Keywords: on-sale bar; offer for sale; offer to license; commercial sale

General: Only an offer which rises to the level of a commercial offer for sale—one which the other party could make into a binding contract by simple acceptance—constitutes an offer for sale under 35 U.S.C. § 102(b); and the sale of patent rights to an invention does not constitute an offer for sale under Section 102(b) of the invention.

Elan Corp. PLC v. Andrx Pharmaceuticals, Inc.
70 U.S.P.Q.2d 1722 (Fed. Cir. 2004)
Decided May 5, 2004

I. Facts

The present case revolves around U.S. Patent No. 5,637,320 ("the '320 patent"), which is assigned to Elan and relates to a controlled-release naproxen formulation. By way of background, naproxen is an anti-inflammatory drug sold under the tradenames of NAPROSYN® and ALEVE®, for example.

Syntex Corporation, an uninvolved third party, is the manufacturer of NAPROSYN® and holds the '966 patent, which is related to compositions and methods for treating pain and inflammation using certain naproxen based compounds. In the late 1980's, Elan began preparations for the December 21, 1993, expiration of the '966 patent. Specifically, Elan began development of a controlled-release naproxen for once-daily administration. Elan also began marketing efforts with respect to this controlled-release naproxen. In a letter dated August 7, 1987 ("the Lederle letter"), Elan discussed details regarding a potential partnership with Lederle Laboratories, to bring the controlled-release naproxen to market. In this letter, Elan outlined certain payment milestones and detailed a "responsibility for supplying bulk tablets with [Elan's] objective being to achieve a price structure allowing [Lederle] an initial gross margin based on current naproxen prices of not less than 70% after taking into account [Elan's] processing charge, A.I. cost, packaging and royalty." Elan also sent similar letters to other potential partners. Additionally, Elan advertised development of its controlled-release naproxen in a 1988 "SCRIP article."

On January 14, 1991, Elan filed a U.S. Patent Application directed to its controlled-release naproxen formulation. After a series of continuation applications, the '320 patent was issued to Elan on June 10, 1997. In the interim between filling and issue, Elan filed a New Drug Application ("NDA") with the Food and Drug Administration ("FDA"). The FDA approved Elan's NDA on January 5, 1996, and Elan began marketing its approved controlled-release naproxen under the tradename NAPRELAN® in April 1996.

In 1998, Andrx submitted an Abbreviated New Drug Application ("ANDA") to the FDA, seeking approval of its own controlled-release naproxen. Elan then sued Andrx for infringement of the '320 patent, and Andrx responded by alleging that the '320 patent was invalid. Specifically, Andrx alleged that the letters to potential partners, like the Lederle letter, constituted offers for sale that clearly occurred more than one year prior to the January 14, 1991, filing of Elan's patent application.

The district court agreed with Andrx and held that the '320 patent was invalid in view of the offer for sale in the Lederle letter. Specifically, the district court noted that the Lederle letter included a price term and referred to a proposed contract. The district court also determined that Elan's controlled-release naproxen was ready for patenting when the Lederle letter was sent.

Subsequently, Elan appealed the district court's decision.

II. Issue

Did the district court err by holding the '320 patent invalid under the on-sale bar?

III. Discussion

Yes. The district court incorrectly interpreted the Lederle letter as an offer for sale. In contrast, the Federal Circuit determined that the Lederle letter only offered a license with respect to a potential patent and merely suggested terms for a potential partnership in bringing the developed naproxen to market.

In the seminal case of *Plaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), the Supreme Court held that the on-sale bar applies if, before the critical one-year date, the invented product was the subject of a commercial offer for sale and the invented product was ready for patenting. Subsequently, the Federal Circuit elaborated on *Plaff* and held that "only an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance … constitutes an offer for sale under § 102(b)." *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1048 (Fed. Cir. 2001). The Federal Circuit further elaborated on *Plaff*, holding that an offer to license a patent claiming an invention after further research and development had occurred, without more, is not an offer to sell the invention. *In re Kollar*, 286 F.3d 1326, 1331 (Fed. Cir. 2002).

In the present case, the Federal Circuit determined that the Lederle letter lacked sufficient specificity to rise to the level of a commercial offer for sale. First, the Federal Circuit noted that the Lederle letter contained no statement regarding how many tablets would be provided in exchange for the funds provided to Elan. Second, the Lederle letter lacked a price term. Although the Lederle letter expressed a price "structure allowing [Lederle] an initial gross margin based on current naproxen prices of not less than 70% after taking into account [Elan's] processing charge…, A.I. cost, packaging and royalty," the Federal Circuit viewed this as a speculative statement incapable of being determined at least until the 1993 expiration of the '966 patent held by Syntex. Moreover, the Federal Circuit also viewed the term "current naproxen prices" as indeterminate until Elan's formulation had been finalized and proved safe and effective for its intended use.

In concluding that the Lederle letter did not constitute an offer for sale, the Federal Circuit did not address the second prong of the *Plaff* test, i.e., whether the invention was ready for patenting.