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Examining the Boundaries of API Supplier Liability In ANDA Cases in Light of Recent Federal Circuit Decisions

By Douglas R. Nemec and Rachel R. Blitzer

Introduction

The prescription drug industry is booming in the United States, generating revenues of hundreds of billions of dollars annually.[1] It therefore comes as no surprise that Abbreviated New Drug Application (''ANDA'') litigation filings have reached record levels in recent years.[2] With considerable profits to be made, brand name drug companies and their generic competitors are litigating as vigorously as ever in an effort to acquire, or hold on to, as large a portion of the prescription drug market as possible.

Over the last twenty years or so, the courts have quietly tried to ascertain the role of active pharmaceutical ingredient (API) suppliers in these litigations. A recent decision from the Federal Circuit—*Shire, LLC v. Amneal Pharms., LLC*[3] —provided some much-needed clarification, ostensibly confirming that API suppliers generally should not be parties to ANDA litigations. However, that decision avoided disrupting seemingly inconsistent (or at least, incongruous) precedent, leaving litigants with a number of unanswered questions about API suppliers' exposure.

This article first reviews the statutory scheme that authorizes ANDA filings and litigations, as well as the role of API suppliers within that scheme. Next, the article analyzes two key Federal Circuit cases addressing API suppliers. Finally, the article considers the unintended consequences of these discordant precedents, and proposes practice lessons to consider.

The Role of API Suppliers

Pharmaceutical companies work with a host of supporting players during the drug development, approval, and manufacturing processes. Prominent among them are API suppliers, who provide the active ingredients that are incorporated into pharmaceutical products to be marketed to the public.

Due to the significance of API to final drug products, API suppliers can take on a rather involved role in phar-

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[1] *See, e.g.*, U.S. Gov't Accountability Off., Report No. GAO-12-371R, Savings from Generic Drug Use 1 (2012) (''US GAO Report'').

[2] *See* Brian C. Howard & Jason Maples, Lex Machina, Hatch Waxman / ANDA Litigation Report (2014) at 3 (reporting 2014 to be a record year for ANDA litigation, with 323+ cases filed).

[3] 802 F.3d 1301 (Fed. Cir. 2015).

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maceutical companies' drug approval processes. To begin with, API suppliers regularly participate in the research and development of new or improved compounds, often independently identifying areas of potential drug development before pharmaceutical companies do.[4] Once formulated, API suppliers provide research quantities of their API to their interested pharmaceutical company customers, along with access to information about the physical properties of the API material.[5]

Additionally, API suppliers provide a portion of pharmaceutical companies' submissions to the FDA. All drug manufacturers, brand and generic, must seek approval to market their drug products from the FDA by filing New Drug Applications (''NDAs'') or ANDAs, respectively. In connection with these applications, drug companies are required to concurrently provide data to the FDA about the API to be used in the proposed products.[6] Third party API suppliers provide API specifications to the FDA in confidential Drug Master Files (DMFs).[7] With the DMF holder's permission, NDA and ANDA applicants may refer the FDA to a given DMF in order to provide the required information about the properties of the API that will be incorporated into their pharmaceutical products.[8] In such situations, the FDA requires a letter from the DMF-holding API supplier authorizing review of its DMF in connection with the NDA or ANDA in question.[9]

The Hatch-Waxman Act, and its Interpretation by the Courts

Litigation between brand name drug manufacturers and ANDA filing generic drug companies is controlled by the 1984 Drug Price Competition and Patent Term Restoration Act and related statutes, commonly known as the Hatch-Waxman Act.[10] In accordance with the Act's goal of ''balanc[ing] the need to stimulate innovation against the goal of furthering the public interest,''[11] the Act creates a mechanism for generic drug manufacturers to challenge the patents ostensibly covering the brand name drug in advance of the lengthy process of FDA approval and preparing for commercial launch. An aspiring generic manufacturer may challenge the validity or the infringement of those patents by including a ''Paragraph IV'' certification[12] with its ANDA, which creates subject matter jurisdiction that permits a patent owner to initiate suit.[13] The intent of the Act is to ''facilitate[] challenges to a patent's validity,''[14] and provide a swift resolution—a procedure that is in the interest of the brand name company, the generic, and, most importantly, the public.[15]

The Act does not explicitly address the role of API suppliers. On its face, the Act only addresses infringement by one who ''submits'' an ANDA.[16] Specifically, under the Act, a patent holder may file a patent infringement suit against an ANDA ''submitter''[17]; or, if the patent holder forgoes that option, an ANDA ''filer'' may bring a declaratory judgment action against the patent holder.[18]

The Act does, however, address activity that could be construed to encompass the participation of API suppliers in the ANDA process. In what is known as the ''safe harbor provision,'' 35 U.S.C. § 271(e)(1) exempts from infringement liability parties that ''make, use, offer to sell, or sell . . . or import . . . 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.'' This safe harbor can apply to any entity—ANDA filer or otherwise—and protects ''*all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use or distribution of drugs.''[19]

Naturally, patent holders and API suppliers dispute the extent to which various provisions of the Hatch-Waxman Act apply to the API suppliers. Patent owners have offered, with varying success, theories as to how API suppliers may be liable for patent infringement under § 271(e)(2), including by inducing the filing of an ANDA,[20] sharing a corporate relationship with the

[4] *See generally* Edward M. Cohen and Steven Sutherland, *Active Pharmaceutical Ingredients*, in Generic Drug Product Development: Solid Oral Dosage Forms, 19-29 (Leon Shargel, Isadore Kanfer, eds., 2013).

[5] *See, e.g.*, *Genpharm Inc. v. Pliva-Lachema a.s.*, 361 F. Supp. 2d 49, 54 (E.D.N.Y. 2005) (discussing the practice of supply of research quantities by API manufacturers).

[6] *See, e.g.*, Arthur B. Shaw, Drug Master Files Under GDUFA: DMF Basics, at 6 (Feb. 11, 2013).

[7] DMFs are FDA submissions that can include the chemistry, manufacturing and controls (''CMC'') of a component of a drug product. 21 C.F.R. § 314.420(a) (2011).

[8] API suppliers may use their DMFs to ''authorize other persons to rely on the information to support a submission to FDA without . . . having to disclose the information to the person.'' 21 C.F.R. § 314.20(a).

[9] 21 C.F.R. § 314.420(a)-(b) (2011).

[10] 21 U.S.C. §§ 355, 360 (2006); 35 U.S.C. §§ 156, 271 (2006).

[11] H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. 2, at 29–30 (1984) .

[12] 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006).

[13] 35 U.S.C. § 271(e)(2) (''It shall be an act of infringement to submit'' an ANDA ''if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.'')

[14] *F.T.C. v. Actavis*, 133 S. Ct. 2223, 2234 (2013).

[15] The Act thus accomplishes the dual goals of (1) enabling a generic company to challenge the patents listed in the Orange Book which allegedly cover the brand name drug by filing a Paragraph IV certification against such patents, *see Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003); and (2) permitting a brand name drug manufacturer to challenge the filing of an ANDA before a generic product is commercialized, *see Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

[16] 35 U.S.C. § 271(e)(2)(A). Note that the Act also authorizes subject matter jurisdiction over other filers not relevant to this paper. *See* 35 U.S.C. § 271(e)(2)(B)-(C).

[17] 35 U.S.C. § 271(e)(2)(A).

[18] 35 U.S.C. § 271(e)(5). If a patent owner faced with a Paragraph IV certification declines to file suit within forty-five days, § 271(e)(5) confers subject matter jurisdiction over a declaratory judgment action brought by the ''person [who] has filed an application described in paragraph (2) [i.e., the filer of an ANDA containing a Paragraph IV certification].''

[19] *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206 (2005) (citation omitted) (emphasis in original); *see also id.* at 202 (noting that ''the statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process'').

[20] *See, e.g.*, *SmithKline Beecham Corp. v. Geneva Pharmaceuticals, Inc.*, 287 F. Supp. 2d 576, 585-86 (E.D. Pa. 2002)

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ANDA filer,[21] or indicating an intent to commit future acts of infringement.[22]

Two decisions of the Court of Appeals for the Federal Circuit together provide the controlling law on the viability of Hatch-Waxman claims against API suppliers: 2007's *Forest Laboratories, Inc. v. Ivax Pharmaceuticals, Inc.* (''*Forest*''),[23] and 2015's *Shire, LLC v. Amneal Pharms., LLC* (''*Shire*'').[24] We will review these decision in reverse chronological order, as *Shire* serves to clarify *Forest*, and provides the most recent guidance on API supplier liability in ANDA litigation.

The Shire Decision

In *Shire*, the brand name plaintiff filed suit against multiple ANDA filers, as well as the single API supplier referenced in each of their ANDAs.[25] The API supplier had engaged in the typical acts of supplying research quantities to the ANDA filers and allowing the ANDAs to reference its DMF[26]—''the kinds of things Defendants in these cases typically do when they seek to market a generic version of a pharmaceutical protected by patents.''[27] At summary judgment, the district court found the API supplier liable for patent infringement by virtue of giving the ANDA filers permission to identify the supplier as their manufacturer and to reference its DMF in their ANDAs.[28,29] On appeal, the Federal Circuit reversed this ruling, and held that, based on the rather typical actions undertaken by the API supplier, ''it cannot be liable for the API it sold the ANDA defendants up to this point.''[30] The *Shire* decision thus finally confirmed that an API supplier acting in the typical manner (providing research samples, filing a DMF, and authorizing reference to its DMF in ANDAs) should be protected from suit by the safe harbor.[31]

The Forest Decision

Based on the holding in *Shire* alone, it might seem that API suppliers no longer have anything to fear in Hatch-Waxman litigations.[32] However, *Shire* deliberately left intact the Federal Circuit's earlier *Forest* decision, which can be read to endorse API supplier liability in certain circumstances.

Forest addresses a more atypical procedural posture than *Shire*. In *Forest*, after denial of a motion to dismiss, the API supplier in question, as well as the ANDA filer, stipulated to infringement of the patents in suit.[33] After a bench trial, the district court found the patents valid, and enjoined both the ANDA filer and the API supplier from manufacturing or selling the proposed drug product.[34] The defendants appealed the scope of the injunction, and specifically the inclusion of the API supplier.[35]

The *Forest* Court generally confirmed the same safe harbor scope that later formed the basis of the *Shire* opinion. It explained that, ''[the API supplier] is providing information, and will provide material, that [the ANDA filer] will use to obtain FDA approval. Up to that point, there is indeed no infringement.''[36] The *Forest* dissent is instructive, as it explains in further detail why the API supplier's actions fell with the § 271(e)(1) safe harbor, and thus did not qualify as infringement under § 271(e)(2)[37]—a point with which the majority agreed.[38]

Nevertheless, the Federal Circuit upheld the injunction against the API supplier. Specifically, it ruled that, ''it was not inappropriate for the district court to include [the API supplier] within the scope of the injunction,'' and further that ''when the question of an injunction against commercial activity arises, [the API supplier] is as culpable, and hence entitled to be enjoined, as [the ANDA filer].''[39] The *Shire* Court, when faced with arguments regarding the applicability of *Forest*, distinguished it, leaving its holding intact: ''*Forest* involved the scope of an injunction under § 271(e)(4). No

(finding that an API manufacturer could be liable for inducement where it ''collaborated as a partner'' with the ANDA filers); *SmithKline Beecham Corp. v. Pentech Pharmaceuticals*, Inc., No. 00 C 2855, 2001 WL 184804, at *3 (N.D. Ill. Feb. 20, 2001) (allowing an inducement claim against an API manufacturer where the API manufacturer was alleged to have ''collaborated'' in the research and development of the ANDA product).

[21] *See, e.g., In re Cyclobenzaprine*, 693 F. Supp. 2d 409, 418 (D. Del. 2010) (extending Hatch-Waxman liability to a related corporate entity of the ANDA filer); *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 494 (E.D. Va. 2005) (same).

[22] *AstraZeneca AB v. Mylan Laboratories, Inc.*, 265 F. Supp. 2d 213, 218 (S.D.N.Y. 2003) (''Hatch-Waxman does not permit the Court to enjoin [third parties] from acts in furtherance of filing a future ANDA.'')

[23] 501 F.3d 1263 (Fed. Cir. 2007).

[24] 802 F.3d 1301 (Fed. Cir. 2015).

[25] *Id* at 1305.

[26] *Id.* at 1310.

[27] *Shire LLC v. Amneal Pharm., LLC*, No. 2:11-cv-03781-SRC-CLW, 2014 BL 174718, at *8-9 (D.N.J. June 23, 2014).

[28] 802 F.3d at 1305, 1310; *see also Shire LLC v. Amneal Pharm., LLC*, 2014 BL 174718 at*10-12.

[29] More specifically, the district court found that the safe harbor protected the API supplier from a finding of direct patent infringement, but nevertheless held that the API supplier had induced infringement of the patent at issue. *Shire LLC v. Amneal Pharm., LLC*, 2014 BL 174718, at *10-12. This distinction is not relevant to the scope of the *Shire* CAFC ruling.

[30] 802 F.3d at 1310. The Federal Circuit equivocation with the phrase ''up to this point'' certainly leaves open the question of what type of activity could later expose an API supplier to liability.

[31] *Id.*

[32] Even prior to the *Shire* holding, numerous district court cases had reached the same result. *See, e.g., AstraZeneca AB v. Mylan Laboratories, Inc.*, 265 F. Supp. 2d 213, 217-18 (S.D.N.Y. 2003) (denying plaintiff's motion to amend its Hatch-Waxman complaint to include four non-party API suppliers where the suppliers were involved in partnerships with the ANDA filers, helped develop the ANDA product, and ''would likely'' participate in the manufacture of the proposed product upon FDA approval, agreeing with the defendants' contention that ''whether the submission of an ANDA was induced is not the proper subject of a Hatch-Waxman action''); *United Therapeutics Corp. v. Sandoz Inc.*, No. 13-cv-00316-PGS-LHG, slip op. at 6 (D.N.J. Mar. 31, 2014) (rejecting effort to ''broaden the statute's language by applying it against [an API supplier]'').

[33] 501 F.3d at 1266. It is mere conjecture to speculate about the API supplier's rationale for signing such a stipulation, but one can imagine it was a strategic case management decision.

[34] *Id.* at 1267.

[35] *Id.* at 1271-72.

[36] *Id.* at 1272.

[37] *Id.* at 1273-74.

[38] *Id.* at 1272 (''It is true that, as the dissent states, § 271(e)(2) defines [the generic]'s filing of its ANDA as an infringement, and [the API supplier] did not file the ANDA.'').

[39] *Id.*

such injunction has been issued against [the API supplier] here and thus *Forest* is inapposite.''[40]

Uncertainty in the Wake of Forest and Shire

The *Shire* ruling could have brought some much needed finality—and reassurance—to the API supplier community. And to some extent, it did. However, the Federal Circuit's pointed decision to maintain the *Forest* holding in its *Shire* decision confirms that there are still circumstances in which those who supply API to ANDA filers are vulnerable to suit in Hatch-Waxman litigations.

There are costs to this ambiguity. The Hatch-Waxman Act scheme was designed ''to bring low-cost, generic copies of [brand name] drugs to market.''[41] It has been effective so far, with generic drugs saving the health care industry an estimated one trillion dollars in just 12 years.[42] However, the recent rash of litigations against API suppliers of ANDA filers, and the Federal Circuit's choice to leave the door open some unknown amount, threaten to curtail these savings by making the generic development process more expensive.

With the threat of litigation hovering, some API manufacturers simply may not be willing to supply generic companies pursuing Paragraph IV challenges. API supply for ANDA filing-customers is already a risky venture, as only about half of ANDA challenges are successful[43] and even successful generic manufacturers may switch API suppliers down the line. In the absence of an available API supplier, generic companies would be required to develop their API on their own or through their subsidiaries. In house API development would vastly increase generic costs over the commonplace arrangement where a single API manufacturer supplies multiple generic companies, thereby consolidating development and FDA submission costs.[44] If each generic must incur the full cost of API development and approval, rather than distributing the costs of a single API supplier among multiple generics, the result would be a significant increase in generic development costs and a needless waste of resources. Even if some API suppliers are willing to accept the risk of ANDA litigation, each supplier's capacity, constrained by resources such as plant space, is limited, and a few API suppliers cannot possibly cover the needs of all ANDA filers. With fewer API suppliers available, some prospective generic endeavors will be scrapped, denying the public potentially significant cost savings.

And even if the majority of API manufacturers remain willing to supply ANDA filers, the costs of the API may go up. API suppliers will need to cover the cost of potential litigation in some way. They can factor litigation cost into their budgets, as generic drug manufacturers do, and pass that cost along to their customers. Or they may require their generic customers to indemnify them against the cost of an ANDA lawsuit. Either way, the cost of generic drug development will increase, and with it, the ultimate price for generic drugs paid by the public. API suppliers will also be forced to undertake sophisticated legal analyses of the merits of their customers' Paragraph IV certifications, including with regard to portions of the ANDA product other than the API, such as the ingredients that control the drug release mechanism.

It is worth noting that these significant costs are not offset by any appreciable gain to brand name companies. The net result of an ANDA suit will be the same with or without the inclusion of the API supplier: if the patents-in-suit are upheld and deemed to be infringed, the ANDA filer will be enjoined and will not purchase the API in question; and of course, if the patents are found invalid or not infringed, then there can be no direct infringement by either the generic drug manufacturer or the API supplier.[45] Judge Sue L. Robinson of the District of Delaware has recognized as much, openly questioning the value of including API manufacturers in ANDA cases:

> Indeed, except to pursue discovery more easily, I am not sure why it makes sense to join the API manufacturers or similarly situated third parties at this juncture since, if the ANDA products are deemed to infringe the patents-in-suit, no third party may make, use, sell, or offer to sell such products without similarly infringing the patents-in-suit.[46]

The only real benefit to brand name drug companies of including API suppliers in ANDA litigations, other than the discovery logistics mentioned by Judge Robinson, is extrajudicial control over the API suppliers, and by extension their customers. API supplier defendants, or potential defendants, may be willing to accept settlements that deprive their ANDA co-defendants of future API supply. Such settlement would derail the development and approval timelines of the former generic customers and delay the public's access to cheaper generic drugs, even where the relevant patents are found invalid and not infringed.[47] Additionally, patentees may hope for injunctions that foreclose an API manufacturer's ability to supply other generic manufacturers, even were such products would not infringe.[48] Either way, such a scheme would reinstate ''the patentee's *de facto*

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[40] 802 F.3d at 1310.

[41] *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1325 (Fed. Cir. 2003) (per curiam); *see also Caraco Pharm. Labs. Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)). (''[T]his process is designed to speed the introduction of low-cost generic drugs to market.'')

[42] US GAO Report at 4.

[43] 2014 PwC Patent Litigation Study, pp. 4, 20-21, https://www.pwc.com/us/en/forensic-services/publications/assets/2014-patent-litigation-study.pdf (reporting an average success rate of 52% for adjudicated ANDA challenges between 2006 and 2013).

[44] For example, in *Shire,* a single API manufacturer supplied all five ANDA filers. 802 F.3d at 1305.

[45] *See Limelight Networks, Inc. v. Akamai Techs., Inc.* 134 S. Ct. 2111, 2117 (2014).

[46] *LEO Pharma A/S v. Tolmar, Inc.*, Civ. No. 10-269-SLR, 2011 BL 277900, at *2 n.3 (D. Del. Oct. 28, 2011).

[47] Brand name drug companies and API suppliers alike should consider that such settlements may implicate antitrust concerns. *Cf. Advocate Health Care v. Mylan Labs., Inc. (In re Lorazepam & Clorazepate Antitrust Litig.)*, 202 F.R.D. 12 (D.D.C. 2001).

[48] For example, an injunction against an API manufacturer could prevent later supply of a generic manufacturer pursuing an ANDA for a non-infringing use of a patent under 21 U.S.C. § 355(j)(2)(A)(viii).

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monopoly,'' which the Hatch-Waxman Act was designed to eliminate.[49]

Guidance for API Suppliers

While uncertainty in the law remains, API suppliers would be well-advised to operate mindful of the circumstances that led to an injunction in *Forest*.

Based on the straightforward facts of that case, an API supplier seeking to avoid an injunction should think long and hard before stipulating to infringement. While this may seem obvious to anyone seeking to avoid infringement liability, a stipulation may sometimes be economically attractive to an API supplier in the midst of an ANDA litigation. An API supplier struggling with a pricey litigation may be tempted, after an initial motion to dismiss is denied, to stipulate to infringement and focus on a validity challenge or an appeal. API suppliers committed to avoiding infringement liability should resist this shortcut. However, bear in mind that certain API suppliers may be willing to accept a *Forest*-like injunction, especially where the ANDA filer in question is likewise enjoined. Evading an infringement ruling at a significant expense may be a Pyrrhic victory for an API supplier that is left with no customer.

API suppliers may also want to consider the nature of their relationships with generic pharmaceutical companies. In *Forest*, the Federal Circuit relied on some much-scrutinized language regarding the relationship between the API supplier (Cipla) and the ANDA filer (Ivax) to support an induced infringement theory:

> An inquiry into induced infringement focuses on the party accused of inducement as the prime mover in the chain of events leading to infringement. Here, we do not know if Cipla first approached Ivax or vice versa, but the plan to manufacture, import, market, and sell the [] products described in the ANDA was undoubtedly a cooperative venture, and Cipla was to manufacture and sell infringing [] products to Ivax for resale in the United States. Under the standards for inducement which we apply to 35 U.S.C. § 271(b), Cipla has therefore actively induced the acts of Ivax that will constitute direct infringement upon approval of the ANDA, and it was thus not inappropriate for the district court to include Cipla within the scope of the injunction.[50]

There is much confusion in the case law regarding the distinction between inducement of acts of infringement by the proposed ANDA product (*i.e.*, a proposed generic drug product, the use of which would cause a doctor to infringe a method patent)[51] and inducement of the filing of an ANDA (*i.e.*, an API supplier who assists a generic drug manufacturer in filing an ANDA).[52] Judge Alvin A. Schall's dissent in *Forest* succinctly distinguishes the two.[53] While the confusion persists, API suppliers would do well to manage their relationship with generics to avoid being characterized as a ''prime mover'' in a ''cooperative venture.''[54]

Additionally, as contemplated above, API suppliers may simply want to plan for the possibility of ANDA litigation as part of their business model. The cost of litigation could be included in API manufacturers' budgets—a measure that would likely require increasing the price of APIs. Alternatively, API suppliers could require that their generic customers indemnify them against ANDA litigations. Though indemnification would require some concessions from a supplier's customers, it may be the most effective way to limit costs, as ANDA filers are already prepared to take on full scale litigations as part and parcel of their ANDA submissions.

Finally, API suppliers should be prepared to contend with alternative avenues of attack from brand name companies dealing with Paragraph IV certifications. Patent holders may test creative theories to sustain traditional § 271(a)-(c) causes of action against API suppliers. For example, though the Supreme Court has emphasized the breadth of § 271(e)(1) safe harbor,[55] an ANDA plaintiff may try to develop a case alleging that an API supplier has stepped outside of it. Brand name companies may scrutinize an API supplier's activity in search of sales that are not ''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*'' (§ 271(e)(1)), such as international sales to foreign companies pursuing drug development under another country's laws, or domestic sales to a company that has indicated it is not pursuing FDA approval. One area of much examination is the distinction between sales of research quantities protected by § 271(e)(1) and commercial sales subject to § 271(a) liability.[56] The case law provides little clarity on the amount or type of manufacture that would remove an API supplier from the safe harbor,[57] which provides fertile ground for patent holders to attempt to institute actions against API suppliers that sidestep the *Shire* decision. Section 271(a)-(c) actions may be particularly attractive to brand name companies because, unlike § 271(e)(2) actions, they provide the prospect of a damages recovery.[58] At the very least, API suppliers

[49] *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990).

[50] 501 F.3d at 1272.

[51] *See, e.g.*, *Allergan* 324 F.3d at 1330; *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370 , 1375 (Fed. Cir. 2012).

[52] *See, e.g.*, *SmithKline Beecham Corp. v. Geneva Pharmaceuticals, Inc.*, 287 F. Supp. 2d 576, 586 (E.D. Pa. 2002); *SmithKline Beecham Corp. v. Pentech Pharmaceuticals, Inc.*, No. 00 C 2855, 2001 WL 184804, at *3 (N.D. Ill. Feb. 20, 2001).

[53] 501 F.3d at 1274.

[54] *Shire LLC v. Amneal Pharm., LLC*, 2014 BL 174718 , at *9 (referring to the brand name plaintiff's contention that the API supplier was a ''prime mover'').

[55] *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (''[W]e think it apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA.'')

[56] Commercial sales are also covered by § 271(e)(4)(C), where infringement under § 271(e)(2) is established.

[57] *Compare NeoRX Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 206-07 (D.N.J. 1994) (holding commercial stockpile quantities were protected by safe harbor and reasonably related to the FDA approval process), *with Biogen, Inc. v. Schering AG*, 954 F. Supp. 391, 396-97 (D. Mass. 1996) (holding stockpiling in order to market immediately upon FDA approval was not protected by the safe harbor).

[58] *But see* Transcript of Conference, *Astra Aktiebolag v. Andrx Pharm., Inc.*, No. 1:99-cv-09887-DLC (S.D.N.Y. Sept. 26, 2013) (D.I. 239) (suggesting that damages in such cases ''would be for a trifling amount'').

can expect to receive third party subpoenas in ANDA litigations, which is already an established practice.

Conclusion

The Federal Circuit has not yet been forced to reconsider its holding in *Forest*—and has not taken the opportunity to clarify it when presented with an opening in *Shire*. As such, the current state of the law leaves open questions about how exactly API suppliers may expose themselves to infringement liability and/or injunctions in ANDA litigations. Until the Federal Circuit, the Supreme Court, or the legislature provides further guidance, API suppliers are encouraged to stick within the bounds sanctioned by the *Shire* decision, and conduct their business with generic customers with care to avoid the circumstances underlying the *Forest* decision—perhaps at great expense to the prescription drug-using public that the Hatch-Waxman Act was intended to protect.

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