

PRACTICE POINTS

THE KEY TO PROSECUTION LACHES

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I. INTRODUCTION

Patent practitioners must balance their clients' needs for cost-effective representation, uncertainty about a technology's future value, and the obligations imposed by patent laws. This is especially true for technologies having developmental and regulatory timelines of a decade or more, such as pharmaceuticals and medical technologies.¹ Hundreds of pharmacological agents can be tested and discarded before one is determined to meet the regulatory requirements of safety and effectiveness. Meanwhile, the patent-seeking organization is often a non-profit entity facing extremely tight budget restrictions. Substantive prosecution may be delayed until funding becomes available or it is clear that the technology has sufficient value to warrant patent protection. A risk associated with such a strategy, however, is that prosecution laches may bar enforcement of the resulting patent.

A recent case heard by the United States Court of Appeals for the Federal Circuit (CAFC), *Cancer Research Technology, Ltd. v. Barr Laboratories (CRT v. Barr)*, clarifies the requirements for showing laches by the defendant.² This Practice Point summarizes the current state of the law on prosecution laches in view of *CRT v. Barr* and provides guidelines for practitioners needing to balance client needs with equitable obligations of timely prosecution.

II. PROSECUTION LACHES BEFORE *CRT V. BARR*

Prosecution laches, in use since 1923 as an equitable defense to a charge of patent infringement, was revived in 2002 in *Symbol Technologies, Inc. v. Lemelson Medical (Symbol Technologies I)*.³ *Symbol Technologies I* established the modern doctrine of prosecution laches as applicable "to bar enforcement of patent claims that issued after an unreasonable and unexplained delay in prosecution even though the applicant complied with pertinent statutes and rules."⁴ *In re Bogese II*,⁵ extended the doctrine to grant the United States Patent and Trademark Office (USPTO) authority to apply prosecution laches to pending applications.⁶ Though these two cases established that prosecution laches is still an effective defense, the rulings failed to define fully the standard for an effective claim of prosecution laches, thus presenting challenges for district courts interpreting these rulings.

¹ Christopher Adams & Van Brantner, *Spending on New Drug Development*, 19 HEALTH ECON. 130 (2010).

² 625 F.3d 724 (Fed. Cir. 2010) [hereinafter *CRT v. Barr*].

³ 277 F.3d 1361 (Fed. Cir. 2002) [hereinafter *Symbol Techs. I*].

⁴ *Id.* at 1363.

⁵ 303 F.3d 1362 (Fed. Cir. 2002).

⁶ *Id.* at 1367–68.

District courts uniformly have taken the approach that prosecution laches should be used “sparingly in only the most egregious of cases,”⁷ such as an eighteen year delay.⁸ Most courts agree that relatively short prosecution times are not sufficient for prosecution laches, such as when patents issue less than two and a half years from the application date or within seven years from the earliest priority application.⁹

The difficulties in applying the standard for prosecution laches lie within the boundaries marked by the above-described extremes. In the gray areas, courts continue to employ the defense in moderation, ruling that an eleven year term between the priority application filing and the patent claim issuance does not constitute laches without evidence of deliberate or inexcusable delay.¹⁰ Courts have also considered delays associated with the field of the invention when determining whether to apply the doctrine,¹¹ holding no prosecution laches where a fifteen year time gap existed between the first filed application and the subject patent and where no evidence was presented that this time lapse was unordinary in the prosecution of a life sciences application. The hesitancy to apply prosecution laches is further compounded when considering USPTO and government actions.¹²

In instances where the patent term is not affected, such as when the patent is subject to a terminal disclaimer or in certain post-GATT patents, courts tend not to find prosecution laches even when delays are considerable.¹³ Additionally, the patent owner’s actions during prosecution, such as filing continuation or divisional applications after receiving a notice of allowance or responding to office actions using full extensions, and after prosecution, such as seeking a certificate of correction twelve years after issuance, are not normally grounds for a prosecution laches ruling.¹⁴

⁷ *Intuitive Surgical, Inc. v. Computer Motion, Inc.*, 2002 No. Civ. A. 01-203-SLR, WL 31833867 (D. Del. Dec. 10, 2002).

⁸ *Symbol Techs., Inc. v. Lemelson Med.*, 422 F.3d 1378, 1385–86 (2005) [hereinafter *Symbol Techs. II*].

⁹ See *Stambler v. RSA Security, Inc.*, 243 F. Supp. 2d 74, 76 (D. Del. 2003).

¹⁰ *Gen-Probe Inc. v. Vysis, Inc.*, No. 99-CV-2668, 2002 U.S. Dist. LEXIS 25020, at *118–19 (S.D. Cal. Aug. 5, 2002).

¹¹ *Centocor Ortho Biotech., Inc. v. Abbott Laboratories*, 669 F. Supp. 2d 756, 771–72 (E.D. Tex. 2009).

¹² *Honeywell Intern. Inc. v. United States*, 81 Fed. Cl. 514, 580 (Fed. Cl. 2008), *rev’d*, 377 Fed. Appx. 14 (Fed. Cir. 2010) (holding no prosecution laches after a seventeen year delay when a portion of the delay was caused by the issuance of a secrecy order).

¹³ See *Ormco Corp. v. Align Technology, Inc.*, 647 F. Supp. 2d 1200 (C.D. Cal. 2009); *Cordance Corp. v. Amazon.com, Inc.*, 631 F. Supp. 2d 484 (D. Del. 2009).

¹⁴ See *Lucent Technologies, Inc. v. Microsoft Corp.*, No. 06-CV-0684-14, 2008 WL 410692 (S.D. Cal. Feb. 12, 2008); *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 529 F. Supp. 2d 106 (D. Mass. 2007); *Kothmann Enterprises, Inc. v. Trinity Industries, Inc.*, 455 F. Supp. 2d 608 (S.D. Tex. 2006).

III. *CRT V. BARR*

A. UNDERLYING FACTS

The disputed patent was U.S. Pat. No. 5,260,291 (the '291 patent) covering an anti-cancer drug called temozolomide.¹⁵ The '291 patent issued in November 1993 from the eleventh application in a chain of continuation applications claiming priority to a first-filing in the United States in August 1982.¹⁶ The first application included the same claims as those that issued in the '291 patent and was rejected for lacking proof of utility:

Proof of utility under this section [608.01(p)] may be established by clinical or in vivo or in vitro data, or combinations of these, which would be convincing to those skilled in the art. . . . More particularly, if the utility relied on is directed solely to the treatment of humans, evidence of utility, if required, must generally be clinical evidence, although animal tests may be adequate where the art would accept these as appropriately correlated with human utility. . . or where animal tests are coupled with other evidence, including clinical evidence and a structural similarity to compounds marketed commercially for the same indicated uses.¹⁷

The response to this rejection was to file a continuation with the same claims. A same or similar pattern of rejection and response occurred through the sixth application. The rejection of the seventh application added another ground for rejection under the best mode requirement and mentioned the lack of in vivo or in vitro data.¹⁸

On the eleventh continuation (and after ten abandonments), filed on October 18, 1991, the applicant filed a preliminary amendment with remarks pointing to the animal data described in the specification.¹⁹ Despite this, another office action was issued with the same utility rejection but noting that the "[r]emission of a specific leukemia could be established, but has not been so accomplished or so claimed."²⁰ The first substantive response to an office action was subsequently filed, again citing the specification of the application as proof of utility.²¹

¹⁵ *CRT v. Barr*, 625 F.3d 724, 726 (Fed. Cir. 2010).

¹⁶ *Id.*

¹⁷ *Cancer Research Technology v. Barr Laboratories, Inc.*, 679 F. Supp. 2d 560, 565–66 (D. Del. 2010), *rev'd*, 625 F.3d 724 (Fed. Cir. 2010) (internal citations omitted).

¹⁸ *Id.* at 566.

¹⁹ *Id.* at 568.

²⁰ *Id.* at 569.

²¹ *Id.*

In April 1993, a Notice of Allowance was issued with the examiner citing a publication by one of the inventors as proof of utility.²² The court noted that the publication did not disclose human data, but showed activity of mitozolomide and other related compounds against tumors in mice.²³ The patent issued in November 1993 and a new drug application was filed with the FDA a few days later.²⁴ Human trials were conducted from 2000 to 2004, with approval for sale of the drug granted in 2005.²⁵ Barr filed its generic drug application in 2007.²⁶

Commercialization of the invention occurred continuously during prosecution, including an exclusive license of the invention by CRT to Schering Plough in June 1992, contemporaneous with CRT's first efforts to respond substantively to the examiner's rejection.²⁷

B. DISTRICT COURT DECISION

The district court construed the law as requiring a high burden for finding prosecution laches, but found that burden was met considering the length of the delay and CRT's lack of efforts to rebut the rejection during the delay until it benefitted CRT to do so.²⁸ It noted that the authority cited when a substantive response was ultimately filed by CRT was from a 1986 Board decision citing even earlier case law to support its statement that substantiating evidence may be in the form of animal tests.²⁹ Although the evidence presented by CRT seemed to indicate CRT's genuine belief that they needed human data to successfully rebut the Examiner's arguments, the applicable standard is whether CRT's belief was objectively reasonable.³⁰

The District Court did recognize that previous decisions addressed the issue of prejudice to the defendant,³¹ but found prejudice arising from the infringers' intervening activities during the delay to be only a factor and not a requirement.³² "Nowhere 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."³³

²² *Id.* at 570.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.* at 569.

²⁸ *Id.* at 573.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.* at 572.

³² *Id.* at 573-74.

³³ *Id.*

C. CAFC DECISION

The CAFC reversed the District Court's decision based on its failure to recognize that prejudice to the defendant is a requirement for a defense of prosecution laches.³⁴ Barr, prepared for such an exigency, also presented arguments that the public is inherently prejudiced if a delay extends a patent monopoly into the future, thus preventing Barr's earlier entry into the temozolomide market.³⁵ The CAFC was unconvinced, however, because of Barr's four year delay in filing its own generic drug application with the FDA.³⁶ In addition, the CAFC noted that no other applications for FDA approval were made when permitted under the FDA's regulations.³⁷

The CAFC also observed that CRT's delay was not without consequence to CRT because it ran the risk of intervening activity by competitors, even though no such activity occurred.³⁸ Also, CRT lost some of its patent term extension due to its delay.³⁹

[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. [35 U.S.C.] § 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.⁴⁰

Perhaps the most interesting observation (most likely dicta) of the case was that prosecution laches should be increasingly rare in the future because the patent term now runs from filing instead of issuance and term extensions are relatively limited.⁴¹

Circuit Judge Prost dissented from the decision, believing that the case law did not support a requirement of prejudice.⁴² Prost's dissent also differed with the finding that prejudice must be tied to the period of the delay, writing that "[s]uch 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."⁴³ Instead, Prost felt that the

³⁴ CRT v. Barr, 625 F.3d 724, 736 (Fed. Cir. 2010).

³⁵ *Id.* at 736–37.

³⁶ *Id.* at 731.

³⁷ *Id.* at 742.

³⁸ *Id.* at 743.

³⁹ *Id.* at 731–32.

⁴⁰ *Id.*

⁴¹ *Id.* at 744.

⁴² *Id.* at 735 (Prost, J., dissenting).

⁴³ *Id.* at 736.

Supreme Court in its decisions recognized that delaying a patent's monopoly period harms the public by delaying free use of the invention.⁴⁴

IV. PRACTICAL IMPLICATIONS

Although the CAFC decided that prosecution laches requires some type of prejudice specific to the defendant, caution should be used when following *CRT v. Barr* for guidance. The dissent by Judge Prost was well supported and the Supreme Court is fond of overturning the CAFC when it decides to apply a bright-line rule in favor of examining the facts and circumstances of each dispute.⁴⁵

For a rare long-pending application still qualifying for a term calculated from the issue date, it would be safest to apply the lower court's decision as if it were upheld. Steer clear of situations that would give a foothold to arguments of prosecution laches. Avoid delays tied to filing non-responsive amendments or continuations. Do not be overly deferential to examiner rejections, even if they appear rational on their face or serve the client's interest in delaying prosecution. Consider the timing of any delays relative to what is happening in the business world and whether such delays would appear to be offensive to equitable principles. Delays should be for obtaining protection, such as developing secondary evidence to overcome an obviousness rejection, not to gain the upper hand on a competitor. Also, be aware of a competitor's market readiness. Any excessive delay after the competitor is ready to enter the market could be construed as prejudicing the defendant.

The risk seems to be very small for the majority of patent applications having a term based on their filing date because of the dicta in *CRT v. Barr* and the decisions on patents subject to terminal disclaimers. The loss of term ameliorates the concern about prejudice to the general public espoused by Judge Prost and even, to some extent, eliminates the specific prejudice to a defendant since expiration of the patent will almost be a time certain. One exception might be where the applicant's activities serve to induce delay by the patent office, resulting in patent term adjustment for USPTO delays or patent term extension.⁴⁶ For example, filing an application, responses to office actions, or appeal briefs that are so voluminous as to induce delay past the applicable deadlines, may result in patent term adjustment. In an instance where the patent applicant stands to be awarded a lengthy patent term extension or patent term adjustment, prosecution laches may again become an issue.

⁴⁴ *Id.*

⁴⁵ *See, e.g.,* *Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *KSR Intern. Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

⁴⁶ *See* 35 U.S.C. §§ 154(b)–156 (2002).

V. CONCLUSION

As long as some care is used to avoid appearing to induce delays that result in patent term extension or adjustment, prosecution laches is unlikely to be a viable defense to patents with a term calculated from the priority date. For the rare patent application still pending since the June 8, 1995 deadline and entitled a term calculated from the issue date, care should be used not to appear to be delaying prosecution for competitive reasons.