

United States Court of Appeals for the Federal Circuit

99-1262, -1263, -1264, -1303

ELI LILLY AND COMPANY,

Plaintiff-Cross Appellant,

v.

BARR LABORATORIES, INC.,

and

APOTEX, INC. and BERNARD C. SHERMAN,

and

GENEVA PHARMACEUTICALS, INC.,

Defendants-Appellants,

and

INTERPHARM, INC.,

Defendant.

Charles E. Lipsey, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for plaintiff-cross appellant, Eli Lilly and Company. With him on the brief were Allen M. Sokal, Kenneth M. Frankel, and David S. Forman. Of counsel was L. Scott Burwell. Of

counsel on the brief were [Douglas K. Norman](#), and [James P. Leeds](#), Eli Lilly and Company, of Indianapolis, Indiana.

[Richard S. Clark](#), [Rochelle K. Seide](#), [Marta E. Delsignore](#), [Louis Sorell](#), [Robert Neuner](#), and [Thomas J. Parker](#), Baker & Botts, of New York, New York, for defendant-appellant, Geneva Pharmaceuticals, Inc.

[George C. Lombardi](#), Winston & Strawn, of Chicago, Illinois, argued for defendant-appellant Barr Laboratories, Inc. With him on the brief were [James F. Hurst](#), [Dan K. Webb](#), [Bradley C. Graveline](#), [Christine J. Siwik](#), and [Taras A. Gracey](#). Of counsel on the brief was [Mark E. Waddell](#), Bryan Cave, LLP, of New York, New York. Of counsel was [Derek John Sarafa](#).

[Hugh L. Moore](#), and [Diane I. Jennings](#), Lord, Bissell & Brook, of Chicago, Illinois for defendants-appellants Apotex, Inc. and Bernard C. Sherman.

[Jeffrey P. Kushan](#), Powell, Goldstein, Frazer & Murphy LLP, of Washington, DC, for amicus curiae Biotechnology Industry Organization. Of counsel on the brief were [Richard Medway](#) and [Eric M. Solovy](#), Powell, Goldstein, Frazer & Murphy LLP; and [Charles E. Ludlam](#), Biotechnology Industry Organization, of Washington, DC.

[William L. Mentlik](#), Lerner, David, Littenberg, Krumholz & Mentlik, LLP, of Westfield, New Jersey, for amicus curiae Zenith Goldline Pharmaceuticals, Inc.

[Joseph P. Lavelle](#), Howrey Simon Arnold & White, of Washington, DC, for amicus curiae Intellectual Property Owners Association.

[John C. Vassil](#), Morgan & Finnegan, L.L.P., of New York, New York, for amicus curiae Federal Circuit Bar Association. With him on the brief were [Michael P. Dougherty](#), [Tony V. Pezzano](#), and [Tini Thomas](#). Of counsel on the brief were [George E. Hutchinson](#) and [Philip C. Swain](#), Federal Circuit Bar Association, of Washington, DC.

[Janice M. Mueller](#), Associate Professor, The John Marshall Law School, of Chicago, Illinois, amicus curiae.

[Nancy J. Linck](#), Guilford Pharmaceuticals Inc., of Baltimore, Maryland, for amicus curiae Guilford Pharmaceuticals Inc.

Appealed from: United States District Court for the Southern District of Indiana

Chief Judge Sarah Evans Barker

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ORDER

Eli Lilly and Company filed a combined petition for panel rehearing and rehearing en banc. Responses thereto were invited by the court, and filed by Geneva Pharmaceuticals, Inc., and Barr Laboratories, Inc. The petition for rehearing and responses were referred to the panel that heard the appeal, and thereafter, referred to the circuit judges who are in regular active service.

Acting en banc, the court accepted the petition for rehearing en banc, and vacated the panel's opinion entered on August 9, 2000, which is reported at 222 F.3d 973 (Fed. Cir. 2000). The en banc court reassigned the appeals to the panel, which issues a separate opinion today.

Circuit Judge Newman dissents in a separate opinion.

Circuit Judge Linn did not participate in the vote.

FOR THE COURT,

May 30, 2001 Jan Horbaly

Date Jan Horbaly

Clerk

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NEWMAN, Circuit Judge, dissenting from the refusal to reconsider the case *en banc*.

The Federal Circuit, sitting *en banc*, vacated the panel's prior opinion issued on August 9, 2000 and returned the case to the panel for further consideration. The panel now again holds claim 7 of the '549 (Molloy) patent invalid for double patenting, but this time it bases that determination on a different patent, the '213 patent (Stark). The panel now grants summary judgment invalidating claim 7 of the '549 patent for double patenting with the Stark patent.

However, this shift has led the panel into factual and legal areas that were not developed at trial, and into misapplication and misstatement of the law of double patenting. I must, respectfully, dissent.

Obviousness-Type Double Patenting

The judgemade law of obviousness-type double patenting was developed to cover the situation where patents are not citable as a reference against each other and therefore can not be examined for compliance with the rule that only one patent is available per invention. Double patenting thus is applied when neither patent is prior art against the other, usually because they have a common priority date. See General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1278-81, 23 USPQ2d 1839, 1843-46 (Fed. Cir. 1992) (summarizing the criteria for obviousness-type double patenting). As the court explained in In re Boylan, 392 F.2d 1017, 1018 n.1, 157 USPQ 370, 371 n.1 (CCPA 1968), "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."

These fundamental requirements for application of the law of double patenting are not met by the '549 and Stark patents. The Stark patent was filed nine years after the effective filing date of the '549 patent; there is no formal relationship between them; the '549 disclosure was a cited reference against Stark; and they have different inventorships. The panel ignores these routine criteria and the effect they have on a double patenting analysis. Whatever effect the '549 and Stark patents may have on each other, it is not "double patenting."

The district court had rejected Barr's double patenting arguments after summary judgment proceedings, ruling that:

Barr's primary contention is that claim 7 of the '549 patent is invalid for double patenting because it merely sets forth the "scientific explanation" for the subject matter of certain of Lilly's other patents. Barr's summary judgment briefing on this issue is a confusing amalgamation of broad patent law principles that are not clearly applicable to the issues before the Court. In fact, the only case law cited in support of its theory is a dissenting opinion, never adopted thereafter by any court as best we could determine. Even disregarding any limitation on the application of this legal theory to the issues at hand, we observe that Barr's briefs focus extensively on the formulation and restatement of its legal theory to the exclusion of any evidence sufficient to explain or support it. Most notably, Barr has failed to provide any authoritative, reliable scientific opinion to establish that claim 7 of the '549 patent constitutes merely the later scientific explanation of what has already been claimed in the patents that came before.

On presumably the same record, the panel now grants summary judgment and *sua sponte* finds double patenting between claim 7 of the '549 patent and claim 1 of the Stark patent. The '549 disclosure, in the form of three issued divisional patents, was prior art cited against the Stark patent. Patentability of the Stark claims over this prior art was successfully argued in the PTO. The panel reaches the anomalous conclusion that the earlier filed '549 patent (effective

filing date January 10, 1974) is invalid for obviousness-type double patenting with the Stark patent that was filed nine years later (April 8, 1983). Such a result is not available under the laws of 35 U.S.C. §102 and §103; neither can it be achieved under the rubric of double patenting.

The claims are:

Claim 7 of the '549 Molloy patent:

The method of claim 4 [blocking the uptake of monoamines by brain neurons in animals] comprising administering to said animal a monoamine blocking amount of N-methyl-3--p-trifluoromethylphenoxy)-3-phenylpropylamine [fluoxetine] or a pharmaceutically-acceptable acid addition salt thereof.

Claim 1 of the '213 Stark patent:

A method for treating anxiety in a human subject in need of such treatment which comprises the administration to said human of an effective amount of fluoxetine or norfluoxetine or pharmaceutically-acceptable salts thereof.

The panel holds that the later-discovered and later-filed anxiety-treatment use of fluoxetine invalidates the patent on the earlier discovery of monoamine (serotonin) blocking use because the earlier discovery is "inherent" in the later one. That is not a correct statement of either the law of double patenting or the law of inherency. The 1974 invention can not be invalidated based on what was filed and claimed in the 1983 application, even on the panel's incorrect view of the law of inherency as applied to biological inventions.

The district court remarked on the absence of reliable evidence as well as legal precedent to support Barr's proffered theories. The panel, however, finds that "Barr has offered a panoply of evidence to support the recognition of this inherent biological function." Panel op. at 23. I take note that the panel cites only references dated after the '549 application was filed. These references are not prior art to the '549 claims. Later discoveries and scientific advances may well elucidate the earlier ones, but that does not retrospectively erase the patentability of the earlier work.

The complex factual issues that have been raised in the record, in connection with the relationship between serotonin uptake and the various pharmaceutical uses of fluoxetine, can not be resolved in favor of Barr and adversely to Lilly on the summary judgment record, for the material facts have been placed squarely at issue. Indeed, the scientific evidence in the record weighs heavily against the panel's findings.

It is highly relevant that the Stark application was examined in light of prior art that included the '549 Molloy disclosure. While Barr cites cases that established rules with respect to the subsequent patentability of a genus when a species is known, this has no relevance to the

question at bar. Further, these rules relate to whether a subsequent invention is patentable, not a prior one. Here, however, it is the first-filed (Molloy) invention that the panel invalidates in view of the later-filed Stark invention. Although the Stark patent issued seven months before the '549 patent, the panel incorrectly holds that the later-filed but earlier-issued Stark claim renders obvious the '549 claim of nine years earlier priority. Neither In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998), relied on by the panel, nor any other case, supports such an inverted holding.

When two patents issue with claims that are not patentably distinct, the principle served by the judgemade law of double patenting is that because patent protection started with the first patent to issue, it should not extend to the expiration of the second patent to issue. Thus the law of double patenting does not consider the patents as prior art; the law simply requires elimination of the extension of exclusivity by truncating the term of the second patent to issue, to coincide with the term of the first patent to issue.

When the second patent to issue is (as here) the first patent that was filed, an anomaly may arise when there is a valid charge of obviousness-type double patenting. I repeat, that charge is not here available because the first patent that was filed was in fact a reference against the second patent. The panel, ignoring this immutable fact, undertakes an obviousness-type double patenting analysis. When two patents are appropriately considered for obviousness-type double patenting, an anomaly arises, for example, when the claims of patent B are "obvious" in light of the claims of patent A, but the claims of patent A are not obvious in light of the claims of patent B. An illustration is shown in In re Berg, where one patent was directed to a species, and the other to a genus that included the species. A genus is usually not patentable over a species, but a species may, depending on the facts, be patentable over the genus. Judgemade law has developed a special and simple test for double patenting in such a situation: the requirement of "cross-reading." By applying the rules of cross-reading, double patenting will not lie, for cases in which the first patent to issue is the second patent that was filed, unless the claims cross read; that is, unless the claims of each patent would have been obvious in view of the claims of the other patent. This simple expedient avoids the analytical trap into which the panel fell.

The panel has reached the truly anomalous result of holding invalid for obviousness, on a theory of obviousness-type double patenting, an invention that was made and applied for nine years before the asserted "prior art" was filed.

The panel states that In re Berg requires that unless the PTO is solely and exclusively responsible for all delays in issuing the first-filed patent, the patentee can not rely on the fact of its earlier filing. That is not the Berg holding. In Berg the same inventors filed, on the same day, patent applications whose claims stood in the relationship of genus and species of the same method for preparing an abrasive particle suitable for use in an abrasive composition. When the species application was about to issue, the examiner rejected the genus application on the grounds of obviousness-type double patenting. Berg argued that each application should be evaluated as to whether it represented a patentable advance over the other, a two-way test of cross-reading applied in particular circumstances. This court stated that the purpose of the two-way test, as it had been developed in our precedent, was "to prevent rejections for obviousness-type double patenting when the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing, rejecting the basic application although it would have been allowed if the applications had been decided in the order of their filing." The

Federal Circuit then held that Berg was not entitled to the benefits of the two-way test because he could have included all of the claims in a single application. Neither the facts of Berg nor the law as developed therein applies to the patents here under consideration.

The panel also holds that because Lilly disclaimed the Stark patent before trial, this bars Lilly from disclaiming that portion of the '549 patent that would have extended beyond the Stark patent's original life. No precedent so holds, and I discern no basis for such a new rule. A terminal disclaimer is a standard response to a charge of double patenting; this remedy need not be withheld, at least in the absence of fraud or bad faith. To deny a patentee the opportunity of simplifying the issues or improving its litigation position is an unnecessary if not a punitive action, unwarranted on this record.

The New Rules of Patentability of Biological Inventions

The panel states that "the natural result of fluoxetine hydrochloride is the inhibition of serotonin uptake," and holds that a discovery of a new and unobvious biological property is unpatentable because it is inherent in the chemical compound. As authority the panel cites a dissenting opinion in Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1233, 32 USPQ2d 1915, 1924 (Fed. Cir. 1994) (Lourie, J. dissenting in part), the dissent suggesting that a patent to a method which "is an inherent, inevitable result of the practice" of another method patent constitutes same-invention double patenting. Thus the panel holds the '549 claim to serotonin inhibition to be invalid as the natural and inherent result of the Stark treatment for relief of anxiety. However, every biological property is a natural and inherent result of the chemical structure from which it arises, whether or not it has been discovered. To negate the patentability of a discovery of biological activity because it is "the natural result" of the chemical compound can have powerful consequences for the patentability of biological inventions. The narrow facts of Burroughs Wellcome and the dissenting view therein do not warrant the new rule now adopted.

The panel also states that "there is not sufficient evidence on which a jury could base a finding that fluoxetine hydrochloride does not inhibit the uptake of serotonin." Indeed, it is far from clear what could be proved, as well as what must be proved, on the panel's theory of double patenting, for the many scientific articles cited in the record show the complexity of the mechanism of action of fluoxetine. However, the panel's ruling that Lilly would have to prove that serotonin inhibition does not occur on treatment with fluoxetine, in order to avoid double patenting invalidity of its claim for serotonin inhibition on treatment with fluoxetine, will surely add confusion and uncertainty to patent practice.

In this period of unprecedented development of patent-supported biological advance, the nation needs a stable and comprehensible patent law, lest this court falter in its leading role in implementing the law's fundamental purposes.

FOOTNOTES:

[1] Amicus curiae briefs were filed by:

- a- Intellectual Property Owners Association
- b- Federal Circuit Bar Association
- c- Professor Janice M. Mueller
- d- Guilford Pharmaceuticals Inc.
- e- Biotechnology Industry Organization
- f- Zenith Goldline Pharmaceuticals, Inc.

[2] A biological property or new use of a composition is claimed as a "method of use," in accordance with 35 U.S.C. 101. Both claim 7 of the '549 patent and claim 1 of the Stark patent are method-of-use claims.