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Federal Circuit Adopts Narrowing, Bright-Line Rule for Product-by-Process Patent Claims

In *Abbott Laboratories v. Sandoz, Inc.*[1], the Federal Circuit in an unannounced and possibly rule-contraverting partial-*en banc* decision, adopted a bright-line rule for determining infringement of a product-by-process patent claim. In short, the Court held that "process terms in a product-by-process claim serve as limitations in determining infringement."

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This ruling is important for several reasons; most notably, it is likely to result in the significant narrowing of the scope of product-by-process claims. To the extent patent holders had relied a broader interpretation of product-by-process claims, the ruling may also call in to serious question the scope of the protection afforded by these types of patents.

Background

It is not unusual for patents for complex substances to claim those substances by claiming the steps of the process that is used to create them. This is particularly true where the final product is a composition whose structure is not fully known or readily described. A simplistic example of such a claim is "Product X obtained by step 1, followed by step 2." The question addressed in *Abbott* is whether a defendant should be held to infringe if it makes the same "Product X," but does so by way of an admittedly different process, *i.e.*, "Product X obtained by step A, followed by step B, followed by step C."

Since the early 1990s, there were two competing lines of Federal Circuit case law that attempted to answer this question. The *Scripps*[2] line of cases held that product-by-process claims "are not limited to products prepared by the process set forth in the claims." This tended to result in a broader claim construction that was more likely to implicate a defendant's accused "Product X" even if the defendant's production process differed from that set forth in the plaintiff's product-by-process claim. On the other hand, the *Atlantic Thermoplastics*[3] line of cases held that the "process terms in product-by-process claims serve as limitations in determining infringement." Application of the *Atlantic Thermoplastics* line of cases tended to result in a narrower claim construction that was less likely to result in a finding of infringement.

In *Abbott v. Sandoz*, the Federal Circuit chose to "clarify *en banc* the scope of product-by-process claims by adopting the rule of *Atlantic Thermoplastics*." It did so, however, in an unusual fashion: only the part of the opinion dealing with the interpretation of product-by-process claims was *en banc*, and there was no prior notice given to the public or to any of the litigants that any part of the appeal would be addressed *en banc*.

The Abbott Opinion

Abbott was two consolidated cases relating to the same Abbott patent, one a declaratory judgment action filed against Abbott in the Eastern District of Virginia, the other a patent infringement lawsuit filed by Abbott in the Northern District of Illinois. The court in the Eastern District of Virginia construed the relevant claims of the Abbott patent and granted the declaratory judgment plaintiff's motion for summary judgment of noninfringement. The court in the Northern District of Illinois in turn applied the bulk of the

claim construction from the Virginia case and denied Abbott's motion for preliminary injunction.

The product-by-process claims at issue "begin by reciting a product, crystalline cefdinir, and then recite a series of steps by which this product is 'obtainable.'" Abbott argued that the correct interpretation of these claims was "in accordance with *Scripps*," that "they are not limited to product prepared by the process set forth in the claims." The Virginia court, however, construed them under the rule in *Atlantic Thermoplastics*, that "process terms in product-by-process claims serve as limitations in determining infringement."

The Federal Circuit agreed with the Virginia court, announcing that it was taking "this opportunity to clarify *en banc* the scope of product-by-process claims by adopting the rule in *Atlantic Thermoplastics*." Taking a cue from a number of recent Supreme Court decisions relating to patent law, the majority[4] cited to a series of Supreme Court cases dating as far back as 1874, stating that "[i]n these cases, the Supreme Court consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations." It disagreed with idea expressed in the dissenting opinions that the decision somehow represented the loss of a "right," noting that "the right to assert a product-by-process claim against a defendant who does not practice the express limitations of the claim" was one "that has never existed in practice or precedent."

Going further, the Court pointed out that "this decision merely restates the rule that the defining limitations of the claim – in this case process terms – are also the terms that show infringement." Or, perhaps more emphatically: "The issue here is only whether such a claim is infringed by products made by processes other than the one claimed. This court holds that it is not."

The Court went on to explain that "if an inventor invents a product whose structure is either not fully known or too complex to analyze . . . this court clarifies that the inventor is absolutely free to use process steps to define this product. The patent will issue subject to the ordinary requirements of patentability. The inventor will not be denied protection. Because the inventor chose to claim the product in terms of its process, however, that definition also governs the enforcement of the bounds of the patent right."

The practical effect of the Court's ruling is to narrow significantly the scope of product-by-process patent claims, since under *Atlantic Thermoplastics* (and now *Abbott*) products created by a process that materially differs from the one recited in the claim would not infringe the product-by-process claim.

The *Abbott* Dissent

Judge Newman filed a stinging dissent that attacked both the procedure by which the *en banc* opinion was decided and its underlying rationale. The procedure, Judge Newman asserted, violated both the Federal Rules of Appellate Procedure[5] and the Federal Circuit's own Internal Operating Procedure[6]. She was particularly concerned that the "*en banc* court has received no briefing and held no argument, although the rules so require. The communities of inventors, innovaters, and the public who may be affected by this change of law have had no opportunity to be heard. The court has received no information concerning the effect on patents that were granted based on this long-established practice, no advice on what kinds of inventions may now lie fallow because they are unprotected. Nor does the court explain its suspension of the standards of judicial process." (Some of these practical points are ones that patent holders faced with the implications of the *Abbott* ruling are likely to agree with.)

Judge Newman also attacked the majority's "bright line" rationale. She cited for her position a number of Court of Customs and Patent Appeals and Court of Claims cases that advocated the "rule of necessity," a more nuanced view of product-by-process claims. In her view, such claims should be read in the broader sense advocated by *Scripps* (an opinion which she authored), but only in situations where the new product for whatever reason could not be fully described by its structure. A new product that was capable of being described by its structure would not meet this requirement; as a result, the "rule of necessity" would only apply in a relatively small percentage of product-by-process cases.

Judge Newman also issued a case-by-case attack on the cases cited by the majority in support of its adoption of the *Atlantic*

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Thermoplastics bright-line rule, finding fault with each of them. It would not be surprising to see many of Judge Newman's points echoed in any appeal brief that may be filed in this case.

Action Items

For now, at least, it is likely that the process terms in product-by-process claims are going to be read as limitations when determining infringement. Patent holders with significant patents that include such claims should consider taking one or more of the following steps:

(1) identify key patents that rely on product-by-process claims and determine how *Abbott* may limit the strength of those claims;

(2) for pending applications and those capable of being continued that have product-by-process claims, include wherever possible structure claims or claims which recite identifying "fingerprint" data that cover the patented product;

(3) for new applications, consider including more support for "fingerprint data" or one or more characteristics that can serve to differentiate the patented product from other products;

(4) when drafting product-by-process claims, be ever more vigilant in providing claims of varying scope, paring down the process terms recited to those minimally necessary to provide a claim offering "broader" protection;

(5) keep a watch for any further appeal of this case, and any opportunity to submit an *amicus* brief to educate the Court as to the implications of ruling one way or another on the issue.

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[1] Federal Circuit appeal nos. 2007-1400 and 2007-1446, decided May 18, 2009.
[2] Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991).
[3] Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834 (Fed. Cir. 1992).
[4] The majority consisted of Chief Judge Michel and Judges Rader, Bryson, Gajarsa, Linn, Dyk, Prost, and Moore. Judge Newman, joined by Judges Mayer and Lourie, dissented, and Judge Lourie filed a separate dissent. Judge Schall did not participate.
[5] In particular, Fed.R.App.P 34(a)(2) and 35(a).
[6] Internal Operating Procedure 14.3(c).

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