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Court Ruling Limits Patent Protection For Complex Products

The nation's top patent court recently issued a decision that limits patent protection for complex products whose structures cannot be described. Drug formulations, biological molecules, cells and organisms are examples of types of inventions that are affected. In the new decision, the U.S. Court of Appeals for the Federal Circuit resolved a conflict dating from the early 1990s in the interpretation of patent claims for such complex products. The practical effect of the decision is to limit patent protection for complex products. The decision affects existing patent claims and may encourage inventors to delay disclosure of new, complex inventions until they determine sufficient structural characteristics.

The decision, *Abbott Laboratories v. Sandoz*, involved a particular type of patent claim, referred to as a product-by-process claim, that is used to protect newly invented products that the inventor cannot adequately describe by the product's structure. Chemical compositions and biological molecules used for medical treatment often fall into this category. For example, a new formulation of a drug produced by a new process may have better properties than old formulations. The new formulation is clearly different from old formulations, but the inventor may not be able to determine the structural differences. What the inventor does know is a process to make the new formulation. In such cases, patent law has long allowed inventors to protect the new formulation by claiming the formulation in terms of the method of making it.

The use of product-by-process claims has been justified by the recognition that not all new products can be fully described by their structure, due to the state of scientific knowledge or available analytical techniques. It was also justified by the recognition that new products could be distinguished from old products by reference to how the new product was made. The question in *Abbott* was how product-by-process claims should be interpreted when deciding if a product infringes a product-by-process claim. In numerous older cases, courts had considered that if the product, regardless of how it was made, was the same as the product made by the method in a product-by-process claim, then the product infringed the patent claim. This rationale serves the purposes justifying product-by-process claims. The U.S. Patent & Trademark Office has also applied this standard in examining product-by-process claims.

In 1992, a panel of the Federal Circuit created a conflict with this practice in the case of *Atlantic Thermoplastics v. Faytex Corp.* (970 F.2d 834 (Fed. Cir. 1992)). In this case, the court held that patent protection for product-by-process claims should be limited to only those products actually made by the process in the product-by-process claim. Because the decision in *Atlantic Thermoplastics* conflicted with earlier decisions (most notably, *Scripps Clinic & Research Foundation v. Genentech*, 927 F.2d 1565 (Fed. Cir. 1991), the impact of its decision was muted.

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In the *Abbott* decision, the Federal Circuit sitting en banc has now resolved this conflict in the interpretation of product-by-process claims. The court established that a product-by-process claim protects only products actually made by the method in the claim, rather than all products that are the same as the product made by the method. Judge Newman—a trained chemist who worked in the pharmaceutical industry before becoming a judge—issued a lengthy dissent supporting the traditional interpretation of product-by-process claims. Although the decision and the dissent discuss prior cases and disagree on what those prior cases held, the most significant disagreement comes in an area that the decision and the dissent do explicitly discuss. The decision argues that, because product-by-process claims include process steps, and because all limitations of a claim must be enforced, only products made by the process in the product-by-process claim are covered by the claim. The dissent focuses on interpretation of product-by-process claims as, fundamentally, claims to a product. The dissent notes that a product-by-process claim is intended to use the process steps merely to define the product, not as a limitation to how the product can be made. Both points of view make logical sense, so the decision is ultimately based on a policy choice. The policy choice made in the *Abbott* decision is to limit the protection provided by product-by-process claims, and thus to limit the patent protection available for some complex products that can only be adequately defined by the process by which they are made.

Although it is certainly true today that there are many analytical tools that can be used to describe complex inventions, it is also true today that many inventions are more complex than earlier inventions. The usefulness of product-by-process claims to protect such inventions is diminished by the *Abbott* decision. There is also another danger with the *Abbott* decision. The logic and the principles of the decision may be applied to claims other than classic product-by-process claims with the result that many more claims will lose scope and value.

The *Abbott* decision can be found at <http://www.cafc.uscourts.gov/opinions/07-1400.pdf>.

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