

## Cancer Research Tech. v. Barr Laboratories: The federal circuit unreasonably delays a clear directive on doctrine of prosecution laches

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Spring 2011

The most troubling aspect of the federal circuit's recent ruling in *Cancer Research v. Barr Labs*<sup>1</sup> is that a third of the judges currently sitting on the court think it is wrong. On Feb. 28, 2011, Barr's petition for rehearing en banc was denied; five federal circuit judges voted in favor of rehearing the matter en banc, and five voted against – one shy of the required majority.<sup>2</sup> What patent practitioners are left with in the wake of this deadlock is uncertainty in the doctrine of prosecution laches and a newly crafted, significantly narrowed legal standard for evaluating the defense. As Judge Dyk succinctly stated in dissent to the denial of rehearing, "Patent prosecutors require guidance as to when they risk a defense of prosecution laches. We should grant en banc review to provide that guidance."<sup>3</sup>

### Factual background

The application that matured into U.S. Patent No. 5,260,291 (the '291 patent) was filed on Aug. 23, 1982. The patent was issued on Nov. 9, 1993. During the 11-year pendency of the application, the applicant—initially a British pharmaceutical company that assigned its rights in the application to Cancer Research in 1991—filed 11 continuation applications, 10 abandonments, and failed to substantively advance prosecution for nearly a decade.<sup>4</sup>

The '291 patent is directed to a method of treating leukemia by administering a tetrazine compound. The specification initially disclosed animal testing designed to establish the claimed invention's efficacy. Initially, the U.S. Patent and Trademark Office rejected claim 31 of the application for want of utility and recommended that utility could be established "by clinical reports and data, the acceptance of the drug employed by the Food and Drug Administration and the American Medical Association Council on Pharmacy."<sup>5</sup> The applicants did not respond to the action, but instead filed a continuation application on March 6, 1984, and abandoned the original application. On Oct. 24, 1984, the USPTO again rejected claim 31 on the same grounds. Again, the applicants responded by filing a continuation application and abandoning the pending application. "This pattern repeated itself eight more times, with the examiner ultimately rejecting all the pending claims for lack of utility."<sup>6</sup>

Once Cancer Research took over prosecution of the application in 1991 it began to challenge the USPTO's utility rejection, asserting that the animal testing data was sufficient to establish utility in humans.<sup>7</sup> For this argument, Cancer Research relied on the Court of Custom and Patent Appeals' 1969 decision from *In re Buting*,<sup>8</sup> which stated that "[s]ubstantiating evidence may be in the form of animal tests which constitute recognized screening procedures with clear relevance to utility in humans." Cancer Research also cited human trials conducted throughout the late 1980s showing that a tetrazine derivative—temozolomide—was safe and had some anti-cancer activity.<sup>9</sup>

After the patent issued, the USPTO granted a patent term extension pursuant to 35 U.S.C. §156, which added 1,006 days to the '291 patent's term. The USPTO also granted a pediatric exclusivity period until February 2014. On March 19, 2007, Barr filed an ANDA under the Hatch-Waxman Act, 21 U.S.C. §355, challenging the validity of the '291 patent and seeking FDA approval for a generic drug equivalent. Cancer Research sued Barr for patent infringement on July 20, 2007 in the U.S. District Court for Delaware.

### **District court proceedings**

Judge Robinson of the District Court of Delaware—a well-respected and patent savvy jurist—presided over the trial court proceedings between Cancer Research and Barr. The parties stipulated to infringement and validity, leaving only Barr's counterclaims for the unenforceability of the '291 patent for prosecution laches and inequitable conduct at stake. In its thorough and well-reasoned opinion, the district court found the '291 patent unenforceable due to prosecution laches.<sup>10</sup> Citing the federal circuit's 2005 opinion in *Symbol Tech. v. Lemelson*,<sup>11</sup> the court employed the under a totality of the circumstances test, concluding that:

[T]he “ends”—commercialization of a very successful cancer drug -- do not justify the “means” employed by CRCT in this case. Taken in the totality, this case involves eleven patent applications, ten abandonments, and no substantive prosecution for a decade. CRCT's primary justification for delay, that neither Examiner ... would have allowed the applications at issue absent human data, is not objectively reasonable in view of the fact that CRCT never attempted to traverse the rejections (thereby either validating its position or obtaining allowance of its claims). CRCT's delay, therefore, cannot “be explained by reference to [ ] legitimate considerations and/or expectations.” ... CRCT only engaged the PTO once it had a profit motive to do so. ... The court finds the conduct at bar sufficiently egregious to warrant rendering the '291 unenforceable due to prosecution laches.<sup>12</sup>

Additionally, the district court found that whether the accused infringer was prejudiced by prosecution delay could be taken into account under the totality of the circumstances, it was not required of the accused infringer to show that it—or another entity—had “intervening rights” to the claimed invention.<sup>13</sup> The district court stated that “[n]owhere in its discussion did the federal circuit affirmatively impose a particular requirement that a competitor have invested in the technology claimed in order for prosecution laches to apply. Such a holding would be inconsistent with the Federal Circuit's general reluctance to impose “firm guidelines” (such as time limits) for determining when the equitable doctrine should apply.”<sup>14</sup>

### **Federal circuit panel**

The federal circuit panel consisting of Judges Newman, Lourie, and Prost reversed the district court by a 2-to-1 ruling, with a dissent authored by Judge Prost. The majority, in an opinion written by Judge Lourie, found that the defense of “prosecution laches” requirement of an unreasonable and unexplained delay includes a finding of prejudice, as does any laches defense.<sup>15</sup> The court continued:

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.<sup>16</sup>

In justifying its new requirement, the majority harkened back four Supreme Court opinions of the 1920s and 1930s, which it claimed all required a showing of intervening rights during the period of delay. In *Woodbridge v. United States*,<sup>17</sup> the Supreme Court found that prosecution laches barred a patentee's right to enforce his patent after delaying its issuance of for nine and a half years, and requesting a broader claim to cover the subsequent commercial development of others in similar technology.<sup>18</sup>

In *Webster Electric Co. v. Splitdorf Electrical Co.*,<sup>19</sup> the Court held that a divisional application with broader claims filed eight years after the parent application was unenforceable due to prosecution laches where patentee "simply stood by" while the technology came into general use thereby "bring[ing] about an undue extension of the patent monopoly against private and public rights."<sup>20</sup>

The federal circuit found further support for its "new" intervening rights requirement in the Supreme Court's latest opinions on prosecution laches—both from 1938. In *Crown Cork & Seal Co. v. Ferdinand Gutmann Co.*,<sup>21</sup> the Court stated that 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." And in *General Talking Pictures Corp. v. Western Electric Co.*,<sup>22</sup> the Court held that "[i]n 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." And finally, the court found in its own precedent—namely its decision in *Symbol Tech. v. Lemelson*—an intervening rights requirement.

However, Judge Prost's dissent found no precedent—based on either Supreme Court or Federal Circuit case law—requiring a showing of intervening rights to establish prosecution laches. Judge Prost further objected to "the majority's further temporal limitation that the prejudice exists during the period of delay."<sup>23</sup> Moreover, Judge Prost relied on the same Supreme Court and federal circuit case law in rejecting the intervening rights requirement, stating:

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 *Wood-bridge 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, 44 S. Ct. 45, 68 L. Ed. 159, 59 Ct. Cl. 952, 1924 Dec. Comm'r Pat. 534 (1923) (quoting *Kendall v. Winsor*, 62 U.S. 322, 329, 16 L. Ed. 165 (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)). Our precedent 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.<sup>24</sup>

Ultimately, Judge Prost agreed with the district court that nothing in the cases relied on by the majority requires a showing of intervening rights by the party asserting the prosecution laches defense where the totality of the circumstances indicated an unreasonable delay by the patentee to prosecute the application.

### **Petition for rehearing en banc**

The federal circuit requires a majority of the court’s members to vote in favor of a rehearing en banc in order to grant a petition requesting one.<sup>25</sup> The vote resulted in a five-to-five tie, and accordingly, rehearing has been denied. In dissent to the denial of rehearing, Judge Prost again voiced disagreement with the majority’s narrowing of the doctrine through both the intervening rights requirement and “during the period of delay” temporal limitation. “In my view, [the totality of the circumstances] should remain intentionally flexible in order to accommodate the different ways in which the public might be harmed by a delay in the patent monopoly.”<sup>26</sup>

Judge Prost also asserted that the majority’s newly fashioned standard for prosecution laches was too inflexible. “The rigidity of the majority’s rule is of particular concern because the Supreme Court has repeatedly—and recently—cautioned against such excessive formalism in application of the patent laws.”<sup>27</sup>

No longer going it alone on this issue, Judge Prost gained the support of Judges Gajarsa, Moore and O’Malley, who all joined her dissent. Judge Dyk wrote separately in dissent, approving Judge Prost’s rejection of the intervening rights requirement, and “during the period of delay” limitation, but declining to continue to endorse the totality of the circumstances test, “which is really no test at all.”<sup>28</sup>

Although perhaps apropos of nothing, it is interesting to note that the five dissenting judges to Barr’s petition for rehearing en banc—Judges Gajarsa, Dyk, Prost, Moore and O’Malley—represent five of most recent six judges to be appointed to the federal circuit.

### **Supreme Court review**

Although one cannot expect the recent trend of the Supreme Court’s granting certiorari to patent cases to continue at its current pace (all good things must come to an end), this case is ripe for review for a number of reasons. First, the Supreme Court prefers to take cases where a circuit split poses the risk of lack of uniformity in the law. Here, there is a significant split among the judges of the only appellate court to hear prosecution laches

defenses. Accordingly, we can expect the Court to resolve this difference of opinion among the federal judiciary's patent specialist.

Second, both the majority and dissenting opinion in *Cancer Research* evaluated the same Supreme Court precedent in reaching opposite conclusions. Correction of the federal circuit's interpretation of Supreme Court precedent—especially when used as the basis of applying a formulaic instead of flexible legal standard—has become the high Court's *raison d'être* with respect to patent law. If it grants cert, the Supreme Court is likely to return the standard for prosecution laches to a more flexible approach, rejecting the rigid intervening rights and temporal limitation requirements imposed by the federal circuit.

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## Endnotes

<sup>1</sup>*Cancer Research Technology Ltd. v. Barr Laboratories Inc.*, 625 F.3d 724 (Fed. Cir. 2010).

<sup>2</sup>*Cancer Research Technology Ltd. v. Barr Laboratories Inc.*, Case No. 2010-1204, 2011 U.S. App. LEXIS 3816 (Fed. Cir. Feb. 28, 2011).

<sup>3</sup>*Id.* at \*9 (Dyk, J., dissenting).

<sup>4</sup>See *Cancer Research*, 625 F.3d at 728.

<sup>5</sup>*Id.* at 726 (quoting the USPTO's First Office Action, Nov. 18, 1983, which cited *Ex Parte Timmins*, 123 USPQ 581 (BPAI 1959)).

<sup>6</sup>*Id.*

<sup>7</sup>*Id.* at 727.

<sup>8</sup>*In re Buting*, 418 F.2d 540 (CCPA 1969).

<sup>9</sup>See *Cancer Research*, 625 F.3d at 727.

<sup>10</sup>The district court also concluded that the '291 patent was unenforceable due to inequitable conduct, a ruling that the federal circuit overruled on appeal. See *Cancer Research*, 625 F.3d at 734.

<sup>11</sup>*Symbol Technologies Inc. v. Lemelson Medical, Education & Research Foundation*, 422 F.3d 1378 (Fed. Cir. 2005),

<sup>12</sup>*Cancer Research Technology Ltd. v. Barr Laboratories Inc.*, 679 F. Supp. 2d 560, 575 (D. Del. 2010) (citations omitted).

<sup>13</sup>*Id.* at 573.

<sup>14</sup>*Id.* at 572.

<sup>15</sup>See *Cancer Research*, 625 F.3d at 729 (citing *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992) (stating that "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").

<sup>16</sup>*Id.* (emphasis added).

<sup>17</sup>*Woodbridge v. United States*, 263 U.S. 50, 52-53 (1923).

<sup>18</sup>*Id.*

<sup>19</sup>*Webster Electric Co. v. Splitdorf Electrical Co.*, 264 U.S. 463, 466 (1924).

<sup>20</sup>*Id.*

<sup>21</sup>*Crown Cork & Seal Co. v. Ferdinand Gutmann Co.*, 304 U.S. 159, 167-68 (1938).

<sup>22</sup>*General Talking Pictures Corp. v. Western Electric Co.*, 304 U.S. 175, 183 (1938).

<sup>23</sup>See *Cancer Research*, 625 F.3d at 735.

<sup>24</sup>Id. at 736.

<sup>25</sup>*Cancer Research Technology Ltd. v. Barr Laboratories Inc.*, Case No. 2010-1204, 2011 U.S. App. LEXIS 3816 (Fed. Cir. Feb. 28, 2011).

<sup>26</sup>Id. at \*5.

<sup>27</sup>Id. at \*7, referencing *Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *KSR Intern'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); and *eBay Inc. v. MercExchange LLC*, 547 U.S. 388 (2006).

<sup>28</sup>Id. at \*9.