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# *FEDERAL TRADE COMMISSION VS. WATSON*: THE SUPREME COURT TAKES UP "REVERSE PAYMENTS"

*By*
*Frederick Ball*[1]

On December 7, 2012, the United States Supreme Court (SCOTUS) granted certiorari in *Federal Trade Commission vs. Watson Pharmaceutical, Inc*., a case out of the Eleventh Circuit.[2] SCOTUS will be addressing a circuit split between, on one side, the Second, Eleventh and Federal Circuit and the Third Circuit on the legal issue of the anti-trust implications of using reverse payments to settle Hatch-Waxman litigation. The question presented to the Court by the Federal Trade Commission (FTC) was whether such payments are "per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the Eleventh Circuit held), or instead of presumptuously anti-competitive and unlawful (as the Third Circuit has held)."[3]

In 1984, Congress enacted Hatch-Waxman amendments to the United States Food Drug and Cosmetic Act (the "Act" or "Hatch-Waxman"). Hatch-Waxman was "designed to speed the introduction of low cost generic drugs to market."[4] The Hatch-Waxman amendments provide for an abbreviated Food and Drug Administration (FDA) approval process for "generic versions" of a prescription drug for which there is an approved New Drug Application (NDA). In essence, the Hatch-Waxman Amendments allow an Abbreviated New Drug Application (ANDA) filer to rely on the safety and efficacy studies of the NDA filer rather than conducting its own. The ANDA filer, however, must still establish therapeutic and bio-equivalence.

The Hatch-Waxman amendments also provide for resolving patent disputes related to the proposed generic product's introduction into the market prior to the expiration of those patents which could "reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."[5] The patent(s) which the holder of the NDA believes are covered by this section of the Act are submitted to the FDA. The FDA then lists those patents in an FDA publication known as the "Orange Book."[6] If the NDA holder has patent(s) listed in the Orange Book, then the generic manufacturer's submission to FDA of an ANDA must include a certification with respect to each of those patent(s).[7] Those certifications can vary. For example, if the ANDA filer does not intend to market its product prior to the expiration of a listed patent, it may file a "Paragraph III" certification. If, however, it seeks to market the product prior to the expiration of the patent, then it must provide a Paragraph IV certification.

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[1] **Frederick (Rick) R. Ball** is vice-chair of the White-Collar Criminal Defense division of Duane Morris' Trial Practice Group and heads the Firm's Pharmaceutical, Pharmacy, Medical Device, and Food Practice Group. Mr. Ball focuses his practice on assisting companies or individuals when they are adverse to state or federal governments, including administrative, civil and criminal matters, with the FDA, FTC, DEA, CMS, OIG and other federal and state regulatory agencies. Mr. Ball helps generic pharmaceutical companies, biologics manufacturers, food companies (including supplement manufacturers), pharmacies, long term care providers, and other health care providers navigate the complex challenges faced by state and federal regulation of their industries including complying with current Good Manufacturing Practices, price reporting (AMP, AWP, ASP, etc.), the Foreign Corrupt Practices Act, False Claims Act, and Anti-Kickback Statute, as well as meeting labeling and advertising requirements. Mr. Ball also assists generic manufacturers bring product to market through patent analysis and Hatch-Waxman litigation. Mr. Ball is experienced in conducting internal investigations and advising companies on actions following the investigation. Finally, Mr. Ball helps companies maintain their trade secrets and competitive advantage through trade secrets litigation and enforcement of restrictive covenants. Mr. Ball emphasizes a team approach to client problem solving and manages matters to achieve client goals both financial and legal.

[2] *FTC v. Watson Pharms., Inc.*, ___ U.S. ___, ___ S. Ct. ___, 184 L. Ed. 2d 527, *cert. granted* (Dec. 12, 2012).

[3] Petition for writ of certiorari of the Federal Trade Commission, *FTC v. Watson Pharms*., ___ U.S. ___, 133 S. Ct. 787, 184 L. Ed. 2d 527, *cert. granted* (Dec. 12, 2012).

[4] *Caraco Pharm. Labs., Ltd v. Nova Nordisk A/S*, ___ U.S. ___, 132 S. Ct. 1670, 1676, 182 L. Ed. 2d 678 (2012).

[5] 21 U.S.C. § 355(b)(1)(G); *see also* 21 C.F.R. § 314.53.

[6] *See* 21 C.F.R. § 314.53.

[7] *See* 21 U.S.C. § 355(j)(2)(A)(vii).

At issue, in *Watson*, as in the cases that arose in the other circuits, was a ''Paragraph IV'' certification. When an ANDA filer submits a Paragraph IV certification to the FDA, the filer alleges that the patent(s) listed in the Orange Book are invalid or unenforceable and/or, that the generic version will not infringe the patent(s).[8] The filing of a Paragraph IV certification is a constructive act of infringement pursuant to the Hatch-Waxman amendments.

Once the FDA has accepted the ANDA for filing and notified the filer that it has done so, the filer must send a ''notice letter'' to the patent holders. The patent holders then have 45 days within receipt of this notice letter to file a lawsuit. If they do so, the FDA may not grant final approval for the ANDA for 30 months after the lawsuit is filed or the ANDA filer prevails in litigation, whichever comes first.[9]

In certain circumstances, the first filer for a generic version of a brand name drug product which makes a Paragraph IV certification is entitled to 180 days of marketing exclusivity. During that time, the FDA is not permitted to grant final approval to subsequent ANDA filers.[10] This 180 day exclusivity period has significant economic value and serves as an incentive for drug manufacturers who challenge patents pursuant to Paragraph IV certifications.

The structure of the Hatch-Waxman amendments has given rise to certain incentives for brand manufacturers and generic manufacturers to use ''reverse payment'' agreements as a way to settle patent litigation that arises out of Paragraph IV certifications. In these types of agreements, the patent holder agrees to pay money to the accused infringer and the accused infringer agrees that it will not challenge the patent and will refrain from seeking FDA approval to market for a specified period of time.

Because of the extreme value of the monopolistic market power of brand name manufacturers, the incentives on both the brand and manufacturer side and the generic side can be significant. In the *Watson* case, experts estimated that delaying generic entry into the market saved Solvay Pharmaceutical $125 million a year. That being said, these types of agreements also help rationalize the litigation process and allow both brand manufacturers and generic manufacturers to allocate the potential risk of loss in litigation. With this in mind, we can take a look at the *Watson* case.

In January 2003, Solvay Pharmaceuticals, Inc. (''Solvay'') received a patent for certain pharmaceutical formulations containing testosterone and other ingredients. Solvay sought and received approval from the FDA to market a trade drug named Androgel for which it sought to have the FDA list this patent in the Orange Book.

In May 2003, Watson Pharmaceuticals Inc. (''Watson'') and Paddock Laboratories Inc. (''Paddock'') submitted separate ANDAs to the FDA seeking approval for generic versions of Androgel.[11] The Watson and Paddock ANDAs included Paragraph IV certifications that their respective generic products did not infringe Solvay's formulation patents and that the patent was invalid. In May 2005, Watson and Paddock filed motions for summary judgment. In January 2006, after the expiration of the 30 month stay, the FDA approved Watson's ANDA. The patent litigation was still pending.

Watson and Paddock expected to begin selling their respective ANDA products no later than 2007. In September 2006, the parties settled both the Watson and Paddock litigations without any ruling on claim construction or the pending summary judgment motions. In those agreements the parties agreed to dismiss the patent cases. Solvay agreed to grant licenses to Watson and Paddock to launch their generic Androgel in August 2015. The parties concluded business deals at the same time.

In those deals, Watson agreed that its sales force would promote Androgel to urologists. In return, Solvay agreed to pay Watson an estimated $19 – $30 million annually. Par agreed to use its sales force to promote Androgel to primary care physicians between 2006 and 2012. Pursuant to that agreement, Solvay agreed to pay Par $10 million annually. Paddock agreed to provide back-up manufacturing

[8] When multiple patents are listed in the Orange Book, the ANDA filer can mix and match its certification. For example, if certain patents are likely to expire before the expiration of the 30 month stay, discussed below, the ANDA filer may decide to certify submit a Paragraph IV certification for later expiring patents and a Paragraph III certification for the earlier expiring patents.

[9] 21 U.S.C. § 355(j)(5)(B)(iii).

[10] 21 U.S.C. § 355(j)(5)(B)(iv).

[11] Par Pharmaceuticals Companies, Inc. (''Par'') agreed to partner with Paddock in sharing litigation costs and promoting Paddock's generic form of Androgel.

capacity for Androgel between 2006 and 2012. For those services, Solvay agreed to pay Paddock $2 million annually.

Shortly thereafter, the Federal Trade Commission (FTC) sued under § 5 of the Federal Trade Commission Act and challenged the agreements. In its complaint, the FTC claimed the agreements between Solvay and the generic filers were, in effect, agreements not to compete in exchange for payment and were therefore unfair methods of competition. In addition, the FTC claimed that Solvay had unlawfully extended its monopoly by compensating its potential competitors. The FTC also claimed that the agreements the parties entered into only made business sense as a way for Solvay to pay its potential generic competitors to delay entry into the market.

Watson moved to dismiss the FTC's complaint. Relying on the Eleventh Circuit's decisions in *Schering-Plough Corp. v. FTC*,[12] *Andrx Pharms., Inc. v. Elan Corp., PLC*[13] and *Valley Drug Company v. Geneva Pharmaceuticals Inc.*,[14] the District Court granted Watson's motion. The FTC did not seek to amend but, rather, appealed.

The Eleventh Circuit affirmed. In so doing, the Eleventh Circuit rejected the FTC's argument that reverse payments are presumptively unlawful and ruled that ''absent shame litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.''[15] The Eleventh Circuit also rejected the FTC's argument that a reverse payment was not lawful ''if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date.''[16] The basis of the Eleventh Circuit's reasoning was the statutory presumption that a patent is valid. The Eleventh Circuit also rejected the FTC's argument as a *post hac* analysis of the likelihood of success on the merits. The Eleventh Circuit argued this would place too great a burden on the courts, undermine the benefits of settlement, and effectively amounted to asking one trial court to decide how another trial court might have ruled if the parties had pursued the case to judgment. This analysis has become known as the ''scope of the patent rule.''[17]

In contrast, the Third Circuit has specifically rejected the scope of the patent rule.[18] In *K-Dur*, the Third Circuit held that reversed-payment agreements were subject to a ''quick look rule of reason analysis'' and that ''any payment from a patent order to a generic patent challenger who agrees to delay entry into the market [is] prima facie evidence of an unreasonable restraint of trade.''[19] This presumption can be rebutted by showing either ''that there is in fact no reverse payment because any money that changed hands was for something other than a delay'' or ''that the reverse payment offers a competitive benefit that would not have been achieved in the absence of a reverse payment.''[20]

Not surprisingly, the FTC has taken the position that the Third Circuit's decision is correct, while the Eleventh Circuit's is not.[21] The outcome of the Supreme Court's decision on this matter will have significant impact. The domestic market in the United States for drug product is close to $245 billion dollars. A significant portion of that cost is covered by taxpayers through the Medicare and Medicaid programs. Experts estimate that drug costs decrease by 80 to 90 percent once a product becomes fully generisized. A significant decrease in costs is achieved when even one generic competitor

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

[13] *Andrx Pharms., Inc. v. Elan Corp., PLC*, 421 F.3d 1227 (11th Cir. 2005).

[14] *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294 (11th Cir. 2003).

[15] *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012).

[16] *Id.*

[17] Other commentators have rightfully pointed out that while this analysis arguably deals with claims of invalidity by the ANDA filer, it fails to address claims of non-infringement. Presumably, the analysis related to respecting the parties decision to settle and avoiding overburdening the courts would be similar.

[18] *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214–218 (3d Cir. 2012), petitions for cert. pending, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012).

[19] *Id.* at 218.

[20] *Id.*

[21] The FTC has long taken the view that reverse payments are presumptively anti-competitive. The United States has taken the same position in recent briefs filed in the Second and Third Circuits. While the United States has not fully endorsed the FTC's views, it has argued that the "scope of the patent test" is an "insufficiently stringent" to determine whether reverse payment agreements are unlawfully anticompetitive. The United States position has been closer to that articulated by the Third Circuit that would require some analysis of the likelihood of the parties claims in the underlying litigation.

enters the market. Thus, earlier entry arguably benefits consumers and payers for drug product by leading to reduced costs. That being said, ''Reverse payment'' settlements generally result in entry by the generic manufacturer prior to the expiration of the patent(s). For example, the Watson settlements resulted in generic entry five years before the expiration of the challenged patents. In addition, a presumption against reverse payments, particularly as broadly interpreted by the FTC, assumes away a patent holder's rights and is inconsistent with the broad recognition that agreeing to settle patent litigation may be pro-competitive. It also truncates the ability of litigants to rationalize and allocate the risk of loss.

Depending on how SCOTUS rules, it will affect how patent holders and ANDA filers approach patent litigation. If generic manufacturers cannot settle complex litigation in a way that makes business sense, they may forgo filing certain Paragraph IV certifications. Moreover, the FTC's broad interpretation of what constitutes a reverse payment presents significant challenges to parties seeking to settle patent litigation in a reasonable way that is not anti-competitive. The FTC claims that unlawful reverse payment includes not just monetary compensation, but business deals between manufacturers and generic companies such as those in the *Watson* litigation, as well as agreements by the branded manufacturer not to enter into an authorized generic agreement or launch an authorized generic.

In short, the FTC's position that all ''reverse payments'' are presumptively anti-competitive is clearly over-broad. Moreover, asking a court not involved in the previous litigation to determine what might have happened is highly speculative and places an undue burden on the litigants and the courts. Thus, while the FTC may have legitimate concerns about the anti-competitive effect of ''reverse payments,'' those concerns arise out of the structure of the Hatch-Waxman Amendments and patent law and, thus, are more appropriately addressed by Congress than the courts.

We will know in the next few months if SCOTUS agrees.