

The Limited Benefits of Product-By-Process Claims

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A product-by-process claim defines a product in terms of how it is made. In May 2009, the Court of Appeals for the Federal Circuit in *Abbott Labs. v. Sandoz, Inc.*,² held that a product-by-process claim is construed as a process claim for infringement and that it is not infringed by products made by processes other than the one claimed. That holding was made *en banc* to resolve what a majority of the circuit judges concluded to be a split in the court's precedents. Although the court's *en banc* decision introduced some clarity, it also introduced some confusion and, importantly, casts doubt on the value of product-by-process claims.

Long-standing precedent requires courts to construe patent claims the same way for validity as for infringement.³ But, the majority's opinion in *Abbott* did not expressly acknowledge this precedent and, importantly, it did not state that the validity of a product-by-process claim depends on the process steps recited in the claim. Further, that opinion tacitly referred to the court's precedents that require Patent Office patentability determinations of product-by-process claims on bases independent of the process limitations recited in the claims. Recently, in September 2009, a three-judge panel of the Federal Circuit in *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*,⁴ acknowledged that the analysis for determining infringement of a product-by-process claim is different than the analysis for determining validity of that claim, and that the "impact of these different analyses is significant."

I.

Product-by-process claims "developed in response to the need to enable an applicant to claim an otherwise patentable product that resists definition by other than the process by which it is made."⁵ Initially, product-by-process claims had to satisfy the Rule of Necessity and therefore "were only permissible where the invention could not otherwise be adequately defined."⁶ Eventually, product-by-process claims became allowable even when the product could be defined using structural features, rather than process elements.⁷

In several key cases, the Federal Circuit defined the scope of product-by-process

claims. In *In re Thorpe*, the court articulated the rule that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself."⁸ Two cases decided in the early 1990s addressed the standard for infringement of product-by-process claims. In *Scripps Clinic & Res. Found. v. Genentech, Inc.*,⁹ the Federal Circuit 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." One year later, in *Atlantic Thermoplastics v. FAYTEX Corp.*,¹⁰ the court ruled that "process terms in product-by-process claims serve as limitations in determining infringement."

District courts struggled with these decisions because advocates repeatedly argued that the decisions were contrary to one another. Judge Newman addressed this struggle in 2006, stating "[w]hen correctly viewed, these two decisions are not in conflict; they simply deal with different situations."¹¹ In her assessment, the product-by-process claims in the two cases are importantly distinguished from each other because the "*Scripps* claims are of the class sometimes called 'true' product by process claims, in that their patentability and validity depends on the novelty and unobviousness of the *product*, and it is immaterial whether the process is also patentable."¹² In contrast, the *Atlantic* claims are "product of the process" claims, such as may be allowed when the *process* is found patentable."¹³ Stated another way, the "*Scripps* class of claim" is "when the product is new and unobvious, but is not capable of independent definition," and the "*Atlantic* class of claim" is "when the product is old or obvious, but the process is new."¹⁴

In *Abbott*, an *en banc* panel of the Federal Circuit resolved the struggle and held that a product-by-process claim is not infringed by products made by processes other than the one claimed.¹⁵ The court expressly adopted the rule in *Atlantic Thermoplastics* and overruled *Scripps*.¹⁶ While clarifying that process steps limit infringement, the court (specifically, the majority opinion) did not address whether process steps also affect the validity of product-by-process claims.

II.

For patentability, the "Patent Office bears a lesser burden of proof in making

out a case of prima facie obviousness for product-by-process claims ... than would be the case when a product is claimed in the more conventional fashion."¹⁷ That "lesser burden" is appropriate because in "weighing patentability, the [Patent Office lacks] facilities to replicate processes and compare the resultant product with the prior art."¹⁸ The standard is that "when the prior art discloses a product which reasonably appears to be identical with or only slightly different than a product claimed in a product-by-process claim, a rejection alternatively on either section 102 or 103 of the statute [35 U.S.C.] is appropriate."¹⁹

Product-by-process claims are currently treated as product claims for patentability, so "[i]f the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."²⁰ The Federal Circuit has stated that the Patent Office is "to give claims their broadest reasonable meaning when determining patentability," and the "treatment of product-by-process claims as a product claim for patentability is consistent with policies giving claims their broadest reasonable interpretation."²¹ Current MPEP guidelines—which predate the 2009 *Abbott* decision—emphasize that "product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps... [which] should be considered when assessing the patentability of product-by-process claims over the prior art."²²

According to the *Abbott* majority, its decision does not disturb the legitimacy of product-by-process claims or the effect of process steps on patentability of such claims.²³ After *Abbott*, product-by-process claims "will issue subject to the ordinary requirements of patentability."²⁴ *Abbott* followed *Atlantic Thermoplastics*, which upheld the patentability standard articulated in *In re Thorpe* and presently articulated in the MPEP.²⁵ Judge Newman's dissent in *Abbott* confirmed that an "applicant would still have to demonstrate patentability of the new product as a product (independent of the process)."²⁶

III.

The Federal Circuit "treats claims differently for patentability as opposed to validity."²⁷ In contrast to the broad meaning given to product-by-process claims for patentability, for "litigation determining validity...this approach is inapplicable."²⁸ To evaluate validity, "the courts must consult the specification, prosecution history, prior art, and other claims to determine

the proper construction of the claim language.”²⁹ A patent is presumed valid under 35 U.S.C. § 282, and clear and convincing evidence is necessary to invalidate a patent—a higher standard than for rejecting a patent claim for unpatentability.

For claim interpretation, it is “an inviolate rule that patent claims are construed the same way for validity and for infringement.”³⁰ In view of that rule, the *Abbott* decision, in resolving how product-by-process claims are evaluated for infringement, would appear to address how those claims are evaluated for purposes of validity. Not so, however. The *Abbott* majority did not state that process steps should be considered for validity in the same manner they are considered to limit infringement. And it did not have to say anything about that because validity was not an issue on appeal.

The dissenting judges in *Abbott* interpreted the decision and the majority opinion as establishing that process steps limit infringement, but not validity:

For the first time, claims are construed differently for validity and for infringement.... As interpreted for validity, the claims obtained under the expedient of necessity are product claims, and are subject to the requirements of novelty, unobviousness, and all other requirements for new products, independent of how the products can be made. [The majority holds] that these are product claims for validity, but process claims for infringement.³¹

Five months after *Abbott*, in *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, a three-judge panel of the Federal Circuit acknowledged that in determining validity of a product-by-process claim, the focus is on the product and not the process of making it, whereas in determining infringement of that claim, the focus is on the process of making the product as much as it is on the product itself.³² The court further explained the impact of the different analyses compelled by the different foci:

The impact of these different analyses is significant. For product-by-process claims, that which anticipates if earlier does not necessarily infringe if later. That is because a product in the prior art made by a different process can anticipate a product-by-process claim, but an accused product made by a different process cannot infringe a product-by-process claim. Similarly, that which infringes if later does not necessarily anticipate if ear-

lier. That is because an accused product may meet each limitation in a claim, but not possess features imparted by a process limitation that might distinguish the claimed invention from the prior art.³³

In *Amgen*, the court considered infringement and validity of claims reciting a product described in terms of its source. Under the facts of that case, as articulated in the court’s decision, the source imparted structural and functional differences to the claimed product when compared to a prior art product. Those differences were relevant as evidence of no invalidity because of the source limitation.³⁴ The court did not require the patentee to demonstrate the accused product was structurally and functionally different from the prior art product, but it did require the patentee to demonstrate that the accused product satisfied the recited source limitation.³⁵ The panel concluded that the district court did not err in conducting different validity and infringement analyses.

IV.

The facts in *Amgen* demonstrate how *Abbott* can be applied to reach conclusions that a product-by-process claim is not invalid and is infringed. But, patent applicants must now more carefully consider the value of product-by-process claims. It is becoming increasingly difficult for patent applicants to successfully rely on the process of manufacture to impart patentability to products where those products may be characterized with conventional analytical techniques. It remains unclear what effect *Abbott* will have where characterization of the product is not possible with such techniques and the product resists definition by other than the process by which it is made.³⁶ But, if that characterization is possible, there may be no good reason to claim the product by its process of manufacture in U.S. patent applications. To do so would require the applicant to demonstrate patentability of the product independent of its process of manufacture, and then limit enforcement against infringement to only those instances where the accused product was made by the same process. Thus, if the presence of process limitations is going to be required to establish infringement by the accused product but those limitations are not going to aid in establishing patentability or defending against a validity challenge, then why bother with product-by-process claims? **IP**

ENDNOTES

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2. 566 F.3d 1282, 1293 (Fed. Cir. 2009) (“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.”).
3. See, e.g., *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1279 (Fed. Cir. 1988); see also, *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) (stating that “claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses”).
4. 2009 U.S. App. LEXIS 20409, at *77 (Fed. Cir. Sept. 15, 2009).
5. *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985).
6. Eric P. Mirabel, *Product-by-Process Claims: A Practical Perspective*, 68 J. PAT. & TRADEMARK OFF. SOC’Y. 3, 11 (1986).
7. *In re Hughes*, 496 F.2d 1216, 1219 (CCPA 1974).
8. *Thorpe*, 777 F.2d at 697.
9. 927 F.2d 1565, 1583 (Fed. Cir. 1991).
10. 970 F.2d 834, 846-47 (Fed. Cir. 1992).
11. *Smithkline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1323 (Fed. Cir. 2006).
12. *Atlantic Thermoplastics v. Faytex Corp.*, 974 F.2d 1279, 1282 (Fed. Cir. 1992) (J. Newman dissenting from the court’s denial of rehearing en banc).
13. *Id.*
14. *Id.* at 1284.
15. *Abbott*, 566 F.3d at 1293.
16. *Id.* at 1291, 1293.
17. *In re Fessmann*, 489 F.2d 742, 744 (CCPA 1974).
18. *Atlantic Thermoplastics*, 970 F.2d at 844.
19. *In re Brown*, 459 F.2d 531, 535 (CCPA 1972); see also, *In re Pilkington*, 411 F.2d 1345, 1348 (CCPA 1969) (“[P]atentability of a claim to a product does not rest merely on a difference in the method by which that product is made. Rather, it is the product itself which must be new and unobvious.”).
20. *Thorpe*, 777 F.2d at 697.
21. *Atlantic Thermoplastics*, 970 F.2d at 846.
22. MPEP § 2113 (8th ed., Rev. 7, July 2008).
23. *Abbott*, 566 F.3d at 1293 (stating that this “decision in no way abridges an inventor’s right to stake claims in product-by-process terms”).
24. *Id.* at 1294.
25. *Atlantic Thermoplastics*, 970 F.2d at 847 (“Neither does this court disturb the PTO’s present practice for assessing patentability of product-by-process claims.”).
26. *Abbott*, 566 F.3d 1317 (J. Newman dissenting).
27. *Atlantic Thermoplastics*, 970 F.2d at 846.
28. *Id.*
29. *Id.*
30. *Abbott*, 566 F.3d 1317 (J. Newman dissenting).
31. *Id.* at 1317-18 (J. Newman dissenting).
32. *Amgen*, 2009 U.S. App. LEXIS 20409, at *75-76 (citing each of *Atlantic Thermoplastics*, 970 F.2d at 841, *Brown*, 459 F.2d at 535, *Pilkington*, 411 F.2d at 1348, and *Abbott*, 566 F.3d at 1293).
33. *Id.* at *77-78.
34. *Id.* at *78.
35. *Id.* at *77.
36. *Abbott*, 566 F.3d 1301 (J. Newman dissenting) (“The effect of this decision on innovation in complex fields of science and technology is unknown to the court, for we have had no advice on the consequences of this change of law.”).