IP Alert: Is a Product-by-Process Limitation a Fig Leaf?

Is a Product-by-Process Limitation a Fig Leaf?

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Patent applicants may claim their product inventions using product-by-process recitations. These can be useful when one has no analysis at hand that permits describing a product with sufficient physical attributes. Yet, for patentability, the physical attributes must be such that the product is novel and non-obvious over the prior art. Thus, an applicant guesses that the product is different but does not yet know how to describe it or compare it to the prior art.

When confronted with prior art during examination or in a post-issuance challenge, one must be able to successfully distinguish the product. Moreover, the distinction must be made without regard to the process by which the product is made. Thus, the use of a product-by-process claim permits a

patent applicant to file earlier, but ultimately the patent applicant must do the analytic work necessary to distinguish over prior art.

The downside to a product-by-process claim is that it will have a narrower scope of protection to stop infringers. It will only encompass products that are actually made by the recited process. Thus, it must be patentable over a broader range of subject matter than the protection it provides.

The indirect description of a product-by-process claim may collide with an assertion of inherent anticipation, in which case both items will need to be analyzed and compared. Such a collision is at issue in a pending appeal to the Federal Circuit from a decision in an inter partes review (IPR) at the Patent Trial and Appeal Board (PTAB). The parties presented their oral arguments to the court on November 7, 2017, in United Therapeutics Corp. v. SteadyMed LTD (Case No. 17-2121).

All of United Therapeutics' challenged claims in U.S. Patent 8,497,393 are product-by-process claims. The process involved both synthesizing a compound (step (a): "alkylating a compound of structure II with an alkylating agent….") and purifying it (steps (b)-(d): "hydrolyzying, …contacting… with a base B to form a salt, …reacting the salt with an acid…."). United Therapeutics aimed to distinguish its claims over the prior art by asserting a higher average level of purity. But it was foiled in its attempt by the PTAB's construction of claim 1. Claim 1 reads:

> A product comprising a compound of formula I or a pharmaceutically acceptable salt thereof, wherein said product is prepared by a process comprising….

By construing the claim terms "product" and "comprising" according to their usual and customary meanings, the PTAB rendered United Therapeutics' purity distinction untenable. The open-ended term "comprising" permits other components in the product. Thus, even if United Therapeutics successfully showed that the recited process yielded a higher purity compound than the prior art, it would not distinguish claim 1 over the prior art because the product recited in the claim was open to, e.g., contaminants.

United Therapeutics did not appeal claim 1, but did appeal a selected set of claims dependent on claim 1. United Therapeutics challenges the PTAB's construction of claim 1 (as it is incorporated into the appealed dependent claims), seeking a construction that includes impurity profiles as part of the meaning of "product."

Claim 2 recites that "the purity of compound of formula I in said product is at least 99.5%." This claim potentially avoids the open-ended "comprising," but the PTAB found this claim to be inherently anticipated by the cited Phares reference. On appeal, United Therapeutics challenges the legal and factual basis for the PTAB's conclusion of inherent anticipation of claim 2. United Therapeutics urges that the case law supporting the PTAB's conclusion actually pertained to

obviousness rather than anticipation. Applying obviousness case law, United Therapeutics asserted, inappropriately shifted the burden of proof to United Therapeutics. Proper inherent anticipation case law requires that the prior art necessarily demonstrate the recited property, not as a matter of possibilities and probabilities. United Therapeutics explained that the scientific evidence relied on by the PTAB to infer purity of Phares' product was highly variable, and thus the Phares' product did not necessarily have the recited purity level.

Both a product-by-process claim and inherent anticipation create definitional and evidentiary issues for a patentee. A patent applicant cannot always avoid an assertion of inherent anticipation, but it can avoid product-by-process claims. If a patent applicant wants to take advantage of the early filing benefit of a product-by-process claim when analysis of the product is still unavailable, it may be prudent to follow up its initial filing with a second filing when product analysis is available. A second filing may be, e.g., a second provisional application or a continuation-in-part application. At that time, it may replace or augment its product-by-process claims with straight product claims. These should reduce the evidentiary showings that may be required later in a contested setting.

A product-by-process claim may seem like a boon when trying to file early, but it may obscure a future problem.

Click here to listen to the arguments in United Therapeutics Corp. v. SteadyMed LTD.

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