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LEGAL ALERT

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Federal Circuit Clarifies Limited Scope of Product-by-Process Claims

In a divided en banc decision on May 18, 2009, the Federal Circuit held that infringement of a product-by-process claim requires the accused to have practiced the "process terms" of the claim. The decision, *Abbott Laboratories v. Sandoz, Inc.*, resolves the longstanding ambiguity resulting from two conflicting lines of cases.

In *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), the Federal Circuit previously held that "process terms in product-by-process claims serve as limitations in determining infringement." In *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991), however, Judge Newman writing for the Federal Circuit had held that product-by-process claims were not limited to products prepared by the process set forth in the claims. In *Abbott Labs*, the Federal Circuit expressly overruled the *Scripps* decision and established the test from *Atlantic Thermoplastics* as controlling precedent.

Product-by-process claims define a product, at least in part, in terms of the process used to make the product. Product-by-process claims are predominately used in the pharmaceutical, chemical and biotech fields, particularly in cases where it is difficult to characterize a complex chemical or biological structure or where the product resulting from the process is unknown to the inventor.

In *Abbott Labs*, the claims at issue recited a crystalline "which is obtainable by" performing specific process steps. Although the term "obtainable by" appears to indicate that the claimed product may also be made by other non-recited processes, the court construed the term to mean the same as the more traditional product-by-process term "obtained by." In doing so, the court held that the claim was limited to products made by the recited process. The court reasoned that since the inventor only teaches, in the specification of such a patent, the method for making the compound, it would be an unreasonable expansion of patent rights to permit the inventor to exclude the public from using other methods to make the same product.

The en banc decision addresses the construction of product-by-process claims only in the context of infringement. For purposes of assessing the patentability or validity of product-by-process claims, it is uncertain as to whether the *Abbott Labs* decision opens the door to claiming known products by new methods in a product-by-process claim. The current practice of the U.S. Patent and Trademark Office, however, is to reject claims as being anticipated or obvious where the prior art discloses a product that reasonably appears to be either identical with or only slightly different from a product claimed in a product-by-process claim.

It is significant that the court acted *sua sponte* in rendering its decision en banc as to the scope of product-by-process claims. Judge Newman, writing the dissent for the divided court, argued that the court violated the Federal Rules of Appellate Procedure and the Federal Circuit's Internal Operating Procedures by failing to provide proper notice of the impending en banc action. As a result, the Federal Circuit rendered its opinion without being briefed or without hearing oral arguments on the issue. The dissent further argued that the majority's decision marked a change in "law and practice with roots in century-old decisions."

This case makes it clear that practitioners should seek to claim new products and methods of making the products separately where possible. In cases where the precise structure of a composition is yet

unknown, practitioners should consider alternatives to characterizing the composition simply by the process of making it. Inventors and practitioners should diligently attempt to identify and define distinguishing structures or functions of the resulting new composition by any available analytical techniques. Provisional patent filing practice may be a useful strategy for first filing an application on the new process, followed within the one-year period by additional provisional applications containing supporting data to characterize the composition. Furthermore, this case makes it clear that any terms used in a product claim that refer to a process for making the product are likely to be construed as limiting in any subsequent infringement litigation.

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If you have any questions regarding this Legal Alert, please feel free to contact any of the attorneys listed below or the Sutherland attorney with whom you regularly work.

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