

Patent Misuse and Abuse in the United States and Europe: The Case of Pharmaceuticals

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On November 20, 2008, the Health Care & Pharmaceuticals Committee of the ABA's Antitrust Law Section and The George Washington University Law School's Competition Law Center co-sponsored a panel discussion of leading antitrust practitioners who reviewed trends in cases and governmental investigations of alleged anticompetitive behavior relating to pharmaceutical patents in the United States and Europe. Philip B. Nelson, a Principal at Economists Incorporated, moderated the panel. The panel provided different perspectives on the impact of the Court of Appeals for the Federal Circuit's recent *In re Ciprofloxacin*¹ decision on challenging patent settlements between patent holders and generic competitors in the United States. The panel further discussed whether, by contrast, the European Commission's "dawn raids" and industry-wide investigation to explore agreements between generic entrants and patent holders signals increased enforcement activity in Europe. They also identified policy issues and counseling considerations that arise in this area.

Lore Unt

Principal Counsel for Intellectual Property Litigation, Federal Trade Commission

Ms. Unt began with some background on the regulatory framework relating to approval of generic pharmaceutical products in United States, i.e., the "Hatch-Waxman Act"² and state automatic substitution laws. She discussed the average historic impact of generic entry on pharmaceutical prices. She further identified incentive structures faced by both brand and generic companies that she said could encourage the parties to agree to delay generic entry.

Ms. Unt next provided an overview of five main areas where conduct relating to the procurement and use of patents has triggered antitrust challenges in the pharmaceutical sector in the United States: (1) "exclusion payments;" (2) "sham" or bad faith litigation; (3) *Walker Process*³ fraud and similar abuse of process cases; (4) patent acquisition; and (5) product switching strategies.

Ms. Unt described "exclusion payments" (also referred to as "reverse payments")—payments that flow from the patent holder to the generic challenger in a patent suit settlement and are alleged to be anticompetitive—as an area of "great debate." Four Federal Circuit Courts of Appeal have addressed the legality of patent settlements involving reverse payments. The Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*,⁴ has been described as applying a *per se* illegality standard to reverse payment patent settlements. The Eleventh Circuit applies a three-part test under the rule of reason that examines (i) the patent's "potential exclusionary effect;" (ii) the extent to which the settlement agreement exceeds that scope; and (iii) the resulting anticompetitive effects.⁵ The Second Circuit in *Tamoxifen*, applied similar reasoning to that of the Eleventh Circuit, evaluating whether the "exclusionary effects of the agreement exceed the scope of the patent's protection."⁶ And, very recently, the Federal Circuit essentially adopted the Second Circuit's standard and reasoning in the *Cipro* case.⁷

While a number of commentators have pointed to the trends in the caselaw, including most importantly the Federal Circuit's recent *Cipro* decision, as

converging on a legal standard that is supportive of patent settlement even where reverse payments are involved, Ms. Unt stated that the issue is by no means resolved. She pointed out that there are cases pending in district courts in circuits that have yet to address the issue, such as the Federal Trade Commission's ("FTC") suit against Cephalon,⁸ which is pending in the Eastern District of Pennsylvania and would go to the Third Circuit on appeal, and that the Supreme Court has yet to weigh in on the legal standard.⁹ Moreover, there are differences in approach regarding how to assess the "scope of the patent." She stated that, with the change in administration, there would be a new Solicitor General who might have a different approach than that expressed during the Bush administration in the Department of Justice's brief opposing certiorari in the *Schering-Plough* case. Ms. Unt further noted that federal legislation aimed at curtailing reverse payment settlements is pending in Congress.

Ms. Unt next discussed "sham" patent litigation, which involves monopolization or attempted monopolization claims based on alleged bad faith enforcement of a patent known to be invalid or not infringed. While most efforts to enforce patents are protected against antitrust claims by the *Noerr-Pennington* doctrine,¹⁰ such patent enforcement efforts are not immune from antitrust scrutiny if such efforts are (1) objectively baseless and (2) subjectively in bad faith, i.e., there is a subjective intent to interfere with competition. Ms. Unt stated that sham litigation cases are hard to prove. There have, however, been some instances in which defendants have lost motions to dismiss sham litigation claims where,

¹ 544 F.3d 1323 (Fed. Cir. 2008).

² Drug Price Competition and Patent Term Restoration Act of 1984, codified at 21 U.S.C. § 355.

³ *Walker Process Equip. Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

⁴ 332 F.3d 896 (6th Cir. 2003).

⁵ See, e.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

⁶ *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 396-97 (2d Cir. 2005) (internal quotations omitted).

⁷ *Ciprofloxacin*, 544 F.3d at 1323.

⁸ *FTC v. Cephalon, Inc.*, No. 08-cv-2141-RBS (E.D. Pa.).

⁹ The plaintiffs in the *Cipro* Federal Circuit case are now seeking Supreme Court review.

¹⁰ The doctrine is named for *Eastern R.R. Presidents' Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965), the first two cases in which the Supreme Court limited the enforcement of the antitrust laws against private petitioning of government action.

Ms. Unt said, the defendants have seen that these cases will go badly for them and have settled.

Ms. Unt also discussed “abuse of process” cases—those involving allegations that patents were improperly listed in the Orange Book for the purpose of delaying generic competition by triggering multiple 30-month litigation stays.¹¹ She noted that recently fewer cases have been brought making such allegations and attributed that to congressional amendments to Hatch-Waxman such that only one 30-month litigation stay is now available, reducing the incentive for improper Orange Book listings.

Ms. Unt concluded with a brief overview of “product switching” cases. These cases involve allegations that pharmaceutical patent holders implement new minor product design changes, just as patents or Hatch-Waxman litigation stays are about to expire, for the purpose of further delaying generic competition.¹² Ms. Unt indicated that the trend appears to be for courts to apply a rule of reason analysis in these cases, analyzing whether anticompetitive effects are outweighed by procompetitive benefits of the new products, such as consumer preferences, technical superiority, or cost reductions.

Marleen Van Kerckhove

Partner, Arnold & Porter LLP

Ms. Van Kerckhove started out observing that, in contrast to the United States, where patent abuse in the pharmaceutical sector has been an area of great concern and activity by the FTC for some time, this is an area that until a few years ago had received little or no attention in EU antitrust law. She illustrated this, stating there has been only one European Commission decision in this area (*AstraZeneca*¹³), that there has yet to be any decision from the European courts in this area (although *AstraZeneca* is on appeal to the Court of First Instance (“CFI”)), and that there are few pending European Commission investigations. Despite this prior lack of attention, however, the EC now is looking into the topic of pharmaceutical patent abuse and misuse in what has been described in some quarters as the widest-

ranging EC sector inquiry ever. Currently, the sector inquiry is focused on fact-finding; there have yet to be any resulting prosecutions.

Ms. Van Kerckhove noted preliminarily that, unlike the United States (where Sherman Act § 1 reverse payment cases have and continue to be a hot area), in Europe, patent misuse/abuse cases typically involve unilateral conduct. She explained that under EU antitrust rules (Article 82¹⁴), unilateral conduct by a patent holder will be found to infringe only where a company is considered “dominant.” However, there is no precedent regarding market definition and “dominance” regarding the pharmaceutical industry for purposes of Article 82, that is, outside of the merger context. This is an area on which the CFI may shed light in the *AstraZeneca* case. Additionally, Ms. Van Kerckhove noted that regulatory controls in the pharmaceutical sector, particularly price controls, and the variation in such regulation between the various EU member states, make any assessment of market dominance in pharmaceuticals in Europe particularly complex.

Ms. Van Kerckhove next summarized the *AstraZeneca* case, which involved Losec, a proton pump inhibitor. The abuses alleged involved (1) knowing misrepresentations to various patent offices to obtain Supplementary Protection Certificates and thereby extend patent protection on Losec and (2) “product switching” whereby AstraZeneca switched in a tablet version for the Losec capsule and then deregistered the original capsule version of Losec in certain countries thereby preventing generic authorization and competition.

Ms. Van Kerckhove then provided an overview of the EU Pharmaceutical Sector Inquiry. She explained that the inquiry involved a combination of “dawn raids,” extensive and multiple information requests to all stakeholders, a preliminary report, to be followed by opportunities for sector and public reaction and a final report. The inquiry could result in individual antitrust investigations and possibly changes in regulatory and/or

intellectual property law. She noted that some of the issues the inquiry will deal with include defining dominance; analyzing the appropriate interface between IP and antitrust law; and assessing the regulatory framework and evaluating whether infringing behavior can be remedied by other regulatory rules. Ms. Van Kerckhove noted that the regulatory framework that has shaped US caselaw in this area is quite different from the EU regulatory framework. For example, the incentives for reverse payment patent settlements in the United States do not exist in the EU. She added that past EC policy documents and cases recognize that patent settlements can be pro-competitive. Further, EU precedent regarding “vexacious” litigation (i.e., “sham” litigation) suggests that antitrust infringement in this area rarely occurs.

Mike Cowie

Partner, Howrey LLP

Mr. Cowie, providing a U.S. private practitioner perspective, also has experience from the FTC side, as he worked at the FTC during the *Schering-Plough* case. Mr. Cowie started his presentation with a discussion of the Federal Circuit’s decision in the *Cipro* case, which he described as the “single most important case in this field.”

Mr. Cowie explained that Federal Circuit judges are the appellate patent experts. In the context of reverse payment settlements, the Federal Court has held that a patentee has the right to exclude within the scope of the patent. It has weighed in on the side of favoring dispute settlement.¹⁵ He further noted that the Federal Circuit was clear that there should be no consideration of the strength of the patent in reverse payment settlement cases in the absence of fraud or sham litigation.¹⁶ Noting that most of the Federal Circuits that have addressed the issue have weighed in on the side of supporting these patent settlements,¹⁷ Mr. Cowie offered a different perspective from Ms. Unt, stating that it is not clear that there is even a circuit split. In *Cardizem*, the brand-generic settlement provided that the generic manufacturer would not market non-infringing versions of generic drugs,¹⁸ and thus, as noted by the Federal Circuit in

¹¹ See, e.g., *In re Bristol-Myers Squibb Co.*, 2003 FTC LEXIS 34 (F.T.C. 2003).

¹² See, e.g., *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006).

¹³ Case T-312/05.

¹⁴ Article 82 EC.

¹⁵ *In re Ciprofloxacin*, 544 F.3d at 1333-34.

¹⁶ *Id.* at 1336-37.

¹⁷ See *In re Ciprofloxacin*, 544 F.3d 1333; *Schering-Plough Corp. v. FTC*, 402 F.3d at 1074; *In re Tamoxifen*, 429 F.3d 370, 389 (2d Cir. 2005).

¹⁸ *In re Cardizem CD Antitrust Litigation*, 332 F.3d at 909 n.13.

Cipro, the agreement in that case clearly had anticompetitive effects outside the scope of the patent.¹⁹

Mr. Cowie referenced the FTC's continued efforts to bring cases challenging patent settlements involving payments to generics in an effort to bring about a circuit split, including the *Barr/Warner Chilcott* case,²⁰ which settled, and the pending *Cephalon* case.²¹ However, in Mr. Cowie's view, in light of what he saw as a convergence in the Circuits on standards, further action to curtail brand-generic patent settlements is likely to be focused in the legislative arena.

Mr. Cowie next spoke about scrutiny of authorized generics. He noted that most courts have ruled that authorized generics are pro-competitive.²² Moreover, the FTC has treated authorized generics as competitive constraints, requiring divestitures in the *Teva/Ivax*²³ and *Watson/Andrx*²⁴ investigations. Even so, the FTC launched an extensive study of the competitive impact of authorized generics.²⁵

Mr. Cowie ended with a discussion of product switching or "hopping," which he sees as a hot and unsettled area. He cited the District Court ruling in *Walgreens v. Astra-Zeneca*²⁶ as providing considerable freedom to innovator drug companies with regard to how they design and alter products. The FTC has yet to bring an enforcement action in this area, though there have been some non-public investigations, and Mr. Cowie stated that this will be an interesting area to watch and see what the FTC does.

Theodore Whitehouse

Partner, Willkie Farr & Gallagher LLP

Mr. Whitehouse rounded out the panel with a private-sector generic pharmaceutical company perspective. He said there exist a variety of issues at the intersection of patent and antitrust law that are of importance to generic pharmaceutical companies, including streamlining regulatory approval for generic biologics, but his remarks focused on restrictions on the ability of generic companies to settle patent litigation with innovator companies.

Regarding patent settlements, Mr. Whitehouse took issue with Ms. Unt's characterization of patent settlements where consideration flows to generic companies as "exclusion payments." He recognized the concern expressed by the FTC and certain members of Congress that brand pharmaceutical companies are using "reverse payments" to pay generic companies to abandon Hatch-Waxman Paragraph IV patent challenges, with the effect of delayed competition and higher prices to consumers. However, some generic companies are concerned that restricting their ability to settle Paragraph IV patent cases would make such litigation more risky and costly and, thus, will deter generic companies from mounting such challenges in the first place. Mr. Whitehouse asserted that a reduction in these Paragraph IV challenges would hurt consumers and generic companies. Generic companies should have the freedom to settle when necessary so as to deploy their finite resources on those cases most likely to produce new generic entry.

As other panelists had provided an overview of caselaw in the "reverse payment" settlement area, Mr. Whitehouse next focused on legislative initiatives that would restrict brand-generic patent settlements and the policy issues raised by these proposals. While the FTC Commissioners have generally supported the Kohl legislation in the Senate²⁷ and the Rush bill in the House, the pharmaceutical industry—both brand and generic companies—has generally opposed such legislation. Mr. Whitehouse provided several reasons for opposition to new legislative restrictions on Paragraph IV settlements. First, Paragraph IV cases have become more difficult and risky, as they increasingly tend to involve invalidity rather than non-infringement issues and earlier cases involved weaker patents. Second, there is a general presumption in favor of settlements because they reduce burdens on courts and the parties and also can result in generic products coming to the market earlier than they would have had the generic company

lost the patent case altogether. Further, he asserted that Hatch-Waxman as modified is working well, and much criticism of Paragraph IV settlements derives from an unjustified assumption that the generic company would have won the case had it not settled. Moreover, Mr. Whitehouse explained that generic companies need the flexibility to focus their resources on the patent litigation cases most likely to succeed and to exit from weaker cases. The more restrictions that there are on settling parties, the less likely it is that cases will settle. Finally, he noted that, even without changes to current law, it is still possible for challenges to be brought to "bad" settlements, such as in the *Cardizem* case.²⁸

Mr. Whitehouse noted some possible alternatives to current legislative proposals for which some generic companies have expressed support. These include Senator Spector's proposal for review and approval of Paragraph IV settlements by the court before which the patent case is pending or a formal review process by the FTC with procedural deadlines similar to those of the Hart-Scott Rodino premerger notification process. According to Mr. Whitehouse, a key issue for generic companies in any proposed amendment to existing Hatch-Waxman provisions is the interplay between settlements of Paragraph IV litigation and retention or forfeiture of the first filer 180-day exclusivity period.

Moderated Discussion

Ms. Unt emphasized on rebuttal that it is clearly possible for brand and generic companies to settle litigation without payment flowing from brand to generic companies. She noted that the antitrust agencies saw this in the aftermath of the Commission's decision in the *Schering-Plough* case before the appeal was decided. She cited with approval other alternatives, such as the Department of Justice's suggestion for a mini-review of the merits of the patent case. Ms. Unt did not concur that the *Cipro* decision was so important, noting that the analysis applied by the Federal Circuit was not much different from the

¹⁹ *In re Ciprofloxacin*, 544 F.3d at 1335.

²⁰ *FTC v. Warner Chilcott Holdings Co., III, Ltd.*, No. 1:05-cv-2179-CKK, 2007 WL 158746 (D.D.C. Jan. 22, 2007).

²¹ *FTC v. Cephalon, Inc.*, No. 08-cv-2141-RBS (E.D. Pa.).

²² Michael Cowie & Melissa Jensen, *Misguided Attempts to Restrict Competition from Authorized Generics*, HEALTH LAWYERS NEWS, July 2007, at 6-12.

²³ *In re Teva Pharmaceutical Indus. & IVAX Corp.*, FTC Dkt. No. C-4155 (Jan. 23, 2006), <http://www.ftc.gov/os/caselist/0510214/0510214do060307.pdf>.

²⁴ *In re Watson Pharmaceuticals, Inc. & Andrx Corp.*, FTC Dkt. C-4172 (Dec. 12, 2006), <http://www.ftc.gov/os/caselist/0610139/index.shtml>.

²⁵ See *FTC Proposes Study of Competitive Impacts of Authorized Generic Drugs*, Mar. 29, 2006, <http://www2.ftc.gov/opa/2006/03/authgenerics.shtml>.

²⁶ 534 *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F.Supp. 2d 146 (D.D.C. 2008).

²⁷ S. 369, 111th Cong. § 3 (2009).

Second Circuit's position and stressed that each case was limited to its facts. For example, in *Cipro*, the 180-day exclusivity period was not at issue and other cases where it is at issue could turn out differently. She also reiterated that, with a new administration and a new Solicitor General, things could change, given the Supreme Court's track record of siding with the Solicitor General in every case over the past several years.

Mr. Cowie responded that *Cipro* was indeed important. While the Federal Circuit's message may have been the same as that of the Second Circuit, it was a "different messenger"—that is, the "experts" had spoken.

Mr. Nelson then asked the panelists to weigh in on what would be a framework under which the Federal Circuit or the Supreme Court might find a reverse payment settlement to be an antitrust violation. Ms. Unt replied, first, that the Federal Circuit, while an expert in patent law, is not the expert body for antitrust law. She stated that the problem that arises in the context of these cases is the deference given to patent validity; that is, validity is presumed, but many patents are weak. She advocated for an approach similar to the Solicitor General/DOJ position in the *Schering-Plough* petition for certiorari briefing²⁹ and the FTC briefing in *Cephalon*³⁰—i.e., a "mini-trial" involving analysis of patent strength. Mr. Cowie's response was that the FTC has argued its

position to the appellate courts and lost, and the action on this issue will now be in Congress.

Mr. Nelson next questioned the panel as to the appropriate standard for analyzing product switching cases. Ms. Unt stated that the hard cases will be those where brand companies bring new products to the market but continue to make available the similar, existing product. She contrasted these "hard cases" with the *TriCor* litigation where the brand company obsoleted its original products by removing the old NDC codes, thereby preventing generic substitution.³¹ Ms. Unt said the focus of the analysis should be on whether there is consumer choice, whether the new product is better, whether it is cheaper, and whether consumers like it better.

The next question was a follow-up to Ms. Van Kerckhove regarding the direction in which she expected the EC to go. She replied that the first draft report of the EC sector inquiry will be instructive and, soon after that, a result from the CFI in *AstraZeneca* would be forthcoming. Ms. Van Kerckhove further commented that, with regard to private sector litigation, unlike in the United States, there has been little eagerness to pursue private antitrust litigation in Europe, which to this point has been limited primarily to cartels. However, if there is greater encouragement by the government, there is likely to be more follow-on private litigation in this area as well.

In audience questioning, David Balto inquired whether, if the action in the

Paragraph IV patent settlement context is moving to the legislative realm, and amending antitrust laws is rare, the solution is to change the Hatch-Waxman law. He pointed to the Rush bill, which provides for automatic forfeiture by a generic company of the 180-day exclusivity if the company settles the Paragraph IV litigation. Mr. Whitehouse replied that the Rush bill would create incentive problems for generic companies—i.e., if settling a Paragraph IV case results in automatic loss of 180-day exclusivity, it would reduce the incentive of generic companies to bring Paragraph IV challenges in the first place.

Conclusion

The panel discussion evidenced that antitrust implications of agreements between branded and generic drugs in settling patent litigation and brand name pharmaceutical life cycle management strategies will continue to be an area of lively debate in the United States. While the FTC continues to bring reverse payment settlement challenges in the federal courts, an increased focus on legislation regarding these issues, particularly with the new presidential administration, is expected. While the different regulatory regimes mean that brand-generic patent settlements do not raise the same issues in Europe as in the United States, the European Commission is increasingly focused on practices believed to be aimed at delaying the entry of generics or innovative products, as evidenced by the sector-wide enquiry into these issues.

²⁸ 332 F.3d at 896.

²⁹ Brief for the United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273).

³⁰ See Brief for the Federal Trade Commission in Opposition to Cephalon's Motion to Dismiss, *FTC v. Cephalon, Inc.*, Civil Action No.: 08-cv-2141-RBS (D.D.C. June 2, 2008), available at <http://www2.ftc.gov/os/caselist/0610182/080602opposition.pdf>.

³¹ *Teva Pharm. USA v. Abbott Labs.*, No. 02-1512-SLR (D. Del.); *Impax Labs., Inc. v. Abbott Labs.*, No. 03-120-SLR (D. Del.); *In re TriCor Direct Purchaser Antitrust Litigation*, No. 05-340-SLR (D. Del.); and *In re TriCor Indirect Purchaser Antitrust Litigation*, No. 05-360-SLR (D. Del.).