Keywords: public use bar; invalidity; ready for patenting; competent cells

General: Infringement plaintiff's use of claimed process for producing "transformable" cells in its own laboratories, more than one year before application for patent in suit was filed, was not "public use" that bars patentability, since plaintiff's invention was not given or sold to "another," or used to create product given or sold to another.

Invitrogen Corp. v. Biocrest Manufacturing L.P.
76 U.S.P.Q.2d 1741 (Fed. Cir. 2005)
October 5, 2005

I. Facts

Invitrogen owns U.S. Patent No. 4,981,797 (hereinafter "the '797 patent"). The `797 patent is directed to a process for improving the "competence" of *E. coli* cells. "Competence" is a term used to describe the ability of a cell to take up foreign DNA. Competence may be achieved by several known processes that introduce holes in the bacterial cell membrane to allow DNA to pass into the cell. Because scientists rely on the rapid growth of bacteria to replicate foreign DNA of interest, competent cells are a staple of molecular biology research protocols.

Claim 1 of the '797 patent is representative of the claims at issue:

> 1. A process for producing transformable E. coli cells of improved competence by a process comprising the following steps in order:
>
> (a) growing E. coli cells in a growth-conducive medium at a temperature of 18°C to 32°C;
>
> (b) rendering said E. coli cells competent; and
>
> (c) freezing the cells.

Invitrogen sued Biocrest Manufacturing, L.P. and its parent company, Stratagene, Inc. (hereinafter "Stratagene"), for infringement of the '797 patent. The district court construed the claims and granted Stratagene's motion for summary judgement of noninfringement. On a first appeal, the Federal Circuit decided that the district court had incorrectly construed a claim limitation and remanded for further proceedings. On remand, the District Court found literal infringement of various claims, but also found the claims invalid under the public use provision of 35 U.S.C. § 102(b). 35 U.S.C. § 102(b) states that a person shall be entitled to a patent unless "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."

On subsequent appeal, the parties did not dispute that Invitrogen had used the claimed process before the critical date (i.e., more than one year prior to filing the application that issued as the '797 patent) in its own laboratories. Invitrogen maintained that it did not sell the claimed process or any products made with it prior to the critical date, and further, that use of the claimed process was maintained as a secret within the company until some time after the critical date.

On appeal, Invitrogen argued that that its secret internal use was not public use under the "totality of the circumstances" test as found by the district court, because it neither sold nor offered for sale the claimed process or any product derived from the process, nor did it otherwise place into the public domain either the process or any product derived from it.

II. Issue

Did the district court properly determine that Invitrogen's internal use of its process triggered the public use bar?

III. Discussion

No. In contrast to the district court, the Federal Circuit determined that Invitrogen's secret internal use of its patented process before the critical date did not trigger a public use bar, regardless of whether the process was applied to other ongoing projects to provide a general commercial advantage. In reaching this determination, the federal circuit reviewed the policy considerations underlying the "on-sale" and "public use" statutory bars as set forth by the Supreme Court in *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998), and rejected a "totality of the circumstances" analysis as the test for public use under §102(b).

The Federal Circuit began its analysis by rejecting the "totality of the circumstances" test for determining whether an invention was in public use as contrary to *Pfaff*, in which the Supreme Court rejected the "totality of the circumstances test" in the context of the "on sale" bar of 35 § U.S.C. 102(b). In *Pfaff*, the Supreme Court set forth that the "on-sale" bar and the "public use" bar were based on identical policy considerations, namely "the reluctance to allow an inventor to remove existing knowledge from public use." Thus, the Federal Circuit determined that not only was the "totality of the circumstances" test inappropriate for determining a public use, but also that the "ready for patenting test" of *Pfaff* applied to both the on sale and public use bars. Thus, the Federal Circuit held that a "public use" bar under 102(b) arises where, before the critical date, the invention is (i) in public use and (ii) ready for patenting. Further, the Federal Circuit stated that "the proper test for the public use prong of the § 102(b) statutory bar is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited." Evidence related to experimentation, the nature of the activity that occurred in public, public access to the use, confidentiality obligations imposed on members of the public who observed the use, and commercial exploitation may be considered.

In applying the Pfaff test, the Federal Circuit found that no public use bar arose because Invitrogen neither sold nor offered for sale the claimed process or any product derived from the process, nor did it otherwise place into the public domain either the process or any product derived from it. The process also was maintained under a strict obligation of secrecy prior to the critical date.

Additionally in this decision, the court affirmed the finding of infringement, affirming the admissibility of an expert's tests showing that 28 of 33 of Stratagene's cell strains showed "improved competence" as claimed. Finally, the court affirmed the finding that the `797 patent was not indefinite, distinguishing between the requirement that a claim delineate to a skilled artisan the bounds of the invention, and a potential infringer's ability to ascertain the nature of its own accused product to determine infringement.