

Intervening Rights Essential to Find Patents Unenforceable for Prosecution Laches

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In *Cancer Research Technology Limited v. Barr Laboratories, Inc.*, Cancer Research sued Barr Laboratories for patent infringement regarding U.S. Patent 5,260,291 (“the ‘291 patent”), wherein the ‘291 patent claims a genus of tetrazine derivative compounds and methods for treating cancer by administering those compounds. A claimed compound in the ‘291 patent is the active ingredient in the drug Temodar[®] that is used to treat two types of brain cancer, refractory anaplastic astrocytoma and glioblastoma multiforme. In the beginning of the ‘291 patent’s prosecution, a major factor that contributed to Barr’s defense of prosecution laches was that there were eleven continuation applications, 10 abandonments, and no substantive prosecution for nearly a decade. Essentially, after an office action was filed by the United States Patent and Trademark Office, the applicant filed a continuation application, abandoned the pending application, and did not respond to the office action.

The United States District Court for the District of Delaware construed these facts to hold that the ‘291 patent was unenforceable for prosecution laches, finding that “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.” The district court also stated that these facts were a sufficiently egregious misuse of the patent system to bar enforcement of the ‘291 patent for prosecution laches.

On appeal, Cancer Research argued that the district court erred as a matter of law because the court failed to find any evidence of actual prejudice either to the defendant, Barr, or to the public. Cancer Research continued by stating that the doctrine of prosecution laches was meant to bar enforcement of a patent when an applicant purposefully delays prosecution in order to encompass technology that has been exploited by others who have no knowledge of the patent. Therefore, Cancer Research argued that the doctrine of prosecution laches required 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.

The Court of Appeals agreed, and stated that prosecution laches’ requirement of an unreasonable and unexplained delay includes a finding of prejudice and 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 Court of Appeals relied on two Supreme Court cases, *Woodbridge v United States* and *Webster Electric Co. v. Splitdorf Electrical Co.*, which state that unreasonable delay and intervening adverse rights are necessary to hold a patent forfeited by prosecution laches.

In this case, Barr filed its ANDA more than 13 years after the issuance of Cancer Research’s patent and more than seven years after the approval of Cancer Research’s product. Thus, the Court concluded that Barr was not prejudiced by the delay in the issuance of the ‘291 patent; nor was any other party prejudiced, because there was no evidence to demonstrate that any party was deterred from entering the market for temozolomide due to the fact that Cancer research’s patent issued in 1993 rather than several years earlier. Therefore, the delay had only limited consequences to Barr and the public. Since Barr failed to establish that it or that others developed or invested in temozolomide or any other claimed tetrazine compound between 1982 and 1991, the period of delay, Barr could not establish prosecution laches as a matter of law because Barr failed to provide any evidence of intervening rights.

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