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GENERIC PHARMACEUTICALS

-- Note by South Africa --

18-19 June 2014

This note is submitted by South Africa to the Competition Committee FOR DISCUSSION under Item VI of the agenda at its forthcoming meeting to be held on 18-19 June 2014.

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1. Introduction

1. The OECD has invited written submissions from members and observer members of the OECD to join in the roundtable discussions relating to generics and competition.

2. We begin this submission by providing an overview of the pharmaceutical industry in South Africa and how the industry fits into the broader government policy discussions. The South African pharmaceutical industry is an important component of the Industrial Policy Action Plan (IPAP) and National Industrial Policy Framework¹. There are at least 8 local South African generic players in this sector including Adcock Ingram, Ranbaxy, BioTech, Cipla and Feza, and at least 25 foreign originators selling drugs in the South African market. The sector is characterised by a large trade imbalance and limited capacity to manufacture active pharmaceutical ingredients.

3. The reliance on imports is problematic, particularly in the market (s) for ARVs and Active Pharmaceutical Ingredients (“APIs”). South Africa is the world’s largest consumer of ARV’s and yet imports all of its ARV’s and 95% of its APIs. Given that South Africa is a major centre of the HIV/AIDS epidemic and accounts for about 5.4 million of the total global infections of 33 million.² The treatment of such large numbers of patients with ARV is a major public health challenge.

4. According to the National Association of Pharmaceutical Manufacturers (NAPM)³, the total sale in the South African private market for pharmaceuticals in 2013 was about R20bn (US\$2bn). Local pharmaceutical manufacturers in South Africa produce mostly generics with almost all originator companies coming from abroad. The NAPM represents 24 members involved in the production and distribution of generic drugs.⁴ This excludes other local generic manufacturers such as Aspen, Adcock Ingram, Biotech and Feza. The Innovative Pharmaceutical Association of South Africa (IPASA) represents 25 companies of which most are originator pharmaceutical producers⁵. Almost all of these companies operate at international level and include, Boehringer Ingelheim, Novartis, Eli Lilly, Pfizer, Merck, AstraZeneca, Sanofi.

5. Prescription drugs represent 70% of the pharmaceutical market and the rest is over the counter (OTC) medicines. In South Africa, more generic prescription drugs are sold (in volume) as opposed to

¹ The IPAP is an industrial action plan compiled by the Department of Trade and Industry. It aims to promote diversification in the economy, promote a labour-absorbing industrialisation path, contribute to industrial development in other African countries, and facilitate a movement towards a knowledge economy. The National Industrial Policy Framework is the policy framework for the IPAP.

² Walwyn, D., (2008). Briefing note for the pharmaceutical industry: proposed support for the local manufacture of active pharmaceutical ingredients.

³ National Association of Pharmaceutical Manufacturers, 2014. The challenges facing generic medicines in South Africa, available: <http://www.slideshare.net/fullscreen/napmSA/market-access-conference-napm-presentation/2>, viewed 13 May 2014.

⁴ National Association of Pharmaceutical Manufacturers, 2014. About us, available: <http://napm.co.za/#/about-us-2/>, viewed 14 May 2014.

⁵ Innovative Pharmaceutical Association of South Africa (IPASA), 2014. IPASA members, available: http://ipasa.co.za/ipasa_members/, viewed 14 May 2014.

originator prescription drugs, but more (in monetary value) is spent on originator prescription drugs than generic prescription drugs. Originator drugs are more expensive than generics in general⁶.

6. Practices that may harm competition in the pharmaceutical sector have emerged as important and controversial issues. There are usually two forms of competition: competition among different originator 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.

7. The competitive entry by generic drug manufacturers into the pharmaceutical market has been important in ensuring substantial benefits to consumers and reducing costs of health care to millions of poor persons living with HIV/AIDS. Yet 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.

8. To put context to the discussion, we highlight below some of the cases that the Competition Commission (“Commission”) has dealt with in the pharmaceutical industry. The Commission’s assessments did not view patent rights as being beyond competition scrutiny. Rather, the exploitation of these rights was assessed against competition principles and the benefits they provide to end-consumers.

2. Competition cases

2.1 *The Hazel Tau & others v. GlaxoSmithKline (“GSK”) & Boehringer Ingelheim (“BI”) (“Hazel Tau Case”)*

9. One of the most notable cases raising intellectual property issues in South Africa was Hazel Tau case.⁷ The complaint was filed by individuals infected with HIV/AIDS, health care professionals, trade unions, and several non-governmental organisations. In particular, the complainants alleged that GSK and BI violated the Competition Act by charging excessive prices for their patented ARV medicines.

10. The Commission expanded the investigation to include allegations that GSK and BI had further violated the Competition Act by refusing to give competitors access to an essential facility when it was economically feasible to do so, and by engaging in exclusionary conduct. These complaints were based on allegations of the failure by the pharmaceutical firms to licence their patents on reasonable commercial terms.

11. At the conclusion of the investigation, the Commission announced that it was referring the matter to the Competition Tribunal for adjudication. The Commission found that GSK and BI had abused their dominant positions in their respective ARV markets.⁸ They had charged excessive prices, refused to give competitors access to essential facilities when it was economically feasible to do so and engaged in exclusionary behaviour in which the anti-competitive effect outweighed technological, efficiency or other pro-competitive gains.

⁶ For instance 1 month’s supply of generic Gleevec, a cancer treatment drug, cost US\$166 in India but US\$2913 as the original drug in South Africa.

⁷ Competition Commission Case Number: 2002Sep226.

⁸ Competition Commission, Media release No. 29 of 2003, 16 October 2003: *Competition Commission finds pharmaceutical firms in contravention with the Competition Act.*

12. Before the referral and prosecution of the case, GSK and BI, negotiated a settlement agreement in terms of which they admitted no liability. GSK and BI 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.

13. In 2007, the Commission received another complaint⁹ relating to HIV/AIDS medicine from the TAC alleging that Merck (and its South African subsidiary, MSD) has abused their dominant positions in the markets for the ARV medicine efavirenz (EFV) by refusing to license other firms to import and/or manufacture generic versions of this medicine on reasonable and non-discriminatory terms.¹⁰ MSD holds a twenty-year patent on efavirenz that expired in 2013. The TAC case resulted directly in MSD and Merck reaching agreement with multiple licensees on reasonable terms to bring a wide range of generic products containing EFV (an essential drug used as part of first-line ARV treatment in South Africa) to market.¹¹ While, the Hazel Tau case was settled only after the Commission had taken a decision to refer the matter to the Tribunal for adjudication, the TAC case was resolved before the Commission completed its investigation on the matter.

2.2 *The GlaxoSmithKline (GSK) / Aspen merger*

14. In February 2009, Aspen notified the Commission of its intention to acquire the Lanoxin brand from GSK South Africa. In its investigation, the Commission noted that GSK had voluntarily licensed three patented antiretroviral medicines including, Zidovudine where the parties (GSK and Aspen) held a combined market share of 95.7%, Lamivudine where the parties held a combined market share of 88.5%, and the Zidovudine Lamivudine combination, a cocktail including both products where the parties held a combined market share of 85.3%.

15. The Commission focused predominantly on the horizontal aspects of the merger since GSK, to some degree also competed with its generic licensees. Accordingly, no competition issues were recognized with respect to Zidovudine, Lamivudine and the Zidovudine/Lamivudine cocktail since GSK licensed the production and supply of these medicines to various other generic medicine companies such as Adcock Ingram, Ranbaxy (Sonke), BioTech, Cipla and Feza.

16. To avoid the reversal of gains obtained by licensing of patented products in the Hazel Tau case (above), the Commission sought conditions for extension of the license of antiretroviral medicines to

⁹ Commission case number 2007Nov3328.

¹⁰ The TAC's full complaint and supporting documents is available at <http://www.tac.org.za/documents/TACvMSDFinalCompCompapersFinalOf041107.zip>

¹¹ See Section 27 Discussion paper on compulsory licencing available at <http://www.section27.org.za/wp-content/uploads/2010/10/S27submissionToDIPP.pdf>

include the Abacavir product. Abacavir was a GSK patented product which was used primarily for the treatment of children suffering from HIV. At the time of the merger, GSK was the only supplier of this product in South Africa. The Commission sought and obtained as a condition for the approval of the merger an undertaking by GSK to not only license the production and/or importation of this product by Aspen but to also extend the license to other generic companies.

2.3 *Aspen Pharmacare Holdings limited & Mylan Inc., Mylan Laboratories Limited and Mylan South Africa Inc (“Aspen Mylan Case”)*¹²

17. In September 2012, the Commission received a complaint from Medesins Sans Frontieres, commonly known as Doctors Without Borders (“MSF”) against Aspen Pharmacare Holdings Limited (“Aspen”) and Mylan Inc. (“Mylan”). The complaint by MSF concerns a vertical supply agreement for the supply of active pharmaceutical ingredients (“API Agreement”) between Aspen and Mylan which, inter alia, allegedly precludes Mylan from bringing its fixed dose combination antiretroviral drugs to the South African market. The Commission is at an advanced stage with its investigations and a decision will be made in the coming few months.

3. The National Drug Policy

18. Section 27 of the Constitution 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”.

19. In order to promote the availability of safe and effective drugs at the lowest possible costs, the NDP recommended that a pricing committee be established within the Department of Health (“DoH”) to monitor and regulate drug prices; and recommended the use of generic drugs.

20. Following the mandate of the NDP, the South African government introduced a single exit price (“SEP”) for generic and branded medicines in 2004 and put a stop to discounts and additional levies on medicines. This was done in the hope of ensuring transparency in medicine pricing and following the discovery of excessive secret rebates passing between manufacturers and private hospitals. 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 DoH. The DoH must then approve these price increases within 30 days of receipt of an application by the manufacturer.

21. According to the DoH, the introduction of the SEP resulted in an average reduction in medicine prices of 19% in South Africa.

4. New Intellectual Property Rights (“IP”) policy

22. Patent protection promotes innovation in the pharmaceutical industry by allowing originator brand companies to recoup the costs of their innovations and to prevent free riding. The interaction between IP, which rewards innovators by granting them some protection from competition, and competition law, which seeks to ensure a competition and limit the creation or maintenance of monopoly power has attracted growing attention, particularly because of the expansion of IP law at the global scale.

¹² This case is still under investigation and a decision will be made in the coming few months.

23. On 4 September 2013, the South African government published a draft documenting its new policy stance on IP in South Africa. The final document on IP policy has not been published as yet. The essence of the new IP policy captures a move from a depository patenting system to a substantive patenting system. This means that patent applications would have to undergo intense scrutiny in order to prove that a patentable product is novel and that an inventive step has been taken rather than merely ticking off a set of requirements. Secondly it allows for pre- and post- patent approval opposition. Thirdly it advocates the integration of databases between the patent office and the Medical Control Council (MCC)¹³ in order to share information. This will limit the granting of some second generation patents. Lastly the new IP policy also allows South Africa to take advantage of the flexibilities granted to developing countries under the TRIPS agreement. These flexibilities include making use of parallel imports, compulsory licensing and the Bolar provision. The amendment of South Africa's IP policy is a step forward in creating a more competitive pharmaceutical sector.

5. Conclusion

24. The Commission is currently undertaking a market inquiry into private healthcare. The major focus of this market inquiry is on private hospitals, medical schemes and other healthcare related goods and services which include doctors, specialists, nurses, pathologists, medical devices and pharmaceuticals. The relationship between pharmaceutical manufacturers and other stakeholders such as doctors, hospitals and retail pharmacy will be the subject of the inquiry. The purpose is to understand how pharmaceuticals act as a cost driver in private healthcare. This analysis however does not take into account a full investigation into the pharmaceutical sector but the Commission reserves the right to extend the scope of the inquiry if there are grounds to do so¹⁴.

Reference

HLATSHWAYO, N. (2008) The Challenges of IP Protection and Competition Enforcement: An Analysis of the Microsoft Decisions (US and EU) and their Implications for South African IP and Competition Law. *Journal of Information, Law & Technology*.

¹³ The MCC is a South African statutory body that regulates medicines ensuring that they are safe, therapeutically effective and that they meet certain quality standards.

¹⁴ Section 43B(5) of the Competition Act gives the Commission permission to amend the terms of reference and the scope of the inquiry.