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### **Understanding Product by Process Claims**

# Introduction:

Claims of a patent specification are interpreted to define the scope of protection granted to an invention, and hence immense care is exercised while drafting claims. There are various types of claims that can be drafted to protect an invention, and one such type of claim is a "product-by-process" claim. Generally a product claim is used for protecting a product. However, in some cases one may find it difficult to describe a product in a claim, and in such scenarios a product-by-process claim is considered as an option to protect the product. A product-by-process claim attempts to protect the product by describing the process by which the product is manufactured. An example of a product-by-process claim is provided below.

Claim from US4935507:

Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4carboxylic acid (syn isomer) which is obtainable by dissolving 7-[2-(2-aminothiazol-4yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room temperature and allowing the solution to stand.

# Novelty and Obviousness:

The approach taken to judge novelty and obviousness of a product-by-process claim is significantly different from the approach adopted to judge novelty and obviousness of other types of claims, such as product claims and process claims.

A product-by-process claim is considered to be novel only if the product mentioned in the preamble is novel. For example, a product-by-process claim claims a product X prepared by a process Y. Product X is known in art, whereas the process Y for manufacturing the product X in new. Even though the process Y is not known in the art, the product-by-process claim will lack novelty because the product X is known in the art.

It is therefore advisable to claim a process for obtaining the product by a process claim, rather than claiming the product using a product-by-process claim.

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# Infringement of product-by-process claims

Earlier, a product claimed by a product-by-process claim was considered to be infringed even if the product claimed was prepared using a different process. However, at present, a product claimed by a product-by-process claim is considered to be infringed only if the product is obtained by a process claimed but not by a different process.

The earlier approach of determining infringement of a product-by-process claim is evident in *Scripps Clinic & Research Foundation v. Genentech, Inc.* 

# Scripps Clinic & Research Foundation v. Genentech, Inc.

Scripps' patent (RE 32,011) included both product-by-process claim and process claim. The litigation concerns a substance called human Factor VIII:C. Scripps had used chromatographic adsorption technique for obtaining the aforementioned substance. Genentech isolated the same substance as Scripps, although the process used by Genentech was recombinant DNA technique.

# District Court Judgement:

No infringement as the product is obtained by different process.

# Federal Circuit judgement:

The Federal Circuit held that Scripps' product-by-process claims were infringed by Genentech's product however made.

In the above case it was set forth that the claims may not be construed one way in order to obtain their allowance and in a contrary way against infringers.

The current approach of determining infringement of a product-by-process claim is evident in *Atlantic Thermoplastics Co. Inc. v. Faytex Corp.* 

# Atlantic Thermoplastics Co. Inc. v. Faytex Corp.

The views expressed in Scripps was no longer followed, and a landmark decision was passed in the instant case.

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Atlantic had a patent (US4674204) granted for "Shock absorbing innersole and method for preparing same". Atlantic patent included process claims as well as a product-by-process claim.

Atlantic sued Faytex for infringement of their patent. Faytex however argued stating that they have not manufactured the innersole, and had bought the innersole from two different manufacturers, Surge and Sorbothane. The court found that Surge process includes each limitation of the claim and therefore infringes the patent owned by Atlantic. However, the process used by Sorbothane was found to be different from the process claimed in the product-by-process claim, and therefore did not infringe the product-by-process claim.

In this case, it was set forth that infringement analysis and patentability analysis will be judged based on different criteria. A product claimed by a product-by-process claim is considered to be infringed only if the product is obtained by a process claimed but not by a different process.

# Abbott Laboratories v. Sandoz, Inc.

The views expressed in Atlantic Thermoplastics was upheld in *Abbott Laboratories v*. *Sandoz, Inc.* bringing to rest the contradictory views in analyzing infringement of product-by-process claims.

# Federal Circuit decision:

The court today overturns this expedient for all circumstances, brooking no exception. Acting en banc for the purpose, the court rules that if any process term or descriptive aspect is included in a product claim to aid in distinguishing a new product, the claim cannot be infringed by the identical product unless the same process aspect is used in making the accused product.

#### **Conclusion:**

The current approach of analyzing infringement of product-by-process claims has significant implication on patent holders and those attempting to work around existing patents. Patent holders or applicants have to exercise caution while considering a product-by-process claim to protect a product. On the other hand, those attempting to work around existing patents can consider developing a process that is different from a process described in a product-by-

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process claim, even though the developed process results in the same product claimed in the product-by-process claim.

Feel free to check our patent services page to find out, if we can cater to your requirements.

Best regards – Team InvnTree

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