Bloomberg Law Reports® Intellectual Property

Prosecution Laches: Defining an Equitable Doctrine of Patent Unenforceability

Contributed by Christopher E. Chalsen and James R. Klaiber, Milbank, Tweed, Hadley & McCloy LLP

The defense of prosecution laches has been available to accused patent infringers since the Federal Circuit's 2002 decision in *Symbol Technologies v. Lemelson*. This equitable doctrine allows a court to hold a patent unenforceable based on the patentee's delay in prosecuting the asserted patent.

In its *Cancer Research Technology v. Barr Laboratories* decision of November 2010, the U.S. Court of Appeals for the Federal Circuit reversed a district court's holding of patent unenforceability based on prosecution laches, concluding that the absence of prejudice during the period of the patentee's delay precluded that holding. Recently, the Federal Circuit denied en-banc 'rehearing of this decision, and in strongly-worded dissents, five of ten judges disagreed with the Court's requirement for a showing of prejudice, in the form of intervening rights, during the period of delay.

Given the deep division in the Federal Circuit, and because both the panel majority and the rehearing dissenters relied on the same U.S. Supreme Court cases in support of their positions, it seems that the definition of prosecution laches is ripe for high court review. A review of the Supreme Court's laches jurisprudence, however, appears to support the panel's requirement for prejudice to the accused infringer during the patentee's prosecution delay.

The Cancer Research Panel Decision

On November 9, 2010, the Federal Circuit reversed a decision by the U.S. District Court for the District of Delaware holding Cancer Research's patent unenforceable for prosecution laches. The Federal Circuit held that the district court committed legal error in holding the patent unenforceable for prosecution laches in the absence of any evidence of prejudice, specifically the lack of intervening rights during the period of delayed prosecution.

Cancer Research's U.S. Patent No. 5,260,291[1] ("the '291 patent"), claims a genus of tetrazine derivative compounds and methods for treating cancer using those compounds. The original specification for the '291 patent was filed on August 23, 1982 and disclosed thirteen tetrazine derivative compounds identified as having valuable antineoplastic activity based on animal data. From 1983 to 1991, the U.S. Patent and Trademark Office examiner repeatedly rejected the claims for lack of utility and the applicant filed ten continuation applications instead of responding to the office actions. In 1991, Cancer Research obtained ownership of the patent application, filed another continuation application, and for the first time responded to the examiner's

utility rejection arguing that the disclosure of animal data in the original specification was sufficient to establish utility in humans. The examiner found the claims allowable, and the patent issued on November 9, 1993.

During the prosecution of the '291 patent, one of the claimed tetrazine compounds, temozolamide, advanced to human clinical trials and was approved by the U.S. Food and Drug Administration for the treatment of two different types of brain cancer. Temozolamide is marketed as Temodar®. The '291 patent was granted a patent term extension of 1,006 days and also a pediatric exclusivity period, and thus will expire in 2014.

In 2007, Barr filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval for a generic form of Temodar® as well as a Paragraph IV certification that challenged the validity of the '291 patent. Cancer Research sued Barr for patent infringement, andBarr counterclaimed that the patent was unenforceable for prosecution laches and for inequitable conduct.

After a bench trial, the district court found the '291 patent unenforceable due to prosecution laches. The district court agreed with Barr that the delay caused by eleven continuation applications, ten abandonments, and no substantive prosecution for nearly a decade was unreasonable and unexplained. The district court entered final judgment in favor of Barr, and Cancer Research appealed.

On appeal, the Federal Circuit held that the doctrine of prosecution laches requires both an unreasonable and unexplained delay in prosecution and a finding of prejudice to the accused infringer. Moreover, the Federal Circuit held 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."[2] In arriving at this decision, the panel first cited *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*[3] to support its holding that prosecution laches, like all laches defenses, requires a finding of prejudice. Then, the panel reviewed the Supreme Court cases underlying the doctrine, *Woodbridge v. United States*[4] and *Webster Electric Co. v. Splitdorf Electrical Co*.[5] The panel found that both these cases relied on unreasonable delay and its adverse effect on others working in the same field. In so doing, the panel noted two other Supreme Court cases where a lack of intervening rights precluded a finding of prosecution laches,[6] and observed that its own *Symbol Technologies* decisions[7] relied on the existence of intervening rights.

The Court found that neither Barr nor anyone else developed or invested in temozolomide or any of the claimed tetrazine compounds between 1982 and 1991, noting that even Barr, who was entitled under the law to file an ANDA in 2003, did not do so until 2007. Therefore, neither Barr nor anyone else was prejudiced by the delay in the issuance of the '291 patent in 1993. In the Federal Circuit's view, the only consequence of the delay is that the '291 patent was not entitled to a term extension longer than the fourteen-year exclusivity maximum under the Hatch-Waxman Act. Accordingly, the Federal Circuit concluded 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.

In a strongly-worded dissent, Judge Sharon Prost disagreed with the panel's requirement of prejudice, and specifically intervening rights, to support unenforceability due to prosecution laches. Judge Prost penned her own review of the prosecution laches holdings of both the Supreme Court and the Federal Circuit, concluding that these cases did not compel a finding of prejudice. Furthermore, in her view, unreasonable prosecution delay inherently prejudices the public, so no particularized showing of intervening rights during the period of delay is necessary.

The Rehearing Denial

On March 7, 2011, the Federal Circuit denied Cancer Research's petition for rehearing en banc. As the judges were evenly split, with five judges voting

each way, there was no simple majority and the petition failed. Judge Prost dissented from the denial, and issued a detailed opinion in which Judges Gajarsa, Moore, and O'Malley joined.

Judge Prost's dissent, as in her panel dissent, focused on the harm to the public from unreasonably delayed patent prosecution. Citing *Woodbridge* and *Webster Electric*, her dissent parsed the Supreme Court's decisions in an effort to show that either unreasonable delay or intervening rights could result in patent unenforceability. Accordingly, she urged a "totality of the circumstances" test for prosecution laches, noting that the Supreme Court's recent patent cases[8] favored flexible tests over rigid formalism.[9]

Why Did The Federal Circuit's Judges Come to Opposite Interpretations of the Supreme Court's "Prosecution Laches" Decisions?

The strongly voiced concerns in Judge Prost's dissents suggest a deep division within the Federal Circuit on the issue of prosecution laches. The two Supreme Court decisions relied on by both the panel majority and Judge Prost provide some basis for sorting out the differences among the judges.

In *Woodbridge*, the inventor, Woodbridge, filed a patent application for an improved cannonball in 1852, the claims of which were allowed a few months later. At that time, Woodbridge requested that his application be held in the Patent Office's secret archives for one year. However, after more than nine years of inactivity, and shortly after the start of the Civil War, Woodbridge finally requested that his patent be issued, as well as requesting the allowance of additional, broader claims. The Patent Office refused to issue the patent, and Woodbridge's subsequent appeals were unsuccessful. However, by a special 1901 statute, Woodbridge was entitled to claim compensation for the use by the U.S. government of his cannonball invention as if a patent had issued in 1852, unless he had forfeited his right to a patent by "publication, delay, laches, or otherwise."[10] The Supreme Court noted that Woodbridge had intentionally delayed his patent for more than nine years, and had done so "for the admitted purpose of making the monopoly square with the period when the commercial profit from it would be highest."[11] In particular, the Court stated that "[m]any inventors were at work in the same field and had made advances in the art and the Government had used them."[12] Accordingly, while the *Woodbridge* opinion did not use the phrase "prosecution laches," it did affirm the Court of Claims's holding that "Woodbridge had forfeited or abandoned his right to a patent by his delay or laches."[13]

The Supreme Court's *Webster Electric* decision related to patents held by Webster Electric Co. ("Webster") based on an application originally filed in February 1910. Webster's original application issued as a U.S. patent in November 1916, and a divisional application was filed in 1915. Meanwhile, Webster had filed an infringement suit against Splitdorf Electrical Co. ("Splitdorf") based on another patent that had issued in 1914. In June 1918, Webster added two broader claims to its divisional application, which issued as a patent in September 1918 and was added to the suit against Splitdorf in October 1918. The Court found that the subject matter of these broader claims was "in general use," and that Webster had "simply stood by and awaited developments" during the more than eight years between its 1910 application and its 1918 amendments.[14] The Court found that Webster's "delay was unreasonable, and, under the circumstances shown by the record, constitutes laches," requiring dismissal of the suit against Splitdorf.[15]

Although the Supreme Court's opinions in both *Woodbridge* and *Webster Electric* found that "laches" barred plaintiffs from enforcing their patent rights, neither decision outlines precisely what the court was referring to by the term "laches." In particular, neither opinion appeared to expressly require prejudice, nor did either decision expressly indicate that such prejudice must be shown by the presence of intervening rights during the period of unreasonable delay. Without a clear

definition of the requirements of a laches defense based on prosecution delay, it is not surprising that both the *Cancer Research* panel and the en banc dissenters found support for their positions in these cases. It appears, however, that the judges may not have considered either the Supreme Court's laches opinions from around the time of *Woodbridge* and *Webster Electric*, or the Court's more recent decisions that considered the requirements of a laches defense.

Does Laches Require a Showing of Prejudice During the Period of Unreasonable Delay?

The Supreme Court's 1892 *Galliher v. Cadwell* decision,[16] as well as the Court's recent laches jurisprudence, reveal consistency with the Federal Circuit's decision in *Cancer Research*.

In the *Galliher* case, Cadwell had sued Mrs. Galliher and others to quiet title to land in Tacoma, Washington. On the issue of laches, the Court noted that the value of the land had greatly increased between 1879, when Galliher's homestead claim to the land expired, and 1886, when she asserted her claim against Cadwell. In explaining its reasoning for finding laches, the Court included the following discussion (emphasis added):[17]

> [T]he question of laches turns not simply upon the number of years which have elapsed between the accruing of her rights, whatever they were, and her assertion of them, but also upon the nature and evidence of those rights, the changes in value, and other circumstances occurring during that lapse of years. The cases are many in which this defence has been invoked and considered. It is true, that by reason of their differences of fact no one case becomes an exact precedent for another, yet a uniform principle pervades them all. They proceed on the assumption that the party to whom laches is imputed has knowledge of his rights, and an ample opportunity to establish them in the proper forum; that by reason of his delay the adverse party has good reason to believe that the alleged rights are worthless, or have been abandoned; and that because of the change in condition or relations during this period of delay, it would be an injustice to the latter to permit him to now assert them.

Thus, the Supreme Court's *Galliher* opinion supports the proposition that the party asserting a laches defense must show prejudice during the period of unexcused delay, as required by the Federal Circuit panel in *Cancer Research.*

The Supreme Court's most recent discussion of the elements of a laches defense dates from 2002, in the *Nat'l R.R. Passenger Corp. v. Morgan*[18] opinion authored by Justice Clarence Thomas. There, the Court considered whether an employer may assert a laches defense against a late-filed discrimination claim by an employee, stating that "a laches defense . . . bars a plaintiff from maintaining a suit if he unreasonably delays in filing a suit and as a result harms the defendant."[19] The Court relied on its earlier opinion in *Costello v. United States*,[20] which stated that "[t]his defense requires proof of (1) lack of diligence by the party against whom the defense is asserted, and (2) prejudice to the party asserting the defense."[21] The Court did not, however, address whether the elements were made out in that case, stating only that the defense may be raised "in the face of unreasonable and prejudicial delay."[22]

Furthermore, in the more than 100 years between the *Galliher* and *Nat'l. R.R. Passenger Corp.* decisions, the Supreme Court has had five opportunities to address the issue of whether a lack of either unreasonable delay or prejudice prohibited the defendant from succeeding in its defense.[23] While no laches was found in any of these cases, the Court expressly stated that a lack of prejudice supported the decision reached in four of the five cases.[24]

Possible Supreme Court Review

In determining whether to grant any *certiorari* petition by Barr,[25] the Supreme Court may consider that the number of U.S. patents likely to be subject to a prosecution laches defense would seem to be decreasing as time marches on because the patent laws were amended in 1995 to set the expiration of U.S. patents at 20 years from their respective filing dates.[26] In addition, while the Supreme Court's recent patent jurisprudence has generally favored flexible tests over rigid requirements, more than 100 years of Supreme Court laches decisions support a bright-line line requirement of prejudice caused during the patentee's delay. Accordingly, it appears that even if *certiorari* were granted, the Supreme Court may let stand the Federal Circuit's *Cancer Research* panel decision.

Mr. Chalsen is a partner and Mr. Klaiber is a special associate in the Intellectual Property and Litigation Group of Milbank, Tweed, Hadley & McCloy LLP. Mr. Chalsen and Mr. Klaiber are both resident in Milbank's New York Office, 1 Chase Manhattan Plaza, New York, NY 10005. Mr. Chalsen can be reached at (212) 530-5380 and cchalsen@milbank.com, and Mr. Klaiber can be reached at (212) 530-5363 and jklaiber@milbank.com.

---

1 U.S. Patent No. 5,260,291.

2 *Cancer Research Tech. Ltd. v. Barr Labs. Inc.*, 625 F.3d 724, 729 (Fed. Cir. 2010) ("*Cancer Research*") (emphases added).

3 906 F.2d 1020 (Fed. Cir. 1992).

4 263 U.S. 50 (1923).

5 264 U.S. 463 (1924).

6 *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).

7 *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., LP*, 277 F.3d 1361 (Fed. Cir 2002) ("*Symbol Techs. I*"); *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., LP*, 422 F.3d 1378 (Fed. Cir 2005) ("*Symbol Techs. II*"). In a third decision, granting a limited panel reh'g and denying a petition for reh'g en banc, the Federal Circuit extended its holding in *Symbol Techs. II* from the 76 asserted claims to all claims of the asserted patents, noting 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." *Cancer Research*, 625 F.3d at 731; *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found. LP*, 429 F.3d 1051, 1052 (Fed. Cir 2005).

8 *Cancer Research Tech. Ltd. v. Barr Labs. Inc.*, 2011 BL 51069 (Fed. Cir. Feb. 28, 2011) (Prost, J. dissenting) (citing. *Bilski v. Kappos*, 561 U.S ___, 2010 BL 146286 (June 28, 2010); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)).

9 Judge Dyk authored his own short dissenting opinion. In his view, prosecution laches does not require a showing of intervening rights, but he also rejected Judge Prost's proposed "totality of the circumstances" test as both confusing and unsupported by the Supreme Court's precedent.

10 *Woodbridge*, 263 U.S. at 51.

11 *Id.* at 56.

12 *Id.* at 58.

13 *Id.* at 51, 63.

14 *Webster Electric*, 264 U.S. at 465.

15 *Id.* at 466, 471.

16 *Galliher v. Cadwell*, 145 U.S. 368 (1892).

17 *Galliher*, 145 U.S. 371-372 (emphasis added).

18 536 U.S. 101 (2002).

19 *Id.* at 121.

20 365 U.S. 265 (1961). The Supreme Court's definition of laches in *Costello* rested on three of its earlier opinions, each of which found that both unreasonable delay and prejudice to the defendant were required to succeed in the defense. *Id.*, 365 U.S. at 282 (citing *Galliher*, 145 U.S. at 372; *Southern Pacific Co. v. Bogert*, 250 U.S. 483, 488-490 (1919); *Gardner v. Panama R. Co.*, 342 U.S. 29, 31 (1951)).

21 *Nat'l R.R. Passenger Corp.*, 536 U.S. at 121-122 (internal quotation marks omitted).

22 *Id.* at 122.

23 *Southern Pacific*, 250 U.S. at 488-490; *Gardner*, 342 U.S. at 30-32; *Costello*, 365 U.S. at 281-284; *Kansas v. Colorado*, 514 U.S. 673, 687-689 (1995); *New Jersey v. New York*, 523 U.S. 767, 806-807 (1998).

24 *Southern Pacific*, 250 U.S. at 490 ("[T]he defendant was not prejudiced by the delay."); *Gardner*, 342 U.S. at 31 ("There is no showing that the respondent's position has suffered from the fact that the claim has not yet proceeded to trial on its merits."); *Costello*, 365 U.S. at 282 ([T]he record is clear that the petitioner was not prejudiced by the Government's

delay. . . ."); *New Jersey v. New York*, 523 U.S. at 806 ("The claim of prejudice that New York raises under the guise of a laches defense includes no prejudice in defending against suit . . . ."). One aspect of the definition of laches that was not addressed in any of these Supreme Court cases is whether a showing of intervening rights of "others," or "the public as a whole," would have been prejudice sufficient to support a finding of laches, as the Federal Circuit has suggested it could be. *Cancer Research*, 625 F.3d at 729, 731 (emphases added).

[25] Barr has requested and received an extension to file any petition for certiorari until July 28, 2011. *See* http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/10a1085.htm, retrieved May 17, 2011.

[26] *See* 35 U.S.C. § 154(a)(2) and enabling legislation. According to one source, however, as of December 2010 there were still approximately 600 pre-1995 unclassified patent applications pending in the U.S.P.T.O. *See* http://www.patentlyo.com/patent/2010/12/old-school-submarine-patents.html (dated December 14, 2010; accessed April 15, 2011).