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Abbott Laboratories v. Sandoz, Inc.: The Federal Circuit Finally Aligns Its Precedent On Product-By-Process Claims

By Rachel C. Hughey

For many years, there was a Federal Circuit split on the issue of product-by-process limitations. One panel of the Federal Circuit had declared that when a patent claim is directed to a product-by-process, the process is not a limitation for infringement. Another panel disagreed, asserting that process terms in product-by-process claims serve as limitations in determining infringement. In *Abbott Laboratories v. Sandoz, Inc.*, the court, *en banc*, resolved the split and concluded that in a product-by-process claim, the process is a limitation for infringement.¹

I. Background

A product-by-process claim is one directed to a product, but with a statement in the claim of the process used to obtain the product. While the law of infringement of product-by-process claims had not been clear for years, a specific circuit split formed the early 1990s. In 1991, Judge Newman wrote the opinion in *Scripps Clinic & Research Foundation v. Genentech, Inc.*, and declared 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," reasoning that claims must be construed the same way for validity and for infringement.²

A year later Judge Rader authored the decision in *Atlantic Thermoplastics Co. v. Faytex Corp.*, which held the opposite—namely that product-by-process claims are limited by the process.³ That panel asserted that Supreme Court case law required the process limitations to be met for infringement of product-by-process claims.⁴ The panel reasoned that the *Scripps* panel failed to consider this controlling Supreme Court precedent, and thus did not control.⁵

II. The District Court Opinions

Abbott's '507 patent claimed a product with a statement in the claims that the product "is obtainable by" different specific processes.⁶ Lupin filed declaratory judgment in the Eastern District of Virginia against Abbott, asserting that it did not infringe the '507 patent.⁷ The district court concluded that the claims were product-by-process claims and that the phrase "obtainable by" limited the claims to the specified process steps.⁸ Because Lupin made its products with processes other than those claimed the '507 patent, the district court granted Lupin's motion for summary judgment that it did not infringe the product-by-process claims.⁹ Abbott appealed.¹⁰

In a separate action in the Northern District of Illinois, Abbott sued Sandoz and other defendants for infringement of the '507 patent.¹¹ Abbott sought a preliminary injunction in that case, and the parties agreed for the purposes of the motion to adopt the Eastern District of Virginia's construction.¹² Based on that construction, the district court denied the preliminary injunction.¹³ Abbott appealed.¹⁴

III. The Federal Circuit Decision

The cases were combined on appeal.¹⁵ The Federal Circuit, *suo sponte*, took up the issue of product-by-process claims *en banc*.¹⁶ In an opinion authored by Judge Rader, the court agreed that the claims were product-by-process claims.¹⁷ It then adopted the rule in *Atlantic* and declared that product-by-process claims are limited by the process recited in the claims.¹⁸ The court asserted that this rule found extensive support in relevant Supreme Court decisions that found infringement of a product claim only if the process in the claim was employed as well.¹⁹ The court further pointed to the language in the Supreme Court's *Warner-Jenkinson* case (dealing with the doctrine of equivalents) that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention."²⁰ The court also explained that Federal Circuit case law supported its decision, noting the Federal Circuit case of *In re Thorpe*, where the court stated that "even though *product-by-process claims are limited by and defined by the process*, determination of patentability is based on the product itself."²¹ The court then explicitly overruled the *Scripps* case.²² The majority also suggested that the reasons for product-by-process claims—namely, that the new product is not fully known or too complex to analyze for the purposes of claiming it in a patent—"may no longer in reality exist."²³

Judge Newman issued a scathing twenty-page dissent, joined by Judges Mayer and Lourie.²⁴ Judge Newman asserted that the court's decision was contrary to practice and overturned a century of precedent. While she agreed that *en banc* review was appropriate (suggesting a conflict in court precedent existed since 1992—the date of Judge Rader's *Atlantic* decision), she argued that the court's procedure in deciding the issue *en banc* was in error, as it did not receive briefing or argument after it decided to consider the issue.²⁵ Further, she asserted that the court failed to mention the long-established precedent it was overturning that allowed a product to be described by the process of producing it without limiting the product to that process.²⁶ She cited several cases where the courts recognized when an invention "cannot be defined except by the process used in its creation" a claim to the product by means of the process would be allowed.²⁷ Judge Newman then dissected the cases relied on by the majority, distinguishing *Thorpe* because that case did not involve a new product and thus was outside of the product-by-process exception.²⁸ Finally, Judge Newman argued that the majority's rule requires a patent applicant to demonstrate patentability of a new product independent of the process, while enforcement of the patent against an identical product would be limited to the infringer's use of the process.²⁹ She concluded that, "[f]or the first time, claims are construed differently for validity and for infringement."³⁰

Judge Lourie authored a second dissent. He agreed that there is "substantial Supreme Court precedent that holds that product-by-process claims require use of the recited process for there to be infringement" but suggested that many of those cases applied "overly broad language to fact situations involving old products or used vague language that makes it difficult to determine whether the products were old or new."³¹ He reasoned that while an old product is unpatentable and cannot be claimed with a process to claim a product made

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by any process, there is a different situation when the product is new.³² He argued that in such a case—which may arise in the chemical or biological field when the product's structure is unknown at the time it is claimed—there should not be a bright-line rule that a new product claimed by a process cannot be infringed when made by another process.³³ He suggested that if at the time infringement is asserted there is still no means to determine whether the accused product is structurally the same as the one claimed, there is no infringement if the accused product is made by a different process.³⁴ Judge Lourie concluded that it is possible that there is little need for product-by-process claims with today's analytical techniques, but he would draw a distinction between old products and new products.³⁵

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IV. Discussion

The *Abbott* case has settled the law that infringement of a product-by-process claim is limited to the process in the claim, even if the product is new and not otherwise definable. The court followed Supreme Court precedent that required all elements of a claim to be met for infringement, including the statement in *Warner-Jenkinson* that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." It remains to be seen if the court will extend this reasoning to other aspects of infringement, such as claim preambles, which are not considered a limitation unless they give "life and meaning" to the claims under current law.

Judge Newman asserts that "For the first time, claims are construed differently for validity and for infringement." The majority appears to agree that this is now the law, as it did not suggest otherwise and it cited *Thorpe's* statement on the point with approval. It also remains to be seen if this divergence will affect other claim construction doctrines or prosecution of product-by-process claims.

Judge Lourie agrees with Judge Newman that there should not be a bright-line rule. He also worries that in certain biological or chemical technologies a patentee might be not know the structure of the invention at the time it is claimed, although he acknowledges that this may not be as much of an issue with today's analytical techniques. The majority also suggests that this concern may no longer exist. If this is true, there may be no reason to claim new products in terms of their process limitations anyway. But to the extent that a new product cannot be claimed other than by reference to the process of making it, the process will be a limitation for infringement.

1 566 F.3d 1282 (Fed. Cir. 2009) (*en banc*).

2 927 F.2d 1565, 1583 (Fed. Cir. 1991) (Newman, J.).

3 970 F.2d 834 (Fed. Cir. 1992) (Rader, J.).

4 *Id.* at 883-47.

5 *Id.* at 838 n.1.

6 *Abbott*, 566 F.3d at 1286.

7 *Id.* at 1285.

8 *Id.*

9 *Id.*

10 *Id.* at 1287.

11 *Id.* at 1285-86.

12 *Id.* at 1286.

13 *Id.*

14 *Id.* at 1287.

15 *Id.* at 1286.

16 *Id.* at 1291 n.1.

17 *Id.* at 1291.

18 *Id.*

19 *Id.* at 1291-92.

20 *Id.* at 1293 (quoting *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 39 n.8 (1997)).

21 *Id.* (quoting *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985)) (emphasis in original).

22 *Id.*

23 *Id.* at 1294.

24 *Id.* at 1299-1320 (Newman, J., dissenting)

25 *Id.* at 1301.

26 *Id.* at 1303.

27 *Id.* at 1303-04 (citation omitted).

28 *Id.* at 1308.

29 *Id.* at 1317.

30 *Id.*

31 *Id.* at 1320 (Lourie, J., dissenting).

32 *Id.*

33 *Id.*

34 *Id.*



35 *Id.* at 1320-21.

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