Westlaw Journal Formerly *Andrews Litigation Reporter*
PHARMACEUTICAL
Litigation News and Analysis • Legislation • Regulation • Expert Commentary
VOLUME 27, ISSUE 2 / APRIL 2011

Expert Analysis

Federal Circuit Narrows Test For Prosecution Laches

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In February, in *Cancer Research Technology Ltd. v. Barr Laboratories,* 2011 WL 710476 (Fed. Cir. Feb. 28, 2011), an evenly divided U.S. Court of Appeals for the Federal Circuit, sitting *en banc*, let stand its prior decision narrowing the doctrine of prosecution laches. The narrowed test requires *both* a showing of delay during prosecution *and* prejudice as shown by intervening rights arising during the delay.

In so doing, the Federal Circuit rejected its own "totality of the circumstances" test, recently enunciated in *Symbol Technologies, Inc. v. Lemelson Medical, Education, & Research Foundation*.[1]

FACTUAL BACKGROUND

The application for the patent in *Cancer Research* was originally filed Aug. 23, 1982, by a British pharmaceutical company. The specification identified and characterized 13 tetrazine compounds, including one called temozolomide. The specification stated that these derivatives possessed anticarcinogenic activity in several animal models.

On Nov. 18, 1983, in the first substantive office action, the examiner rejected claims to a method of treating leukemia through administration of a tetrazine compound for lack of utility. The examiner suggested that utility could be established through clinical reports and data, Food and Drug Administration acceptance, or other methods.

Rather than respond to the office action, the applicant initiated a cycle of filing continuation applications and then abandoning them 12 times over the next nine years. Only in the 12th cycle did the applicant file a substantive response to the nonutility rejection, arguing that the animal data disclosed in the *original specification* established the claimed utility in humans. After two more office actions, the U.S. Patent and Trademark Office allowed the claims and the patent issued Nov. 9, 1993.

In the meantime, drug development of temozolomide had progressed. Phase I testing of temozolomide began in 1987. By 1989, reports showed that temozolomide was

safe and had some anticancer activity. In 1999 the FDA approved temozolomide for treatment of a particular form of cancer.

On March 19, 2007, Barr Laboratories filed an abbreviated new drug application , with a Food, Drug and Cosmetic Act paragraph 4 certification, 35 U.S.C. 156, challenging the validity of the patent and seeking FDA approval for a generic version.

Cancer Research filed suit in Delaware July 20, 2007. After a four-day bench trial, the District Court held Cancer Research's patent unenforceable in part due to prosecution laches. Cancer Research appealed to the Federal Circuit.

Going forward, accused infringers will have to show that they or others acquired intervening rights during the delay to prove the necessary prejudice.

THE FEDERAL CIRCUIT'S DECISION

In deciding *Cancer Research*, the Federal Circuit adopted a narrower test for prosecution laches, abandoning the "totality of the circumstances" test laid out in *Symbol Technologies*. Reversing the finding of prosecution laches, Judge Alan D. Lourie, writing for the majority, held that prosecution laches requires a finding of prejudice during the period of delay. Thus, an accused infringer must show that it or others invested in, worked on or used the technology during the period of delay. The majority emphasized that material prejudice is a requirement of any laches defense. Further, Judge Lourie pointed to Supreme Court precedent as requiring intervening rights to support a finding of prosecution laches. For example, in *Woodbridge v. United States*, the Supreme Court held that an inventor had forfeited his right to a patent where he delayed the issuance of his patent for eight-and-a-half years longer than he was entitled.[2] The inventor admitted delaying to increase his commercial profit and cover products released during the delay.

Similarly, *Webster Electric Co. v. Splitdorf Electrical Co.* held a patent unenforceable because of an eight year delay in prosecuting broad claims and the intervening rights of others.[3] The majority also pointed to *Crown Cork & Seal Co. v. Ferdinand Gutmann Co.*[4] and *General Talking Pictures Corp. v. Western Electric Co.*[5] for the proposition that no excuse is necessary for a delay in presenting new claims in a continuation or division application in the absence of intervening rights.

In contrast to these cases, Barr Laboratories had not been prejudiced during the period of delay. Barr delayed four years before filing an ANDA, thus allowing a 13-year lapse between the patent issuance and its ANDA filing. Further, Barr failed to present evidence that others acquired intervening rights by 1993. The majority rejected Barr's argument that the public was inherently prejudiced by Cancer Research's delays in prosecution and bringing the patented drug to market.

Cancer Research claimed that it could not have developed the drug without licensing the drug to a pharmaceutical company. Because Barr filed its investigational new drug applications promptly once it was licensing the patent, the majority did not tally this delay against Cancer Research.

The majority also emphasized that the delay harmed Cancer Research because it did not get the full patent term extension allowed under FDCA Section 156, 21 U.S.C. § (b)(2)(A)(iv), which allows patentees to extend the term of the patent based on FDA approvals.

Judge Sharon Prost dissented from the ruling and emphasized that the majority's approach ignored the equitable nature of the defense when it shifted the inquiry from the behavior of the applicant to the behavior of the defendant.

According to Judge Prost, the precedent discussed in the majority opinion did not require establishing prejudice and intervening rights: *Woodbridge* held that willful or neglectful postponement of prosecution was sufficient for unenforceability. *Webster* emphasized that "laches, equitable estoppel, or intervening public or private rights" could bar the right to a later-filed claim.[6]

Finally, Judge Prost pointed out the harm to the public by Cancer Research's strategy: The company obtained a patent that expires nearly 32 years after the initial application was filed. By extending its monopoly, Cancer Research increased the cost of temozolomide to the public, as generic entry into the market was delayed. According to Judge Prost, this more generalized public harm was sufficient to justify application of the equitable defense.

THE FEDERAL CIRCUIT'S DENIAL OF REHEARING

Barr petitioned for rehearing and rehearing *en banc*. The Federal Circuit denied Barr's petition for rehearing and rehearing *en banc* Feb. 28, splitting evenly 5 to 5. Judge Prost, joined by Judges Arthur J. Gajarsa, Kimberly Ann Moore and Kathleen M. O'Malley, built on her prior dissent and emphasized that the majority opinion encourages applicants "to keep prosecution open and reshape their claims to capture later technological and business developments, all to the public's injury."

Arguing that the proper test is the "totality of the circumstances" test, Judge Prost's dissent emphasized that the prosecution laches aims in large part to prevent improper prosecution from harming the public. Consequently, where an applicant seeks to unduly postpone the time when the public may freely use the invention, equity bars the inventor from excluding the public.

Judge Prost reiterated her view that the Supreme Court precedent does not mandate a finding of intervening rights to impose prosecution laches. In both *Woodbridge* and *Webster*, the Supreme Court was careful to emphasize that willful postponement like laches *or* intervening rights could support unenforceability.

Judge Timothy B. Dyk filed a separate dissent, joining Judge Prost's dissent, with the exception that he believed that rehearing *en banc* was necessary to determine a more well-defined test than "totality of the circumstances."

CONCLUSION

Through its denial of rehearing, the Federal Circuit let stand its narrowed test for prosecution laches. Going forward, accused infringers will have to show that they or others acquired intervening rights during the delay to prove the necessary prejudice.

Practically speaking, this opinion grants applicants more leeway to delay issuance of a patent until the invention is ready for commercialization, provided that the field of invention is not crowded. Those hoping to attack such patents must now uncover evidence showing that they or others invested in, worked on or used the technology during the delay.

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However, given the even split among the Federal Circuit judges, it may be that this issue is ripe for Supreme Court review, particularly because the different tests depend on differing interpretations of high court precedent.

NOTES

1 422 F.3d 1378 (Fed. Cir. 2005).

2 263 U.S. 50 (1923).

3 264 U.S. 462 (1924).

4 304 U.S. 159 (1938).

5 304 U.S. 175 (1938).

6 264 U.S. at 471.

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