e-commercelawreports

THE PRACTITIONERS' GUIDE TO E-COMMERCE CASES
VOLUME 12 ISSUE 02 WWW.E-COMLAW.COM
[2012] ECLR 1- 24

VOLUME 12 ISSUE 02 [2012] ECLR 1-24

Federal Trade Commission v. Watson Pharmaceuticals, Inc.

No. 10-12729 (11th Cir. Apr. 25, 2012)

A reverse payment agreement between a generic drugs manufacturer having filed a paragraph IV certification to produce a generic form of a patented drug, with the pioneer manufacturer, does not violate U.S. antitrust laws.

In Watson, despite previous rejections of its position, the U.S. Federal Trade Commission (FTC) once again argued that a patent litigation settlement between a branded pharmaceutical manufacturer (the patentee) and a generic pharmaceutical manufacturer that results in a payment from the branded manufacturer to the generic in return for the generic's agreement to stay off the market can violate the antitrust laws. The FTC added a new gloss to its argument in Watson: such an agreement violates the antitrust laws if, at the time of the patent settlement, the patent was more likely than not invalid.

The Eleventh Circuit rejected the FTC's argument. In so doing, the court made it very difficult (if not in most cases impossible) to challenge so-called 'pay for delay' or 'reverse payment' agreements, as discussed below. Before summarising the holding of the case and the court's rationales, I will first quickly provide some background on the U.S. drug approval process and the Watson facts. I will conclude by offering some thoughts about whether Watson applies to other litigation settlements outside the patent context.

Background: U.S. Food and Drug Administration (FDA) Pharmaceutical Approval Process

Developing new pharmaceuticals is a laborious and expensive process. Very few compounds that are investigated become drugs that are commercially marketed. Many new drugs are protected by one or more patents, and those patents are crucial because they enable new drug manufacturers to earn during the patent term monopoly profits, which reward companies for making the very substantial R&D investments necessary to develop new drugs.

In the U.S., new or 'pioneer' drugs must be approved by the FDA. A pioneer drug manufacturer initiates the process by filing a New Drug Application (NDA). In that application, the pioneer manufacturer must disclose relevant patent information. If the FDA approves the NDA, it publishes the new drug and patent information in a publication colloquially known as the 'Orange Book'.

Generic manufacturers can apply for permission to make drugs under a more abbreviated process: they can file an Abbreviated New Drug Application (ANDA). The ANDA applicant certifies that its drug is chemically identical to a pioneer drug, i.e., that it has the same active ingredients as, and is biologically equivalent to, the brand-name drug.

An ANDA filer must address any relevant patent on file in the Orange Book. One common way to do so is to file a so-called 'paragraph IV' certification, stating that the patent is invalid or will not be infringed by the generic drug.

If the generic manufacturer files a paragraph IV certification, the patent holder has 45 days to file an infringement suit. If a suit is timely filed, the FDA stays the ANDA approval process for 30 months to allow the parties or a court to resolve the infringement dispute.

The first ANDA applicant making a paragraph IV certification that receives FDA approval is granted a 180-day 'exclusivity period' during which the FDA postpones its approval process for other ANDA applications for generic versions of the same Orange Book-listed drug. That exclusivity period begins to run after the date of the first commercial marketing of the generic drug. The exclusivity period is a significant incentive for generic manufacturers to challenge weak or narrow drug patents.

The Watson Suit

In April 1999, Solvay Pharmaceuticals filed an NDA for AndroGel, a topical gel that treats the symptoms of low testosterone in men. The FDA approved AndroGel in February 2000. Solvay began marketing the drug with great success. Shortly after FDA approval, Solvay filed a patent application with the U.S. Patent and Trademark Office relating to the particular gel formulation used in the drug. The patent issued in January 2003. Within 30 days, Solvay asked the FDA to include the patent information in the Orange Book listing for AndroGel. Watson Pharmaceuticals (and another company) filed ANDAs and paragraph IV certifications in May 2003. Solvay then filed a timely patent infringement suit. The automatic 30-month FDA ANDA approval stay was set to expire in January 2006.

The parties litigated the case, and the defendants filed motions for summary judgment on the validity of the patent at issue. The motions were fully briefed when the FDA ANDA stay expired, and the FDA approved Watson's generic AndroGel product in January 2006. As a result, Solvay was facing the possibility of losing its monopoly in the AndroGel market in early 2006.

The parties decided to settle the matter. Watson (and others) agreed not to market generic versions of AndroGel until August 2015, unless another manufacturer launched one before then. Watson also agreed to promote branded AndroGel. Solvay agreed to pay monies to Watson (and others).

The FTC brought a separate suit, alleging that the parties' patent settlement violated Section 5(a) of

the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1) (banning '[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce'). The FTC alleged that Solvay was not likely to prevail in the patent litigation, i.e., that Watson was likely to demonstrate that the patent was invalid or unenforceable. The district court dismissed the FTC's complaint, and the FTC appealed.

The Eleventh Circuit's Ruling

Relying upon several of its earlier pharmaceutical patent settlement cases, the Eleventh Circuit held that unless a patent is obtained fraudulently, or unless the patent litigation is itself a sham, a settlement of patent litigation cannot violate the antitrust laws. (The one exception to this rule: if the settlement imposes restrictions beyond the terms of the patent itself, e.g., if it restricts competition beyond the remaining term of the patent.) As the court wrote, 'absent sham 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.'

Thus, a patent settlement that extends a pioneer's monopoly beyond the scope of its patent(s) could violate the antitrust laws. Because of the peculiar nature of the Orange Book process in effect at the time of the Watson patent settlement, a generic drug manufacturer's intention not to market its generic drug could also violate the antitrust laws[1] because the FTC had not alleged either of these scenarios, it could not challenge the Solvay-Watson settlement.

Rationales for the Ruling

The Eleventh Circuit articulated several rationales for its ruling, including the fact that patent litigation is usually high stakes, and parties rationally may want to settle even if the probability of a finding of validity or infringement is, strictly speaking, less than 50%. As the Court wryly wrote, '[w]ith four chambers of a seven-chamber revolver unloaded, a party pulling the trigger is likely (57% to 43%) to survive, but the undertaking is still one that can lead to undertaking.'

Additionally, the FTC's approach would require an after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not settled. Making such predictions is very difficult, and 'is too perilous an enterprise to serve as a basis for antitrust liability and treble damages.' The FTC's approach would also impose heavy burdens on the parties and the courts to essentially re-litigate patent issues, entailing the analysis of numerous depositions and thousands of pages of documents. 'Our legal system can ill afford that.' And finally, circuit courts other than the Federal Circuit (which has exclusive appellate jurisdiction over patent issues) have no expertise in the patent area, and they are not well-equipped to make determinations about patent infringement.

The court rejected the FTC's concern that reverse payment settlements would allow pioneer and generic drug manufacturers to split up monopoly profits and in so doing harm consumers. While a pioneer might enter into settlements with one or two generics, other generics have strong incentives to try to enter the market and challenge the patent(s). 'Blood in the water can lead to a feeding frenzy. Although a patent holder may be able to escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers, those profits will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications and attacking the patent.'

Perhaps the best lines of the opinion are the following: 'In closing, it is worth emphasising that what the FTC proposes is that we attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment. If we did that we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task. Even if we found that prospect palatable, we would be bound to follow the simpler recipe for deciding these cases that is laid out in our existing precedent.'

Application in Other Contexts and Concluding Thoughts

Can we extend the reasoning of Watson to other contexts? Suppose that you represent a widget monopolist, which has achieved an 80% market share through much hard work. Unfortunately, your client's competitor has accused it of unlawfully monopolising the market through predatory pricing - pricing widgets below some applicable measure of cost. The competitor files suit. The two parties engage in lengthy litigation, and now want to settle. The plaintiff proposes an agreement that bars your client from pricing below cost, and sets forth a general formula for how to measure costs and ensure that prices exceed costs by at least X%. The competitor seeks only a negligible amount of compensation. 'Great,' you think. But can you settle?

You could counter that the

agreement is not a 'naked' agreement, but is ancillary to the Section 2 litigation settlement. Under case law dating back to United States v. Addyston Pipe & Steel Co., 85 F. 271 (6th Cir. 1898), aff'd, 175 U.S. 211 (1899), a restraint that is ancillary to a legitimate agreement or venture and 'reasonably necessary' to achieve its pro-competitive purposes will not be condemned - at least not under the per se rule, and not without a full inquiry into the likely pro- and anti-competitive effects of the restraint.

In principle, this argument seems compelling. In practice, it meets two potential roadblocks. First, outside the narrow set of pharmaceutical patent cases, appellate courts have not squarely applied the ancillary restraint doctrine in the antitrust settlement context. Although cases such as Blackburn v. Sweeney, 53 F.3d 825 (7th Cir. 1995), and Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50 (2d Cir. 1997), are suggestive, they are not definitive, given the specifics of their fact patterns. However, the dearth of case law also means that the argument has not been rejected by the courts.

Additionally, Watson suggests that an agreement to settle predatory pricing litigation would also not be subject to challenge - or at least not subject to per se condemnation - if the litigation is not collusive. However, a patent either is valid (and thus would keep a competitor off the market anyway), or is not. As long as there is some chance it is valid, a reverse payment agreement is no more anti-competitive than the patent.

In contrast, a Section 2 court's assessment of predatory pricing claims is less binary - it could find some pricing behaviors unlawful, while others not, and it could enjoin some, but not other, actions. These differences complicate the ancillary restraint analysis, which effectively asks: what legal outcome can be obtained but for the settlement?

Although such considerations caution against simplistic pronouncements, the differences between the patent cases and the predatory pricing case do not seem fundamental. However, given the FTC's apparent continued hostility to such settlements and appetite to litigate the issue, for now, the patent-type analysis can probably, but not definitely, be applied to other contexts.

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1. The 180-day period begins to run after the date of first commercial marketing. If the first ANDA filer had no intention of ever marketing a generic, the exclusivity period could act like a cork in a bottle, blocking other generic competition from pouring into the market. Congress fixed this cork-in-the-bottle problem in 2003, but the statutory amendment was not retroactive.