United States Court of Appeals for the Federal Circuit

SUN PHARMACEUTICAL INDUSTRIES, LTD.,
Plaintiff-Appellee,

v.

ELI LILLY AND COMPANY,
Defendant-Appellant.

2010-1105

Appeal from the United States District Court for the Eastern District of Michigan in case no. 07-CV-15087, Judge George Caram Steeh.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

CHARLES E. LIPSEY, Finnegan, Henderson, Farabow, Garrett & Dunner LLP, of Reston, Virginia, filed a combined petition for panel rehearing and rehearing en banc for defendant-appellant. He also filed a reply to the brief amici curiae of Teva Parenteral Medicines, Inc., et al. With him on the petition and reply were ROBERT D. BAJEFSKY, HOWARD W. LEVINE, ROBERT F. SHAFFER, and JESSICA R. UNDERWOOD, of Washington, DC. Of counsel on the petition and reply was JAMES P. LEEDS, Eli Lilly and Company, of Indianapolis, Indiana.

JAMES F. HURST, Winston & Strawn LLP, of Chicago, Illinois, filed a response to the combined petition for plaintiff-appellee. With him on the response were GAIL J. STANDISH and PETER E. PERKOWSKI, of Los Angeles, California.

MATTHEW D. MCGILL, Gibson, Dunn & Crutcher LLP, of Washington, DC, for amicus curiae Washington Legal Foundation. With him on the brief was WILLIAM G. JENKS. Of counsel on the brief were DANIEL J. POPEO and RICHARD A. SAMP, Washington Legal Foundation, of Washington, DC.

LESLIE MORIOKA, White & Case LLP, of New York, New York, for amicus curiae Biotechnology Industry Organization. Of counsel on the brief were HANS SAUER, Biotechnology Industry Organization, of Washington, DC; CHRISTOPHER M. HOLMAN, UMKC School of Law, of Kansas City, Missouri.

DAVID W. OGDEN, Wilmer Cutler Pickering Hale and Dorr LLP, of Washington, DC, for amicus curiae Pharmaceutical Research and Manufacturers of America. With him on the brief were DAVID A. MANSPEIZER, of New York, New York and FELICIA H. ELLSWORTH, of Boston, Massachusetts.

ELIZABETH J. HOLLAND, Kenyon & Kenyon LLP, of New York, New York, for amici curiae Teva Parenteral Medicines, Inc. and Teva Pharmaceuticals USA, Inc. With her on the brief was SHEILA MORTAZAVI.

Before RADER, *Chief Judge*, NEWMAN, LOURIE, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, *Circuit Judges*.

PER CURIAM.

NEWMAN, *Circuit Judge*, with whom RADER, *Chief Judge*, and LOURIE and LINN, *Circuit Judges*, join, dissents from the denial of the petition for rehearing en banc.

O R D E R

A combined petition for panel rehearing and rehearing en banc was filed by Defendant-Appellant, and a response thereto was invited by the court and filed by Plaintiff-Appellee. The court granted leave to Defendant-Appellant to file a reply.

The court also granted leave to file briefs amici curiae to Pharmaceutical Research and Manufacturers of America, Biotechnology Industry Organization, Washington Legal Foundation, and Teva Parenteral Medicines, Inc. (f/k/a SICOR Pharmaceuticals, Inc.), et al. Appellant filed a motion for leave to file a reply to the brief amici curiae filed by Teva Parenteral Medicines, Inc., et al.

The petition for panel rehearing was considered by the panel that heard the appeal, and thereafter the petition for rehearing en banc, response, reply, and briefs amici curiae (and Appellant's reply thereto) 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) Appellant's motion for leave to file a reply to the brief amici curiae submitted by Teva Parenteral Medicines, Inc., et al. is granted.

(2) The petition of Defendant-Appellant for panel rehearing is denied.

(3) The petition of Defendant-Appellant for rehearing en banc is denied.

(4) The mandate of the court will issue on November 8, 2010.

FOR THE COURT

November 1, 2010 /s/ Jan Horbaly

Date Jan Horbaly
Clerk

cc: James F. Hurst, Esq.
Charles E. Lipsey, Esq.
Leslie Morioka, Esq.
David W. Ogden, Esq.
Elizabeth J. Holland, Esq.
Matthew D. McGill, Esq.

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ON PETITION FOR REHEARING EN BANC

NEWMAN, Circuit Judge, with whom RADER, Chief Judge, and LOURIE and LINN, Circuit Judges, join, dissenting from denial of the Petition for Rehearing En Banc.

I respectfully dissent from the court's denial of the request to rehear this case *en banc*, for inconsistent precedent warrants clarification. Until recently the law of double patenting was clear, but it has become distorted by divergent statements, leading to this flawed ruling.

Until recently it was beyond dispute that the law of double patenting is concerned only with what is patented—that is, what is claimed. To determine whether there is double patenting it is the claims that are compared; thus, obviousness-type double patenting occurs when the claims of a later patent are an obvious variant of the claims of an earlier patent. The specifications of the patents are irrelevant to the double patenting analysis, other than to guide in construing the claims. A double patenting analysis occurs only when the earlier patent is not prior art against the later patent.

For the patents here at issue, the first application filed on behalf of the Eli Lilly inventors described a new class of chemical compounds having antiviral utility, including the compound named gemcitabine. Thereafter, Lilly filed a continuation-in-part application disclosing but not claiming the anticancer utility of gemcitabine, and on the same day Lilly filed a separate application having a different inventive entity, describing and claiming the use of gemcitabine to treat cancer.[1] The parent specification, but not the continuation-in-part, is prior art against the application claiming the anticancer use.

It has been held that the claims to gemcitabine and its antiviral use do not render obvious the claims to use of gemcitabine to treat cancer, and that the anticancer use claims are patentable over all of the known prior art.[2] This

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[1] Lilly explains that the anticancer information was concurrently added to the specification for the compound claims in an abundance of caution concerning the "best mode" of use of these compounds.

[2] After the district court here entered final judgment, a district court held that the earlier patent disclosing gemcitabine and its antiviral use do not render the anticancer method claims obvious under §103. *See Eli Lilly & Co. v.*

issue is not now before us. However, the panel held the claims to the anticancer use to be invalid for double patenting because the anticancer use was mentioned (but not claimed) in the continuation-in-part specification that is not prior art, stating that "[t]he asserted claims of the later '826 patent simply claim the anticancer use disclosed in the specification of the '614 patent," reported at 611 F.3d at 1389. This is the double patenting ruling for which Lilly seeks review *en banc*.

The law of double patenting is contrary to the panel's holding. In *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1277 (Fed. Cir. 1992), the court stated the established rule that "[d]ouble-patenting is altogether a matter of what is claimed." Precedent illustrates this rule in a variety of situations. *See id.* at 1281 ("Our precedent makes clear that the *disclosure* of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, *even where the disclosure is found in the claims*."); *In re Braat*, 937 F.2d 589, 594 n.5 (Fed. Cir. 1991) ("The patent disclosure must not be used as prior art."); *In re Kaplan*, 789 F.2d 1574, 1579 (Fed. Cir. 1986) ("In considering the question [of obviousness-type double patenting], the patent disclosure may not be used as prior art.").

This law was also fully established in our predecessor court. *E.g.*, *In re Vogel*, 422 F.2d 438, 441 (CCPA 1970) ("In considering the question [of obviousness-type double patenting], the patent disclosure may not be used as prior art."); *In re Plank,* 399 F.2d 241, 242 (CCPA 1968) ("Its claims are used as the basis for a double patenting rejection. It is not a prior art reference."); *In re Aldrich,* 398 F.2d 855, 859

Sicor Pharms., Inc., 705 F. Supp. 2d 971, 1004–10 (S.D. Ind. 2010).

(CCPA 1968) ("[W]e reiterate that double patenting rejections cannot be based on section 103, or on the disclosures of the patents whose claims are relied on to demonstrate double patenting or on the 'disclosures' of their claims."); *In re Boylan,* 392 F.2d 1017, 1018 n.1 (CCPA 1968) ("[I]n analyzing cases of these types, it must always be carefully observed that the appellant's patent is not 'prior art' under either section 102 or section 103 of the 1952 Patent Act . . . ."); *In re Braithwaite,* 379 F.2d 594, 600 n.4 (CCPA 1967) ("While analogous to the non-obviousness requirement of 35 U.S.C. § 103, that section is not itself involved in double patenting rejections because the patent principally underlying the rejection is not prior art."); *In re Borah,* 354 F.2d 1009, 1018 (CCPA 1966) ("We have no prior art here."); *In re Sutherland,* 347 F.2d 1009, 1015 (CCPA 1965) (stating that claims relied on in double patenting rejections are not treated as prior art); *In re Sarett,* 327 F.2d 1005, 1013 (CCPA 1964) ("We are not here concerned with what one skilled in the art would be aware from reading the claims but with what inventions the claims define.").

Uniformly, unlike examination for obviousness based on prior art, the issue of obviousness-type double patenting is directed to whether the invention claimed in a later patent is an obvious variant of the invention claimed in an earlier patent. The panel opinion violates a vast body of precedent.

The panel apparently was misdirected by an overly-broad statement in *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003). *Geneva* stated that "[o]ur predecessor court recognized that a claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." *Id.* at 1385–86. The court cites a 1931 decision, *In re Byck*, 48 F.2d 665, 666 (CCPA 1931), in which the court stated:

> It would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted.

The *Geneva* decision does not mention *Byck*'s further statement that the patentee "might have disclosed a use of the invention which, together with other elements, might have constituted a separate invention for which he would be entitled to a patent. This, we hold, he did not do, in view of the [prior art] Baekeland reference." *Id.* at 667. However, as in this case, there is no "shock" to "one's sense of justice" where the non-obvious, later-claimed use is the result of a later discovery. Yet the statement in *Geneva* took on a life of its own, as in *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008), where the court declined to apply section 121 (negating double patenting among divisionals) and found double patenting despite a restriction requirement, citing *Geneva* for authority.

Extending *Geneva* to cover the facts of this case does not further the policy of obviousness-type double patenting. "Obviousness-type double patenting is a judicially created doctrine intended to prevent *improper* timewise extension of the patent right by prohibiting the issuance of claims in a second patent which are not 'patentably distinct' from the claims of a first patent." *Braat*, 937 F.2d at 592. The panel failed to explain how Lilly's claims to the use of gemcitabine to treat cancer, discovered after gemcitabine's antiviral use was disclosed in the original application, improperly extend the patent right to gemcitabine as a compound, let alone

how these claims would "shock one's sense of justice." For purposes of this case, there is no dispute that Lilly would be entitled to a separate patent on the anticancer use if Lilly had not included the disclosure of anticancer use in the specification of the continuation-in-part filed the same day. Such disclosure does not "improperly extend" any patent.

The *amici curiae* explained that particularly for biological/pharmaceutical products, new uses may be discovered as research continues after the initial filing. The Biotechnology Industry Organization explains:

> BIO's members routinely engage in continuing research on basic biotechnology inventions even after initial patent applications have been filed. Often, such research reveals something new about a basic invention, including better and unexpected new ways of using it that require patent protection for their commercial development.

Br. of *Amicus Curiae* in Support of Def.-Appellant Eli Lilly & Co.'s Combined Pet. for Panel Reh'g and Reh'g *En Banc* at 1.

A change of law "in ways that negatively impact the patentability of important later-discovered uses" serves no public purpose in areas in which commercial development requires patent protection. *Id.* If the majority of the court now believes, as a matter of policy, that the law should be changed in this new direction, *en banc* treatment is particularly appropriate, for the court's rule is that the earlier precedent prevails unless overruled *en banc*. A situation in which the court ignores this rule, and applies whatever law the panel prefers, is an indictment of the ability of this court to provide stable law in the areas entrusted to us.

The denial of Eli Lilly's petition for rehearing *en banc* leaves the innovation community without guidance on which the trial courts, and the users of the patent system, can rely. I respectfully dissent.