

Federal Circuit KO's *Scripps*: Resolves Scope of Product-by-Process Claims

In *Abbott Laboratories v. Sandoz, Inc.*, ___F.3d___, 2009 WL 1371410 (Fed. Cir. May 18, 2009), the Federal Circuit resolved a significant decisional conflict regarding the interpretation of product-by-process claims in determining infringement. In doing so, the court clarified the scope of product-by-process claims and the activity that could give rise to liability for their infringement.

Since 1992, a decisional split regarding the scope of protection afforded by product-by-process claims had existed in the Federal Circuit as a result of the holdings in *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) and *Atlantic Thermoplastics v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992). In *Scripps*, the Federal Circuit ruled that product-by-process claims encompassed otherwise identical products made by a process different from that specified in the claim. The patent at issue in *Scripps* claimed, *inter alia*, a complex protein essential for clotting, which naturally occurs in human blood plasma, by reciting a method for its isolation. Defendant Genetech was able to isolate the same protein, but did so using a different process. After the district court found no infringement, a three-judge panel of the Federal Circuit (Newman, Markey and Beer) reversed. Writing for the court, Judge Newman reasoned that claims should be construed the same way for both patentability and infringement. Thus, because product-by-process claims cannot be distinguished from an identical product in the prior art on the basis of the recited process steps when being examined for patentability, product-by-process claims in an issued patent are likewise "not limited to product prepared by the process set forth in the claims" for purposes of determining infringement.

One year later, a different panel of the Federal Circuit (Rader, Michel and Archer) confronted the same issue in *Atlantic Thermoplastics v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992). Atlantic's patent claimed shock-absorbing innersoles for use in footwear produced by a particular molding process. The defendant, Faytex, manufactured identical innersoles, but used a different molding process. Atlantic argued that a finding of infringement was nevertheless warranted in light of the *Scripps* decision. Writing for the court, Judge Rader conducted an extensive review of case law and determined that the longstanding rule regarding product-by-process claims was that, for purposes of infringement, the accused product must be produced by the process described in the claim. In so holding, the *Atlantic* panel recognized that product-by-process claims would receive different treatment for administrative patentability determinations than for judicial infringement determinations. Nevertheless, the panel found such a distinction justified by noting that the *Scripps* court ruled without reference to the previous Supreme Court cases involving product claims with process limitations, and suggested that the *Scripps* panel would have reached a different conclusion if it had considered controlling precedent.

The conflict between *Scripps* and *Atlantic* was solidified when the Federal Circuit denied a rehearing en banc in *Atlantic. Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279 (Fed. Cir. 1992). In concurring with the denial, Judge Rader observed that the process itself was the only limitation actually stated in a product-by-process claim; if courts declined to consider these

limitations, he argued, product-by-process claims would have few practical limitations and every applicant would claim in process, rather than structural terms.

In *Abbott Labs*, the Federal Circuit took the opportunity to resolve the conflict en banc, by adopting the rule in *Atlantic*. The patent-in-suit asserted by Abbott, as the exclusive licensee, included product-by-process claims directed to crystalline forms of cefdinir, an antibiotic. Abbott's marketed form of cefdinir contained the Crystal A form while the defendant's proposed generic version contained almost exclusively the Crystal B form of cefdinir, which was also produced by a different process than those claimed. In affirming the district court's claim interpretation, the Federal Circuit explicitly adopted the *Atlantic* rule that "process terms in product-by-process claims serve as limitations in determining infringement." *Atlantic*, 970 F.2d at 846-47.

In following the *Atlantic* rule, the Federal Circuit expressly overturned *Scripps* to the extent that it was inconsistent with the holding in *Atlantic*. The court found the *Atlantic* rule to be extensively supported by Supreme Court opinions that have addressed the proper reading of product-by-process claims, which have consistently noted that the process terms in a product-by-process claim define the product and serve as limitations. See, e.g. *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 493 (1877) ("The process detailed is therefore made as much a part of the invention as are the materials of which the product is composed."). In addition, the *Abbott* court found that the CCPA and regional circuits had also followed the general rule that process terms limit product-by-process claims. See, e.g. *Hide-It Leather v. Fiber Prods.*, 226 F. 34, 36 (1st Cir. 1915).

Judge Newman, who wrote the *Scripps* decision, filed a vigorous dissent from the *Abbott Labs* majority. She noted that the decision overturned the so-called "rule of necessity," which protected novel products whose structure was not fully known at the time of filing, and which were therefore filed as product-by-process claims out of necessity. Under Judge Newman's view, the *Scripps* claim was a "true" product-by-process claim, where the product was new, nonobvious and incapable of definition independent of the process by which it was made. In contrast, the *Atlantic* claim was a "product of the process" claim, where the process was patentable even though the product itself was well-known. Newman argued that the precedents cited in the *Atlantic* decision did not address "true" product-by-process claims, and were therefore distinguishable from *Scripps*.

The Federal Circuit's holding essentially merges the scope of protection afforded by product-by-process into the protection already provided by process claims. For various reasons, including an enhanced ability to police patent rights, product claims not limited to process steps can be more valuable than process claims. The holding in *Abbott Labs* compels applicants with novel products or compositions to not rely solely on a product-by-process claiming strategy. Instead, applicants should make efforts to characterize the novelty of their inventions without resort to process limitations, even if describing or analyzing the structure of their inventions proves difficult. To afford the greatest protection for novel products or compositions, inventors may need to forge new analytical methods or measured performance criteria in order to adequately define their inventions apart from the process by which it is made.