

LOSS OF PATENT RIGHTS – “EXPERIMENTAL USE” VS. ON-SALE BAR/PUBLIC USE

Patents are often one of the most important assets a company possesses. The timing of patent filings is a crucial consideration for companies as new products are developed. Uniquely, the United States patent laws provide for a “first to invent” system (rather than a “first to file” system as in most foreign countries) and a one year grace period for a patent filing from the date of first public use or sale of the invention.

Despite the costs associated with bringing a new drug product to market and the consequences if the patents protecting that new drug product are later determined in litigation to be invalid, in many cases too little consideration is paid to events which take place during product development and the potential catastrophic results if a patent strategy has not been implemented to address those events.

One situation which consistently arises is the tension between presenting data in scientific conferences and/or publishing the same to promote scientific achievements or to enhance prospects of raising capital, and the potential loss of patent rights as a result of doing so. Activities seemingly as innocent as running clinical studies in support of a potential FDA filing can have far-reaching implications on the ability to obtain patent coverage encompassing the results of such testing, if sufficient care and attention is not paid to the development, timing and implementation of a patent strategy. The impact of clinical studies which occur more than one year prior to the filing date of patent applications may become a focal point concerning the validity of resulting patents particularly in view of a recent court decision. Activities seemingly as innocent as seeking a partner to commercialize a drug product may have similar implications, in certain situations. The issue to be considered is when those activities took place in comparison to when patent applications were filed.

What is the Law?

A patent claim is not valid if “the invention was... in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States”. 35 U.S.C. §102(b). The fact that, e.g., the use was an experimental use, may be deemed by a court to negate public use in certain circumstances, but that experimental use must be deemed by the court to have perfected a feature in the patent claim(s) in question, or to have improved or verified a feature of the invention which is inherent that that claim(s). Recent court decisions confirm the fact that the one year grace period should not be relied on whenever possible, and certainly that activities that might be considered by the inventor and/or the assignee of the invention (hereinafter collectively referred to as “the inventive entity”) to fall within exemptions to the §102(b) statutory bar need to be carefully scrutinized because such activities may later be deemed by a U.S. federal court to invalidate patent claims covering the invention.

The test which is now applied by the courts concerning whether an invention was in public use or on sale was set forth by the U.S. Supreme Court in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998). The test articulated in *Pfaff* is whether, prior to the critical date (i.e., one year prior to the original filing date of the U.S. application), the claimed invention (i) was the subject of a commercial sale or offer for sale, or was publicly used by a person other than the inventor who is under no confidentiality obligation; and (ii) was ready for patenting.

The *Pfaff* court decision did not elaborate on what was meant by “a commercial offer for sale” (the first prong of its test), as it was clear in that case that a commercial offer had been made and accepted. In applying the ruling in *Pfaff*, the courts have generally construed that requirement to mean that the offer must meet the level of an offer for sale in the contract sense, to be analyzed under the law of contracts as generally understood. *Group One Ltd. v. Hallmark Cards, Inc.*, 254 F. 3d 1041 (Fed. Cir. 2001). It has further been construed to mean that activity which does not arise to the level of a

formal offer under contract law principles does not constitute a commercial offer for sale under *Pfaff*.

With respect to the second prong of the §102(b) bar test articulated in *Pfaff*, the Supreme Court in that case stated that the “ready for patenting” test may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.

The federal courts have now had an opportunity to apply the holding in *Pfaff* in a number of important pharmaceutical litigations, discussed below.

Clinical Trials May Constitute Invalidated Public Use

Recently, the Court of Appeals for the Federal Circuit (“CAFC”) held that the clinical testing of a drug product does not qualify as an experimental use to negate the §102(b) bar where the tests were conducted to determine safety and efficacy, and did not involve the claimed features of the invention. *SmithKline Beecham v. Apotex*, 365 F. 3d 1306 (Fed. Cir. 2004)¹. In this case, the United States District Court for the Northern District of Illinois considered whether claim 1 of U.S. Patent No. 4,721,723 (the ‘723 patent) owned by SmithKline would be infringed by Apotex’ generic product. Claim 1 of the ‘723 patent recited in its entirety “crystalline paroxetine hydrochloride hemihydrate.” Following a bench trial, the court determined that the paroxetine hydrochloride anhydrate product produced by Apotex will not infringe claim 1. On appeal, the CAFC reversed the lower court’s decision concerning non-infringement, but nevertheless determined that there was a public use bar under 35 U.S.C. §102(b) which rendered claim 1 of the ‘723 patent invalid.

¹ Decided April 23, 2004.

The pertinent facts considered on appeal are as follows. In May 1985, SmithKline began double-blind clinical trials in the United States to determine the safety and efficacy of paroxetine hydrochloride (“PHC”) hemihydrate capsules to treat depression symptoms. These clinical trials occurred more than one year before SmithKline’s October 23, 1985 filing date for the ‘723 patent. The CAFC determined that those clinical trials constituted a public use of the invention.² The CAFC then considered whether those tests qualified for the experimental use negation of the statutory public use bar. The CAFC determined that the claim on appeal (claim 1), which simply read “crystalline paroxetine hydrochloride hemihydrate,” embraced the compound itself, without any further limitation regarding efficacy, commercial use, or pharmaceutical viability. *Id.* at 16. Consequently, the court found that the clinical tests in question (which measured the efficacy and safety of the compound as an antidepressant) did not involve testing concerning the claimed features of the invention, and concluded that the 1985 clinical tests did not qualify as an experimental use to negate the statutory bar, as these tests did not perfect a claimed feature of claim 1, nor did the testing improve or verify a feature of claim 1. *Id.* at 34. Mentioning the fact that only claim 1 was before it on appeal, the court also provided some insight into how these same clinical trials might have met the experimental use negation of the §102(b) bar with respect to inventions claimed in the more specific claims of the ‘723 patent. Clearly, the court was hinting that claim 5 (which called for the pharmaceutical composition to have an “effective anti-depressant amount” of the hemihydrate) and claim 6 (which was a method of treatment of depression by administering the hemihydrate) might have met a different fate, because the language of those claims might be sufficiently connected to efficacy such that the clinical efficacy testing would have qualified for the experimental use negation of the §102(b) bar.

² The *Pfaff* Court did not address the question of when a use is “public.” The CAFC in *SmithKline* made the express assumption that the clinical trials were subject to satisfactory controls based on them by SmithKline, but nevertheless noted that the clinical trials were conducted without any apparent confidentiality restrictions on the patients or the administering physicians. This was an apparent nod to the CAFC’s earlier decisions where it was stated that factors that are considered in determining whether a use is experimental include the nature of the clinical trials; and whether the participants were placed under any limitation or obligation of confidentiality. *See, e.g., Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F. 2d 1158, 1564 (Fed. Cir. 1987); *In re Brigrance*, 792 F. 2d 1103, 1107-08 (Fed. Cir. 1986).

The On-Sale Bar

Consistently applied by the courts, it is not even necessary to any party to the use, sale or offer for sale recognize the patentable characteristics of the product at that time for the §102(b) bar to apply. For example, in *Abbott Laboratories v. Geneva Pharmaceuticals, et al.*, 182 F. 3d 1315 (Fed. Cir. 1999)³, Abbott sued Geneva Pharmaceuticals, Novopharm Limited, and Invamed, Inc., for infringement of its U.S. Patent No. 5,504,207 after each of these companies filed an abbreviated new drug application (ANDA) seeking approval to market a generic version Abbott's hypertensive drug product, Hytrin[®] (terazosin hydrochloride). Each of the generic products contained the Form IV anhydrate of Hytrin. Form IV was the subject matter of at least three commercial sales (the first prong of *Pfaff*) by a third party in the United States more than one year prior to the filing date of the '207 patent, and the CAFC held that the parties' ignorance to the fact that they were dealing with the Form IV anhydrate was irrelevant to meeting the commercial sale prong of *Pfaff*. The CAFC further held that it was clear that the invention was "ready for patenting" (the second prong of *Pfaff*) because the *third party* that had sold the Form IV had in turn bought the drug from two foreign manufacturers, who had already reduced it to practice. The court noted that there was no requirement that the sales offer specifically identify all the characteristics of an invention offered for sale or that the party recognizes the significance of all the characteristics at the time of the offer; if the product offered for sale inherently possesses each limitation of the claims, then the invention was "on sale." For these reasons, the CAFC affirmed the lower court's holding that the relevant claim of the '207 patent was invalid.

On the other hand, the CAFC has made it clear that only an offer which rises to the level of a commercial offer for sale in which the other party could make into a binding contract by simple acceptance constitutes an offer for sale under 102(b) which implicates the on-sale bar. In *Elan Corporation, PLC, v. Andrx Pharmaceuticals, Inc.*,

³ Rehearing denied and rehearing on En Banc declined August 5, 1999, reported at: 1999 U.S. APP. LEXIS 19681; cert. denied January 19, 2000, reported at: 2000 U.S. LEXIS 169.

366 F. 3d 1336 (Fed. Cir. 2004)⁴, Elan sued Andrx after Andrx submitted an ANDA seeking approval of a generic version of Elan's Naprelan[®] (once daily naproxen) formulation. More than the one year prior to Elan filing a patent application covering Naprelan, Elan had written letters to Lederle and other potential licensees offering to supply its once daily naproxen tablets. The issue before the court was whether Elan's letter to Lederle or any of its letters to potential licensees prior to the critical date contained "offers for sale". The CAFC held that the Lederle letter was not an offer to sell which implicated the §102(b) bar because the letter was "clear on its face that Elan was not offering to sale naproxen tablets to Lederle, but rather was offering a license under the patent and offering Lederle the opportunity to become its partner in the clinical testing in the eventual marketing of such tablet at some indefinite time in the future." *Id* at 14. Important to the court was the fact that the letter to Lederle lacked any mention of quantities, time of delivery, place of delivery, or product specifications beyond the general statement that a potential product would be a 500 mg once-daily tablet containing naproxen. Also, important was the fact that the Lederle letter did not include a sales price for sale tablets but rather referred to a "licensee fee." Because the CAFC held that there was no offer for sale, the court did not address the "ready for patenting" prong of the on-sale bar test.

Conclusion

The impact of early clinical trials on later filed patents may additionally be felt in view of the urging by various groups (including the American Medical Association and the International Committee of Medical Journal Editors) that it be required that all U.S. clinical trials are entered into a registry at their start so as to ensure that all clinical trial data is made public.⁵ The gamut of activities associated with clinical studies (the studies themselves, presentation at scientific meetings, publication of articles and registry of the same), as well as other pre-commercialization activities (such as seeking marketing

⁴ Decided May 5, 2004.

⁵ Merck has now announced that it supports the idea of a government-run database. Other groups, such as the Pharmaceutical Research and Manufacturers Association of America, have expressed concerns (such as the risk of disclosing proprietary information to competitors, and whether the requirements would include not just drug makers, but also researchers who conduct drug tests).

partners, licensees, etc.) taking place prior to the filing of patent applications should be carefully considered in order to ensure compliance with 35 U.S.C. §102(b). Since the courts have focused on features of the patent claims with respect to §102(b) bar issues, patent claim strategies and patent filings should be developed early and matched with critical development dates in order to avoid a possible loss of patent rights.

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