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ANDA Update

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FOLLOW-ON BIOLOGICS/BPCIA

180-Day Notice Period for Biosimilar Approval Is Always Mandatory and Enforceable by Injunction

Amgen Inc., v. Apotex Inc., (Fed. Cir. July 5, 2016)

Jeffrey R. Gargano

A year after analyzing the patent dance and notice requirements of the Biologics Price Competition and Innovation Act (BPCIA) in *Amgen Inc. v. Sandoz Inc.*, the US Court of Appeals for the Federal Circuit has ruled that a follow-on biologic or biosimilar applicant is *always* required to provide a 180-day notice of marketing to the reference product sponsor (RPS) after the biosimilar product is licensed by the US Food and Drug Administration (FDA). *Amgen Inc., v. Apotex Inc.*, Case No. 2016-1308 (Fed. Cir. July 5, 2016), (Taranto, C.J.).

BPCIA Background

The BPCIA allows biosimilar applicants to gain approval for a drug that is biosimilar to a reference product without repeating all of the testing done by the original RPS. Instead the biosimilar applicant can use publicly available information about the reference product's safety, purity and potency in support of the application. In order to balance innovation with consumer interests, the BPCIA prohibits a biosimilar application from being submitted until four years after the reference product was licensed, and prohibits biosimilar approval until 12 years after the reference product was licensed.

The most heavily litigated part of the BPCIA is 42 USC § 262(l), which established a patent-dispute-resolution regime related to biosimilars. Section 262(l) includes provisions related to what has been called the "patent dance"—the exchange of patent information between the biosimilar applicant and the RPS that potentially culminates in a patent infringement lawsuit brought by the RPS. The BPCIA also describes a scenario in which the biosimilar applicant is required to give a 180-day notice prior to the first marketing of the biosimilar, to allow the RPS to seek a

preliminary injunction based on patents not subject to an infringement suit pursuant to the "patent dance."

In *Amgen Inc. v. Sandoz Inc.*, the Federal Circuit first dealt with the dispute resolution provisions, ultimately ruling that a biosimilar applicant could opt out of the "patent dance." However, even if the applicant chose not to be involved in the "patent dance" it was still required to give a 180-day notice to the RPS after the biosimilar had been licensed by the FDA and prior to the marketing of the biosimilar.

180-DAY NOTICE IS REQUIRED EVEN IF THE BIOSIMILAR APPLICANT ENGAGES IN THE PATENT DANCE

In 2014, Apotex filed a biosimilar application for pegfilgrastim, identifying Amgen's Neulasta® product as the reference product. Apotex initiated the patent dance by providing Amgen with a copy of the Apotex application on December 15, 2014. After completing the statutorily required steps, Apotex identified one Amgen patent that it believed was invalid and not infringed by its biosimilar product. Apotex also sent a letter stating that it was providing 180-day notice of future marketing—even though Apotex's product had not yet been licensed by the FDA.

In August 2015, Amgen brought an infringement suit against Apotex. As part of that lawsuit, Amgen filed a preliminary injunction, asking the court to require Apotex to provide notice after the FDA licensed its pegfilgrastim biosimilar and preventing Apotex from marketing its product for 180 days following that notice. Apotex argued that its participation in the patent dance rendered the 180-day notice not mandatory and unenforceable by an injunction. The US District Court for the Southern District of Florida disagreed and granted the injunction. Apotex appealed.

The Federal Circuit reviewed the district court's interpretation of the BPCIA *de novo*, and affirmed the granting of the preliminary injunction.

The Federal Circuit focused on the statutory language of the notice provision, and relied on its prior interpretation of the section in *Amgen Inc. v. Sandoz Inc*. The court pointed out that the relevant language of the statute: the "applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biologic product licensed under subsection (k)" includes the word "shall" which indicates that the notice period is mandatory. The court also emphasized that none of the statutory language suggested any connection between the "patent dance" and the 180-day notice requirement. Instead, the 180-day notice requirement is a standalone provision not dependent on the "patent dance."

The Federal Circuit also dismissed Apotex's policy arguments. While the court acknowledged that in some cases the 180-day notice period would extend RPS exclusivity past the 12 year mark, it reasoned: (1) many RPS products get more than 12 years of exclusivity because of delays in biosimilar application or FDA licensing, so the additional 180-day notice is consistent with the statutory regime as a whole; and (2) the FDA can license a biosimilar product before 12 years have passed and simply make the license effective at the 12-year mark—which would allow the 180-day notice to overlap with the end of the 12-year period. The court also noted that the 180-day notice period was consistent with the overall goals of the statute—permitting the parties to conduct patent litigation without time pressure that would impair its fairness and outcome.

Finally, the Federal Circuit addressed Apotex's argument that the exclusive remedy for violating the 180-day notice provision is a declaratory judgment action. While the BPCIA does include a section authorizing a RPS to bring a declaratory judgment action for patent infringement if the biosimilar applicant fails to complete either the "patent dance" or the 180-day notice requirement, the court rejected Apotex's argument that a declaratory judgment action was the only possible remedy. The court emphasized that none of the statutory language suggested that the declaratory judgment remedy was exclusive, and pointed out that a declaratory judgment action would serve no purpose as a remedy for violating the 180-day notice requirement.

Ultimately, the court ruled that the BPCIA's 180-day notice requirement is always mandatory and can be enforced by a preliminary injunction.

OBVIOUSNESS

Product *sans* Problem Can Be Obvious Even though a Source of the Problem Is Non-Obvious

Purdue Pharma L.P. v. Epic Pharma, LLC (Fed. Cir. February 1, 2016)

Bhanu K. Sadasivan, PhD

Addressing obviousness in the context of a non-obvious problem source, the US Court of Appeals for the Federal Circuit affirmed the US District Court for the Southern District of New York's ruling that the claimed product was obvious where one would have arrived at the claimed product without knowing the source of the problem. *Purdue Pharma L.P. v. Epic Pharma, LLC.*, 811 F.3d 1345 (Fed. Cir., Feb. 1, 2016) (Prost, C.J.)

The case concerned an improved version of the opiate pain reliever OxyContin® (oxycodone HCl) that no longer contained an excessive amount of a toxic byproduct, 14-hydroxy. The excess 14-hydroxy was thought to be derived from two sources: 8α and 8β. While 8β was known in the art to be a source of 14-hydroxy, Purdue scientists were the first to discover 8α as a source. They found that 8α, formed early in the manufacturing process, was being converted to 14-hydroxy during the step of converting the oxycodone free base to oxycodone hydrochloride (the API)—the salting step. The scientists also determined that adding a hydrogenation step after the salting step fixed the problem of excess 14-hydroxy. The claims at issue cover the API with low levels of the toxic 14-hydroxy, but explicitly recite 8α as the source of at least a portion of 14-hydroxy remaining after the salting step.

On appeal, Purdue argued that the lower court failed to properly credit the core of its claimed inventions, *i.e.* its discovery of 8α. According to Purdue, because the source of the problem was non-obvious, the solution also is non-obvious as a matter of law, and that without knowing that 14-hydroxy is derived from 8α, a skilled artisan would not know when and under what conditions to perform the hydrogenation step. The Federal Circuit rejected Purdue's arguments. It distinguished legal precedent, explaining that Purdue is not claiming the remedy to the problem of excess 14-hydroxy after the salting step, *i.e.*, performing the second hydrogenation step, but instead is claiming the end-product which may be arrived at even if the source of the problem was unknown. Expanding further on the breadth of the patent claims at issue, the court noted that if the patent claims had required the remedy of hydrogenating the salt, Defendants' product would not infringe. Likewise, the court noted that the conditions for removing 14-hydroxy derived from 8β would not be any different from that for removing 14-hydroxy derived from 8α, rejecting Purdue's argument that one would not know the conditions necessary for the hydrogenation step without knowing that 14-hydroxy is derived from 8α.

Purdue also contended that the claim limitation "derived from 8α[ ]" was improperly identified as a process limitation and incorrectly disregarded. Rejecting Purdue's arguments, the court explained that "derived from 8α[ ]" is a process limitation: it does not describe the structure of 14-hydroxy, impart any new structure on 14-hydroxy or require a different hydrogenation process for removal. As to the relevance of a process limitation in obviousness analysis, the court noted that the focus remains on the product, not the process by which it is made in a product-by-process claim because of the "longstanding rule that an old product is not patentable even if it is made by a new process." The court also declined to find this case to be an exception because the claim limitation did not impart any new "structural or functional differences" distinguishing the claimed product from prior art. According to the court, no new structure is imparted on 14-hydroxy nor is the hydrogenation process different because 14-hydroxy is derived from 8α.

PRACTICE NOTE

Do not assume that a solution to a problem would be non-obvious because a source of the problem was non-obvious—how the invention is claimed matters. Beware of drafting the novel aspect of the invention as a process limitation in a product claim.

INVALIDITY §§ 101/112, DAMAGES AND EQUITABLE DEFENSES (UNCLEAN HANDS/WAIVER)

Merck's Damages Award for Infringement Thwarted by Gilead's Equitable Defenses of Unclean Hands

Gilead Sciences, Inc. v. Merck & Co., et al. (N.D. Cal. January 13, 2016)

Krista Vink Venegas, PhD

In this ongoing, multi-faceted case, the parties recently received the US District Court for the Northern District of California's rulings on whether Merck's asserted patents were obtained with unclean hands and/or whether Merck waived its right to sue for infringement. The court determined Merck was barred from collecting the damages previously awarded for Gilead's undisputed infringement of Merck's patents. *Gilead Sciences, Inc. v. Merck & Co., et al.*, Case No. 13-cv-04057 (N.D. California, Judge Beth Labson Freeman).

Gilead filed this case in August 2013, before the launch of its hepatitis C virus (HCV) products containing sofosbuvir (Sovaldi® and Harvoni®). Gilead sought a declaratory judgment that its products would not infringe Merck's patents directed to nucleoside prodrug compounds and methods for treating HCV using the claimed compounds.

In December 2015, both parties moved for summary judgment, and the court ruled on the motions one month before trial. Merck sought a judgment that patients and caregivers who use Sovaldi and Harvoni directly infringe the asserted patent claims, and Gilead's sales of these products induces and contributes to direct infringement by patients and caregivers. Gilead did not contest Merck's infringement allegations, and consequently, the district court granted Merck's motion on infringement. (ECF 214). Gilead sought a judgment of invalidity under 35 USC §§ 101 and 112, arguing that Merck's claims lacked utility, and further that the claims were not enabled because "the how to use prong of section 112 [requires] that the specification disclose as a matter of fact a practical utility for the invention." Gilead asserted that when Merck's patents were filed, prodrug delivery was unpredictable, and without reliable data, one of skill would not have accepted that the claimed nucleoside compounds would be effective in treating HCV. Merck countered that one of skill in the art would have understood the claimed compounds to be useful in treating HCV because the art disclosed using nucleoside analogs in HCV therapy and the US Food and Drug Administration (FDA) had approved 17 such drugs for treating viral infections, including HCV. The court found that Merck presented sufficient evidence that one of skill "could have accepted without question the alleged utility of the asserted patents," and denied Gilead's motion. *Id*.

In March 2016, following a two-week trial on the issue of validity, the jury found that Gilead did not prove by clear and convincing evidence that the asserted claims were invalid for lack of enablement or written description. (Gilead subsequently filed a renewed motion for a judgment as a matter of law, seeking to overturn the jury's determination that it had not proved invalidity of the asserted patents due to a lack of written description, lack of enablement and/or derivation of the invention by another (Pharmasset).) In spite of upholding the validity of the asserted patents, the jury only awarded Merck $200 million for Gilead's undisputed infringement (a four percent royalty on $5 billion sales)—well short of Merck's proposed damages (10 percent royalty rate on a $20 billion royalty base). In order to collect its damage award, Merck had to prevail on Gilead's two equitable defenses that were heard in a follow-on bench trial.

First, Gilead argued Merck's patents are unenforceable due to unclean hands. "Merck's dishonesty and misuse of Pharmasset's information in obtaining its patents prevents Merck from asserting those patents against Gilead, under the doctrine of unclean hands." (ECF 368 at 2–8, 9–11). Specifically, Gilead contended that Merck's patent prosecutor, who prosecuted Merck's HCV patents, improperly attended a confidential 2004 licensing call between Merck and Pharmasset, the developer of Gilead's products. During the licensing call, Pharmasset disclosed the structure of their lead compound, as well as the fact that their own patent application would soon publish. Pharmasset asserted these disclosures were only made because it believed that the Merck participants were walled-off from Merck's HCV program, in compliance with the confidentiality agreement entered between the parties. At deposition, the prosecutor stated that Merck's own policy would have prohibited him from attending licensing discussions with third parties in an area where he

was prosecuting because it would have tainted his judgment as to what claims to pursue on behalf of Merck. Further, at deposition, the prosecutor testified *did* not receive Pharmasset's structure, but at trial testified he had forgotten that he *did* receive the structure. Gilead characterized the prosecutor's testimony, and justifications as lacking credibility.

At trial, the prosecutor claimed that prior to receiving Pharmasset's structure, Merck concluded that there was no overlap between the prosecutor's work and Pharmasset's disclosure. And, after receiving the structure, the prosecutor recused himself from the Pharmasset due diligence, but not Merck's prosecution related to HCV. Following the call and publication of Pharmasset's patent application, Merck's patent claims were revised to capture "subject matter most important to" Merck, but Merck apparently never tested the type of nucleoside recited in the revised claims (Pharmasset's 2' methyl up, 2' F down nucleosides).

Second, Gilead argued that Merck waived its right to sue, and should not be entitled to collect damages. Specifically, Gilead asserted while Merck was attempting to cover Pharmasset's proprietary compounds as part of its patent strategy, it was also engaged in numerous licensing and acquisition discussions with Pharmasset between 2003 and 2011. (ECF 368 at 8–9, 11–12). Gilead believed these negotiations were inconsistent with Merck's intent to enforce its patent rights, and during the negotiations Merck never raised the threat of patent infringement suit against Pharmasset.

Merck responded that Gilead's unclean hands theory should be precluded because the jury explicitly decided that the compounds in the asserted patents were derived by Merck, and not Pharmasset. (ECF 409). Further, with respect to the salient facts surrounding the licensing call, Merck did not dispute that its prosecutor attended the confidential call, but alleges that he voluntarily announced his conflict, and Pharmasset none-the-less disclosed the structure of their compound. Additionally, Merck insisted its patent applications as originally drafted were broad enough to cover Pharmasset's compounds, and it was Pharmasset that used Merck's application to facilitate development of their compounds. In any event, Merck maintained that it was not improper to amend patent claims to cover a competitor's product, and Merck did not do so until after Pharmasset's patent application was published. In sum, Merck contended the facts here were not the type of egregious misconduct, nor was there the requisite intent by Merck, sufficient to support a finding of unclean hands. Additionally, according to Merck, once the structure of Pharmasset's compound was disclosed, Merck disclosed that its patents presented freedom to operate issues for Pharmasset. Consequently, Merck did not waive its right to enforce its patents against Pharmasset or Gilead.

On April 22, Gilead moved the court to reopen the record to allow additional evidence that responded to the patent prosecutor's testimony or strike the testimony from the record. (ECF 410). On April 29, the court heard the motion, and instructed the parties on additional submissions. On June 6, the court issued its findings of fact and conclusions of law as to Gilead's equitable defenses. The court found that Gilead failed to prove that Merck impliedly waived its right to enforce the asserted patents, either by a preponderance of or clear and convincing evidence – the standard for which was unclear. (ECF 422 at 1, 34-38). The court found Gilead did not offer evidence showing "that it or Pharmasset reasonably believed that Merck had relinquished its patent rights." Instead, the court found the nature of the business negotiations conducted between 2008 and 2011, including negotiations for a license to Merck's patents, demonstrated Merck's intent to enforce its patent rights. Additionally, the court found Merck did not have an affirmative duty to take action to enforce its patents until Gilaead's product launched in 2013, and therefore, Merck's earlier alleged "failure to take action cannot be interpreted as implied waiver."

However, with respect to Gilead's unclean hands defense, the court found Gilead demonstrated by clear and convincing evidence "a pervasive pattern of [egregious] misconduct by Merck and its agents constituting unclean hands." (ECF 422 at 1, 38–65). Specifically, the court found Merck engaged in both unethical business conduct and litigation misconduct, including "lying to Pharmasset [about Merck's counsel being firewalled in order to obtain confidential information], misusing Pharmasset's confidential information [to benefit the prosecution of Merck's asserted patents], breaching confidential and firewall agreements, and lying under oath at deposition and trial." The court noted Merck's "acts are even more egregious because the main perpetuator of its

misconduct was its attorney." In balancing the equities between the parties, the court considered the "weight of wrongdoing by one party against the wrongdoing of the other." Although Gilead admittedly infringed the asserted patents, the court found "Merck's persistent misconduct involving repeated fabricated testimony and improper business conduct outweighs its right to maintain its suit against Gilead," barring Merck's recovery against Gilead for infringement.

HATCH-WAXMAN ACT

New Jersey Court Grants Motion to Dismiss by Patentee Drug Maker, Further Defining an Officially Received ANDA

Amarin Pharma, Inc. v. Apotex, Inc., et al. (D.N.J. January 22, 2016)

Robert H. Underwood, PhD and Hak J. Chang, PhD

Granting a motion to dismiss, US District Court for the District of New Jersey held that the statutory act of patent infringement no longer exists; therefore, there is no "case or controversy" necessary for the court to exercise subject-matter jurisdiction over, as a result of the US Food and Drug Administration's (FDA) action which vitiated the justiciable controversy. *Amarin Pharma, Inc. v. Apotex, Inc., et al.* (D.N.J., January 22, 2016) (Cooper, M.).

The plaintiff, Amarin Pharma, Inc., holds 16 patents related to a pharmaceutical product known as Vascepa® (icosapent ethyl), an adjunct to diet to reduce triglyceride levels in patients. Named defendant Apotex and five other defendants previously filed abbreviated new drug applications (ANDA) with the FDA under Paragraph IV. Amarin alleged in six separate actions that defendants were infringing the patents. Amarin also challenged the FDA's determination that Vascepa is entitled to only three-year market exclusivity, not five-year exclusivity. The US District Court for the District of Columbia agreed with Amarin and vacated and remanded the FDA's decision denying five-year exclusivity for Vascepa. Based on the court order, the agency suspended review of all ANDAs filed by the defendants and informed the defendants that if it determines Vascepa qualifies for five-year exclusivity, the exclusivity would bar submission of an ANDA that references Vascepa until at least July 26, 2016, and that it considers the ANDAs by the defendants to have been "submitted, but not yet received." Amarin filed a motion to dismiss under Rule 41(a)(2).

Acceptance of an ANDA by the FDA triggers the statutory act of patent infringement under 35 USC §271(e). It is this act of infringement that provides the case or controversy for the court to exercise subject-matter jurisdiction over Hatch-Waxman patent infringement cases. The court stated that the FDA's role in accepting an ANDA for review, so that it is received and not merely delivered, acts as a safeguard against premature litigation. In this case, the FDA effectively informed the defendants that it had suspended review and considered the ANDAs not yet received. Granting the motion to dismiss, the court concluded that the FDA had effectively revoked its acceptance for the ANDAs at issue due to a recent court order, which rendered the dispute no longer judiciable. The court stated that there was nothing for the court to adjudicate because the ANDA litigation process cannot proceed without the existence of a "received" ANDA by the FDA. Thus, the statutory act of patent infringement no longer existed and there was no case or controversy. The court also held that any pending counterclaims in the consolidated action would be also dismissed without prejudice.

This case affirms that an ANDA is not considered filed until the FDA acknowledges receipt. Accordingly, an ANDA applicant must notify the patent holder following confirmation from the FDA that the ANDA has been *accepted as received*. Further, even if an ANDA had been filed with the FDA, courts would not exercise subject-matter jurisdiction over an ANDA action if the FDA suspended review and revoked a previously accepted ANDA as a result of a court order, *e.g.*, a pending decision on the length of market exclusivity by the agency.

OBVIOUSNESS

Federal Circuit Rejects Argument that Claim Is Novel because Composition Exhibits 'Pharmaceutically Effective Absorption'

Warner Chilcott Co., LLC v. Teva Pharmaceuticals USA, Inc. (Fed. Cir. March 18, 2016)

Michael O'Shaughnessy

Where a claim was distinguished from the prior art only because it contained a limitation requiring "pharmaceutically effective absorption," the US Court of Appeals for the Federal Circuit affirmed an opinion from the US District Court for the District of New Jersey that such a claim was obvious, concluding that one of ordinary skill in the art would have been motivated to modify or combine the art to produce such a result. *Warner Chilcott Co., LLC v. Teva Pharmaceuticals USA, Inc.*, No. 2015-1588 (March 18, 2016 Fed. Cir.) (Lourie, J.).

Warner Chilcott owned two patents claiming oral dosage forms comprising risedronate and ethylenediaminetetraacetic acid (EDTA), and methods for treating disorders characterized by abnormal calcium and phosphate metabolism, such as osteoporosis. Warner Chilcott's commercial embodiment of the patented invention is known as Atelvia® (risedronate sodium). Teva filed an abbreviated new drug application (ANDA) seeking approval of a generic version of Atelvia. In response, Warner Chilcott filed suit alleging infringement. Teva conceded infringement but asserted that Warner Chilcott's patents were invalid.

During a bench trial, the parties agreed that a prior art Brazilian patent application disclosed all limitations of the Warner Chilcott patent claims except for a limitation requiring "pharmaceutically effective absorption." In evaluating whether the Brazilian patent application disclosed that limitation, the district court concluded that the application taught using an amount of EDTA sufficient to bind ions in food, but only in an amount low enough that it would not significantly alter absorption. Thus, the district court did not find that the Brazilian reference inherently anticipated the Warner Chilcott patents. Nevertheless, the district court concluded that the Warner Chilcott patents were obvious because the "food-effect problem" affecting absorption had been "well explored in the literature," and numerous references explicitly taught that EDTA would increase absorption.

On appeal, Warner Chilcott argued that the district court misinterpreted the phrase "pharmaceutically effective absorption," and erroneously equated the invention with overcoming food effects. As a result, Warner Chilcott disputed the district court's finding of a motivation to modify the prior art to achieve the claimed invention.

The Federal Circuit affirmed the finding of obviousness, concluding that the Brazilian patent application nearly anticipated the claimed invention. Indeed, the Federal Circuit agreed that the only limitation lacking in the prior art was "pharmaceutically effective absorption." Noting that common sense suggests that any pharmaceutical composition entitled to a patent would have to be pharmaceutically effective, the Federal Circuit recognized that Warner Chilcott was able to overcome a rejection at the patent office by including this limitation referring to the fed/fasted absorption defined in the specification. Thus, the Federal Circuit agreed with the district court that the limitation logically referred to fed/fasted absorption as defined in the specification. The court further agreed with the district court that the prior art references and teachings would have led one of ordinary skill in the art to use EDTA to sufficiently reduce or negate the food effect to obtain the claimed invention.

With respect to a claim directed to a specific amount of EDTA (100 mg), the court concluded that such a limitation to a specific amount was nevertheless obvious. The Federal Circuit reasoned that the specification included a broad disclosure, including embodiments with varying levels of EDTA, and nothing within the specification established that the specifically claimed amount resulted in "pharmaceutically effective absorption." Moreover, nothing within the specification suggested that the specific amount of EDTA was critical to the invention. As a result, the Federal Circuit affirmed the decision of the district court that the claims were invalid as obvious.

PLEADINGS/PERSONAL JURISDICTION/FAILURE TO STATE A CLAIM

District Court of New Jersey Boots Hospira's Personal Jurisdiction and Rule 12(b)(6) Motions

Helsinn Healthcare S.A. v. Hospira, Inc. (D.N.J. Apr. 5, 2016)

Kevin P. Shortsle

Relying on the US Court of Appeals for the Federal Circuit's recent decision in *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals, Inc.*, Nos. 15-1456, 15-1460, 2016 WL 1077048 (Fed. Cir. Mar. 18, 2016) and the plain language of 35 U.S.C. §271, the US District Court for the District of New Jersey denied Defendants' motions to dismiss for lack of personal jurisdiction and failure to state a claim. *Helsinn Healthcare S.A. v. Hospira, Inc.* Civ. Action No. 15-2077, 2016 WL 1338601 (D.N.J. Apr. 5, 2016) (Cooper, D.J.).

Personal Jurisdiction

Plaintiffs Helsinn Healthcare, Eisai, Inc. and Roche sued Hospira and its subsidiary Hospira Worldwide (Worldwide) alleging infringement of several Orange-book listed patents for Aloxi® (palonosetron HCI injection), which is used to prevent and treat chemotherapy-induced nausea and vomiting. Worldwide markets, sells and distributes Hospira's products in the United States and would be the entity marketing, selling and distributing generic Aloxi upon approval from the US Food and Drug Administration (FDA).

Defendants moved to dismiss for lack of personal jurisdiction arguing the following:

1. The court did not have general jurisdiction because
    a. Neither Hospira nor Worldwide were incorporated or had their principal places of business in New Jersey; and
    b. The case did not fall within an exception set forth in the Supreme Court of the United States' *Daimler* decision.
2. Worldwide did not consent to jurisdiction simply because it is registered to do business in New Jersey. The court did not have specific jurisdiction because
    a. Sending its notice letter to Helsinn in New Jersey was not a purposeful direction of activities to a New Jersey resident;
    b. The sale and distribution of Hospira products in New Jersey cannot confer jurisdiction since no sales of generic Aloxi by Defendants had yet to occur; and
    c. Conferring jurisdiction based on the possibility of sale or distribution would confer a "virtually unbounded" opportunity for forum-shopping.

Not reaching the issue of general jurisdiction because consent by registering to do business is the subject of a circuit split and open question at the Federal Circuit, the court found it had specific jurisdiction over Defendants. Analogizing the facts at issue to the Federal Circuit's *Acorda* decision, the court found Hospira and Worldwide had minimum contacts with New Jersey because Hospira's marketing of generic Aloxi "will, at least in some part, take place in New Jersey," and because Worldwide is registered to do business in New Jersey and will market, sell and distribute its generic Aloxi in New Jersey.

Turning to the fairness factors, the court found no unfairness since Hospira had previously litigated Hatch-Waxman cases in New Jersey, including initiating at least two actions and the court had, and is currently adjudicating, many similar cases related to generic Aloxi. The court also applied the *Acorda* holding that abbreviated new drug application (ANDA) filings establish a substantial connection to the forum state because they predict the ANDA filer's future activities within the forum state (*e.g.*, marketing, selling and distributing).

FAILURE TO STATE A CLAIM

Defendants next argued that Worldwide should be dismissed from the action because Worldwide did not submit the ANDA to the FDA so they cannot be liable for induced infringement under 35 USC §271 and Plaintiffs inducement claims in their complaint did not pass muster under *Twombly and Iqbal*. Rejecting these arguments, the court first held that 35 USC §271(e)(2) does not require a party, such as Worldwide, to

sign the ANDA in order for it to be a properly named defendant. Second, the court found that an inducement claim under §271(e)(2) requires allegations of future acts committed after the ANDA is approved. Because Plaintiffs alleged facts sufficient to show that Worldwide would benefit as the sole marketer, seller and distributor in the United States of Hospira's generic Aloxi product and that these acts would constitute infringement, the court denied Defendants' motion to dismiss Worldwide.

HATCH-WAXMAN EXCLUSIVITY

Fixed-Combination Drug Products Eligible for Five-Year Exclusivity

Ferring Pharmaceuticals, Inc. v. Sylvia M Burwell, et al., (D.D.C. March 15, 2016)

Avani C. Macaluso

Addressing whether the US Food and Drug Administration's (FDA) denial of Ferring Pharmaceutical's application for marketing exclusivity was arbitrary and capricious, the US District Court for the District of Columbia determined the FDA reasonably interpreted the term "drug" to mean "drug product," rendering Ferring's fixed-dose combination drug product ineligible for the statutory five-year exclusivity period, despite containing an active ingredient that had not been previously approved. The FDA announced it would change its interpretation of the statutory requirements for fixed-combination drug products containing a novel drug substance. However, the court declined to address the retroactivity effect of this interpretation on Ferring's application. *Ferring Pharmaceuticals, Inc. v. Sylvia M Burwell, et al.*, 2016 WL 1060199 (D.D.C. March 15, 2016)(J. Contreras).

At issue is Ferring's new drug application (NDA) for fixed-dose combination drug Prepopik® (sodium picosulfate, magnesium oxide, and anhydrous citric acid). Prepopik is intended for use in colon cleansing prior to undergoing a colonoscopy for adults. Two of the active ingredients—magnesium oxide and anhydrious citric acid—were previously approved in a NDA. However, sodium picosulfate—a stimulant laxative—was a new drug substance that had never been previously approved in any NDA. Picosulfate's benefit is only realized in combination with the other active substances, which is why Ferring never sought approval for it as a single ingredient drug product.

Ferring sought five-year exclusivity to market based on the fact that picosulfate had never been previously approved in an NDA. The FDA approved Ferring's NDA in July of 2012, but denied its request for five-year exclusivity, and awarded only three-year exclusivity since Ferring's drug product contained two active substances that had been previously approved. Pursuant the Hatch-Waxman Amendments, five-year exclusivity is granted when a drug application "for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application." Prior to 2014, the FDA interpreted this provision to provide "that only ***drug products*** containing no previously approved drug substances were eligible for exclusivity." If a drug met that requirement, then no application may be submitted "referencing that drug product or any later-approved products containing the product's ***drug substances***." This was an attempt by the FDA to preserve the innovator's exclusivity to the greatest extent possible. The two clauses of this exclusivity provision contain "eligibility" and "bar" clauses, which are relevant to the court's ultimate decision.

Since 2014, the FDA recognized the recent changes in drug development, particularly with respect to fixed-combination drug products containing new active moieties. Therefore, in order to encourage innovation of fixed-combination therapies, the FDA changed its interpretation of the five-year exclusivity provision to account for fixed combinations containing a novel drug substance, regardless of whether the fixed combinations also include drug substances with previously approved active moieties.

Ferring filed the present action challenging the FDA's denial of five-year exclusivity as "arbitrary" and "capricious." Ferring first argued the FDA's prior interpretation of the statute, under which Prepopik was denied five-year exclusivity, contravened the plain language of the Federal Food, Drug, and Cosmetic Act (FD&CA). Second, Ferring argued even if the language of the FD&CA is ambiguous, the FDA's interpretive choice to read "drug" in the eligibility clause to mean "drug product" was an unreasonable reading of the statute or was arbitrary and capricious because it treated similarly situated parties differently. Finally, Ferring claims even if the FDA's prior

interpretation was permissible, its decision not to apply the new interpretation retroactively was arbitrary and capricious.

The district court applied the *Chevron* analysis in determining whether the FDA reasonably interpreted the term "drug" in the context of the five-year exclusivity provision. The court held it did. Since the statute does not specifically define "drug" in the "eligibility" clause, it was reasonable for the FDA to interpret "drug" to encompass "drug product" because the eligibility clause refers to "an application submitted under subsection (b) of [§355] for a drug…." Since applications are typically submitted for drug products, not drug substances, interpreting "drug" to refer to "drug product" is a logical conclusion based on this language. The court further explained the interpretation was reasonable distinguishing between the article for which an application is submitted—a finished drug product, and what the agency approves—active ingredients or drug substances contained within a finished drug product. Finally, the court noted the FDA's appears to define "drug substance" as the equivalent of a single active ingredient. Thus, it is not unreasonable to view "drug product' as including one or more active ingredients.

Once eligible, the FDA interpreted the bar clause to bar all abbreviated new drug applications (ANDAs) and 505(b)(2) applications referencing that drug product or any later-approved products containing the product's ***drug substances***, in order to preserve the innovator's exclusivity to the greatest extent possible. The court found this to be a reasonable interpretation since it was consistent with the intent of the statue to incentivize innovation and improve upon approved drug products. The FDA's pre-2014 interpretation of "drug," in both the eligibility and bar clauses, was not arbitrary or capricious. Although policy considerations have now persuaded the FDA to modify its interpretation of the statute, based on the statutory ambiguity, the FDA's definition was neither unreasonable nor arbitrary and capricious.

The court was not persuaded by Ferring's argument that even if the FDA's prior reading of the statute was reasonable, it arbitrarily treated similarly fixed-dose combination drug products differently. Ferring argued

> [I]f a single-entity drug product containing a new active ingredient is approved before a fixed-dose combination drug product containing the same active ingredient, both products – the single-entity and the combination – receive the benefit of the five-year NCE exclusivity, but if the order of the approvals had been reversed and the fixed-dose combination drug had been approved just hours before the single-ingredient product, *none* of the products would have been awarded NCE exclusivity.

The court pointed out that the administrative record indicates that single-entity drug products have been submitted long before (six to 18 months) combination products. Moreover, the facts of the present case are unique because Ferring's novel active ingredient, sodium picosulfate, is not appropriate for a single-entity form.

Finally, the court declined to decide whether the FDA acted arbitrarily and capriciously by not applying the FDA's post-2014 reinterpretation retroactively, thereby denying new chemical exclusivity (NCE) for Prepopik. Since neither party submitted ample briefing on the retroactive application of a new interpretation by an agency, the court directed the parties to file renewed motions for summary judgment to more fully address the retroactivity issues.

SETTLEMENTS/ANTITRUST IMPLICATIONS

A Directly Impacted Party Can Assign Its Right to Sue

In re Opana ER Antitrust Litigation (N.D. Ill. February 25, 2016)

Melissa Nott Davis

Addressing standing for purposes of antitrust litigation related to reverse payment allegations and assignment of rights, the US District Court for the Northern District of Illinois explained standing in connection with reverse payment abbreviated new drug application (ANDA) litigation and granted Defendants' motion to dismiss the complaint. However, it allowed Plaintiffs 21 days to file an amended complaint. *In re Opana ER Antitrust Litigation*, Case No. 14-C-10150 (N.D. Ill., Feb. 25. 2016) (Leinenweber, J.).

Endo Pharmaceuticals began selling Opana ER® (oxymorphone HCl), an extended release form of oxymorphone hydrochloride marked for the relief of

moderate to severe pain, on June 21, 2006. At the time, Endo had three years of regulatory protection from generic competition. Knowing this, Endo bought the rights to four additional patents that could be used to block generic competition beyond 2009. In November 2007, Impax filed an ANDA seeking to market a generic version of Opana ER. Endo sued Impax, triggering the 30-month stay. Other generic companies also filed ANDAs and Endo sued each for patent infringement. One month before the 30-month stay was to expire, the US Food and Drug Administration (FDA) tentatively approved Impax's ANDA for Opana ER. After two days of trial, and six days before the 30-month stay expired, Endo and Impax settled. The settlement consisted of two agreements: (1) the Settlement and License Agreement; and (2) the Development and Co-Promotion Agreement. Under the Settlement Agreement, Impax agreed to delay its launch of a generic Opana ER until various conditions were met; Endo also agreed not to launch an authorized generic during Impax's 180-day exclusivity period. The Settlement was structured such that Impax would receive compensation based on the volume of Opana ER sales at the time Impax's generic entered the market. By the time Impax entered the market in 2013, sales of Opana ER had declined and, pursuant to the Settlement Agreement, Endo paid Impax $102,049,000.

Walgreen Co. and Rite Aid Corporation, as assignees of various pharmaceutical wholesalers (the Wholesalers), brought claims in a multi-district litigation against Endo and Impax alleging violations of the Sherman Act based on the illegal reverse payment agreement. Each of the Wholesalers had purchased Opana ER from Endo pursuant to Distribution Sales Agreements (DSA). Each DSA included a provision that prohibited the Wholesalers from assigning the agreement without Endo's consent. Endo did not consent to the assignments.

Endo sought to dismiss Walgreen and Rite Aid's claims, arguing (1) the settlement was not a reverse payment; (2) the alleged reverse payment was not large and unjustified; (3) Walgreen and Rite Aid failed to allege antitrust injury; (4) Walgreen and Rite Aid lack standing to assert the claims; and (5) Walgreen and Rite Aid's claims could only be pursued as part of a direct purchaser class and therefore should be dismissed or stayed until class certification is decided.

The court found Defendants' argument that the Settlement Agreement was not a reverse payment unavailing. The court noted that "[w]hen the Court views the components of the Endo-Impax Settlement as a whole, it finds plausible and persuasive [Walgreen and Rite Aid's] allegation" that the agreements "worked in conjunction with one another to ensure payment to Impax." However, the court held that Walgreen and Rite Aid had failed to provide "some reliable foundation to show an estimated value of the reverse payment" and accordingly the court could not determine "whether the payment was large or unjustified in comparison to the avoided litigation costs and any other services provided from Impax to Endo." Based on this failure, the court granted Endo's motion to dismiss, but gave Walgreen and Rite Aid leave to amend their complaint within 21 days.

The court also held that "there was no dispute" that Walgreen and Rite Aid alleged that they had been injured as a result of an illegal agreement between Endo and Impax, giving them Article III standing. The court went on to address the "more difficult" question of whether plaintiffs had antitrust standing, noting that the question turned on whether the assignments from the Wholesalers were valid. The court held that the DSA provision prohibiting assignment was "presumed as a matter of law to refer only to the delegation of contractual duties, not assignment of rights." Accordingly, while the Wholesalers could not delegate performance under the DSA, they could assign a cause of action arising from the DSA. Accordingly, the court found the standing argument "lacks merit."

Addressing whether the court should stay Walgreen and Rite Aid's claims until after class certification, the court found that while the Wholesalers fit the description of membership in the direct purchaser class seeking certification, it was uncertain whether the class would ultimately be certified and if certified whether the Wholesalers would nonetheless opt out of the class. Accordingly, the court found the request to dismiss or stay the partially assigned claims premature because "it remains unclear whether the Wholesalers have reserved for themselves any portion of their right to sue Defendants, and if so, how they will choose to pursue that right."

ANTITRUST; REVERSE PAYMENT SETTLEMENTS; ATTORNEY-CLIENT PRIVILEGE

Use of Privilege Designations during Reverse Payment Settlement Litigation

King Drug Co. of Florence, Inc. v. Cephalon, Inc. (E.D. Pa. Jan. 22, 2016)

Lisa A. Peterson

The US District Court for the Eastern District of Pennsylvania limited antitrust plaintiffs' ability to use argument or evidence based upon invocation of privilege during reverse payment litigation. *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, No. 2:06-cv-1797, 2016 U.S. Dist. LEXIS 7477 (E.D. Pa. Jan. 22, 2016) (Goldberg, J.).

Antitrust Plaintiffs brought Sherman Act claims against a brand-name pharmaceutical company (Cephalon) and four generic pharmaceutical companies (Barr, Mylan, Teva, and Ranbaxy) claiming that payments by Cephalon to the generic companies pursuant to settlement agreements (reverse payment settlements) kept generic drugs off the market in violation of antitrust laws. The defendants countered that the settlement agreements are procompetitive business transactions. The settlements were reached in patent-litigation pursuant to Paragraph IV of the Hatch-Waxman Act. The defendants sought to protect legal advice and strategy surrounding the reverse payment settlements as privileged under the attorney-client communication or work-product doctrine designations. Accordingly, they filed a motion *in limine* to preclude argument or evidence based upon their invocation of the privilege.

The plaintiffs opposed the motion on the grounds that: (1) exploration of the business reasons behind the settlements necessarily implicate legal considerations and (2) statements made during opening arguments or during witness testimony could imply legal advice. On the first point, the plaintiffs argued that fairness dictated allowing discussion of both business and legal motivations for the reverse payment settlements. The court found this argument unpersuasive due to the lack of legal precedent. On the second point, the plaintiffs argued that statements that the brand company had a "strong patent" or that the negotiations between the brand and generic companies were in "good faith" necessarily imply consultation with counsel. The court found this argument to be premature, as a waiver of attorney-client privilege must be viewed in light of the factual circumstances in which the testimony is offered; no witnesses had been sworn and no opening statements had been made in the case. The court ordered that the plaintiffs may not call the jury's attention to the defendants' invocation of privilege nor ask questions of defense witnesses where it would be reasonable to assume the answer would call for the invocation of attorney-client privilege. Such use of arguments and evidence by the plaintiffs would allow the jury to unfairly draw an adverse inference on the defendants' privilege designations. Notably, the court advised the parties that the defendants represented that they would not state or imply that the decisions to settle the Paragraph IV litigation were due to legal advice. The court cautioned the defendants that it would not permit a last-minute decision to reverse this position.

PRACTICE NOTE

Counsel for pharmaceutical companies involved in reverse payment settlements should be mindful that courts will respect invocations of attorney-client privilege and work product doctrine regarding reverse payment settlement legal considerations, as long as counsel does not reverse designations of key arguments or evidence as privileged at the last minute.

ANTITRUST

First Circuit Extends *Actavis* to Non-Cash Payments

In re Loestrin 24 Fe Antitrust Litigation (1st Cir. February 22, 2016)

Alex M. Grabowski

In a decision joining a wave of other courts, the US Court of Appeals for the First Circuit extended the Supreme Court of the United States' *Actavis* decision to non-cash reverse payments. The court overturned a district court decision dismissing antitrust claims by direct and indirect purchasers, and held that a pair of settlements related to the contraceptive Loestrin® 24 Fe (ethinyl estradiol, norethindrone and ferrous fumarate) could violate antitrust laws, despite the fact that neither settlement involved cash payments. *In re Loestrin 24 Fe Antitrust Litigation*, 814 F.3d 538, (1st Cir. 2016) (Torruella J.).

The Underlying ANDA Litigations

The plaintiffs in *In re Loestrin* challenged settlements in two separate Hatch-Waxman litigations over Loestrin 24 Fe, a contraceptive brand sold by Warner Chilcott (now Actavis). Chilcott sued Watson Pharmaceuticals and Lupin Pharmaceuticals in response to the companies' filing abbreviated new drug applications (ANDAs) on Loestrin 24 Fe. Both cases settled before either defendant brought a generic Loestrin 24 Fe version to market. Importantly, neither settlement involved a direct cash payment from the brand to the generics, other than for attorneys' fees. The settlements arranged for other forms of compensation, such as delaying the introduction of an authorized generic, licenses to sell other Warner Chilcott drugs or payments to the defendants for co-promotion of other drugs.

Loestrin Purchasers File Antitrust Claims

Direct and indirect purchasers challenged the settlements under *Actavis* and the defendants moved to dismiss. The US District Court for the District of Rhode Island dismissed the claims. The district court decided that the Supreme Court had been focused entirely on cash payments when deciding *Actavis* and that the difficulty of valuing non-cash payments counseled against extending the decision. The plaintiffs appealed.

Non-Cash Payments Are Subject to Rule of Reason Antitrust Analysis

On appeal, the First Circuit overturned the district court, adopting a more expansive reading of *Actavis*. Rather than attempting to analyze the five antitrust considerations that the Supreme Court enumerated in *Actavis*, the First Circuit focused on *Actavis'* specific facts, as well as the decision's language.

First, the First Circuit noted that *Actavis* itself involved more than just a cash payment. The settlement in that case also included a promotional agreement whereby the generic companies would promote the brand drug in exchange for multi-million dollar payments. The First Circuit took this as evidence that "the Supreme Court recognized that a disguised above-market deal. . . may qualify as a reverse payment subject to antitrust scrutiny. . . ."

With regard to *Actavis'* language, the First Circuit noted that the district court erred when it described the decision as "fixated" on cash. Instead, the First Circuit decided that the key term in the decision was not "cash" or "money," but instead was "payment." The court held that payments could include something other than money and could be "any valuable thing" according to *Black's Law Dictionary*. These references to payment, combined with the court's view that antitrust law elevates substance over form, meant that even non-cash payments could be anticompetitive under the rule of reason.

Pleading an *Actavis* Claim

The court declined to rule on the defendants' other ground for their motion to dismiss, that the plaintiffs had failed to adequately plead that the reverse payments in the settlement were large and unjustified. However, the court did provide guidance *in dicta* that precise figures and calculations were not necessary to survive a Rule 12(b)(6) motion, but that plaintiffs would need to allege "facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*."

INFRINGEMENT

Summary Judgment of Non-Infringement Granted on Composition and Method of Use Claims

Braintree Labs Inc. v. Breckenridge Pharmaceutical, Inc. (S.D.N.Y. March 15, 2016)

Lauren Martin

Addressing the issue of whether composition and method of use claims covered a half dose, or were instead limited to the full dose, the US District Court for the Southern District of New York concluded that the claims were limited to the full dose and granted defendant Breckenridge's motion for summary judgment of non-infringement. *Braintree Labs Inc. v. Breckenridge Pharmaceutical, Inc.*, Case Nos. 12-cv-6851 (S.D.N.Y. March 15, 2016) (Nathan, J.).

Breckenridge filed an abbreviated new drug application (ANDA) seeking approval from the US Food and Drug Administration (FDA) for a generic version of its drug Suprep® (sodium sulfate, potassium sulfate and

magnesium sulfate), which is a laxative indicated for "cleansing of the colon in preparation for colonoscopy in adults." Braintree filed suit contending that Breckenridge's ANDA product would infringe its '149 patent, which covers compositions for inducing "purgation" of the colon and methods of using the claimed compositions. Crucially, the claims at issue all require a composition "comprising *from about 100 mL to about 500 mL*" of solution.

Suprep is sold as a kit that includes two six-ounce bottles of solution, each of which must be diluted with water to 16 ounces (473 mL) prior to consumption. According to the label, the full dose of Suprep taken to achieve cleansing prior to a colonoscopy is 946 mL and is ingested in two half doses of 473 mL over a 10- to 12-hour period. Breckenridge's ANDA provides that its product will be packaged in the same manner, with the same instructions as to dilution and ingestion.

In Breckenridge's motion for summary judgment of non-infringement, it argued that its product (the full 946 mL of solution) would not meet the "about 100 to about 500 mL" volume limitation of the composition claims. In its opposition, Braintree contended that each bottle in the kit constituted an infringing composition. Essentially, the parties' dispute centered on whether the claimed "about 100 mL to about 500 mL" solution was limited to a full dose, or whether it could encompass a half dose.

Turning first to the specification, the court concluded that the disclosure "clearly demonstrates that the 'from about 100 mL to about 500 mL' limitation refers to the entire volume of solution administered to a patient over a treatment period rather than the volume of a single bottle, or half-dose." In the examples cited by the court, the total volume of solution was less than 500 mL and was administered in two separate half-doses. Turning next to the prosecution history, the court noted that during re-examination, Braintree compared the full dose of the prior art compositions with its 100 to 500 mL range. In view of the intrinsic evidence, the court concluded that the volume limitation "refers to the total amount of solution administered to a patient over the treatment period rather than a single bottle, or half-dose" and thus concluded that Breckenridge's ANDA product would not infringe the composition claims.

With respect to the method claims, Breckenridge argued that the sole FDA approved indication, cleansing of the colon in preparation for colonoscopy in adults, was not covered by the '149 patent. According to Breckenridge, the claimed method of "inducing purgation" was not the same as the full cleansing contemplated by the approved indication. This argument was based on the construction of "purgation" that Braintree had successfully advanced in another case over the same patent. In the other case, Braintree had argued, and the US Court of Appeals for the Federal Circuit had agreed, that the "purgation" term meant "something less than a full cleansing." Applying the construction approved by the Federal Circuit, the court found that "it is possible to induce purgation…without achieving the goal of full cleansing sufficient for a colonoscopy." Accordingly, the claimed method of "inducing purgation" refers to "some point on the colon cleansing spectrum short of 'a full cleansing.'" Thus, the court concluded that "[i]nducing purgation without 'achieving a fully cleansed colon for a colonoscopy'…is not an FDA-approved use", so Breckenridge's ANDA product would not induce infringement the asserted method claims.

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