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Watson and Reverse Payments: An Opportunity to Resolve the Competing Tension Between Antitrust and Patent Law Under the Hatch-Waxman Act

On March 25, the Supreme Court will hear arguments in *Federal Trade Commission v. Watson Pharmaceuticals, Inc.*,[1] and take a step toward concluding a long-running and acrimonious dispute between the Federal Trade Commission ("FTC") and several Circuit Courts of Appeal regarding whether patent settlements under the Hatch-Waxman Act[2] containing "reverse payments" violate the Sherman Antitrust Act. For many years, the FTC has taken the position[3] that such payments presumptively violate the Sherman Act, only to be rebuffed by the Second, Sixth, Eleventh, and Federal Circuits[4] as well as by the Supreme Court's refusal to hear the issue until now.

Background: A Quick Look at the Hatch-Waxman Act

Although brand-name (*i.e.*, "pioneer") pharmaceutical manufacturers must invest heavily in new drug development as well as in safety and efficacy trials to gain Food and Drug Administration ("FDA") approval, the Hatch-Waxman Act permits, and indeed encourages, generic competitors to "piggyback" on the FDA's prior approval of a new drug if the generic competitor establishes that the generic drug is chemically identical and will be prescribed for the same indications.[5] Congress intended the use of such Abbreviated New Drug Applications ("ANDA") to stimulate competition between pharmaceutical manufacturers, thereby providing consumers with reduced prescription drug costs.[6] However, because the FDA cannot approve an ANDA application that would infringe a pioneer drug's patent, the generic manufacturer must certify that the patent in question either: (1) has not been filed; (2) has expired; (3) will expire on a certain date, or; (4) is invalid or will not be infringed by the generic drug.[7] If the generic applicant certifies under the latter provision, commonly known as a "paragraph IV certification," the brand-name patent holder has 45 days to file a patent infringement lawsuit against the applicant to prevent generic market entry.[8] Upon the filing of the patent infringement suit, the FDA stays ANDA approval for 30 months.[9] Although paragraph IV certification almost inevitably provokes patent litigation, the first successful ANDA applicant is entitled to 180 days of generic exclusivity, during which time the FDA postpones the approval process for all other generic applicants.[10]

Why Reverse Payments?

Most litigation ends in negotiated settlement agreements among the parties and Hatch-Waxman litigation is no different. However, Hatch-Waxman settlements often include a payment from the patent holder to the generic company, which is not typically seen in traditional patent infringement lawsuits. Such payments from the patent holder to the generic company are called "reverse payment settlements."[11] In such settlements, the first generic challenger typically agrees to delay or forego marketing its generic product in exchange for monetary consideration from the patent holder, thereby reversing the typical flow of consideration from the patent infringer to the patent holder.[12]

The existence of "reverse payment" settlements in Hatch-Waxman litigation can be attributed to the Act's redistribution of patent litigation risks by giving the patent holder the right to sue the generic (ANDA) challenger for infringement and allowing the ANDA filer to challenge patent validity even though the generic company has not incurred the cost of market entry or the risk of incurring damages.[13] Accordingly, the patent holders' upside from litigation is relatively small: preserving only what they already possess (a statutory monopoly) but without an award of infringement damages, while their downside (as in any infringement suit) is enormous: the invalidation of the patent. Conversely, the ANDA infringers' upside is large: invalidation of the patent with immediate exclusive generic market entry as the first ANDA filer, while their downside is small: an injunction preventing them from doing what they have not yet done (enter the market) without any damages owed to the patent holder.[14] Given that the generic company has not incurred liability for damages, there is no reason a payment would flow to the patent holder, whereas it may be economically rational for the patent holder to pay the generic company to settle the litigation and avoid the risk that the challenged patent will be found invalid.[15]

The Scope of the Patent Standard

Most Circuit Courts of Appeal that have considered the issue have held that reverse payments which do not delay generic entry beyond the expiration date of the patent grant do not implicate the antitrust laws' prohibitions on unreasonable restraints of trade.[16] This is known as the "scope of the patent" test. The rationale underlying this standard is that because a patent by definition lawfully excludes competition,[17] "the anticompetitive effect is already present."[18] Thus, the mere existence of anticompetitive effects cannot be the basis for antitrust liability.[19] Instead, antitrust liability attaches only when the anticompetitive effects exceed the exclusionary potential of the patent, or when the infringement suit is brought knowing that the patent is invalid.[20] Thus, while a reverse payment might be "suspicious," it is not unlawful to receive a substantial sum of money "so long as the patent litigation is neither a sham nor otherwise baseless"[21] and the settlement does not extend the scope of the patent monopoly.[22]

The FTC's Position

The FTC has been an unrelenting critic of reverse payments challenging them in court, advocating against them in speeches to professional organizations,[23] and supporting Congressional legislation[24] that would ban them. The FTC has typically challenged reverse payment settlements when the settlements also contain an agreement not to enter the market prior to the expiration of the nominal term of the patent grant, describing such payments as "exclusion payment settlements"[25] or "pay for delay" and ruling on the agency level that they are presumptively illegal.[26] In the FTC's view, a settlement agreement that delays or prevents generic market entry *in any way* precludes consumer access to the more affordable generic product, resulting in consumer harm measured by "the difference between the brand's loss [of profits from generic entry] and the generics' gain."[27] According to a 2010 FTC report, reverse payments prevent downward price pressure caused by generic competition and account for $3.5 billion in annual profits for the pharmaceutical industry.[28]

Last summer, the Third Circuit adopted the FTC's position for the first time in *In re K-Dur Antitrust Litig.*[29]Rejecting the scope of the patent test's "almost unrebuttable" presumption of patent validity, the Third Circuit held that reverse payments were presumptively anticompetitive "because reverse payments permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid."[30] In place of the scope of the patent test, the Third Circuit mandated "a quick look rule of reason analysis based on the economic realities of the reverse payment settlement."[31] Rebuttal of the presumption of invalidity under the Third Circuit's test requires proof that the payment was for a purpose other than to delay entry or proof of procompetitive benefits.[32]

FTC v. Watson Pharmaceuticals

Following the Third Circuit's decision and the resultant circuit split, the FTC successfully petitioned the Supreme Court for reviewin *Watson Pharmaceuticals*, a case in which the Eleventh Circuit dismissed a FTC reverse payment challenge under the scope of the patent test.[33] In *Watson*, the Eleventh Circuit rejected the FTC's argument that Solvay Pharmaceuticals, the manufacturer of AndroGel®, unlawfully settled paragraph IV litigation by paying its generic challengers to postpone market entry.[34] Specifically, the FTC alleged that Solvay utilized reverse payments to extend its monopoly under patent law because it was "unlikely to succeed" in the underlying infringement action and maintain the patent's monopoly grant.[35] By doing so, the FTC argued that the defendants unlawfully restrained competition.[36] At the outset, the Eleventh Circuit cautioned that "[t]he difficulty at the heart of this case is in deciding how to resolve the tension between the pro-exclusivity tenets of patent law and the pro-competition tenets of antitrust law."[37] Turning to Eleventh Circuit precedent, the Court recognized that reverse payments that delay generic entry beyond the expiration date of the patent are illegal:

A patent holder and any of its challengers cannot enter into an agreement that excludes more competition than the patent has the potential to exclude. If a reverse payment settlement reduces generic competition to a greater extent than the patent grant potentially does, the holder of the patent has used the settlement to buy exclusionary rights that are not contained in the patent grant, and those additional rights are vulnerable to antitrust attack.[38]

Notwithstanding, the Court held, absent sham litigation or fraud in obtaining the patent, reverse payments are immune from antitrust attack so long as their anticompetitive effects fall within the exclusionary potential (*i.e.,* temporal duration) of the patent.[39] Furthermore, the *Watson* Court declined the FTC's invitation to assess the legality of reverse payments based on the underlying infringement action's likelihood of success. The Court noted that "[p]redicting the future is precarious at best; retroactively predicting from a past perspective a future that never occurred is even more perilous." [40]

Seizing on the circuit split created by *K-Dur*, the FTC successfully petitioned for *certiorari* to the Supreme Court in *Watson*.[41] The FTC's petition argues that the Eleventh Circuit's decision is incorrect and negatively affects an issue of exceptional importance to the national economy.[42] The FTC further argues that if the circuit split is left unresolved, the divergence in substantive antitrust law will lead to extensive forum shopping wherein private plaintiffs attacking reverse payments will seek to lay venue in the Third Circuit, the location of numerous brand-name and generic pharmaceutical manufacturers, while brand-name manufacturers initiating paragraph IV litigation will lay suit in the Second and Eleventh Circuits.[43] Despite seeking review of the Eleventh Circuit's decision in *Watson*, in which its argument was premised on the likelihood of success in the underlying patent litigation, the FTC's petition endorses the Third Circuit's quick-look rule of reason approach, which holds reverse payments presumptively unlawful.[44] Interestingly, defendant Watson Pharmaceuticals, a generic drug manufacturer, argued in favor of *certiorari* in an attempt to uphold the scope of the patent test.[45]

Conclusion

The Supreme Court's decision in *Watson* is likely to have a profound effect on the economics of the pharmaceutical industry. The Hatch-Waxman Act has forged a marriage between patent and antitrust law whose competing priorities remain unresolved. Application of the scope of the patent test recognizes the primacy of intellectual property rights, while quick-look rule of reason analysis favors increased competition. Should the Third Circuit's approach to reverse payments prevail, the incentives for life-saving pharmaceutical innovation could be curtailed. On the other hand, adoption of the scope of the patent test will likely reduce downward price pressure on prescription drug prices. In the end, however, both antitrust and patent law seek to enhance the public welfare through innovation and the provision of new goods and services. In *Watson*, the Court's role will be to determine through which means this end is to be achieved.

Judge Posner on the Limits of the Per Se Rule against Price Fixing

Every so often a case finds its way to the Seventh Circuit Court of Appeals, which provides Judge Richard Posner, the noted antitrust scholar and jurist, with a vehicle to discuss the contours of a particular antitrust doctrine. Recently, *In re Sulfuric Acid Antitrust Litigation*[46] provided Judge Posner with the opportunity to examine the bedrock antitrust principle that price fixing is illegal *per se* – or is it? True, the Supreme Court in *United States v. Socony-Vacuum Oil*, 310 U.S. 150, 221 (1940), held that "any combination which tampers with price structures is engaged in an unlawful activity." But perhaps a more nuanced look at the rule is required given that *Socony* is "72 years old and showing its age."[47]

Shutdown Agreements

The *In re Sulfuric Acid Antitrust Litigation* case involved the U.S. and Canadian markets for sulfuric acid. The principal defendants are Noranda, Inc. and Falconbridge Ltd., Canadian mining companies that in 2005, after the period of the alleged antitrust violations (1988–2002), merged to form a single company named Xstrata Canada.[48] They produce sulfuric acid as a byproduct of the smelting of nonferrous minerals, such as nickel and copper. In an effort to end the overproduction of sulfuric acid in Canada,[49] the Canadian companies convinced U.S. producers and distributors of sulfuric acid to enter into "shutdown agreements." The shutdown agreements required the U.S. companies to curtail their own production and distribution of sulfuric acid. Instead, the U.S. companies agreed to devote their distribution facilities to the Canadian sulfuric acid and be compensated by the difference between what the Canadian companies would charge for their sulfuric acid and what the U.S. companies could resell it for to U.S. customers. In addition, the U.S. companies were granted exclusive territories.[50] The scheme works because the Canadian sulfuric acid is much cheaper than U.S. sulfuric acid and the exclusive territories insulated the U.S. firms from competition at the distribution level.[51]

The U.S. customers, chemical companies that purchase sulfuric acid as an input into the production of their chemicals, brought a class action challenging the agreements. In their view, the shutdown agreements were "garden variety" price fixing agreements that raised the market price, restricted output and were therefore per se illegal.[52] The district court disagreed and shortly before trial ruled that the case should proceed only on a rule of reason basis. When the plaintiffs refused to continue on that basis the case was appealed[53] to the Seventh Circuit to decide whether to affirm the district court's ruling that the rule of reason standard applied at trial.[54]

The Abiding Puzzle

For Judge Posner, "the abiding puzzle to the plaintiffs' appeal is why the lawyers for the class, having spent almost nine years litigating the case … refused to go to trial."[55] The plaintiffs' answer to the riddle during oral argument was that a rule of reason case is "radically different" than a *per se* case.[56] In a *per se* case, plaintiffs need only prove that the defendants fixed prices and damages. However, in a rule of reason case, the plaintiff must also prove that the defendants have market power to raise price or restrict output and that their behavior was unreasonable.[57] If the plaintiffs can succeed with their prima facie case, the burden then shifts to the defendant who then has "the burden of showing that appearances are deceptive and really the behavior that the plaintiffs have challenged is not anticompetitive."[58] In other words, defendants may offer a legitimate procompetitive business rationale for behavior that is collusive on its face.

In short, "[t]he rule of reason directs an assessment of the total economic effects of a restrictive practice that is plausibly argued to increase competition or other economic values on balance."[59] While this is more work for the parties, it is, according to Posner, "probably less than they think."[60] Perhaps the correct answer to the riddle is that plaintiffs expected that a jury would have found that the shutdown agreements were reasonable.[61]

Judging the Judge

The preceding does not tell us if the trial court was correct in mandating a rule of reason trial; it only describes the parties' burdens once the judge decides how the trial will proceed. Given that indisputably "the shutdown agreements are in effect a form of price fixing,"[62] three principles should guide an antitrust trial court's selection of whether *per se* or rule of reason is the proper mode of analysis: (i) judicial experience with the restraint, and whether the restraint (ii) viewed when adopted (iii) promotes enterprise and production.

Novel or Old Business Practices

First, the presumptive standard for determining whether a restraint harms competition is the rule of reason.[63] In contrast, the *per se* rule is limited to certain restraints that through judicial experience[64] have been found to always, or almost always, restrict competition and decrease output.[65] "The per se rule is designed for cases in which experience has convinced the judiciary that a particular type of business practice has no (or trivial) redeeming benefits ever." [66] In contrast to the plaintiffs, Posner characterized the shutdown agreements as unique in the annals of the law. "[W]e have never seen or heard of an antitrust case quite like this, combining such elements as involuntary production and potential antidumping exposure. It is a bad idea to subject a novel way of doing business … to *per se* treatment under antitrust law."[67]

For Posner, therefore, this case was not a "rerun" of *Socony* as the plaintiffs' claimed, but was fundamentally different from *Socony*. True, the plaintiffs were correct that in *Socony* the big oil refiners were paying the small refiners not to sell their oil, just as the defendants here were paying U.S. producers of sulfuric acid not to produce sulfuric acid. However,

the difference is that the only aim and effect of the price-fixing agreement in *Socony-Vacuum* were to raise price; in this case the aim was to facilitate entry into the U.S. market, which would … lower prices …[68]

Thus, the fact that the judiciary did not have experience with shutdown agreements militated in favor of affirming the trial court's decision.

Promotion of Enterprise and Productivity

Second, the rule of reason is appropriate "if the challenged practice when adopted could reasonably have been believed to promote 'enterprise and productivity.'"[69] This sentence is Posner's summary of a long line of Supreme Court cases holding that agreements that "'increase economic efficiency and render markets more, rather than less, competitive'" are properly evaluated under a reasonableness standard.[70]

New entry is almost always pro-competitive. New entry is "an unequivocally socially beneficial effect from an economic standpoint."[71] In Posner's view, the shutdown agreements facilitated new entry and doing so potentially increased economic efficiency and made the sulfuric acid market more competitive. Thus, if the defendants could prove at trial that the shutdown agreements facilitated entry, "their net effect on economic welfare may well have been positive, especially since the negative effects may have been few because of the high production costs of the U.S. companies."[72] This factor, therefore, also supports the trial court's decision to proceed on a rule of reason basis.

Viewed at the Time It Was Adopted

Third, the restraint should be analyzed from the perspective of "when adopted."[73] At the time the agreements were adopted they reasonably appeared to be a procompetitive solution to an unwanted oversupply in Canada and an overpriced supply in the United States. Without the shutdown agreements the risks of entry may have outweighed the opportunity. If the Canadian companies entered the U.S. market and the U.S. producers continued to produce native sulfuric acid, then supply would greatly exceed demand causing prices to plummet, making it unprofitable for the Canadians to stay in the market, which would result in an eventual increase in the price of sulfuric acid. Alternatively, the Canadians could sell its sulfuric acid below cost and risk a dumping action by the U.S. producers. Alternatively still, the U.S. producers might exit the sulfuric acid business entirely knowing they could not compete against the lower cost Canadian product.

The shutdown agreements rebalanced the scales in favor of opportunity over risk. On the one hand, by agreeing to distribute the Canadian sulfuric acid, the U.S. companies did not have to exit the market entirely, they remained in the market as distributors. On the other hand, the Canadians did not have to incur the risk and expense of developing a distribution network, or risk the threat of a dumping action. The shutdown agreements were procompetitive because they

"facilitated the entry of very low-cost producers into the U.S. market. That benefited U.S. chemical companies that use sulfuric acid as an input … and ultimately the consumers of the products that those companies make."[74]

Unlike the garden-variety price fixing agreement whose "only aim and effect" is to raise price, the aim of the shutdown agreements "was to facilitate entry into the U.S. market, which would (and eventually did …) lower prices and prevent the shutdown of Canadian smelting operations, which would have reduced output and raised the price of sulfuric acid in the United States. The overall effect was thus to lower rather than to raise price." [75]

Likewise, the grant of exclusive territories was procompetitive. The U.S. producers were also taking a big risk when they agreed to change their business model and become mere distributors. Curtailing competition at the distribution level was a procompetitive way of compensating the U.S. producers for this risk they undertook. "Exclusive territories reduce competition at the distributor level but can increase it at the producer level and in this case may well have done so by facilitating the Canadian producers' entry in the U.S. market."[76]

Conclusion

It might be argued that *Sulfuric Acid Antitrust Litigation* does not plow new ground. After all, the Supreme Court in *Broadcast Music*, already warned that "easy labels do not always supply ready answers" and "literalness is overly simplistic and often overbroad." [77] What Judge Posner has done, however, is to provide the roadmap to implement the Supreme Court's sometimes vague aphorisms.

Betting on the Wrong Market Definition

In *IGT v. Alliance Gaming Corporation*[78] slot machine manufacturers, IGT and Alliance Gaming Corp., Bally Gaming International, Inc., and Bally Gaming, Inc. (collectively "Bally") squared off in a high stakes contest with IGT betting on the patent system and Bally on antitrust law to win the day. In the end, both placed losing bets.

The Patent Act and Section 2 of the Sherman Act

Section 2 of the Sherman Act does not proscribe monopolies or the possession of monopoly power;[79] rather, it only proscribes its "willful acquisition or maintenance." [80] In turn, willful acquisition or maintenance of monopoly power has been defined as exclusionary tactics that prevent competition on the merits "as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[81]

In the U.S., a patent gives the patentee or its assignee a right for a limited period of time to exclude others from producing the patented invention.[82] The acquisition of a patent could therefore seem to be the quintessential act of monopolization. However, because patents are a creature of statute obtaining one is not considered an act of monopolization.[83] In addition, the power to exclude granted by the statute does not give the patentee a monopoly or market power unless there are no substitutes for the patented art. If there are no substitutes, the patent might then confer a "monopoly" during the term of the patent.

But a patent is not an impenetrable shield against antitrust scrutiny.[84] When a patentee obtains the patent by fraud[85] or knowingly enforces an invalid patent and excludes others through an infringement action,[86] the putative patentee commits an act of monopolization that may be actionable as a violation of Section 2 of the Sherman Act because the patentee is asserting a monopoly to which he is not entitled. But it is not enough for the plaintiff to establish the act of monopolization. The plaintiff must also establish the other elements of a Section 2 violation, including the identification of the relevant market, a "threshold issue in any monopolization claim."[87] Failure to do so will doom the antitrust action even if the predicate fraud is proven. *IGT v. Alliance Gaming Corporation* illustrates the perils of failing to adequately allege and prove the "threshold issue" -- Bally's antitrust case was dismissed even though it had adequately shown that IGT had endeavored to enforce patents it knew were invalid.

Background of the Case

IGT and Bally Gaming International ("Bally") design, manufacture, distribute and sell computerized gaming machines and systems (slot machines) to casinos. Experts for both parties agreed that slot machines are "differentiated" products, that is, close but not perfect substitutes.[88] The different machines have many features, such as type of display, theme, cabinet design, and bonus features. The most popular type of slot machine is called a "wheel game." Wheel games incorporate a secondary bonus game with a spinning wheel.[89] IGT owned several patents on wheel games and used the patents to block other companies from manufacturing and selling wheel games.[90] The patents allowed IGT command a premium price for its wheel games.

Bally also designs, manufactures, distributes and sells slot machines. When Bally began selling wheel games, IGT sued for patent infringement. As is not unusual, Bally countersued alleging that the infringement lawsuit was an attempt to monopolize the "wheel game market" by asserting patents that IGT knew to be invalid, unenforceable and not infringed.[91] Ultimately, the district court, on Bally's motion for summary judgment, held that the wheel patents were, in fact, invalid and not infringed.[92] The Federal Circuit affirmed.[93]

At least for the purposes of summary judgment, the finding of invalidity and non-infringement provided Bally with the "fraud" predicate it needed as part of its monopolization claim. Bally's antitrust case folded, however, when Bally placed a bet on the wrong market definition. On a subsequent summary judgment motion filed by IGT, the district court dismissed Bally's antitrust claim holding that "the undisputed facts are insufficient to establish the existence of a relevant antitrust market in wheel games,"[94] even though IGT's patents were invalid and not infringed. The Federal Circuit affirmed with one judge dissenting.

Bally's Argument that Wheel Games Are a Distinct Market

Bally argued that market definition is a question for the fact finder[95] and contended that wheel games are a distinct market because (i) IGT, as part of its proof of patent damages, had argued that there were no non-infringing substitutes for its wheel games and (ii) IGT was forced to lower its price for wheel games when Bally introduced its wheel models. This evidence was enough to persuade the dissent.

Bally offered evidence that, when it introduced wheel games into the market, IGT was required to reduce its prices, and that evidence included the amount by which those prices were reduced when competitive wheel games became available. That is precisely the kind of evidence that shows the effect of the allegedly monopolistic conduct on the market.[96]

The Majority's Rationale

The major countered that, as with any other fact issue, the court can grant summary judgment on market definition if the parties do not dispute the material facts.[97] In conducting an antitrust analysis, both the courts and the competition agencies place great weight on party admissions. Here, both parties provided un-rebutted evidence that wheel games competed with all other types of gaming machines on a casino floor. "Both Bally and IGT provided extensive evidence that wheel games compete in the broader gaming machine market."[98] Bally's corporate designee on market definition, as well as its former VP of business development, its Senior VP of Domestic Sales and its Senior VP of Product Development each testified that wheel games "competed with everything that's on the floor ... against everything there."[99] The district court, therefore, correctly concluded from this evidence that "casinos mix and match [different types of slot machines] to maximize floor-space revenue generation."[100]

Bally next argued that even though all slot machines compete against each other, wheel games were a submarket. As support for this proposition, Bally argued that it was undisputed that IGT reduced the price of its wheel games in response to the entry of Bally's wheel games.[101] The majority conceded this point, but found it irrelevant as it only proves that different brands of wheel games compete against each other; it does not prove that non-wheel games are not economic substitutes for wheel games. IGT's price reduction was "the inevitable result of competition among differentiated products following the entry of a substitute to the product at issue."[102]

Bally also incorrectly argued that the price decrease satisfied the Horizontal Merger Guidelines' "small but significant and non-transitory increase in price test" ("SSNIP"). [103] Even if IGT charged supracompetitive prices for its wheel games, which the Federal Circuit conceded, its prices do not represent a "SSNIP." The SSNIP test requires a baseline price from which an increase is then calculated. Bally, however, did not proffer any evidence establishing a baseline price.[104] Moreover, if the supracompetitive price is the baseline, then Bally had only "shown that prices decreased, not that they increased." [105]

Finally, Bally failed to provide evidence of "practical indicia" of a wheel game submarket. [106] Again, according to the Federal Circuit, it was undisputed that wheel games do not require unique production facilities or specialized vendors versus ordinary gaming machines; and wheel games do not have distinct customers - both wheel and non-wheel games are purchased by casinos. The Federal Circuit agreed that some consumers prefer wheel games over non-wheel games. However, this does not support the notion that there is an "industry perception" that wheel games are a separate market. Rather this fact "is in harmony with the rest of the evidence that gaming machines are a differentiated market and that wheel games compete with all gaming machines to accommodate the spectrum of player preferences."[107] Thus, given that all slot machines on the floor compete against each other "a market limited to wheel games would not encompass all economic substitutes."[108]

Bally played one final card. In order to prove patent damages, IGT had argued that there were no non-infringing technological substitutes for its wheel games and that every infringing game sold represented a loss of profits to IGT.[109] Bally argued that this proved that IGT admitted that "non-wheel games are not substitutes for wheel games." [110] Once again, Bally had the losing hand. The fact that "there were no non-infringing technological substitutes cannot be read to mean that there were no economic substitutes."[111] IGT's damages expert had merely assumed, for the purposes of calculating patent damages, that the market was co-extensive with the patent. For antitrust purposes, however, such an assumption would be economically unreasonable. [112]

[1] *FTC v. Watson Pharms., Inc*., 133 S. Ct. 787 (2012).

[2] 21 U.S.C. § 355 *et seq*.

[3] *See In re Schering-Plough* (Opinion of the Comm'n), FTC Dkt. No. 9293, 136 F.T.C. 956, 988 (Dec. 8, 2003) ("Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."), *vacated*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

[4] *See generally In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 526 (E.D.N.Y. 2005), *aff'd*, 544 F.3d 1323 (Fed. Cir. 2008); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1309 (11th Cir. 2003); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

[5] *See* 21 U.S.C. §§ 355(j)(2)(A)(iii)-(v).

[6] *See Caraco Pharm. Labs. Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012); H.R. Rep. No. 98-857(I), at 14-15.

[7] 21 U.S.C. § 355(b)(2)(A)(i)-(iv).

[8] *Id.*at § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A) (paragraph IV certification constitutes a constructive act of patent infringement).

[9] 21 U.S.C. § 355(j)(5)(B)(iii).

[10] *Id.* at § 355(j)(5)(B)(iv).

[11] According to one study, between 1984, when Hatch-Waxman was passed, and August 2008, 60 out of 143 patent infringement settlements between brand and generic companies, concerning 51 drugs, involved some form of reverse payment consideration. *See* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking To Preserve Drug Competition*, 109 Colum. L. Rev. 629 (2009).

[12] *See generally In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206-07 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 250-52 (E.D.N.Y. 2003).

[13] *In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d at 206.

[14] *Id.* at 206-07; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d at 250-52.

[15] *See, e.g.*, Robert Willig and John Bigelow, Antitrust Policy Toward Agreements that Settle Patent Litigation, 49 The Antitrust Bull. 655 (Fall 2004).

[16] *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

[17] *See* 35 U.S.C. § 154(a)(1).

[18 *Schering-Plough*, 402 F.3d at 1066.

[19] *Id.*

[20] *Id.* at 1068.

[21] *In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d 187, 208, 215 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007). *See also id*. at 215 (quoting *Prof'l Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49, 60 (1993)).

[22] *Id.* at 212-214.

[23] *See, e.g.*, Jon Leibowitz, Comm'r, Fed. Trade Comm'n, Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!, Remarks at the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust at 1 (Apr. 24, 2006), *available at* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf. *See also How Pay-For-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the House Comm. on Energy and Commerce*, 111th Cong. (2009) (statement of J. Thomas Rosch, Comm'r, Fed. Trade Comm'n) (advocating a rule of per se illegality), http://www.ftc.gov/speeches/rosch/090331payfordelay.pdf.

[24] *See* Richard Feinstein, Director, Fed. Trade Comm'ns Bureau of Competition, Anticompetitive Pay-For-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs, Prepared Statement of The Federal Trade Commission before the Subcomm. on Courts and Competition Policy of the House Comm. on the Judiciary (June 3, 2009), http://www.ftc.gov/os/2009/06/P859910payfordelay.pdf.; Rosch, Pay-For-Delay (advocating a rule of per se illegality).

[25] *See, e.g.*, Jon Leibowitz, Comm'r, Fed. Trade Comm'n, Prepared Statement of the Fed. Trade Comm'n before the Senate Comm. on the Judiciary, Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution 1 (Jan. 17, 2007), http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.p .

[26] *See In re Schering-Plough* (Opinion of the Comm'n), FTC Dkt. No. 9293, 136 F.T.C. at 988 ("Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.").

[27] Feinstein, Anticompetitive Pay-For-Delay Settlements in the Pharmaceutical Industry at 10.

[28] FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions 2 (2010), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

[29] *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

[30] *Id.* at 214, 216.

[31] *Id.* at 218.

[32] *Id.*

[33] *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 133 S. Ct. 787 (2012).

[34] *Id*. at 1305-06.

[35] *Id*.

[36] *Id*. at 1306.

[37] *Id.*

[38] *Id*. at 1308.

[39] *Id*. at 1312.

[40] *Id*. at 1313.

[41] FTC Pet. for Writ of Cert., No. 12-416, 2012 WL 4750283, at *10-15.

[42] *Id*. at *10, *21-26.

[43] *Id*. at *15.

[44] *Id*. at *21-24.

[45] Br. for Resp. Watson Pharms., Inc., No. 12-416 at 1, 19-27. Defendants Solvay Pharmaceuticals, Par Pharmaceutical Companies, and Paddock Holdings each argued against certiorari. See Br. for Resp. Solvay Pharmaceuticals, Inc., No. 12-416; Par Pharmaceutical Companies, Inc. & Paddock Holdings, Inc. Br. in Opp., No. 12-416.

[46] *In re Sulfuric Acid Antitrust Litig.*, Nos. 12-1109, 12-1224, 2012 WL 6700395 (7th Cir. Dec. 27, 2012).

[47] *Id.*at *6.

[48] *Id.* at *2.

[49] The Canadian oversupply was the result of environmental legislation by the Canadian government. Sulfur dioxide is an immediate byproduct of smelting. When sulfur dioxide is released into the atmosphere it mixes with atmospheric water and becomes acid rain. The legislation required the smelters to convert the sulfur dioxide into sulfuric acid instead of releasing it into the atmosphere, and then either to sell it or to store it. *Id.* at *2-3. The marginal cost of producing the sulfuric acid was near zero as it was essential a byproduct of the smelting process, plus water. The Canadian market for sulfuric acid, however, was very small and storing it was very expensive owing to its corrosive quality. Thus, while the Canadian legislation solved the acid rain problem it had the unintended consequence of creating a glut of cheap Canadian sulfuric acid. *Sulfuric Acid Antitrust Litig.* at *2-3. In contrast to the Canadian market, the U.S. market for sulfuric acid was "large" but unprofitable. *Id.* at *3. In the U.S., sulfuric acid was manufactured by burning elemental sulfur, not as a byproduct to smelting ores. The U.S. plants were old and inefficient and many were closing. While the marginal cost of Canadian sulfuric acid was close to zero, the marginal cost for U.S. chemical producers included the costs of the sulfur and operating the plant. *See* Combined Brief of Defendants-Appellees in No. 12-1109 and Defendants-Cross-Appellants in No. 12-1224 at 7. All things considered, and despite the high cost to transport the acid, Canadian sulfuric acid was cheaper than U.S. produced sulfuric acid.

[50] *Sulfuric Acid Antitrust Litig.,* at *3, *6.

[51] *Id.* at *6.

[52] *Id.* at *3.

[53] The dismissal was final for appellate purposes because the plaintiffs made it clear that the case was over if they were not allowed to try the case on a theory of *per se* liability. *Id.* at *1.

[54] The appeal was not about whether a jury might find that the challenged conduct, in fact, violated the antitrust laws. "Pretrial discovery had supplied the plaintiffs in the present case with all the evidence they needed in order to be able to make a prima facie case of price fixing. So at least they believed and we can assume without deciding that they were right." *Id.* at *5.

[55] *Id.* at *1

[56] *Id.*

[57] *Id.*

[58] *Id.* at *1, *5.

[59] *Id.* at *5.

[60] *Id.* at *1, *5.

[61] *Id.*

[62] *Id.* at *4.

[63] *See Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977); *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006).

[64] *Sylvania*, 433 U.S. at 50. *See also Broadcast Music, Inc. v. Columbia Broadcasting Sys., Inc.*, 441 U.S. 1, 9-10, 20 (1979); *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 886-87 (2007).

[65] *Broadcast Music*, 441 U.S. at 9-10.

[66] *Sulfuric Acid Antitrust Litig.,* 2013 WL 6700395, at *5.

[67] *Id.* (*citing Leegin*, 551 U.S. at 886-87); *Broadcast Music*, 441 U.S. at 9-10.

[68] *Id.* at *5.

[69] *Id*. at *4 (*quoting Polk Bros., Inc. v. Forest City Enterprises, Inc.*, 776 F.2d 185, 189 (7th Cir. 1985)).

[70] *Broadcast Music*, 441 U.S. at 20 (*quoting United States v. United States Gypsum Co.*, 438 U.S. 422, 441 n.16 (1978)). In *Broadcast Music*, the Supreme Court upheld a "literal" price fixing arrangement among composers on the grounds that it created a "different product," namely a blanket copyright license that greatly reduced the cost of license negotiations. *Broadcast Music*, 441 U.S. at 8-9, 21-22. Similarly, "the shutdown agreements could be regarded as enabling or assisting in enabling a new product in the U.S. economy, namely Canadian smelter acid." *Sulfuric Acid Antitrust Litig.*, 2012 WL 6700395, at *5.

[71] *Sulfuric Acid Antitrust Litig.,* 2012 WL 6700395, at *4.

[72] *Id.*

[73] *Id. See also Polk Brothers, Inc. v. Forest City Enterprises, Inc.*, 776 F.2d 185, 189 (7th Cir. 1985) where the court in upholding an ancillary covenant among the parties limiting the products each could sell at a common and jointly financed location said that "If the restraint viewed at the time it was adopted may promote the success of this more extensive cooperation, then the court must scrutinize things carefully under the Rule of Reason."

[74] *Sulfuric Acid Antitrust Litig.,* 2012 WL 6700395, at *5.

[75] *Id.*

[76] *Id.* at *6.

[77] *Broadcast Music*, 441 U.S. at 8, 9.

[78] *IGT v. Alliance Gaming Corp.*, 702 F.3d 1338 (Fed. Cir. 2012).

[79] *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.,* 555 U.S. 438 (2009).

[80] 15 U.S.C. § 2. *See United States v. Grinnell Corp.*, 384 U.S. 563 (1966); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 686-87 (2d Cir. 2009).

[81] *Id.*

[82] 35 U.S.C. § 154a (1)-(2). *See also Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention.").

[83] *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965) (a "patent ... is an exception to the general rule against monopolies and to the right to the access a free and open market ...") (citation omitted); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1203 (2d Cir. 1981) ("the patent laws reward the inventor with a temporary monopoly that insulates him from competitive exploitation of his patented art").

[84] *See, e.g., United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) ("[T]he possession of a valid patent ... does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.") (internal quotation marks and citation omitted).

[85] *Walker Process*, supra note 6. *See also SCM Corp.*, supra note 6.

[86] *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.,* 508 U.S. 49 (1993).

[87] *IGT*, 702 F.3d at 1344.

[88] *Id.* at 1342-43.

[89] *Id.* at 1341.

[90] *Id.*

[91] *Id.*

[92] *Id.* at 1342.

[93] *See IGT v. Alliance Gaming Corp.*, 334 F. App'x 329 (Fed. Cir. 2009).

[94] *IGT*, 702 F.3d at 1341.

[95] *Id.* at 1344.

[96] *Id*. at 1349 (Dissent) (citing 2B Philip E. Areeda et al., Antitrust Law: An Analysis of Antitrust Principles and Their Application §§ 533, 563a (3d ed. 2007)).

[97] *Id.* at 1343-44. When reviewing the relevant market under antitrust law, the Federal Circuit applies the law of the regional circuit in this case the Ninth Circuit. *Id.* (*citing Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 2005)).

[98] *IGT*, 702 F.3d at 1344.

[99] *Id.* at 1344.

[100] *Id.* at 1345.

[101] *Id.* at 1345-46.

[102] *Id.* at 1342 (*quoting* testimony of IGT's expert, Professor Janusz Ordover).

[103] *Id.* at 1345-46. The Federal Circuit noted that under Ninth Circuit law the Horizontal Merger Guidelines are not binding on the courts. *Id.* at 1346 n.3.

[104] *Id.* at 1346.

[105] *Id.*

[106] *Id.* at 1346-47 (*citing Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962)).

[107] *Id.* at 1347.

[108] *Id.* at 1345.

[109] *Id.* at 1347-48 (*citing Rite-Hite Corp. v. Kelly Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc)).

[110] *Id.* at 1347.

[111] *Id.* at 1347-48.

[112] *Id.* at 1348 (*citing Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1435 (9th Cir. 1995)).

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