

Keywords: On-sale Bar; Research and Development Agreement; Offer for Sale; Method claims; Jepson Claims; Ready for Patenting

General: A purchase provision of an agreement otherwise related to research and development can constitute a commercial offer to sell a tangible item or good. An invention can be ready for patenting even though the patentee is unaware or unsure whether the limitations of the claims are met.

Enzo Biochem Inc. v. Gen-Probe Inc.
76 U.S.P.Q.2d 1616 (Fed. Cir. 2005)
Decided September 30, 2005

I. Facts

In June 1982, Enzo Biochem Inc. (“Enzo”) entered into an agreement with Ortho Diagnostic Systems (“Ortho”) involving the joint funding of research and development for a diagnostic product for use in humans. This agreement was amended in August 1983 to clarify that it covered a probe for gonorrhea. Paragraph 2.14 of this agreement provided that:

ENZO shall supply to ORTHO and ORTHO shall purchase from ENZO for use in Licensed Products no less than ninety percent (90%) of ORTHO’s United States requirements or seventy-five percent (75%) of ORTHO’s worldwide requirements of Active Ingredients; *provided*, however, that ENZO shall have this right to supply and ORTHO shall have this obligation to purchase only with regard to Active Ingredients supplied to ORTHO at prices and time schedules which are reasonably competitive with those of other sources. ...

In December 1984, Enzo transferred to Ortho a DNA probe for gonorrhea in compliance with research and development provisions of the agreement. In January 1986, Enzo filed a patent application covering the subject matter of the probe. Within the patent application Enzo cited American Type Culture Collection (ATCC) accession numbers for three deposited sequences, including one sequence, the GC155 sequence, which was essentially the same as the sequence transferred to Ortho in December 1984. Enzo’s patent application issued as U.S. Patent Number 4,900,659 (“the ‘659 patent”).

Enzo sued Gen-Probe, Inc. and Becton Dickinson and Company (collectively “Gen-Probe”) for infringement of the ‘659 patent. In the infringement proceeding Gen-Probe moved for summary judgment of invalidity contending that all claims of the ‘659 patent were barred under 35 U.S.C. § 102(b) by the offer to sell expressed in paragraph 2.14 of the agreement between Enzo and Ortho. The district court granted this motion for summary judgment, invalidating the ‘659 patent for violation of the on-sale bar.

In reaching its decision, the district court made three determinations. First, the court determined that the material offered for sale, presumably the GC155 sequence, was within the scope of all of the claims. Second, the court determined that Enzo offered an embodiment of the ‘659 patent for sale prior to the critical date. Third, the court rejected Enzo’s assertion of experimental use, reasoning that the probe transferred to Ortho was the final product and, thus, reduced to practice and not subject to further experimentation. Enzo appealed the grant of summary judgment.

II. Issues

- A. Did paragraph 2.14 of the Enzo-Ortho agreement constitute a commercial offer for sale?
- B. Was the GC155 probe ready for patenting?
- C. Were the method claims of the '659 patent properly rejected?

III. Discussion

- A. Yes. Under the first prong set forth in *Pfaff*, the product in question must be the subject of a commercial offer for sale. The panel found that paragraph 2.14 of the Enzo-Ortho agreement created the necessary contractual obligations on the parties to constitute a commercial offer for sale. The language of paragraph 2.14 related to the supply of Ortho's worldwide requirements for what were clearly commercial purposes. In particular, the panel noted that an agreement to supply worldwide requirements at reasonable times and prices was an agreement to supply commercially and, further, that the provision within the agreement constituted an offer to sell that had been accepted.

In so finding, the panel distinguished the present case from the *Kollar* decision. In particular, the panel noted that the agreement in *Kollar* conveyed a right to commercialize the invention at issue and was essentially a license, not a sale. The panel further distinguished because the invention of the *Kollar* case was a process rather than a tangible item and only the mere transfer of the knowledge of how to carry out the process had taken place. The process was not carried out or performed as a result of the transaction. Conversely, in the present case, the claimed polynucleotide probe was a tangible item that could be sold or offered for sale.

- B. Yes. Under the second prong set forth in *Pfaff*, the invention must be ready for patenting. With regard to this prong, Enzo argued that claim 1 recited a hybridization ratio of the probe to *N. gonorrhoeae* relative to *N. meningitides* of "greater than about five." Enzo maintained that at the time the probe was provided to Ortho, it was unknown if the probe could achieve this ratio. Gen-Probe argued that the probe was a composition of matter and was ready for patenting once composed. Furthermore, the probe had demonstrated preferential hybridization for *N. gonorrhoeae* relative to *N. meningitides* at the time it was provided to Ortho.

The panel agreed with Gen-Probe and rejected Enzo's argument that there was insufficient knowledge about the probe to render it ready for patenting. In determining that the probe was reduced to practice, the panel relied upon the fact that Enzo scientists knew that the probe did not cross react with *N. meningitides* and, therefore, recognized the specificity requirement set out in the claims. In addition, the panel relied upon the fact that the GC155 probe delivered to Ortho was shown to be the "same" as one of the ATCC deposits.

- C. Yes. Enzo argued that claims 5 and 6 were improperly invalidated because they were method claims which were improperly grouped with the product claims 1-4. Gen-Probe responded that claims 5 and 6 were drafted in Jepson format and were only patentable insofar as they incorporated novel compositions for use in a hybridization test. Because the compositions were subject to a statutory bar, claims 5 and 6 were unpatentable for the same reason.

The panel agreed with Gen-Probe, noting that the shipment of the probe to Ortho was accompanied by instructions on its use. Further, the panel noted that the composition claims

read on probes that hybridize *N. gonorrhoeae*, and, therefore, carrying out a hybridization assay is inseparable from the composition themselves.

IV. Conclusion

A provision to provide a tangible good in an agreement may be interpreted as a commercial offer to sell while a provision providing a right to commercialize or a licensing right may not be so interpreted.

An invention can be ready for patenting even though the patentee is unaware or unsure whether the limitations of the claims are actually met.