Infringement of a Process Patent when an Intermediate is manufactured outside the US and subsequently imported into the US – Case Law and Update

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Direct Infringement

• 35 U.S.C. § 271(a) provides the basis for standard patent infringement within the United States.

• There would be direct infringement if it is proven that the process to make a product was performed in the United States. See, e.g., i4i Ltd. Partnership v. Microsoft Corp., 598 F.3d 831, 850 (Fed. Cir. 2010), aff’d on other grounds, 131 S. Ct. 2238 (2011) (finding infringement where a patented method was performed).

• It is the performance of the process, not the product itself, which provides basis for the liability, for a process patent.
Direct Infringement - Control

• Generally, for there to be direct infringement, all process steps must be performed by one party. *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S.Ct. 2111 (2014).

• However, if each step of the claimed process is performed by multiple parties, the claim will still be infringed if one party exercises “control or direction” over the entire process, evaluated using traditional standards for vicarious liability. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328–30 (Fed. Cir. 2008); see *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007).
Contributory Infringement and Inducement

• 35 U.S.C. § 271(b) establishes liability for those who actively induce infringement of a patent.

• Section 271(c) provides liability for those who sell a component within the United States, knowing the component to be especially made for use in infringing a patent, and not a staple article of commerce suitable for substantial noninfringing use.

• In order to be liable under either Sections 271(b) or (c), a finding of direct infringement is required. See Limelight v. Akamai, 134 S.Ct. at 2116 (2014); see also Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336 (1961).

• The component manufacturer must know that an infringement will occur. See Global-Tech Appliances, Inc. v. SEB SA, 131 S. Ct. 2060 (2011) (holding willful blindness to potential patent infringement sufficient for liability under Section 271(b)).
Infringement via Importation of a product made by process patented in the US

35 U.S.C. § 271(g) provides:

- (g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

  - (1) it is materially changed by subsequent processes; or
  - (2) it becomes a trivial and nonessential component of another product.

Infringement via Importation of a product made by process patented in the US

- Under 271(g), a party can be liable for infringement for importing in the United States, or selling or using in the United States, a product made by a patented process, regardless of where the process is performed or where the product was ultimately made.

- 271(g) was added to increase protection of U.S. technology industries, specifically the pharmaceutical and biotechnology industries.
In the biotechnology field is it well known that naturally occurring organisms contain within them particular genetic sequences composed of unique structural characteristics. The patented process may be for the process of preparing a DNA molecule comprising a specific genetic sequence.

A foreign manufacturer uses the patented process to prepare the DNA molecule which is the product of the patented process. The foreign manufacturer inserts the DNA molecule into a plasmid or other vector and the plasmid or other vector containing the DNA molecule is in turn, inserted into a host organism; for example a bacterium.

The plasmid-containing host organism still containing the specific genetic sequence undergoes expression to produce the desired polypeptide.

Even if a different organism was created by this biotech procedure, if it would not have been possible or commercially viable to make the different organism and product expressed therefrom but for the patented process, the polypeptide product will be considered to have been made by the patented process.
• First part of the “materially changed” test:

• If the only way to have arrived at Y is to have used the patented process at some step, e.g., producing X as an intermediate, Y is infringing.

• If there is more than one way to have arrived at Y, but the patented process is the only commercially viable way to have done so, Y is infringing.

• If there are commercially viable non-infringing processes to have arrived at X, the connection between the patented process for producing chemical X and the ultimate product, chemical Y, is broken, and Y would be a non-infringing product having satisfied both phases of the test.
Senate Report No. 83, 100th Congress.  
1st Session 49 (1987)

• Second part of the “materially changed” test:

• A product will be considered to have been made by a patented process if the additional processing steps which are not covered by the patent do not change the physical or chemical properties of the product in the manner which changes the basic utility of product produced by the patented process.

• However, a change in the physical or chemical properties of a product, even though minor, may be “material” if the change relates to a physical or chemical property which is an important feature of the product produced by the patented process.

• Usually a change in the physical form of a product (e.g., the granules to powder, solid to liquid) or minor chemical conversion, (e.g., conversion of a salt, base, acid, hydrate, ester, or addition or removal of a protection group) would not be a “material” change.
Bio-Technology v. Genentech, Inc.  
(Federal Circuit, April 8, 1996)

- Genentech held patents directed to a recombinant DNA method for producing a 191- or 192-amino acid human growth hormone (hGH) that is identical, or essentially identical, and functionally equivalent to the natural hormone.

- '980 Patent directed to method for directly expressing a human growth hormone expression product without a leader sequence.
  - A method for producing human growth hormone which method comprises:
    1. culturing bacterial transformants containing recombinant plasmids which will, in a transformant bacterium, express a gene for human growth hormone unaccompanied by the leader sequence of human growth hormone or other extraneous protein bound thereto, and
    2. isolating and purifying said expressed human growth hormone.
Bio-Technology v. Genentech, Inc.

• **Question:** does BTG infringe under 271(g) by importing the hGH into the US?

• BTG manufactures hGH by recombinant DNA techniques including a plasmid.

• BTG argued that it “materially changes” the product made by the patented process, met-hGH, into hGH before importing the product into the US.

• Court found that BTG’s imported product (hGH) is within the scope of the claim and held that the “materially changed” exception requires, at a minimum, that there be a real difference between the product imported, offered for sale, sold, or used in the US and the products produced by the patented process.

• If patent were limited to producing met-hGH, then results may be different.
Bio-Technology v. Genentech, Inc.

• ‘832 patent directed to method for constructing a replicable cloning vehicle (e.g., a plasmid) capable, in a microbial organism, of expressing a particular polypeptide (e.g., human growth hormone).

• **Question:** Is hGH “a product which is made by a process patented in the US” even though Claim 1 of the ‘832 patent is directed to a method for producing a replicable cloning vehicle (plasmid), not hGH.

• Court found that the ‘832 patent contemplates the patented process will be used as part of an overall process for producing hGH and the patent discloses in detail how to make hGH by carrying out the claimed process and other necessary steps.

• Affirmed District Court that hGH is a product that is “made by” the ‘832 patented process. The Court, looking toward the legislative history, reasoned that Congress intended a particular carve-out for exactly this type of technology, and ruled the importation of the hGH made using the process to make the plasmid infringing.
Eli Lilly v. American Cyanamid
(Federal Circuit, May 10, 1996)

• Eli Lilly developed cefaclor, a broad spectrum antibiotic.

• The patent in suit related to a method of producing an intermediate compound called “compound 6,” an enol cephem similar to the one that Lilly uses in its process for manufacturing cefaclor.

• Cefaclor differs structurally from compound 6 is three respects, each of which contributes to the effectiveness of the drug.

  • Compound 6 has a hydroxy group at the 3-position on the cephem nucleus, a para-nitrobenzyl carboxylate ester at the 4-position, and a phenylactyl group at the 7-position.

  • Cefaclor has a chlorine atom at the 3-position, a free carboxyl group at the 4-position and a phenylglycl group at the 7-position.
Eli Lilly v. American Cyamid

- Further, to produce Cefaclor from compound 6, four distinct steps need to be taken.
  - The hydroxy group is removed from the 3-position and is replaced by the chlorine atom, which results in the creation of “compound 7”.
  - Compound 7 is subject to a reaction that removes the phylactyl group at the 7-position, which results in the creation of “compound 8.”
  - A phenylglcyl group is added at the 7-position, which results in the creation of “compound 9.”
  - The paranitrobenzyl carboxylate ester is removed from the 4-position, which results in the creation of cefaclor.

- Defendants were sued for attempting to import large amounts of a drug called Cefaclor produced in Italy.
Eli Lilly v. American Cyanamid

• The Federal Circuit held that the importation of Cefaclor, made using the process to make compound 6 found in the patent in suit, does not infringe under § 271(g), as there is a material change that occurs when producing Cefaclor from compound 6.

• The statute refers to changes in the product an permits the importation of an item that is derived from a product made by a patented process as long as that product is “materially changed” in the course of its conversion into the imported item.

• In the chemical context, a “material” change in a compound is most naturally viewed as a significant change in the compound’s structure and process.

• There is at least one known commercial method for making cefaclor that does not use the patented process.
Bayer v. Housey Pharmaceuticals  
(Federal Circuit, August 22, 2003)

• Patents directed to a “method of screening for substances which specifically inhibit or activate a particular protein affecting the cultural or morphological characteristics of the cell expressing the protein.”

• Case concerned with the meaning of the phrase “a product which is made by a patented process.”

• Court held that the production of information is not within the scope of processes of “manufacture.”

• 271(g) statute concerns products that are physical goods produced by a manufacturing process. Does not cover processes other than manufacturing processes.

• Court held that the patented process is not used in the actual synthesis of the drug product.
Amgen v. F. Hoffman – La Roche
(Federal Circuit, September 15, 2009)

• Patents directed to the production of the protein erythropoietin (“EPO”) using recombinant deoxyribonucleic acid (“DNA”) technology.

• Amgen sued Roche alleging that Roche’s product MIRCERA® would infringe the patents if imported into the United States.

• Roche argued that MIRCERA® is materially changed prior to importation into the United States. Argued that drug must be compared to cured product resulting from the claimed process and that unadministerable crude EPO to-FDA approved MIRCERA® evidences a “material change.”

• MIRCERA® possess different structures than EPO and has thousands more atoms, hundreds of new bonds, a significantly higher molecular weight, a different charge and improved kinetic properties.
Amgen v. F. Hoffman – La Roche

• Roche argued that 271(g) requires comparison of the products produced by the patented process to the product imported into the United States, and not to the immediate product that Roche produces by employing the patented process.

• Amgen argued that MIRCERA® still contains EPO, the structure of EPO remains intact, MIRCERA® binds to the EPO receptor, and MIRCERA® retains its claimed ability to increase the production of reticulocytes and red blood cells.

• Court affirmed jury’s finding that the structural and functional differences between MIRCERA® and EPO recited in the process claims were not material.
Zond v. Toshiba
(District of Massachusetts, August 14, 2014)

• Patents directed to the generation, use and/or applications of unique plasma
discharge technology that employs a strongly ionized plasma.

• Toshiba filed a motion to dismiss on the pleadings for failure to state a claim. Toshiba
argues that the microchips contained within its semiconductor devices cannot infringe
Zond’s patents because the product of Zond’s patent process – plasma – is a trivial
and nonessential component of those chips.

• The Court disagreed with Toshiba and held that what is important is not the plasma
itself, but the process used to obtain the plasma and the uses to which the plasma is
put.

• Court held that case was similar to Bio-Tech and that since Toshiba did not argue that
the steps to manufacture its chips were not covered by Zond’s patents and do not
change the properties of the chips, and due to early stage of case, Zond’s allegations
for infringement may proceed.
Flexsys America v. Kumho Tire  
(Northern District of Ohio, July 15, 2010)

• Patents-in-suit identify a new, environmentally friendly method for making 4-aminodiphenylamine (4-ADPA) and its alkylated derivatives, namely alkylated p-phenylenediamines. The derivatives are used as anti-degradants in automobile tires.

• The patents identify a three step process:
  • (1) coupling of aniline and nitrobenzene to produce 4-ADPA intermediates
  • (2) hydrogenating the 4-ADPA intermediates into 4-ADPA
  • (3) alkylating the 4-ADPA to form the antidegradant additive (6PPD).

• Flexsys alleges that Kumho Tire imported 6PPD into the United States with full knowledge and in violation of 271(g) and (b).
Flexsys America v. Kumho Tire

• Flexsys concede that there are other commercially alternative processes for making 4-ADPA that do not employ the process claimed in the patents in suit.

• Furthermore, the process of converting 4-ADPA into 6PPD involves two chemical steps:
  • Two hydrogens bound to the terminal nitrogen of 4-ADPA have been replaced with a double bond between the terminal nitrogen and the alkyl chain.
  • The imine is reduced to make 6PPD and IPPD.

• The chemical structure of 4-ADPA is 500 times more soluble in water than 6PPD and has a much higher melting point.

• Court found that “a material change” occurs when 4-ADPA is converted into 6PPD before it is imported into the United States.
Yangaroo Inc. v. Destiny Media Techs.  
(Eastern District of Wisconsin, June 7, 2010)

- Patents directed to a method of distributing content to a plurality of authorized recipients via various steps.

- Defendants servers located outside of United States and Yangaroo alleged that Destiny imports a product into the US and is liable for infringement under 271(g).

- Destiny argues that it does not make a “product” important into the United States, but rather transmits information. Yangaroo argued that the encrypted music on Destiny’s system is a product.

- The Court found that the patent is directed to a “method of distributing content”, and not a method of manufacturing the digital content that is received in servers and transmitted to authorized recipients.

- Since no method or process for the creation of the content that Yangaroo argues constitutes the product, the infringement claimed failed.
Patents directed to a method of processing digital data for use in facilitating the orthodontic treatment of a patient comprising:

- scanning three-dimensional surfaces that have the shapes of a plurality of the teeth of a patient and generating data thereof;
- from the generated data, producing separate digital representations of the shapes of each of a plurality of individual teeth of the patient.

Question was whether the 3D digital model produced by defendant can be considered a “product made” under 271(g).

The 3D digital model is not tangible. In CNET Networks v. Etilize, 528 F.Supp.2d 985 (ND Cal 2007), the court found that an electronic catalog produced by a patent process was a “product” under 271(g).
Ormco Corp. v. Align Technology

• Court found that the 3D digital model is a “creation” produced by “practicing every step” of a patented process.

• Court rejected arguments that the 3D digital model is not itself bought and sold as a final product from defendants.
Oki America v. Advanced Micro Devices.
(Northern District of California, September 21, 2006)

• Claim 5 of patent directed to a process for the selective removal of coating material from peripheral portions of a coated substrate to reduce inadvertent dislodgement of portions of said coating during processing of the substrate, whereby said coating material on the end edge of said substrate and on a preselected peripheral portion of each of said surfaces of said substrate is removed.

• The imported products are operational semiconductor devices and the patented process produces wafers with reduced debris and presumably fewer defects in the chips on those wafer.

• Defendant argued that its chips imported into the US are not “made by” the process of the patent, the chips underwent “material change” by subsequent processes and the product of the process – clean wafer edges – is a “trivial or nonessential component” of the imported chips.
Oki America v. Advanced Micro Devices.

• It was undisputed that the process acts on material at the edge region whereas the devices are fabricated at the interior region of a semiconductor wafer.

• It was also undisputed that the edges of a wafer are discarded at the end of the fabrication process and do not become part of the product devices.

• Court concluded that the product of the process is a device lacking certain debris and that the devices containing the chips diced from the wafer are directly derived from the wafer processing steps and therefore “made by” the process.

• The process covers a process step in the manufacture of the chip and was not too remove a process form the manufacture of operational devices because it was explicitly contemplated that the patented process would be used as part of the overall device manufacture.

• The Court did not find that the material change exception applied as subsequent processing steps do not impact the product of the process, a debris-free device.
Synaptic Pharmaceutical v. MDS Panlabs
(District of New Jersey, June 20, 2002)

• Patent directed to assay claims.

• Court was unwilling to extend 271(g) to cover the products of diagnostic process patents and drew distinction between method of use patents versus process, or method of manufacture patents.

• Court held that method of use patents do not extend the “materially changed” exception.
“Materially Changed” Tips

• Materially alter any product produced by a process which is covered by a patent in the United States in order to prevent suits under Section 271(g).
  • This analysis occurs on a case-by-case basis.

• “In the chemical context, a ‘material’ change in a compound is most naturally viewed as a significant change in the compound's structure and properties.”

• If there is a patent on a method of producing an intermediate, and the client produces an API using the intermediate, they will likely not infringe so long as there is a material change in the compound’s structure and properties.

• However, if the method patent is on the production of the API, and the client either imports the API or the final dosage form, they are likely infringing, and it is likely that not enough of a change has occurred to get an exception under § 271(g)(1).
Importation may be halted under 19 U.S.C. 1337(a)(1)(B)

- If the product is being imported into the United States, importation may be halted by the United States International Trade Commission under 19 U.S.C. § 1337(a)(1)(B), which bars importation of articles that infringe a patent or were made by a patented process.

- The exceptions available under 35 U.S.C. § 271(g)(1) and (2) are not available under 19 U.S.C. § 1337(a)(1)(B).
US International Trade Commission

• Importation may also be blocked under 19 U.S.C. § 1337 by the United States International Trade Commission ("U.S. I.T.C."). 19 U.S.C. § 1337 provides, in part:
  • (1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
    ******
    (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—
    ******
    (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

• 19 U.S.C. § 1337 (2014). When before the U.S. I.T.C., under 19 U.S.C. § 1337, the defenses under 35 U.S.C § 271 (g)(1) and (2) are not available. Accordingly, clients must be very careful not to import anything made via a process covered by the claims of a patent if they feel they may be challenged in the U.S. I.T.C.


• ITC does not have the power to award damages for patent infringement. ITC decisions are non-binding.
Three patents were at issue, two of which covered a process for making an intermediate compound of sucralose and the other which covered a process for recovering a tin catalyst used in the process for making the intermediate sucralose compound.

With respect to the two patents directed to the intermediate compound, the importer of the sucralose product argued that:

- the imported article was not the intermediate compound covered by the asserted patents.
- in order to produce the actual imported sucralose sweetener, additional process steps were performed subsequent to the patented process steps for producing the intermediate compound.
- with respect to the catalyst recovery patent, the imported sucralose did not contain the tin catalyst and that the tin catalyst itself was not imported.
Certain Sucralose, Sweeteners Containing Sucralose, and Related Intermediate Compounds Thereof

- The Administrative Law Judge ("ALJ") and the Commission agreed that — although there was subsequent processing after the patented process steps were performed to produce the intermediate compound — there was a sufficient “close interdependence between the patented processes and the production of sucralose.”

- The Commission focused on factors such as:
  - (i) the proximity of the intermediate compound and the final imported product (sucralose) in the process chain for producing sucralose;
  - (ii) whether the intermediate compounds had any alternate uses other than being used in the production of sucralose; and
  - (iii) the purpose of the patent.
Certain Sucralose, Sweeteners Containing Sucralose, and Related Intermediate Compounds Thereof

With respect to the catalyst recovery patent, the ALJ and Commission determined that the claims covering the process of removing and recycling the tin catalyst from the process of making the intermediate compound were not contemplated by the trade statute under section 1337(a)(1)(B)(ii); because the tin catalyst was neither a precursor of sucralose nor the imported article, there was no “close interdependence between the patented process and the production of sucralose.”

The ITC noted that the catalyst, once recycled, could have been used for other processes not related to the production of sucralose.
Thank you