Appeal Nos. 2014-1736, -1737, -1738, -1739, -1740, -1741

United States Court of Appeals

for the

Federal Circuit

SHIRE LLC, SHIRE DEVELOPMENT INC., SHIRE DEVELOPMENT, LLC.,

Plaintiffs-Appellees,

– v. –

AMNEAL PHARMACEUTICALS, LLC, ROXANE LABORATORIES INC., SANDOZ INC., MYLAN INC., MYLAN PHARMACEUTICALS INC., JOHNSON MATTHEY INC., JOHNSON MATTHEY PHARMACEUTICAL MATERIALS, ACTAVIS ELIZABETH LLC, ACTAVIS LLC,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
IN CASE NOS. 11-3781, 11-4053, 11-3787, 11-3886, AND 12-3234,
JUDGE STANLEY R. CHESLER.

NON-CONFIDENTIAL COMBINED PETITION OF PLAINTIFFS-APPELLEES FOR PANEL REHEARING AND REHEARING *EN BANC*

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October 26, 2015

CERTIFICATE OF INTEREST

Counsel for Appellees Shire LLC and Shire Development LLC (f/k/a Shire Development Inc.) certify the following:

1. The full name of every party represented by me is:

   Shire LLC and Shire Development LLC (f/k/a Shire Development Inc.)

2. The names of the real parties in interest represented by me are:

   Shire LLC and Shire Development LLC

3. All parent corporations and any publicly held companies that own 10 percent or more stock of the party or amicus curiae represented by me are:

   Shire LLC and Shire Development LLC are wholly-owned subsidiaries of Shire plc

4. The names of all law firms and the partners and associates that have appeared for the party represented by me in the trial court or are expected to appear in this court are:

   FROMMER LAWRENCE & HAUG LLP: Edgar H. Haug, Porter F. Fleming, Sandra Kuzmich, Angus Chen, Jason A. Lief, David A. Zwally, Joseph Saphia, Nicholas F. Giove, Andrew S. Roper, Richard F. Kurz, Stephanie M. Roberts, Leann M. Clymer, Michael W. Harkness, and Eric A. Lindberg (former).

   GIBBONS P.C.: Michael R. Griffinger, Robert C. Brady, Charles H. Chevalier, Lisa H. Wang (former), and Ralph A. Dengler (former).

Respectfully submitted,

Dated: October 26, 2015

/s/ Edgar H. Haug
Edgar H. Haug
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Counsel for Appellees
Shire LLC and
Shire Development LLC
(f/k/a Shire Development Inc.)

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CONFIDENTIAL MATERIAL OMITTED

Pages 2, 4, 11-12 of the Non-Confidential version of this Petition include redactions to omit material that has been designated by Defendants as confidential, and according to Defendants these pages contain confidential business information.

The redacted information was designated as Confidential or Highly Confidential under the Discovery Confidentiality Order dated March 5, 2012.

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

TABLE OF ABBREVIATIONS

"'630 patent"	U.S. Patent No. 7,655,630 (A227-A332)
"'787 patent"	U.S. Patent No. 7,662,787 (A583-A673)
"'253 patent"	U.S. Patent No. 7,659,253 (A333-A476)
"A____"	Page number(s) of the Confidential Joint Appendix, ECF No. 104
"ANDA"	Abbreviated New Drug Application
"ANDA-Defendants"	Collectively the Actavis Elizabeth LLC, Actavis LLC, Amneal Pharmaceuticals, LLC, Mylan Inc., Mylan Pharmaceuticals Inc., Roxane Laboratories Inc., and Sandoz Inc. parties
"API"	Active Pharmaceutical Ingredient
"compound claims"	Claims 1-4 of the '630 patent, claim 3 of the '787 patent, and claims 1-12 of the '253 patent
"DMF"	Drug Master File, 21 C.F.R. § 314.420(a)
"FDA"	United States Food and Drug Administration
"FDCA"	Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, ch. 675, 52 Stat. 1040 (1936) (codified at scattered sections of title 21 of the United States Code)
"JM"	Collectively the Johnson Matthey Inc. and Johnson Matthey Pharmaceutical Materials parties
"JMBr.___"	Page number(s) of the Confidential Opening Brief of Appellants Johnson Matthey Inc. and Johnson Matthey Pharmaceutical Materials, ECF No. 64

"ShireBr.___"	Page number(s) of the Corrected Brief on Behalf of Plaintiffs-Appellees, ECF No. 90
"Slip Op.___"	Page number(s) of the Slip Opinion, ECF No. 119-2, attached as an addendum

FEDERAL CIRCUIT RULE 35(b) STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to the following precedents of this Court: *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007); *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004); *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322 (Fed. Cir. 2003); and *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003).

Based on my professional judgment, I believe this appeal requires answers to the following precedent-setting questions of exceptional importance:

1) Whether a non-ANDA filer (e.g., parent company, related affiliate, distributor, contract manufacturer, or API supplier) can be liable for future infringement under 35 U.S.C. § 271(e)(2) when its proposed activity infringes under a traditional patent infringement analysis (i.e., under §§ 271(a), (b), or (c))?

2) Whether infringement under 35 U.S.C. § 271(e)(2) includes future induced infringement of compound and composition patents; or whether compound and composition patents should be treated differently than method of use patents in an induced infringement analysis?

Dated: October 26, 2015 By: /s/ Edgar H. Haug
Edgar H. Haug
Counsel for Appellees Shire LLC and Shire Development LLC (f/k/a Shire Development Inc.)

PRELIMINARY STATEMENT

Plaintiff-Appellee Shire respectfully requests panel rehearing and/or rehearing *en banc* of the portion of the September 24, 2015 panel decision (the "Decision") that reversed the district court's induced infringement judgment against API-supplier Johnson Matthey ("JM"). (ECF No. 119.) The reversal was contrary to principles of *stare decisis*. In this Hatch-Waxman litigation, it is undisputed that the active pharmaceutical ingredient ("API") used by all five ANDA-Defendants infringes Shire's compound patents, that the infringing API was supplied by JM, and that JM collaborated with the ANDA-Defendants to support their ANDAs [redacted] The district court correctly found that JM induced the ANDA-Defendants' ***future*** infringement of the compound patents under § 271(e)(2), which is consistent with this Court's precedent. But the Decision held that the district court erred because JM "did not submit an ANDA, [so] it cannot be liable for infringement under § 271(e)(2)" and because the § 271(e)(1) safe harbor made JM "not currently liable for infringement." (Slip Op.16.) The Decision is contrary to *Forest*, which came to the opposite conclusion on similar facts, as well as contrary to *Glaxo*, *Allergan*, and *Warner-Lambert*. Shire respectfully requests that this petition be granted to resolve the conflict that the Decision created in this Court's precedent.

The Decision is irreconcilable with *Forest*. In *Forest*, the Court determined that "***[s]ection 271(e)(2) may support an action for induced infringement***," and found that an API supplier induced the future acts of an ANDA filer "that ***will*** constitute direct infringement [of a compound patent] ***upon approval*** of the ANDA." 501 F.3d at 1266, 1272 (emphasis added). Thus, the Decision that JM cannot infringe under § 271(e)(2) is directly contrary to *Forest.*

The Decision's reversal of the induced infringement judgment against JM also conflicts with this Court's long-standing jurisprudence, which provides that § 271(e)(2) provides a vehicle for finding ***future*** infringement based on a traditional infringement analysis (which includes induced infringement) of the product to be sold if an ANDA is approved. *Glaxo*, 376 F.3d at 1351; *Allergan*, 324 F.3d at 1335; *Warner-Lambert*, 316 F.3d at 1366; *see also Forest*, 501 F.3d at 1272 (citing *Allergan*). As this Court explained:

> Section 271(e)(2) is not a jurisdictional statute in the strict sense of the word. . . . In short, section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed. . . . ***[T]he language of section 271(e)(2) does not limit the reach of the statute to direct infringement actions to the exclusion of actions for induced infringement***. . . . [A] court must employ a traditional infringement analysis, focusing on all of the elements of infringement. The only difference in the analysis of a traditional infringement claim and a claim of infringement under section 271(e)(2) is the timeframe under which the elements of infringement are considered. *Glaxo* does ***not*** preclude patentees from asserting claims for induced infringement under 35 U.S.C. § 271(e)(2). . . . ***Therefore, section 271(e)(2) may support an action for induced infringement***.

Allergan, 324 F.3d at 1330-31 (emphasis added, citations to *Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) omitted). It is undisputed that the product to be sold, if the ANDAs are approved, will use infringing API supplied by JM. Thus, applying the requisite traditional infringement analysis leads to the conclusion that JM is properly subject to a finding of future induced infringement.

The Decision's application of the safe harbor defense to reverse the district court's induced infringement judgment against JM is also wrong. (Slip Op.15.) The safe harbor is irrelevant to a finding of JM's ***future*** infringement under § 271(e)(2) and the remedies provided by § 271(e)(4)—for the same reasons that the safe harbor is irrelevant to an ANDA-filer's future infringement. *Forest* rejected the dissent's argument that the safe harbor immunized an API supplier. 501 F.3d at 1272. Furthermore, the Decision incorrectly found that JM "has thus far done nothing more than provide material for use by the ANDA defendants in obtaining FDA approval" and that such "activities are protected by the safe harbor." (Slip Op.15.) The Decision did not address JM's commercial [redacted] Such commercial activity is ***not*** protected by the safe harbor. The Decision was wrong to find that the safe harbor protected JM from induced infringement under these circumstances.

Finally, if allowed to stand the Decision will result in differential treatment of method patents (the types of patents at issue in *Allergan* and *Warner-Lambert*)

and compound patents (such as those at issue here) under § 271(e)(2). There is no principled reason for such disparate results. The Decision's new precedent that compound/composition patents are evaluated differently from method patents under § 271(e)(2) should be vacated as inconsistent with this Court's § 271(e)(2) jurisprudence in *Glaxo*, *Allergan*, *Warner-Lambert*, and *Forest*.

The Decision should be vacated as to JM's non-infringement, and the district court's induced infringement judgment against JM should be affirmed.

ARGUMENT

I. The Decision Is Contrary to This Court's Controlling *Forest* Precedent

This Court has previously held that the Hatch-Waxman Act provides for a finding of future induced infringement when, as here, there is a cooperative venture between an API supplier and an ANDA-filer. In *Forest*, the Court found that an API supplier induced infringement of a compound patent under § 271(e)(2) because "[u]nder the standards for inducement which we apply to 35 U.S.C. § 271(b), [the API supplier] has . . . actively induced the acts of [the ANDA-filer] that will constitute direct infringement upon approval of the ANDA," and thus the API supplier was enjoined under § 271(e)(4). 501 F.3d at 1272.

In contrast to this precedent, the Decision incorrectly dismissed *Forest* as "inapposite," noting that *Forest* "involved the scope of an injunction under § 271(e)(4)." (Slip Op.16.) But the injunction was predicated on the principle that

"[s]ection 271(e)(2) may support an action for induced infringement," *Forest*, 501 F.3d at 1272, and the Decision does address the underlying issue that § 271(e)(4)'s injunctive relief is available against "an infringer" based on an ANDA filed under § 271(e)(2)—including an infringer that actively induced infringement under§ 271(b).

Under § 271(e)(4), the relief following a finding of infringement is ***not*** limited to an ANDA-filer. Section 271(e)(4) provides the following:

> (4) ***For an act of infringement described in paragraph (2)*** . . . (B) injunctive relief may be granted against ***an infringer*** to prevent the commercial manufacture, use, offer to sell, or sale . . . of an approved drug.

§ 271(e)(4) (emphasis added). Furthermore, § 271(b) broadly states that "***[w]hoever*** actively induces infringement . . . shall be liable as an infringer." § 271(b) (emphasis added). Thus, *Forest* correctly applied a finding of induced infringement against an API supplier, and structured a remedy against that API supplier under § 271(e)(4).[1] 501 F.3d at 1272. The same result should apply in this case.[2] The Decision did not distinguish any of JM's activities from *Forest*'s binding precedent. *Forest* is on-point and fully supports the district court's induced infringement judgment against JM.

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[1] In *Forest*, the parties stipulated that the compound directly infringed. 501 F.3d at 1266. Here, the district court found that the ANDA-Defendants directly infringed the compound claims, and that ruling was not appealed. (A20.) *Forest*'s stipulation is consistent with the facts here.

[2] Issues relating to a "safe harbor" are more fully addressed in Section III.B, *infra*.

Accordingly, principles of *stare decisis* compel affirming the district court's judgment that JM induced infringement. "Panels of this court are bound by previous precedential decisions until overturned by the Supreme Court or by this court *en banc*." *Barclay v. United States*, 443 F.3d 1368, 1373 (Fed. Cir. 2006). *Stare decisis* strongly applies to statutory interpretation, as is the case with *Forest*, because "[t]he presumption that a court will adhere to its prior rulings has 'special force' for precedents that resolve non-constitutional issues, for 'Congress remains free to alter what [the courts] have done.'" *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272, 1282 (Fed. Cir. 2014) (en banc); *see Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398, 2411 (2014).

Based on *Forest* and principles of *stare decisis*, the Decision should be vacated as to JM's non-infringement, and the district court's induced infringement judgment against JM should be affirmed.

II. The Decision Conflicts with This Court's Long-Standing Precedent, which Broadly Applies § 271(e)(2) to Future Infringement

The Decision's application of § 271(e)(2) to treat differently the types of parties in a Hatch-Waxman action is not consistent with this Court's long-standing precedent. The Decision's holding that JM cannot infringe because it "did not submit an ANDA" is unsupported by precedent and improperly limits the § 271(e)(2) infringement inquiry to just ANDA-filers. (Slip Op.16.) The Decision is contrary to the precedent in *Glaxo*, *Allergan*, *Warner-Lambert*, and *Forest*.

Infringement in a Hatch-Waxman context is not limited to only the particular party that filed the ANDA, and includes non-ANDA filers (e.g., parent company, related affiliate, distributor, contract manufacturer, and API supplier). The filing of the ANDA is the predicate act establishing § 1338(a) jurisdiction. *Allergan*, 324 F.3d at 1330-31. "Once jurisdiction is established, [] the substantive determination whether actual infringement or inducement ***will*** take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits, including those in a non-ANDA context, the ***only*** difference being that the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed." *Warner-Lambert*, 316 F.3d at 1365-66 (emphasis added).

Since the § 271(e)(2) inquiry considers future infringement under a traditional infringement analysis, it includes "whoever" is involved in making, using, offering to sell, selling, importing, inducing, or contributing to infringement of a patented product. §§ 271(a), (b), (c). Finding infringement against a non-ANDA filer is consistent with this Court's precedent. *See, e.g.*, *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 528-29 (Fed. Cir. 2012) (affirming an infringement judgment against a parent company and its subsidiary who "intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution and/or sale of the generic drug"); *Forest*, 501 F.3d at 1272 (finding that both an ANDA-filer and its API suppler infringe because "the plan to

manufacture, import, market, and sell the [infringing] products was undoubtedly a cooperative venture").

Therefore, the filing of an ANDA (albeit by the ANDA-Defendants) creates liability against JM under § 271(e)(2) for inducing the ANDA-Defendants' ***future*** infringement of the compound patents. Using a traditional § 271(b) infringement analysis, the district court properly found that JM induced the ANDA-Defendants' infringement. With JM's assistance and express written permission, each of the ANDA-Defendants incorporated infringing API from JM into their products and seek FDA approval to commercially market the infringing products. (A19-21; *e.g.*, A58361.) Thus, the Decision should be vacated as to JM's non-infringement because, under the precedent established in *Glaxo*, *Allergan*, *Warner-Lambert*, and *Forest*, and the traditional infringement analysis conducted by the operation of § 271(e)(2), JM induced infringement of the compound claims. The district court's induced infringement judgment against JM should be affirmed.

III. JM's Activities Are Not Shielded by the Safe Harbor

The Decision wrongly found that the safe harbor protects all of JM's activities "up to this point." (Slip Op.15.) Based on this Court's precedent, the safe harbor does not protect JM's future infringement, nor does it protect the commercial marketing and sales of JM's infringing API to date.

A. Under § 271(e)(2), JM's Future Infringement Is Not Protected by the Safe Harbor

The safe harbor is irrelevant to JM's future infringement under § 271(e)(2), just as is the case for the ANDA-Defendants. Thus, the Decision was wrong to expressly overturn the district court's induced infringement judgment based on the § 271(e)(1) safe harbor. (Slip Op.15.) Indeed, such reasoning was asserted by *Forest*'s dissent, but the majority rejected it:

> The dissent asserts that § 271(e)(1) [safe harbor] exempts [the API supplier] from being enjoined with [the ANDA-filer]. We disagree. . . . ***[J]ust as [the ANDA-filer] will be liable for, and hence is being enjoined from, the commercial exploitation of [the API] when it is approved by the FDA and during the life of the patent, so should [the API supplier] be enjoined***. . . . It is true that, as the dissent states, § 271(e)(2) defines [the ANDA-filer's] filing of its ANDA as an infringement, and [the API supplier] did not file the ANDA; ***however, when the question of an injunction against commercial activity arises, [the API supplier] is just as culpable, and hence entitled to be enjoined, as [the ANDA-filer]***.

501 F.3d at 1272 (emphasis added).

Regardless of whether the safe harbor protected JM's activities "up to this point" (Slip Op.15), the issue is that JM induced ***future*** infringement because JM is in a cooperative venture with each of the ANDA-Defendants. As the Decision recognized, JM filed a DMF in support of the ANDAs for the commercial exploitation of infringing API in the ANDA products once the ANDAs are approved. (Slip Op.14.) It is undisputed that the API supplied by JM directly infringes the compound claims, JM provided access to its DMF for the infringing

API to assist the ANDA-Defendants with their ANDAs, and the ANDA-Defendants will use infringing API supplied by JM when the ANDAs are approved. (A20-21.) [redacted] Thus, like *Forest*, "the plan to manufacture, [] market, and sell the [] products described in the ANDA[s] was undoubtedly a cooperative venture, and [the API-supplier] was to manufacture and sell infringing [API] to [the ANDA-filers] for [sale]." 501 F.3d at 1272. "[The API-supplier] has therefore actively induced the acts of [the ANDA-filer] that will constitute direct infringement upon approval of the ANDA." *Id.*

B. The Safe Harbor Does Not Protect JM's Commercial Marketing and Sales of Infringing API

"[T]here is an important limitation [to the safe harbor]: the use ***must be*** 'for uses reasonably related to the development and submission of information.'" *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1356 (Fed. Cir. 2012) (quoting § 271(e)(1)) (emphasis added). But JM did ***not*** merely "provide material for use by the ANDA defendants in obtaining FDA approval." (Slip Op.15.) JM's use of its DMF is commercial. [redacted]

[redacted]

Further, JM did not submit the DMF for its infringing API to the FDA as part of a federal law or regulatory process for the API. JM's API "is not itself subject to the FDA premarket approval process."[3] *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008). The FDA "neither independently reviews [DMFs] nor approves or disapproves submissions to a [DMF]." 21 C.F.R. § 314.420(a). (A58342.) Thus, this Court should "hold that the section 271(e)(1) safe harbor does ***not*** immunize [API-suppliers] from infringement." *Proveris*, 536 F.3d at 1265 (emphasis added).

C. JM Should Not Have Immunity from Infringement under These Circumstances

JM's commercial offers to sell and sales of its infringing API cannot be said to be "solely for uses reasonably related to the development and submission of information," § 271(e)(1), and thus are not shielded by the safe harbor. JM infringes the compound claims, and should not have amnesty to commercially

[3] Other FDCA policy considerations are not relevant because statutory symmetry is not required. *Proveris*, 536 F.3d at 1265; *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997).

offer to sell and sell its infringing API, whether to the ANDA-Defendants or others for commercial marketing of ANDA products upon FDA approval.[4]

By giving JM immunity from liability solely because it did not file an ANDA and without addressing JM's commercial activities, the Decision ignores the language of the statute directed to "whoever" infringes (§§ 271(a), (b), and (c)), and substantially undermines the value and importance of the compound claims. The Decision will lead to judicial inefficiencies, including duplicative adjudication of the merits of patent infringement, needless and wasteful adjudication of preliminary injunction motions, and unnecessary damages trials.

The statute clearly provides that Shire is entitled to the Hatch-Waxman Act's remedy for an act of infringement under § 271(e)(2) by seeking § 271(e)(4) injunctive relief against "an infringer," which includes JM's induced infringement under § 271(b). JM should face the same liability for infringement as anyone else. Shire should be able to seek the Act's remedy for "an act of infringement described in [§ 271(e)(2)]" by seeking injunctive relief "***to prevent*** the ***commercial*** manufacture, use, offer to sell, or sale" of infringing API. § 271(e)(4)(B) (emphasis added). "[J]ust as [the ANDA-filer] will be liable for, and hence is

[4] Shire believes that JM infringed under § 271(a), in addition to §271(b). (A21-22.) Shire has not conceded or waived this issue, as summary judgment denials are not appealable. *Classen Immunotherapies, Inc. v. Biogen Idec*, 659 F.3d 1057, 1069 (Fed. Cir. 2011); *Rivas v. City of Passaic*, 365 F.3d 181, 191 (3d Cir. 2004).

being enjoined from, the ***commercial*** exploitation of [the API] . . . so should [the API supplier] be enjoined." *Forest*, 501 F.3d at 1272 (emphasis added).

IV. Compound and Composition Patents Should Not Be Excluded from Induced Infringement under Section 271(e)(2)

Nothing in § 271(e)(2) excludes compound and composition patents from induced infringement. It is well-settled law that an ANDA-filer may be liable for future inducement of method patents. *Allergan*, 324 F.3d at 1331; *Warner-Lambert*, 316 F.3d at 1356. Notwithstanding these precedents, the Decision's finding effectively excludes liability for future induced infringement of compound patents, while permitting future induced infringement of method claims.

There is no principled reason why compound/composition patents should be treated differently from method patents and excluded from induced infringement liability under § 271(e)(2). "The proper inquiry under § 271(e)(2)(A) is whether, if a particular drug ***were*** put on the market, it ***would*** infringe the relevant patent." *Warner-Lambert*, 316 F.3d at 1366 (quotation omitted, emphasis in original). "The only difference in the analysis of a traditional infringement claim and a claim of infringement under section 271(e)(2) is the timeframe under which the elements of infringement are considered." *Allergan*, 324 F.3d at 1331. Furthermore this Court has broadly recognized that "section 271(e)(2) may support an action for induced infringement" under § 271(b). *Allergan*, 324 F.3d at 1331 (citing *Glaxo, Inc.*, 110 F.3d at 1567, 1569); *Forest*, 501 F.3d at 1272 (citing *Allergan*, 324 F.3d at 1331).

Accordingly, induced infringement applies to compound claims infringed by an API supplier in a cooperative venture with an ANDA-filer. *See id*.

The Decision's new precedent that compound/composition patents should be treated differently from method of use patents when evaluating induced infringement under § 271(e)(2) should be vacated.

CONCLUSION

The Decision should be vacated as to JM's non-infringement, and the district court's induced infringement judgment against JM should be affirmed. The district court correctly held that JM induced infringement of the compound claims (claims 1-4 of the '630 patent, claim 3 of the '787 patent, and claims 1-12 of the '253 patent). With JM's support, each of the five ANDA-Defendants relied on JM's infringing compound and DMF for their ANDAs. There is no dispute that the ANDA products use infringing API supplied by JM. Even though JM did not file an ANDA, JM actively induced the acts of the ANDA-Defendants that will constitute infringement upon approval of the ANDAs. Furthermore, under this Court's precedent the safe harbor should not protect JM's commercial activities. JM has induced infringement of the compound claims under §§ 271(e)(2) and 271(b).

Dated: October 26, 2015

Respectfully submitted,

/s/ Edgar H. Haug

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ADDENDUM

United States Court of Appeals for the Federal Circuit

SHIRE LLC, SHIRE DEVELOPMENT INC., SHIRE DEVELOPMENT, LLC,
Plaintiffs-Appellees

v.

AMNEAL PHARMACEUTICALS, LLC, ROXANE LABORATORIES INC., SANDOZ INC., MYLAN INC., MYLAN PHARMACEUTICALS INC., JOHNSON MATTHEY INC., JOHNSON MATTHEY PHARMACEUTICAL MATERIALS, ACTAVIS ELIZABETH LLC, ACTAVIS LLC,
Defendants-Appellants

2014-1736, 2014-1737, 2014-1738, 2014-1739, 2014-1740, 2014-1741

Appeals from the United States District Court for the District of New Jersey in No. 2:11-cv-03781-SRC-CLW, 2:11-cv-04053-SRC-MAS, 3:11-cv-03787-PGS-LHG, 2:11-cv-03886-SRC-MAS, 2:12-cv-03234-SRC-MAS, Judge Peter G. Sheridan, Judge Stanley R. Chesler.

Decided: September 24, 2015

ANGUS CHEN, Frommer Lawrence & Haug LLP, New York, NY, argued for plaintiffs-appellees. Also represent-

ed by EDGAR HAUG, PORTER F. FLEMING, SANDRA KUZMICH, RICHARD KURZ, ANDREW SCOTT ROPER.

MATTHEW R. REED, Wilson, Sonsini, Goodrich & Rosati, PC, Palo Alto, CA, argued for defendants-appellants Amneal Pharmaceuticals, LLC, Roxane Laboratories Inc., Sandoz, Inc., Mylan Inc., Mylan Pharmaceuticals Inc., Actavis Elizabeth LLC, Actavis LLC. Defendants-appellants Mylan Inc., Mylan Pharmaceuticals Inc. also represented by KATHERINE HASPER; WENDY L. DEVINE, San Diego, CA.

DANIEL E. YONAN, Blank Rome LLP, Washington, DC, for defendant-appellant Amneal Pharmaceuticals, LLC. Also represented by H. KEETO SABHARWAL, MARSHA ROSE GILLENTINE, JEREMIAH B. FRUEAUF, Sterne Kessler Goldstein & Fox, PLLC, Washington, DC.

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DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, for defendant-appellant Sandoz Inc. Also represented by BRIAN ROBERT MATSUI; DAVID CLARENCE DOYLE, MARK ANDREW WOODMANSEE, JAMES CEKOLA, San Diego, CA; ERIC C. PAI, Palo Alto, CA.

JONATHAN A. HARRIS, Axinn Veltrop Harkrider, LLP, Hartford, CT, for defendants-appellants Actavis Elizabeth LLC, Actavis LLC.

CONSTANTINE L. TRELA, JR., Sidley Austin LLP, Chicago, IL, argued for defendants-appellants Johnson Matthey Inc., Johnson Matthey Pharmaceutical Materials. Also represented by JOSHUA JOHN FOUGERE, Washington,

DC; DOUGLAS R. NEMEC, RACHEL RENEE BLITZER, Skadden, Arps, Slate, Meagher & Flom LLP, New York, NY.

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, for amicus curiae Generic Pharmaceutical Association. Also represented by DAVID ZIMMER, San Francisco, CA.

Before MOORE, MAYER, and LINN, *Circuit Judges*.

LINN, *Circuit Judge*.

In this consolidated Hatch-Waxman Act litigation, Amneal Pharmaceuticals, LLC, Actavis Elizabeth LLC, Actavis LLC, Mylan Inc., Mylan Pharmaceuticals Inc., Roxane Laboratories, Inc., Sandoz Inc. (collectively the "ANDA defendants") and Johnson Matthey Pharmaceutical Materials ("Johnson Matthey") (collectively, "defendants") appeal the district court's decision in *Shire, LLC v. Amneal Pharmaceuticals, LLC*, No. 11-3781, 2014 WL 2861430 (D.N.J. June 23, 2014) ("Op."), granting Shire LLC, Shire Development Inc. and Shire Development, LLC's (collectively "Shire's") motion for summary judgment that claim 4 of the U.S. Patent No. 7,105,486 (the "'486 patent"); claims 1–4 of U.S. Patent No. 7,655,630 (the "'630 patent"); claims 1–12 of U.S. Patent No. 7,659,253 (the "'253 patent"); and claim 3 of U.S. Patent No. 7,662,787 (the "'787 patent") (collectively, the "asserted claims") are not invalid. Defendants also appeal the district court's decision in *Shire, LLC v. Amneal Pharmaceuticals, LLC*, No. 11-3781 (D.N.J. May 12, 2014), affirming the magistrate judge's decision denying defendants' motion to amend their invalidity contentions to include an on-sale bar claim, *see Shire, LLC v. Amneal Pharms., LLC*, No. 11-3781, 2013 WL 6858953 (D.N.J. Dec. 26, 2013) ("Magistrate Op."). Johnson Matthey separately appeals the district court's decision that it induced infringement of the claims of the '630, '253 and '787 patents

(the "compound claims") by providing the active pharmaceutical ingredient ("API") L-lysine-d-amphetamine ("LDX") dimesylate to the ANDA defendants. Because defendants have failed to raise a genuine issue of material fact that the asserted claims are obvious, we affirm the district court's judgment of nonobviousness. Because the district court did not abuse its discretion in denying defendants' motion to amend their invalidity contentions to include an on-sale bar claim, we affirm that ruling. Because in the circumstances of this case Johnson Matthey cannot be liable for induced infringement prior to the grant of FDA approval of the application filed by the ANDA defendants, we reverse the district court's judgment that Johnson Matthey has induced infringement of the asserted compound claims and remand the case for further proceedings consistent with this opinion.

I. BACKGROUND

A. The Patents-in-Suit

The '486, '630, '253 and '787 patents (collectively, the "patents-in-suit") share similar specifications and are all directed to derivatives of amphetamine. Amphetamines are a class of drugs that has long been used to treat a variety of disorders, including attention deficit hyperactivity disorder ("ADHD"). *See, e.g.*, '486 patent col.1 l.59–col.2 l.12; Physicians' Desk Reference 2992–93 (2000) ("PDR"). A major drawback to the use of amphetamines is their potential for abuse. '486 patent col.2 l.13–col.3 l.12; PDR at 2992. The goal of the inventions is to "utilize[] covalent modification of amphetamine to decrease its potential for causing overdose or abuse." '486 patent col.9 ll.11–13. Specifically, the patents describe modifying amphetamine in such a way as to decrease its activity when administered in high doses—as happens when the drug is being abused—but to maintain activity similar to that of unmodified amphetamine when the modified amphetamine is delivered at lower doses. *Id.* at col.9

ll.13–21. One embodiment of the invention is LDX dimesylate. *See id.* at col.8 ll.43–67.

The claims of the '486 patent are directed to methods of using amphetamine derivatives, with asserted claim 4 directed to using a mesylate salt of LDX to treat ADHD. The asserted claims of the '630, '253 and '787 patents are compound claims directed to mesylate salts of LDX and crystalline forms thereof.

B. History of the Dispute

Shire is the assignee of the patents-in-suit and markets LDX dimesylate capsules. These capsules are approved by the Food and Drug Administration ("FDA") and distributed under the brand name Vyvanse®. The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") lists all the patents-in-suit for Vyvanse®.

The ANDA defendants filed Abbreviated New Drug Applications ("ANDAs") for their generic versions of Vyvanse® seeking approval prior to the expiration of the patents-in-suit. The ANDAs included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012) (commonly referred to as "Paragraph IV certifications") stating that the claims of the patents-in-suit are invalid and/or not infringed. Pursuant to § 355(j)(2)(B), the ANDA defendants notified Shire of the Paragraph IV certifications. In response, Shire sued the ANDA defendants for infringing the asserted claims, along with certain other claims not at issue in this appeal, under 35 U.S.C. § 271(e) (2012). In each suit, Shire also sued Johnson Matthey. Johnson Matthey supplied LDX dimesylate to the ANDA defendants and correspondingly filed a drug master file with the FDA, *see* 21 C.F.R. § 314.420, but did not itself file an ANDA. The district court consolidated all the lawsuits.

In September of 2013, after discovery was complete, defendants moved to amend their invalidity contentions to allege that the claims of the '253 patent were invalid based on an on-sale bar. Magistrate Op. at *2. Under the District of New Jersey Local Patent Rule 3.7, amendments to contentions must be based on "a timely application and showing of good cause." The rule lists "examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause," including "recent discovery of material prior art despite earlier diligent search." *Id.*

The magistrate judge denied defendants' motion to amend their contentions to assert an on-sale bar. The magistrate judge found the motion untimely because "the summary of documents produced by Shire on May 21, 2012 indicates that Defendants had access to the information [regarding the on-sale bar], or documentation that should have led them to it earlier than they now claim." Magistrate Op. at *3. The magistrate judge also found that defendants lacked good cause, because "[t]he alleged prior art, as it relates to the On–Sale Bar, is referenced in various portions of the document production," and was thus known for some time. *Id.* at *4. Finally, the magistrate judge ruled that allowing defendants to amend their contentions would unduly prejudice Shire, because "Shire ha[d] relied on Defendants' previous invalidity contentions for a year in preparing its case." *Id.* at *5. The district court affirmed. *Shire*, No. 11-3781 (D.N.J. May 12, 2014).

Shire then filed a motion for summary judgment that all the asserted claims were infringed and not invalid. The district court granted Shire's motion in part and denied it in part. It granted summary judgment that: (1) the ANDA defendants infringed all the asserted compound claims, Op. at *11; (2) the ANDA defendants induced infringement of claim 4 of the '486 patent, *id.* at *12; (3) Johnson Matthey induced infringement of the

compound claims, *id.*; and (4) the asserted claims were not invalid as anticipated or obvious, *id.* at *13–20. The district court denied Shire's motion for summary judgment that Johnson Matthey directly infringed the compound claims. *Id.* at *12. The district court certified its ruling for immediate appeal under Federal Rule of Civil Procedure 54(b). *Shire*, No. 11-3781 (D.N.J. July 21, 2014).

All the defendants appeal the district court's grant of summary judgment that the asserted claims are not invalid as obvious under 35 U.S.C. § 103(a) (2006[1]) and the district court's denial of their motion to amend their invalidity contentions. Johnson Matthey separately appeals the district court's grant of summary judgment that it induced infringement of the compound claims. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (2012).

II. DISCUSSION

A. Standard of Review

This court reviews summary judgment decisions according to the law of the regional circuit, here the Third Circuit, which reviews them *de novo*. *MobileMedia Ideas LLC v. Apple Inc.*, 780 F.3d 1159, 1164 (Fed. Cir. 2015) (citing *Gonzalez v. Sec'y of Dep't of Homeland Sec.*, 678 F.3d 254, 257 (3d Cir. 2012)). Accordingly, we reapply the standard applied by the district court. *See id.* In the Third Circuit:

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[1] Pursuant to § 3(n)(1) of the America Invents Act ("AIA"), Pub. L. No. 112–29, amended § 103 applies to patent applications with claims having an effective filing date on or after March 16, 2013. Because the applications for the patents-in-suit were filed before that date, the pre-AIA version of § 103 applies.

> To warrant summary judgment, the movant must show that, viewing the evidence in the light most favorable to the nonmoving party, there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law. The mere existence of a scintilla of evidence in support of the [nonmovant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmovant].

Daniels v. School Dist. of Phila., 776 F.3d 181, 192 (3d Cir. 2015) (alterations in original) (citations omitted).

The application of local patent rules is governed by the law of this court and "[d]ecisions enforcing local rules in patent cases will be affirmed unless clearly unreasonable, arbitrary, or fanciful; based on erroneous conclusions of law; clearly erroneous; or unsupported by any evidence." *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366–67 (Fed. Cir. 2006).

B. Obviousness

A patent is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). As patents are "presumed valid," 35 U.S.C. § 282, a defendant bears the burden of proving invalidity by "clear and convincing evidence," *Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238, 2242 (2011). For a patent to be obvious, "some kind of motivation must be shown . . . so that the jury can understand why a person of ordinary skill would have thought of either combining two or more references or modifying one to achieve the patented method." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008) (citation omitted).

The district court concluded that (1) the prior art did not disclose LDX or make it obvious; (2) even if it did, the prior art did not disclose that LDX was known as an active drug substance; (3) even if it did, the prior art provided no motivation to pick LDX as a starting compound; and (4) even if it did, the prior art provided no motivation to make mesylate salts of LDX. Op. at *15–17. Shire did not introduce and the district court did not analyze any secondary considerations.

Defendants maintain that there is a genuine issue of material fact whether Australian Patent Application No. 54,168/65 ("AU '168"), actually discloses LDX. Specifically, they claim that page 7 of AU '168 identifies 18 amino acids by name, including lysine, and states a preference for L-amino acids and d-amphetamine. Upon reading this passage, defendants argue, a person of skill in the art would immediately envisage LDX. Defendants also claim that Formula IV and Example 24 of AU '168 disclose LDX. Defendants also contend that there is a genuine issue of material fact whether the prior art as a whole rendered the mesylate salts of LDX obvious. There is also a genuine issue of material fact, defendants argue, whether mesylate salts of LDX were obvious and whether there was a reasonable expectation of success that the mesylate salt of LDX would serve its intended purpose. In addition to AU '168, defendants rely on several other pieces of prior art, including U.S. Patent No. 3,843,796 ("Miller"), to bolster their obviousness argument.

Shire denies that AU '168 discloses LDX. Shire claims that the record fails to show that a person of skill in the art would: "(i) start with d-amphetamine, (ii) chemically modify d-amphetamine, (iii) make a prodrug of d-amphetamine, (iv) synthesize [LDX] while ignoring other conjugates of d-amphetamine, (v) make a salt of [LDX] instead of using the freebase form, and finally (vi) specifically choose a mesylate salt rather than any other salt." Resp. Br. at 19. Shire also claims that defendants waived

their arguments that Formula IV and Example 24 of AU '168 rendered the claims obvious.

On this record, there is no genuine issue of material fact that the prior art did not disclose or make obvious the mesylate salt of LDX. Defendants' primary reference is AU '168. AU '168 is listed on the face of the patents-in-suit and therefore the examiner is presumed to have considered it. Defendants therefore "ha[ve] the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008) (citations omitted).

AU '168 discloses combining amphetamine, in any of its stereochemical forms, with numerous amino acids, in various stereochemistries and with many potential protecting groups. Nothing in AU '168 specifically suggests combining d-amphetamine with L-lysine. Page 7 of AU '168, relied on heavily by defendants, lists 18 amino acids "and the like," and states they can belong to the D- or L-series. Even this list, therefore, does not limit itself to 18 amino acids. AU '168 expressly suggests post-translational modifications of the amino acids, *see id.* at 8, thus further increasing the potential amino acid groups to be utilized. While page 7 states that "[a]cids of the L-series are preferred," AU '168 actually describes numerous D-series amino acids. Read in context of the whole reference, a person of skill in the art would, therefore, not focus exclusively on amino acids with the L stereochemistry.

As to Formula IV of AU '168, it does not teach a finite and limited class including LDX. Formula IV shows a compound with a Markush group, 'A.' For Formula IV to

disclose LDX, 'A' must be selected to be L-lysine and the amphetamine must be in the d-configuration. There is no genuine issue of material fact that AU '168 does not disclose L-lysine as part of a limited class of compounds for 'A'. AU '168 suggests that 'A' can be selected from one of three lists, and as defendants' expert candidly admitted, Formula IV "does not indicate any preference" among the different options. Thus, Formula IV discloses all the compounds from all three lists, the first of which lists 17 amino acids (including lysine), the second of which teaches over a hundred possible combinations of amino acids and protecting groups and the third of which does not even provide a definite list of compounds. This too is not a definite and limited class. Further, as described above, AU '168 does not meaningfully describe a preference for the L stereochemistry of its amino acids.

Example 24 is similarly insufficient. Example 24 is N^{α}-Tosyl-L-lysine[D(+)-1-phenyl-propyl-(2)]-amide. Example 24 differs from LDX in that it contains a tosyl group. On page 8, AU '168 describes tosyl as a "protecting group[]," and on page 14, it states that "[a] tosyl group can be removed by . . . treatment . . . with sodium in liquid ammonia." According to defendants, this provides motivation to modify example 24 to make LDX. The problem for defendants is that example 24 is a final product, not an intermediate synthesis product. Defendants therefore have to show a reason why one of skill in the art would decide to start with example 24 and remove the protecting group. They have shown no such motivation. *See also* P. Quitt, *Synthesis of Optically Active N-Methylated Amino-Acids*, *in* PEPTIDES: PROCEEDINGS OF THE FIFTH EUROPEAN SYMPOSIUM OXFORD, September 1962 165, 167 (G.T. Young ed., 1963) (explaining that the N^{α}-tosyl "protected derivative might in most cases be the desired product").

The hindsight nature of defendants' argument is confirmed by the fact that out of the thousands of possible compounds it discloses, AU '168 actually provides thirty

specific examples, none of which is LDX. Thus, read in context, a person of skill in the art would not have any reason to specifically select LDX.

Nor is there a genuine issue of material fact that AU '168 does not render obvious the mesylate salts of LDX. As described above, AU '168 broadly teaches combining amphetamine with many amino acids, protected and unprotected, and in different stereochemistries, but provides "no direction as to which of many possible choices is likely to be successful." *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361 (Fed. Cir. 2011) (citations omitted). Thus, AU '168 does not make LDX obvious to try. *See id.* Defendants can only come to LDX by "retrac[ing] the path of the inventor with hindsight," *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008). We therefore reject the hindsight claims of obviousness. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1071-72 (Fed. Cir. 2012).

Miller does not overcome the deficiencies of AU '168. Defendants focus on Formula II of Miller, which describes a molecule with two Markush groups, [R'] and [X]. Even focusing on Formula II, Miller discloses that [X] can be one of twenty amino acids—including L-lysine—or their derivatives. Miller at col.3 ll.4–52. Defendants have offered no rationale why a person of skill in the art would focus on the specific embodiment of Formula II comprising L-lysine. Moreover, even if [X] were chosen to be L-lysine, Miller's compound is still different from LDX in two ways—to wit, Miller has an OR' where LDX has an H and Miller has a C-OH where LDX has a CH—i.e., the base compound in Miller is not amphetamine. The record provides no reason or motivation why one of skill in the art would combine AU '168 with Miller. Accordingly, there is no genuine issue of material fact that the disclosure in Miller does not overcome the deficiencies in AU '168.

We have considered the other references cited by defendants and find that they too fail to raise a genuine issue of material fact as to whether LDX, let alone the mesylate salt of LDX, was made obvious by the prior art. Because all the asserted claims are limited to mesylate salts of LDX, we need not consider whether additional limitations found in certain claims would separately suffice to make the claims non-obvious. *See SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1375 (Fed. Cir. 2013). Accordingly, the district court's grant of summary judgment that the asserted claims are nonobvious is affirmed.

C. Defendants' Motion to Amend

Defendants allege that they were timely in seeking leave to amend their invalidity contentions, because both Shire and third parties delayed in producing documents relevant to an on-sale bar defense and because defendants had to sift through more than two million pages of documents to find the relevant evidence. Relatedly, defendants argue there was good cause for their delay because they were diligent in their search for evidence. Finally, defendants argue that there is no undue prejudice to Shire because Shire itself was responsible for the delay. Shire responds that the district court properly evaluated all the factors.

Defendants have not shown that the district court abused its discretion in denying defendants' motion to amend. In their opening brief, defendants have not persuasively explained why their motion to assert an on-sale bar defense was not filed earlier and have failed to even challenge the magistrate judge's finding that documents produced by Shire on May 21, 2012, contained information "that should have led" defendants to raise an on-sale bar argument. Moreover, defendants did not ask Shire for permission to supplement their invalidity contentions until August of 2013—more than a year later.

Accordingly, we find no reason to conclude that the district court abused its discretion in denying defendants' motion to amend as untimely and lacking good cause. The decision to deny defendants' motion to amend is therefore affirmed.

D. The Claim Against Johnson Matthey

Under § 271(e)(2), Congress made it "an act of infringement to submit an [ANDA] application . . . for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A). But Congress also provided a safe harbor in § 271(e)(1) for those engaged in certain activities in support of the filing of an ANDA. Specifically, § 271(e)(1) states that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1).

Johnson Matthey does not seek FDA approval to sell a generic form of Vyvanse® and has therefore made no ANDA filing. Its only involvement in this dispute arises from its actions in supplying the ANDA defendants with the active pharmaceutical ingredient LDX dimesylate. The district court found it undisputed that each of the ANDAs at issue lists Johnson Matthey as the manufacturer of the LDX dimesalyate used in their generic products. It was also undisputed that Johnson Matthey filed a drug master file for that ingredient with the FDA in support of the ANDA defendants' applications and in anticipation of the eventual commercial exploitation of both its API and the generic products made from it. From this, the district court entered judgment that Johnson Matthey "has induced infringement of the compound claims at issue." Op. at *20.

Johnson Matthey argues that providing the ANDA defendants with an active ingredient so they could submit their ANDAs was reasonably related to the submission of information under a federal law and was therefore within the safe harbor of § 271(e)(1). Since it did not itself submit an ANDA, Johnson Matthey contends that it cannot be liable under § 271(e)(2) for its past actions and therefore the district court was wrong to enter judgment against it. Further, it asserts that because no direct infringement has yet to occur, it cannot be liable for induced infringement under § 271(b). It thus contends that it should never have been named in the litigation and should be dismissed from the case.

Shire counters by asserting that Johnson Matthey is properly in the suit and can be liable for induced infringement. According to Shire, this court's decision in *Forest Laboratories, Inc. v. Ivax Pharmaceuticals, Inc.*, 501 F.3d 1263 (Fed. Cir. 2007), held that a party can be liable "under section 271(e)(2) for its ***future*** infringement under section 271(b) as the ANDA-filers' API supplier." Resp. Br. at 52. Shire contends that on the facts before us "*Forest* cannot be distinguished." *Id.* at 55 (capitalization altered). Finally, Shire argues that under the reasoning of *Forest Labs.*, Johnson Matthey can be enjoined.

Johnson Matthey is correct that it cannot be liable for the API it sold the ANDA defendants up to this point. Johnson Matthey, as an API supplier, has thus far done nothing more than provide material for use by the ANDA defendants in obtaining FDA approval. As the district court found, these sales, and the ANDA defendants' use of the API for filing the ANDA, were "reasonably related to the submission of an ANDA." Op. at *12. As such, Johnson Matthey's activities are protected by the safe harbor of § 271(e)(1), and the district court erred by entering judgment that Johnson Matthey has induced infringement of the compound claims at issue.

Moreover, as Johnson Matthew did not submit an ANDA, it cannot be liable for infringement under § 271(e)(2). We do not agree with Shire that this Court's decision in *Forest* requires a different result. To the contrary, *Forest* involved the scope of an injunction under § 271(e)(4). No such injunction has been issued against Johnson Matthew here and thus *Forest* is inapposite. Johnson Matthey is therefore not currently liable for infringement.

Accordingly, we reverse the district court's judgment that Johnson Matthey has induced infringement of the compound claims at issue and remand for further proceedings consistent with this opinion.

III. CONCLUSION

For the foregoing reasons the district court's grant of summary judgment that the asserted claims are not invalid as obvious is affirmed; the district court's denial of defendants' motion to amend is affirmed; and the district court's judgment that Johnson Matthey has induced infringement is reversed. The case is remanded for further proceedings consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED

COSTS

Each party shall bear its own costs.

United States Court of Appeals
for the Federal Circuit

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing Combined Petition for Panel Rehearing and Rehearing En Banc with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users. I further certify that the following parties were served with the foregoing via FedEx:

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