OLIFF & BERRIDGE, PLC
ATTORNEYS AT LAW
SPECIAL
REPORT

FEDERAL CIRCUIT RESOLVES CONSTRUCTION OF PRODUCT-BY-PROCESS CLAIMS FOR INFRINGEMENT DETERMINATIONS

May 29, 2009

The Federal Circuit issued an *en banc* decision holding that product-by-process claims are properly construed so as to be infringed only if all of the recited product and process limitations are met, literally or equivalently, by an accused product and the process by which the accused product was produced.

The *en banc* decision was included in the Federal Circuit's consolidated opinion deciding both *Abbott Laboratories v. Sandoz Inc.* and *Lupin Pharmaceuticals v. Abbott Laboratories* (collectively *Abbott*).[1] The *Abbott* decision was otherwise a panel decision of three Federal Circuit judges; i.e., only the product-by-process claim construction infringement issue was decided *en banc*.

The *en banc Abbott* decision is binding upon all panels of the Federal Circuit (as well as all district courts), and thus must be followed by the courts unless/until it is overruled by the Supreme Court. This decision thus carries more weight than the panel decision of the Federal Circuit, which is to be given deference by other panels of the Federal Circuit and is binding on district courts, but is not necessarily binding on other panels of the Federal Circuit.

As discussed below, subject to Supreme Court review, *Abbott* settles a conflict between two prior Federal Circuit panel decisions addressing the construction of product-by-process claims. *Abbott* eliminates the possibility, espoused in one of those prior cases, that a product-by-process claim can be literally construed, at least for infringement determinations, as not limited to products made by the recited process. Related to the *en banc Abbott* decision, the *Abbott* panel decision held that the term "obtainable by" limits product claims in the same way as the term "obtained by."

The *en banc Abbott* decision limits itself to the construction of product-by-process claims for infringement determinations. It does not directly address construction of product-by-process claims for validity or patentability determinations. As pointed out by Judge Newman in dissent, the majority decision will apparently require product-by-process claims to be construed differently for validity determinations than for infringement determinations. The majority decision did not disturb precedent holding that if a product recited in a product-by-process claim is old, the claim is not patentable or valid regardless of the process recited for making the product. In other words, for validity and patentability determinations, it is the product of the product-by-process claim that must be evaluated for novelty, without regard to whether that product is actually made by the process recited in the claim. (The product would, however, have any structural and/or property characteristics imposed by the recited process.)

Abbott likely will not affect the U.S. Patent Office's handling of product-by-process claims in pending patent applications. In pending applications, Examiners give weight only to the recited product features of a product-by-process claim unless/until it is established that the recited process imparts distinct structural and/or property characteristics to the claimed product.

[1] Appeal Nos. 2007-1400 and 2007-1446 (May 18, 2009).

May 29, 2009

I. The Claims At Issue

The patent claims at issue in *Abbott* were directed to a pharmaceutical compound "which is obtainable by" either (1) acidifying a solution of the compound at room temperature or under warming, or (2) dissolving the compound in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room temperature and allowing the solution to stand.

II. The Legal Background

Prior to the *en banc* decision in *Abbott*, there has been a conflict between the Federal Circuit panel decisions in (1) *Scripps Clinic & Research Foundation v. Genentech, Inc.*[2] and (2) *Atlantic Thermoplastics Co. v. Faytex Corp.*,[3] with respect to how to construe product-by-process claims for infringement determinations. The *Scripps* case held that: "Since 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." *Atlantic Thermoplastics* held that *Scripps* was not controlling in view of prior Supreme Court precedent, and that "process terms in product-by-process claims serve as limitations in determining infringement." Judge Newman (author of the *Scripps* decision), dissented from a decision not to grant rehearing *en banc* in *Atlantic Thermoplastics*. Her dissent in that case attempted to reconcile the two decisions by arguing that *Scripps* was limited to those few "pure" product-by-process claims in which the product was incapable of being defined other than by the process by which it was made.

Subsequent to *Scripps* and *Atlantic Thermoplastics*, most courts have followed *Atlantic Thermoplastics*. Those courts have found product-by-process claims to be infringed only when an accused product included, literally or equivalently, all product limitations and the accused product was made by the same or equivalent process steps. However, numerous courts and commentators have called for the Federal Circuit to resolve the conflict.

In *Abbott*, the trial courts construed the product-by-process claims in accordance with *Atlantic Thermoplastics*, and held the claims to be limited for infringement purposes to products made by the recited process steps. Abbott appealed this claim construction, arguing that the claims should encompass products made by other processes (1) in accordance with the *Scripps* decision, and (2) in view of the fact that the claims used the facially broader term "obtainable by" instead of "obtained by."

III. Process Limitations Must be Met by the Process by Which the Accused Product Was Made

The *Abbott en banc* decision held that "process terms in product-by-process claims serve as limitations in determining infringement." The Federal Circuit reiterated that for an accused product to infringe a product-by-process claim, the recited process must be employed in making the accused product. For example, the Federal Circuit quoted from the 1880 Supreme Court decision in *Goodyear Dental Vulcanite Co. v. Davis*[4] that "to constitute infringement of the patent, both the material of which the [product] is made … and the process of constructing the [product] … must be employed." The Federal Circuit also quoted with approval a 1977 Third Circuit decision in *Paeco, Inc. v. Applied Moldings, Inc.*[5] that "A patent granted on a product claim describing one process grants no monopoly as to identical products manufactured by a different process." In its own words, the *en banc* Federal Circuit majority in *Abbott* concluded:

> 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.

[2] 927 F.2d 1565 (Fed. Cir. 1991).
[3] 970 F.2d 834, *reh'g en banc denied*, 974 F.2d 1279 (Fed. Cir. 1992).
[4] 102 U.S. 222, 224 (1880).
[5] 562 F.2d 870, 876 (3d Cir. 1977).

In other words, as a limitation to the claim, the process terms must be found to be met, literally or equivalently, in order to find infringement. The Federal Circuit adopted *Atlantic Thermoplastics* and held that "to the extent that *Scripps Clinic* is inconsistent with this rule, this court expressly overrules *Scripps Clinic*." Thus, *Abbott* makes clear that product-by-process claims must always be construed as limited to products made by the process recited therein for purposes of infringement determinations. As so construed, a product-by-process claim can only be infringed if all of the product and process limitations are found literally or equivalently in an accused product and the process by which it was made.

IV. "Obtainable By" Is The Same As "Obtained By"

The *en banc Abbott* decision confirmed that the "obtainable by" language of the claims created a "product-by-process" limitation, even though the word "obtainable" does not by definition limit the process by which the claimed product was actually made. In the panel portion of the *Abbott* decision, the Federal Circuit explained that "obtainable by" as recited in the subject claims is the same as "obtained by" in terms of defining the process by which the product has to be made. The panel analogized the "obtainable by" language to language addressed by the Supreme Court in *Cochrane v. Badische Anilin & Soda Fabrik* (*BASF*)[6] ("produced by [specified methods] … or by any other method which will produce a like result"). In *BASF*, the Supreme Court refused to give any weight to the "any other method" language, and in *Abbott*, the Federal Circuit panel relied on *BASF* to refuse to give any weight to the "-able" suffix on "obtainable."

In so holding, the panel disagreed with Abbott's argument that "obtainable by" recited an optional process, rather than a required process such as would be defined by reciting "obtained by." The panel held that "if this court does not require, as a precondition for infringement, that an accused infringer actually use a recited process, simply because of the patentee's choice of the probabilistic suffix 'able,' the very recitation of that process becomes redundant." The panel held that this would improperly widen the scope of what was actually invented, at the expense of future innovation and the notice function of claims. The panel thus held that there was no distinction between "obtainable by" and "obtained by" in defining the required process of the product-by-process claims.

V. Validity Of Product-By-Process Claims

The *en banc Abbott* decision does not decide how to construe product-by-process claims for purposes of validity determinations, limiting the decision to construction in an infringement context. However, the *en banc Abbott* decision does refer to cases, including Supreme Court and Federal Circuit precedent, holding that product-by-process claims are valid only when the claimed product is novel. That is, a product-by-process claim defining an old product is not patentable or valid regardless of the process recited for making the product. *Abbott* thus appears to endorse construing product-by-process claims differently for validity determinations than for infringement determinations.

This apparent contrast between construction of product-by-process claims for validity versus infringement appears to be supported by the *Atlantic Thermoplastics* decision followed by *Abbott*. In *Atlantic Thermoplastics*, the Federal Circuit cited *BASF* for the proposition that:

> In judging infringement, the Court treated the process terms as limitations on the patentee's exclusive rights. In assessing validity in terms of patentability, the Court forbade an applicant from claiming an old product by merely adding a new process. The infringement rule focused on the process as a limitation; the other rule focused on the product with less regard for the process limits.

Thus, the Federal Circuit appears to acknowledge that product-by-process claims are an exceptional

[6] 111 U.S. 293 (1884).

class of claims where different construction for infringement determinations than for validity determinations is appropriate.

VI. Patent Office Procedure

The *en banc Abbott* decision also does not address how product-by-process claims should be construed by the Patent Office during examination for patentability. However, *Abbott* is unlikely to have any effect on the way the Patent Office examines product-by-process claims.

As summarized in MPEP 2113, the Patent Office examines product-by-process claims by searching for the product as claimed regardless of the process specified for making the product. Once the examiner provides a rationale tending to show that the claimed product appears to be the same as or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. The applicant can submit evidence that the process as claimed produces a product that is patentably distinct from the prior art.

As discussed above, *Atlantic Thermoplastics* endorsed the Patent Office construing product-by-process claims differently for patentability determinations. The court reasoned that the Patent Office must give claims their broadest reasonable interpretation when examining the claims for patentability, something that courts are not permitted to do when construing the claims for infringement and validity.

In view of the Federal Circuit having previously endorsed the Patent Office construing product-by-process claims differently for purposes of evaluating patentability, and *Abbott* apparently endorsing this approach, the Patent Office will most likely continue to follow its present examination procedure for product-by-process claims.

VII. The Dissents And The *En Banc* Court's Response To Them

Judges Newman, Lourie, and Mayer dissented from the *en banc* decision.

In her lengthy dissenting opinion, Judge Newman (joined by Judges Lourie and Mayer) disputed the majority's application of precedent and again focused on so-called "pure" product-by-process claims. She argued that it was unfair and improper to apply the majority's universal rule to claims to a product that could not be defined without reference to how the product was made.

In his separate dissent, Judge Lourie disagreed with the majority's interpretation of "obtainable" as having the same meaning as "obtained." He also argued that product-by-process claims should be reviewed on a case-by-case basis without a bright line test. He argued that Supreme Court precedent requiring process terms to be limitations for infringement evaluation of old (known) products should not control the construction of product-by-process claims in which the product is novel. Judge Lourie argued that courts should be able to construe product-by-process claims to novel products to be infringed by the same novel products made by any method.

The *en banc* decision disagreed with both, and expressly held that it was unnecessary and "logically unsound" to create a rule that process limitations in product-by-process claims should not be enforced in those cases where it was established that the product could not be defined independent of the process.

Judge Newman's dissent also took issue with the *en banc Abbott* decision establishing a rule requiring product-by-process claims to be construed differently for infringement and validity purposes. As noted above, the *en banc* decision did not address this issue directly, but implied that such different construction is acceptable.

Finally, Judge Newman's dissent argued that the *en banc* decision should not have been made without notice and without a more in-depth briefing and hearing process. The *en banc* decision did not address this argument.

VIII. Possible Supreme Court Review

Abbott may appeal the decision to the Supreme Court, and it remains to be seen if the Supreme Court will agree to hear the appeal. The Supreme Court has been active in patent law recently, rendering several decisions where bright line tests and rigid rules from the Federal Circuit were found improper. For example, in *Festo Corp. v. Shoketsu Kinzoku Kogyokabushiki Co.*,[7] the Supreme Court rejected a rigid rule barring application of the doctrine of equivalents if prosecution history estoppel was found. In *KSR International Co. v. Teleflex Inc.*,[8] the Supreme Court rejected a rigid application of the teaching-suggestion-motivation test in determining obviousness. If the Supreme Court perceives *Abbott* to impose an improperly rigid rule of claim construction, it could take up *Abbott* on appeal so as to speak definitively on the issue.

IX. Recommendations

It remains proper to define an invention in product-by-process format, and there are many circumstances in which the use of product-by-process claims is appropriate. Examples include:

(1) where it is desired to provide an alternative basis for claiming the product,

(2) where it is difficult to define a product other than by the process by which it is made,

(3) where the process is believed to impart novel aspects to the product, and

(4) where there is uncertainty as to whether ingredients that are combined to make a product remain present in the product (e.g., where a chemical reaction may change the ingredients when they are combined).

Thus, we recommend continuing to include product-by-process claims in patent applications, with an understanding that (1) unless *Abbott* is overruled by the Supreme Court, product-by-process claims will only be infringed by products made by the recited process, and (2) the Patent Office will likely continue to examine product-by-process claims under its current practice.

When evaluating a competitor's patent claims for infringement issues, we recommend literally construing any product-by-process claims to be limited by the process terms therein unless *Abbott* is overruled by the Supreme Court. However, a doctrine of equivalents analysis should still be applied as to each product and process limitation in the claims.

* * * * *

Oliff & Berridge, PLC is a full-service Intellectual Property law firm based in historic Alexandria, Virginia. The firm specializes in patent, copyright, trademark, and antitrust law and litigation, and represents a large and diverse group of domestic and international clients, including businesses ranging from large multinational corporations to small privately owned companies, major universities, and individual entrepreneurs.

For further information, please contact us by telephone at (703) 836-6400, facsimile at (703) 836-2787, email at email@oliff.com or mail at 277 South Washington Street, Suite 500, Alexandria, Virginia 22314. Information about our firm can also be found on our web site, www.oliff.com.

スペシャル･レポートの日本語版は、英語版の発行後、二週間以内にウエッブ･サイトでご覧いただけます。

[7] 535 U.S. 722 (2002).
[8] 550 U.S. 398 (2007).