PRODUCT-BY-PROCESS CLAIMS OF PATENTS ARE LIMITED TO PRODUCTS MADE BY THE RECITED PROCESS

On May 18, 2009, in *Abbott Labs. v. Sandoz, Inc.*, 2009 U.S. App. LEXIS 10476, 30 (Fed. Cir. 2009) ("*Abbott*"), the Court of Appeals for the Federal Circuit announced a clear standard for the proper treatment of product-by-process claims in infringement litigation. The court held en banc that "process terms in product-by-process claims serve as limitations in determining infringement."[1]

The *Abbott* case clarifies conflicting prior panel decisions and establishes that product-by-process claim language will not allow a claimed product to escape the process limitations used to describe it.

Conflicting Federal Circuit Case Law

In 1991 and 1992 two different Federal Circuit panels announced conflicting rules for the proper analysis of product-by-process claims in infringement actions, *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) ("*Scripps*") and *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992) ("*Atlantic Thermoplastics*").

In *Scripps*, the Federal Circuit addressed the interpretation and scope of claims exemplified by a product-by-process claim to a highly purified concentrated blood clotting factor. The court reasoned that "[s]ince claims must be construed the same way for validity and for infringement, 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."[2] Thus, the court determined that the defendant infringed the asserted claims even though its product was made by a different process than that recited in the claims.

The *Atlantic Thermoplastics* court considered the scope of product-by-process claims to molded shoe innersoles. Here, the allegedly infringing innersoles were also made by a process different than that recited in the claims, but the court construed the claims as limited by the recited process. The court explained that the *Scripps* court had "ruled without reference to the Supreme Court's previous cases involving product claims with process limitations" and that it "would have reached a different conclusion if it had considered controlling precedent." [3] Further, the

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[1] *Abbott*, at 26-27.

[2] *Scripps*, 927 F.2d at 1583.

[3] *Atlantic Thermoplastics*, 970 F.2d at 839, fn. 2.

court found that *not* limiting product-by-process claims to the recited process would unacceptably "require this court to disregard several other mainstay patent doctrines" including the rules that: (1) "infringement requires the presence of every claim limitation or its equivalent"; (2) "infringement analysis compares the accused product with the patent claims, not an embodiment of the claims"; and (3) "infringement analysis proceeds with reference to the patent claims."[4]

The *Abbott* Opinion

The court acted *sua sponte* in *Abbott* "to clarify en banc the scope of product-by-process claims."[5] Ruling that product-by-process claims are not infringed by products made by processes not meeting claimed process limitations, the court explained that "this decision merely restates the rule that the defining limitations of a claim -- in this case process terms -- are also the terms that show infringement."[6] Thus, inventors who choose to claim products in terms of the process by which they are made are on notice that this definition "also governs the enforcement of the bounds of the patent right."[7]

The majority overruled *Scripps* to the extent that it "is inconsistent with this rule."[8] The court based its adoption in *Abbott* of "the rule in *Atlantic Thermoplastics*" on Supreme Court and other precedent.[9] The court noted that it did not "question at all" the legitimacy of the claim form, but rather decided only the proper scope of such claims for infringement purposes.[10] The inventor employing such claims "will not be denied protection."[11] However, the court refused to "simply ignore as verbiage the only definition supplied by the inventor."[12] The court also ruled that the use of the phrase "obtainable by" in Abbott's patent did not provide a "free pass" from the product-by-process rule. The court noted that a contrary result would provide a "windfall" to inventors at the expense of future innovation and proper notice to the public of the scope of the claimed invention.[13]

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[4] *Id*. at 846.

[5] *Abbott*, 2009 U.S. App. LEXIS 10476, 20-21. The en banc portion of the opinion was authored by Circuit Judge Rader and joined by Chief Judge Michel and Circuit Judges Bryson, Gajarsa, Linn, Dyk, Prost, and Moore. Judges Lourie, Newman and Mayer dissented.

[6] *Id*. at 28.

[7] *Id*. at 30.

[8] *Id*. at 27.

[9] *See id*. at 21.

[10] *Id*. at 28.

[11] *Id*. at 30.

[12] *Id*.

[13] *Id*. at 36.

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Willkie Farr & Gallagher LLP successfully represented Teva Pharmaceuticals USA, Inc. in *Abbott*. For further information regarding this memorandum or intellectual property issues generally, please contact Thomas J. Meloro (212-728-8248, tmeloro@willkie.com), or the attorney with whom you regularly work.

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May 29, 2009