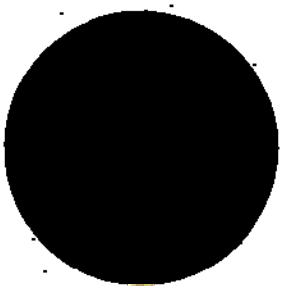

Federal Trade Commission

FTC Litigation at the Antitrust/Intellectual Property Interface

Remarks of J. Thomas Rosch, Commissioner[1]

[1] The views expressed herein are my own, and do not necessarily represent the views of the Federal Trade Commission or any other individual Commissioner. I would like to express my appreciation to Holly Vedova and Kyle Andeer, my attorney advisors, for their invaluable contributions to this paper.

[2] F.M. Scherer, The Political Economy of Patent Policy Reform in the United States, Working Paper 06-22, Oct. 2006, AEI-Brookings Joint Center For Regulatory Studies, *available at:*

Commission's complaint against Schering Plough was dismissed by the 11th Circuit,[4] and in June 2006, the Supreme Court declined *certioriari*. That opinion, and the Second Circuit's decision in *In Re: Tamoxifen Citrate Antitrust Litigation*,[5] impose limits on when some possible abuses of intellectual property rights ("patents," for simplicity's sake) can be challenged under the antitrust laws. Under *Schering* at least, the viability of many, if not all, challenges to patent abuses turns on whether or not "the exclusionary effects of the agreement fall within the scope of the patent's protection."[6] This standard undoubtedly makes it more difficult for the Commission to challenge exclusion payment settlements (and possibly other patent abuses).

I believe that *Schering* and *Tamoxifen* are bad law and should be reversed. This could happen in one of two ways. First, the Supreme Court has just asked for the Justice Department's recommendation whether the Court should review the decision in *Tamoxifen*. The Commission is hopeful that the Supreme Court will review and reverse *Tamoxifen* in a fashion that will discredit *Schering.* Second, Senators Kohl, Iu-2.33 TD0.00ensi2(shicond, S)>4i(ll wi, ITc 4)3.8(a)-0.4(shion tho

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4 *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

5 429 F.3d 370 (2d Cir. 2005).

6 *Schering*, 402 F.3d at 1076.

7 *See* 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, *available at*: <http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf>.

supports the intent of this legislation.

In the event this legislation, or other legislation, doesn't overtake this controversy, or that this Supreme Court does not overturn *Tamoxifen,* and the *Schering* 11th Circuit decision remains in effect, I believe it is possible for the Commission to challenge some settlements of patent litigation in the H-W-A arena consistent with these decisions.[8] And I believe it is important for the Commission to do that in order to protect consumers from the tremendous harm that these settlements can cause. Here are several options that I believe may be the best ways to approach exclusion payment settlements.

1. Challenges to H-W-A Patent Settlements that Include a Generic's Covenant Not to Compete

A. Scenario 1: Suppose a brand and a generic enter into an exclusion payment settlement, and that the generic's covenant not to compete applies to a product of the generic that is clearly outside the scope of the brand's patent. A challenge would be warranted even under *Schering and Tamoxifen*.[9] That agreement is *per se* illegal because insofar as the settlement falls outside the protection of patent, it is nothing more than an agreement between potential

[8] In the Commission's recent settlement with Warner Chilcott, the Order includes a fencing-in provision that prohibits Warner Chilcott from entering into any branded/generic agreement where the NDA holder provides anything of value to the ANDA filer, the ANDA filer refrains from entering the market, and the agreement unreasonably restrains competition. *See Federal Trade Commission v. Warner Chilcott Holdings Co. III, Ltd.,* Civil Action No. 05-2179 (U.S. D.C. D.C.) Final Order and Stipulated Permanent Injunction (Oct. 23, 2006).

[9] *See Schering,* 402 F.3d at 1066; *Tamoxifen*, 429 F.3d at 397; *see also In re Cardizem CD Antitrust Litigation,* 332 F.3d 896 (6th Cir. 2003).

competitors not to compete with each other.[10]

In some instances, it is unclear whether the generic's product is within the scope of the brand's patent. The answer might depend on a laborious claim construction analysis of the brand's patent – an often difficult task. I think the Commission should avoid challenges on this

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[10] *See Palmer v. BRG of Ga.*, 498 U.S. 46 (1990) (per curiam) (applying *per se* rule to a market divisions agreement between potential competitors involving a copyright); *Cardizem CD Antitrust Litigation*, 105 F.Supp. 2d 682, 700 (E.D. Mich. 2000).

[11] *See Schering*, 402 F.3d at 1066 note 14; *see also Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 491 (treating as patent misuse a lease tying the use of patented machines to the purchase of unpatented materials for use in the machines; stating that "[a] patent affords no immunity for a monopoly not within the grant…and the use of it to suppress competition in the sale of an unpatented article may deprive the patentee of the aid of a court of equity to restrain an alleged infringement. . .").

[12] *See Schering*, 402 F.3d at 1065, n.14; *Tamoxifen*, 429 F.3d at 401; *see also Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) ("a patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly. But to use that leverage to project those royalty payments beyond the life of the patent is analogous to an effort to enlarge the

lacking patent protection, it is nothing more than a naked agreement not to compete between competitors.[13]

C. Scenario 3: The third scenario is the one addressed in *Schering.* Suppose the covenant not to compete applies to a generic product that may infringe a "reasonable interpretation" of the brand's patent (assuming that patent is valid). The covenant delays the generic's entry for some period of time but the generic could enter the market prior to the patent's expiration. I think the Commission can continue to scrutinize these settlements and challenge them under appropriate circumstances, consistent with *Schering.*

Schering holds that if the settlement allows the generic to introduce a product that

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monopoly of the patent by tieing [sic] the sale or use of the patented article to the purchase or use of unpatented ones.").

[13] *Palmer*, 498 U.S. 46; *Cardizem*, 105 F.Supp. 2d at 700.

[14] *Schering*, 402 F.3d at 1068, 1076.

issue as being whether the covenant is outside the protection afforded by the patent, and 2) it concludes, based on the record before it, that the covenant is outside the protection afforded by the patent because the patent is invalid or the generic's product will not infringe the patent.

The validity or scope of the brand's patent does not need to be taken at face value. In other words, *Schering* does not create an *irrebuttable presumption* that the brand's patent is valid and/or that it will be infringed by the generic. The question is one of proof – what the Commission must do in order to prevail on the issues of validity and/or infringement.

One way to do that is to engage in the battle of experts that often occurs in patent litigation. That is expensive and would require either in-house or outside expertise. A second way is by use of direct evidence of invalidity or non-infringement.[15] Such direct evidence, however, rarely exists. A third way is by relying on circumstantial evidence, including the parties' positions prior to settlement, the parties' views about validity and infringement as reflected in their contemporaneous statements and documents, and the existence of a demonstrably excessive "reverse payment." Given the burden of engaging in a battle of experts and the scarcity of direct evidence in most cases, I think the third approach is generally the best.

Schering does not reject the use of circumstantial evidence to resolve the issues of validity and/or infringement. To be sure, *Schering* rejects as a sufficient basis for finding

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[15] Judge Posner provided the following example: "Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues it competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices – masks – for fixing prices, in violation of antitrust law." *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003).

invalidity or non-infringement the existence of a reverse payment, standing alone.[16] Moreover, in *Schering* the court said that "the size of the payment should not *dictate* the availability of the settlement remedy."[17] Thus, the circumstantial evidence of invalidity or non-infringement cannot, consistent with *Schering*, consist *solely* of the existence of a reverse payment; nor can the size of the payment, standing alone, *dictate* findings of invalidity or non-infringement.

This is not to say, however, that the existence and size of such a payment lack probative value in evaluating whether the patent is valid and whether there is infringement. Thus, evidence that the reverse payment equals or exceeds the generic's potential profits if it wins (taking into account the remaining life of the patent and the lower profit margins if there is competition), buttressed by other evidence (for example, that the payment was made despite the presumption of validity or evidence from an ex-employee or because the parties' documents show the payment was made because it was believed the brands' patent was invalid) should be sufficient to create an inference that the patent is in fact invalid.

This approach does not treat "the private thoughts of a patentee, or of the alleged infringer who settles with him" as the ultimate issue.[18] The ultimate issue under this approach is whether the covenant not to compete exceeds the protection afforded by the patent, and what matters in deciding that issue is whether the patent is *actually* valid and infringed, not whether the parties thought it was valid and infringed. The thoughts of the parties on that score, as

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[16] *Schering*, 402 F.3d at 1075 ("Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the *sole* basis for a violation of the antitrust law. . . ").

[17] *Id.*

[18] *Tamoxifen*, 429 F.3d at 394.

[19] *See United States v. Microsoft Corp.*, 253 F.3d 34, 59 (D.C. Cir.), *cert. denied*, 534 U.S. 952 (2001) ("[e]vidence of the intent behind the conduct of a monopolist is relevant . . . to the extent it helps us understand the likely effect of the monopolist's conduct."); *see also Chicago Board of Trade v. United States*, 246 U.S. 213, 238 (1918) ("knowledge of intent may help the court to interpret facts and to predict consequences. . . "); *United States Football League v. NFL*, 842 F.2d 1335, 1359 (2d Cir. 1988) ("[e]vidence of intent *and* effect helps the trier of fact to evaluate the actual effect of challenged bu004 Tro evaluw .t Tm87rhe trn.t 5 of intent onoaluuyupTm87rh

boundaries set forth by *Schering*

[21] *See Gordon v. New York Stock Exchange*, 422 U.S. 659, 682, 688 (1975); *Pan Am. World Airways v. United States*, 371 U.S. 296, 305, 309-10 (1963).

[22] *See* C. Scott Hemphill, Paying For Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem, 81 N.Y.U.L. Rev. 1553 (Nov. '06).

policy – one which favors litigation over settlement – *in a very specific and limited industry context.* Thus, it seems strongly arguable to me that the H-W-A, not the patent laws, is the more relevant regulatory regime in these cases.

Moreover, certain aspects of the H-W-A widen the potential for competitive harm from exclusion payment settlements. For example, the 180 day exclusionary period provides that first-to-file ANDA holders can create a bottleneck if the first to file ANDA holder agrees not to enter; subsequent ANDA filers are prohibited from entering until they obtain a favorable court decision in patent infringement litigation in which they are involved. Exclusion payment settlements can take advantage of this and other aspects of the H-W-A and disrupt the balance articulated by Congress by favoring patentee rights over consumer access to generic pharmaceuticals. In short, it is strongly arguable that in the limited circumstances of the H-W-A, that Act, not the patent law regime, is the relevant regulatory regime in determining whether and how antitrust law should apply to exclusion payment settlement agreements, and it is also strongly arguable that under the H-W-A regulatory regime, the antitrust laws should apply on a broader basis than described in the *Schering* decision.[23]

At the very least the fundamental legislative intent behind the H-W-A – *i.e.*, the intent to facilitate generic competition by encouraging challenges to branded product patents – counsels that the presumptions with respect to validity and infringement (the latter erroneous) which the *Schering* court described ought to be eliminated in H-W-A litigation. *A fortiori* those

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[23] *See id.* at 142-43, 157.

presumptions should not apply in Commission challenges to reverse payment settlements.[24]

2. Blocking Patent Assertions.

Let me now turn to abuses of patent rights outside of the exclusion payment context. Suppose in a merger to monopoly or duopoly, the parties argue that there is no horizontal overlap in the relevant product market because the acquiring party has a blocking patent. They argue, invoking *United States v. General Dynamics Corp.*,[25] that the competitive picture is misleading because the acquired firm is not a lawful competitor and, but for the acquisition, it would be eliminated by an infringement suit. The Commission is hearing this claim more often these days.

The initial question is whether *Schering* and *Tamoxifen* require the Commission to capitulate to the argument, absent proof that the patent asserted is invalid or that there is no infringement. The answer should be no. Unlike the settlements in those cases, an acquisition of the sort hypothesized will *eliminate the acquired firm altogether* – not only during the period of the patent but after its acquisition. Thus, there is a powerful argument that the merger exceeds the scope of the protection afforded by the patent and hence is subject to challenge under both

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[24] The Commission's October 2003 report, "To Promote Innovation: the Proper Balance of Competition and Patent Law and Policy, a Report by the Federal Trade Commission," *available at*: <http://www.ftc.gov/opa/2003/10/cpreport.htm> made a similar recommendation. Recommendation 2 recommends enactment of legislation that specifies that challenges to the validity of a patent are to be determined by courts based on a "preponderance of the evidence" standard instead of "clear and convincing evidence."

[25] 415 U.S. 486 (1974).

afforded by a patent can be challenged under Section 1 or Section 2.

Even if that were not so, in asserting *General Dynamics* the parties are in effect asserting a defense. The burden of proof is therefore on the parties to prove the facts necessary to make the defense viable – in this case that the patent is valid and that the acquired firm's products infringe.[26]

The simple assertion of the patent should not be enough to carry that burden. Nor should the Commission accept the patent as issued by the PTO at face value. The merger parties must grapple with the inherent uncertainty of patent litigation. The parties should have to convince the Commission, and perhaps eventually a court hearing the challenge to the merger, that the

[26] *See Olin Corp. v. FTC*, 986 F.2d 1295, 1305-06 (9th Cir. 1991), *United States v. Baker Hughes*, 908 F.2d at 991 ("[t]he more compelling the prima facie case, the more evidence the defendant must present to rebut it successfully.").

applications covering certain features of those products and the patents issue. After the competing products have been brought to market one of the competing firms acquires additional patents from third parties. It then uses those patents to threaten its present and potential competitors with litigation and "build a wall" around the market, eliminating competition and preventing entry.

This is not a new scenario. In *United States v. Singer Manufacturing Co.*[27] the Supreme Court held that, in the context of a broad monopolistic scheme, the transfer of a patent from a Swiss manufacturer to its U.S. licensee to facilitate bringing infringement actions against Japanese competitors violated Section 1. Similarly, in *Kobe, Inc. v. Dempsey Pump Co.*[28] the Tenth Circuit found the acquisition, nonuse and enforcement of "every important patent" in the field with a purpose to exclude competition, together with other anticompetitive acts, constituted a violation of Section 2. And in *Xerox Corp.*[29] the Commission entered into a consent decree with Xerox settling a Commission challenge to Xerox's acquisition of the Battelle patents on plain paper copiers allegedly with the purpose and effect of monopolizing the plain paper copier market.[30]

Suppose a company pursues a strategy of patent acquisitions, infringement suits and

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[27] 374 U.S. 174 (1963).

[28] 198 F.2d 416 (10th Cir. 1952).

[29] 86 F.T.C. 364 (1975).

[30] Subsequently, in *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195 (2d. Cir. 1981) the Second Circuit held that the same acquisitions did not violate either Section 7 or Section 2 because, inter alia, the acquisitions were made many years before there was a plain paper copier market. In a challenge to the creation of a patent thicket it would be important to challenge acquisitions made only after there was a product market.

licenses from third parties, in addition to its own development efforts, and thereby builds a patent portfolio that allows it to control the market. Absent *Schering* and *Tamoxifen*, it would appear that this conduct would be ripe for challenge on a Section 2 theory under *Singer* and *Kobe Pump*. The principal question, however, is whether *Schering* and *Tamoxifen* require proof that the patents acquired are not valid or whether they have been asserted against competitors or would-be competitors who were not infringers. The question becomes especially acute if some of the patent acquisitions are made as a result of patent litigation settlements in which the company obtains licenses from alleged infringers of patents that the company had previously acquired.

It is strongly arguable that proof of actual invalidity and/or noninfringement is not required. No such proof was required in *Singer* or *Kobe Pump*ono.165uired.

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[31] *Sargent-Welch Scientific Co. v. Ventron Corp.*, 567 F.2d 701, 711-12 (7th Cir. 1977) ("[t]here are kinds of acts which would be lawful in the absence of monopoly but, because of their tendency to foreclose competitors from access to markets or customers or some other inherently anticompetitive tendency, are unlawful under § 2 if done by a monopolist . . ."); *California Computer Prods., Inc. v. IBM*, 613 F.2d 727, 735-36 (9th Cir. 1979) (acts otherwise lawful must be "unreasonably restrictive of competition" to violate § 2); *Greyhound Computer Corp., Inc. v. IBM*, 559 F.2d 488, 498 (9th Cir. 1977) (monopolist "precluded from employing otherwise lawful practices that unnecessarily excluded competition . . .").

All of this said, however, the scheme itself, as well as the fact that the acquisitions were made in furtherance of it – *i.e.* that the company would not have obtained the monopoly power it obtained but for the acquisitions and that was the purpose and effect of the acquisitions – must be proved by either direct or circumstantial evidence.

4. Challenging Patent "Trolls"

Suppose a firm acquires one or more patents from a third party who never sought to license or otherwise assert its patents in a market. The new patent holder never seeks to develop, license, market or otherwise invest in the technologies covered by the patents. Instead, it simply puts them in its pocket and waits for others to develop products that may infringe on the acquired patents. Eventually the patent holder identifies a feature or component of the product that it believes infringes on its patents, and it seeks to assert the patents against all firms manufacturing the product. The patent holder enjoys some additional leverage because redesign of the product to avoid the patent would be expensive and time consuming. Thus, the patent holder can engage in patent "hold up." This of course is not a new scenario. It is the strategy being followed by firms that are acquiring patent portfolios without any intention to use them to develop a product.

The first question is whether this conduct can be challenged under the Sherman Act. It is strongly arguable that it can be. However, it is doubtful that a challenge could be based on effects of the conduct in a product market because, by definition, the "troll" does not participate as a competitor in that market.[32]

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[32] *See Official Airline Guides, Inc. ("OAG") v. FTC*, 630 F.2d 920, 925-926 (2d Cir. 1980).

clearly covered by the Sherman Act. Nor would such a challenge be foreclosed by *OAG*. To be sure, *OAG* rejected a stand alone Section 5 claim where the respondent was not a participant as a competitor in the market impacted by the challenged conduct.[35] However, if the relevant market is the technology licensing and/or innovation market, the troll would be a participant in the market. Moreover, in its subsequent *Ethyl* decision the Second Circuit left the door open to a Section 5 claim if there was evidence of "oppressiveness" in the form of an "anticompetitive intent" or the "absence of a legitimate business purpose."[36]

Conclusion

The *Schering* and *Tamoxifen* decisions present a challenge to the Commission's enforcement efforts against abuses of patent rights, but these decisions are not a complete obstacle. I have outlined several viable approaches to reconcile the Commission's enforcement activities against exclusionary payment settlements and other patent rights abuses with those decisions. Particularly in the pharmaceutical industry, it is vitally important for the Commission to actively work to protect competition, because both innovation and competition are immensely important to consumer welfare. I look forward to answering any questions you may have. Thank you.

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[35] *OAG*, 630 F.2d at 926.

[36] *E.I. Du Pont De Nemours & Co. v. FTC, ("Ethyl"),* 729 F.2d 128, 139-140 (2d Cir. 1984).