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IP NEWSLETTER

INFRINGEMENT OF A PRODUCT-BY-PROCESS CLAIM REQUIRES THE PRACTICE OF THE CLAIMED PROCESS

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In 1991, the U.S. Court of Appeals for the Federal Circuit (CAFC), in *Scripts Clinic & Research Foundation v. Genentech, Inc.*, held that "the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims." In 1992, however, the CAFC suggested the opposite view and held in *Atlantic Thermoplastics Co. v. Faytex Corp.* that "process terms in product-by-process claims serve as limitations in determining infringement."

In May, 2009, in *Abbott Laboratories v. Sandoz, Inc.*, a full panel of CAFC judges resolved the confusion between the two opposing lines of cases regarding the proper scope of product-by-process claims on infringement issues.

The issue in the *Abbott Laboratories* case is whether infringement of a product-by-process claim requires the practice of the claimed process. In resolving this issue, the court favored the position taken by the 1992 *Atlantic Thermoplastics Co.* case, and held that "process terms in product-by-process claims serve as limitations in determining infringement," and that "product by process claims are limited by and defined by the process." In explaining its logic in deriving this resolution, the court stated as follows:

> Assume a hypothetical chemical compound defined by process terms. *The inventor declines to state any structures or characteristics of this compound.* The inventor of this compound obtains a product-by-process claim: "Compound X, obtained by process Y." Enforcing this claim without reference to its defining terms would mean that an alleged infringer who produces compound X by process Z is still liable for infringement. *But how would the courts ascertain that the alleged infringer's compound is really the same as the patented compound? After all, the patent holder has just informed the public and claimed the new product solely in terms of a single process.* Furthermore, what analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes? If the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed. Why also would the courts deny others the right to freely practice process Z that may produce a better product in a better way?

Emphasis added.

While the court's language focuses specifically on claim construction for purposes of finding infringement, it may also have ramifications regarding the validity of a product-by-process claim. In light of this case, it appears that when drafting product-by-process claims, it is imperative to understand that if the product can be made by another method, the claim scope will be narrow and infringement may be easily avoided. Thus, if the structure of the product can be sufficiently defined under 35 U.S.C. §112, this decision reinforces that it may be more advisable to draft the claim so as to define the structure of the product, rather than the process of making the product.

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