Anticompetitive Activities in the Pharmaceutical Industry

Prepared Remarks of

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I. Introduction

I would like to thank the Generic Pharmaceutical Association and the International Generic Pharmaceutical Alliance for inviting me to speak today. Ensuring robust competition in the pharmaceutical industry is one of the key priorities of the Federal Trade Commission and, obviously, the input of GPhA and IGPA is important to this mission.

As those of you here today know better than most, competition in the pharmaceutical industry is an important concern to American consumers. The issue is also of utmost concern to pharmaceutical firms and insurance companies, but the concern reaches far broader. As a result of continuing innovations, American healthcare consumers today have come to rely on pharmaceuticals to address a wider variety of health concerns than ever before. These innovations, however, have not been costless. Helping ensure that needed drugs are made available to the broadest possible spectrum of healthcare consumers at reasonable and affordable prices has been the critical, and continuing, role of generic drug manufacturers.

All of which brings us to the Hatch-Waxman Act.[2] One cannot discuss competition in the pharmaceutical industry, and the respective roles of branded and generic drug manufacturers, without discussing the Hatch-Waxman Act. Though once the exclusive domain of pharmaceutical firms, lawyers, and Food and Drug Administration ("FDA") officials, the Act has become the

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[1] I would like to acknowledge the assistance of FTC attorney John T. Delacourt in the preparation of these remarks. The views expressed herein are my own and do not necessarily reflect the views of the Commission or any individual Commissioner.

[2] Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

source of national debate. Not more than two weeks ago, for example, the Act featured prominently in a front page story in the Washington Post[3] regarding Prilosec – the best selling drug in the world in the Year 2000.[4] As the article pointed out, pharmaceutical regulatory policy may not register as a day-to-day concern for the average American consumer, but paying $152 for a 30-day supply of heartburn medication might. Such a concern might assume even greater importance if the consumer in question is employed by, or holds shares of, General Motors, where some 346,000 Prilosec prescriptions were written for employees last year.[5] With such enormous sums of money at issue, it is hardly surprising that even the Washington Post finds it necessary to delve into the statutory minutiae of Hatch-Waxman. In a follow-up editorial on the Prilosec story, for example, the paper advocated such specific reforms as limiting innovator companies to a single 30-month stay per drug and requiring innovator companies to demonstrate a likelihood of success on a patent infringement claim before triggering a statutory stay in the first instance.[6]

Although such proposals may warrant attention elsewhere, legislative reform is not the subject of my remarks today. Instead, I intend to focus on the threats to competition that the Federal Trade Commission has observed, and attempted to address, in the Hatch-Waxman context. In so doing, I hope also to provide some guidance regarding the types of steps that generic manufacturers can take – and, equally importantly, *not* take – to ensure that competition in the pharmaceutical industry remains robust. The Commission's activities in this area have, to date, focused on two principal areas of potential abuse of the Hatch-Waxman process: improper Orange Book listings and collusive settlements.

II. The Hatch-Waxman Process

Before moving on to the discussion of specific abuses, however, I should provide some general background on the Hatch-Waxman regulatory process. As the members of this audience are almost surely more familiar with the details of this process than I, my description will necessarily be brief.[7]

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[3] Ceci Connolly, *Coalition Seeks to Curb Drug Patent Extensions*, Washington Post, Mar. 25, 2002, at A1.

[4] Geoff Dyer, *AstraZenneca in the Pink with 'Purple Pill,'* Financial Times, Dec. 4, 2001.

[5] *See* Connolly, *supra* note 3.

[6] *Patent Abuses*, Washington Post, Mar. 29, 2001, at A22.

[7] For a more complete discussion of the Hatch-Waxman regulatory framework, *see* Thomas B. Leary, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes (Nov. 3,

In order to obtain FDA approval to market a new drug, a branded manufacturer must file a New Drug Application ("NDA"). As part of this process, the NDA filer is required to submit a list of all the patents that cover the drug product, including its formulation, composition, or method of use.[8] This patent information is then published by the FDA in the Orange Book.[9]

In the event that a competitor wishes to market a generic version of the drug covered by an NDA, that competitor must file an Abbreviated New Drug Application ("ANDA"). As part of this process, the ANDA filer is required to provide a certification with respect to each patent listed in the Orange Book in conjunction with the relevant NDA.[10] One way to satisfy this requirement is to provide a Paragraph IV certification, asserting that the patent in question is invalid or not infringed.[11] Any ANDA filer that includes a Paragraph IV certification in its application must also provide notice to the NDA filer,[12] and, upon receipt of this notice, the NDA filer has 45 days within which to bring a patent infringement suit.[13] If the NDA filer elects to file suit, approval of the ANDA is automatically stayed for a period of 30-months.[14] And, as an incentive to undertake this potentially burdensome task, the first generic competitor to file an ANDA containing a Paragraph IV certification is granted a 180-day period of marketing exclusivity once the generic drug is on the market.[15]

2000) *available at* <http://www.ftc.gov/speeches/leary/learypharma.htm>; Thomas B. Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II (May 17, 2001) ("Leary Part II") *available at* <http://www.ftc.gov/speeches/leary/learypharmaceutical settlement.htm>.

[8] 21 U.S.C. ' 355(b)(1).

[9] *Id*. at ' 355(j)(7)(A). The FDA publication referred to herein as the "Orange Book" is officially entitled "Approved Drug Products with Therapeutic Equivalence."

[10] *Id*. at ' 355(j)(2)(A)(vii).

[11] *Id*. at ' 355(j)(2)(A)(vii)(IV).

[12] *Id*. at ' 355(j)(2)(B).

[13] *Id*. at ' 355(j)(5)(B)(iii).

[14] *Id.*

[15] *Id*. at ' 355(j)(5)(B)(iv).

III. Objectionable Conduct by Branded Manufacturers: Improper Orange Book Listings

In all likelihood, many, if not most, branded and generic pharmaceutical firms operate in good faith under Hatch-Waxman and endeavor to comply fully with the law. Unfortunately, not all firms have done so, and the Hatch-Waxman process has proven to be susceptible to abuse in at least some circumstances. Among the most notorious of these abuses are improper Orange Book listings. Pursuant to current FDA policy, the agency does not review patents presented for listing in the Orange Book to determine whether they do, in fact, claim the drug product described in the relevant NDA.[16] Instead, the FDA takes at face value the declaration of the NDA filer that listing is appropriate. As a result, an NDA filer intent on acting in bad faith can list questionable, and even clearly unlistable, patents. Once listed in the Orange Book, these patents have the same potential to trigger a 30-month stay of ANDA approval as any validly listed patent, thereby delaying generic entry and potentially costing consumers millions or even billions of dollars without valid cause.

A. Antitrust Enforcement as a Source of Relief

Initial private efforts to address fraudulent listing practices have not met with substantial success. For example, in November 2000, Mylan Pharmaceuticals sought to challenge Bristol-Myers' listing of a patent on Bristol's anti-anxiety drug, BuSpar. Rather than filing a Paragraph IV certification, and thereby triggering an automatic 30-month stay of approval of its ANDA, Mylan brought suit against both Bristol and the FDA. Mylan asserted that the patent in question did not cover BuSpar. Mylan therefore requested that the court issue an order requiring Bristol to de-list the patent and directing FDA to approve Mylan's ANDA. Although Mylan succeeded at the district court level, the Federal Circuit reversed that decision, holding instead that the Food Drug and Cosmetic Act ("FDC Act")[17] did not provide a private right of action to compel de-listing of a

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[16] *See* 21 C.F.R. § 314.53(f). *See also* Abbreviated New Drug Application Regulations – Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50343 (1994) ("FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims."); Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28910 (1989) ("In deciding whether a claim of patent infringement could reasonably be asserted . . . the agency will defer to the information submitted by the NDA applicant.").

[17] 21 U.S.C. § 301 *et seq*.

patent from the Orange Book.[18]

With the Federal Circuit's *Mylan* decision blocking any remedy under the FDC Act, some generic drug manufacturers have turned to the antitrust laws for relief. Here too, however, they may face a formidable obstacle in the form of the *Noerr-Pennington* doctrine. The *Noerr* doctrine – first articulated as an interpretation of the Sherman Act in *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*[19] and *United Mine Workers of America v. Pennington*[20] – provides antitrust immunity for individuals "petitioning" government. In the judicial context, *Noerr* immunity has been held to encompass, *inter alia*, the filing of lawsuit.[21]

The breadth of *Noerr-Pennington* immunity has been an ongoing interest of the FTC, of Chairman Muris in particular, and of the Office of Policy Planning, which has chaired an FTC Task Force on *Noerr-Pennington* since early last summer. Because filing a patent with the FDA could arguably be characterized as "petitioning" and because the filing of a patent infringement suit is what triggers the 30-month stay under the Hatch-Waxman Act, there has been significant concern, at the Commission and elsewhere, that overbroad application of the *Noerr* doctrine could effectively bar efforts to remedy fraudulent Orange Book listings through application of the antitrust laws.

This concern led the FTC to file an *amicus* brief in exactly such a dispute between generic and branded pharmaceutical firms in the Southern District of New York. That case – *In re Buspirone* – involves many of the same underlying facts as *Mylan*, and likewise involves a legal challenge to Bristol-Myers' alleged fraudulent listing of a patent on BuSpar. Rather than seeking to compel Bristol-Myers to de-list the patent from the Orange Book, however, the *Buspirone* plaintiffs challenged Bristol-Myers' conduct under a monopolization theory. Specifically, plaintiffs alleged that, though fraudulent patent filings with the FDA, Bristol-Myers caused the agency to list the patent in question in the Orange Book, thereby blocking any generic competition with BuSpar in violation of Section 2 of the Sherman Act.[22]

As anticipated, Bristol-Myers responded to these allegations by filing a motion to dismiss raising, principally, a claim of *Noerr-Pennington* immunity. Given the importance of the issue to

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[18] *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1331-32 (Fed. Cir. 2001).

[19] 365 U.S. 127 (1961).

[20] 381 U.S. 657 (1965).

[21] *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11 (1972).

[22] 15 U.S.C. § 2.

competition in the pharmaceutical industry, and to ongoing FTC investigations, the Commission filed an *amicus* brief opposing the motion to dismiss.[23] I had the opportunity to argue that case on behalf of the Commission and, on February 14, 2002, the Southern District of New York issued its decision denying Bristol-Myers' immunity claim and accepting much of the Commission's reasoning on the *Noerr-Pennington* issue.[24]

The court's order was broad, rejecting Bristol-Myers's claim of *Noerr-Pennington* immunity on three independent and alternative grounds. The first, and perhaps most important, of these grounds was that Orange Book filings simply do not constitute protected "petitioning." The court agreed with the Commission's argument that an Orange Book filing is analogous to a tariff filing. In both cases, "the government does not perform an independent review of the validity of the statements, does not make or issue an intervening judgment, and instead acts in direct reliance on the private party's representations."[25] The court also agreed that an Orange Book filing is not incidental to petitioning, holding that Bristol-Myers could have listed its patent in the Orange Book "without subsequently bringing infringement suits . . . [and] could have brought these suits without relying on its Orange Book listing."[26] The court's rejection of *Noerr* immunity based on an absence of petitioning conduct was particularly significant, as it did not require an examination of the accuracy and truthfulness of Bristol-Myers' individual representations to the FDA. Rather, it ensured that antitrust scrutiny, although not necessarily ultimate liability, would apply to improper Orange Book filing practices.

The court further concluded that, even if Orange Book filings were to constitute "petitioning," application of two specific exceptions to the *Noerr* doctrine – the *Walker Process* and "sham" exceptions – would preclude a finding of antitrust immunity. In contrast to the court's "petitioning" analysis, both the *Walker Process* and "sham" analyses required an examination of the veracity of Bristol-Myers' alleged statements to FDA.

Under *Walker Process*,[27] a patent holder may be subject to antitrust liability for attempting

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[23] Memorandum of Law of *Amicus Curiae* the Federal Trade Commission in Opposition to Defendant's Motion to Dismiss *available at* <http://www.ftc.gov/os/2002/01/busparbrief.pdf>.

[24] *In re Buspirone Patent Litigation/In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) ("*In re Buspirone*").

[25] *Id.* at 370.

[26] *Id.* at 372.

[27] *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp*, 382 U.S. 172 (1965).

to enforce a patent procured through fraudulent misrepresentations to the Patent and Trademark Office ("PTO"). The *Buspirone* court concluded that the Orange Book listing and patent prosecution processes were sufficiently analogous to warrant extension of the *Noerr* exception. The court noted that, like patent prosecution proceedings, Orange Book listing proceedings are not adversarial.[28] Furthermore, "[t]he FDA is required by law to perform even less independent review of the statements made in a listing submission than the Patent Office performs in the patent application review process, thus making the risks of abuse even greater."[29] Notably, the *Buspirone* court's decision is one of the first to apply the *Walker Process* exception outside the narrow PTO context.

The court's third alternative holding was that the plaintiffs' allegations satisfied the "sham" exception to *Noerr* immunity. Under the "sham" exception, a party filing a lawsuit may be subject to antitrust liability if the suit is a mere pretext for a predominantly anticompetitive objective. As clarified by the Supreme Court in *Professional Real Estate Investors* ("*PRE*"),[30] the "sham" exception to *Noerr* immunity applies when a suit is both "objectively baseless" and intended, not to achieve a successful result, but rather to burden the opposing party through use of the litigation process. The first prong of the *PRE* test – objective baselessness – is frequently difficult to satisfy, and has often ended the *Noerr* analysis in favor of immunity. Nevertheless, after an examination of the prosecution history of Bristol-Myers' patent, as well as the specification and claims, the *Buspirone* court concluded that Bristol-Myers' position that the patent was listable because it in fact claimed the drug described in its NDA was objectively baseless.[31] The court's holding was emphatic on this point, noting that "[t]his is . . . not a case in which Bristol-Myers has been arguing for reasonable extensions or developments of the law. Bristol-Myers has taken the straightforward position that it can, in effect, extend a monopoly and reclaim an invention after the expiration of its patent on the invention . . . . Bristol-Myers's argument ignores the law and tries to justify taking property that belongs to the public."[32]

B. Role of Generics in Antitrust Enforcement

In light of the *Buspirone* decision, and the force of the court's underlying reasoning,

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[28] *In re Buspirone*, 185 F. Supp. 2d at 373-74.

[29] *Id*. at 374.

[30] *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993).

[31] *In re Buspirone*, 185 F. Supp. 2d at 375-76.

[32] *Id*. at 376 (citations omitted).

Noerr-Pennington immunity may not prove as large an obstacle to using the antitrust laws to remedy improper Orange Book filings as was once feared. It is worth noting, and indeed emphasizing, that the *Buspirone* decision does not mean that all improper, or even negligent, Orange Book filings will give rise to antitrust liability. Any antitrust liability must necessarily be predicated on a clear showing of a violation of substantive antitrust law. But, under *Buspirone*, Orange Book filings are not automatically *immune* from those laws or exempt from their scrutiny.

Thus, generic pharmaceutical firms can play an important role in ensuring that Orange Book filings are not abused. Aside from any private recourse to the antitrust laws you may choose to pursue, you can also inform the federal antitrust authorities if you suspect illegal conduct. As we have discussed, the Federal Trade Commission has an ongoing interest in anticompetitive abuses in the pharmaceutical industry, and we remain very interested in hearing about such abuses.

It should be noted that abuses under Hatch-Waxman are a relatively new concern for the FTC, so our understanding of the scope and complexity of possible abuses is still developing. At its most basic level, what concerns the FTC about conduct under Hatch-Waxman is when private parties attempt to "game the system" by using the statutory regime to exclude competition beyond the lawful scope of their patent rights. It is not possible, at this stage, to catalogue every specific type of abuse that could possibly occur, but several potential "red flags" can be identified. None of these necessarily mean that the firm is in violation of the antitrust laws, but they are factors that suggest that competition may be being improperly foreclosed.

Examples of "red flags" that we have identified in the Orange Book filing context include, but are not necessarily limited to,[33] the following:

- listings that on their face do not satisfy the statutory listing criteria (*e.g.*, the patent at issue does not claim a formulation, composition, or method of use of the drug described in the relevant NDA);

- listings that appear to be strategically timed (*e.g.*, the patent at issue is submitted for listing in the Orange Book at a time when, but for the new listing, FDA approval of a pending ANDA would have been granted);

- listings based on patents that are on their face invalid or unenforceable; and

[33] The Federal Trade Commission is currently conducting a comprehensive study of competition in the pharmaceutical industry pursuant to Section 6(b) of the Federal Trade Commission Act, 15 U.S.C. § 46(b). *See* 65 Fed. Reg. 61334 (Oct. 17, 200); 66 Fed. Reg. 12512 (Feb. 27, 2001). One objective of the 6(b) Study is to identify additional examples of conduct in the Hatch-Waxman context that raise significant antitrust concerns.

- listings based on patents that appear to have been acquired from competitors solely for the purpose of listing.

IV. Objectionable Conduct by Generic Manufacturers: Collusive Settlements

Thus far I have discussed steps that generic manufacturers can take to promote competition in the pharmaceutical industry. There are, however, steps that are equally important *not* to take. While fraudulent Orange Book listings are, by definition, the exclusive terrain of branded manufacturers, there are abuses of the Hatch-Waxman process in which generic manufacturers can – and, in some instances, do – participate. The most prevalent of these abuses, to date, has been the collusive settlement of patent infringement litigation.

Patent settlement agreements are, by their very nature, agreements between horizontal competitors that, in the absence of the statutory patent monopoly, could raise serious questions under the antitrust laws. That being said, such agreements are a legitimate means of managing litigation risks and can be pro-competitive. The question, then, is: how one can reliably distinguish a pro-competitive patent settlement from an anticompetitive settlement?

In the Hatch-Waxman context, the answer often lies in an examination of the settlement payment.[34] The key question is: what is the payment for? In a traditional patent settlement, the alleged infringer pays a royalty to the patent holder for the right to make, use, or sell the patented invention. Such an agreement is pro-competitive, as it provides for *more* competition. A competitor that was barred from the market by operation of the patent monopoly is, as a result of the settlement, permitted to enter. Although the terms of the patent license may limit the new competitor's entry in important respects, there is little question that, overall, the new entry is competition-enhancing.

In contrast, the settlements in the Hatch-Waxman context that have drawn such intense antitrust scrutiny have tended to *impede* entry. Rather than opening the door to additional competition, the settlement payments in these cases appear to be in return for a commitment to delay. The hallmark of such a collusive agreement is a role reversal of the settling parties, pursuant to which, instead of the paying the patent holder for an opportunity to compete, the alleged infringer is paid to postpone competition or to compete less vigorously.

A. Conduct the FTC Has Seen in the Past: Patent Settlement Agreements Between Brands and Generics

[34] The term "payment" suggests a straight forward cash transaction, but the competitive implications are the same regardless of whether the settlement payment is made in cash or disguised, for example, as a license fee.

One reason there has been such close antitrust scrutiny of patent settlements between branded and generic drug manufacturers is that both parties may have economic incentives to collude to delay generic entry. As you know well, the first generic competitor typically enters the market at a significantly lower price than its branded counterpart, and gains substantial share from the branded product.[35] Subsequent generic entrants typically bring prices down even further.[36] The policies of many health plans requiring generic substitution whenever possible accelerate this trend. This competition substantially erodes the profits of branded manufacturer. Furthermore, because of the significant price differential between branded and generic products, the profits gained by the generic are often substantially less than profits lost by the brand.

Given these incentives, colluding to delay entry may be a profit-maximizing alternative for both parties. By blocking entry, the branded manufacturer can preserve its monopoly profits. A portion of these profits, in turn, can be used to fund payments to the generic manufacturer to induce it to forgo the profits it could have realized by selling its product. Furthermore, by delaying the first generic's entry – and with it, the triggering of the 180 days of exclusivity – the branded and first-filing generic firms can sometimes forestall the entry of other generics. Entering into litigation settlement agreements, purportedly for the purpose of resolving patent infringement claims, is one method that certain drug manufacturers have used to effect such a collusive scheme.

As a result of two particularly well known cases involving brand/generic settlements – *Abbott/Geneva* and *Hoechst/Andrx* – at least some contours of problematic settlements are now relatively familiar.[37]

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[35] *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>. *See generally* David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002) ("Reiffen and Ward"), *available at* <http://www.ftc.gov/be/econwork.htm>.

[36] *See* CBO Study, *supra* note 35; Reiffen and Ward, *supra* note 35, at 4.

[37] Similar issues are raised by a third case – *Schering-Plough* – that is still in litigation. *See In the Matter of Schering Plough Corp.*, Docket No. 9297 (March 30, 2001) (complaint) *available at* <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf>. The administrative hearing against Schering and defendant Upsher-Smith concluded on March 22, 2002. An initial opinion from the presiding Administrative Law Judge, and possible appeal to the full Commission, remain pending. On April 2, 2002, the Commission resolved all claims against defendant American Home Products ("AHP") by issuing a final consent order. Pursuant to the terms of the order, AHP is prohibited from entering into two categories of agreements: (1) those in which the brand makes a

The first of these cases involved an agreement between Abbott Laboratories and Geneva Pharmaceuticals, Inc. relating to Abbott's branded drug Hytrin. The Commission's complaint alleged that Abbott paid Geneva approximately $4.5 million/month to delay entry with its generic Hytrin product, potentially costing consumers hundreds of millions of dollars a year.[38] The complaint further alleged that Geneva agreed not to enter the market with *any* generic Hytrin product – including a non-infringing product – until: (1) final resolution of the patent infringement litigation involving Geneva's generic Hytrin tablets, or (2) market entry by another generic Hytrin manufacturer. Geneva also allegedly agreed not to transfer its 180-day marketing exclusivity rights.

The second case involved an agreement between Hoechst Marion Roussel and Andrx Corp. relating to Hoechst's branded drug Cardizem CD. The Commission's complaint alleged that Hoechst paid Andrx over $80 million, during the pendency of patent litigation, to refrain from entering the market with its generic Cardizem CD product.[39] The complaint further alleged that Andrx agreed to this arrangement without regard to the merits of the underlying patent infringement claim. As in the *Abbott/Geneva* case, the Commission also asserted that agreement called for Andrx, as the first ANDA filer, to use its 180-day exclusivity rights to impede entry by other generic competitors.

Both cases were resolved by consent order.[40] The orders prohibited the defendant companies from entering into brand/generic agreements pursuant to which a generic company that is the first ANDA filer with respect to a particular drug agrees not to: (1) enter the market with a non-infringing product, or (2) transfer its 180-day marketing exclusivity rights. In addition, the companies were required to obtain court approval for any settlement, entered into during the pendency of patent litigation, that provided for payments to the generic to stay off the

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payment to the generic in return for delayed entry, and (2) those in which the generic agrees not to enter the market with a non-infringing product. *See In the Matter of American Home Products Corp*., Docket No. 9297 (April 2, 2002) (consent decree) *available at* <http://www.ftc.gov/os/2002/04/scheringplough_do.htm>.

[38] *See In the Matter of Abbott Laboratories*, Docket No. C-3945 (May 22, 2000) (complaint) *available at* <http://www.ftc.gov/os/2000/03/abbottcmp.htm>.

[39] *See In the Matter of Hoechst Marion Roussel, Inc*., Docket No. 9293 (Mar. 16, 2000) (complaint) *available at* <http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm>.

[40] *See In the Matter of Abbott Laboratories*, Docket No. C-3945 (May 22, 2000) (consent decree) *available at* <http://www.ftc.gov/os/2000/03/abbottagreement.htm>; *In the Matter of Hoechst Marion Roussel, Inc*., Docket No. 9293 (May 8, 2001) (consent decree) *available at* <http://www.ftc.gov/os/2001/04/hoechstdo.pdf>.

market. Advance notice to the Commission, rather than court approval, was required before entering into such agreements in non-litigation contexts.

Although the terms and operation of each of these agreements were unique, a few generalizable rules can be drawn from the resulting FTC actions. As with the Orange Book filings, the Commission's understanding of the myriad factual possibilities is still developing, but, again, there are several "red flags" (illustrated in all three consent decrees) that can be expected to draw close scrutiny:

- *Provisions that restrict the generic's ability to enter with non-infringing products.* Such provisions can extend the boundaries of the patent monopoly without providing any additional public disclosure or incentive to innovate, and therefore can run afoul of traditional principles of antitrust law.[41]

- *Provisions that restrict the generic's ability to assign or waive its 180-day marketing exclusivity rights.* Under the prevailing interpretation of the Hatch-Waxman Act, a second ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired.[42] Restrictions on assignment or waiver of the exclusivity period can consequently be substantially competition-reducing, as they can function as a bottleneck that can potentially prevent subsequent generic entry for an extended period.[43]

- *Provisions that provide for "reverse" payments.* Both the courts and the Commission have tended to regard so-called "reverse" payments (*i.e.*, a substantial payment from the patent holder to the alleged infringer) as strong evidence that the settlement at issue may represent an anticompetitive division of monopoly profits. Accordingly, "reverse" payments have merited very close scrutiny.

B. Conduct Likely to Draw Future Antitrust Scrutiny: Agreements Between First and Second Generic Entrants

Although agreements between first and second generic entrants have attracted significantly less attention to date, they too can raise competitive concerns and may draw antitrust scrutiny in

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[41] *Cf. Brulotte v. Thys. Co.*, 379 U.S. 29, 33 (1964) (holding that "enlarg[ing] the monopoly of the patent" by collecting post expiration royalties constitutes patent misuse).

[42] 21 U.S.C. § 355(j)(5)(B)(iv)(II).

[43] *But see* Leary Part II, *supra* note 7, at 7 (arguing that agreements regarding waiver of the 180-day exclusivity period may have no anticompetitive effect absent reverse payment).

the future. As in the case of agreements between brands and generics, the incentives to collude are strong. The data suggest that the first generic typically enters the market at 70-80% of the price of the corresponding brand,[44] and rapidly secures as much as a two-thirds market share. The second generic typically enters at an even lower price and, like the first, rapidly secures market share. Collusion between the generics can thus be a means of preventing price erosion in the short term, though it becomes substantially less feasible as subsequent ANDAs are approved and additional competitors enter the market.

In its investigations to date, the Commission has had significantly less experience with agreements of this kind than with the brand/generic settlement agreements discussed previously. It is consequently much more difficult at this stage to generalize "red flag" provisions that suggest an anticompetitive purpose. Two potentially problematic types of agreements, however, are worth noting for illustrative purposes.

The first involves an exclusive distributorship arrangement. It is conceivable that a second generic entrant, rather than bringing a competing product to market, might agree to become the exclusive distributor of the first entrant. Such an arrangement would essentially grant the second entrant an agreed upon share of the market, rather than requiring it to secure that share at the expense of the first entrant through aggressive price competition.

The second involves the division of market segments. One can hypothesize, for example, an arrangement pursuant to which the first entrant agrees to market its product exclusively in one strength, while the second entrant agrees to market its product exclusively in another. Like the exclusive distributorship arrangement, the objective of such an agreement would appear to be *less* vigorous competition, as the agreement would simply grant each company a reciprocal market segment that would otherwise need to be secured through competition on price and other terms.

As with any antitrust case, the analysis would depend on the actual facts, but, at a minimum, such hypothetical arrangements would arouse significant interest at the Commission.

V. Conclusion

As healthcare costs continue to rise, helping maintain robust competition in the pharmaceutical industry is a key priority of the Federal Trade Commission. In some instances – such as improper Orange Book listings – achieving this objective will require the vigilance of generic drug manufacturers. In others – such as collusive settlements – it will require your cooperation in avoiding such conduct. We look forward to working with the generic industry on both aspects of this ongoing endeavor. Thank you again for the invitation to join you today and for your ongoing efforts to compete vigorously in providing needed pharmaceuticals to American

[44] *See* CBO Study, *supra* note 35; Reiffen and Ward, *supra* note 35, at 22.

consumers.