IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

- -

INNOGENETICS, N.V.,

ORDER

Plaintiff,

05-C-0575-C

v.

ABBOTT LABORATORIES,

Defendant.

- -

In an opinion and order entered on January 3, 2007, I found that plaintiff Innogenetics met three of the four criteria for a grant of a permanent injunction barring defendant Abbott Laboratories from selling or making their infringing HCV diagnostic products. However, I reserved ruling on the final criterion, the public interest, pending further development by the parties of two issues: plaintiff's products' compliance with FDA requirements for labeling and plaintiff's ability to fill the HCV diagnostic market need if defendant were precluded from selling its products.

An evidentiary hearing was held on the motion for permanent injunction on January 10, 2007. After hearing plaintiff's evidence, I am persuaded that plaintiff has ample capacity to supply HCV diagnostic products, that plaintiff's manufacturing process complies with

Good Manufacturing Practices and that its products comply with FDA labeling requirements. Defendant made an effort to show through cross examination of plaintiff's witnesses that it would be risky to public health to enjoin defendant from the market both because reliance on one major manufacturer was risky in and of itself and because plaintiff's manufacturing facility had quality control problems with another product over a period of years. However, plaintiff proffered evidence that even if it were unable to manufacture the diagnostic product for a short period of time, the risk to public health would be non-existent, for two reasons. First, other diagnostic techniques exist and would suffice, even if they are not as effective as the patented technique. Second, Hepatitis C is a chronic disease that does not require instant genotyping. A delay in obtaining a test would not have any perceptible adverse effect on a person suffering from the disease.

Plaintiff introduced evidence that its manufacturing facility has sufficient product in stock to supply the market for two years and that 60% of its production capacity is available if increased production of the ASRs is necessary in the future. The evidence showed that defendant has been selling 90% of its product to one laboratory, LabCorp, and that LabCorp has begun taking steps to substitute plaintiff's product for defendant's. There is no evidence that any other laboratory that had been buying the infringing product would require more than a few weeks to validate plaintiff's product and resume HCV diagnostic work.

B. Scope of Permanent Injunction

Plaintiff has asked for an injunction that would read as follows:

THEREFORE, IT IS ORDERED that Abbott Laboratories and its subsidiaries, parents, officers, directors, agents, servants, employees, affiliates, attorneys and all others in active concert or participation with any of them who receive actual knowledge of this order, are hereby permanently enjoined from making, advertising, promoting the use of, selling, offering to sell, using, permitting to be used, contributing to the use, sale or offering for sale of, or inducing the use, sale or offering for sale of the Accused Products, or of any other product used in a method that meets all the limitations of the asserted claims.

FURTHER, IT IS ORDERED that Abbott Laboratories and its subsidiaries, parents, officers, directors, agents, servants, employees, affiliates, attorneys and all others in active concert or participation with any of them who receive actual knowledge of this order, are hereby permanently enjoined from supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Products, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside the United States in a manner that would infringe the asserted claims if such combination occurred within the United States.

FURTHER, IT IS ORDERED that notwithstanding the foregoing and pursuant to 35 U.S.C. § 271(e)(1), Abbott is not enjoined from making or using Product 3 solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs. However, Abbott is permanently enjoined from making, using, offering to sell or selling Product 3 for any purpose not covered explicitly by the safe harbor established by 35 U.S.C. § 271(e)(1), including, but not limited to making, using, offering to sell or selling Product 3 when and if Product 3 is approved for sale by the United States Food and Drug Administration.

FURTHER, IT IS ORDERED that Abbott Laboratories is to destroy its existing inventory of Product 1 and Product 2 within ten days of the final resolution of any appeal by Abbott Laboratories.

> FURTHER, IT IS ORDERED that Abbott Laboratories shall notify its current customers of the Accused Products (other than customers using Product 3 solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs) of the outcome of this litigation within ten days of this order and instruct them that they may not use those products in a method that meets all of the limitations of any of the asserted claims.

Defendant objects to the proposed injunction on three grounds: (1) it is overbroad under § 271(f) because it covers "merely supplying products" that could be used to practice the method claims of the '704 patent abroad; (2) it instructs defendant's customers that they may not use their inventories of any of the accused products despite the fact that such products are covered by the jury's award of damages; and (3) the proposed injunction conflicts with Fed. R. Civ. P. 65(d). The first objection can be disposed of fairly quickly. Section 271(f)(1) provides that persons infringe if, without authority, they supply or cause to be supplied in or *from* the United States "all or a substantial portion of the components of a patented invention . . . in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States."

Defendant cites NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005), as supporting its position that § 271(f) does not apply to the sale of components by a company in the United States even if the sale of those components would enable someone outside the country to practice plaintiff's patented method. NTP, Inc. is readily

distinguishable from defendant's circumstance, as the court of appeals' decision in Union Carbide Chemicals & Plastics Tech. Corp. v. Shell Oil Co., 425 F.3d 1366 (Fed. Cir. 2005), makes plain. In NTP, Inc., the same court had held that Research in Motion's shipments of handheld devices and associated products from Canada to customers in the United States did not constitute the supply of component steps for practicing a method. In Union Carbide, the issue was the supply to foreign customers of catalysts used in the commercial production of ethylene oxide. The court emphasized that § 271(f) makes no distinction between method claims and other forms of patentable inventions. Id. at 1379. It explained that in NTP, Inc., the defendant itself did not supply any component to a foreign affiliate and therefore, did not violate § 271(f), whereas in Union Carbide, the defendant was the direct supplier to foreign customers of a component that could used in the performance of a patented process or method. ("NTP is different from this case because Shell supplies catalysts from the United States directly to foreign customers. . . .Shell's exportation of catalysts may result in liability under § 271)(f)"). Id. at 1380. Under Union Carbide, an injunction can be granted in this case, prohibiting defendant from selling its components to customers outside the United States for use in practicing the method of the '704 patent.

In response to defendant's objection to the destruction of inventory, plaintiff agrees that customers that purchased defendant's HCV genotyping products up to the jury's damages decision on September 8, 2006, may use those products because the damage award

compensates plaintiff for those products. In addition, assuming that defendant provides an accounting of its product sales from September 8, 2006, until the date of entry of a permanent injunction, plaintiff will not object to the use by defendant's customers of products purchased from defendant during this time period.

Defendant's third objection is that the proposed injunction conflicts with the provisions of Fed. R. Civ. P. 65(d) because it includes the term "affiliates" in addition to the persons and entities identified in Rule 65(d). This is no longer an issue. Plaintiff has advised the court and opposing counsel that it has no objection to removing the term "affiliates" from any permanent injunction entered by the court.

ORDER

IT IS ORDERED that the motion of plaintiff Innogenetics, N.V. for a permanent injunction is GRANTED.

FURTHER, IT IS ORDERED that Abbott Laboratories and its subsidiaries, parents, officers, directors, agents, servants, employees, attorneys and all others in active concert or participation with any of them who receive actual knowledge of this order, are hereby permanently enjoined from making, advertising, promoting the use of, selling, offering to sell, using, permitting to be used, contributing to the use, sale or offering for sale of, or inducing the use, sale or offering for sale of the Accused

Products, or of any other product used in a method that meets all the limitations of the asserted claims.

FURTHER, IT IS ORDERED that Abbott Laboratories and its subsidiaries, parents, officers, directors, agents, servants, employees, attorneys and all others in active concert or participation with any of them who receive actual knowledge of this order, are hereby permanently enjoined from supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Products, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside the United States in a manner that would infringe the asserted claims if such combination occurred within the United States..

FURTHER, IT IS ORDERED that notwithstanding the foregoing and pursuant to 35 U.S.C. § 271(e)(1), Abbott is not enjoined from making or using Product 3 solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs. However, Abbott is permanently enjoined from making, using, offering to sell or selling Product 3 for any purpose not covered explicitly by the safe harbor established by 35 U.S.C. § 271(e)(1), including, but not limited to making, using, offering to sell or selling Product 3 when and if Product 3 is approved for sale by the United States Food and

Drug Administration.

FURTHER, IT IS ORDERED that Abbott Laboratories is to destroy its existing inventory of Product 1 and Product 2 within ten days of the final resolution of any appeal by Abbott Laboratories.

FURTHER, IT IS ORDERED that Abbott Laboratories shall notify its current customers of the Accused Products (other than customers using Product 3 solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs) of the outcome of this litigation within ten days of this order and instruct them that they may not use any of the Accused Products that were purchased after the date of this order in a method that meets all of the limitations of any of the asserted claims.

Entered this 12th day of January, 2007.

BY THE COURT:
/s/
BARBARA B. CRABB
District Judge