

United States Court of Appeals for the Federal Circuit

MISCELLANEOUS DOCKET NO. 854

IN RE ROCHE MOLECULAR SYSTEMS, INC.,
ROCHE DIAGNOSTICS CORPORATION,
and ROCHE DIAGNOSTICS OPERATIONS, INC.,

Petitioners.

Adrian M. Pruetz, Pruetz Law Group, LLP, of El Segundo, California, for petitioners. With him on the petition was Erica J. Pruetz. Of counsel on the petition were Brian C. Cannon and Tun-Jen Chiang, Quinn Emanuel Urquhart Oliver & Hedges LLP, of Redwood Shores, California.

Ricardo Rodriguez, Cooley Godward Kronish LLP, of Palo Alto, California, for respondents The Board of Trustees of the Leland Stanford Junior University, et al. With him on the response were Michelle S. Rhyu and Benjamin G. Damstedt.

On Petition for Writ of Mandamus from the United States District Court for the Northern District of California

Judge Marilyn Hall Patel

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IN RE ROCHE MOLECULAR SYSTEMS, INC.,
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On Writ of Mandamus from the U.S. District Court for the Northern District of California
in case no. 05-CV-04158, Judge Marilyn Hall Patel.

ON PETITION FOR WRIT OF MANDAMUS

Before NEWMAN, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and MAYER, Circuit Judge.

Order for the Court filed PER CURIAM. Dissenting order filed by Circuit Judge NEWMAN.

ORDER

Roche Molecular Systems, Inc. et al. (Roche) petition for a writ of mandamus to direct the United States District Court for the Northern District of California to (1) vacate its April 16, 2007 order granting in part The Leland Stanford Jr. University's (Stanford) motion for summary judgment and denying Roche's motion for summary judgment and (2) enter judgment in favor of Roche. Stanford opposes. Roche moves for leave to reply, with reply attached. Stanford opposes and moves, in the alternative, for leave to file a surreply, with surreply attached. Roche opposes Stanford's motion for leave to file a surreply.

Stanford sued Roche for patent infringement. On cross motions for summary judgment, the district court determined, inter alia, that Roche was barred from asserting

(1) that it was the owner of the patents, (2) that it had a license, and (3) that Stanford lacked standing. Roche petitions for a writ of mandamus to direct the district court to vacate its summary judgment order and to enter judgment in favor of Roche.

The remedy of mandamus is available only in extraordinary situations to correct a clear abuse of discretion or usurpation of judicial power. In re Calmar, Inc., 854 F.2d 461, 464 (Fed. Cir. 1988). A party seeking a writ bears the burden of proving that it has no other means of attaining the relief desired, Mallard v. U.S. Dist. Court for the Southern Dist. of Iowa, 490 U.S. 296, 309 (1989), and that the right to issuance of the writ is "clear and indisputable." Allied Chem. Corp. v. Daiflon, Inc., 449 U.S. 33, 35 (1980). A court may deny mandamus relief "even though on normal appeal, a court might find reversible error." In re Cordis Corp., 769 F.2d 733, 737 (Fed. Cir. 1985); see also United States v. Watson, 603 F.2d 192, 196-97 (C.C.P.A. 1979) ("the writ will not issue to cure the mere commission of reversible error"). That a petitioner may suffer hardship, inconvenience, or an unusually complex trial does not provide a basis for a court to grant mandamus. See Watson, 603 F.2d at 195 ("Neither the general rule limiting the appellate function to review of final judgments, nor the statute so limiting our appellate function . . . can be evaded by use of an extraordinary writ to avoid delay entailing hardship, inconvenience, or an unnecessary trial") (citations omitted); cf. Federal Trade Comm'n v. Standard Oil Co., 449 U.S. 232, 244 (1980) (expenses and burdens of defending action do not constitute irreparable harm).

Roche argues that Stanford lacks standing and thus this court should direct the district court to vacate its summary judgment order and enter judgment in Roche's favor. Stanford asserts that Roche has not shown that it has a clear and indisputable

right to a writ because the relief it seeks may be obtained on direct appeal after the district court enters a final judgment.

We determine that Roche has not shown that it cannot obtain the relief it seeks by review after final judgment. Thus, mandamus relief is not appropriate.

Accordingly,

IT IS ORDERED THAT:

- (1) The petition for a writ of mandamus is denied.
- (2) Roche's motion for leave to reply is granted.
- (3) Stanford's motion for leave to file a surreply is granted.

FOR THE COURT

DATED: February 1, 2008

/ s / Jan Horbaly
Jan Horbaly, Clerk

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NEWMAN, Circuit Judge, dissenting.

I respectfully dissent. By declining this writ, the court is permitting the trial to proceed on material errors of law. Absent our intervention, the scheduled trial will not include issues that can be dispositive of the entirety of the litigation and whose facts would remain unresolved. This is one of the rare cases in which the writ should be granted, for it meets the criteria for intervention by way of mandamus.

The district court ruled, on summary judgment, that Roche is barred by a California statute of limitations from presenting its license defenses to the charges of patent infringement. The court also ruled that in all events the Bayh-Dole Act was violated by the license rights in the contracts between Stanford and Cetus, rendering the licenses void. Thus the infringement trial, scheduled for July 2008, will proceed without development of any of Roche's defenses of license or assignment or shop right, although these issues involve some or all of the technology charged with infringement, and can dispose of the case.

The district court did not determine Roche's license rights to the subject matter in suit, instead holding that this defense was barred. Roche argues that the district court's rulings on the statute of limitations and the Bayh-Dole Act are incorrect as a matter of law.

Postponing review of this law, as my colleagues have ruled, can result in trial of possibly unnecessary issues, while omitting critical issues that could resolve the dispute. This posture can only serve to extend the proceedings as well as the uncertainty as to important technology, serving no one, and least of all the interests of efficient justice.

Therefore I would grant the writ to the extent of reviewing the district court's rulings that (1) the California statute of limitations bars Roche from raising the defense of its right to practice the challenged technology, and (2) the Bayh-Dole Act voids any license grant in the Cetus/Stanford contracts. Resolution of these issues of law would permit exploration at trial of the facts relevant to the asserted rights concerning this technology, including determination of the scope of the licenses. Failure to resolve these issues would simply require another trial on the correct law.

DISCUSSION

Review by way of mandamus is appropriate only when the need for the writ is "clear and indisputable." Cheney v. U.S. Dist. Court for the District of Columbia, 542 U.S. 367, 380 (2004); see Allied Chem. Corp. v. Daiflon, Inc., 449 U.S. 33, 34 (1980), and the petitioner reasonably has no other means of obtaining the relief desired. Mallard v. U.S. Dist. Court, 490 U.S. 296, 309 (1989); cf. United States v. Watson, 603 F.2d 192, 197 (CCPA 1979) (denying a requested writ that would have limited the issues of trial and review of countervailing duty). The "stringent standard" for mandamus, Gulfstream Aerospace Corp. v. Mayaxamas Corp., 485 U.S. 271, 289 (1988), has been met, for the district court resolved fundamental issues in ways that appear to be incorrect. These issues can resolve the dispute, but they have been removed from the forthcoming trial. Thus issuance of the writ is "necessary or appropriate in aid of [the courts'] respective jurisdictions and agreeable to the usages and principles of law." 28 U.S.C. §1651.

The contracts between Stanford and Cetus/Roche

The district court held that the California four-year statute of limitations for contracts has run, barring any defense or counterclaim based on the license and other rights in the contracts between Stanford and Cetus. On this ground the district court granted summary judgment that Cetus/Roche has no rights and can acquire none of the rights set forth in the contracts with Stanford.

Two written agreements are involved. A contract called a Materials Transfer Agreement (MTA) in 1988 provided the terms whereby Cetus agreed to train and assist Stanford scientists in connection with the polymerase chain reaction:

Cetus Corporation agrees to provide [Thomas C. Merigan and David Schwarz] with certain research substances and know-how [concerning polymerase chain reaction (PCR), and that the scientists will] inform CETUS, in confidence, of research results related to the Material, [and that] CETUS shall be free to use such data and information for any purpose In consideration of CETUS' providing of the Material, [Stanford], to the extent it is legally able to do so, hereby grants CETUS the first option to an exclusive license, at a reasonable royalty to be negotiated in good faith . . . or at CETUS' option, a nonexclusive license.

This agreement was signed for Stanford by Dr. Merigan, Dr. Schwartz, and Robert C. Baum, who was identified as Contract Officer and Stanford's "Authorized Representative."

The district court found that:

The contract granted Cetus, by default, a free non-exclusive license. The contract further permitted Cetus to exercise an option to pay royalties for exclusivity. Either way, Cetus' right to use the inventions was secured by the MTA.

Memorandum and Order of April 16, 2007, at 25.

A few weeks later Stanford sent Dr. Mark Holodniy, a scientist at Stanford's Division of Infectious Diseases, to Cetus to learn about PCR for use in developing an assay for HIV

nucleic acids. Dr. Holodniy executed a Visitor Confidentiality Agreement (VCA) that included the following provision:

If, as a consequence of my access to CETUS' facilities or information, I conceive of or make, alone or with others, ideas, inventions and improvements thereof or know-how related thereto that relate in any manner to the actual or anticipated business of CETUS, I will assign and do hereby assign to CETUS, my right, title, and interest in each of the ideas, inventions and improvements thereof described in this paragraph.

In the VCA Dr. Holodniy was described as "acting as a consultant and an independent contractor," with the address of the Stanford University Medical Center Division of Infectious Disease. The Joint Statement of Undisputed Facts states that Dr. Holodniy was at Cetus "on a regular basis" for eight or nine months, and it is not disputed that he had unrestricted access to Cetus personnel, materials and equipment. It was stipulated that he was given the materials, equipment, and cRNA standard needed to perform PCR and HIV assays, that he had not previously performed any of the steps of an HIV PCR assay, and that he was taught how to do so by Cetus scientists. The district court made the following finding:

Holodniy's own testimony establishes that he went to Cetus with the goal of "develop[ing] an assay at Stanford that we could use to monitor treatment [of HIV]," that he spent nine months working onsite at Cetus, using Cetus equipment and materials and obtaining advice from Cetus personnel, and that he developed the PCR assay "with assistance from Cetus scientists while [he] was at Cetus."

Memorandum and Order of April 16, 2007, at 23 (quoting Dr. Holodniy's testimony).

The district court stated that it is "undisputed that Stanford developed the PCR assay disclosed in its patents after working with Cetus Corporation, which later sold its PCR assets and business to Roche." Id. at 2. A scientific paper reporting this research was published in the Journal of Infectious Diseases, with Dr. Holodniy as lead author and several co-authors from both Cetus and Stanford. The district court concluded that Dr.

Holodniy "effectively assigned any rights that Holodniy had in the patented inventions to Cetus," Memorandum and Order at 20, but the court ruled that such rights could not now be raised as a defense to the charge of patent infringement because of the California four-year statute of limitations for contract actions. The court held that no rights could be claimed, of ownership or license or shop right, after four years from "no later than April 2000." The court also held that Roche's claims were barred by laches because of "evidentiary prejudice" to Stanford.

It is not disputed that state contract law is relevant to patent licenses. See General Mills, Inc. v. Kraft Global Foods, Inc., 487 F.3d 1368, 1373 (Fed. Cir 2007) (interpreting patent license transfer provisions under state law). However, state contract law does not automatically void patent-related contracts after four years; the law of contracts requires consideration of the life of the contracted subject matter and other aspects of the contracts. Roche argues that it is not in accord with the contractual purpose that the license rights from Stanford to Cetus under the agreement would be discontinued after four years, while Stanford's right to use the Cetus technology obtained under the agreement would be unlimited in time.

The issue of the applicability of the California statute of limitations requires review, for it appears to have been wrongly applied. Indeed, California precedent itself casts doubt on the district court's application, for California holds that "a defense may be raised at any time, even if the matter alleged would be barred by a statute of limitations if asserted as the basis for affirmative relief." Styne v. Stevens, 26 Cal. 4th 42, 51 (Cal. 2001). I would grant the writ to resolve the issue.

The Bayh-Dole Act

The district court held that "the legal requirements of the Bayh-Dole Act, 35 U.S.C. §§200-212, mandated that Stanford be given a superior right to retain title to the patents." The court ruled that because of Bayh-Dole "Holodniy had no interest to assign to Cetus," that the Bayh-Dole Act was violated by the Stanford contracts with Cetus, and therefore that any licenses were illegal and void. Memorandum and Order of April 16, 2007, at 22. Mandamus is required to correct legal error in interpretation of the Bayh-Dole Act.

The Bayh-Dole Act does not bar the grant of a license or the right to acquire a license to technology developed by University scientists. The district court erred in ruling that the Act was violated by Dr. Holodniy's and Stanford's agreements with Cetus. The purpose of the Bayh-Dole Act is as an incentive, not a bar, to university-industry collaboration and commercial development through licensing:

The Bayh-Dole Act is intended to promote investment by the private sector in commercialization of federally funded research discoveries for the public good Rights retained by the government under Bayh-Dole include a nonexclusive license to practice the patent and march-in rights. *March-in rights* allow the government to 'march in' and take over an invention if commercialization of an important invention is not being executed with due diligence by a university or licensee. The government has not, to date, invoked march-in rights.

Martha Mutschler and Gregory D. Graff, Introduction to IP Issues In the University Setting: A Primer for Scientists, in INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION 748-49 (Anatole Krattinger et al., eds., MIHR and PIPRA 2007).

The district court ruled that Stanford's disposition of patent rights in the agreements with Cetus was void, and that this was an alternate ground for barring Roche from raising the defense that it acquired rights under the license agreements between Stanford and Cetus. The Bayh-Dole Act does not render these licenses illegal and automatically void. See Central Admixture Pharmacy Services, Inc. v. Advanced Cardiac Solutions, P.C., 482

F.3d 1347, 1352 (Fed. Cir. 2007) (an inventor's failure to comply with a provision of the Bayh-Dole Act may have voidable consequences, but any license granted is not automatically void). Mandamus review is plainly warranted.

Other issues

The district court held that Roche, in purchasing Cetus' business, could not acquire any of the non-exclusive licenses held by Cetus unless the licensor expressly agreed or the license itself permitted its transfer. This holding was based on bankruptcy principles, and Roche appears to be correct in pointing out that it is contrary to California contract law. See Farmland Irrigation Co. v. Dopplmaier, 48 Cal.2d 208, 220 (1957) (California contract law governs transfer of patent licenses and does not require licensor approval). Indeed, the district court found that the transfer of the license from Cetus to Roche, when Roche acquired the Cetus PCR business, did not require Stanford's approval. Memorandum and Order of April 16, 2007 at 10. And Roche correctly states that in all events such a bankruptcy-derived rule does not void Cetus' shop rights for work done using its facilities and information and scientists and materials. Although the district court also held that the existence of the invention agreement forecloses resort to shop rights, Roche also challenges this interpretation.

Precedent provides support for Roche's argument that it already owns at least some of the disputed subject matter, for a contract that "does hereby assign" operates to assign inventions when they are made. See Speedplay, Inc. v. Bebo, Inc., 211 F.3d 1245, 1253 (Fed. Cir. 2000) (title is transferred by a contract that "does hereby assign," without further action); FilmTec. Corp. v. Allied-Signal, Inc., 939 F.2d 1568, 1572 (Fed. Cir. 1991) (grant of an expectant interest in future inventions passes title to the assignee when the invention is made). In turn, Stanford states that at least some of the patented potential subject

matter is not covered by the license rights. The district court removed all of these issues from the case without considering their merits, holding them barred by limitations or Bayh-Dole. Judicial economy, as well as resolution of uncertainty, weigh heavily toward mandamus review instead of waiting until after a potentially unnecessary trial, as this court holds.

Conclusion.

The criteria for issuance of a writ have been met, for if Roche's contract-based and related defenses are not barred by the California statute of limitations and are not void under the Bayh-Dole Act, the posture of the dispute is significantly changed. It is as inappropriate as it is unnecessary to require trial to proceed on the issues of infringement, without resolving these threshold questions of ownership of the inventions.