

On May 18, 2009, the Federal Circuit's decision in *Abbott Labs v. Sandoz* finally resolved a long-standing debate as to whether the process steps in a product-by-process claim must be performed in order for infringement to occur. By holding that process terms in product-by-process claims serve as limitations in determining infringement, the Federal Circuit has defined the scope of a product-by-process claim to exclude a product made by a different process.

A product-by-process claim permits a patent applicant to claim a product that is at least partially defined by the process of its manufacture, for example, "Product A produced by reaction of B and C." The issue faced by district courts was whether infringement occurs when Product A is produced *regardless* of the process used (e.g., Product A produced by reaction of D and E), or whether Product A must be produced by the claimed reaction of B and C in order for infringement to occur.

In 1991, a Federal Circuit panel in *Scripps Clinic v. Genentech* held that a product-by-process claim may be infringed by the product alone, even if made by a different process. A year later in *Atlantic Thermoplastics v. Faytex*, however, a different panel came to an overtly contrary conclusion, holding that all of the process steps of a product-by-process claim must be performed in order for a product to infringe the claim. Thus, courts have been split as to whether the process steps in a product-by-process claim must be performed in order for infringement to occur.

This week, the Federal Circuit decided two cases together on appeal from district court decisions involving Abbott's assertion of U.S. Pat. No. 4,935,507 (the '507 Patent) against various alleged infringers. Certain claims of the '507 Patent were directed to a product (crystalline cefdinir) and recited a series of steps by which this product is "obtainable." The Court agreed with the district court that such claims were correctly categorized as product-by-process claims and addressed *en banc* the part of the opinion pertaining to the proper interpretation of product-by-process claims in determining infringement.

In its decision, the Court affirmed the rule set forth in *Atlantic Thermoplastics* that "process terms in product-by-process claims serve as limitations in determining infringement." The Court found this rule was consistent with Supreme Court precedent and was reinforced by the Supreme Court's statement in *Warner-Jenkinson* of the broad principle that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." To the extent that the *Scripps* decision was inconsistent with this rule, the Federal Circuit expressly overruled *Scripps*.

Judge Newman's dissent argued that the Court's decision overturned a century of precedent that allowed patentees to protect a new product whose structure was not fully known or readily described, by merely including sufficient reference to how it can be made. The majority opinion, however, found it "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 where 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 scope of protection afforded by a patent beyond the subject matter that the inventor has "particularly point[ed] out and distinctly claim[ed]" as his invention. The Court also questioned how a court would ascertain whether an alleged infringer's product is really the same as the patented product, if the patented product is described by the way it is made.

The holding has broad implications for products formerly defined by method of making steps. As a result of this decision, an applicant seeking broad patent protection for a product should be wary of including process limitations in any claim directed to the product. Also, literal infringement of a product-by-process claim can now be avoided with more certainty by using a process different from that recited by the claim.