CAFC Split on Product-by-Process Claims Finally Resolved

By:Lisa M. Warren
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A product-by-process claim in a patent specifies a product with reference to the method by which the product is made (e.g., product X produced by, obtained by, made by, obtainable by, etc., process Y). Historically, the use of product-by-process claims was reserved for circumstances in which the product could not be defined or distinguished from the prior art except by reference to the process by which the product was made. Inherent in this format was the presumption that the process by which the product was made imparted distinctive characteristics to the product. However, today product-by-process claims are commonplace even where the process imparts no distinctive characteristics to the product in comparison with prior art products.

The U.S. Patent & Trademark Office (PTO) analyzes patentability of a product-by-process claim based on the product itself, without deference to its method of production. That is, if the product in the product-by-process claim is the same as or obvious from a prior art product, the claim is unpatentable even though the prior art product was made by a different process.

Interestingly, the law with regard to infringement of product-by-process claims has been less clear. Different panels of the Court of Appeals for the Federal Circuit have set out differing opinions on the question of whether process limitations of product-by-process claims are limiting. One panel held that product-by-process claims cover any product that is the same as the product produced by the recited process steps (i.e., that the claim is not limited by the recited process steps). This panel reasoned that product-by-process claims must be considered the same way for both validity (or patentability) and infringement; that is, the claims may not be construed one way in order to obtain their allowance and in a contrary way with regard to infringement. A different, subsequent panel held that product-by-process claims cover only those products that are, in fact, produced by the recited process steps.

Since 1992 this split at the Federal Circuit has made it difficult to determine the scope of product-by-process claims and to assess whether a product made by a different process infringed such claims. Happily, the Federal Circuit has finally reviewed this question en banc and brought clarity to the picture.

In *Abbott Labs v. Sandoz* (Fed. Cir. 2009), the Court of Appeals for the Federal Circuit, sitting *en banc*, chose to follow the line of cases holding that infringement of a product-by-process claim requires practicing the claimed process steps. Thus, one may produce the claimed product using a different method and avoid infringing a product-by-process claim.

This decision results in an interesting dichotomy: in order to be patentable in the eyes of the PTO, a product-by-process claim must define a novel and unobvious product without reference to the process by which it is made. However, such a claim will not be construed to cover all such products when the patent is enforced; rather the claim will only cover a product produced by the recited process. Accordingly, patent applicants are well advised to include claims to the novel and unobvious product *per se*, perhaps including unique properties conferred by the process of

making it but without reference to the process itself, in order to preserve the broadest claim scope.

For more information, contact **Lisa M. Warren**.