For Official Use DAF/COMP/WD(2009)116

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development 14-Oct-2009

English text only

ROUNDTABLE ON GENERIC PHARMACEUTICALS

-- Note by the United States --

1. 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

2. 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]

3. 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

---

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. 2002); 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.

substantial share from the brand-name product in a short period of time.[5] Subsequent generic entrants may 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]

4. 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]

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.

6. A brand-name drug manufacturer seeking to market a new drug product must first obtain

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 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 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

11. 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.[30]

12. 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"

companies if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and agree to defer entry.[21]

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.

17. 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

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 a late patent 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]

20. After bringing these initial cases, the FTC sought additional information about the prevalence of

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 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 cheap 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.

2.3 Current Status of Reverse Payment Jurisprudence

27. 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

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 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 the 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.

29. 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.

30. 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.

31. 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

---

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

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

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

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.

35. In 2002, the FTC charged that Biovail Corporation and Elan Corporation agreed to unreasonably

43. 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

46. 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 menopause 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.

47. 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 Un the

54. 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 competition between 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.

---

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