Evaluating the Limited Applicability of Product-By-Process Claims in the U.S.

The Federal Circuit’s decision last year in *Abbott Labs. v. Sandoz, Inc.*[^1], clarified conflicting precedent regarding product-by-process claims. The court held that infringement of a product-by-process claim requires showing that an equivalent process was used in making the alleged infringer’s product. In light of this decision, it would be prudent for patent applicants to carefully evaluate their inventions to determine if their inventions implicate the specialized circumstances in which the product-by-process claim format is useful. If their inventions warrant this format, applicants should consider the impact such claims may have during the different stages of patent procurement and patent enforcement.

A typical product or apparatus claim recites a product in terms of its structural composition and/or function, while a typical process or method claim recites a process in terms of the steps necessary to perform it. As implied by its name, a product-by-process claim is a hybrid of typical product and process claims that recites a product in terms of the process in which it is produced. Product-by-process claims are only proper when the inventive product cannot be recited in terms of its structure but can only be recited in terms of the process used to create it. Such circumstances are generally rare. They usually arise in very complex chemical or biotech arts where a structure may be invented but include a composition that is unidentifiable, at least given the confines of current technology.

The USPTO evaluates product-by-process claims for patentability differently than typical product claims and process claims. In contrast, courts evaluate product-by-process claims for validity and infringement similar to typical product claims and process claims, and thus in a different manner than the USPTO. These differences between evaluation of product-by-process in prosecution and after issuance give rise to a number of issues that patent applicants should be cognizant of during prosecution.

As discussed in the Manual of Patent Examining Procedure §§ 2113 and 2173.05(p), and as confirmed by the Federal Circuit in *Abbott*, product-by-process claims are examined only with regard to the product they recite. In other words, for a product-by-process claim to be rejected for substantive reasons, the prior art need only disclose the claimed product, regardless of the process used to create the prior art product, except to the extent that any portion of the recited process includes structural product limitations, which are considered for patentability. For example, a product-by-process claim reciting “Product X, produced by Step 1, Step 2, and Step 3,” would be examined by the USPTO only on the basis of the existence of Product X in the prior art and of any structural product limitations recited in any of Steps 1, 2, and 3. The USPTO’s determination of a product-by-process claim’s patentability helps ensure that patents do not issue covering known products, thereby depriving the public of the right to make and use recognized goods.
As decided in Abbott, courts must consider both the product itself and the recited process steps when assessing validity and infringement of product-by-process claims. Thus, a potentially-infringing product will only infringe a product-by-process claim if the potentially-infringing product is the same as the claimed product and is produced in the same manner as required by the claim. Such an evaluation clearly differs from the USPTO’s patentability evaluation of product-by-process claims.

The differing standards for pre-issuance and post-issuance evaluation of product-by-process claims create greater unpredictability in enforcement of product-by-process claims. Judge Newman’s dissent in Abbott discusses this dichotomy, emphasizing its unacceptability yet apparent endorsement by the majority. At least while this apparent tension exists between examination at the USPTO and adjudication in the courts, it may be prudent for patent applicants to carefully evaluate their inventions to ensure that they present claims in product-by-process form only when required.

As mentioned above, product-by-process claims are very limited in their applicability to an invention. Patent applicants should keep this narrow applicability in mind and carefully consider whether their product inventions can only be defined in terms of their production, in which case product-by-process claims may be desirable, or if their product inventions can be more traditionally claimed in terms of structure.

If product-by-process claims are pursued, patent applicants should also take care in presenting process steps in the claim even if the process steps are not commented on during prosecution because the process steps will become important during any post-issuance evaluation of the claim. Furthermore, any comments regarding the process steps that are made by the applicant during prosecution may give rise to estoppel, just as can occur with any other claim type.

Patent applicants should also consider performing a pre-issuance patentability search on at least the process steps recited in product-by-process claims because these recitations will not be independently searched and examined by the USPTO. Such a search may help limit any surprises during any post-issuance litigation in which process steps not particularly evaluated for patentability during patent prosecution will now be subject to interpretation and increased consideration.


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