisances

du régime de la propriété intellectuelle. En ce qui concerne les restrictions horizontales anticoncurrentielles, il peut exister des cas dans lesquels l'innovation est en jeu et cela peut affecter l'évaluation des entraves à la concurrence. Dans un certain nombre de juridictions, parmi lesquelles l'Union européenne et les États-Unis, la politique en matière de fusions a fini par reconnaître que les transactions potentiellement anticoncurrentielles qui ont pour effet de regrouper des actifs novateurs complémentaires peuvent mériter un régime moins rigoureux dans le cadre de la législation sur les fusions. En termes d'accords de paiements inversés, il y a lieu de souligner que les pertes de bien-être pour les consommateurs et pour la collectivité peuvent représenter en fait plusieurs fois le versement initial de l'entreprise qui produit le médicament de marque à celle qui produit le médicament générique. Il existe un écart important entre ce que l'entreprise de marque perdra du fait de la concurrence des produits génériques et ce que l'entreprise fabriquant des produits génériques gagnera. Par conséquent, un versement relativement modeste peut préserver une marge bénéficiaire considérable.

Le Président conclut la table ronde en notant que les préoccupations des autorités de la concurrence sont doubles : (i) que faire, face aux pratiques anticoncurrentielles et (ii) quels sont les types de réglementations requises pour faire en sorte que le fonctionnement du marché soit bénéfique pour les consommateurs. Si la concurrence est nécessaire, elle n'est pas toujours suffisante, et les produits pharmaceutiques génériques donnent un excellent exemple de marchés où ce n'est pas le cas.