Product-by-Process Claims: Patentability and Infringement

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Definition

• A product-by-process claim defines a product in terms of the process used to produce that product.

• At one time, the use of a product-by-process format was limited to the situation where the product could not be defined or distinguished from the prior art except by reference to the process by which the product is made (Rule of Necessity).
Definition

• The USPTO now issues product-by-process claims where the applicant chooses to claim his invention as such, even though the invention can be distinguished from the prior art in terms of composition and/or structure.
Patent Office Examination
MPEP §2113

• Patentability of a product-by-process claim is based on the product itself and does not depend on its method of production. That is, if the product in the product-by-process claim is the same as or obvious from a prior art product, the claim is unpatentable even though the prior art product was made by a different process.
Patent Office Examination

• On the other hand, the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims, especially where the product can only be defined by the process steps by which the product is made. For example, terms such as “welded,” “intermixed,” “interbonded by diffusion,” press fitted,” and “etched” can be construed as structural limitations.
Patent Office Examination

• The PTO will reject product-by-process claims over prior art products that appear to be the same although produced by a different process. This is because the PTO does not have facilities to replicate processes and compare the resultant product with the prior art.
Patent Office Examination

EXAMPLE

• Suppose that the examiner applied a prior art reference which teaches an LED wafer that appears to be the same as the inventive LED wafer, but which was prepared by a CVD process as opposed to liquid phase epitaxy (LPE).
Patent Office Examination

EXAMPLE

• The burden then falls on the applicant to show that there is an unobvious difference between the claimed LED wafer prepared by a LPE process and the prior art LED wafer prepared by a CVD process.
Patent Office Examination

EXAMPLE

• Suppose that the specification describes that the inventive LED wafer provides very high breakdown voltage.
Patentability may then be established, for example, by showing that the inventive LED wafer produced by a LPE process provides a breakdown voltage that is materially different to that of the similar prior art LED wafer produced by a CVD process – the difference in breakdown voltage being indicative of an unobvious difference in structure.
Scope of Product-by-Process Claim: Infringement – Historical Perspective

• Since 1992, there had been a decisional split in the Federal Circuit regarding the scope of protection afforded by a product-by-process claim as a result of opposite holdings in the Scripps and Atlantic Thermoplastics panel decisions.
Scope of Product-by-Process Claim: Infringement
The Scripps Case (Fed. Cir. 1991)

• The invention is Scripps was the development of a method for obtaining purified Factor VIII:C (a blood clotting protein) from plasma using a chromatographic adsorption technique.
Scope of Product-by-Process Claim: Infringement
The Scripps Case (Fed. Cir. 1991)

- Scripps filed suit against Genentech for patent infringement. At issue was whether Genentech’s Factor VIII:C prepared by a recombinant technique infringed Scripps’ product-by-process claims directed to purified Factor VIII:C prepared using a chromatographic adsorption technique.
Scope of Product-by-Process Claim: Infringement
The Scripps Case (Fed. Cir. 1991)

- In Scripps, a three judge panel (Judges Newman, Markey and Beer) held that the “product-by-process” claims at issue were properly interpreted as product claims, independent of how the product was made.
Scope of Product-by-Process Claim: Infringement
The Scripps Case (Fed. Cir. 1991)

• The court reasoned that Scripps distinguished the claimed product over the prior art based on product characteristics (potency and purity) as opposed to the particular process (i.e., chromatographic adsorption to a specific monoclonal antibody) used to accomplish the separation, and was therefore patentable independent of the process used to make the product.
Scope of Product-by-Process Claim: Infringement
The Scripps Case (Fed. Cir. 1991)

• Further, because the validity of the Scripps product-by-process claims depended on the novelty and unobviousness of the product, the court held that Scripps’ product-by-process claims were infringed by Genentech’s product however made.
Scope of Product-by-Process Claim: Infringement

The Scripps Case (Fed. Cir. 1991)

• The basic reasoning of Scripps was that product-by-process claims must be considered the same way for both validity (or patentability) and infringement. That is, the claims may not be construed one way in order to obtain their allowance and in a contrary way against infringers.
Scope of Product-by-Process Claim: Infringement
Atlantic Thermoplastics (Fed. Cir. 1992)

• In Atlantic Thermoplastics (1992), a subsequent panel of the Federal Circuit (Judges Archer, Michel and Rader) held that product-by-process claims are limited in an infringement inquiry by the process terms recited therein. This panel declined to follow the prior ruling of the court in Scripps.
Scope of Product-by-Process Claim: Infringement
Atlantic Thermoplastics (Fed. Cir. 1992)

• In Atlantic Thermoplastics, the issue related to the interpretation of a product-by-process claim concerning a shoe innersole. The shock-absorbing innersole was produced by a method of manufacturing which comprised the step of “placing an elastomeric insert material into a mold.”
Scope of Product-by-Process Claim: Infringement

Atlantic Thermoplastics (Fed. Cir. 1992)

• The issue was whether this claim was infringed by an identical structure that was produced by a different, non-infringing process.
Scope of Product-by-Process Claim: Infringement

Atlantic Thermoplastics (Fed. Cir. 1992)

• The Atlantic Thermoplastics panel relied on the fundamental rule of infringement that requires the presence of every claim limitation (or its equivalent). “An accused infringer can avoid infringement by showing that the accused device lacks even a single claim limitation.”
Scope of Product-by-Process Claim: Infringement

Atlantic Thermoplastics (Fed. Cir. 1992)

• Thus, because the accused product was made by a process that did not include each of the claimed process limitations, the Atlantic Thermoplastics panel found that the accused product did not infringe the patented product-by-process (PBP) claims.
Scope of Product-by-Process Claim: Infringement

Atlantic Thermoplastics (Fed. Cir. 1992)

• Both panels recognized that product-by-process claims must define a novel and unobvious product, and that patentability cannot depend on the novelty and unobviousness of the process limitations alone.
Scope of Product-by-Process Claim: Infringement
Atlantic Thermoplastics (Fed. Cir. 1992)

• However, it is one thing to permit claims to be drafted in a product-by-process format. It is a different matter to determine the scope of such claims for infringement purposes.
Scope of Product-by-Process Claim: Infringement
Atlantic Thermoplastics (Fed. Cir. 1992)

• If a claim directed to the product of the process is protected without regard to the process limitations recited therein, a similar or equivalent product could be challenged as being infringing even if produced through a materially different process.
The Abbott Laboratories Decision (Fed. Cir. 2009)

- The Scripps and Atlantic Thermoplastics decisions cannot be reconciled, and had been a source of conflict until the decision of Abbott Laboratories (Fed. Cir. 2009).
• Under Federal Circuit rules, a later issued panel decision (Atlantic Thermoplastics) cannot overturn an earlier issued panel decision (Scripps) - so this matter had been ripe for *en banc* review since the Atlantic Thermoplastics decision in 1992.
The Abbott Laboratories Decision (Fed. Cir. 2009)

• At issue was Abbott’s licensed patent for a semi-synthetic “crystalline” compound of cephalosporin which is used as a broad spectrum antibiotic.
Claim 1 of the patent defines crystalline cephalosporin using its chemical name and defining its crystal structure by reference to particular powder X-ray diffraction peaks. This crystalline form of the compound is known as Crystal A. Another form is also known – Crystal B – which this claim did not cover.
The Abbott Laboratories Decision (Fed. Cir. 2009)

- Sandoz and other generic drug makers developed cephalosporin compounds (Crystal B) to compete with Abbott that were produced by different processes from that set out in the product-by-process claims of the Abbott patent.
The Abbott Laboratories Decision
(Fed. Cir. 2009)

• Representative Product-by-Process Claim:
Crystalline compound X which is obtainable by acidifying a solution containing compound Y (a syn isomer) at room temperature or under warming.
The Abbott Laboratories Decision (Fed. Cir. 2009)

• In upholding the trial court decision against Abbott, the *en banc* Federal Circuit held that “process terms in product-by-process claims serve as limitations in determining infringement.”
The Abbott Laboratories Decision  
(Fed. Cir. 2009)

• In rejecting the minority view, Judge Rader commented that the earlier Scripps panel had attempted to bestow a “right” that never existed, namely, “the right to assert a product-by-process claim against a defendant who does not practice the express limitations of the claim.”
The Abbott Laboratories Decision
(Fed. Cir. 2009)

- The court expressly adopted the rule in Atlantic Thermoplastics and overruled Scripps.
The Abbott Laboratories Decision (Fed. Cir. 2009)

• Abbott Laboratories embodies the fundamental rule of infringement that requires the presence of every claim limitation or its equivalent.
The Abbott Laboratories Decision (Fed. Cir. 2009)

- As a result, issued patents that have product-by-process claims are considerably narrower than they were before the Abbott Laboratories case was decided. Essentially, product-by-process claims are no more than process claims.
Why Bother with Product-by-Process Claims?

• There is little reason to claim a product by its process of manufacture.
Why Bother with Product-by-Process Claims?

- To do so would require the Applicant to demonstrate patentability of the product independent of its process of manufacture, and then limit enforcement against infringement to only those instances where the accused product was made by the same process.
Protection of Products Difficult to Define in Structural Terms

• Define in terms of a partial structure to the extent possible
• Recite physical and chemical (or biological) properties
Protection of Products Difficult to Define in Structural Terms

• If a product-by-process format is the only way to define the product, the process limitations will be relied upon to determine infringement, making for a very narrow claim which is easily avoided by a competitor.
Prior to the Teva Pharmaceuticals case, PBP claims had been categorized either as “pseudo” or “genuine” PBP claims.
• “Pseudo” PBP claims in which the product could be defined without resort to process limitations (Manufacturing Process Limitation Theory) were limited to products prepared by the claimed process.
PBP Claims in Japan
Admissibility and Scope of Protection
Teva Pharmaceuticals Case

• “Genuine” PBP claims where circumstances at the time of filing made it impossible to define the product in a different way other than by its production process (Product Identity Theory) would not be so limited.
PBP Claims in Japan
Admissibility and Scope of Protection
Teva Pharmaceuticals Case

• The Japanese Supreme Court eliminated the distinction between “pseudo” and “genuine” PBP claims.

• Two points were stressed.
PBP Claims in Japan
Admissibility and Scope of Protection
Teva Pharmaceuticals Case

• First: a product claim protects the product regardless of the manufacturing process. Therefore, infringement exists even if the accused product is manufactured in a different way than in the protected product claim, although the accused product must have the same features as the patented product.
Second: A product claim is normally unclear if it contains characteristics of the manufacturing process. Namely, it is not clear what structural features result from a manufacturing process.
PBP Claims in Japan
Admissibility and Scope of Protection
Teva Pharmaceuticals Case

• An unclear claim violates the clarity requirement and is therefore null and void. The claim is to be admitted only if the patentee can demonstrate that at the time of filing, circumstances existed that made it impossible or highly impractical to characterize the product without resort to process steps.
Rationale?

- A claim should be construed the same way for infringement as it is for purposes of assessing validity.
### Product-by-Process Claims

**U.S. – JAPAN – EP Comparison**

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<thead>
<tr>
<th>Threshold “Clarity” Requirement</th>
<th>U.S.</th>
<th>JAPAN</th>
<th>EP</th>
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<tbody>
<tr>
<td>None. Akin to former “Rule of Necessity”</td>
<td>A product-by-process claim will satisfy the clarity requirement only if the product was otherwise “impossible or entirely impractical” to define by its structure or properties as of the filing date. The burden is on the Applicant to make this showing.</td>
<td>No other information is available in the application which could enable the applicant to define the product satisfactorily by reference to its composition, structure or some other testable parameter. Allowable only under limited and exceptional circumstances.</td>
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**Product-by-Process Claims**

**U.S. – JAPAN – EP Comparison**

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<th>EP</th>
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<tr>
<td>Patentability of the product itself (product must be new and unobvious), and not on the recited process for making the product.</td>
<td>Based on patentability of the product made by the process recited in the claim.</td>
<td>Product must be new and inventive, regardless of the process for making the product. Claimed as &quot;Product X obtainable (not obtained) by way of process Y.&quot;</td>
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Product-by-Process Claims

<table>
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<th>Infringement of Product-by-Process Claims</th>
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<th>EP</th>
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<tr>
<td>Covers only those products made by the process steps recited in the claim.</td>
<td>Covers any product identical to the claimed product regardless of the process by which the product was made</td>
<td>A product-by-process claim covers the product <em>per se</em> and confers absolute protection upon the product.</td>
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Validity of Product-by-Process Claims
Amgen Inc. v. F. Hoffman-La Roche Ltd.
(Fed. Cir. 2009)

• In Amgen, the court considered infringement and validity of PBP claims reciting a product (EPO) described in terms of its source (made by recombinant technology) which was found to impart structural and functional differences to the claimed product when compared to a prior art product (EPO derived from urine).
Validity of Product-by-Process Claims
Amgen Inc. v. F. Hoffman-La Roche Ltd. (Fed. Cir. 2009)

• To prove infringement, Amgen had to show that the accused product (MIRCERA®) comprises EPO made by recombinant technology, which the court concluded it did (infringement of a product-by-process claim requires that the accused product be made by the steps recited in the claim).
Validity of Product-by-Process Claims
Amgen Inc. v. F. Hoffman-La Roche Ltd. (Fed. Cir. 2009)

• As to validity, and in affirming the district court’s holding of no anticipation, the court found that the source limitation imparted differences in structure and composition (higher molecular weight and different charge due to differences in carbohydrate composition) which distinguished the patented product from urinary EPO.
Validity of Product-by-Process Claims
Amgen Inc. v. F. Hoffman-La Roche Ltd.
(Fed. Cir. 2009)

• For validity, the court construed the source limitation to impart novel structure onto EPO so as to distinguish it from urinary EPO. However, for assessing infringement, the court did not require the accused product to also possess novel structure that distinguished it from urinary EPO.
Validity of Product-by-Process Claims
Amgen Inc. v. F. Hoffman-La Roche Ltd. (Fed. Cir. 2009)

• Hoffman-La Roche argued that because the source limitation was construed to impart novel structure onto EPO that distinguished it from urinary EPO (for purposes of validity), the patent owner should be required to prove that the accused product also possessed the same novel structure (for purposes of infringement) that distinguished the patented product from urinary EPO.
Validity of Product-by-Process Claims
Amgen Inc. v. F. Hoffman-La Roche Ltd. (Fed. Cir. 2009)

• However, the court did not accept Hoffman-La Roche's argument. That is, the axiom that “claims must be interpreted and given the same meaning for purposes of both validity and infringement analysis” does not hold true for PBP claims.
Validity of Product-by-Process Claims
Amgen Inc. v. F. Hoffman-La Roche Ltd. (Fed. Cir. 2009)

• The court explained that in determining validity of a product-by-process claim, the focus is on the product and not on the process of making it. This is because an old product is not patentable even if made by a new process. As a result, a PBP clam can be anticipated by a prior art product that does not adhere to the claim’s process limitations.
Validity of Product-by-Process Claims
Amgen Inc. v. F. Hoffman-La Roche Ltd.
(Fed. Cir. 2009)

• In determining infringement, the focus is on the process of making the product as much as it is on the product itself. This is because process terms in PBP claims serve as limitations in determining infringement. As a result, a PBP claim is not infringed by a product made by a process other than the one recited in the claim.
Case Citations

*Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 USPQ2d 1001, (Fed. Cir. 1991)

*Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 23 USPQ2d 1481 (Fed. Cir. 1992)

*Abbott Laboratories v. Sandoz Inc.*, 90 USPQ2d 1769 (Fed. Cir. 2009)

*Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 92 USPQ2d 1289 (Fed. Cir. 2009)
Thank you!