Working Party No. 2 on Competition and Regulation

COMPETITION IN THE PHARMACEUTICAL INDUSTRY

-- Note by James F. Rill, BIAC --

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by James RILL*, BIAC

Introduction

1. There are three themes that I would like to emphasize today:

1. Intellectual property rights play a key role in rewarding investments in research and development, and therefore are critical to promoting innovation and the development of new pharmaceutical products. Diluting the intellectual property rights of pharmaceutical manufacturers (for example, by imposing compulsory licensing requirements) in an attempt to limit manufacturers’ profits and to address anticompetitive conduct in the pharmaceutical industry will decrease both the quantity and quality of drugs available to consumers.

2. Pharmaceutical economics dictate that manufacturers earn prices above marginal cost on successful drugs; pricing above marginal cost, in and of itself, should not be considered anticompetitive. Genuine abuses of market dominance undertaken by patent holders in the pharmaceutical industry can be addressed through the nondiscriminatory and rational application of traditional competition law principles. Traditional antitrust enforcement, together with an FDA-type framework that regulates the introduction, production and marketing of pharmaceutical products, is the most efficient means of insuring that consumers receive the benefits of safe, effective and affordable pharmaceutical products. Price controls and other forms of regulatory intervention distort market mechanisms and threaten to lower the quantity and quality of pharmaceutical products ultimately available to consumers.

3. To the extent that the proposals in the Secretariat’s Note attempt to replace the application of traditional competition law principles with other types of regulatory intervention in the pharmaceutical industry, and/or to dilute the intellectual property rights of pharmaceutical companies, those proposals should be rejected as harmful to consumer welfare.1

II. First Principles: The Proper Blend of Intellectual Property Rights and Rational Antitrust Law Enforcement is Best Suited to Enhancing Consumer Welfare

2. A recent speech by Debra Valentine, General Counsel of the U.S. Federal Trade Commission, illustrates well the complementary roles of strong intellectual property rights and judicious antitrust enforcement in enhancing consumer welfare.

“On their face, [the antitrust and intellectual property law] regimes may appear to conflict: intellectual property law rewards and encourages innovation by providing limited monopoly rights, while antitrust law prohibits monopolization. But ultimately, both serve, and are

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1. To properly consider regulation consistent with consumer welfare, one should examine the full range of factors that affects this market, such as health insurance.
interpreted by U.S. courts and enforcers to further, ‘the common purpose of promoting innovation and enhancing consumer welfare.’ “

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“Antitrust law promotes market structures that encourage initial innovation with a competitive market ‘stick’ – that is, firms that fail to innovate will get left behind. Intellectual property law encourages initial innovation with the ‘carrot’ of limited exclusivity, and the profits that flow therefrom. Antitrust law enables follow-on innovation by protecting competitive opportunities beyond the scope of the exclusive intellectual property right. Intellectual property law enables follow-on innovation by requiring public disclosure of the initial innovation (at least in the patent context) and affording follow-on innovators rights of ‘fair use’ and freedom from intellectual property ‘misuse.’ The basic principle that mediates the tensions [between these two bodies of law] . . . is that intellectual property rights provide legal monopoly power, but only within the defined, limited scope of that right.”


III. Diluting or Abolishing Intellectual Property Rights in the Pharmaceutical Industry Will Decrease Consumer Welfare

3. The Secretariat’s Note states that patent protection is “a blunt instrument” that is “subject to forms of abuse” and that “induces a distortion in economic decisions and gives rise to the potential for various forms of anticompetitive behaviour.” Secretariat’s Note at 20. To address this potential for anticompetitive conduct, the Note offers various proposals that rely on the dilution of intellectual property rights for pharmaceutical manufacturers, including compulsory licensing.

4. It is widely acknowledged that patents play a critical role in stimulating and rewarding research and innovation in the pharmaceutical industry. A strong system of intellectual property rights that includes both patents and trademarks should be used to promote and reward research and innovation in this industry. The essence of the patentee’s patent right is the right to exclude others from the use of the invention for a period of years. Requiring compulsory licensing or diluting the rights of intellectual property holders in other ways ultimately will decrease the quantity and quality of pharmaceutical products available to consumers.

Secretariat’s Note:

5. The Secretariat’s Note itself acknowledges that the “protection of intellectual property rights lies at the foundations of R&D investment in the pharmaceutical industry. In the absence of that protection,

2. In fact, the U.S. Congress repeatedly has modified the patent laws as they relate to pharmaceutical products. For example, the U.S. Congress has enacted term extensions, modifications to the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), exceptions from patent infringement for R&D, and a number of other changes designed to address concerns about competition in the pharmaceutical industry.
margins on pharmaceutical products and the incentives for R&D investment would decline.” Secretariat’s Note at 18 (emphasis added).

6. In addition, the Secretariat’s Note acknowledges that “almost all the R&D effort of the pharmaceutical industry is carried out by large multinational firms” and that this R&D “is funded primarily from the profits flowing from exclusive rights granted to a patent holder during a patent’s life time,” Secretariat’s Note at 2-3. Wholly apart from the fact that cash flow is the relevant factor in funding research, the implicit conclusion that can be drawn from this statement is that, absent the patent protection that permits patent holders to generate profits, the funding to support additional R&D could not be obtained.

Economic Literature:

7. A significant body of economic literature supports the proposition that intellectual property rights promote research and innovation in the pharmaceutical industry. The Secretariat’s Note cites one study, for example, which found that 65 percent of pharmaceutical products would not have been introduced, and 60 percent would not have been developed, without adequate patent protection. See Secretariat’s Note at 18, citing Edwin Mansfield, Patents and Innovation: An Empirical Study, Management Science, 173-181 (Feb. 1986). See also Richard C. Levin et al., Appropriating the Returns from Industrial R&D, Yale Cowles Foundation Discussion Paper 862, Yale University (Feb. 1988); Richard C. Levin et al., Appropriating the Returns from Industrial R&D, Brookings Papers on Economic Activity, 783-820 (1987).

8. Pricing above marginal cost on successful pharmaceutical products, by itself, should not be considered anticompetitive. Indeed, pharmaceutical economics dictate that manufacturers earn higher prices on successful medicines. The Secretariat’s Note itself recognizes the high-risk nature of pharmaceutical research, which militates in favor of significant rewards.

a) The Note acknowledges that “[r]esearch-based pharmaceutical companies operate in a high-risk/high-reward environment. The process of obtaining marketing approval for a new drug is very long and costly, taking around 8 years and with a cost of hundreds of millions of dollars. Very few new chemical compounds that are created ever receive marketing approval, and of those only a few are successful.” Secretariat’s Note at 3. In addition, the Note states that “according to one commentator, for every 10,000 pharmaceutical products patented, about 100 will get into human trials and less than 10 will actually reach the market… Even those drugs which are successfully cleared by the licensing authorities do not necessarily sell in sufficient quantities to be profitable.” Id. at 12.

b) “It takes an average of 12 to 15 years and more than $500 million to bring a new drug from the laboratory to the patient. Only 1 in every 5,000 compounds tested becomes a marketed drug, and only 3 out of 10 approved drugs make more money than the average drug development costs.” PhRMA, Prescription Medicines: Benefits and Costs, www.phrma.org.


“The supply of brand-name prescription drugs depends critically on the research and development (R&D) activities of pharmaceutical companies. R&D activities, in turn,
depend on the companies’ access to intellectual property rights . . .” \textit{The Pharmaceutical Industry} at 173.

“Although intellectual property rights protection might not be necessary to foster innovation in all industries, pharmaceutical companies rely especially heavily on intellectual property rights in the form of patents and trademarks. In fact, empirical research indicates that new product development in the pharmaceutical industry is more dependent on patent protection than in many other industries, including . . . semiconductors, computers, [and] automobiles . . . In particular, some evidence suggests that 65 percent of pharmaceutical products would not have been introduced and 60 percent would not have been developed without adequate patent protection . . . .” \textit{Id.} at 179-180 (footnotes and citations deleted).

“[T]he Waxman-Hatch Act of 1984 . . . encouraged additional brand-name drug development by effectively extending patent protection on brand-name pharmaceutical products.” \textit{Id.} at 139.

10. Given the widely acknowledged importance of patent protection in stimulating R&D and innovation in the pharmaceutical industry, it seems clear that any dilution of intellectual property rights in an attempt to address anticompetitive conduct in the pharmaceutical industry would result in less innovation and, ultimately, fewer and lower-quality drugs, and further would adversely affect innovation in related biotechnology and other healthcare product industries. Thus, any weakening of intellectual property rights in this industry would diminish first funding, then innovation, and then development, all to the detriment of consumer welfare.

\textit{Competition Law Principles Best-Suited to Address Anticompetitive Conduct in the Pharmaceutical Industry}

11. The Secretariat’s Note asserts that the presence of limited competition and barriers to entry in pharmaceutical markets “fosters anticompetitive behaviour” in the industry. Secretariat’s Note at 4. For example, the Note observes that pharmaceutical manufacturers “have often been prosecuted for antitrust violations, including for cartels, price-fixing, forms of tying, exclusive marketing agreements and agreements to delay the entry of generics.” \textit{Id.}

12. The U.S. antitrust authorities have prosecuted various types of anticompetitive conduct in the pharmaceutical industry and related industries during recent years. \textit{See} Bureau of Competition, U.S. Federal Trade Commission, \textit{FTC Antitrust Actions in Pharmaceutical Services and Products} (Dec. 1999). Of concern, however, is the fact that the Secretariat’s Note appears to overstate the presence of collusion in the pharmaceutical industry, at least with respect to the support for this assertion that can be provided by certain U.S. precedents. Specifically, to support the assertion that pharmaceutical companies “have on many occasions been found to be colluding.” (Secretariat’s Note at 41), the Note references the prescription drugs antitrust litigation and the vitamins antitrust litigation. These references do not support the Secretariat’s assertions.

1. To support its assertions regarding the presence of collusion in the pharmaceutical industry, the Secretariat’s Note references the 1996 opinion of the district court denying summary judgement in the \textit{Brand Name Prescription Drugs Antitrust Litigation}. In fact, several defendants took the federal class action case to trial in 1999, and the same judge who denied summary judgement in 1996 ultimately granted the defendants’ motion for a directed verdict after hearing the plaintiffs’ evidence. Announcing his decision orally in court, the judge
stated that the “evidence of conspiracy is meager, and the evidence as to individual
defendants is paltry or non-existent. It would be a miscarriage of justice to hold otherwise.”
(11/30/98 Trial Tr. at 6442). In his written opinion, the judge held that the evidence was
“incompatible with the antitrust conspiracy set forth in the Class Plaintiffs’ complaint” and
that the plaintiffs had relied on “speculation and conjecture rather than fair or reasonable
inferences for the conclusions they offer[ed] . . .” (1/19/99 Op. at 15, 23). A few months
after issuing this opinion, the judge sanctioned the class plaintiffs’ lawyers for
misrepresenting the record at the summary judgement stage, which misrepresentations
contributed to the denial of the motions in 1996 and the issuance of the opinion now relied
upon by the Secretariat’s Note.

2. The Secretariat’s Note also references price-fixing in the vitamins industry as evidence of the
many instances of collusion in the pharmaceutical industry. It is worth noting that while
some of the companies allegedly implicated in that conduct are also pharmaceutical
manufacturers, that conduct involves the price-fixing of commodity products. As a
commodity market, the vitamins industry lacks the unique characteristics that the Note says
make the pharmaceutical industry particularly conducive to anticompetitive behavior. It
seems inappropriate to base an argument for revision of patent protection on a case involving
commodity products like vitamins.

13. To address anticompetitive conduct in the pharmaceutical industry, the Secretariat’s Note
proposes that price controls or other forms of regulatory intervention could be used. In fact, a wealth of
economic theory and experience indicates that price controls and other types of regulatory intervention
introduce market distortions and impede allocative efficiency.

“The enactment of cost-containment programs, price controls, or both, on a national level, often
results in decreased levels of R&D spending in that these programs reduce revenues that can be
reinvested in R&D programs. Several countries that have implemented such programs have seen
their pharmaceutical industries weaken or shift outside their borders.” U.S. International Trade

“In countries that have imposed [price regulations on pharmaceutical products], patients face
delays of months and years for surgery, government bureaucrats decide treatment options instead
of doctors and patients, and innovations in medical techniques and pharmaceuticals are
drastically reduced.” Open Letter from 565 Economists to President William J. Clinton, New

“Economists may not know much. But we know one thing very well: how to produce surpluses
and shortages . . . Do you want a shortage? Have the government legislate a maximum price that is
below the price that would otherwise prevail.” Milton Friedman, Economist, quoted in Price

14. Thus, reliance on price controls to correct anticompetitive conduct or market distortions in the
pharmaceutical industry will further diminish, rather than enhance, efficiency and consumer welfare.

15. To the extent that it exists, anticompetitive conduct in the pharmaceutical industry is best
addressed through the enforcement of traditional competition law principles. The pharmaceutical industry
does have certain characteristics that distinguish it from the “smokestack industries” for which the antitrust
laws were originally designed in the nineteenth century: the pharmaceutical industry is a health care
industry, a high-technology industry, and heavily reliant on intellectual property rights. While these
characteristics of the industry may warrant a judicious approach toward antitrust enforcement, they do not
render traditional competition law principles inadequate to address abuses of market power by pharmaceutical manufacturers.

16. The U.S. antitrust enforcement authorities have recognized that it is appropriate to apply traditional competition principles to the health care industry and to high-technology industries, including the pharmaceutical industry, just as these principles are applied to other industries:

The Introduction to the 1996 U.S. Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care states that traditional competition principles are “sufficiently flexible to take into account the particular characteristics of health care markets and the rapid changes that are occurring in those markets.”

Similarly, enforcement authorities have emphasized in several recent speeches that it is appropriate to apply traditional antitrust principles to high-technology industries, including the pharmaceutical industry. See U.S. FTC Press Release, Current Antitrust Laws Adequate to Address High-Tech Competition Issues (Feb. 25, 1999) (U.S. FTC Chairman Robert Pitofsky stated that nineteenth century antitrust laws are adequate to address competition issues presented by twenty-first century high-technology industries, including the drug industry); U.S. FTC Commissioner Orson Swindle, A Common Sense Approach to High Tech, Before the Continuing Legal Education Program, San Diego, California (Nov. 4, 1999) (“There is a recurring topic of discussion as to whether or not traditional antitrust concepts apply to … rapidly changing [high-technology] industries. Rest assured, they do.”); U.S. FTC Commissioner Thomas B. Leary, Antitrust Law as a Balancing Act, Before the Ninth Annual Seattle Computer Law Conference, Seattle, Washington (Dec. 17, 1999) (“it is not necessary to develop new antitrust principles to deal with so-called ‘high-tech’ industries; what is required is a discriminating application of familiar principles to the special facts of a ‘high-tech’ environment.”).

17. The U.S. antitrust enforcement authorities routinely employ traditional antitrust enforcement to address anticompetitive conduct in the pharmaceutical industry. See, e.g., FTC v. Mylan Laboratories, Inc., CV-98-03114 (complaint) (D.D.C., filed Dec. 22, 1998; amended complaint filed Feb. 8, 1999) (FTC charged Mylan Laboratories, one of the largest generic drug manufacturers in the U.S., with monopolization, attempted monopolization and conspiracy to eliminate much of Mylan’s competition for two widely prescribed drugs by tying up key active ingredients); In re Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andryx Corp., Docket No. 9293 (March 16, 2000) (complaint and proposed consent order) (FTC complaint alleged that Hoechst (now Aventis) agreed to pay Andryx millions of dollars to delay bringing to market a drug that would compete with Hoechst’s Cardizem product while Hoechst sued Andryx for alleged patent infringement); In re Abbott Laboratories, FTC File No. 981 0395 (Mar. 16, 2000) (complaint and proposed consent order) and In re Geneva Pharmaceuticals, Inc., FTC File No. 981 0395 (Mar. 16, 2000) (complaint and proposed consent order) (Abbott Laboratories and Geneva Pharmaceuticals agreed to settle FTC charges that Abbott paid Geneva approximately $4.5 million per month to keep Geneva’s generic version of Abbott’s Hytrin product off the U.S. market).

18. Thus, governments can use patents to stimulate R&D and reward innovation in the pharmaceutical industry while addressing anticompetitive conduct in this industry through the nondiscriminatory application of traditional competition law principles. Rather than enhancing consumer welfare, addressing anticompetitive conduct in the pharmaceutical industry through the use of price controls and other types of regulatory mechanisms further lessens consumer welfare.
V. Proposals in the Secretariat’s Note Undermine These Principles

19. If implemented, proposals in the Secretariat’s Note would upset the delicate balance between the protection of competition and pharmaceutical manufacturers’ incentives to innovate, thereby harming consumers by depriving them of more and better-quality pharmaceutical products.

20. For example, the Secretariat’s Note proposes that drug competition could be improved by using a system of compulsory licensing under which the patent holder would be required to sub-license the right to manufacture and market a drug to any requesting firm. The requesting firm would pay the patent holder a royalty fee determined by regulation. Secretariat’s Note at 34:

While emphasizing the “advantages” of this approach, including controls on profit and limits on the likelihood of anticompetitive behavior (e.g., tying of drug products and exclusive contracts with pharmaceutical distributors) by drug companies, the Note fails to describe the disadvantages to compulsory licensing.

The essence of the patentee’s patent right is the right to exclude others from the use of the invention for a period of years. Compulsory licensing would severely weaken intellectual property rights by abolishing this right and consequently would diminish pharmaceutical manufacturers’ incentives to innovate. Limiting profits would further diminish incentives to innovate. In addition, having a government panel establish royalty rates would add more regulatory intrusion and, consequently, more market distortion. Finally, as noted above, the goal of eliminating anticompetitive conduct by pharmaceutical manufacturers is best achieved by relying on antitrust enforcement.

21. The Note identifies as an “ideal R&D policy” one that would reward only those innovations for which the total value to the economy exceeds the R&D costs. The Note also suggests that it may be inappropriate for small, inexpensive innovations to receive the same intellectual property protection as large, expensive innovations. Secretariat’s Note at 18-19. This policy presumably would offer rewards only for successful products and would ignore the high cost of R&D failures, thereby diminishing incentives to innovate.

22. The Note proposes mechanisms to “reduce the negative impact of market power,” including having national health insurers pay a fixed annual fee in exchange for purchasing a brand-name drug at its marginal cost. The fee would “compensate the manufacturer for its market power (and therefore its R&D expenditure) while, at the same time, eliminating the distortionary effect of pricing above marginal cost.” Secretariat’s Note at 20. Alternatively, the Note proposes that governments or large insurers could buy out a manufacturer’s patent rights and then manufacture the drug directly and distribute it at marginal cost. Id. These proposals would compensate the manufacturer only for its success on the purchased product and would ignore the high cost of R&D failures, thereby diminishing incentives to innovate.

23. The Note appears to favor a greater role for government-funded R&D. Secretariat’s Note at 20. This proposition ignores the fact that industry members are almost always better-suited to make drug development decisions than are bureaucrats.

24. Other proposals discussed in the Secretariat’s Note, including using price controls more extensively and allowing parallel trade, would further distort market mechanisms and weaken intellectual property rights, and therefore should be rejected as well. For example, the current patchwork of EU Member State reimbursement and price control legislation, in conjunction with the principle of free movement of goods among Member States, distorts the market, limits patient choice and impedes
innovation. The unintended effect is the partitioning of the EU market, the enrichment of price arbitrageurs engaged in parallel trade, and the attendant loss of scarce Member State healthcare resources.

25. In the final analysis, as stated by Raymond V. Gilmartin, Chairman, President and Chief Executive Officer of Merck & Co., Inc:

“Evidence shows that by supporting the five enabling conditions necessary for pharmaceutical innovation, namely continued government support of basic biomedical research; a free market for pharmaceuticals based on competition and choice; effective intellectual property protection; efficient and effective regulatory systems; and a global business environment conducive to free trade and medical innovation, countries can develop and maintain strong, globally competitive pharmaceutical industries that excel at breakthrough research. Support of those enabling conditions also will ensure that citizens have access to the latest innovative medicines…”

It is important to continue to advocate policies that support innovation and to build and cultivate environments worldwide that encourage investment in exploratory basic research and drug development efforts. If society is to make major advances against diseases that cause so much suffering and economic hardship, diseases such Alzheimer’s, depression and cancer, new innovative medicines must be brought to market.”