

United States Court of Appeals for the Federal Circuit

02-1540,-1541,-1542,-1543,-1544,-1545,-1546,-1547,-1548,-1549,
03-1021,-1022,-1023,-1025,-1027

SCHERING CORPORATION,

Plaintiff-Appellant,

v.

GENEVA PHARMACEUTICALS, INC. and NOVARTIS CORPORATION,

and

TEVA PHARMACEUTICALS USA, INC.,

and

ANDRX CORPORATION, ANDRX PHARMACEUTICALS LLC,
and ANDRX PHARMACEUTICALS, INC.,

and

MYLAN PHARMACEUTICALS, INC.,

and

WYETH, ESHLEDERLE, WYETH PHARMACEUTICALS, and WYETH
CONSUMER HEALTHCARE (formerly American Home Products Corporation,
Wyeth-Ayerst Laboratories, and Whitehall Robbins Healthcare),

and

IMPAX LABORATORIES, INC.,

APOTEX, INC. and NOVEX PHARMA,

COPLEY PHARMACEUTICAL, INC.,

and

GENPHARM, INC.,

Defendants-Appellees.

Robert G. Krupka, Kirkland & Ellis LLP, of Los Angeles California, filed a combined petition for panel rehearing and rehearing en banc for plaintiff-appellant. Of counsel on the petition were David P. Swenson, Kirkland & Ellis, of Washington, DC; John M. Desmarais, Peter J. Armenio, Maxine Y. Graham, Monica V. Bhattacharyya, Young J. Park, and Eric W. Dittmann, Kirkland & Ellis, of New York, New York. Also of counsel on the petition were John F. Hoffman and Arthur Mann, Schering Corporation, of Kenilworth, New Jersey.

Robert D. Bajefsky, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, filed a response to the petition for defendants-appellees Wyeth, ES-Lederle, Wyeth Pharmaceuticals and Wyeth Consumer Healthcare (formerly American Home Products Corporation, Wyeth-Ayerst Laboratories, and Whitehall Robbins Healthcare). With him on the response was Barbara R. Rudolph. Of counsel on the response were David A. Manspeizer and Lawrence Alaburda, WYETH, of Madison, New Jersey. On the response was Julie A. Petruzzelli, Venable, LLP, of Washington, DC, for defendant-appellee Impax Laboratories, Inc. Also on the response were Edgar H. Haug, Daniel G. Brown, and Porter F. Fleming, Frommer Lawrence & Haug LLP, of New York, New York; and Robert J. Stickles, Klett Roonery Lieber & Schorling, of Newark, New Jersey, for defendant-appellee Genpharm Inc.; Colin A. Underwood, Proskauer Rose LLP, of New York, New York, for defendants-appellees Andrx Corporation, Andrx Pharmaceuticals LLC, and Andrx Pharmaceuticals, Inc.; E. Anthony Figg, and Joseph A. Hynds, Rothwell, Figg, Ernst & Manbeck, of Washington, DC, for defendant-appellee Mylan Pharmaceuticals, Inc.; and Thomas L. Creel, Frederick H. Rein, and Keith A. Zullo, Goodwin Procter LLP, of New York, New York, for defendants-appellees Teva Pharmaceuticals USA, Inc., and Copley Pharmaceuticals, Inc.

Robert S. Silver and William J. Castillo, Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd., of Philadelphia, Pennsylvania for defendants-appellees Apotex, Inc. and Novex Pharma.

Douglass C. Hochstetler, Schiff, Hardin & Waite, of Chicago, Illinois, filed a response to the petition for defendants-appellees Geneva Pharmaceuticals, Inc. and Novartis Corporation. With him on the response were Patricia J. Thompson and Jo-Anne M. Kokoski. Of counsel on the response was Kevin M. Flowers, Ph.D., Marshall Gerstein & Borun, of Chicago, Illinois.

Appealed from: United States District Court for the District of New Jersey

Chief Judge John W. Bissell

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Defendants-Appellees.

ON COMBINED PETITION FOR PANEL REHEARING
AND REHEARING EN BANC

O R D E R

A combined petition for panel rehearing and rehearing en banc was filed by the Appellant, and responses thereto were invited by the court and filed by the Appellees. This petition for panel rehearing was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and responses 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 panel rehearing is denied.
- (2) The petition for rehearing en banc is denied.

NEWMAN, Circuit Judge, dissents from the denial of rehearing en banc in a separate opinion.

LOURIE, Circuit Judge, dissents from denial of the petition for rehearing en banc in a separate opinion.

GAJARSA, Circuit Judge, would rehear the appeals en banc.

SCHALL, Circuit Judge, did not participate in the vote.

The mandate of the court will issue on November 4, 2003.

FOR THE COURT

October 28, 2003

Jan Horbaly

Date

Jan Horbaly
Clerk

cc: Robert G. Krupka, Esq.
Robert D. Bajefsky, Esq.
Douglass C. Hochstetler, Esq.
Thomas L. Creel, Esq.
E. Anthony Figg, Esq.
Robert S. Silver, Esq.
Edgar H. Haug, Esq.
Julie Ann Petruzzelli, Esq.
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NEWMAN, Circuit Judge, dissenting from denial of rehearing en banc.

I write to state my concern for the panel's departure from the established law of anticipation. The court holds "anticipated" a novel chemical compound

(descarbethoxyloratidine or DCL), a compound not known to the prior art and that did not previously exist. The Schering inventor discovered it in vivo as a degradation product of loratidine, isolated it, determined its structure, and found its biologic properties. The panel nonetheless holds that this new compound is unpatentable on the ground of "inherent anticipation."

The law is that a product is "anticipated" if it is not new. Conversely, it is not anticipated if it is new. A new product may of course be unpatentable based on obviousness, but it is not subject to unpatentability for lack of novelty. No precedent supports the position that a product whose existence was not previously known and is not in the prior art is always unpatentable on the ground that it existed undiscovered. If the law is to be changed in this direction it must be done en banc.

DISCUSSION

The panel appears to have reached the correct result of no liability for infringement, but for the wrong reason. According to the briefs, the defendants are doing only what was claimed in the expired loratidine patent, not in suit. However, instead of simply ruling that Schering cannot prevent the practice of the expired patent in accordance with its teachings, the panel strains to hold that this newly discovered, previously unknown product cannot be validly patented. That is not the law. I also point out that the issue here is validity, not infringement.

Note the word "discovery" in the patent statute. "The term 'invention' means invention or discovery." 35 U.S.C. §100(a). It was and is well understood that an inventor

may discover something that already existed. That the thing was there, undiscovered, does not render it "inherently anticipated." The panel's proposed rule may have particular impact on the discovery of biological products. Does the panel intend that no newly discovered product found in an organism can be patented? Such a ruling does not comport with either the patent statute or the incentive purposes of the patent system.

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Precedent concerning "anticipation" has dealt with diverse factual situations, applying the common thread that novel subject matter may or may not be patentable, depending on whether it is also unobvious, while subject matter that is not novel cannot be patented. A newly discovered attribute or property of something that was already known is patentable only as a method-of-use, but does not impart patentability to the known product. However, a previously unknown product does not become unpatentable simply because it existed before it was discovered. Precedent deals primarily with application of the law to situations where (1) a single prior art reference teaches all the elements of a product as claimed; in such case, the discovery of a new use or function does not render the product itself patentable; and (2) a single prior art reference does not teach all of the claimed elements; in such case the factual question arises of whether the omitted element is shown elsewhere (in which event the issue is obviousness) or whether the omitted element would have been known to be present in the reference subject matter, in which case the issue is anticipation. For example, in In re Schreiber, 128 F.3d 1473 (Fed. Cir. 1997) the applicant sought to patent a conical spout to dispense popped popcorn; the same conical spout was shown in the prior art as an oil dispenser. The product itself was thus held unpatentable as anticipated. In MEHL/Biophile International Corp. v. Milgraum, 192 F.3d 1362 (Fed. Cir. 1999) the prior art showed all of the claimed steps of laser irradiation of hair follicles, but did not mention hair removal; the court held that this effect was inherent in the prior art process, and that the same process steps could not be claimed, the court stating that "nothing in the claim limits the method's reach to human skin." Id. at 1366. In Titanium Metals Corp. v. Banner, 778 F.2d 775 (Fed. Cir. 1985) the court held that the discovery of

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the property of corrosion resistance of a known alloy did not impart patentability to the known alloy, for the property was inherent in the alloy.

In all applications of the law of anticipation, the initial consideration is whether the thing that is claimed was disclosed in a single prior art reference. When all of the elements of the claim are not shown in the prior art, precedent requires that the missing element was nonetheless known to be present in the subject matter of the reference, and that the claim is directed to the known subject matter. Although the panel now purports to disavow this precedent, such a change of law requires en banc action of the court. See, for example, the precedent represented by and cited in such cases as Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264 (Fed. Cir. 1991), where the law of "inherency" is applied to subject matter wherein all of the elements of the claim are not shown in the prior art:

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. . . .

This modest flexibility in the rule that "anticipation" requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges.

Id. at 1269-70. The analytic tool of "inherency" allows determination of whether subject matter that is not taught in the single reference was nonetheless known in the field of the invention. This was acknowledged in EMI Group North America, Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342 (Fed. Cir. 2001):

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This requirement, that a person of ordinary skill in the art must recognize that the missing descriptive matter is necessarily present in the reference, may be sensible for claims that recite limitations of structure, compositions of matter, and method steps which could be inherently found in the prior art. Such recognition by one of ordinary skill may be important for establishing that the descriptive matter would inherently exist for every combination of a claim's limitation.

Id. at 1350-51. The panel now contradicts this body of precedent, stating that it "rejects the contention that inherent anticipation requires recognition in the prior art." A rejection of precedent requires en banc action, not panel disruption.

No reference shows the claimed descarbethoxyloratidine, or that a person of ordinary skill would have known that DCL is formed in vivo upon ingestion of loratidine. Precedent is directly contrary to the panel's holding that although no one knew of the existence of DCL, it is unpatentable because it in fact existed.

Whether it is desirable new policy to bar the patentability of products that have not yet been discovered is a result I seriously doubt. The court should speak with one voice on this important question. Thus I must, respectfully, dissent from the court's refusal to review this case en banc.

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LOURIE, Circuit Judge, dissenting from denial of petition for rehearing en banc.

I respectfully dissent from the court's decision not to hear this case en banc. I do so because it is an extraordinary decision, effectively precluding virtually all patents on human metabolites of drugs. It thus qualifies as an issue of exceptional importance, justifying en banc consideration.

The holding of the panel, which the full court left standing, is that an issued patent on a pharmaceutical product provides an enabling disclosure of all of that product's metabolites (i.e., compounds that are formed in a patient's body upon ingestion of the pharmaceutical product), simply by disclosing that the product can be used by administration to a human. Because product patents covering pharmaceutical products generally issue before clinical trials on the product have revealed the identity or nature of any metabolites, this decision will preclude protection of those metabolites, as the issued patent will be effective prior art against such application.

I do not question that when a pharmaceutical product has been in actual public use prior to the filing of a patent application on its metabolite, the metabolite will also have been in public use and hence will be unpatentable. The holding of this case, however, goes much further, mandating that the mere issuance of the patent on the product--or any other publication of that product--inherently anticipates claims to the metabolite merely by disclosing that the product can be administered to a patient, on the theory that such administration would inevitably cause the human body to "make" the metabolite. The decision holds that an enabling disclosure of "how to make" metabolites is provided by the mere recitation that one can administer a prior art compound to humans.

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If U.S. Patent 4,282,233 really taught how to make metabolites, it might be another story. However, that patent simply included a minimal, boilerplate statement of how to use the claimed products, sufficient to satisfy the requirements of 35 U.S.C. § 112, but far from the careful and thorough prescribing information required by the FDA. The disclosure of the patent, like similar disclosures in other such patents, merely stated:

The compounds of the present invention are useful as non-sedating antihistamines. These compounds act as anti-allergic agents in the treatment of such conditions as perennial and seasonal allergic rhinitis and chronic urticaria.

The compounds of the present invention are administered in pharmaceutical formulations comprising the compound in admixture with a pharmaceutical carrier suitable for enteral or parenteral administration. The formulations may be in solid form . . . or in liquid form

Although the required dosage will be determined by such factors as the patient's age, sex, weight and the severity of the allergic reaction to be treated, the preferred human dosage range is likely to be 4 to 50 mg of the effective compound 1 to 3 times per day. The preferred dosage ranges for other animals can readily be determined by using standard testing methods.

'233 patent, col. 4, ll. 42-66. That is hardly an enabling disclosure of how to make any metabolites, whatever they might turn out to be, sufficient to anticipate them by inherency. The '233 patent does not identify or even mention any of the claimed products' metabolites. Yet the court here sweepingly holds that the patent anticipates those metabolites.

It may be asked why, if a developer of a new product has a patent on that product, does it also need a patent on its metabolite. However, that is not the patent law question before us. Moreover, another company might hold a patent on the metabolite, having independently invented it before the product patent issued and before the product went into public use. In any event, we deal here with issues of patent law, not policy or equity, and to hold that a patent on a product, with a minimal disclosure of administering it to a human or

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other subject, anticipates a later application on a metabolite, of which no mention appears whatsoever in the patent, cannot be correct.

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