Antitrust Group

Client Alert

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Court Dismisses *In Re Humira* Antitrust Suit Against AbbVie, Including Early-Entry Reverse Payment and "Patent Thicket" Allegations

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On June 8, 2020, Judge Manish Shah of the United States District Court of the Northern District of Illinois dismissed a complaint alleging a novel "patent thicket" monopolization claim under Section 2 of the Sherman Act and a geographic market allocation "pay-for-delay" claim under Sherman Act Section 1 challenging AbbVie's settlement of patent litigation claims involving its blockbuster rheumatoid arthritis biologic drug, Humira, and several of its biosimilar Humira patent challengers. The decision has important implications for companies in the biologic space as well as patent holders in other industries that have amassed significant patent portfolios.

KEY POINTS:

In a matter of first impression, the court:

- Rejected Plaintiffs' "**patent thicket**" theory of antitrust liability under Section 2 of the Sherman Act based on allegations that a biologic drug manufacturer acquired and exercised a large numbers of patents (i.e., the so-called "patent thicket") to stifle competition by potential biosimilar competitors.
- Reaffirmed that activities by biotech companies to **reinforce a patent portfolio** such as seeking and defending patents before the PTO and prosecuting patent rights in infringement actions, are immunized from antitrust liability under the *Noerr-Pennington* doctrine unless they constitute "sham" petitioning activity that is designed to thwart competition.
- Rejected Plaintiffs' novel argument that ***early market entry*** (here, in European markets), allegedly provided in exchange for delayed entry in the US, was an anticompetitive **reverse payment** or **geographic market allocation**.

The court also declined to expand the potential scope of antitrust liability for alleged pay-for-delay patent litigation settlement agreements by reaffirming the Supreme Court's holding in *FTC v. Actavis Inc.* that a settlement providing for generic entry prior to patent expiry, without a "large and unjustified payment" to the alleged generic infringer, is permissible under the rule of reason. In doing so, the court recognized the critical role that global settlements play in resolving patent disputes, and the opinion preserved biotech companies' ability to do so by rejecting Plaintiffs' attempt to impose expansive antitrust liability. The decision validates AbbVie's aggressive efforts to safeguard Humira's US market exclusivity using extensive layers of patent protection, and it likely will encourage the development of patent thickets in the biotech industry and beyond.

Background

On August 9, 2019, a putative class of indirect purchasers filed an amended consolidated complaint against Defendants AbbVie Inc. and AbbVie Biotechnology Ltd. (together, "AbbVie"), as well as Amgen Inc., Samsung Bioepis Co. Ltd, Sandoz Inc., and Fresenius Kabi USA, LLC (together, the "Biosimilar Defendants"), alleging violations of federal antitrust and state antitrust and consumer protection laws in connection with AbbVie's blockbuster rheumatoid arthritis drug, Humira.[1] Humira, a biologic drug, was first approved in the US in 2002 and, according to Plaintiffs, has generated over $20 billion in sales worldwide. Plaintiffs alleged that Humira's original patent was set to expire in 2016, and with it AbbVie's market exclusivity, but that AbbVie found an "ingenious—albeit illegal—way to bridge" a "gaping hole" in its product pipeline by conspiring to exclude Humira biosimilars from entering the US market and competing for Humira sales until 2023.[2]

Plaintiffs alleged that AbbVie and the Biosimilar Defendants violated Section 1 of the Sherman Act by entering into "pay-for-delay" agreements that permitted the Biosimilar Defendants to enter European markets as early as 2018, purportedly in exchange for dropping their challenges to the validity and non-infringement of Humira patents in the US and agreeing to a US entry date in 2023. As part of these purportedly unlawful agreements, Plaintiffs further claimed that AbbVie and Amgen agreed to a five-month period of exclusivity for Amgen's Humira biosimilar in the US, with AbbVie allegedly agreeing not to give other biosimilars an entry date prior to Amgen's entry date.[3] In addition, Plaintiffs asserted that the purported agreements to delay biosimilar Humira market entry in the US in exchange for earlier European market entry separately constituted unlawful geographic market allocation, a *per se* violation of Sherman Act Section 1.

Plaintiffs further alleged that AbbVie unlawfully monopolized the US market for Humira in violation of Section 2 of the Sherman Act. Plaintiffs asserted the novel antitrust claim that AbbVie monopolized the market for Humira by acquiring a "patent thicket" of over 100 patents protecting Humira, which Plaintiffs alleged was "not undertaken and executed in furtherance of legitimate use of the patent system" but was done "solely to restrain trade, harass potential competitors, and perpetuate AbbVie's monopoly in the relevant market."[4]

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[1] Consolidated Amended Complaint, *In Re: Humira (Adalimumab)Antitrust Litigation*, 19-cv-1873 (N.D. Ill.), Dkt. #109 ("Am. Compl.").
[2] Am. Compl. ¶ 3.
[3] With respect to the allegations of a five-month period of biosimilar exclusivity for Amgen, Defendants attached the settlement agreement between AbbVie and Amgen to their motion to dismiss under seal, which Defendants argued contained no agreement to exclude other Biosimilar Defendants from the US market. The settlement agreement with Amgen and portions of Defendants' brief discussing it were redacted on the public docket. However, after AbbVie filed the settlement agreement under seal, Plaintiffs dropped their allegations relating to biosimilar market exclusivity for Amgen. *See In Re: Humira (Adalimumab)*, No. 19 CV 1873, slip opp. at 13 n.7 (N.D. Ill. June 8, 2020).
[4] Am. Compl. ¶¶ 297, 303.

Decision

On June 8, 2020, Judge Shah dismissed the claims against Defendants with leave to amend the complaint. The court held that AbbVie did not violate the US antitrust laws, but rather "exploited advantages conferred on it through lawful practices" provided by US patent law.[5]

Pay-for-delay and market allocation: Rejecting Plaintiffs' contention that the alleged "pay-for-delay" and geographic market allocation was *per se* unlawful under Section 1, the court explained that the "agreements do not justify *per se* treatment because they are not facially anticompetitive in any way that would always or almost always tend to restrict competition."[6] While the court recognized that market allocation is a "classic example" of a *per se* violation, Plaintiffs failed to allege that AbbVie had agreed to stop selling Humira in Europe (i.e., that AbbVie actually allocated the European markets to the Biosimilar Defendants). And more importantly, the court explained that, pursuant to US patent law, patentees have the right to selectively license their patents in select geographies and settle intellectual property disputes by issuing "territorial licenses that allow competitors to sell patented products in some foreign countries but not others (and not in the U.S.)."[7] The court further explained that, for these reasons, "patents are different from other types of intellectual property when it comes to geographic restrictions, and an agreement to permit entry into a market previously protected by a patent does not become a *per se* invalid market allocation agreement just because it is specific to one territory (or one country)."[8] Given these patent law principles and the fact that there were legitimate, procompetitive justifications for the parties' agreements, such as litigation certainty and avoided litigation costs, the court found that Plaintiffs' market allocation claims were subject to rule of reason analysis.[9]

The court then turned to the analytical construct established by the Supreme Court in *Actavis*—that so-called pay-for-delay patent litigation settlement agreements between pioneer and generic drug manufacturers are subject to antitrust scrutiny under the rule of reason. The court explained that underpinning *Actavis'* holding was the recognition that the large "reverse" payment to the generic in that case suggested that the patents were weak and that "the patentee purchased an opportunity to keep prices set at its preferred level—sharing monopoly profits with a [generic] competitor without consumer gains."[10] However, the *Actavis* court carved out a safe harbor to avoid deterring patent litigation settlements for fear of antitrust liability: "Parties remain free to settle on other terms—for example, 'by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.'"[11] Applying these principles to the case at hand, although the court recognized that early biosimilar entry in Europe constituted a transfer of value in a broad sense, it held that "[t]here was no antitrust violation because the only 'payment' [to the biosimilar] was competition itself"[12] and, therefore, the two early-entry settlement agreements fell within *Actavis'* safe harbor.[13]

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[5] *In Re: Humira (Adalimumab)*, No. 19 CV 1873, slip opp. at 2 (N.D. Ill. June 8, 2020).
[6] *Id.* at 36.
[7] *Id.* at 39.
[8] *Id.*
[9] *Id.* at 40.
[10] *Id.* at 41-42.
[11] *Id.* at 42 (quoting *FTC v. Actavis Inc.*, 570 U.S. 136, 158 (2013)).
[12] *Id.* at 44 (citing *Asahi Glass Co. v. Pentech Pharm., Inc.,* 289 F.Supp.2d 986, 994 (N.D. Ill. 2003), *dismissed,* 104 Fed. App'x 178 (Fed. Cir. 2004)).
[13] *Id.* at 44. Furthermore, the court noted that "the complaint itself alleges that AbbVie's European adalimumab patent expired on the same day that the agreements allowed Amgen, Samsung Bioepis, and Sandoz to enter the European market, further undermining the implication that the European early entry dates were worth all that much

Patent thicket monopolization: The court also dismissed Plaintiffs' "patent thicket" monopolization claim under Section 2 of the Sherman Act. At the outset, the court noted that Plaintiffs were asserting a "new theory" of Section 2 liability whereby AbbVie purportedly "obtain[ed] and assert[ed] swaths of invalid, unenforceable, or noninfringed patents without regard to the patents' merits" in order to "to delay its competitors and avoid any real examination of the patents' validity long enough to reap a few more years' worth of monopoly profit on its lucrative, patent-protected product, Humira."[14] In assessing Plaintiffs' novel theory, the court explained that, while "petitioning the government (during patent prosecutions, the FDA approval process, and in the courts)" is generally protected by the First Amendment and exempt from antitrust liability under the *Noerr-Pennington* doctrine, it "can violate the antitrust laws if, in reality, that petitioning is nothing more than a sham meant to inhibit competition."[15] Such petitioning activity must be "'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.'"[16] If petitioning activity is found to be objectively baseless, the court then proceeds to a subjective test to determine "'whether the baseless lawsuit conceals an attempt to interfere *directly* with the business relationships of a competitor, through the use of the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon.'"[17] Key to a finding of antitrust liability is a "'pattern of baseless, repetitive claims' that shows the 'administrative and judicial processes have been abused.'"[18]

The court held that Plaintiffs failed to allege a viable Section 2 claim "because most of the conduct upon which their allegations are based was immunized [by the *Noerr-Pennington* doctrine], and because plaintiffs' theory depends on considering AbbVie's conduct as a whole."[19] While the court found that Plaintiffs' complaint plausibly alleged "a kernel of objectively baseless petitioning" as related to its "patent dances" (the pre-litigation exchange of patent information required under the Biologics Price Competition and Innovation Act) with its potential Humira biosimilar competitors that was not immunized under *Noerr-Pennington*, it also determined that AbbVie engaged in various other types of legitimate petitioning activity due to the fact that 53.4% of its applications for Humira patents were successful, it was largely successful in convincing the Patent Trial and Appeal Board to decline to initiate inter partes patent reviews, and its patent infringement prosecutions resulted in settlements that provided it with substantial value "on terms that foreclose a finding of objective baselessness."[20] "[B]ecause plaintiffs' theory depend[ed] on all the components of AbbVie's conduct as the means to suppress competition[,]" it found that "the entirety of the alleged monopolization scheme" was immunized from antitrust scrutiny pursuant to the *Noerr-Pennington* doctrine.[21]

Antitrust injury: Finally, the court found that Plaintiffs failed to plausibly allege "antitrust injury"—a required element of Plaintiffs' Section 1 and Section 2 claims. "[A]ntitrust injury is any 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.'"[22] To satisfy the causation element, Plaintiffs must plausibly allege that the antitrust violation

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(or that they were 'early' at all)" although it did not rely on this allegation in reaching its decision on the motion to dismiss. *Id.* at 45 n.17.

[14] *Id.* at 19.
[15] *Id.* at 20.
[16] *Id.* at 21 (quoting *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.,* 508 U.S. 49, 51 (1993)).
[17] *Id.* at 21-22 (quoting *Prof'l Real Estate Inv'rs, Inc.*, 508 U.S. at 60-61) (emphasis in original).
[18] *Id.* (quoting *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972)).
[19] *Id.* at 27 n.14.
[20] *Id.* at 24-31.
[21] *Id.* at 31-32.
[22] *Id.* at 49 (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)).

was the "cause-in-fact" of their injury, that "but for" the violation, the injury would not have occurred.[23] Rejecting Plaintiffs' claim that one of the biosimilar challengers *could* have succeeded in the underlying patent litigation and competed for Humira sales in the absence of AbbVie's purportedly baseless patent infringement actions, the court held that Plaintiffs' allegations were too speculative to establish causation because "it only takes one valid, infringed patent to render all the rest—whether invalid, infringed, or not—irrelevant for purposes of cause-in-fact analysis."[24] Additionally, the court rejected Plaintiffs' argument that certain biosimilars *could* have launched "at-risk" but chose not to do so due to the uncertainty of possible infringement resulting from AbbVie's patent infringement actions.[25] The court found, once again, that Plaintiffs' allegations were insufficient to establish causation because "plaintiffs' theory rests on speculative guesses about what hypothetically competitive biosimilar manufacturers might have done."[26]

Analysis

This case is notable as the first decision to reject an antitrust challenge to the conduct of biologic drug patent holders and biosimilars in settling patent litigation. Additionally, the complaint alleged novel theories of harm based on conduct that is standard fare for pharmaceutical patent holders (e.g., the acquisition and enforcement of patent portfolios and the global settlement of patent claims). Judge Shah's decision is another rejection of efforts by class plaintiffs to challenge pharmaceutical patent settlement agreements with early market entry provisions that lack the hallmark "large and unjustified" reverse payment to the generic (or in this case, biosimilar) drug manufacturer that the *Actavis* Court condemned.[27]

Judge Shah also rejected the theory that accumulation of a large number of patents can be anticompetitive even without a claim of fraud with respect to the procurement of the patents. Importantly, Judge Shah suggested that if the PTO is issuing questionable patents, the remedy should not be to permit collateral attacks on the patents through antitrust claims.[28] In this respect, Judge Shah's decision is an important one for biologic patent holders, as well as other sectors where large patent portfolios are common. If the court had not dismissed Plaintiffs' patent thicket theory, these innovators would have almost certainly seen an explosion of lawsuits alleging patent thicket claims.

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[23] *Id.* at 50.
[24] *Id.* at 52.
[25] *Id.* at 55-56.
[26] *Id.* at 56.
[27] *Compare In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *15-16 (S.D.N.Y. Sept. 22, 2015) (holding that an acceleration clause did not constitute a reverse payment on a motion to dismiss because it would increase competition if a generic challenger entered the market earlier than contemplated by the settlement agreement), *aff'd in part, vacated in part* 848 F.3d 89 (2d. Cir. 2017), *with In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 334 (D.R.I. 2017) (holding an acceleration clause may constitute a "component" of a reverse payment on a motion to dismiss).
[28] *In Re: Humira (Adalimumab)*, No. 19 CV 1873, slip opp. at 32.

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