United States Court of Appeals for the Federal Circuit

01-1369, -1370

MINNESOTA MINING AND MANUFACTURING COMPANY
and RIKER LABORATORIES, INC.,

Plaintiffs-Appellants,

and

ALPHAPHARM PTY. LTD.,

Plaintiff-Appellant,

v.

BARR LABORATORIES, INC.,

Defendant-Appellee.

Donald R. Dunner, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for plaintiffs-appellants. On the brief were Allen M. Sokal, Charles E. Lipsey, David S. Forman, and Gregory A. Chopskie. Of counsel on the brief were Kevin H. Rhodes, and MarySusan Howard, Office of Intellectual Property Counsel, of St. Paul, Minnesota.

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James F. Hurst, Winston & Strawn, of Chicago, Illinois, argued for defendant-appellee. With him on the brief were Christine J. Siwik and Christopher Shearer.

Appealed from: United States District Court for the District of Minnesota

Judge Michael J. Davis

United States Court of Appeals for the Federal Circuit

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MINNESOTA MINING AND MANUFACTURING COMPANY
and RIKER LABORATORIES, INC.,

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BARR LABORATORIES, INC.,

Defendant-Appellee.

DECIDED: May 1, 2002

Before MICHEL, GAJARSA, and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge DYK. Opinion concurring in judgment filed by Circuit Judge GAJARSA.

DYK, Circuit Judge.

This case presents a question under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282. Appellants, Minnesota Mining and Manufacturing Co. ("3M") and Alphapharm Pty. Ltd.

("Alphapharm"), urge that the district court should have dismissed 3M's infringement action against appellee, Barr Laboratories, Inc. ("Barr"), without prejudice pursuant to Rule 41(a)(2) of the Federal Rules of Civil Procedure, so that the dismissal of that suit would not have triggered the running of a 180-day waiting period under 21 U.S.C. § 355(j)(5)(B)(iv)(II) for approval of Barr's Abbreviated New Drug Application ("ANDA"). Appellants urge that a dismissal without prejudice was required because Barr improperly caused the 3M suit to be brought. Barr allegedly did so by failing to provide 3M with information (before 3M filed suit) showing that Barr did not infringe. In particular appellants alleged that Barr failed to comply with the requirement of 21 U.S.C. § 355(j)(2)(B)(ii) that it provide "a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." Pursuant to our decisions in Mylan Pharmaceuticals, Inc. v. Thompson, 268 F.3d 1323, 60 USPQ2d 1576 (Fed. Cir. 2001) and Andrx Pharmaceuticals, Inc. v. Biovail Corp., 276 F.3d 1368, 61 USPQ2d 1414 (Fed. Cir. 2002), we hold that § 355(j)(2)(B) cannot be enforced by a private party in a patent infringement action, but must be enforced, if at all, only in the context of an action under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702-706. We also conclude that the district court did not lack subject matter jurisdiction to determine the form of dismissal or otherwise abuse its discretion in declining to dismiss without prejudice. We accordingly affirm the judgment of the district court.

I

The overall scheme of the Hatch-Waxman Amendments is described in detail in our decisions in Mylan and Andrx and need not be repeated here. The facts of this case are relatively simple considering the complexity of the statutory scheme.

3M is the assignee of U.S. Patent No. 4,642,384 (the "'384 patent"). The '384 patent claims intermediate compounds that result from a process for producing a drug product containing the active ingredient flecainide acetate.[1] As required by 21 U.S.C. §§ 355(b)(1) and 355(c)(2), 3M notified the Food and Drug Administration ("FDA") that the '384 patent claims a drug for which 3M had filed a New Drug Application ("NDA"). The FDA then listed the '384 patent in the so-called Orange Book. 3M's NDA was approved on October 31, 1985, and 3M currently markets the drug under the trade name TAMBOCOR. Alphapharm, as permitted by the statute, sought to piggyback on the approval of 3M's NDA, and filed an ANDA on July 16, 1998. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), on November 20, 1998, Alphapharm provided a paragraph IV notice to 3M, and stated that even if Alphapharm's proposed product is manufactured from any of the intermediate compounds claimed in the '384 patent, Alphapharm would not infringe the '384 patent because manufacturing of the product would occur outside the United States.

Despite the paragraph IV certification, 3M brought suit for patent infringement against Alphapharm in the district of Minnesota on January 4, 1999. Under the Hatch-Waxman Amendments, a consequence of that filing was that the FDA could not approve Alphapharm's ANDA until thirty months after the date 3M received notification from Alphapharm or the termination of the infringement suit in favor of Alphapharm, whichever was earlier. 21 U.S.C. § 355(j)(5)(B)(iii). 3M's suit against Alphapharm is still pending, but the thirty-month period expired in May 2001. Accordingly, the FDA approved

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[1] 3M is also the assignee of U.S. Patent No. 4,650,873 (the "'873 patent"), which claims this process for producing flecainide acetate. 3M originally alleged that Barr infringed the '873 patent, but later dropped that claim. The '873 patent is not involved in this appeal.

Alphapharm's ANDA, but Alphapharm apparently has not begun marketing its drug product, and intends to defer marketing until 3M's infringement suit against it is resolved.

Barr also sought to piggyback on the approval of 3M's NDA and filed an ANDA on May 22, 2000. Barr provided its paragraph IV certification that it did not infringe the '384 patent to 3M by letter dated July 12, 2000. As the second ANDA filer, Barr was not only potentially subject to the thirty-month stay under 21 U.S.C. § 355(j)(5)(B)(iii) (if 3M filed an infringement suit) but also to a 180-day stay pursuant to § 355(j)(5)(B)(iv) of the statute, which provides:

> If the [ANDA] application contains a [paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection continuing [sic] such a certification, the application shall be made effective not earlier than one hundred and eighty days after--
>
> (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
>
> (II) the date of a decision of a court in an action described in [21 U.S.C. § 355(j)(5)(B)(iii)] holding the patent which is the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

(emphases added).

This provision is designed to provide an incentive, in the form of a 180-day period of marketing exclusivity, to an ANDA filer that is the first to challenge a patent listed in the Orange Book. The running of the 180-day period is triggered by "the Secretary['s]

receiv[ing] notice from the [first ANDA applicant] of [its] first commercial marketing of the drug" or by "a decision of a court in an action described in [21 U.S.C. § 355(j)(5)(B)(iii)] holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv). Since Alphapharm has apparently not commenced marketing, we are concerned here with the second triggering condition – a "decision of a court in an action described in [21 U.S.C. § 355(j)(5)(B)(iii)] holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(II). This provision has been construed by the District of Columbia Circuit to include not only a successful judgment of noninfringement or invalidity in a suit against the first ANDA filer but also a successful judgment of noninfringement or invalidity in a suit brought against a later ANDA filer. Teva Pharms., USA, Inc. v. United States FDA, 182 F.3d 1003, 1010, 51 USPQ2d 1432, 1437 (D.C. Cir. 1999).

Following Barr's initial notice to 3M of its paragraph IV certification, 3M sought additional information from Barr regarding its noninfringement position and on August 10, 2000, Barr elaborated, stating that "[a]s detailed in our letter dated July 12, 2000, Barr's proposed product does not contain any of the compounds claimed in the '384 patent and, in fact, Barr's active ingredient was known well over a year before your client filed its earliest relevant patent application." Letter from Samuel L. Fox, Counsel to Barr, to Allen M. Sokal, Counsel to 3M (Aug. 10, 2000). Barr, however, declined to provide further information, which it regarded as proprietary.

Unsatisfied by Barr's claim of noninfringement, 3M filed an infringement suit against Barr in the district of Minnesota on August 25, 2000. Alphapharm intervened because of its interest in delaying approval of Barr's ANDA application. Because 3M filed this suit within 45 days of receiving notice of Barr's paragraph IV certification, the thirty-month or

litigation termination stay period under 21 U.S.C. § 355(j)(5)(B)(iii) was triggered with respect to Barr. Barr brought counterclaims seeking, among other things, a declaration of noninfringement. Barr also moved for summary judgment of noninfringement.

In the course of discovery, information was disclosed by Barr that convinced 3M that Barr did not infringe the '384 patent. 3M sought to dismiss its suit without prejudice, because, it urged, a dismissal without prejudice would prevent the triggering of Alphapharm's 180-day period of exclusivity. In effect, 3M sought to prevent approval of Barr's ANDA until 180 days after Alphapharm began marketing its approved product. 3M urged that Barr had "hoodwinked" 3M into filing a suit by refusing to provide a more detailed statement as to why it did not infringe the '384 patent.

The district court declined to dismiss 3M's action without prejudice. The district court recognized that the decision whether to allow a party to voluntarily dismiss an action after filing, pursuant to Rule 41(a)(2), is generally within the discretion of the district court, and that under governing Eighth Circuit law factors to consider in exercising this discretion include: whether the party has presented a proper explanation for its desire to dismiss; whether a dismissal would result in a waste of judicial time and effort; whether a dismissal would prejudice the defendant; and whether the dismissal was designed to avoid an adverse judgment. Minn. Mining & Mfg. Co. v. Barr Labs., Inc., 139 F. Supp. 2d 1109, 1115 (D. Minn. 2001). The district court found no impropriety in Barr's declining to provide further information before 3M brought suit, finding specifically that "Barr's assurances [that it did not infringe the '384 patent], together with 3M's knowledge that other methods existed for producing flecainide acetate [that did not involve producing the claimed intermediate compounds], were sufficient to satisfy the notice requirements of the ANDA process." Id. at 1115. The district court further found that 3M was merely attempting to avoid an adverse

judgment in the district court proceeding and was therefore not entitled to a voluntary dismissal. Id. at 1116. Finally, the district court granted Barr's motion for summary judgment of noninfringement because 3M did not object to Barr's motion on the merits. Id. 3M and Alphapharm filed this timely appeal. We heard argument on March 7, 2002.

II

While we review the district court's decision not to allow 3M to voluntarily dismiss its action for abuse of discretion, L.E.A. Dynatech, Inc. v. Allina, 49 F.3d 1527, 1530, 33 USPQ2d 1839, 1841 (Fed. Cir. 1995), the issue here is primarily a legal one – whether the district court was required to dismiss without prejudice or whether it grounded its dismissal on an erroneous proposition of law – namely Barr's compliance with the requirement of § 355(j)(2)(B)(ii) that it provide 3M with a "detailed statement of the factual and legal basis of [its] opinion" that it did not infringe the '384 patent. We review legal questions concerning the interpretation of a statute without deference. Barton v. Adang, 162 F3d 1140, 1144, 49 USPQ2d 1128, 1132 (Fed. Cir. 1998).

III

A predicate to appellants' arguments is that a dismissal with prejudice would trigger the running of the 180-day period. The District of Columbia Circuit has explicitly held that § 355(j)(5)(B)(iv)(II) is triggered by the termination of an action commenced by the second ANDA filer, and we agree. Teva, 182 F.3d at 1010, 51 USPQ2d at 1438. As the district court here noted "it would be contrary to the very purpose of the Act to allow the first filer to block market entry of other generic manufacturers because the first filer is involved in protracted litigation." Minn. Mining, 139 F. Supp. 2d at 1115.

IV

3M argues that the district court lacked subject matter jurisdiction and therefore should have dismissed the action without prejudice because, after filing the infringement action, 3M agreed that no infringement had occurred. The suggestion that the district court originally lacked subject matter jurisdiction is unfounded and incorrect. There was a clear controversy between 3M and Barr as to whether the '384 patent was infringed. The mere fact that 3M may have been operating under a misapprehension of the facts cannot affect the original subject matter jurisdiction of the district court.

However, if this case did not involve the Hatch-Waxman Amendments, appellants might well be correct that a case or controversy ceased to exist in the course of the litigation when 3M represented that it no longer claimed infringement by Barr. See Fina Research, S.A. v. Baroid Ltd., 141 F.3d 1479, 1483-84, 46 USPQ2d 1461, 1465 (Fed. Cir. 1998). But the case does involve the Hatch-Waxman Amendments, and the parties strenuously disagree about whether the action should be dismissed with or without prejudice. 3M urges that the form of dismissal could have significant consequences in the FDA proceedings. Whether or not 3M is correct that the form of dismissal will have consequences in the FDA proceedings,[2] these differences are more than sufficient to create subject matter jurisdiction as the Supreme Court has made clear in ASARCO, Inc. v. Kadish, 490 U.S. 605 (1989). There the Court found that the original controversy between the parties in a state court action did not satisfy the requirements for federal jurisdiction (because the plaintiffs' interest did not confer standing), but the ensuing controversy over the propriety of the relief awarded was sufficient for federal subject matter jurisdiction. Id.

[2] In Teva, the District of Columbia Circuit held that even a dismissal for lack of subject matter jurisdiction would trigger the 180-day exclusivity period. 182 F.3d at 1011, 51 USPQ2d at 1438. We do not decide here whether that holding is correct or incorrect.

at 618. So here, the underlying patent controversy under Fina may not have been sufficient for continuing federal jurisdiction, but the controversy over the form of dismissal was itself sufficient under ASARCO. See also City of Erie v. Pap's A.M., 529 U.S. 277, 288 (2000) (a court's interest in preventing litigants from attempting to manipulate the court's jurisdiction to achieve a favorable decision counsels against a finding of mootness); Richard H. Fallon, et al., Hart and Wechsler's The Federal Courts and The Federal System 221-22 (4th ed. 1996) (collateral consequences may prevent mootness).

V

Appellants urge that the district court was obligated to use its inherent power to sanction misconduct by Barr by dismissing the action without prejudice. Initially in their briefs to this court appellants complained that Barr had "hoodwinked" 3M into filing suit, and had violated a duty under the Federal Rules of Civil Procedure to disclose facts to 3M that would have resulted in a decision to forgo suit. Appellants argued, as well, that Barr could not properly cause the initiation of baseless litigation by 3M to secure an advantage under the Hatch-Waxman Amendments. We are aware of no such pre-filing disclosure obligation. Nor did Barr have any obligation to avoid triggering litigation that would advantage Barr by starting the 180-day exclusivity period.[3] At oral argument 3M wisely receded from these arguments, urging only that Barr had violated its duty under the Hatch-Waxman Amendments to file a compliant notice of its noninfringement position that would enable 3M to make an informed judgment as to whether to bring suit. As noted above, the district court rejected this argument, holding that Barr's notice was compliant.

[3] As the district court noted here, "Teva . . . supports the position that a subsequent ANDA filer can participate in litigation in order to trigger the exclusive marketing period granted the first filer." Minn. Mining & Mfg. Co. v. Barr Labs., Inc., 139 F. Supp. 2d 1109, 1116 (D. Minn. 2001).

3M's claim concerning compliance with the paragraph IV certification requirement is not insubstantial. The statute requires that:

> (i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to--
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> (I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and
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> (II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.
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> (ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

21 U.S.C. § 355(j)(2)(B) (emphasis added). The FDA has interpreted this statute to require, inter alia, "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed[; and] (ii) [f]or each claim of a patent

alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.52(c)(6).

In Barr's initial July 12, 2000, notification to 3M, it stated that its proposed drug product would not infringe any claim of the '384 patent because "the active ingredient [in the proposed product] is . . . not the same as the compound claimed in . . . the '384 patent," and that "because the active ingredient was known before the earliest effective filing date of the '384 patent, the active ingredient cannot infringe . . . under the doctrine of equivalents." However, because it is clear that the compounds claimed in the '384 patent are not the active ingredients in the drug, this notice was of no assistance to 3M, and 3M therefore sought additional information regarding Barr's noninfringement position. In its second, August 10, 2000, letter to 3M, Barr stated that "[a]s detailed in our letter dated July 12, 2000, Barr's proposed product does not contain any of the compounds claimed in the '384 patent and, in fact, Barr's active ingredient was known well over a year before your client filed its earliest relevant patent application." (emphasis added).

The appellants argue that this notice was legally deficient under the statute because Barr's statement that its "proposed product does not contain any of the compounds claimed in the '384 patent" was at best ambiguous. Appellants urge that Barr, by referring to its statements in the July 12, 2000, letter, indicated that its noninfringement position had not changed, and that Barr still based its opinion of noninfringment on a comparison between the active ingredient in its proposed product and the claimed compounds, rather than on a comparison between any compounds in the proposed product and the compounds claimed in the '384 patent.

However, we hold that we need not, indeed cannot, decide this question of compliance with the paragraph IV certification requirements. Under the Hatch-Waxman

Amendments we cannot enforce the requirements of paragraph IV certifications in an infringement suit.

In our decision in Mylan we confronted a claim that a particular patent listing in the Orange Book was improper because the listed patent did not claim a drug for which an NDA had been submitted, as required by 21 U.S.C. § 355(b)(1). Mylan, 268 F.3d at 1332, 60 USPQ2d at 1538. In Mylan, the ANDA applicant sued the FDA and the NDA holder, alleging that the pertinent patent had been improperly listed in the Orange Book, and moved for declaratory and injunctive relief requiring the NDA holder to take measures to delist the patent from the Orange Book and requiring the FDA to immediately approve the ANDA. Id. at 1328, 60 USPQ2d at 1580. The district court issued injunctions requiring the private defendant to withdraw the Orange Book listing and requiring the FDA to approve the ANDA. Mylan Pharms., Inc. v. Thompson, 139 F. Supp. 2d 1, 29-30 (D.D.C. 2001). The private defendant appealed, arguing that the FFDCA did not grant a private right of action, but the FDA did not appeal.

On appeal, the appellee-ANDA applicant (the declaratory judgment plaintiff) urged that its action was proper because it arose under the patent laws (Title 35 of the United States Code). The ANDA applicant claimed that its declaratory judgment action asserted a defense to patent infringement, because listing in the Orange Book was an element of any patent infringement cause of action which the NDA holder might have asserted. Mylan, 268 F.3d at 1330-31, 60 USPQ2d at 1581-82. We rejected the ANDA applicant's attempt to bring its action under the patent laws because we concluded that its cause of action was not tied to any recognized patent infringement defense but rather was "an attempt to assert a private right of action for 'delisting' under the FFDCA." Id. at 1332, 60 USPQ2d at 1583.

We also made clear that there was no private cause of action for delisting under the FFDCA. Id.

We reaffirmed this holding in Andrx. In Andrx, in an infringement action between a patentee and an ANDA filer, the district court shortened the thirty-month stay period, citing 21 U.S.C. § 355(j)(5)(B)(iii), because it found that the patentee's listing of the second patent in the Orange Book was done improperly to delay the resolution of the patent actions between the parties. We reversed, holding that "the district court ha[d] no authority in the infringement action, as opposed to an action under the Administrative Procedure Act, to shorten the thirty-month stay because of allegedly improper conduct before the FDA." Andrx at 1376, 61 USPQ2d at 1419. We held that a claim of improper conduct in the FDA proceeding was required to be raised initially before the FDA itself and thereafter in a judicial review proceeding brought under the APA. Id. at 1379, 61 USPQ2d at 1421.

We conclude that this case is governed by Mylan and Andrx. Like Mylan, 3M here attempts to assert a private right of action under the FFDCA because of another party's alleged failure to comply with the statute. As we held in Mylan,

> We see nothing in the Hatch-Waxman Amendments to alter the statement in section 337(a) of the FFDCA that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C § 337(a) (1994). "In a case in which neither the statute nor the legislative history reveals a congressional intent to create a private right of action for the benefit of the plaintiff," the inquiry is at an end. Northwest Airlines, Inc. v. Transp. Workers, 451 U.S. 77, 94 n.31, 101 S.Ct. 1571, 67 L.Ed.2d 750 (1981).

Mylan at 1332. Accordingly, we hold that appellants cannot seek a judicial determination of whether a private party's paragraph IV certification complies with 21 U.S.C. § 355(j)(2)(B). Thus, the district court should not have decided the issue of compliance.[4]

VI

We also hold that the district court did not abuse its discretion in ordering a dismissal with prejudice. Under Federal Rule of Civil Procedure 41(a)(2), once an answer or a motion for summary judgment has been filed, an action may be dismissed at the plaintiff's request only upon order of the court and upon such terms and conditions as the court deems proper. Here, because the district court's dismissal with prejudice was not contrary to law, we review that decision for an abuse of discretion, applying the law of the Eighth Circuit. Hamm v. Rhone-Pôulenc Rorer Pharms., Inc., 187 F.3d 941, 948 (8th Cir. 1999), cert. denied, 528 U.S. 1117 (2000). The district court here considered appellant's claimed entitlement to a dismissal without prejudice under Rule 41(a)(2), but found no legitimate justification for the appellants to dismiss the action without prejudice. The district court concluded that the appellants were seeking to avoid a judgment that would be adverse to their interest in delaying Barr's entrance in the market and that this was not a legitimate justification for their desire to dismiss without prejudice. Minn. Mining, 139 F. Supp. 2d at 1116.

Because the district court properly found that 3M had not offered a sufficient justification for a dismissal without prejudice, we hold that the district court did not abuse its discretion in denying 3M's motion. Indeed, under the circumstances, a dismissal without

[4] For the same reason, the district court did not err in failing to order that the grant of summary judgment would not trigger the 180-day period. Such an order would also constitute improper judicial enforcement of the provisions of the Hatch-Waxman Amendments, outside of the context of an APA suit.

prejudice might well have constituted an abuse of discretion since 3M was plainly seeking to avoid an adverse judgment. We also perceive no merit in Alphapharm's alternative contention that the district court erred in granting summary judgment without allowing it further discovery.

VII

Finally, in affirming the judgment of the district court, we think it appropriate to make clear what we are not deciding. First, we do not decide whether parties such as 3M and Alphapharm have standing to complain to the FDA, and to maintain a suit under the APA, concerning Barr's satisfaction of the paragraph IV certification requirement, nor do we decide when and whether the FDA must address such claims.[5] Second, we do not decide whether, if the FDA had determined that Barr did not satisfy the paragraph IV notice requirement, this would have entitled 3M to a dismissal without prejudice in the infringement suit. Third, we do not decide whether a dismissal without prejudice would avoid triggering the running of the first ANDA filer's 180-day exclusivity period. Finally, we do not decide Barr's alternative claim that a dismissal without prejudice would not have mooted Barr's counterclaims, which Barr agreed to dismiss in this case because the

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[5] The concurring opinion misreads the majority opinion in suggesting that it imposes a new administrative requirement that the FDA determine compliance with 21 U.S.C. § 355(j)(2)(B), a requirement which will require that district courts stay infringement suits pending a determination by the FDA or dismiss infringement claims without prejudice pending such a determination. Concurring Opinion at 6. The majority opinion does no such thing. We hold only that if there is an issue as to compliance with § 355(j)(2)(B), that question is not to be decided by the district court in an infringement suit. The majority makes no determination as to what the statutory requirements may be or even whether the FDA is required to or should adjudicate a claim that the statutory requirements are violated. We in no way suggest that it would be appropriate for the district court to stay an infringement action or dismiss without prejudice pending such a determination. All we hold in this respect is that claims of violation of § 355(j)(2)(B), claims which are asserted in this infringement action, cannot be adjudicated by a district court in this proceeding.

district court granted Barr's motion for summary judgment of noninfringement. Resolution of these questions must await another day. We hold only in this case that the district court properly dismissed 3M's infringement action with prejudice and granted Barr's motion for summary judgment of noninfringement because we cannot decide whether Barr complied with the statutory and regulatory requirements for providing notice of a paragraph IV certification, and the district court did not otherwise abuse its discretion.

CONCLUSION

For the foregoing reasons, we affirm.

COSTS

No costs.

United States Court of Appeals for the Federal Circuit

01-1369, -1370

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GAJARSA, Circuit Judge, concurring in judgment.

I agree with the majority that the judgment of the district court should be affirmed; however, I disagree with their attempt to impose an administrative requirement by an expansive interpretation of two of our prior decisions. The majority fails to address the key issues in this appeal and adds an entire layer of administrative complexity to create a sizeable procedural Gordian knot.

On the one hand, the majority affirms the lower court because it did not abuse its discretion in dismissing the action with prejudice after determining that the notice sent to 3M by Barr was in compliance with 21 U.S.C. § 355(j)(2)(B)(ii). Maj. Op. at 14. On the other hand, the majority holds that section 355(j)(2)(B)(ii) cannot be enforced by a private party in a patent infringement action but must be enforced in the context of the Administrative Procedure Act ("APA"). Maj. Op. at 11-12. It is inconsistent to say that the

trial court did not abuse its discretion in finding the notice sufficient in a non-APA action and thereby dismissing the action with prejudice, and then to conclude that the sufficiency of notice cannot be considered outside the context of the APA. If it is the case that the sufficiency of the notice cannot be considered, then the appropriate remedy is not to affirm the dismissal with prejudice but to remand to the district court to either stay the action pending administrative review of the sufficiency, or dismiss the action without prejudice so that it can be brought after the FDA has reviewed the sufficiency of the notice. Either way, affirming the district court implicitly condones its authority to assess the sufficiency of the notice. Moreover, the determination of who has authority to consider the sufficiency of notice is not necessary to resolve the issue before us. Once this court decides that there has been no abuse of discretion, the case is resolved. Furthermore, the issue of who can properly determine the sufficiency of notice was not raised below and was not briefed before us. Therefore, the holding with respect to the determination of section 355(j)(2)(B) is unadulterated sophistry.

The majority opinion fails to recognize the requirements of the specific policies expressed by the Congress when it enacted the Abbreviated New Drug Application ("ANDA") statutory scheme, 21 U.S.C. § 355(j). The statute was an attempt by the Congress to balance the competing interests between the patented drug and the generic drug manufacturers. In order to create an incentive for generic manufacturers, Congress provided the first manufacturer to successfully challenge a drug patent with a 180-day exclusivity period.

I. The Definition of "Court Decision"

The relevant statutory provision 21 U.S.C. § 355(j)(5)(B)(iv)(II)[1] has been interpreted to mean that the exclusivity period is triggered by a court decision finding that the patent is either invalid or not infringed. The Food and Drug Administration ("FDA") recognized that a "court decision" for purposes of triggering the exclusivity period in 21 U.S.C. § 355(j)(5)(B)(iv) is not limited to actions involving the first ANDA filer, as did the District of Columbia Circuit, in Teva Pharmaceuticals v. FDA, 182 F.3d 1003, 1009, 51 USPQ2d 1432, 1437 (D.C. Cir. 1999) (stating that a dismissal for lack of case or controversy of a declaratory judgment suit for noninfringement brought by a second ANDA filer "would appear to meet the requirements of a 'court decision'"). The majority wisely agrees. Maj. Op. at 7. The reason that "court decision" must be interpreted so that the exclusivity period can be triggered by a court decision of noninfringement or invalidity involving a subsequent ANDA filer, is that allowing first ANDA filers to hold up all the generic drug manufacturers for an indefinite amount of time would stifle Congress's attempt to expedite the marketing

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[1] 21 U.S.C. § 355(j)(5)(B)(iv) states in pertinent part:

> (iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after–
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> > (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
> >
> > (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (Supp. V 1999).

of generic products. The provision allowing a second ANDA filer to trigger the period by a "court decision" comports with the statute and the intent of Congress.

II. The Availability of a "Court Decision"

The Congressional policy with respect to generic drugs is clear: generic manufacturing of a drug should be allowed as soon as it is determined that it does not violate patent rights. Given this policy, the statute's provisions on the exclusivity period should not be read to reach nonsensical results. It should not be the case that a second ANDA filer whose method may infringe a patent can bring a suit that can trigger the exclusivity period, while a second ANDA filer whose method clearly does not infringe a patent cannot. In an effort to avoid this potential problem that has not yet been addressed by this court, Barr Labs, in this case, availed itself of the opportunities provided by the statutory scheme, by giving notice (albeit ambiguous) and inducing 3M to bring an action against them. The majority today, instead of addressing the correct interpretation of the statutory scheme and quelling the need for anyone to exploit the system, places another hurdle before the ANDA filers who clearly do not infringe: they must now survive administrative challenge to their paragraph IV certification notice before they can obtain a favorable judgment. There is no doubt that this process will increase the time period required to resolve these time-sensitive cases because district court infringement suits will need to be stayed pending administrative proceedings or may not be brought if the NDA patentee avails himself of the APA procedures proposed by the majority.

III. The Creation of an Unnecessary Administrative Quagmire

Today the majority extends the requirement of Mylan Pharmaceuticals, Inc. v. Thompson and Andrx Pharmaceuticals, Inc. v. Biovail Corp. beyond the necessary demands of the statute. Mylan, 268 F.3d 1323, 60 USPQ2d 1576 (Fed. Cir. 2001); Andrx, 276 F.3d 1368, 61 USPQ2d 1414 (Fed. Cir. 2002). In both of those cases the issue was whether or not the FDA had taken proper action in listing patents in the Orange Book. In Mylan, the ANDA applicant sued the FDA and the New Drug Application ("NDA") holder alleging that the pertinent patent had been improperly listed in the Orange Book. Mylan, 268 F.3d at 1328, 60 USPQ2d at 1580. This court held that there was no private cause of action for de-listing a patent. Id. at 1332, 60 USPQ2d at 1583. In Andrx, the ANDA applicant had complained before the district court that the FDA and the NDA patentee had improperly listed a patent in the Orange Book in violation of the APA and that they improperly stayed approval of Andrx's ANDA based on the patentee's filing of a new patent, which the FDA said triggered a new 30-month stay period. Andrx, 276 F.3d at 1373-74, 61 USPQ2d at 1415-16. This court held that Mylan did not preclude an APA challenge to the listing of a patent, but such a challenge was not properly brought in this case. Id. at 1378-80, 61 USPQ2d at 1421-22. It also held that the district court did not have authority, in an infringement action as opposed to an action under the APA, to shorten the stay period because of alleged improper conduct before the FDA. Id. at 1376, 61 USPQ2d at 1419-20. Both cases dealt with an action that alleged improper conduct by the FDA or between the patentee and the FDA. Thus it was logical to conclude that the FDA and the district court should have the first opportunity to resolve the matter. In this case, however, there is no improper conduct before the FDA. The plaintiffs do not complain of an improper interaction between the defendants and the FDA. The alleged improper

conduct according to 3M is the failure of the notice sent by Barr Labs to 3M. The FDA plays no role in the disputed matter. There is no statutory or regulatory requirement that the notice be sent to the FDA. Mylan and Andrx should not govern the case because in each of their instances FDA action was involved. Therefore the majority, by its blanket dicta, creates an unnecessary barrier to ANDA applicants that is totally outside of the statute.

Moreover, the proposed shift of the burden to the FDA is not required. The majority now metamorphosizes into an APA action the sufficiency of the statutory notice requirement, failing to perceive that under subparagraph 355(j)(2)(B)(i) an applicant who makes a paragraph IV certification "shall include in the application a statement that the applicant will give notice required by clause (ii) to –

(i) each owner of the patent . . . and

(ii) the holder of the approved [NDA] application. . . ."

The statute does not require the notice to be filed with the FDA, the body now given the task of adjudicating its sufficiency. Moreover, the FDA regulations, which are in compliance with the statute, state that "[a] copy of the notice itself need not be submitted to the agency." 21 C.F.R. § 314.95 (2001). This court is imposing its own independent requirement that the notice be subject to an APA proceeding. We are substituting our interpretation of the statute over the FDA's regulatory requirement by such an imposition.

Indeed the FDA has stated that the sufficiency of the notice is an issue to be resolved by the applicant and the patent owner without involvement of the FDA. The FDA published responses to comments about the proposed notice rules in the Federal Register. With respect to 21 C.F.R. § 314.52, which is almost identical to 21 C.F.R. § 314.95 but relates to the filing of subsequent NDAs which may infringe listed patents instead of ANDAs which may infringe listed patents, the FDA stated:

18. FDA received three comments on proposed § 314.52(c) regarding the content of a notice of certification of invalidity or noninfringement of a patent. . . .

In general, the statute requires a notice of certification of invalidity or noninfringement of a patent to state that an application has been submitted and to include "a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." (See section 505(b)(3)(B) and 355(j)(2)(B)(ii).) The proposed rule listed the type of information FDA considered necessary to enable patent owners to decide whether to sue for patent infringement. The list at proposed §§ 314.52(c) and 314.95(c) generated substantial debate, as reflected in the comments, as to the details to be included in a notice. The agency is neither prepared nor required to become involved in issues concerning sufficiency of notice for purposes of enforcing patent law. Therefore, FDA has revised both §§ 314.52(c) and 314.95(c) so that the detailed statement of the factual and legal basis behind the applicant's opinion that the patent is invalid, unenforceable, or will not be infringed must include: (1) For each claim of the patent alleged not to be infringed, a full and detailed explanation why the claim is not infringed; and (2) for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation. These provisions, as revised, paraphrase the statutory language. The sufficiency of the notice, for purposes of patent enforcement,

is an issue to be resolved by the applicant and the patent owner or the holder of the approved application.

Abbreviated New Drug Application Regulations; Patent Exclusivity Provisions, 59 Fed. Reg. 50338, 50342 (October 3, 1994) (emphasis added).

With respect to § 314.95, which relates to ANDAs, the FDA stated:

> 54. One comment recommended that FDA revise the regulation by adding a mechanism whereby FDA or the United States Patent and Trademark Office would review notices of certification of invalidity or noninfringement. The comment would have FDA suspend the 45-day period provided by section 505(j)(4)(B)(iii) of the act until FDA or the United States Patent and Trademark Office determined that the notice was sufficient.
>
> FDA declines to adopt the comment. As stated elsewhere in this preamble, FDA lacks expertise in patent law. Moreover, neither FDA nor the United States Patent and Trademark Office currently has access to the additional resources that would be necessary to review these notices, and a patent certification review system would subject the agency's decisions to questioning that would require further resource expenditures and create delays in the statutory patent certification and challenge process.
>
> The agency does note, however, that in cases where the notice was deemed

inadequate by the patent owner or exclusive patent licensee and where the ANDA applicant subsequently amends the notice, the agency may, if the applicant amends its ANDA with a written statement that the date of receipt of the amended notification should be considered the date of receipt of notice, use the date of the amended notification to begin the 45-day statutory period for institution of an action for patent infringement (see 54 FR 28872 at 28888; see also § 314.95(f)).

. . .

60. FDA received five comments regarding the exact contents of a notice of certification of invalidity or noninfringement of a patent. . . .

As noted above in comment 18, the agency did not anticipate that the list in proposed § 314.95(c) would generate the debate reflected in the comments and, again, reiterates that the agency does not have the expertise or the desire to become involved in issues concerning patent law and sufficiency of notice. Therefore, FDA has revised § 314.95 to require that the detailed statement of the factual and legal basis behind the applicant's opinion that the patent is invalid, unenforceable, or will not be infringed include the following: (1) For each claim of a patent alleged not to be infringed, a full and detailed explanation why the claim is not infringed; and (2) for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation (see §§ 314.52(c)(6)(i) and (c)(6)(ii) and 314.95(c)(6)(i) and (c)(6)(ii)). Disputes involving the sufficiency of the

notice must be resolved by the applicant, patent owner, and holder of the approved application rather than by action on the part of FDA.

61. FDA also received five comments opposing the use of a referee or designated intermediary under proposed § 314.95(c)(6)(iii). The proposal would have required an ANDA applicant to describe a mechanism for disclosing the formulation or composition of the proposed drug product to the patent owner or to a "designated intermediary who will act as a referee" on the subject of patent invalidity or noninfringement. The comments said that the concept was legally unauthorized and interfered with the traditional judicial process for resolving patent disputes.

FDA agrees that traditional processes for resolving patent disputes, which do not involve the agency's regulations, are appropriate under these circumstances. Therefore, the agency has deleted the provision in its entirety.

Id. at 50349-50 (emphasis added).

Thus, there is no doubt that FDA has no intention of entering into disputes over the sufficiency of the notice, and indeed is unqualified to do so. The statute is silent on the question of who determines the sufficiency of notice. Given such a statutory ambiguity, this court must defer to the agency's reasonable interpretation of the statute. Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843-44 (1984). The FDA has

reasonably interpreted the statute to mean that the FDA should not review the sufficiency of the notice. This court must defer to that interpretation.

IV. The Declaratory Judgment as the "Court Decision"

The majority's addition of new administrative obstacles certainly deters Barr-like behavior, but it does so by creating a disincentive to challenging drug patents. Yet the problem with Barr's type of "hoodwinking" is not that we do not want companies to challenge drug patents. The problem is that there is no sense in making second ANDA filers go through this labyrinth to trigger the exclusivity period that they have every right to trigger. Congress wanted second ANDA filers to be able to manufacture their drugs quickly if they could prove noninfringement. In a case where proving noninfringement is effortless, it should be a simple process.

Appellants argue that it would be frivolous for someone in Barr's position to seek a declaratory judgment of noninfringement. Therefore, appellants assert, Barr would have no standing to bring a declaratory judgment action.[2] This misses the logic of the statute. Because Congress has mandated a court decision in order to trigger the exclusivity period, it is incumbent upon second ANDA filers who clearly do not infringe to obtain a court decision. This is in accordance with the congressional purpose. They can do this in one of two ways: by being sued for infringement or by seeking a declaratory judgment.

Congress contemplated the availability of a declaratory judgment action in this context. Subsection (j)(5)(B)(iii) states:

> (iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately

[2] The irony of using the argument that the invention is so easily avoided as to create a frivolous declaratory judgment action as a way of preventing competitors from marketing their product appears to be lost on 3M.

unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that–

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

> In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

21 U.S.C. § 355(j)(5)(B)(iii) (Supp. V 1999) (emphasis added). This language indicates that while a declaratory judgment action is not available for ANDA filers during the forty-five day period, it is available after that period.

This court has repeatedly articulated the requirements for a declaratory judgment action in patent suits.

> In declaratory judgment patent suits, there are two prerequisites for establishing the existence of a case or actual controversy between the parties: first, the defendant must have engaged in conduct giving rise to a reasonable apprehension on the plaintiff's part that it will face an infringement suit or the threat of one if it commences or continues the activity in question; second, the plaintiff must have actually produced the accused device or have actually prepared to produce it.

Cordis Corp. v. Medtronic, Inc., 835 F.2d 859, 862, 5 USPQ2d 1118, 1120 (Fed. Cir. 1987) (citing, inter alia, Jervis B. Webb Co. v. Southern Sys., Inc., 742 F.2d 1388,

1398-99, 222 USPQ 943, 949 (Fed. Cir. 1984)); see also Sandt Tech., Ltd. v. Resco Metal and Plastics Corp., 264 F.3d 1344, 1356 n.4, 60 USPQ2d 1091, 1098 n.4, (Fed. Cir. 2001). The second prong of the test has been characterized as requiring "present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978, 28 USPQ2d 1124, 1126 (Fed. Cir. 1993).

Given that Congress contemplated the availability of declaratory judgment actions for ANDA filers, as seen in subsection (j)(5)(B)(iii), the language of 21 U.S.C. § 355(b)(1) setting forth the requirements for filing a NDA is not coincidental. That section states, in pertinent part that:

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1) (emphasis added). Thus, by the terms of the statute, filing an NDA application meets prong one of the declaratory judgment case or controversy requirement, because filing the application requires the patentee to maintain that an infringement suit could "reasonably be asserted" against one who "engages in the manufacture, use or sale of the drug." This is "conduct giving rise to a reasonable apprehension on the plaintiff's part that it will face an infringement suit or the threat of one." Cordis, 835 F.2d at 862, 5 USPQ2d at 1120.

Prong two is also met by statutory terms under 35 U.S.C. § 271 which defines submitting an ANDA application under § 355(j) for a drug claimed in a patent or the use of which is claimed in a patent to be an act of infringement. Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). This clearly meets the test as a "present activity which could constitute infringement."

Therefore, the logical conclusion, which also solves the dilemma in this case, is to make it clear that a declaratory judgment suit is available for ANDA filers who are not sued by the NDA patentee within the 45-day period. The two acts of (1) a patentee listing a patent in the Orange Book through the filing of a NDA, and (2) a generic manufacturer filing an ANDA, together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement.

It is noteworthy that the District of Columbia Circuit, which also handles a large number of ANDA cases, has suggested an alternative method of explaining the availability of declaratory judgment actions in this context. In Mova Pharmaceutical Corp. v. Shalala, the court stated,

> [T]he Federal Circuit has had no occasion to decide whether there is "a controversy of sufficient immediacy and reality" to support a declaratory judgment action, . . . when the plaintiff requires a judgment under section 355(j)(5)(B) in order to bring its product to market. It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a "case or controversy" without demonstrating an immediate risk of being sued.

140 F.3d 1060, 1073 n.18, 46 USPQ2d 1385, 1396 n.18 (D.C. Cir. 1998) (citations omitted). Therefore, the inability to market a product without a court decision may create sufficient case or controversy for purposes of a declaratory judgment action. Certainly, in cases such as this, there is a controversy over whether a triggering decision is permissible, and the parties have much at stake in that determination.

Whether the basis for a case or controversy for declaratory judgment purposes is the statutory threat and injury or the bottleneck, any resolution which does not allow for declaratory judgments in this context would result in the noninfringing methods being unable to trigger the exclusivity period, while the more ambiguous methods, causing a court action to be brought, would trigger the exclusivity period. The alternative, permitting declaratory judgment actions for paragraph IV certifiers, addresses the heart of the issue and cuts away the Gordian knot created by the majority. The sufficiency of a paragraph IV certification notice will rarely be challenged when there is no incentive to evade the notice. These additional administrative requirements imposed by the majority become unnecessary. I do not accept the majority's need to decide this case on such a digression.

V. The Majority's Loose Ends

In addition, Part VII of the majority opinion continues its illogical pursuit by positing numerous issues that it does not decide, including the standing of parties to bring an APA administrative proceeding before the FDA. If we do not decide them, then all of these observations and conclusions are advisory and dicta. It is unnecessary to delineate them in order to decide this appeal.

Because I find the majority's holding to be inconsistent with the goals established by Congress and inconsistent with the internal logic of the statute, I concur in judgment only.