FEDERAL CIRCUIT PATENT LAW CASE UPDATE

Enzo-Biochem v. Gen-Probe, II, 04-1570b (Fed. Cir. Sept. 30, 2005) (Lourie, J.)

The court affirmed the summary judgment that Enzo's patent for "nucleic acid probes that selectively hybridize with the bacteria that cause gonorrhea" was invalid under the on-sale bar. There was a commercial offer for sale embedded in Enzo's research agreement with Ortho, and Enzo made a shipment to Ortho under the agreement.

Enzo owns U.S. Pat. No. 4,900,659, "which relates to nucleic acid probes that selectively hybridize with the bacteria that cause gonorrhea, namely, Neisseria gonorrhoeae, as well as methods for using those probes to detect the bacteria."

> In June 1982, Enzo and [Ortho] . . . entered into an agreement involving joint funding of research and development on "any human diagnostic product resulting from the program of research" (defined elsewhere in the agreement) "whether or not invented or developed by Enzo prior to the effective date of this agreement." In August 1983, the parties executed an amendment that made it clear that a probe for gonorrhea was part of the agreement.

Several paragraphs of the agreement recited an arrangement for Enzo to supply to Ortho, as a purchase, Ortho's supply of licensed products as defined in the agreement.

> In December 1984, apparently in satisfaction of paragraph 2.12, a key research and development provision of the agreement, Enzo transferred to Ortho a probe that was essentially the same as GC155, one of the three probes that Enzo deposited at the ATCC [for the patent]. Enzo filed a patent application on that subject matter in January 1986, more than one year after the transfer of the probe and the execution of the agreement, that eventually issued as the '659 patent . . . . The ATCC accession numbers were cited in the patent.

The court noted that the first prong of the on sale bar test, whether there was a commercial offer for sale, was the primary issue.

> We agree with Gen-Probe that paragraph 2.14 of the Enzo-Ortho agreement created the necessary contractual obligations on the parties to constitute a commercial offer for sale. . . . paragraph 2.14 is distinctly different from those earlier [research] sections because it relates specifically to supply of Ortho's worldwide requirements for what are clearly commercial purposes. Supply of worldwide requirements at reasonable times and prices surely means commercial supply, and the provision constitutes an offer to sell that has been accepted.

The court found Enzo's reliance on In re Kollar, 286 F.3d 1326 (Fed. Cir. 2002) misplaced: "An offer to sell a claimed product in being is quite different from a license to an undeveloped claimed process [as in Kollar]." It also affirmed the factual determinations supporting the on-sale bar.

> We agree with the district court that there was no genuine issue of material fact as to whether the material that Enzo shipped to Ortho in December 1984 was GC155. Gen-Probe refers to several documents, including contemporaneous documents such as the shipping invoice and accompanying letters, that overwhelmingly refer to the material as "GC155" or simply "155."

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