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### PATENTS

The Federal Circuit's recent en banc holding on the showing needed to establish infringement of a product-by-process patent claim left questions about how such patent claims should be construed in other contexts.

#### ***Abbott Laboratories v. Sandoz Inc.:* Patenting a Product by Defining How It's Made**

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**A** product may be patented either by defining the product itself in a "product" patent or by defining how it is made in a "product-by-process" patent. The U.S. Court of Appeals for the Federal Circuit recently held en banc in *Abbott Laboratories v. Sandoz Inc.*, 566 F.3d 1282, 90 USPQ2d 1769 (Fed. Cir. 2009) (78 PTCJ 106, 5/29/09), review sought, No. 09-335 (U.S. Sept. 16, 2009) (78 PTCJ 693, 10/9/09), that to establish infringement of a product-by-process patent, the paten-

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tee must prove that the accused infringer performs all of the claimed process limitations. Because the court was specifically addressing infringement issues and not challenges to the claims in view of prior art, some questions remain about the ramifications of the court's decision.

In *Abbott*, the Federal Circuit resolved an ambiguity originating in the early 1990s when two Federal Circuit panels issued arguably conflicting opinions on whether infringement of a product-by-process claim requires proof that an infringer performs all claimed process steps. The *Abbott* court held that "process terms in product-by-process claims serve as limitations in determining infringement." Therefore, if the same product is created by another process, it will not directly infringe the product-by-process claim.

The court also held that if the same product is created by another process that is not substantially the same as the process defined in the claim, then the product will not infringe under the doctrine of equivalents.

*Abbott* therefore does not support the assertion of product-by-process claims against those who create the same product by a substantially different process.

### Differences of Opinion

The earlier split in Federal Circuit arose from *Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991). In *Scripps*, a Federal Circuit panel held that product-by-process claims are not limited by the processes set forth in the claims.

The legal discussion in support of this holding was relatively brief. In the one paragraph devoted to the issue, the panel cited several cases holding that patentability of product-by-process claims in view of prior art historically has been determined independent of the process. None of the cited cases involved infringement or validity determinations. Yet the panel relied on these patentability cases to support its reasoning 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.”

It seems that the panel equated “patentability” and “validity” in applying this axiom, but it is not clear that claims should be construed the same way in the patentability and validity contexts. Accordingly, it is also not necessarily clear that claims must be construed the same way for patentability and infringement.

The *Scripps* holding did not remain unchallenged for long. Barely more than a year after *Scripps*, another Federal Circuit panel in *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 23 USPQ2d 1481 (Fed. Cir. 1992), held that product-by-process claims are limited by the processes set forth in the claims. The discussion in *Atlantic Thermoplastics* included a number of cases not addressed in *Scripps*.

For example, the panel discussed *Cochrane v. Badische Anilin & Soda Fabrik*, where the Supreme Court noted that “[e]very patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.” 111 U.S. 293 (1884). In addition to citing precedent specific to product-by-process claims, the panel emphasized precedent stating that every claim limitation must be met in an infringement analysis.

The panel also challenged the implicit assumption in *Scripps* that claims should be construed the same for patentability and infringement. “The entire history of product-by-process claims suggests a ready explanation for the apparent difference of view about treatment of those claims during *ex parte* [patentability] proceedings and during litigation.”

The panel reasoned that during patent prosecution, claims are construed as broadly as possible for the purpose of determining patentability, but during litigation “courts must consult the specification, prosecution history, prior art, and other claims to determine the proper construction of the claim language.” Therefore, while agreeing with the statement in *Scripps* that “claims must be construed the same way for validity and for infringement,” the *Atlantic Thermoplastics* panel disagreed with the implied assumption in *Scripps* that claims must be construed the same way for patentability and for validity.

Consequently, the *Atlantic Thermoplastics* panel held that process descriptions in product-by-process claims are limiting in the infringement context.

### Abbott: Resolving Differences

In *Abbott*, the Federal Circuit convened en banc to resolve this nearly 17-year split. The court essentially adopted the holding of *Atlantic Thermoplastics* while explicitly overruling *Scripps*. Judge Randall R. Rader wrote for the majority. Judge Pauline Newman—joined by Judges Alan D. Lourie and Haldane Robert Mayer—filed a dissenting opinion. Lourie also filed a separate dissent.<sup>1</sup>

The majority relied on Supreme Court precedent in holding that when a patentee asserts infringement of a product-by-process patent, the recited process terms limit the scope of the claims. However, the majority did not discuss the different treatments of product-by-process claims in the prosecution and litigation contexts as the panel did in *Atlantic Thermoplastics*.

In addition to resolving the split, the *Abbott* majority discussed two product-by-process issues not explored in the previous cases. First, the majority addressed the use of open-ended language that does not exclusively tie the product to the process. In this case, the claims referred to a product “obtainable by” (rather than “made by”) a defined process. However, the majority made clear that regardless of how open-ended the language in the claim is, if the product is defined by the process for making it, the scope of the claim will be limited to the recited process.

Second, the majority discussed the applicability of the doctrine of equivalents when the allegedly infringing product is created by a process different from the claimed process. The majority explained that the doctrine of equivalents could not be used to expand the scope of a product-by-process claim to include all incarnations of the product. The majority supported its view with an analysis of the two primary tests for equivalency under the doctrine of equivalents.

The “function-way-result” test requires that “the accused product or process performs substantially the same function, in substantially the same way, to achieve substantially the same result, as disclosed in the claim.” See *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605, 85 USPQ 328 (1950). The other test for equivalency requires that differences between the claimed invention and the accused product or process be insubstantial. See *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 35 USPQ2d 1641 (Fed. Cir. 1995) (*en banc*).

The majority in *Abbott* reasoned that in neither case could individual claim elements be ignored when applying the doctrine of equivalents. Therefore, the doctrine of equivalents cannot be used to effectively broaden product-by-process claims to capture products made by substantially different processes.

Newman’s and Lourie’s separate dissenting opinions both criticized the majority on a number of fronts. Newman argued that the majority should have solicited opinions from the scientific and legal communities before ruling on this issue, maintaining her view from *Scripps* that the Supreme Court precedent cited by the majority in fact favors a broader scope for product-by-

<sup>1</sup> Rader also authored *Atlantic Thermoplastics*, while Newman also authored *Scripps*.

process claims. Her dissent emphasized the “rule of necessity” that certain products can only be described by reciting the processes by which they were made. Newman expressed reluctance to eliminate an inventor’s ability to obtain broad claims in such circumstances.

While the *Abbott* majority implied that advances in analytical chemistry were bringing the rule of necessity close to obsolescence, both dissenting opinions emphasized that products still exist that cannot be described by characteristics independent of the processes by which they are made. Lourie’s dissent did not adopt Newman’s interpretation of Supreme Court precedent but generally agreed with her “rule of necessity” analysis.

## Unanswered Questions

The majority decision in *Abbott* seems to raise a number of questions about how product-by-process claims should be construed in other contexts, including validity and patentability; and whether the claims should be construed differently depending on context.

The first question regarding product-by-process claims in the validity context follows from the panel opinions in *Atlantic Thermoplastics* and *Scripps*. Both panels held that claims must be construed the same way for infringement and invalidity. Because *Abbott* held that product-by-process claims should be limited by the recited processes for infringement, it seems to follow that product-by-process claims may also be limited by their recited processes for validity.

The second question is more complicated: how product-by-process claims should be approached in the patentability context. *Abbott* does not seem to change the historical rule that if the product created by product-by-process claim is anticipated or obvious, the product-by-process claim should be considered anticipated or obvious as well.

Arguably this rule need not change, because product-by-process claims still cover the ultimate product. If the product as a whole is anticipated or obvious, then arguably the product should not be patentable by virtue of claiming it as a product-by-process. Advocates of this approach might find support in the rule that during patent examination, pending claims must be “given

their broadest reasonable interpretation consistent with the specification,” a rule that the Federal Circuit has recognized.

An alternative view is that process limitations matter as much for analyzing patentability as for infringement or validity. Therefore, a claim to a product-by-process arguably should not be unpatentable unless the prior art teaches or suggests the claimed process limitations.

Advocates of this approach might argue that if the patentee will be required to prove that a putative infringer practices the claimed process steps, then so too should someone challenging the claims be required to establish that the prior art discloses all process limitations.

But advocates of the first approach might respond that the bar for patentability *should* be higher when the applicant is disclosing only process steps and not the actual product. In that situation, the applicant is arguably giving the world less teaching and notice about the claimed *product* as part of the quid pro quo exchange for patent rights, which forecloses further patenting of the product by others.

Another patentability question is whether a product-by-process should be patentable if the process is obvious or anticipated but the product itself is not. Should such a claim be patentable provided the process limitations adequately define and limit the claimed subject matter to a product that is nonobvious?

Other questions, which are perhaps even more complicated, include how broadly product-by-process claims should be applied when cited as prior art in order to render later inventions unpatentable or to render later patents invalid. The answer may depend on the whether the target claims themselves are product-by-process claims.

## Conclusion

*Abbott* resolves an inconsistency in Federal Circuit precedent regarding product-by-process claims and provides helpful guidance in construing such claims for infringement. Additional questions remain, particularly in the patentability context. How the court resolves such questions remains to be seen.