

# Abbott Labs v. Sandoz: The Federal Circuit Provides Clarity On Product-By-Process Claims

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Drafting a patent claim to a new composition of matter requires translating the characteristics of the product into the written word. This is recognized as a challenging task, as even the United States Supreme Court has noted that the specification and claims of a patent “constitute one of the most difficult legal instruments to draw with accuracy.” (*Topliff v. Topliff*, 145 U.S. 156, 171 (1892)). Drafting patent claims is especially difficult when the new composition is of a complex nature that cannot be adequately analyzed or quantified. U.S. Patent Laws have addressed this conundrum by allowing a product to be described in a patent claim by the implied characteristics of its process of preparation in “product-by-process” claims. For example, a product-by-process claim encompassing product X could be: “Product X prepared by a process comprising the steps of: (1) preparing an aqueous solution of ingredients A, B, and C; (2) drying the aqueous solution; and (3) mixing the composition of step (2) with ingredient D.” During examination of product-by-process claims for patentability, the product which is the subject of the claim is not limited to the particular recited process steps, but rather to the characteristics implied by the steps. Accordingly, a prior art product that shows the same characteristics as the product-by-process claim would bar patentability, even if the process for preparing the prior art product is different. If patentability is not limited to the process steps, but rather to the product itself, it seems logical that a potential infringing product with the same characteristics, albeit prepared by a different process, would infringe the product-by-process claims.

The Federal Circuit, however, disagrees with this proposition. The Federal Circuit recently resolved years of inconsistent case law regarding product-by-process claim infringement analysis, addressing the question of whether a product-by-process claim is infringed by an identical product that was made by a process other than the process set forth in the claim. In *Abbott Labs v. Sandoz*, 566 F.3d 1282, (Fed. Cir. 2009), the Federal Circuit decided *en banc* that the answer to this question is no, holding that the process steps of a product-by-process claim serve as limitations in determining infringement.

## Background Of The Case

Abbott Laboratories markets the pre-

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scription antibiotic cefdinir under the trade name Omnicef®. The FDA approved Omnicef in 1997 and U.S. Patent No. 4,935,507 (“the ‘507 patent”) was listed in the Orange Book (*Approved Drug Products with Therapeutic Equivalence Evaluations*, published by the FDA's Center for Drug Evaluation and Research) as covering the product.

*Abbott Labs* arose from two district court cases, which were combined on appeal to the Federal Circuit. In one case, the district court for the Eastern District of Virginia granted summary judgment of noninfringement to Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively “Lupin”). The FDA had previously approved Lupin's Abbreviated New Drug Application (“ANDA”) to market a generic version of Omnicef. In the other case, the district court for the Northern District of Illinois denied Abbott's motion for a preliminary injunction based on the claim construction of the Eastern District of Virginia court. Abbott brought suit against several defendants including Sandoz and Teva, alleging infringement of the ‘507 patent. Like Lupin, these defendants had previously filed ANDAs, also seeking to market generic versions of Omnicef. Claims 2-5 of the ‘507 patent were categorized by the Eastern District of Virginia as product-by-process claims, as they initially recited a product, crystalline cefdinir, and then recited a series of steps by which the product is “obtainable.” On appeal, Abbott asserted that the district court erred in construing the process steps of claims 2-5 as limitations in determining infringement, arguing that the accused infringing products need not be made by the process steps in order for infringement to be found.

## Inconsistent Case Law Finally Resolved

*Abbott Labs* resolved an 18-year-old inconsistency in Federal Circuit jurisprudence regarding how to analyze infringement of product-by-process claims. In 1991, 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.” *Scrrips Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991). In other words, *Scrrips Clinic* held that although a claim may recite a product in terms of a



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process that produces it, identical products produced in other ways will still infringe such a claim. A year later, however, the Federal Circuit concluded that, “process terms in product-by-process claims serve as limitations in determining infringement.” *Atlantic Thermoplastics v. Faytex Corporation*, 970 F.2d 834, 846 (Fed. Cir. 1992). The *Atlantic Thermoplastics* court, aware of the inconsistency with *Scrrips Clinic*, stated in a footnote that the *Scrrips Clinic* ruling had been made “without reference to the Supreme Court's previous cases involving product claims with process limitations.” The court further stated that “a decision that fails to consider Supreme Court precedent does not control if the court determines that the prior panel would have reached a different conclusion if it had considered controlling precedent” and accordingly concluded that *Scrrips Clinic* did not control its disposition of the instant case.

The Federal Circuit's attempt to undermine the precedential strength of *Scrrips Clinic* with a simple footnote left inconsistent case law on the books. Some 15 years later, when Abbott sought to enforce its ‘507 patent against alleged infringers, *Scrrips Clinic* provided Abbott with a position for alleging that the generic products of Lupin and others infringed the ‘507 patent regardless of the way such products were manufactured, and thus gave rise to the need for an opinion to clarify the final rule once and for all.

In *Abbott Labs*, the court engaged in a lengthy review of product-by-process jurisprudence, citing Supreme Court cases dating back as far as 1874. The court ultimately concluded that

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.

*Abbott Labs* at 1294. Relying on Supreme Court precedent, the treatment of product-by-process claims throughout the years by the United States Patent and Trademark Office, and other binding court decisions, the Federal Circuit restated the *Atlantic Thermoplastics* rule that “process terms in product-by-process claims serve as limitations in determining infringement” and overruled the *Scrrips Clinic* decision. *Abbott Labs* at 1293, citing *Atlantic Thermoplastics* at 846-47.

The court's opinion with regard to the rule governing product-by-process infringement analysis was decided *en banc* and was accompanied by a strong dissenting opinion by Judge Newman (who also wrote the overturned *Scrrips Clinic* opinion), joined by Judges Mayer and Lourie. Judge Lourie also provided a short dissent. Judge Newman's dissent echos with concern for technological advances that are incapable of being described in any way other than the process by which they are made, characterizing the majority's decision as “a new restraint on patents for new products, particularly today's complex chemical and biological products whose structure may be difficult to analyze with precision.” *Abbott Labs* at 1300 (Newman, J. dissenting from *en banc* Section III.A.2). Judge Newman appears to be deeply concerned with having a single universal rule for determining whether a product-by-process claim has been infringed, recognizing that while product-by-process claims may not be ideal, sometimes they are simply the only way to claim an innovation in complex fields of science. A rule that hinders the strength of a product-by-process claim, she cautions, has “unknown consequences for patent-based innovation.” *Id.*

## Implications

The *Abbott Labs* decision follows a string of recent court decisions that arguably resulted in an erosion of innovators' patent rights (e.g., *KSR v. Teleflex*, 550 U.S. 398 (2007) directed to the standard of obviousness; *eBay v. MercExchange*, 547 U.S. 388 (2006) directed to injunctive relief). This decision has the potential to be especially problematic for biological products that have a history of being difficult to analyze and quantify. Without the incentives of a strong patent system, there could be decreased investment in biotechnology and other complex arts, which would ultimately stifle innovation and negatively impact the public. While it is important that a granted patent adequately identify the metes and bounds of an invention and place the public on notice as to what constitutes an infringing product, this requirement must be balanced against an innovator's interest in obtaining meaningful patent coverage. As further discussed in Judge Newman's dissent, the majority did not appear to weigh these considerations in reaching their conclusion. The ultimate result of *Abbott Labs* is that product-by-process claims are no more than disguised process claims, leaving innovators of complex materials with one less arrow in their quiver in their quest to obtain adequate patent coverage.

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