# Infringement Of Product-By-Process Claims In US Clarified

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*Abbott Labs. v Sandoz, Inc.*, No. 2007-1400, and *Lupin Ltd v Abbott Labs.*, No. 2007-1446, US Court of Appeals for the Federal Circuit, 566 F.3d 1282, 18 May 2009 (en banc).

**A product must be made by claimed process to infringe a product-by-process claim.**

**Legal context**

US patent law has long allowed a patentee to claim an invention in which a product is made by a particular process in the format of a so-called 'product-by-process' claim: see eg, *Ex parte Painter*, 1891 C.D. 200, 200–201 (Comm'r Pat. 1891). Precedent from the US Court of Appeals for the Federal Circuit was arguably in conflict as to whether an accused product must be made by the claimed process in order to be found to literally infringe the claim. In *Scripps Clinic & Research Foundation v Genentech, Inc.,* 927 F.2d 1565, 1583 (Fed. Cir. 1991), the panel found that 'the correct reading of productby-process claims is that they are not limited to product prepared by the process set forth in the claims'. However, in the following year, a different panel in *Atlantic Thermoplastics Co. v Faytex Corp.*, 970 F.2d 834, 846-47 (Fed. Cir. 1992), found that 'process terms in product-by-process claims serve as limitations in determining infringement'. The full Court sua sponte took the issue as to whether process limitations incorporated into product-by-process claims serve as limitations in determining infringement in the pair of appeals brought involving Abbott Labs. US Patent No. 4,935,507 ('the '507 patent'): see *Abbott Labs. v Sandoz, Inc.*, No. 2007-1400 & *Lupin Ltd v Abbott Labs.*, No. 2007-1446, 566 F.3d 1282 (Fed. Cir. 18 May 2009) (en banc). It is only this issue that the present summary addresses.

**Facts**

Abbott Labs., the exclusive licensee of the '507 patent, made and sold crystalline cefdinir made in accordance with the '507 patent under the trade name Omnicef. That patent was owned by Astellas Pharma Inc.

Two separate patent infringement actions were brought relating to efforts by other pharmaceutical companies to offer generic versions of Omnicef.

In one action, Lupin brought an action in the Eastern District of Virginia for declaratory

relief of non-infringement regarding its generic version of Omnicef, which is made almost exclusively of a different crystalline form of cefdinir to Abbott's and which is also made by processes other than those claimed in the '507 patent. The Virginia court, having construed the claims (see *Lupin Ltd v Abbott Labs.*, 484 F. Supp. 2d 448 (E.D. Va. 2007)), ultimately granted Lupin's motion for summary judgment of non-infringement, as to both literal infringement and under the doctrine of equivalents for claims 2–5 and under the doctrine of equivalents under claim 1: *Lupin Ltd v Abbott Labs.*, 491 F. Supp. 2d 563 (E.D. Va. 2007).

Abbott brought a separate action in Illinois against other groups of competitors who also sought to market their own generic versions of Omnicef: Sandoz, Inc., Sandoz GmbH, Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries, Ltd, Ranbaxy Laboratories, Ltd, Ranbaxy, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical (collectively, 'Sandoz and Teva'). In the Illinois action, Abbott sought a preliminary injunction against Sandoz and Teva. Although the parties agreed to adopt the Virginia court's claim constructions for purposes of the preliminary injunction motion, further disputes as to the meaning of those claim constructions arose, and were resolved by the Illinois court (*Abbott Labs. v Sandoz, Inc.,* 486 F. Supp. 2d 767 (N.D. Ill. 2007)). Ultimately, the Illinois court denied Abbott's motion for a preliminary injunction.

The Federal Circuit heard both cases together on appeal, and issued a joint decision deciding them together. Before the panel decision was issued, the full court sua sponte took the issue of how to interpret product-by-process claims for the purpose of determining infringement, in an effort to resolve the prior conflicting panel opinions in *Scripps Clinic* and *Atlantic Thermoplastics*.

**Analysis**

Although the Federal Circuit addressed various issues raised on the appeal, the focus of the present discussion is on the en banc analysis of how product-by-process claims should be interpreted for purposes of an infringement analysis.

In section III.A.2 of the opinion, the full court addressed the proper interpretation of product-by-process claims in determining infringement. This portion of the panel's decision was joined in by Chief Judge Michel and Judges Rader, Bryson, Gajarsa, Linn, Dyk, Prost, and Moore. Judges Newman and Lourie dissented in separate opinions. Judges Mayer and Lourie joined in Judge Newman's dissent. Judge Schall did not participate as a member of the en banc court. The panel itself included Judge Rader, the author of the panel's decision and the majority en banc opinion, and Judge Plager and Bryson, who joined in the decision in its entirety.

The court, citing *Ex Parte Painter*, above, noted it was not necessary to resolve the question of whether product-byprocess claims are a legitimate form of claim, since that issue has been long resolved. Instead, the court focused its inquiry narrowly on whether such a claim is infringed by products made by processes other than the one claimed, holding that it was not.

To support this holding, the court relied upon various decisions of the US Supreme Court, its predecessor courts, and sister circuits, as well as its own earlier panel decisions.

The court recognized that the historical logic for granting such claims was to allow an inventor to claim a product that cannot be described in any manner other than how it is manufactured. With this logic in mind, the court further expressed its 'own simple logic' for holding that product-by-process claims should be limited to the product made by the process as claimed:

This court's rule regarding the proper treatment of product-by-process claims in infringement litigation carries its own simple logic. Assume a hypothetical chemical compound defined by process terms. The inventor declines to state any structures or characteristics of this compound. The inventor of this compound obtains a productby-process claim: "Compound X, obtained by process Y." Enforcing this claim without reference to its defining terms would mean that an alleged infringer who produces compound X by process Z is still liable for infringement. But how would the courts ascertain that the alleged infringer's compound is really the same as the patented compound? After all, the patent holder has just informed the public and claimed the new product solely in terms of a single process. Furthermore, what analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes? If the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed. Why also would the courts deny others the right to freely practice process Z that may produce a better product in a better way? (566 F.3d at 1294).

In sum, the majority found 'it is both unnecessary and logically unsound to create a rule that the process limitations of a product-by-process claim should not be enforced in some exceptional instance when the structure of the claimed product is unknown and the product can be defined only by reference to a process by which it can be made. Such a rule would expand the protection of the patent beyond the subject matter that the inventor has "particularly point[ed] out and distinctly claim[ed]" as his invention, 35 U.S.C. 112 ¶ 6 (Id. at 1294-95)'.

Thus, the panel affirmed the grant of summary judgment of non-infringement and denial of the preliminary injunction since the allegedly infringing products were not made by the processes claimed.

Judge Newman, in a dissent joined by Judges Mayer and Lourie, argued that the Court overturned 'a century of precedent and practice (Id. at 1299)'. Her dissent objected to the Court's adoption of a 'simplistic universal rule' which fails to distinguish between 'whether the product is new or was known', 'whether the product could have been fully described by its structure at the time of the patent application', or 'whether the particular invention is a new product or is actually a process (Id. at 1300)'.

In particular, Judge Newman's dissent took issue with both the procedure used by the Court to reach this en banc ruling and with the ruling itself.

With respect to the procedure used, she objected that the Court provided no opportunity for the parties or amici to brief or argue the issue to the full Court before reaching its decision: in her view, this procedure was contrary to the Federal Rules of Appellate Procedure and good sense.

On the merits, this dissent points to the historical practice that inventors were entitled 'to a patent on a new article of manufacture, ... claimed by reference to the process of producing it, when the inventor lacks other language to "define and discriminate" the invention (Id. at 1303)'. This practice was distinguished from the case where the product could be defined structurally.

Most of the support relied upon by Judge Newman's dissent came from decisions of the Federal Circuits' predecessor court, the Court of Customs and Patent Appeals. The majority discounted this authority on the ground that its predecessor court did not hear infringement disputes and was not therefore provided with the opportunity to address the issue at hand.

Judge Newman took issue with this characterization too. Judge Newman's dissent responds to the panel's 'own simple logic' for its ruling with the following retort:

I do agree with my colleagues that their logic is "simple." Maj. op. at 1294. However, today's inventions are not simple. The needs of inventions of the past and present, and more so the future, are not simple. The public interest in invention and development of today's complex sciences, is not simple. The en banc court's "simple" hypothetical about "compound X, obtained by process Y," is simply irrelevant to the issues we must resolve. Scientists know that it is often easier to show that two products are the same, than to decipher their chemical or biological structure; for example, in the case at bar, comparing the X-ray diffraction patterns and absorption spectra could show that the products are the same, although their exact crystal structure is undefined. However, my colleagues announce that the only way to establish whether the accused compound is the same as the patented compound is by inquiring whether they were prepared by the same method. Maj. op. at 1293–94 ("[W]hat analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes?"). That question has many answers, now stated to be irrelevant. (566 F.3d at 1318).

Judge Lourie in his dissent advocated two different rules for product-by-process claims. When such a claim is directed to an 'old' product, the claim should be limited to the products made by the claimed processes. However, when the claim is directed to a 'new' product, which is claimed by how it is prepared, Judge Lourie advocated a broader rule to cover the product itself. Judge Lourie's dissent 'would make a distinction between old products and new products in interpreting product-by-process claims' (Id. at 1320-21).

**Practical significance**

In Abbott, the Federal Circuit provides a simple and clear rule on interpreting product-by-process claims: a product must be made by the claimed process in order to infringe

literally. The court's new universal rule, while simple and clear, and thus easy to apply, may, at least according to the dissent, fail to give some inventors the full scope of patent protection of which their inventions may be deserving. When a new product (such as a chemical composition) is developed and not capable of a description solely in terms of its structure and characteristics other than by the process by which it is made, at the time a patent application is prepared and filed, the majority's simple and clear rule will provide for only a narrow range of protection. This clarified rule will do doubt give many pharmaceutical patents, like the patent at issue in Abbott, a narrower scope than their patentees may have originally intended or thought would be provided.

Although the court's decision provides some clarity as to when a product-by-process claim may be infringed, it unfortunately does not address the question of whether a product-by-process claim can be anticipated when the claimed product is made by a different process. Further, while one would presume that since a patent claim should be construed the same for purposes of validity and infringement, as Judge Newman notes, the court's ruling should apply for validity analyses too, this discussion was notably absent in the majority opinion, and appears to be part of the cause of the conflict that gave rise to this issue in the first place.

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