United States Court of Appeals for the Federal Circuit

CANCER RESEARCH TECHNOLOGY LIMITED AND SCHERING CORPORATION,
Plaintiffs-Appellants,

v.

BARR LABORATORIES, INC. AND BARR PHARMACEUTICALS, INC.,
Defendants-Appellees.

2010-1204

Appeal from the United States District Court for the District of Delaware in Case No. 07-CV-0457, Judge Sue L. Robinson.

Decided: November 9, 2010

MATTHEW D. POWERS, Weil Gotshal & Manges LLP, of Redwood Shores, California, argued for plaintiffs-appellants. With him on the brief were NICOLAS G. BARZOUKAS and JASON C. ABAIR, of Houston, Texas; and JENNIFER H. WU, of New York, New York.

GEORGE C. LOMBARDI, Winston & Strawn LLP, of Chicago, Illinois, argued for defendants-appellees. With him on the brief were LYNN M. ULRICH, MAUREEN L. RURKA,

IVAN M. POULLAOS, and JULIA MANO JOHNSON. Of counsel on the brief was STEFFAN N. JOHNSON, of Washington, DC.

Before NEWMAN, LOURIE, and PROST, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE, in which *Circuit Judge* NEWMAN joins.

Dissenting opinion filed by *Circuit Judge* PROST.

LOURIE, *Circuit Judge*.

Cancer Research Technology Limited and Schering Corporation (collectively, "Cancer Research") appeal from the final decision of the United States District Court for the District of Delaware holding U.S. Patent 5,260,291 ("the '291 patent") unenforceable for prosecution laches and inequitable conduct. *Cancer Research Tech. v. Barr Labs., Inc.*, 679 F. Supp. 2d 560 (D. Del. 2010). We reverse.

BACKGROUND

The '291 patent claims a genus of tetrazine derivative compounds and methods for treating cancer by administering those compounds. One claimed compound, temozolomide, is the active ingredient in the drug Temodar®, approved by the Food and Drug Administration ("FDA") for the treatment of two types of brain cancer—refractory anaplastic astrocytoma and newly diagnosed glioblastoma multiforme.

The application for the '291 patent was filed in the United States on August 23, 1982, by a British pharmaceutical company. The original specification identifies and characterizes thirteen "[i]mportant" tetrazine derivative compounds, designated A through M, and it identifies three of the thirteen compounds, including temozolomide

(designated as A) and mitozolomide (designated as C), as having "particular importance." '291 patent col.4 l.57, col.5 ll.17-18. The specification states that the new tetrazine derivatives "possess valuable antineoplastic activity, for example against carcinomas, melanomas, sarcomas, lymphomas and leukaemias" and "have proved particularly active" in several different mouse tumor models. *Id.* col.4 ll.29-56. The specification goes on to disclose positive data from those animal models. *Id.*

In the first substantive office action dated November 18, 1983, the examiner, Examiner Ford, rejected original claim 31 directed to a method of treating leukemia by administering a tetrazine compound because "[t]he treatment of leukaemia is not a believable utility on its face" and objected to the composition claims "pending clarification of utility." A2394-96. The examiner wrote that utility could be established "by clinical reports and data, the acceptance of the drug employed by the Food and Drug Administration and by the American Medical Association Council on Pharmacy," citing *Ex parte Timmis*, 123 U.S.P.Q. 581 (POBA 1959). A2395. The applicants did not respond to the office action but instead filed a continuation application on March 6, 1984, and abandoned the original application. On October 24, 1984, Examiner Ford again rejected claim 31 for lack of utility and objected to the composition claims pending clarification of utility. Again, the applicants, rather than respond to the office action, filed a continuation application and abandoned the pending application. This pattern repeated itself eight more times, with the examiner ultimately rejecting all the pending claims for lack of utility.

On March 25, 1991, ownership of the patent application changed hands, with Cancer Research receiving an absolute assignment of rights. On October 18, 1991, Cancer Research filed another continuation application,

but for the first time challenged the examiner's utility rejection, arguing that the disclosure of animal data in the original specification sufficed to establish utility in humans. In the next office action, a new examiner, Examiner Richter, modified the utility rejection, stating that the disclosure established utility but only for claims limited to the specific antineoplastic activity listed and tested in the specification. In response, Cancer Research again argued patentability based on the animal testing disclosed in the original specification, relying on a quote from *In re Buting*, 418 F.2d 540 (CCPA 1969), that "[s]ubstantiating evidence may be in the form of animal tests which constitute recognized screening procedures with clear relevance to utility in humans." A2086. Subsequently, a third examiner, Examiner Dentz, found the claims allowable, and the '291 patent issued on November 9, 1993.

During the prosecution of the '291 patent, the applicants continued to study tetrazine derivatives as a treatment for cancer, and inventor Dr. Malcolm Stevens coauthored numerous articles reporting both animal and human clinical data to the scientific community. One of the tetrazine compounds described in the '291 patent as having "particular importance," mitozolomide, showed broad spectrum antitumor activity in mice and was advanced to human clinical trials in 1983. Phase I and II human trials showed mitozolomide to have toxic side effects and little activity against many cancers. In light of mitozolomide's toxic side effects, further studies with the compound were halted. Instead, a second tetrazine compound of "particular importance," temozolomide, entered Phase I human testing in 1987. By 1989, reports showed that temozolomide was safe and had some anti-cancer activity. Clinical testing of temozolomide continued after the issuance of the '291 patent, and the FDA approved

Temodar® for the treatment of refractory anaplastic astrocytoma in August 1999, and for the treatment of newly diagnosed glioblastoma multiforme in March 2005. In October 1999, Schering Corp., the new exclusive licensee under the patent, filed for a patent term extension under 35 U.S.C. § 156, which added 1,006 days to the '291 patent's term. The patent also was granted a pediatric exclusivity period and will expire in February 2014.

On March 19, 2007, Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, "Barr") filed an Abbreviated New Drug Application ("ANDA") with a Paragraph IV certification under the Hatch-Waxman Act, 21 U.S.C. § 355, challenging the validity of the '291 patent and seeking FDA approval for generic Temodar®. Cancer Research sued Barr for patent infringement in the United States District Court for the District of Delaware on July 20, 2007. The parties stipulated to infringement and validity of claim 13 directed to temozolomide, leaving only Barr's counterclaims that the patent was unenforceable for prosecution laches and for inequitable conduct.

After a bench trial, the district court held the '291 patent unenforceable for prosecution laches. The district court first decided that under *Symbol Technologies, Inc. v. Lemelson Medical*, 422 F.3d 1378 (Fed. Cir. 2005) ("*Symbol Techs. II*"), prosecution laches did not require a showing of intervening rights but rather turned on whether under the totality of the circumstances Cancer Research's delay in prosecution in light of the PTO's utility rejections was unreasonable and unexplained. *Cancer Research*, 679 F. Supp. 2d at 572-73. The court then found that even assuming, as Cancer Research claimed, that the PTO's rejections required the submission of human clinical data to establish utility in humans, and thus patentability, Cancer Research could have attempted to traverse the rejection based on then-existing case law

holding that such utility could be shown by animal tests, but waited until doing so benefited it commercially. *Id.* at 574. Furthermore, according to the district court, even if the examiner had rejected Cancer Research's position, a subsequent office action would have at the very least clarified the examiner's position on the need for human data without putting the company in a worse position. *Id.* The district court thus held that the delay caused by eleven continuation applications, ten abandonments, and no substantive prosecution for nearly a decade was unreasonable and a sufficiently egregious misuse of the patent system to bar enforcement of the '291 patent for prosecution laches. *Id.* at 575.

The district court also held the '291 patent unenforceable for inequitable conduct. The court first found that Cancer Research failed to disclose highly material information to the PTO. Specifically, the court found that Cancer Research did not disclose Phase I and II human data indicating that mitozolomide failed to treat numerous cancers covered by the '291 patent claims and did not disclose other data indicating that the inventors considered other claimed tetrazine compounds to be inactive in at least one cancer model. *Id.* at 580. The district court found this withheld information to be highly material because it directly contradicted statements in the '291 patent regarding the compounds' broad utility in treating cancers and directly contravened the patentability of broadly written claim 28. *Id.* at 580-81. In so finding, the court rejected Cancer Research's arguments that the Phase I data were not material because they focused on safety rather than efficacy and that the Phase II data were not material because they were preliminary and inconclusive. The court found that those arguments were belied by inventor Stevens's widespread publication of the data. *Id.* at 580. The district court also rejected Cancer

Research's argument that other undisclosed studies were positive and supported the utility of the claims, concluding that the nondisclosure of positive data did not mitigate the fact that Cancer Research withheld negative data or its finding that the negative data were highly material. *Id.* at 581.

The district court next found that inventor Stevens withheld the data with intent to deceive because (1) the withheld information was highly material, (2) Stevens knew about the information and should have appreciated its materiality as it directly contradicted the application's disclosure, and (3) Stevens did not provide a credible explanation for withholding the information. *Id.* With regard to the latter, the district court found not credible Stevens's testimony that he considered the withheld data to be confidential to clinicians and inconclusive in view of Stevens's widespread publication both of the data and of his conclusions that the data showed the compounds to be inactive and toxic. *Id.* The district court also found Stevens's publication of the withheld data a sufficient basis upon which to infer intent to deceive. *Id.* at 582.

The district court entered final judgment in favor of Barr on January 29, 2010, and Cancer Research appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Prosecution Laches

Prosecution laches is an equitable defense to a charge of patent infringement. *Symbol Techs., Inc. v. Lemelson Med.*, 277 F.3d 1361, 1366 (Fed. Cir. 2002) ("*Symbol Techs. I*"). The doctrine "may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution" that constitutes an egregious misuse of the statutory patent system under the

totality of the circumstances. *Symbol Techs. II*, 422 F.3d at 1385-86. We review a district court's determination of prosecution laches for abuse of discretion, *id.* at 1384, but we review the legal standard applied by the district court *de novo*, *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1380 (Fed. Cir. 2005).

Cancer Research first argues that the district court erred as a matter of law in holding the '291 patent unenforceable for prosecution laches because the court failed to find any evidence of actual prejudice either to the defendant, Barr, or to the public. Cancer Research argues that prosecution laches is a limited doctrine that only applies to bar enforcement of a patent when an applicant purposely delays prosecution in an attempt to cover technology that has already been exploited by others who have no knowledge of the patent. In other words, according to Cancer Research, the doctrine of prosecution laches requires both an unreasonable and unexplained delay in prosecution *and* prejudice based on the intervening rights of the defendant or the public during the period of delay. Alternatively, Cancer Research argues that the district court erred in finding that it unreasonably delayed prosecution of the '291 patent because it did not deliberately seek to delay the patent's issuance or the public's access to Temodar®, but rather filed continuations based on a good faith belief that conclusive human clinical data were required to overcome the PTO's utility rejections.

Barr responds that the district court correctly held the '291 patent unenforceable due to prosecution laches. Barr first argues that the district court correctly recognized that the defense of prosecution laches does not require a specific showing of prejudice. Rather, Barr suggests that an unreasonable and unexplained delay in prosecution inherently prejudices the public if, as here, the delay extends the patent monopoly into the future,

thus preventing Barr's earlier entry into the market for temozolomide. Barr also argues that the district court correctly found that the applicants unreasonably delayed prosecution. Specifically, Barr contends that it was unreasonable to file identical continuation applications, abandonments, and requests for extension of time for nine years without any attempt to substantively advance prosecution until it became commercially advantageous to do so. Furthermore, Barr argues that Cancer Research offers no credible justification for the nine-year delay. According to Barr, Cancer Research's alleged belief that clinical human data were required to overcome the PTO's utility rejections not only ignores pre-1982 case law holding that animal data can establish the human utility of anti-cancer compounds, but also is belied by the applicants' use of animal data to secure issuance of the '291 patent and by their failure to submit human data to the PTO as such data became available during prosecution.

We agree with Cancer Research that prosecution laches' requirement of an unreasonable and unexplained delay includes a finding of prejudice, as does any laches defense. *See A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992) ("Two elements underlie the defense of laches: (a) the patentee's delay in bringing suit was unreasonable and inexcusable, and (b) the alleged infringer suffered material prejudice attributable to the delay."). We also agree and now hold that to establish prejudice an accused infringer must show evidence of intervening rights, *i.e.*, that either the accused infringer or others invested in, worked on, or used the claimed technology during the period of delay.

The Supreme Court cases underlying the doctrine all rely on a finding that the applicant's delay in prosecution adversely affected others working in the same field. In *Woodbridge v. United States*, applicant Woodbridge

delayed the issuance of his patent after allowance by requesting that the PTO keep it secret in its archives as the then-governing patent statute permitted for a term not to exceed one year. 263 U.S. 50, 52-53 (1923). Nine and a half years later, Woodbridge requested that the patent issue because the technology had become commercially profitable. *Id.* at 53, 56. He also requested that his specification and claims be broadened to cover related innovations that others had patented in the intervening years. *Id.* at 53, 57. The Court held that Woodbridge had forfeited his right to his patent by "designed delay," and specifically by attempting, for the admitted purpose of capturing the most commercial profit, to extend both the term of his patent monopoly and its scope to cover advances made by others in the field who had obtained patents without knowledge of Woodbridge's patent. *Id.* at 56-57.

Similarly in *Webster Electric Co. v. Splitdorf Electrical Co.*, 264 U.S. 463 (1924), the Court again relied on both an unreasonable delay and intervening adverse rights to hold a patent forfeited for prosecution laches. In *Webster*, the applicant filed new and broader claims in a divisional application over eight years after his original application was filed. Yet during the eight-year delay, the subject matter of those new and broader claims had been disclosed and had come to be in general use while the applicant and his assignee "simply stood by and awaited developments." *Id.* at 465. In holding that the delay was unreasonable and thus constituted laches, the Court concluded that the patent law should not be so loosely construed as to "bring about an undue extension of the patent monopoly *against private and public rights*." *Id.* at 466 (emphasis added).

The Court's last pronouncements on prosecution laches in *Crown Cork & Seal Co. v. Ferdinand Gutmann*

Co., 304 U.S. 159 (1938), and *General Talking Pictures Corp. v. Western Electric Co.*, 304 U.S. 175 (1938), also relied on a requirement for intervening rights. In both cases the Court held that in the absence of intervening rights, no excuse is necessary for a delay in presenting new claims in a continuation or divisional application. *Crown Cork*, 304 U.S. at 167-68 ("It is clear that, in the absence of intervening adverse rights, the decision in *Webster*, . . . does not mean that an excuse must be shown for a lapse of more than two years in presenting the divisional application."); *Gen. Talking Pictures*, 304 U.S. at 183 ("In the absence of intervening adverse rights for more than two years prior to the [filing of new claims in] continuation applications, they were [filed] in time.").

This court's precedent also recognizes intervening adverse rights as a requirement to holding a patent unenforceable for prosecution laches. In first recognizing the doctrine, we relied on the above-cited Supreme Court cases and noted their reliance on intervening rights. *Symbol Techs. I*, 277 F.3d at 1364-65. For example, we stated that in *Crown Cork*, "the [Supreme C]ourt ratified the existence of the prosecution laches defense; it did not apply the defense there in the absence of intervening rights," and we noted that "in *General Talking Pictures*, the Court rejected the defense of prosecution laches because there was no evidence of intervening public rights." *Id.* at 1365. We then applied the doctrine in a manner that recognized the requirement for intervening rights. We held that the district court had not abused its discretion in holding certain patents unenforceable for prosecution laches based on the applicant's unreasonable delay and "the existence of 'intervening private and public rights.'" *Symbol Techs. II*, 422 F.3d at 1386. We also extended the holding to all the remaining claims based on finding that the subject matter of all the asserted patents

had been pending for eighteen to thirty-nine years, an unreasonably long time, and that "prejudice to the public as a whole has been shown here in the long period of time during which parties, including the [declaratory judgment] plaintiffs, have invested in the technology described in the delayed patents." *Id.*

In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002), is not to the contrary. In *Bogese*, we upheld the PTO's forfeiture decision after an applicant filed twelve continuation applications over eight years without presenting any substantive amendments to traverse an outstanding obviousness rejection. *Id.* at 1363-64. In upholding the examiner's decision that the applicant had forfeited his right to the patent, the Board relied on both an unreasonable delay and intervening rights. Regarding the latter, the Board found that documentation filed with the PTO before the period of delay showed that "the applicant was keenly aware, . . . that [articles] embodying [his] invention were being developed and exploited commercially in the market place." *Id.* at 1366. On appeal, Bogese did not challenge the PTO's decision based on the facts of his case, but rather challenged the PTO's authority to require applicants to advance prosecution. *Id.* at 1369. We upheld the PTO's authority to sanction undue delay under the Administrative Procedure Act, 5 U.S.C. § 706, as not arbitrary, capricious, or contrary to law. *Id.* at 1367-69. The court did not discuss intervening rights in its opinion, as it did not need to, but the PTO relied on the existence of intervening rights in its decision in that case.

Barr's argument that the public was inherently prejudiced by Cancer Research's delay is not persuasive. Cancer Research maintains that it could not have developed temozolomide until Schering agreed to become its licensee, after which Schering filed an Investigational New Drug Application ("IND") only one month after the

issuance of the '291 patent. An inventor is not obligated to develop its product at any particular time prior to issuance or within the patent's term, but, once its patent issued and it had a licensee, it filed its IND promptly. Its product was approved for marketing in 1999.

Barr, on the other hand, while entitled under the law to file an ANDA four years after the NDA approval, in this case in 2003, did not do so until 2007. Thus, Barr filed its ANDA more than thirteen years after the issuance of Cancer Research's patent and more than seven years after approval of Cancer Research's product. Barr was thus hardly prejudiced by the delay in the issuance of the '291 patent, in 1993. Nor was anyone else. There has been no evidence presented that anyone was deterred from entering the market for temozolomide because Cancer Research's patent issued in 1993 rather than several years earlier. Thus, the delay had only limited consequences to Barr and the public.

Cancer Research's delay in prosecuting and issuing its patent application, whatever the asserted justifications, and we do not appraise them here, caused it to run the risk that some other pharmaceutical company (*e.g.*, Barr) would intervene and claim prejudice from the delay, but that did not happen. Moreover, a consequence of Cancer Research's delay in prosecuting its patent is that it did not get the full patent term extension allowed under 35 U.S.C. § 156 because of the fourteen-year cap on exclusivity when a patent has been extended under the Hatch-Waxman Act. *Id.* § 156(c)(3). Thus, rather than having consequences for Barr and the public by its delay, Cancer Research incurred a cost to its own patent term.

Finally, we note that the facts of this case are not likely to be frequently repeated, as patent terms are now measured from effective filing date, *id.* § 154(c)(1), subject

to only limited extensions provided by statute, not by delaying issuance by refiling. And, it also should be noted that, when one considers the public interest, the public has benefited here by the fact that Cancer Research did develop and market temozolomide, induced by the protection of its patent. Cancer Research should not lose that protection because its patent issuance was delayed under circumstances where no one suffered prejudice.

In sum, both the Supreme Court and our cases establish that evidence of intervening rights is required to establish "an unreasonable and unexplained delay in prosecution." *Symbol Techs. II*, 422 F.3d at 1385. Barr has failed to establish either that it or that others developed or invested in temozolomide or any other claimed tetrazine compound between 1982 and 1991, the period of delay. Accordingly, Barr cannot establish prosecution laches as a matter of law, and we reverse the decision of the district court.

Because we conclude that the district court committed legal error in holding the '291 patent unenforceable for prosecution laches in the absence of any evidence of intervening rights, we need not decide if Cancer Research's delay in prosecuting the '291 patent was unreasonable or unexplained.

II. Inequitable Conduct

The district court also held the '291 patent unenforceable for inequitable conduct. *Cancer Research*, 679 F. Supp. 2d at 577-82. To successfully prove inequitable conduct, the accused infringer must provide evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) did so with intent to deceive the PTO. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir.

2008). Both materiality and intent must be proven by clear and convincing evidence. *Id.* While deceptive intent can be inferred from indirect and circumstantial evidence, that "inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard." *Id.* at 1366.

This court reviews a district court's determination of inequitable conduct under a two-tiered standard; we review the underlying factual determinations of materiality and intent for clear error, and we review the ultimate decision as to inequitable conduct for an abuse of discretion. *Id.* at 1365. If the district court's inequitable conduct determination rests on a clearly erroneous finding of materiality and/or intent, it constitutes an abuse of discretion and must be reversed. *Id.*

Cancer Research alleges that, *inter alia*, the district court erred in finding that inventor Stevens withheld studies on tetrazine derivatives with deceptive intent. Cancer Research argues that there is no evidence to counter Stevens's testimony that he did not consider the withheld data material and that by identifying only Stevens's publication of the data to establish his knowledge of its materiality, the district court erroneously relied solely on its finding of materiality to infer deceptive intent. Furthermore, Cancer Research argues that Stevens provided a good faith explanation for the nondisclosure, testifying that he honestly and to the best of his ability provided all necessary information about the claimed compounds and, as a laboratory scientist, believed the clinical data were confidential. Finally, Cancer Research asserts that nothing in Stevens's widespread publication of the data evidences wrongful intent, but rather the opposite, extreme candor. Accordingly, Cancer

Research concludes that the district court's inference of deceptive intent is far from the single most reasonable inference to draw from the evidence, and thus the court's determination of inequitable conduct must be reversed.

In response, Barr defends the district court's finding of intent. Specifically, Barr argues that, based on Stevens's testimony at trial, the district court correctly found that Stevens knew he possessed undisclosed data that contradicted the disclosure in the patent application and knew he had a duty to disclose such material information to the PTO but did not do so. According to Barr, the only reasonable inference to draw from this evidence is an intent to deceive. Moreover, Barr argues that the district court found Stevens's explanations for his failure to disclose the information not credible, concluding that Stevens's publication of the data along with statements regarding the compounds' "inactivity" and "toxicity" belied his assertions that he believed the data to be "inconclusive" and "confidential." Finally, Barr argues that, contrary to Cancer Research's contention, the district court did not clearly err in finding that Stevens's publication of the withheld data was relevant to intent; the publications demonstrate that Stevens's stated reasons for not disclosing the data were untrue.

We agree with Cancer Research that the district court clearly erred in finding that Stevens intended to deceive the PTO by not disclosing data on the claimed compounds, and specifically we agree that the district court erred because it relied solely on its finding of materiality to infer intent. The district court found that "Stevens should have appreciated the materiality of the data . . . as they expressly contradicted the disclosure of the pending applications" and that under the circumstances "Stevens' publications to the scientific community [provided] a sufficient basis upon which to infer an intent to deceive."

Cancer Research, 679 F. Supp. 2d at 581-82. The district court, however, relied on the same evidence in finding the withheld data to be "highly material"; the court found that "the withheld information directly contradicts statements made in the '291 patent's specification," making it highly material, and rejected Cancer Research's arguments regarding materiality as "belied by the fact that Stevens . . . thought the data [were] significant enough to describe in publications to the scientific community." *Id.* at 580-81. Because the district court did not rely on any other evidence to support its finding of deceptive intent beyond that used to find the withheld data material, the court in effect relied solely on its materiality finding to infer intent to deceive.

But materiality and intent are separate requirements, and intent to deceive cannot be found based on materiality alone. *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009). A court cannot simply infer that an applicant "should have known" the materiality of withheld information and thus intended to deceive the PTO because the applicant knew of the information and the information is material. A district court must find some other evidence that indicates that the applicant appreciated the information's materiality. *See, e.g.*, *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997) (finding intent to deceive based in part on handwritten notes of prosecution counsel corroborating that counsel subjectively believed the undisclosed patent was material). In this case, evidence that Stevens co-authored articles that contradict the disclosure of the '291 patent specification does not alone establish that Stevens withheld those studies intending to deceive the PTO.

We also disagree with the inference the district court drew from Stevens's publication of the withheld data.

While publication to the scientific community is not the same as disclosure to the PTO and does not foreclose a finding of deceptive intent, *see Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1241 (Fed. Cir. 2003), the prompt publication of data in multiple articles over the entire course of prosecution is inconsistent with finding that intent to deceive is the single most reasonable inference to draw from the evidence in this case, *see Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1252 (Fed. Cir. 2008) (stating that "[p]ublication [to the scientific community] is an act inconsistent with an intent to conceal data from the USPTO."). Also, Stevens did not selectively withhold information; the withheld information includes both positive and negative data regarding the claimed tetrazine derivatives. *Cf. Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1376 (Fed. Cir. 2000) (affirming a finding of intent to deceive based on a partial translation of a prior art reference). Accordingly, an equally reasonable inference to draw from the evidence is that Stevens viewed publication of all the data as important to his career as a scientist but did not appreciate their potential importance to the patentability of the tetrazine derivatives patent claims.

Because we conclude that the district court committed clear error in finding that Stevens acted with deceptive intent, we need not address Cancer Research's argument that the district court also erred in finding the withheld data highly material, and we reverse the district court's decision holding the '291 patent unenforceable for inequitable conduct.

CONCLUSION

For the foregoing reasons, we reverse the district court's decision holding the '291 patent unenforceable for prosecution laches and inequitable conduct.

REVERSED

United States Court of Appeals for the Federal Circuit

CANCER RESEARCH TECHNOLOGY LIMITED AND SCHERING CORPORATION,
Plaintiffs-Appellants,

v.

BARR LABORATORIES, INC. AND BARR PHARMACEUTICALS, INC.,
Defendants-Appellees.

2010-1204

Appeal from the United States District for the District of Delaware in case no. 07-CV-0457.

PROST, *Circuit Judge*, dissenting.

I respectfully dissent. In my view, the majority opinion seriously errs in reversing the district court's findings and conclusions that U.S. Patent No. 5,260,291 ("'291 patent") is unenforceable on the grounds of both prosecution laches and inequitable conduct. In doing so, the majority propounds a new and unsupportable legal standard for prosecution laches. With regard to inequitable conduct, the majority not only creates a new evidentiary standard, but it also ignores virtually unassailable credibility findings made by the district court after a four-day bench trial. I address each in turn below.

I. Prosecution Laches

The majority appears to not take issue with the district court's findings and conclusion that the patentee's almost decade-long delay in prosecuting its application—caused by filing eleven continuation applications, abandoning ten of those applications, and obtaining nearly two years' worth of time extensions merely to file continuation applications rather than responses to the Office Actions—was unreasonable. Despite Cancer Research Technology Limited and Schering Corporation's (collectively, "Cancer Research") excuses justifying the delay, the information eventually used to overcome the examiner's initial rejection was contained in the application as originally filed ten years earlier. The district court carefully rejected all of the patentee's excuses for its delay, ultimately concluding that the applicants did not prosecute the application until it became commercially advantageous to do so.

Instead, the majority rejects the legal standard the district court applied. The district court concluded that under *Symbol Technologies, Inc. v. Lemelson Medical*, 422 F.3d 1378 (Fed. Cir. 2005) ("*Symbol Techs. II*"), prosecution laches does not require a showing of intervening rights, but rather turns on whether under the totality of the circumstances Cancer Research's delay was unreasonable and unexplained. *See Cancer Research Tech. v. Barr Labs., Inc.*, 679 F. Supp. 2d 560, 572-73 (D. Del. 2010). Besides rejecting this standard, the majority says that in order to establish prosecution laches (1) prejudice to the alleged infringer must be shown, and (2) that prejudice requires that "either the accused infringer or others invested in, worked on, or used the claimed technology *during the period of delay*." Maj. Op. at 9 (emphasis added); *see also id.* at 13-14 ("Barr has failed to establish either that it or that others developed or in-

vested in temozolomide or any other claimed tetrazine compound between 1982 and 1991, the period of delay. Accordingly, Barr cannot establish prosecution laches as a matter of law . . . .").

First, I think the district court got it right because I do not agree with the majority that a showing of intervening rights, i.e. prejudice, is compelled by our precedent. Moreover, even if one could construe the case law as requiring prejudice, there is *no* basis, in the relevant case law or otherwise, for the majority's further temporal limitation that the prejudice exists during the period of delay.

Shifting the inquiry regarding prosecution laches from Cancer Research's own conduct to the conduct of the party invoking the defense ignores that prosecution laches is an equitable defense. Neither the Supreme Court nor this court has required a defendant to establish prejudice to assert prosecution laches. Indeed, in *Woodbridge v. United States*, the Court held that a plaintiff's willful or negligent postponement in obtaining patent rights alone can result in forfeiture. 263 U.S. 50, 57 (1923) (quoting *Kendall v. Winsor*, 62 U.S. 322, 329 (1858), for the proposition that an inventor "'may forfeit his rights as an inventor by a willful or negligent postponement of his claims, *or* by an attempt to withhold the benefit of his improvement from the public until a similar or the same improvement should have been made and introduced by others'" (emphasis added)).[1] Our precedent

[1] The majority also cites to *Webster Electric Co. v. Splitdorf Electic Co.*, 264 U.S. 463 (1924), *Crown Cork & Seal Co. v. Ferdinand Gutmann Co.*, 304 U.S. 159 (1938), and *General Talking Pictures Corp. v. Western Electric Co.*, 304 U.S. 175 (1938). None of these Supreme Court cases require a showing of prejudice where an applicant

is no more restrictive. Recognizing that prosecution laches is an equitable doctrine, we have declined to "set forth any firm guidelines for determining when such laches exists." *Symbol Techs. II*, 422 F.3d at 1385. Laches may be triggered by "the totality of the circumstances, including the prosecution history of all of a series of related patents and overall delay in issuing claims." *Id.* at 1386. And we have specifically indicated that "repetitive refilings that demonstrate a pattern of unjustifiably delayed prosecution" "for the business purpose of delaying . . . issuance [of the patent]"—an apt description of Cancer Research's behavior during the prosecution of the '291 patent—supports a finding of laches. *Id.* at 1385-86.

---

unreasonably extends prosecution by refusing to respond to the merits of nine substantially similar Office Actions. Under *Webster*, "laches, equitable estoppel *or* intervening private or public rights" can each alone bar the right to a claim presented in a subsequent divisional patent. 264 U.S. at 471 (emphasis added). The *Webster* Court suggested that there is a presumption that such claims are unreasonable (and thus time-barred) where the applicant waited more than two years to present the claims in a divisional application. *Id.* Under *Webster*, applicants could only obtain such claims if they provided justification for the more than two-year delay. *Id.* In *Crown Cork*, the Court clarified that "in the absence of intervening rights, the decision in [*Webster*] does not mean that an excuse must be shown for a lapse of more than two years in presenting the divisional." 304 U.S. at 167-68; *see also General Talking Pictures*, 304 U.S. at 184. *Crown Cork* and *General Talking Pictures* make clear that a two-year delay in filing a divisional is not *per se* unreasonable in the absence of intervening rights. However, *nothing* in these cases requires a party to show that it had intervening rights or suffered any other prejudice as a prerequisite to asserting the equitable defense of prosecution laches where the patentee's prosecution delays are unreasonable under the totality of the circumstances.

More importantly, even if prejudice is required, there is no basis for the majority's new requirement that one must confine himself to the period of prosecution delay in determining whether prejudice exists. Such a requirement (1) discounts the relationship between prosecution laches and broad public interests in the timely issuance of patents and (2) imposes a novel time restriction on the harm suffered.

By requiring this particularized prejudice, the majority sidesteps the real harm at issue in this case. The Supreme Court has explicitly recognized that delaying a patentee's monopoly period harms the public by delaying its free use of the patented invention. *Woodbridge*, 263 U.S. at 48-49. Here, the applicant first filed the patent application disclosing temozolomide in 1982. By stalling prosecution for its own business purposes for nearly a decade, Cancer Research obtained a patent which does not expire until 2014—almost thirty-two years after the first application in this chain was filed. The majority downplays the public prejudice caused by this delay,[2] Maj. Op. at 12-13; however, Cancer Research's conduct has prejudiced the public by extending its patent monopoly over temozolomide. Indeed, Congress has specifically recognized the public's interest in obtaining affordable prescription drugs by enacting a regulatory scheme to expedite the availability of generic drugs. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 1984 Stat. 1538 (codified as amended

[2] While the majority suggests Cancer Research itself "incurred a cost" due to the prosecution delay, that Cancer Research's delay resulted in its not getting the full patent term extension has absolutely no relevance to whether public or private interests were prejudiced by the delay.

in scattered sections of 21 & 35 U.S.C.). Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, "Barr"), as well as other makers of generic pharmaceuticals, are likewise harmed. It is unable to enter the market without risking a patent infringement suit until a date far later than the one it would have faced had Cancer Research not engaged in its excessive delays.

The majority avoids entirely these harms by confining the relevant harm to the period during which Cancer Research delayed prosecution of its patent application. There is no basis for the majority's limitations. I would hold that the more generalized harm associated with the improper extension of the patent monopoly, including the accompanying market uncertainty and denial to the public of free use of the invention, is sufficient prejudice to justify the use of an equitable defense. Even if our precedent required adverse intervening rights, it is not appropriate to confine the inquiry to the period of time when Cancer Research was actively delaying prosecution. The harm continued though the patent term "extension" Cancer Research improperly created though its delay tactics.

II. Inequitable Conduct

Similarly, in reversing the district court's findings and conclusions regarding inequitable conduct, the majority veers from our precedent in at least two respects: (1) it creates a new evidentiary standard for establishing inequitable conduct, and (2) it inexplicably rejects the district court's unassailable credibility determinations, which served as the basis for its conclusion that inequitable conduct occurred.

Again, in my view, the district court got it exactly right. Here, an inventor, Dr. Stevens, withheld important data from the U.S. Patent and Trademark Office ("PTO") that contradicted the disclosure in the patent applications. The majority does not take issue with the district court's conclusion that this data was highly material. Clearly, it could not, because at a minimum the disclosure would have affected the scope of the patent granted. Rather, it rejects the district court's credibility determination that Dr. Stevens's explanation for not submitting this highly material data was belied by the facts that Stevens found the data conclusive enough (and sufficiently non-confidential) to publish the data and his conclusions of inactivity or toxicity to the scientific community. Stevens did not qualify his statements regarding inactivity. Certainly, if Stevens found the information sufficiently accurate to base conclusions upon and to publish to his peers, it was sufficiently accurate and conclusive enough to submit to the PTO. *Cancer Research*, 679 F. Supp. 2d at 581.

The majority's rejection of the findings and conclusions of the trial judge rests on two faulty pillars. The majority first missteps by determining that materiality and intent require separate evidentiary bases. The majority concludes that the district court erred because it "did not rely on any other evidence to support its finding of deceptive intent beyond that used to find the withheld data material." Maj. Op. at 17. Requiring separate evidence for each prong, however, has no basis in our precedent. The majority is correct that the district court cited to the same evidence in support of its findings of intent and materiality. But it by no means rested on its finding of materiality to infer intent. Rather, the evidence presented at trial separately supports the district court's findings on both prongs, and when combined with

the district court's credibility findings regarding Dr. Stevens's "explanation" for his failure to disclose, is absolutely sufficient to support the conclusion that highly material evidence was withheld from the PTO with intent to deceive.

Further, the majority's treatment of the district court's credibility determinations—which are virtually unreviewable by this court—is baffling. *See LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1361 (Fed. Cir. 2001). The majority concludes that the district court did not draw the most reasonable inference regarding Stevens's withholding of the published data. Maj. Op. at 17-18. Instead, the majority believes that there is another "an equally reasonable inference"—Stevens did not appreciate the potential importance of the data to the patentability of the claims. We should not draw inferences that the district court has already excluded based on its own credibility findings with respect to Stevens's explanations for the withholding.

In sum, in light of our prosecution laches precedent, I would not require that Barr have intervening rights during the period that Cancer Research delayed prosecution of its patent. Even if I did, I would not limit the prejudice inquiry to the period of delay. Further, given our differential standard of review, I cannot agree that the district court's intent finding with regard to inequitable conduct is clearly erroneous. Accordingly, I would uphold the district court's application of prosecution laches and its finding of inequitable conduct.