

United States Court of Appeals for the Federal Circuit

03-1285, -1313

SMITHKLINE BEECHAM CORPORATION
and BEECHAM GROUP, P.L.C.,

Plaintiffs-Appellants,

v.

APOTEX CORP., APOTEX, INC., and TORPHARM, INC.,

Defendants-Cross Appellants.

Ford F. Farabow, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, filed a petition for rehearing en banc for plaintiffs-appellants. With him on the petition were Robert D. Bajefsky, Howard W. Levine, Scott J. Popma and Jennifer S. Swan.

Hugh L. Moore, Lord, Bissell & Brook, LLP, of Chicago, Illinois, filed a petition for rehearing en banc for defendants-cross-appellants. With him on the petition were Keith D. Parr, Hugh S. Balsam, Scott B. Feder and Kevin M. Nelson.

Paul H. Berghoff, McDonnell Boehnen Hulbert & Berghoff LLP, of Chicago, Illinois, filed an amicus curiae brief for the Intellectual Property Owners Association. With him on the brief was Joshua R. Rich. Of counsel on the brief was J. Jeffrey Hawley, President, Intellectual Property Owners Association, of Washington, DC.

Rudolf E. Hutz, Connolly Bove Lodge & Hutz LLP, of Wilmington, Delaware, filed an amicus curiae brief for Pfizer Inc.

Frederick H. Rein, Goodwin Procter LLP, of New York, New York, filed an amicus curiae brief for Teva Pharmaceuticals USA, Inc.

Christine J. Siwik, Rakoczy Molino Mazzochi LLP, of Chicago, Illinois, filed an amicus curiae brief for the Generic Pharmaceutical Association. With her on the brief was Lara E. Monroe-Sampson.

Christopher N. Sipes, Covington & Burling, of Washington, DC, filed an amicus curiae brief for the Pharmaceutical Research and Manufacturers of America.

Richard A. Samp, Washington Legal Foundation, of Washington, DC, filed an amicus curiae brief for the Washington Legal Foundation. With him on the brief was Daniel J. Popeo.

Appealed from: United States District Court for the Northern District of Illinois

Judge Richard A. Posner

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ON PETITION FOR REHEARING EN BANC

Before MICHEL, Chief Judge, NEWMAN, MAYER, CLEVENGER, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, and PROST, Circuit Judges.^{*} NEWMAN, Circuit Judge, dissents in a separate order.

ORDER

Petitions for rehearing en banc having been filed by both the Appellants-Cross-Appellees and Appellees-Cross-Appellants, responses thereto having been invited by the court and filed by both the Appellants-Cross-Appellees and Appellees-Cross-Appellants, and briefs of amicus curiae having been filed by Teva Pharmaceuticals USA, Inc. and Generic Pharmaceutical Association, the petitions for rehearing en banc, responses and briefs of amicus curiae having been referred to the circuit judges who are in regular active service, and a poll having been requested and taken,

* LOURIE, Circuit Judge, did not participate in the vote.

IT IS ORDERED THAT:

- (1) The petitions for rehearing en banc are granted for the limited purpose of vacating the panel's original opinion addressing the issue of experimental use. The panel's judgment and original opinion entered on April 23, 2004, as amended April 28, 2004, and reported at 365 F.3d 1306 (Fed. Cir. 2004), is vacated.
- (2) The case is remanded to the panel for further proceedings.

FOR THE COURT

April 8, 2005

Date

s/ Jan Horbaly

Jan Horbaly

Clerk

United States Court of Appeals for the Federal Circuit

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NEWMAN, Circuit Judge, dissenting from the order declining rehearing *en banc*.

The court has granted the petitions for rehearing *en banc* for the limited purpose of remanding to the panel with regard to the issue of experimental use. I write to state my concern that the court has preserved the opinion's enlargement of the ground of invalidity called "inherent anticipation." The panel acknowledges that the hemihydrate had not been discovered until many years after the anhydrate product had been discovered and described in the '196 patent (United States Patent No. 4,007,196, filed July 23, 1975). The panel sustains the district court's findings that the hemihydrate was first discovered in March 1985 and may have existed in December 1984; how then can it have been

"inherently disclose[d]," maj. op. at 18, in a patent application filed in 1975? Unlike any of the cases cited by the majority as ostensible precedent, there was no evidence whatsoever that the hemihydrate existed at the time the anhydrate patent application was filed, and no evidence that such existence would have been recognized by a person of skill in the field of the invention. These findings of chemical fact by this court are devoid of scientific support.

The district court's finding that it had not been established that the hemihydrate was produced in 1975 is in accord with the evidence, and surely has not been shown to be clearly erroneous. There is no evidence to support the panel's current finding that the '196 patent "discloses in an enabling manner the production of the PHC hemihydrate." Maj op. at 20. The evidence before the district court did not show that disclosure and enablement, and did not show that the hemihydrate was produced in 1975, even inherently and undetected. The discovery of the hemihydrate a decade later, and the "seeding" of subsequent production in this crystal form, does not provide retrospective knowledge of this then-unknown compound. The not-unique situation that the air of the manufacturing plant is now seeded with the hemihydrate crystal form does not mean that this situation existed when the anhydrous product was discovered and the patent application thereon was filed.

Invalidity based on "anticipation," 35 U.S.C. §102, requires that the identical invention was known or its existence would reasonably have been known to a person of ordinary skill in the field of the invention -- not that it might have lain hidden in minuscule amount, undetected, unsuspected, and unknown. See In re Oelrich, 666 F.2d 578, 581, (CCPA 1981); Hansgirg v. Kemmer, 102 F.2d 212, 214 (CCPA 1939). The district court correctly found that there was not "clear and convincing evidence that the hemihydrate existed before the critical date of the '723 patent," maj. op. at 23, and on this finding the

district court correctly ruled that there was not inherent anticipation. As summarized in Continental Can Company USA v. Monsanto Company, 948 F.2d 1264, 1269 (Fed. Cir. 1991), "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." The theory of inherent anticipation serves to accommodate "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.

The panel now holds that a product that existed in trace amounts, although unknown and undetected and unisolated, is "inherently anticipated" and barred from the patent system after it is discovered. The patentability of antibiotics, hormones, antibodies, and myriad other previously unknown or unisolated products would be called into question by this new ruling, giving rise to uncertainty as to existing patents, as well as negation of searches for the beneficial components of existing materials. The breadth of the panel's theory of inherent anticipation contravenes long-established precedent. For example, in Tilghman v. Proctor, 102 U.S. 707 (1880), the Supreme Court observed that it would be "absurd" to hold that a patent is anticipated because those skilled in the art later recognize that the discovery was "accidentally and unwittingly produced whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done." See also Eibel Process Co. v. Minn. & Ont. Paper Co., 261 U.S. 45, 66 (1923) ("[A]ccidental results, not intended and not appreciated, do not constitute anticipation."). In In re Seaborg, 328 F.2d 996 (CCPA 1964), our predecessor court rejected the "extrapolation" of the inherency theory to reach trace amounts of a nuclear isotope in a prior art process. See id. at 998-99 ("The record before

us . . . is replete with showings that the claimed product, if it was produced in the Fermi process, was produced in such minuscule amounts and under such conditions that its presence was undetectable.").

Only after a compound is identified does it become subject to patenting; if its existence is not reasonably known to persons of skill in the field, its later discovery cannot be retrospectively "inherently anticipated."