



OUTSIDE COUNSEL

Expert Analysis

Product-by-Process Patent Claims: Contrasting United States and Europe

Product-by-process patent claims have traditionally provided a useful way for protecting products, like chemical compounds, that are difficult to describe by chemical make-up or structure, but can be described by the way they are made. As with other patent claims, the claim—insofar as the product is concerned—must be new and non-obvious to be patentable, regardless of the process for making the product. But the approach is not the same for infringement.

Before *Abbott Labs v. Sandoz Inc.*, 566 F.3d 1282 (Fed. Cir. 2009) (*Abbott/Sandoz*), there were two competing lines of cases in the United States for determining infringement of product-by-process claims—one limiting the patent protection to the methods recited in the patent claim and the other not so limited. *Abbott/Sandoz* ended the division and ruled that the recited process must be satisfied in order to infringe.

European patent practice also permits product-by-process claims, but the rules differ from the U.S. both with respect to patentability and with respect to determining infringement. For patentability of product-by-process claims, while the European Patent Convention (EPC) also requires that the product be new and inventive (regardless of the process for making the product), the EPC additionally



By
**Christopher
A. Hughes**



And
**Bert
Oosting**

requires a showing that the product cannot be described in any way other than by the process for making it. For infringement of product-by-process claims, however, it is not necessary to show that the accused product is made by the recited process. These differences raise an interesting

Product-by-process claims are allowable only in very exceptional circumstances in Europe.

dichotomy between U.S. and European practices for this type of claim.

This article explores the principles underlying product-by-process claims and compares the treatment of these claims in the U.S. with their counterparts in Europe.

Claims in the U.S.

In simple terms, a product-by-process claim describes a product (at least in part) by the method or process for making it. In contrast, a true product claim only describes the structure, characteristics or chemical formulation for the product. Historically, the U.S. Patent and Trademark Office (USPTO)

only allowed product-by-process claims upon a showing that the product could not be described any way other than specifying the process by which it was made. *In re Bridgeford*, 357 F.2d 679, 682 (CCPA 1966); see also 3 Donald S. Chisum, *Chisum on Patents* §8.05[2][a] at 8-366 to 368 (discussing *Ex parte Painter*, 1891 C.D. 200 (Comm'r Pat. 1891)). This approach became known as the “Rule of Necessity.”

Although not limited to that rule today, the USPTO still examines these claims for patentability without considering the recited process. *Smithkline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315-1317 (Fed. Cir. 2006). In other words, in the United States, the patentability of product-by-process claims turns on the patentability of the product itself; and not on the recited process for making the product.

While it is, of course, important to obtain a patent from the USPTO in the first place, the point of obtaining a product-by-process claim—like all patents—is to exploit it by manufacture, license, and/or enforcement. Thus, the flip-side focus is the scope of the protection afforded product-by-process claims—i.e., does the claim cover a product if it is made by a process different from the one recited in the claim?

The Federal Circuit Split

Before *Abbott/Sandoz*, there were two lines of Federal Circuit decisions dealing with product-by-process enforcement, each answering the question differently: *Scripps Clinic & Research Foundation v. Genentech Inc.*, 827 F.2d 1565 (Fed. Cir. 1991) (Answering: YES, the claim covers products made by a different process) and *Atlantic Thermoplastics Co. Inc. v. Faytex Corp.*, 970

CHRISTOPHER A. HUGHES is a partner and the head of the intellectual property group at Cadwalader, Wickersham & Taft. BERT OOSTING is a partner of the intellectual property, media and technology group at Lovells in Amsterdam, the Netherlands. ANDREW C. CHIEN, an associate at Cadwalader, and RUUD VAN DER VELDEN, an associate at Lovells, contributed to this article.

F.2d 834 (Fed. Cir. 1992) (Answering: NO, the claim requires the same process).

Scripps involved a product-by-process claim for a blood clotting compound—Factor VIII:C—derived from a blood-purification process. *Scripps*, 927 F. 2d at 1570. The defendant manufactured Factor VIII:C from recombinant DNA rather than blood-purification. *Id.* at 1580. The Federal Circuit nevertheless concluded that the product-by-process claims were not limited to the recited process, reasoning that the standards for infringement and for patentability (as applied in the USPTO) should exist in parallel—where product-by-process claims must be patentable over the prior art regardless of process of making it, infringement should likewise not be limited by the recited process. *Id.* at 1583.

In *Atlantic Thermoplastics*, decided a year later, the Federal Circuit reached the opposite result. The claim involved a molded shoe innersole manufactured by injecting an expandable polyurethane material into a mold so as to expand around a solid insert previously placed in the mold. *Id.* at 835-836. The defendant sold shoe innersoles made by a different—“two-pour”—process: first injecting a liquid material to form the insert in situ in the mold, then injecting the expandable material while the insert is solidifying. *Id.* at 836. For the “two-pour” approach, the Federal Circuit ruled that the scope of the asserted claim is limited by the recited process and affirmed a finding of non-infringement. *Id.* at 846-847.

‘Abbott/Sandoz’

Seventeen years after the *Scripps* and *Atlantic Thermoplastics* decisions, the Federal Circuit, sitting en banc, resolved its own split. Siding with the *Atlantic Thermoplastics* analysis, the Court ruled that infringement of product-by-process claims is limited to the recited process; a product made by a different process will not infringe the claim. *Abbott/Sandoz*, 566 F.3d at 1294-95.

The *Abbott/Sandoz* patent contained product-by-process claims specifying the method of making an antibiotic (cefdinir) in crystalline form (sold by Abbott as “Omnicef”). *Id.* at 1285. Abbott asserted the patent against several generic companies who secured FDA approval for their generic versions of cefdinir. *Id.* One company argued

that its product was produced by a different process than that specified in the claim, and thus did not infringe. *Id.*

Mirroring the *Atlantic Thermoplastics* opinion, the Federal Circuit analyzed a long line of Supreme Court cases, dating to the late 1800s, as providing the underpinnings for product-by-process claims; in each, the specified process was required for infringement. See *id.* at 1291 (citing, e.g., *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 492-493 (1877) (affirming infringement and validity of claim to artificial teeth by forming a plate of hard rubber); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 224-229 (1880) (finding non-infringement of same claim as *Smith*, because the accused product was not formed by an equivalent material and

In the United States, the patentability of product-by-process claims turns on the patentability of the product itself; and not on the process for making the product.

process); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 294-296 (1884) (no infringement of claim to a dye made by a specified chemical process because defendant used a different process); and *Plummer v. Sargent*, 120 U.S. 442, 450 (1887) (affirming non-infringement of claim to iron treated with a bronzing process where the accused bronzed iron product was the result of a different process)). Cf. *General Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373 (1938) (invalidated claim to a light-bulb filament because it did not properly recite language referring to its process of manufacture).

Judge Randall R. Rader in *Abbott/Sandoz* went so far as to question whether infringement could even be determined if the process limitations were ignored. *Abbott/Sandoz*, 566 F.3d at 1294. Moreover, Judge Rader also commented that because the inventor had chosen to draft the claim using product-by-process form, it provided notice of that process requirement to the public for infringement purposes. *Id.*

While the split between *Scripps* and *Atlantic Thermoplastics* has been resolved in *Abbott/Sandoz* on the infringement issue, related issues—such as claim construction—

can still be expected to arise.

Cases Since ‘Abbott/Sandoz’

One example of a post-*Abbott/Sandoz* issue is *Sanofi-Aventis U.S. LLC v. Sandoz Inc.*, 2009 U.S. App. LEXIS 20294 (Fed. Cir. 2009) (nonprecedential). There, the claim called for an “optically pure [chemical],” *id.* at 4, and the district court construed the term “optically pure” to require use of “the HPLC [high performance liquid chromatography] method described in the ‘874 patent specification.” *Id.* Because the defendants employed a different production method, the district court granted summary judgment of non-infringement. *Id.* at 3. The Federal Circuit rejected the construction which imposed the HPLC-process limitation, reasoning that although the specification did describe the HPLC method, it was only illustrative and not the only method described to obtain the optically pure chemical composition. *Id.* at 8-9. Therefore, as a composition claim (rather than a product-by-process claim), summary judgment was improper.

More recently, in *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009), the Federal Circuit acknowledged the dichotomy between the standard for infringement and that for patentability in product-by-process claims. Indeed, the court observed that the maxim—that which infringes, if later, would anticipate, if earlier—may no longer hold true for product-by-process claims “because a product in the prior art made by a different process can anticipate a product-by-process claim, but an accused product made by a different process cannot infringe a product-by-process claim.” *Id.* at 1370.

Claims in Europe

The European Patent Office (EPO) does not ordinarily allow product-by-process claims. The EPO allows product-by-process claims only if the product itself is new and inventive (regardless of the process for making the product) and if the product can only be described in terms of how it can be made—i.e., it cannot be described in terms of its composition, structure or other physical properties.¹ This will be the case only in exceptional circumstances. That is, the EPO will only allow product-by-process claims if there is an absolute necessity to describe the product by way

of the process by which it can be obtained. (This resembles the “Rule of Necessity,” formerly applied in the U.S.) Under the EPC rules, product-by-process claims should be claimed as “Product X obtainable (not obtained) by way of process Y.”

More specifically, product-by-process claims are allowable under the EPC only under very limited and exceptional circumstances: a product which itself is new and inventive but cannot be described in terms of composition, structural characteristics or other (physical) properties. In other words, the EPO will only accept a product-by-process claim if the product is new—i.e., different from any existing product in the state of the art—and also if this difference cannot be described in chemical or physical terms. The Technical Board of Appeal in *International Flavors & Fragrances Inc.*, [1984] OJ. EPO 309, explained how this may occur in case of “certain natural products or macro molecular materials of unidentified or complex composition which have not yet been defined structurally.”

If, however, the product is not new and inventive—and therefore cannot be protected by a product-by-process claim—it might still be protected through a process claim if it is shown to be the “direct result” of the claimed process and if the process of manufacture is new and inventive.² Article 64(2) of the EPC provides that the protection conferred by a process claim extends to “the products directly obtained by such processes” even if the product directly obtained itself is not new and inventive. Such a product would only infringe if the product is in fact manufactured (“obtained”) by the process recited in the claim.

Turning then to infringement of European product-by-process claims, protection in Europe is not limited to the manufacturing methods (processes) recited in the claim. The reason is that because the claim describes the product by way of the manufacturing method (process) by which the product can be obtained (i.e., is “obtainable”), products which meet the claim features, but are in fact manufactured (“obtained”) by another process, would also be covered by the claim. This has, *inter alia*, been confirmed by the German Supreme Court (Bundesgerichtshof) in its decision of 30 March 1993³:

For the characterization no proof is required that the product described by the breeding process is also in fact manufactured by the indicated process. The subject-matter of the patent is, notwithstanding the description of the manufacturing process, the product as such which must meet the requirements for patentability independently of the manner to manufacture it. Also, in this manner of describing the product lies no limitation for the protection of the product with respect to the indicated manufacturing process. The description of the breeding method only serves to clearly characterize the product.

Therefore, product-by-process claims can be enforced against any product which meets the claim features, irrespective of the method of manufacture.

Summarizing, then, product-by-process claims are allowable only in very exceptional circumstances in Europe, i.e., the product itself is new and inventive (regardless of the process for making the product) and the product can only be described in terms of the process by which it can be obtained (is “obtainable”) and cannot be described in terms of its composition, structure or other physical properties. If these exceptional circumstances occur, the product-by-process claim can, however, cover all products that meet the claim features, irrespective of how (by which process) they are in fact made (“obtained”).

Comparisons and Contrasts

A state of contrast now exists between product-by-process claims as obtained and enforced in the U.S. and in Europe. In Europe, while product-by-process claims are permissible for a new and inventive product (regardless of the process of making it), patentability is much more restricted than in the U.S.—i.e., requiring a showing that the product can only be described by way of the process. For infringement, however, the patent owner in Europe is not bound by the recited process steps in the claims and can seek to enforce its patent against products made by different process steps than those recited in the claims.

In the U.S., the reverse is essentially the rule. Obtaining product-by-process claims is more liberal than in Europe in one sense—namely, it is not required to show

that the product can only be described by its process of manufacture—but the U.S. still requires claim to recite a new and non-obvious product regardless of the process steps. However, the U.S. has created a difference between how claims are construed for patentability and how they are construed for infringement.

In contrast to European law, the U.S. courts will find infringement only if the recited process steps are met. As a result, U.S. product-by-process claims might become less desirable than in Europe because infringement protection is more limited (infringement limited to the recited process). On the other hand, the European product-by-process claim has a higher hurdle for patentability.

.....●.....

1. See the decisions by the Technical Board of Appeal of the EPO of 7 Feb. 1984 (T 150/82, Official Journal 1984, 309) and 26 Nov. 1985 (T 219/83, Official Journal 1986, 211). These criteria are confirmed in many subsequent Technical Board of Appeal decisions (such as T 251/85, T 434/87, T 171/88, T 563/89, T 493/90, T 664/90, T 555/92, T 223/96 T 59/97, T 1164/97, T 238/98, T 748/98 and T 620/99).

2. The earlier practice in the United Kingdom to allow product-by-process claims (referred to as “omnibus claims”) for products that are not in itself new, which treated a product made by a new process as sufficient to distinguish that product from an identical product in the state of the art, has been held unallowable and contrary to the EPC in the decision of the UK House of Lords in *In re Kirin-Amgen Inc.*, 21 Oct. 2004 ([2004] UKHL 46, par. 101 of the Opinion of Lord Hoffmann) and is now effectively no longer applied.

3. Bundesgerichtshof 30 March 1993, X ZB 13/90, GRUR 1993, 665 (unofficial translation).