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Biotechnology & Pharmaceutical Patent Law:

**INTERPRETATION OF PRODUCT-BY-PROCESS CLAIMS BY COURTS
IN THE U.S. AND THE U.K.**

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Whereas product or composition claims recite the product or composition by describing its structure, and process claims recite a method by describing the steps to perform, product-by-process (hereinafter “P-b-P”) claims define a product, at least partially, in terms of the process used to make the product. Such claims are commonly used in the chemical and biological arts where the product resulting from the process is unknown or difficult to characterize. The hybrid nature of P-b-P claims has resulted in some confusion in both the U.S. and the U.K. regarding how one ought to interpret these claims, specifically in patent infringement and patent procurement contexts. The issue courts in the U.S. and U.K recently addressed relates to whether a known product made by a different process infringes a P-b-P claim, and whether such a P-b-P would be valid if the already known product is made by a different process.

On May 18, 2009, the United States Court of Appeals for the Federal Circuit, sitting *en banc*, resolved a conflict between two lines of its own cases², holding that to infringe a P-b-P claim, one must practice the claimed process³. This decision in *Abbott Labs* overruled *Scripps Clinic*, which held that infringement of P-b-P claims does not require practicing the claimed process. In *Abbott Labs*, the claims at issue were directed to the crystalline antibiotic *cefдинir* made by a recited process. The inclusive claim term

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² See *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), and *Scripps Clinic v. Genentech*, 927 F.2d 1565 (Fed. Cir. 1991)

³ *Abbott Laboratories v. Sandoz, Inc.*, 2007-1400 (Fed. Cir. May 18, 2009)

“obtainable by” was narrowly construed as “obtained by,” thereby limiting the claim to the product made by the recited process. However, *Abbott Labs* does not change the interpretation of claims for purposes of patentability. That is, the U.S. Patent and Trademark Office continues to construe P-b-P claims as simply product claims and requires the claimed product alone, without considering the process steps, meet the requisite criteria for patentability.

The practical ramification of this *en banc* decision is that a party can avoid infringing a product-by-process claim of a U.S. patent by using a substantially different process to make the same known product; however, if a party is seeking allowance of a P-b-P claim from the patent office, the same known product will render the claim unpatentable regardless of the method used. Therefore, research and product development teams in the United States and their counsel may wish to consider using any available analytical technique to identify and define the structure or function of the product made by a process. That is, from a strategic perspective, applicants should make concerted efforts to characterize the novelty of their products or compositions without resort to process limitations. Parties with pending P-b-P claims in the United States may wish to consider their options for seeking additional coverage.

Until recently, the situation was different in the United Kingdom. The U.K. House of Lords recently changed long standing U.K. patent practice on the issue of interpreting P-b-P claims for the purposes of patentability. The U.K. Court of Appeal’s view had been that a claim to any product can be characterized by a method of producing the product, and that so long as that method is novel, the product of that claimed method would also be considered novel⁴. The U.K. House of Lords disagreed in the *Kirin-Amgen* case⁵, which involved two P-b-P claims Amgen held for making erythropoietin and Transkaryotic Therapies Inc. (TKT)’s proposal to import into the U.K. erythropoietin it had developed using a different process. The House of Lords overturned existing law in the U.K. and brought U.K. law in conformity with European Patent Office (“EPO”) practice of rejecting P-b-P claims where the product is known, on the basis that it is not novel⁵. That is, the European Patent Office’s view (and now by all accounts U.K. Intellectual Property

⁴ *Kirin-Amgen Inc. and others v. Transkaryotic Therapies Inc and others* [2003] RPC 3 (Court of Appeal)

⁵ *Kirin-Amgen Inc. and others v Hoechst Marion Roussel Ltd and others* [2005] RPC 9 (House of Lords)

Office's position) is that novelty cannot be conferred upon a known substance by a novel process for producing that substance⁶. Indeed, according to a EPO Board of Appeals decision:

“Whether or not the term “directly obtained” or any other term, such as “obtained” or “obtainable” is used in a product-by-process claim, the category of that claim does not change as it is directed to a physical entity and the subject matter of that claims, for which protection is sought, remains the product per se..... Therefore, irrespective of how a product-by-process claim is worded, it is still directed to the product per se and confers absolute protection upon the product, precisely as any other claim to a product per se. That product claim, hence, confers protection upon the product regardless of the process by which it is prepared.”

Amorphous TPM / Enichem (T 0020/94)

It remains unclear how British courts will view P-b-P claims from an infringement perspective because no cases have been handed down on infringement of P-b-P claims post *Kirin-Amgen*. However, it is clear that for the purpose of patentability, currently in U.S. and now also the U.K., a P-b-P claim is anticipated by any prior disclosure of that particular product *per se*, regardless of its method of production. According to the U.K. House of Lords, this change in U.K. law is “*unlikely to be of great practical importance because a patentee can rely instead on the process claim and article 64(2).*” Section 60(1)(c) of the U.K. Patent Act, which corresponds to Article 64(2) of the European Patent Convention, states that the protection provided by a claim for a process extends to the product of that process. Thus, the patentee will still have some protection for products arising from novel process(s); the process claim granted by the EPO should be sufficient.

To infringe a P-b-P claim of a U.S. patent, one must practice every step of the claimed process³, however, to obtain a P-b-P claim from the U.S.P.T.O, the steps of the claimed process are irrelevant and the emphasis is solely on the product resulting from the process. Similarly, when assessing the patentability of a P-b-P claim, the U.K.I.P.O. will focus solely on the product; however, it is less clear how a U.K. court will treat the process steps of a P-b-P claim in a patent infringement action in the United Kingdom.

⁶ It should be noted that under certain conditions the EPO does allow product-by-process claims, for example, where a claim is to a novel and inventive product defined by its method of production where there is no physical, chemical or biological means for distinguishing the product from the prior art.