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HAVE THE COURTS TAKEN THE BITE OUT OF THE FTC WATCHDOG?

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HAVE THE COURTS TAKEN THE BITE OUT OF THE FTC WATCHDOG?

When there is a choice between settlement and litigation, most would agree that a negotiated settlement is in everyone's best interest. However, when two or more competitors reach an agreement, the logical question would be whether the agreement is in the public's best interest. Congress instituted an official federal watchdog on these agreements through the Sherman[1] and Clayton[2] Antitrust Acts, which authorized the Federal Trade Commission's (FTC) oversight of agreements between competitors. These acts have been continually amended over the years to clarify the role of the Commission and even expand it. One such expansion was the result of the Hatch-Waxman Act, also known as the Drug Price Competition and Patent Term Restoration Act of 1984, which explicitly gave the Commission the responsibility to review any agreements reached by holders of pharmaceutical patents and their potential infringing generic competitors.[3] Congress reaffirmed the role of the Commission in the 2003 Medicare Amendments (MAA),[4] which further amended Hatch-Waxman to strengthen the FTC's role in the review of such agreements. The parties are aware the Commission is silently looking over their shoulder during negotiations. They are also aware that the FTC can take action against them if it does not like the final settlement. Several recent federal court rulings now may call the power of this settlement watchdog into question. This paper will give a brief explanation and history of the Hatch-Waxman Act, the FTC's role in reviewing these agreements, and the results of this oversight,

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[1] The Sherman Antitrust Act (originally enacted July 2, 1890, ch. 647, 26 Stat. 209, 15 U.S.C. § 1–7).
[2] The Clayton Antitrust Act of 1914, (originally enacted October 15, 1914, ch. 323, 38 Stat. 730, codified at 15 U.S.C. § 12–27, 29 U.S.C. § 52–53).
[3] 35 U.S.C. 355(j)(5)(D)(i)(V).
[4] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act or MMA), Pub. L. No.1 08-173.

both prior to the 2003 amendments and after. Several court decisions in 2005 have questioned this intersection of patent and antitrust law, and the negotiation climate has changed as evidenced by the nature of the settlements that have been reached after these rulings. This paper will examine the impact of these settlements and the response of the FTC. Analyzing an *amicus curiae* brief the FTC recently filed in the appeal of one of these cases and recent testimony before Congress, we will look at the Commission's own assessment of these decisions and its view of the issues in patent infringement negotiation and settlement. We will look at the Commission's call to Congress for action as well its recommendations for Congressional action. Finally, we will evaluate whether the FTC's role is hampered and its course of action restricted.

THE HATCH-WAXMAN ACT

The manufacture and distribution of pharmaceutical drugs are regulated by the Federal Food, Drug and Cosmetic Act (Act).[5] Congress passed the Hatch-Waxman Amendments to the Act in 1984, after concluding that the Act's cumbersome drug approval process delayed the entry of relatively inexpensive generic drugs into the market place. The Hatch-Waxman Amendments embodied Congress's intent to make available more low cost generic drugs and its attempt to balance two conflicting policy objectives: to induce name–brand pharmaceutical firms ("brand") to make the investments necessary to research and develop new drug products, while

[5] 21 U.S.C. §§ 301, et seq.

simultaneously enabling competitors ("generics") to bring cheaper, generic copies of those drugs to market.[6]

Competitors could market their generic versions through the process of filing an Abbreviated New Drug Application (ANDA). What was to be included in the application involved much less information than was required when an innovator company files what is called a New Drug Application (NDA). The most significant difference is that a NDA must contain "(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use . . ."[7] These required investigations are costly and extensive. The latest estimate is $868 million, up from the 2002 estimate of $802 million, and costs can vary from $500 million to $2 billion, depending on the therapeutic area.[8] In contrast, the ANDA applicant only has to provide such information to show that the labeling proposed for the new drug have been previously approved and is the same, that the active ingredient(s) is (are) the same as that of the listed drug, that the route of administration, the dosage form, and the strength are the same and that the new drug is bioequivalent to the listed drug referred.[9] The other numerous requirements are the same for NDAs and ANDAs except for the safety and efficacy investigations required in (b)(1)(A).[10] All of these requirements generally speak to the quality and identity of both the original drug products as well as their generic equivalents. However, the next clause in subsection (j)

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[6] Ann K. Wooster, Annotation, *Construction and Application of Hatch–Waxman Act, Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C.A. § 355 and 35 U.S.C.A. § 271(e) (1994))*, 180 A.L.R. Fed. 487 (originally published in 2002, updated 2008).
[7] 21 U.S.C. § 355(b)(1)(A)
[8] Christopher P. Adams and Van V. Brantner, *Estimating The Cost Of New Drug Development: Is It Really $802 Million?* 25 HEALTH AFFAIRS 2, 420 (2006)
[9] 21 U.S.C. § 355(j)(2)(a)(i)-(v) (2006)
[10] 21 U.S.C. § 355(j)(2)(a)(vi) (2006)

has been the source of much litigation between the NDA holders and their generic competitors:

> "(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or . . .
>
> (I) that such patent information has not been filed,
> (II) that such patent has expired,
> (III) of the date on which such patent will expire, or
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . .[11]"

The last paragraph is often referred to as Paragraph IV certification and was one of the major innovations of the Hatch-Waxman Act. If the generic manufacturer was found to be infringing a patent at the time of application, it would be without the risk of infringement damages because no sales would have occurred. This clause gives a generic company the right to challenge the validity of a patent prior to obtaining approval of the ANDA and prior to any sales of the product.

HATCH-WAXMAN AND PATENT LAW

In Title 35 of the United States Code, which covers patent law, the rights of the patent holder are spelled out. These rights, sometimes called the patent holder's monopoly, are the rights of exclusion: "(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."[12] The code specifically states that to submit an application to the FDA for approval for a drug whose patent coverage has

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[11] 21 U.S.C. § 355(j)(2)(a)(vii) (2006).
[12] 35 U.S.C. § 271(a)(2006).

not expired was an act of infringement.[13, 14] Hatch-Waxman added this paragraph that allows the courts to determine the invalidity of a patent prior to the actual sale of the generic product in order to minimize any potential damages.

Hatch and Waxman also knew that this legislation could not be one-sided and modified other sections of patent law to grant patent extensions to the brand-name products when prolonged regulatory review results in a loss of significant patent term coverage.[15] These are the only instances where patent terms are extended other than by delay within the Patent Office itself.[16]

HATCH -WAXMAN AND THE ROLE OF THE FTC

The act specifically calls upon the FTC to play the role of watchdog.

> "(V) The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal . . . has been or can be taken that the agreement has violated the antitrust laws . . ."[17]

Since 2004, the Commission has reported annually to Congress on how many agreements it reviews, the nature of the agreements, whether they resolved patent litigation, if payments are made, and if the payments were offered in exchange for delayed entry of the generic into the marketplace.[18] These reports are issued as a result of an amendment to the Hatch-Waxman Act in 2003 under the Medicare

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[13] *Id.* at (e).
[14] *But see,* Glaxo, Inc. v. Novopharm, Ltd. 110 F.3d 1562, 1567 (Fed. Cir. 1997), (holding that the ANDA is not the sole factor in an infringement analysis and that it does not alter a patentee's normal burden of proving infringement by a preponderance of the evidence.).
[15] 35 U.S.C. §156.
[16] 35 U.S.C. §154(b).
[17] 21 U.S.C. 355(j)(5)(D)(i)(V).
[18] Federal Trade Commission – Website, http://www.ftc.gov/reports/index.shtm.

Prescription Drug, Improvement, and Modernization Act of 2003 (MAA).[19] As a result of a report on the generic drug industry by the FTC, Congress had decided that the law needed more teeth. Under the original act, the first generic manufacturer who received approval of their ANDA was granted a 180-day exclusivity period during which the FDA would not approve other ANDAs from other applicants.[20] This exclusivity was triggered either by the generic entering the market or a court decision that the generic product was not infringing. What the amendment did was remove that exclusivity to the applicant if the FTC found that they ". . . have engaged in anticompetitive or collusive conduct, or any other conduct intended to unfairly monopolize the commercial manufacturing of the drug of the application."[21]

RESULTS PRIOR TO THE MEDICARE AMENDMENTS OF 2003

What had prompted the addition of such a disincentive to settlement in the Act were the results of a study that the FTC had conducted covering the period from the time of enactment of Hatch-Waxman up to 2002. The FTC prepared this comprehensive study of the industry along with several legislative recommendations,[22] some of which were eventually incorporated into the MAA. The report acknowledges that overall the Hatch-Waxman Act had been successful in getting more generic drugs into the marketplace. At the time of the report, generics comprised more than forty-seven percent of all prescriptions filled, up from nineteen percent in 1984 – the year when Hatch-Waxman was enacted.[23] It was estimated that in 1994 the availability of

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[19] Note 4, *supra.*
[20] 21 U.S.C. §355(j)(5)(B)(iv).
[21] MAA, § 403(a)(VI).
[22] *See* FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (2002), , http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.
[23] *Id.* at 10.

generic drugs saved purchasers between $8 billion and $10 billion.[24] The study found that for drugs that are available in both generic and brand-name versions, the average price of a generic prescription was approximately half of the average price of a brand-name prescription product.[25] During the 1980s, only two percent of generic applicants sought entry into the marketplace prior to patent expiration, but from 1998 to 2000, the numbers rose to twenty percent.[26] During that time period, for the first time, the FDA granted the 180-day exclusivity to 31 applications as a result of a policy change based on a court ruling.[27] The FTC raised concerns in this report that this 180-day exclusivity could be used in negotiations to settle patent litigation. The report looked at twenty final and four interim settlements during this time period and found that the running of the exclusivity period was an issue that could delay the introduction of other generics.[28] Of these settlements, fourteen of the final settlements (and no interim settlements) within the first generic applicants, at the time they were executed, had the potential to delay the triggering of the first generic applicant's 180-day exclusivity for some period of time, and thus to delay FDA approval of any subsequent eligible applicants.[29] The FTC saw these exclusivity term delays, referred to as "parking,"[30] as barriers to other generic

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[24] *See Id.* at 9 (referencing CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 28, http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf.)

[25] FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 9 (2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf .

[26] *Id.*

[27] *Id.* at 57; *See also Mova v. Shalala*, 140 F. 3d 1060, 1074 (D.C. Cir. 1998) (holding that statute prohibiting FDA from approving second filer's ANDA until a date 180 days after first filer begins commercially marketing its generic drug, or until drug patent is declared invalid or not infringed by first filer, did not permit regulation conditioning 180-day market exclusivity period on requirement that first filer has successfully defended against patent infringement suit).

[28] FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 26 (2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[29] *Id.*

[30] *See Id.* at 12.

manufacturers entering the market, since the FDA could not approve any other ANDA until 180 days after the first generic started marketing.[31] Since there was no litigation as the result of the settlement, only marketing would trigger the running of the period. In theory, approval of other generic versions of a product could be kept off the market indefinitely. Congress was surprised by the anticompetitive loophole and incorporated several of the FTC made recommendations into the MMA.[32]

RESULTS AFTER THE MEDICARE MODERNIZATION ACT

Because Congress was concerned that the pharmaceutical industry would find other ways to slow the entry of generics, it required the FTC to report annually on settlements between pharmaceutical patent holders and generic companies. These can be found at the FTC website.[33] The last three years for which there are statistics show some interesting and unexpected trends. The FTC looked at all of the agreements in the industry involving generics and classified them according to the following: whether the agreement was between brand-generic or generic-generic manufacturers, whether the agreement resolved patent litigation, whether the agreement restricted generic entry, whether the agreement involved any payments between the parties, and whether the agreement involved the first generic to file for FDA approval or a subsequent generic filer.[34]

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[31] *See Id.* at 57-63.
[32] *Id.* See Executive Summary and Legislative Recommendations at i – xi.
[33] Footnote 18, *supra*.
[34] All data and information reported here and in the following paragraphs have been extracted from the three annual reports found at the website at footnote 18, supra: Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in Fiscal Year 2004: A Report by the Bureau of Competition (January 2005); Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in Fiscal Year 2005: A Report by the Bureau of Competition (April 2006); and Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act

In FY2004, the FTC received twenty-two agreements for review, in FY2005, twenty, and in FY2006 an increased load of forty-five, more than the two previous years combined. Fourteen 2004 settlements, eleven 2005 settlements and twenty-eight 2006 settlements resolved patent litigation, with 2006 again having more than the two previous years combined. The nature of these settlements also changed as further analysis shows.[35]

In 2004, there were fourteen brand-generic agreements resolving patent infringement, nine of which had no restrictions on the generic entry into the market and no or varying payment arrangements. Several reasons why there was no restriction on the generic: in three agreements, the generic was already on the market and the settlement did not require the generic to withdraw; five agreements allowed the generic to market its product upon FDA approval and one brand agreed to supply the product to the generic to market. (This allows the brand to still profit by manufacturing the generic version of the product for the generic company to sell.) Three of these settlements did not involve payments, two involved royalties to the brand and four involved payment to the generic.[36]

In 2005, there were eleven settlements of patent litigation and for the first time, three final settlements included both compensation to the generic and a restriction on the generic's ability to market its product.[37] These three agreements covered a total of five products. Between 1992 and 1999, half (eight) of the settlements included

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of 2003: Summary of Agreements Filed in Fiscal Year 2006: A Report by the Bureau of Competition (January 2007). All years referenced in the reports refer to federal fiscal years.

[35] *Id.*

[36] *Id*. FY2004 Report

[37] *Id.* FY 2005 Report. The Commission pointed out that it lacked data for the period from June 1, 2002 and January 07, 2004, which was the interval between its Generic Drug Study reported at note 22, *supra*, and the MMA reporting requirements.

provisions to restrict market entry. None of the twenty settlements in 2000, 2001 or 2004 involved these restrictions. In 2005, in all three of these agreements, both the brand and generic company received compensation. The brand received a royalty in exchange for granting the generic a license to the patent at issue in the litigation. One deal involved the agreement that the brand company would not launch its own authorized generic during the 180-day exclusivity period. (A brand-name firm always has the option of introducing its own generic version, because it only requires FDA approval of a new label. Brand-name firms that have generic divisions often do this to minimize the impact of other generic competition with the brand.) Two of the agreements included side deals for other products unrelated to the alleged infringing product. In one agreement, the brand allowed the generic to co-promote the brand product and the generic received royalties, and in the other, the generic received licenses to sell authorized generic version of unrelated products for which the generic company had not filled an ANDA. The length of time that the generic was delayed was related to the size of the market. For three products exceeding $150 million in annual sales, the agreed entry date varied from 30 to 100 months. For the two products with lower sales, the entry time was four to 10 months.[38] A fourth agreement created a restriction on the generic's entry into the market, but did not provide compensation to the generic. Seven of the remaining final settlements included no restriction on market entry.[39]

FY2006 showed an increased number and overall increased proportion of these types of agreements between the brand and the generic that both provided

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[38] *Id.* at 4-5.
[39] *Id.* at 6.

compensation to the generic company accompanied by restrictions on market entry. There were a total of twenty-eight patent litigation settlements with fourteen (or fifty percent) with these payment-restriction features. By contrast, only twenty-seven percent of the patent litigation settlements in the previous years had these elements. Ten of these had complex side-deals not directly related to the original patent dispute. Two either paid the saved litigation expenses to the generic, or in addition to the saved litigation expenses, an agreement by the brand not to launch its generic version during the 180-day exclusivity of the first filer's rights.[40]

In summary, over a three-year period, 2006 showed a significant increase over the previous two years in settlements, totaling more than the two previous years combined. The number of patent litigation settlements proportionally increased, again with 2006 seeing more than the two previous years combined. More significantly, in 2005 the settlement structure combining the delay of the generic's market entry in combination with some type of payment appeared for the first time with twenty-seven percent of the patent litigation settlements having this form. 2006 followed closely on its heels with fourteen settlements adopting this structure, a whopping fifty percent of all the patent litigation settlements, almost doubling the percentage of the total patent litigation settlements in a year with the largest number of settlements. The obvious question is – what changed? Congress did not amend the statute changing any obligations nor did it create an exemption that these agreements would not be in violation of the Clayton Act. The FTC points out in the FY2005 Report and FY2006

[40] *Id.* 2006 Report at 3.

reports that these new agreements came on the heels of significant court decisions that have seriously questioned the ability of the FTC to police these agreements.[41]

THREE COURT DECISIONS THAT BIT THE WATCHDOG

The federal courts in 2005 rendered three decisions that changed the climate for patent infringement settlements. The first one, an Eleventh Circuit decision that ruled against the FTC, was issued on March 8, 2005. In that case, *Schering-Plough Corporation v. Federal Trade Commission*, the court looked directly at the intersection of patent and antitrust law.[42] The case began in the mid-90's when Upsher-Smith Laboratories filed an ANDA for a generic version of Schering-Plough's K-Dur 20, a form of potassium chloride in an extended-release form.[43] Schering sued Upsher-Smith for infringement, but in 1997, prior to trial, the two companies began settlement discussions.[44] They agreed that September 1, 2001 would be the earliest date Upsher-Smith could enter the market, but Schering refused to pay cash for the agreement.[45] Upsher insisted it needed cash.[46] Schering agreed to a separate deal to license other Upsher products in the therapeutic area which it had an interest, including a sustained release niacin product.[47]

ESI Lederle filed an ANDA in the same year as Upsher for a potassium chloride extended release tablet.[48] Schering also sued ESI for infringement.[49] The trial judge prompted the parties to engage in a court-supervised mediation. Schering offered ESI

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[41] *Id.* 2005 Report at 3, 2006 Report at 1.
[42] *Schering-Plough Corp. v. The Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005).
[43] *Id.* at 1058.
[44] *Id.*
[45] *Id.* at 1058-59.
[46] *Id.* at 1059.
[47] Schering-Plough Corp., 402 F.3d at 1059.
[48] *Id.* at 1060.
[49] *Id.*

entry into the market on January 1, 2004, almost three years prior to patent expiration.[50] Schering agree to pay ESI $5 million, attributed to legal fees, but ESI wanted another $10 million.[51] Schering agreed only if ESI received FDA approval by a certain date.[52] The settlement was signed in the presence of the trial judge.[53]

In 2001, the FTC filed a complaint against the three companies.[54] The case was tried before an Administrative Law Judge who found that both agreements were lawful settlements of legitimate patent lawsuits and dismissed the complaint.[55] The complaint was appealed before the full Commission who reversed the ALJ ruling, and the appeal from that finding went to the Eleventh Circuit who reviewed the FTC's finding of fact and economic conclusions under the substantial evidence rule.[56]

The court vacated the Commission's order and rejected any rule of law that would "automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and in an ancillary transaction, pays for other products."[57] It held that "[s]uch a result does not represent the confluence of patent and antitrust law."[58] Patents, by their nature, create an environment of exclusion and consequently, cripple competition. The court gave a three fold analysis of antitrust liability that it had previously established in *Valley*

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[50] *Id.*
[51] *Id.*
[52] *Id.*
[53] Schering-Plough Corp., 402 F.3d at 1060-61.
[54] *Id.* at 1061.
[55] *Id.*
[56] *Id*. at 1062.
[57] *Id.* at 1076.
[58] *Id*.

Drug[59]: ". . .(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope and (3) the resulting anticompetitive effects."[60] The court relied on its holding in *Valley Drug* that a patent holder does not incur antitrust liability when it chooses to exclude others from producing patented work.[61] Further explaining that "[a]lthough the exclusionary power of patent may seem incongruous with the goals of antitrust law, a delicate balance must be drawn between the two regulatory schemes. . .application of antitrust law . . .cannot discount the rights of the patent holder."[62]

Shortly after the Eleventh Circuit handed down this decision, the Second Circuit decided on*, In Re: Tamoxifen*.[63] That case involved an appeal by consumers and third-party payors against the dismissal of their complaint against Zeneca, AstraZenca Pharmaceuticals LP, along with Barr Labs, a generic manufacturer, for violation of antitrust law.[64] After Barr filed its ANDA, ICI (the predecessor in patent ownership and former parent company to Zeneca) sued for infringement. ICI's patent was found to be invalid based on inequitable conduct. During ICI's appeal, the parties came to an agreement where Barr agreed to drop its Paragraph IV certification, thus agreeing not to enter the market until the patent had expired. In exchange, Zeneca granted Barr a license to sell a generic version, tamoxifen, manufactured by Zeneca.[65] In the

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[59] *See Valley Drug Co. v. Geneva Pharms. Inc.*, 344 F.3d 1294 (11th Cir. 2003)(holding that subsequent invalidation of patent does not alone render the challenged agreement anticompetitive.)
[60] *Id. at* 1319.
[61] *Id.* at 1305.
[62] *Schering-Plough Corp.*, 402 F.3d. at 1067.
[63] In Re: Tamoxifen Citrate Antitrust Litigation; *sub nom* Joblove v. Barr Labs, Inc., 429 F.3d 370, (2d Cir. 2005) amended, 466 F.3d 187 (3d Cir. 2006).
[64] *Id.*
[65] *Id.* at 193–94. (The structure of the agreement is more complex, including a filing in the trial court to dismiss and vacate the judgment concerning the validity of the patent, but this simplified version captures the major agreement.)

meantime, other generic manufactures became involved in patent litigation over tamoxifen.[66] Thirty lawsuits were filed by various consumers and consumer groups challenging the agreement between the parties, which were consolidated in the Eastern District of New York and dismissed. The appeal attempted to overturn the District's dismissal.[67] The Second Circuit, relying on *Schering-Plough* as well as a decision that had been reached in a similar case in the Eastern District of New York, affirmed the dismissal. The court held that the reverse payment did not provide benefits to Zeneca, the patentee, outside the scope of the tamoxifen patent.[68] In fact, the court found that by the parties reaching a settlement, it avoided creating the 180-day bottleneck that would have been created by Barr's market introduction and thus cleared the way for other generics to enter the fray.[69] The court cited the Eleventh Circuit's *Schering-Plough* decision fourteen times, agreeing that a delicate balance must be drawn between the two regulatory schemes.[70]

Around the same time, the District Court for the Eastern District of New York delivered a judgment that similarly dealt a blow to the FTC. *In Re: Cipro (III)*[71] is a case similar to *Schering-Plough* involving reverse payments with a similar long history. In 1991, Barr Labs filed an ANDA for ciprofloxacin hydrochloride (Cipro) along with a Paragraph IV certification. Rugby, a subsidiary of HMR, agreed to help Barr with financing the patent challenge.[72] In 1997, just weeks before the trial, Bayer and Barr

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[66] *Id.* at 196
[67] In Re: Tamoxifen Citrate Antitrust Litig., 196 F. Supp. 2d 1371 (J.P.M.L. 2001).
[68] *Id*. at 216.
[69] *Id.* at 215.
[70] *Id*. at 202.
[71] In Re: Ciprofloxacin Hydrochloride Antitrust Litigation, 363 F. Supp 2d. 514(E.D.N.Y. 2005)
[72] *Id.* at 519.

reached separate settlements with Barr, Rugby and HMR, and Apotex.[73] Under the Barr Settlement, Bayer paid Barr $49.1 million and required Barr to change the Paragraph IV certification to Paragraph III, which meant that Barr had to wait until the Bayer patent expired.[74] Barr retained the right to go back to Paragraph IV if the Bayer patent was found invalid.[75] It was also agreed that Bayer would either supply Cipro or make quarterly payments to Barr until the patent expired in 2003.[76] Bayer chose to make payments, which totaled $398 million including the initial payment.[77]

Bayer's patent was reexamined by the Patent and Trademark Office and found to be valid. Four other companies challenged the patent and Bayer prevailed over all of them either through summary judgment, trial or dismissal.[78]

The Eastern District Court of New York began its analysis using the rule of reason established by the Second Circuit, which involved the plaintiff proving that agreement had an actual adverse effect on competition as a whole in the relevant market, the defendant showing the pro-competitive virtues of the agreement, and then the plaintiff showing that an alternative, less restrictive means was available.[79] The court acknowledged that the Eleventh Circuit in *Schering-Plough* used a slightly different method, the per se rule, but the outcome would be the same regardless.[80] The court either dismissed the complaints or granted the defendants partial or full summary judgment. The court held that the plaintiffs failed to demonstrate anti-competitive

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[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] *Id.* at 520.
[79] *Id.*
[80] *Id.*

effects in the market and the restrained competition did not go beyond the scope of the claims of the patent. The patent allows a zone of exclusion within the bounds of its claims and the zone is undiminished by any potential invalidity of the claims, which is compelled by the presumption of validity that is accorded to patents.[81] The court cited *Schering-Plough* dozens of times in the opinion. The case is under appeal in the Court of Appeals for the Federal Circuit.[82]

FTC RESPONDS

Based on the annual reports made to Congress, the FTC had picked up the climate change that occurred after *Schering-Plough* as well as the other cases. As a result, in 2007 Commissioner Jon Leibowitz appeared before the U.S. Senate Committee on the Judiciary[83] and the House of Representatives Subcommittee On Commerce, Trade, And Consumer Protection of the Committee On Energy And Commerce.[84] His testimony before the Committee and Subcommittee was essentially identical except for several brief paragraphs discussing the specific bills being introduced before each body on that day.

The Commissioner started off with the statement that recent decisions have made it more difficult to stop exclusion payment settlements, also known as reverse payments, something the Commission had challenged and had successfully stopped in

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[81] *Id.* at 545.
[82] Docket 2008-1097.
[83] Prepared Statement of the Federal Trade Commission before the Committee on the Judiciary of the United States Senate on Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution, January 17, 2007. Can be found at http://www.ftc.gov/os/testimony/110hearings.shtm.
[84] Prepared Statement of the Federal Trade Commission before the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, United States House of Representatives on Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative solution to Anticompetitive Patent Settlements in the Pharmaceutical Industry, May 2, 2007. Can be found at http://www.ftc.gov/os/testimony/110hearings.shtm.

the past, in the wake of antitrust enforcement from 2000 to 2004.[85] He cited specifically the *Schering-Plough* and *In re: Tamoxifen* appellate decisions in 2005 as the change in the legal landscape that evoked a response from the industry. He stated explicitly that "[t]hese rulings disrupt the careful balance between patent protections and encouraging generic entry that Congress sought to achieve in the Hatch-Waxman Act."[86] He noted the number and percentage of 2006 settlement agreements (fourteen of twenty-eight or 50 percent, respectively) that involved compensation to the generic and delay of market entry.[87]

The Commissioner uses a strong economic argument against these appellate rulings and also stressed the harm to consumers. He cites that consumers have been saved more than $9 billion from generic competition following successful patent challenges to just four brand-name drugs.[88] He countered the argument that generic entry based on a successful challenge to a patent is too uncertain to be a competitive concern with the 75 percent success rate that generics have achieved in Hatch-Waxman patent litigation.[89] Finally, he countered that exclusion payments are not necessary for parties to reach settlement based on the five-year period when there were no reverse payments, but still many settlements.[90]

Finally, the Commission stated that the FTC would continue to be diligent about enforcement through the courts, but that realistically, it would take years for a case to come to conclusion and that the outcome was uncertain. In the meantime, exclusion

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[85] *Id.* at 1, 3.
[86] *Id.* at 5.
[87] *Id.* at 3.
[88] Id. at 18.
[89] Id. at 20.
[90] Id.

payment agreements would continue, delaying generic entry and costing consumers, employers and the government through its various prescription programs billions of dollars.[91]

The Commissioner requested the passage of Senate Bill S.316, which was introduced into the 110th Congress on the date of his Senate Committee testimony and House of Representatives Bill H.1902, which was introduced on the date of his House Subcommittee testimony. Both bills remain in Committee as of this summer.

The FTC also has filed an *amicus curiae* brief in the appeal of *In Re: Ciprofloxacin* in its attempt to continue its vigilance.[92] In the brief, the FTC argues against the court's holding, that as long as exclusionary terms are within the scope of the patent, the settlements are immune from antitrust scrutiny. This contravenes well-established antitrust principles and clear Congressional intent as expressed in Hatch-Waxman.[93] The Commission further argues that Bayer did not obtain Barr's absence from the market through its patent, but through its substantial payment.[94] The Commission argues how a patent holder and an infringer should view their relative negotiating positions. If a patentee's validity and infringement arguments are strong, the more advantageous the terms it can negotiate. The accused infringer will accept a limitation based on its ability to compete in proportion to its view of the probable outcome of the patent limitation. The entry date will reflect their views of the probable outcome of the patent litigation and demonstrate the exclusionary power of the patent.

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[91] Id.
[92] Corrected Brief Of Amicus Curiae Federal Trade Commission In Support Of Appellants And Urging Reversal Ark. Carpenters Health & Welfare Fund v. Bayer AG (*In re* Ciprofloxacin Hydrochloride Antitrust Litig.), 544 F.3d 1323 (Fed. Cir. 2008)) (No. 08-1097), http://www.ftc.gov/os/2008/01/ciprobrief.pdf
[93] *Id.* at 15.
[94] *Id.* at 16.

The patentee hopes that the strength of its patent will result in accession by the infringer or an injunction by the court.[95]

The FTC argues that Bayer did neither. Instead it chose to avoid the court's scrutiny of its patent by making exclusion payments and the accession by Barr was not based on the strength of Bayer's patent and its power to exclude, but with payments that were in excess of what Barr could have hoped to make with a successful entry.[96] The FTC referred to them as "naked exclusion payments,"[97] based on the theory that Bayer knew that the exclusionary power of the patent at the time of settlement was insufficient to obtain continuing exclusivity, so they bought off Barr along with the possibility of their patent failing. Since this exclusion is not based on the power of the patent, the court wrongly decided that the patent immunized the agreement from antitrust scrutiny.[98] The FTC discounts the argument that Bayer's patent was sufficiently strong to withstand challenge since it survived various court challenges. It argues, ironically relying on *Valley Drug Co*.,[99] that it matters what the company believed at the time of settlement.

The FTC's second argument, consisting of equating the exclusionary power of a patent with its antitrust immunity, ignores the existence of uncertainty regarding whether a patent is valid. Once Barr filed its ANDA it was clearly a potential competitor, and the potential as a competitor was proportional to the uncertainty of the patent validity. The FTC argue,s based on years of case law, that antitrust law condemns restraint on potential as well as actual competition. The FTC also cites *United States v. Griffith*,

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[95] *Id.* at 17.
[96] *Id.*
[97] *Id.*
[98] *Id.* at 18.
[99] See note 48, *supra.*

quoting "[T]he anti-trust laws are as much violated by the prevention of competition as by its destruction.[100] *Palmer v. BRG of Ga., Inc.*[101] was cited about two competitors who provided bar exam reviews dividing up the market between them, and the Court held it was a violation of the antitrust law. However, this is not a strong argument against a potential competitor since the two parties in that case were actual competitors. The Commission poses the hypothetical that if Bayer had paid Barr to forego market entry based on the probability to obtain FDA approval of its ANDA, that it would be clearly anticompetitive. The Commission's reasoning is that the uncertainty around the validity of the patent should be treated the same and that cash payment is based on the analogous uncertainty and not the strength of the patent.

The FTC's final argument was that the rulings were contrary to legislative intent and imposed a great economic harm to the consumer, and subvert the Congress's intended policies.[102] The FTC claimed the court misinterpreted the intent of Hatch-Waxman as not intending to thwart settlements and asserts that Congress specifically sought to encourage litigation.[103] The Commission also accuses the court of not addressing the consumer harm and not understanding the economics of the pharmaceutical industry.[104]

WHERE DOES THE FTC STAND NOW?

The FTC is seemingly caught in a legislative limbo and judicial standstill, pending the outcome of the appeal in the Federal Circuit of the *In Re: Ciprofloxacin*. The Supreme Court has denied certiorari in *Schering-Plough* and the Commission has not

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[100] U.S. v. Griffith, 334 U.S. 100, 107 (1948)
[101] Palmer v. BRG of Ga., Inc.498 U.S. 46(1990)
[102] Amicus brief at 24.
[103] *Id.* at 27.
[104] *Id.*

prepared another brief concerning *In Re: Tamoxifen* since the amended ruling was issued in 2006. Legislation is stalled in committee. The Commissioner has clearly stated that the power and authority of the FTC has been severely diminished by these court rulings, and this has been validated by the nature and number of reverse payment agreements that have been reached by the companies post-*Schering-Plough*. Even a positive ruling in the Commission's favor by the Federal Circuit will not resolve the issues definitely. Until Congress acts, as Leibowitz stated, the only thing the Commission can do is continue to be vigilant, report to Congress annually on the number and nature of patent litigation settlements and decide whether to pursue more enforcement actions in the present unfavorable judicial climate. This is clearly not the role Congress envisioned when it passed The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which was to give the Commission more bite. The watchdog, while not losing its bite in general, has been put on a very short leash when it comes to antitrust enforcement under Hatch-Waxman. It is clearly up to Congress to take action if the watchdog is to be effective in the pharmaceutical industry.