

## Double Standards at the Federal Circuit

By Jeff Wolfson<sup>1</sup> and Evert Uy<sup>2</sup>

### Introduction

Generally, “product” claims in a patent define a product in terms of its structure, properties, or composition. A product claim could thus cover a pharmaceutical composition or formulation with a well-characterized compound and useful excipients, a light-weight alloy used in windmill blades for renewable power, or an electrolyte composition for a fuel cell. In contrast, a “product-by-process” claim defines the product partly by how it is made, *i.e.*, the claim recites process or method steps. Product-by-process claims are typically used for newly discovered products with physical characteristics that are unknown or initially difficult to determine. A newly discovered chemical/pharmaceutical compound or a complex protein molecule might be a candidate for product-by-process claim coverage, because the claim includes the steps required to obtain the product without needing substantial information to characterize the product.

Because of the process steps recited in product-by-process claims, courts have been unclear how to determine what products would actually infringe such product-by-process claims. On the one hand, some courts interpreted the claims to require the products be made by the process recited. Other courts, however, found that the same type of claims covered the resultant product regardless of whether or not it was prepared by the process recited in the product-by-process claim. The Federal Circuit resolved the dispute in *Abbott Laboratories v. Sandoz, Inc.* But in doing so, it created a double standard between patentability and infringement of product-by-process claims.

### Abbott Labs. v. Sandoz, Inc.

Abbott is the exclusive licensee of U.S. Patent No. 4,935,507 (“the ‘507 patent”), which claims crystalline cefdinir in part with product-by-process claims. After its Abbreviated New Drug Application (“ANDA”) for cefdinir was approved, Lupin Ltd. and Lupin Pharmaceuticals Inc. (“Lupin”) sought a declaratory judgment of non-infringement in the Eastern District of Virginia. Lupin makes its cefdinir with processes other than those claimed in the ‘507 patent. In the Northern District of Illinois, Abbott sued Sandoz and other companies for infringement of the ‘507 patent.

Claim 1 of the ‘507 patent claims crystalline cefdinir using its chemical name and with powder X-ray diffraction (PXRD) data. Claims 2-5, however, claim crystalline cefdinir by reciting processes by which the crystalline product is obtainable. The Virginia court in the first case construed claims 2-5 as product-by-process claims, and held that infringement of the claims was limited to products made by the process recited. The Illinois court in the second case adopted the Virginia court’s claim construction. The Virginia court had thus granted Lupin’s motion for partial summary judgment of non-infringement for claims 2-5 because Lupin did not use the required process to obtain its crystalline product, and the Illinois court denied Abbott’s request for a preliminary injunction.

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<sup>1</sup> Jeff Wolfson is a partner in the Washington, D.C. office of the law firm of Haynes and Boone, LLP. His practice emphasizes patent and trade secret law, with a focus on strategic client counseling, patent procurement and management, and due diligence and IP-related agreements. He may be reached at [jeff.wolfson@haynesboone.com](mailto:jeff.wolfson@haynesboone.com) or 202.654.4565.

<sup>2</sup> Evert Uy is an associate in the Washington, D.C. office of the law firm of Haynes and Boone, LLP. Her practice emphasizes patent law, including patent procurement and counseling. She may be reached at [evert.uy@haynesboone.com](mailto:evert.uy@haynesboone.com) or 202.654.4544.

Abbott appealed the decisions, and argued that product-by-process claims are not limited to the process described in the claims. The Federal Circuit, sitting *en banc sua sponte*, ruled that a product made by a process other than the one claimed does not infringe the claim. As long as there are process limitations in a product-by-process claim, then the process will be required for infringement.

### **Infringement v. Patentability: The Inconsistency Conundrum**

In announcing the bright line rule, the Federal Circuit majority reasoned that it was consistent with the “all elements” approach of construing patent claims, where every element of a claim must be accounted for to infringe. Moreover, if no structure or characteristic is provided, the court concluded that it would be difficult to determine if the infringing product is the same as the claimed product. They found that there is no other way to test the product besides what is in the claim itself. Yet another reason given in the court’s decision was that a different interpretation would expand protection beyond what the inventor described.

The dissent argued in favor of the rule of necessity. The rule of necessity permits a new product to be defined by the process of making it if there is no other way to describe the product. That is the fundamental reason for the existence of product-by-process claims. The three judges in dissent made a distinction between old and new products. Their position is that, while newly discovered or created products can be defined by process terms and construed strictly as a product for infringement, old products cannot be patented through a product-by-process claim, even if process steps are required by the claim. In short, the dissent’s position is that product-by-process claims include process steps only to provide written description and enablement to help those of ordinary skill in the art actually obtain the newly discovered product because there is no other way to characterize it to enable others to obtain it.

The majority barely acknowledged that the ruling creates a double standard between infringement and patentability. Product-by-process claims are still interpreted as product claims by the Patent Office to determine patentability. Thus, a patent applicant must demonstrate the product itself is patentable to achieve patentability, even if process steps are present. These same claims, however, are now construed as requiring the process features (along with any product features) for determining claim infringement.

The dissent stated that it was an inviolate rule that patent claims are construed the same way for validity and for infringement. Yet apparently, the majority has now violated that rule. The patent applicant must demonstrate patentability of a product-by-process claim as a new product, independent of the process features. Accordingly, enforcement of the claim should also be based on the product features, rather than on the alleged infringer’s use of the same process.

### **A Pole Vault Between Two Standards – Poles Apart**

The double standard created a huge gap that is likely to damage patent holders and aid accused infringers. Take, for example, the following claim:

A chemical compound X produced by the process Y.

Because the claim is a product claim, a Patent Examiner determines patentability based on the product. Thus, a prior art compound that appears to be the same as compound X (or that renders compound X obvious), regardless of how it is made, would render the claim unpatentable in most cases. The applicant can then come forward with evidence establishing that compound X is different and/or unobvious over the prior art compound. Such evidence usually takes the form of comparative testing presented in a Declaration or simply sufficient information to illustrate the Examiner misunderstood the reference or the claimed product. If the patent applicant successfully overcomes the anticipation and/or obviousness rejections, the claim is deemed patentable based on the features of the product recited in the claim. This

examination process should eliminate applicants attempting to use a product-by-process claim to obtain a patent to an old product with a new process. For example, you can't patent the allegedly unknown compound S by evaporating off the liquid from seawater and resulting in compound S.

A few years later, another cheap overseas supply of compound X arrives on the market. The patentee sues this alternate supplier of X for infringement. The Federal Circuit, however, would now have courts interpret the product-by-process claims to require that process Y be used to produce compound X. The alternate supplier uses process Z to prepare compound X, however, and the court finds non-infringement under the new double standard. Thus, the alternate supplier escapes a finding of infringement merely by using a different process.

The double standard thus improperly construes product-by-process claims one way to obtain their allowance, and then another way against accused infringers. That can't be right. After all, didn't the Patent Office grant an exclusive right to the product, regardless of how it was made? That was the hoop the patentee had to jump through to obtain allowance of a product-by-process claim, but the *Abbott* decision upends this conventional thinking and significantly minimizes the value of existing and future product-by-process claims.

As can be seen from this example, the patentability standard remains high, and the standard for determining infringement has been raised even higher. Now, the patentee must not only prove that the accused infringer makes, uses, offers to sell, or sells compound X, but must also prove that compound X was produced by process Y.

If the accused infringer does, however, use process Y to prepare compound X, he will have a more difficult time invalidating the claim. Presumably, the Federal Circuit would agree that such product-by-process claims are narrower than just a pure product claim if the law now requires the process steps be present in the accused product to show infringement. To prove invalidity, the accused infringer now has to show that it was known to produce compound X, not just by any process, but by process Y, or that it would have been obvious to do so. In short, the defendant must prove more elements to invalidate the claim.

### **Conclusion**

Thanks to technological advances in science, product-by-process claims are not as popular today as they were in the past. With the arrival of x-ray diffraction, infrared, and nuclear magnetic resonance spectroscopy, the characteristics of chemical compounds can now be more easily characterized.

Given the advancements in technology and the retreat in the usefulness of product-by-process claims, patent applicants should use product-by-process claims sparingly if at all. Product-by-process claims may be useful in some contexts, such as for patentees when the accused infringer attempts to invalidate the claim. But a process claim would be easier to obtain and still prove just as difficult to invalidate. If product-by-process claims are used, a variety of product claims that encompass the product and that do not recite process limitations should also be included.

A better practice tip for patent applicants is that patenting of a newly discovered compound, molecule, or product that is incapable of being physically characterized (except by how it is made) can be pursued initially through a provisional patent application. Then, a one-year period exists where additional data can be collected to help better characterize the product's structure and this can be included in a non-provisional patent application along with claims that use regular product or process claims without resorting to product-by-process claims alone.