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, filed a combined petition for rehearing and rehearing en banc for plaintiffs-appellants. On the petition were Allen M. Sokal, Charles E. Lipsey, David S. Forman, and Gregory A. Chopskie. Of counsel on the petition were Kevin H. Rhodes, and MarySusan Howard, Office of Intellectual Property Counsel, 3M Innovative Properties Company, of St. Paul, Minnesota.

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

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

Judge Michael J. Davis

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ON PETITION FOR REHEARING AND REHEARING EN BANC

O R D E R

A combined petition for rehearing and rehearing en banc was filed by the plaintiffs-appellants, and a response thereto was invited by the court and filed by the defendant-appellee. This matter was referred first to the merits panel that heard this appeal. Thereafter, the petition for rehearing en banc, and response were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition for rehearing is denied.

(2) The petition for rehearing en banc is denied.

LOURIE, Circuit Judge, with whom GAJARSA, Circuit Judge, joins, dissents in a separate opinion.

The mandate of the court will issue on July 8, 2002.

SCHALL, and LINN, Circuit Judges, did not participate in the vote.

FOR THE COURT

June 28, 2002
Date

/s/
Jan Horbaly
Clerk

cc: Allen M. Sokal, Esq.
Edgar H. Haug, Esq.
James F. Hurst, Esq.

United States Court of Appeals for the Federal Circuit

01-1369, -1370

MINNESOTA MINING AND MANUFACTURING COMPANY
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and

ALPHAPHARM PTY. LTD.,

Intervenor-Appellant,

v.

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Defendant-Appellee.

LOURIE, Circuit Judge, dissenting from the order denying rehearing en banc, in which Circuit Judge GAJARSA joins.

The panel majority's holding confuses an issue concerning a patent infringement action with a purely FDA matter. When an ANDA applicant makes a paragraph IV certification that it is not infringing a listed patent or that a listed patent is invalid, it is required under the statute to 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." 21 U.S.C. § 355(j)(2)(B)(ii). Such a statement is directly relevant to the patent infringement action that the patentee is entitled to bring. It is indeed different from the propriety of a listing of the patent in the FDA's Orange Book, which is the FDA's responsibility to administer. Moreover, the statement is made only to another private party, not to the FDA. Thus, Andrx and Mylan, which relate to the listing or delisting of a patent with the FDA, are not binding on the facts of this case. See Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 61

USPQ2d 1414 (Fed. Cir. 2002); Mylan Pharms. Inc. v. Thompson, 268 F.3d 1323, 60 USPQ2d 1576 (Fed. Cir. 2001).

I would go further, however, and even overrule Andrx and Mylan because, while, as indicated, they are somewhat distinguishable from this case, they do relate to listing of patents, a matter which the statute does not require be decided in an action brought by the United States. The FDA performs essentially a ministerial task when it lists patents in the Orange Book. See 21 C.F.R. § 314.53(f) (2001) (stating that the FDA will not change the patent information for a listing unless the NDA holder withdraws or amends its patent information in response to FDA's request that it confirm the correctness of that information). When the statute was enacted, the FDA never expected to have anything to do with substantive issues of patent listing and notice (see infra). Requiring patent listings to be addressed only by APA actions involving the FDA amounts in practical terms to a distortion of the provisions of the Food and Drug Act relating to patent listings and challenges.

The panel majority relies heavily on 21 U.S.C. §337(a), which requires that all enforcement proceedings of the FDA Act "shall be by and in the name of the United States," and interprets that statute as precluding parties in ANDA litigations from challenging compliance with the litigation provisions of that statute. I disagree. Section 337, although ostensibly inclusive ("all such proceedings") does not concern and cannot sensibly be read to govern compliance with provisions such as the requirement in 21 U.S.C. §355(j)(2)(B)(ii) that an ANDA applicant provide the NDA holder with a detailed statement of the bases for its patent non-infringement or invalidity position. In fact, § 337 long precedes the introduction of these patent issues into the Food and Drug Act, and plainly was not intended to govern the present type of dispute.

Rather, § 337 is typical of provisions in public laws that preclude citizen suits against private parties for enforcement of those provisions of the Act that are meant to benefit the public as a whole. Such suits are to be brought in the name of the United States. In contrast, the provisions of § 355 address, albeit briefly, the responsibilities of private parties engaged in private litigation. The detailed statement required by § 355(j)(2)(B)(ii) is intended to enable the NDA holder to evaluate the possible merits of an infringement suit. Courts, in infringement suits, should have the power to determine whether the parties are complying with that requirement of the statute. They have indeed done so. See Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1347-48, 56 USPQ2d 1641, 1647 (Fed. Cir. 2000) (affirming district court's award of attorney fees for Danbury's baseless paragraph IV certification); Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297, 1304, 57 USPQ2d 1813, 1818-19 (Fed. Cir. 2001) (concluding that Andrx's failure to notify Biovail of eleven amendments to the ANDA as required by § 355(j)(2)(B) did not warrant a determination of reversible error).

This is not a case in which 3M is asserting that noncompliance with § 355(j)(2)(B)(ii) constitutes an independent cause of action. Rather, compliance is ancillary to the underlying patent infringement suit, and as such should not properly be viewed as a separate action requiring separate resolution. Prompt resolution of the compliance issue is relevant to the prompt resolution of the underlying patent infringement action.

Moreover, a district court is in a better position than the FDA to determine whether an ANDA applicant has provided sufficient information in its § 355(j)(2)(B)(ii) statement because the court will be immersed in the litigation positions of the parties and will have a good sense of whether the certification was sufficiently detailed to enable the NDA holder to evaluate whether to sue within the forty-five-day statutory period. District courts have the power to rein in either party's attempts to delay litigation by controlling the timing of the

proceedings. See 21 U.S.C. § 355(j)(5)(B)(iii) (authorizing the district court to change the date on which an ANDA application may be approved if "either party to the action failed to reasonably cooperate in expediting the action"). Thus, if an NDA holder sought to delay the litigation (and thus prolong its exclusivity) by challenging compliance with § 355(j)(2)(B)(ii), the district court could expedite the suit so as to mitigate any timing advantage the NDA holder might have gained.

District courts also have inherent powers to determine the most appropriate remedy for noncompliance. If a statement of reasons why an ANDA applicant is not infringing or the patent is invalid is inadequate and unjustified litigation results, the district court could assess sanctions against the ANDA applicant. On the other hand, if adequate reasons are provided leading to a judicial conclusion that an infringement suit was frivolous or otherwise unjustified, sanctions against the patent owner might be appropriate. Moreover, the efficiency of any litigation is enhanced by compliance with the statutory requirement for a detailed statement of reasons. In any event, the district court is in the best position to assess the conduct of the parties and grant appropriate relief.

As Judge Gajarsa pointed out in his concurrence in the judgment in this case, the FDA did not desire or expect to adjudicate these disputes, as it clearly set forth in its Abbreviated New Drug Application Regulations, Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338 (Oct. 3, 1994):

> 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.

Id. at 50,350 (emphases added).

I believe this decision erroneously continues the trend begun in prior decisions shifting patent issues in litigation relating to the Hatch-Waxman Act from infringement suits in the district courts, where they belong, to APA actions involving the FDA, which is fully engaged in administering and enforcing the provisions of the Food and Drug Act relating to the health and safety aspects of foods and drugs. I would therefore rehear this case en banc and, overruling Andrx and Mylan, hold that resolution of patent issues arising in patent infringement suits relating to listing of patents and certification relating to patents is not governed by § 337 and should be decided by the district court before which the matter arises in an infringement suit. I thus dissent from the court's decision not to rehear this case en banc.