United States Court of Appeals for the Federal Circuit

2009-1032

BOEHRINGER INGELHEIM INTERNATIONAL GMBH
and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiffs-Appellants,

v.

BARR LABORATORIES, INC.
and BARR PHARMACEUTICALS, INC.,

Defendants,

and

MYLAN PHARMACEUTICALS, INC.,

Defendant-Appellee.

Shannon M. Bloodworth, Perkins Coie LLP, of Washington, DC, filed a combined petition for panel rehearing and rehearing en banc for defendant-appellee. With her on the petition was David J. Harth, The Law Office of David J. Harth, of Madison, Wisconsin.

Bruce M. Wexler, Paul, Hastings, Janofsky & Walker LLP, of New York, New York, filed a response to the petition for plaintiffs-appellants. With him on the response were Joseph M. O'Malley, Jr., Eric W. Dittmann and Angela C. Ni; and Stephen B. Kinnaird, of Washington, DC.

Vincent L. Capuano, Duane Morris LLP, of Boston, Massachusetts, for amici curiae Apotex, Inc. and Apotex, Corp. With him on the brief were Richard T. Ruzich, of Chicago, Illinois, Robert L. Byer, of Philadelphia, Pennsylvania, and Vicki G. Norton, of San Diego, California.

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

Judge Joseph J. Farnan, Jr.

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Appeal from the United States District Court for the District of Delaware in consolidated cases 05-CV-700 and 05-CV-854, Judge Joseph J. Farnan, Jr.

ON PETITION FOR REHEARING AND REHEARING EN BANC

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, RADER, BRYSON, GAJARSA, LINN, DYK, and PROST, Circuit Judges.[*]

PER CURIAM.

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissents from the denial of the petition for rehearing en banc.

O R D E R

Defendant-Appellee Mylan Pharmaceuticals Inc. filed a combined petition for panel rehearing and rehearing en banc. The panel requested a response from Plaintiffs-Appellants Boehringer Ingelheim International GmbH and Boehringer Ingelheim

[*] Circuit Judge Moore took no part in the consideration of this case.

Pharmaceuticals, Inc. The court granted Apotex, Inc. and Apotex Corp. leave to file a brief amici curiae in support of Defendant-Appellee's petition.

The petition for rehearing was considered by the panel that heard the appeal, and thereafter the petition for rehearing en banc, the response to the petition, and amici curiae brief were referred to the circuit judges who are authorized to request a poll on whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition of Defendant-Appellee Mylan Pharmaceuticals Inc. for panel rehearing is denied.

(2) The petition of Defendant-Appellee Mylan Pharmaceuticals Inc. for rehearing en banc is denied.

(3) The mandate of the court will issue on May 14, 2010.

FOR THE COURT

May 7, 2010
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Bruce M. Wexler, Esq.
Shannon M. Bloodworth, Esq.
Vincent L. Capuano, Esq.

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ON PETITION FOR REHEARING EN BANC

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissents from the denial of the petition for hearing en banc.

Because the majority's decision improperly expands the statutory safe-harbor provision of 35 U.S.C. § 121 beyond Congress's intended scope, I respectfully dissent from the court's denial of Mylan's petition for rehearing en banc. While the Supreme Court has not construed § 121, the majority's expansive opinion is inconsistent with our longstanding precedent, and will work a major change in our jurisprudence.

The purpose of § 121 is to prevent the inequity that resulted from an examiner's improper restriction requirement (separating out supposedly patentably distinct inventions that were in fact the same or not patentably distinct), whereby a patentee's

compliance with an examiner's incorrect restriction would result in the original application being used as a reference against the later divisional application and a rejection on double patenting grounds. See Pfizer, Inc. v. Teva Pharms. USA Inc., 518 F.3d 1353, 1361 (Fed. Cir. 2008); Studiengesellschaft Kohle mbH v. N. Petrochem. Co., 784 F.2d 351, 359 (Fed. Cir. 1986) (Newman, J., concurring). Thus, § 121 "effects a form of estoppel" against the PTO, "that shields the applicant from having to prove the correctness of the restriction requirement in order to preserve the validity of the second patent." Studiengesellschaft, 784 F.2d at 361. In our past decisions, we have limited § 121 in accordance with its language and clear purpose to situations in which the patent applicant has been forced to divide his application by action of the PTO. We have interpreted the statute to include a requirement of consonance, requiring that the later application or applications follow the original examiner's restriction requirement, and we have interpreted the statute to include a requirement that the later application or application be filed "as a result of" the original PTO restriction.

In addressing § 121, the majority opinion commits two legal errors. First, it significantly undermines this court's "consonance" precedence by permitting a patentee to ignore the examiner's demarcation of independent and distinct inventions in subsequent divisional applications. Second, it engages in an impermissible and expansive reading of § 121's "as a result of" language. Either error in isolation would be worthy of en banc review; coupled together, the errors threaten to significantly broaden § 121's safe-harbor provision in clear defiance of this court's "strict test for application of § 121." Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1382 (Fed. Cir. 2003).

I. BACKGROUND

There is no dispute as to the operative facts in Boehringer Ingelheim v. Barr Laboratories, Inc., 592 F.3d 1340 (Fed. Cir. 2010). The patentee filed U.S. Patent Application No. 06/810,947 (the "First Application") on December 19, 1985. The First Application contained fifteen claims directed to a variety of compounds, methods of using those compounds, and methods for preparing those compounds. An examiner issued a restriction requirement dividing the fifteen claims into ten groups (five compound groups, two process groups, and three method of use groups) and instructed the patentee to elect either (1) one of the compound groups and one of the method of use groups or (2) one of the process groups. The patentee elected to claim one of the compound groups and one of the method of use groups in the First Application.

Subsequently, the patentee filed U.S. Patent Application No. 07/124,197 (the "Second Application") as a divisional of the First Application. The Second Application initially contained all the remaining claims from the First Application, but ultimately only claimed the remaining method of use groups (excluding the method of use combined with the particular compound claimed in the First Application). The Second Application issued as U.S. Patent No. 4,843,086 (the "'086 patent"). While the Second Application was pending, the patentee filed U.S. Patent Application No. 07/256,671 (the "Third Application"), as a divisional of the Second Application. The Third Application claimed the remaining four compound groups and issued as U.S. Patent No. 4,886,812 (the "'812 patent").

It is undisputed that the Second and Third Applications claim more than one of the independent and distinct inventions identified in the examiner's restriction requirement. It is also undisputed that the PTO did not issue a restriction requirement against the Second Application.

In the underlying litigation, Mylan alleged that the '812 patent was invalid for obviousness-type double patenting based on the '086 patent. The district court held that Boehringer could not seek shelter in § 121's safe-harbor provision and invalidated the '812 patent for obviousness-type double patenting. See Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc., 562 F.Supp.2d. 619, 635, 640 (D. Del. 2008). The majority reversed and remanded holding that (1) the patentee did not err in combining independent and distinct inventions in subsequent divisional applications and (2) the patentee's motivations for filing subsequent divisional applications were irrelevant so long as the later-filed claims could have been filed in the initial application absent the restriction requirement. See Boehringer, 592 F.3d at 1352-54.

II. CONSONANCE

In holding that later divisional applications filed in response to a restriction requirement "need not be limited to a single one of the examiner's demarcated inventions to preserve the right to rely on the safe harbor of § 121," Boehringer, 592 F.3d at 1354, the majority's opinion seriously undermines this court's requirement that "the applicant must maintain the line of demarcation between the independent and distinct inventions that prompted the restriction requirement." Pfizer, 518 F.3d at 1359.

In Boehringer, the examiner issued a restriction requirement on the First Application because it contained several distinct and independent inventions. To satisfy

the examiner, the patentee elected to prosecute one of the distinct and independent inventions in the original application. The patentee did this, not out of convenience, but because he was required to by the PTO. See 35 U.S.C. § 121 ("[T]he Director may require the application to be restricted to one of the inventions." (emphasis added)). The patentee then filed the Second Application, including four inventions that the original examiner found to be distinct, and a Third Application also combining inventions that the original examiner found to be distinct.

The majority holds consonance is met because "[n]one of the inventions claimed as between the '374 original patent, the '086 division, and the '812 division of the division, crosses the examiner's lines of demarcation of inventions identified in the restriction requirement." Boehringer, 592 F.3d at 1354. Under this approach, the fact that multiple independent and distinct inventions are claimed within a single application – the very reason the PTO issued the original restriction requirement – is of no concern. This is neither consistent with our precedent nor with the purpose of the statute.

Our precedent in Texas Instruments Inc. v. U.S. International Trade Commission, 988 F.2d 1165 (Fed. Cir. 1993) and Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc., 98 F.3d 1563 (Fed. Cir. 1996) requires later applications filed in response to a restriction requirement "keep separate the inventions that the original examiner identified as being separate." Boehringer, 592 F.3d at 1359 (Dyk, J., dissenting). In both Texas Instruments and Applied Materials, the patentee was entitled to § 121's safe-harbor provision because he filed separate divisional applications for each invention identified by the restriction requirement as independent and distinct. See Texas Instruments, 988 F.2d at 1179; Applied Materials, 98 F.3d at 1568 ("[T]he

examiner's demarcation among the separate inventions should be preserved." (emphasis added)).

The majority relies on Gerber Garment Technology, Inc. v. Lectra System, Inc., 916 F.2d 683, 688 (Fed. Cir. 1990) to support its holding. See Boehringer, 592 F.3d 1354. While Gerber Garment mentions limiting a subsequent divisional to "[a] non-elected invention or inventions," there were only two inventions in the original patent application. Id. at 684. Conversely, Texas Instruments involved an original patent application with three distinct and independent inventions. See id. at 1178-79. There, the court stressed, citing the Gerber Garment language relied upon by the majority, that the patentee had to maintain the "demarcation between the independent and distinct inventions." Id. at 1179 (internal quotation marks omitted). In Texas Instruments, the patentee divided the three inventions into three divisional applications, and we found no obviousness-type double patenting. See id.

If an examiner's initial restriction requires a patentee to elect only "one of the inventions" to prosecute, see 35 U.S.C. § 121, I see no logical reason why the patentee should be permitted to combine the remaining inventions into a subsequent single divisional application. Indeed, § 121 refers to "the other invention" being made "the subject of a divisional application," suggesting that the subsequent divisional would contain only the other invention demarcated by the examiner's restriction requirement. The majority's broad language would allow patentees to respond to a restriction requirement by electing to prosecute a later divisional application ignoring the original restriction requirement and claiming more than one separate and distinct invention. Section 121 clearly forbids this.

III. THE "AS A RESULT OF" LANGUAGE

Not only does the majority's opinion undermine our consonance precedence, it misconstrues § 121's "as a result of" language. Section 121 states in part: "A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference . . . ." (emphasis added). The majority's opinion interprets the phrase "as a result of such a requirement" to mean simply that "absent the restriction requirement, the applicant could have retained in the [First Application] . . . the claims prosecuted in the [Third Application]." Boehringer, 592 F.3d at 1353 n.3.

In so interpreting § 121, the majority approves the patentee's decision to file a second divisional (i.e., the Third Application), not because of a second restriction requirement placed on the Second Application or because of the original restriction requirement, but because the patentee feared an interference proceeding with a competitor. See Boehringer, 562 F. Supp. at 634 ("[T]he prosecution history suggests that Boehringer chose to file the preliminary amendment canceling the claims in the '086 patent in order to place them in the [Third Application] because of concerns over potentially interfering matter in a patent filed by Eli Lilly, No. 747,748."). In response to a claim rejection – not a restriction requirement – the patentee removed various claims directed to certain inventions from the Second Application and placed them in a second divisional application, the Third Application. See id. It is indisputable that the second divisional was filed in response to a rejection not "as a result of [] a [restriction] requirement." 35 U.S.C. § 121. It is unclear how the second divisional can be "due to the administrative requirements imposed by the Patent and Trademark Office," when no

such requirement was imposed on the Second Application, and the applicant was not following the original restriction requirement. See Boehringer, 592 F.3d at 1353 n.3 (quoting Applied Materials, 98 F.3d at 1568).

The majority's construction of § 121 is untenable and its approval of the patentee's conduct unwise. Section 121's unambiguous language provides a safe-harbor only for those divisional applications filed "as a result of" the initial restriction requirement. Our predecessor court, the Court of Customs and Patent Appeals, invalidated claims in a later-filed divisional application because the later-filed divisional was not a "result of" a restriction requirement since the original restriction was withdrawn. See In re Ziegler, 443 F.2d 1211, 1215-16 (CCPA 1971); see also Bristol-Myers Squibb Co. v. Pharmachemie B.V., 361 F.3d 1343, 1348 (Fed. Cir. 2004) (holding that a divisional was not filed "as a result of" a restriction requirement where the original restriction requirement in the parent application was later superseded by a new restriction requirement in a continuation application). The Manual of Patent Examining Procedure ("MPEP") also states that § 121's safe harbor "does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction." MPEP § 804.01 (2008). Here, there is no question that the Second Application was not the subject of a restriction requirement compelling the filing of the Third Application.

* * *

Finally, Title 35's compliance with the Uruguay Round Agreement Act does not alleviate my concerns with the majority's opinion. While the terms for all patent applications filed on or after the June 8, 1995 effective date of the Uruguay Round

Agreement Act are fixed at twenty years from "the date on which the application for the patent was filed in the United States," 35 U.S.C. § 154, double-patenting rejections remain important during examination for the thousands of applications filed before 1995 as to which divisional applications remain pending. Even as to applications filed after 1995, the PTO regulations point out that double-patenting remains important with respect to applications subject to prosecution delay extensions. See MPEP § 804.02 ("Terminal disclaimers required to overcome nonstatutory double patenting rejections in applications filed on or after June 8, 1995.").

IV. CONCLUSION

"[T]his court applies a strict test for application of § 121." Geneva Pharms., Inc., 349 F.3d at 1382. I believe the majority's opinion significantly weakens our § 121 jurisprudence, leaving open the possibility for "extreme mischief." Id. at n.2 (quoting Martin J. Adelman, Patent Law Perspectives § 2.8[2] at 2-921 (2d ed. 1997)). Section 121's safe-harbor provision "can extend the patent term for inventions that are not patentably distinct" and provide patentees with a "potential windfall." Id. Such protection is antithetical to the patent system's quid pro quo in which the public "receive[s] meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time." Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 970 (Fed. Cir. 2004). Because § 121 is an exception to the patent system's quid pro quo, it should be strictly construed. Accordingly, I dissent from the court's denial of Mylan's request for rehearing en banc.