Pravastatin Sodium Case, Product-by-Process Practice Modified in Japan: A Comparative View of the American Practice*

As analyzed by Dr. Shoichi Okuyama,** the Supreme Court of Japan has defined the scope of a product-by-process claim as including that product even if made by a different process than recited in the claim. In the Pravastatin Sodium Case (Japan Supreme Court, June 5, 2015, Second Petty Bench, case Nos. 2012(ju)1204 and 2012(ju)2658), Japan’s highest judicial tribunal reversed the Grand Panel of the IP High Court to upset longstanding precedent. The Supreme Court held that:

“[E]ven if a patent claim concerning a product invention recites the manufacturing process of a product, the technical scope of the patented invention should be determined to cover products that have the same structure and characteristics, etc., as those of the product made in accordance with the manufacturing process.”


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* Analysis by Harold C. Wegner, June 9, 2015.

** Dr. Shoichi Okuyama, Pravastatin Sodium Case, Japan Product-by-Process Claiming Practice: Supreme Court Overrules the Grand Panel of the IP High Court (June 8, 2015), privately circulated by Dr. Okuyama, so@tokyo.email.ne.jp
The American View

Product-by-process claiming in the United States has a rich history that dates back to nineteenth century Supreme Court precedent. Since 1992, however, there has been a long-standing controversy over the issue decided in the Pravastatin Sodium Case.

In one group stands former Judge Rader: He takes the view that a product-by-process claim *does not* cover the otherwise identical product if the process used by the accused infringer differs from that of the claim. Eight judges stood in the majority including Michel, C.J., Rader, Bryson, Gajarsa, Linn, Dyk, Prost, Moore, JJ.

Judge Newman was the leader of the other side saying that a product-by-process claim *does* cover the otherwise identical product if the process used by the accused infringer differs from that of the claim. The Newman group includd Mayer, Lourie, JJ.

Other Issues

The Pravastatin Sodium Case opinion has other also very important points which are outside the scope of the present paper: Relevant extracts from the opinion are provided in the excellent analysis provided by Dr. Shoichi Okuyama (available as cited at footnote **). The view of the Patent Office is expressed in two sections of the Manual of Patent Examining Procedure:

MPEP § 2113 Product-by-Process Claims page 1
MPEP § 2173.05(p) Claim Directed to Product-By- Process page 4

PDF files provided with this note include the complete text of the Manual of Patent Examining Procedure sections relevant to product-by-process claiming and excerpts from Abbott v. Sandoz.

| Rader, J., majority opinion (joined by Michel, C.J., Bryson, Gajarsa, Linn, Dyk, Prost, Moore, JJ.) | pp. 1-6 |
| Newman, J., joined by Mayer, Lourie, JJ., dissenting as to § III-A.2 | pp. 7-32 |
| Lourie, J., dissenting as to § III-A.2 | pp. 33-34 |

RADER, Circuit Judge.

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[§ III.A.]2 Proper Interpretation of Product-by-Process Claims

Footnote 1: “This court, sua sponte, took en banc [the subject matter of this section]. The following judges join this section of the opinion: Chief Judge Michel and Judges Rader, Bryson, Gajarsa, Linn, Dyk, Prost, and Moore. Judges Newman and Lourie dissent in separate opinions. Judges Mayer and Lourie join in Judge Newman's dissent. Judge Schall did not participate as a member of the en banc court.”

This court *** addresses the proper interpretation of product-by-process claims in determining infringement. *** In reaching [its] conclusion, the trial court followed this court's opinion in Atlantic Thermoplastics [Co. v. Faytex Corp., 970 F.2d 834 (Fed.Cir.1992)]. *** This court takes this opportunity to clarify en banc the scope of product-by-process claims by adopting the rule in Atlantic Thermoplastics.

In Atlantic Thermoplastics [Co. v. Faytex Corp., 970 F.2d 834 (Fed.Cir.1992)], this court considered the scope of product-by-process claim 26 in the patent at issue: "[t]he molded innersole produced by the method of claim 1." 970 F.2d at 836. The patentee urged that competing, indistinguishable innersoles made by a different method nonetheless infringed claim 26. Id. at 838. This court rejected the patentee's position. This court in Atlantic Thermoplastics construed product-by-process claims as limited by the process. Id. at 846-47.
This rule finds extensive support in Supreme Court opinions that have addressed the proper reading of product-by-process claims. See *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 493 (1877) ("The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed."); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 224 (1880) ("[T]o constitute infringement of the patent, both the material of which the dental plate is made ... and the process of constructing the plate ... must be employed."); *Merrill v. Yeomans*, 94 U.S. 568 (1877); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884) (BASF); *The Wood-Paper Patent*, 23 Wall. 566, 90 U.S. 566, 596 (1874); *Plummer v. Sargent*, 120 U.S. 442 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364 (1938); see also *Atl. Thermoplastics*, 970 F.2d at 839-42 (discussing each of these cases). In these cases, the Supreme Court consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations. In addition, the binding case law of this court's predecessor courts, the United States Court of Customs and Patent Appeals (see *In re Hughes*, 496 F.2d 1216, 1219 (CCPA 1974) (acknowledging that "true product claims" are "broader" in scope than product-by-process claims), and the United States Court of Claims (see *Tri-Wall Containers v. United States*, 408 F.2d 748, 751 (Ct. Cl. 1969)), followed the same rule.

This court's sister circuits also followed the general rule that the defining process terms limit product-by-process claims. See, e.g., *Hide-Ite Leather v. Fiber Prods.*, 226 F. 34, 36 (1st Cir.1915) ("It is also a well-recognized rule that, although a product has definite characteristics by which it may be identified apart from the process, still, if in a claim for the product it is not so described, but is set forth in the terms of the process, nothing can be held to infringe the claim which is not made by the process."); *Paeco, Inc. v. Applied Moldings, Inc.*, 562 F.2d 870, 876 (3d Cir. 1977) ("A patent granted on a product claim describing one process grants no monopoly as to identical products manufactured by a different process."). Indeed, this court itself had articulated that rule: "For this reason, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself." *In re Thorpe*, 777 F.2d 695, 697 (Fed.Cir.1985) (emphasis added).

The Supreme Court has long emphasized the limiting requirement of process steps in product-by-process claims. In BASF, the Court considered a patent relating to artificial alizarine. Specifically, the patent claimed "[a]rtificial alizarine, produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result." 111 U.S. at 296 (quoting U.S. Patent Reissue No. RE 4,321). In turn, the specification
Abbott Laboratories v. Sandoz, page 3

generally described a method for making artificial alizarine involving anthracine or its derivatives. Alizarine had been in use for thousands of years as a red textile dye, traditionally extracted from madder root. Pure alizarine has the chemical formula C_{14}H_{8}O_{4}, but "artificial alizarines" available in the market at the time of the litigation varied from almost completely pure alizarine, to combinations of alizarine and anthrapurpurine, to pure purpurine containing no alizarine whatsoever. Id. at 309-10. The defendant's product contained approximately sixty percent anthrapurpurine. Thus both alizarine and artificial alizarines were known in the prior art. The Supreme Court clearly articulated some of the scope and validity problems that arise when process limitations of product-by-process claims are ignored:

"[The defendant's product] is claimed by the plaintiff to be the artificial alizarine described in No. 4,321, and to be physically, chemically, and in coloring properties similar to that. But what that is is not defined in No. 4,321, except that it is the product of the process described in No. 4,321. Therefore, unless it is shown that the process of No. 4,321 was followed to produce the defendant's article, or unless it is shown that that article could not be produced by any other process, the defendant's article cannot be identified as the product of the process of No. 4,321. Nothing of the kind is shown. * * *"

"If the words of the claim are to be construed to cover all artificial alizarine, whatever its ingredients, produced from anthracine or its derivatives by methods invented since Graebe and Liebermann invented the bromine process, we then have a patent for a product or composition of matter which gives no information as to how it is to be identified. Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.:"

Id. at 310, 4 S.Ct. 455 (emphasis added).

After BASF, the Supreme Court continued to emphasize the importance of process steps in evaluating the infringement of product-by-process claims. See, e.g., Plummer, 120 U.S. at 448 ("[W]hatever likeness that may appear between the product of the process described in the patent and the article made by the defendants, their identity is not established unless it is shown that they are made by the same process."); Gen. Elec. Co., 304 U.S. at 373 ("[A] patentee who does not distinguish his product from what is old except by reference, express or
constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced." (footnote omitted)).

Thus, based on Supreme Court precedent and the treatment of product-by-process claims throughout the years by the PTO and other binding court decisions, this court now restates that "process terms in product-by-process claims serve as limitations in determining infringement." Atl. Thermoplastics, 970 F.2d at 846-47. As noted earlier, this holding follows this court's clear statement in In re Thorpe that "product by process claims are limited by and defined by the process." 777 F.2d at 697.

More recently, the Supreme Court has reiterated the broad principle that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." Warner-Jenkinson, 520 U.S. at 19. Although Warner-Jenkinson specifically addressed the doctrine of equivalents, this rule applies to claim construction overall. As applied to product-by-process claims, Warner-Jenkinson thus reinforces the basic rule that the process terms limit product-by-process claims. To the extent that Scripps Clinic is inconsistent with this rule, this court hereby expressly overrules Scripps Clinic.

The dissenting opinions lament the loss of a "right" that has never existed in practice or precedent—the right to assert a product-by-process claim against a defendant who does not practice the express limitations of the claim. This court's en banc decision in no way abridges an inventor's right to stake claims in product-by-process terms. Instead this decision merely restates the rule that the defining limitations of a claim—in this case process terms—are also the terms that show infringement.

Thus this court does not question at all whether product-by-process claims are legitimate as a matter of form. The legitimacy of this claim form was indeed a relevant issue in the nineteenth century when Ex parte Painter, 1891 C.D. 200, 200-01 (Comm'r Pat. 1891), and some later cases were before the Commissioner of Patents. However, this court need not address that settled issue. The issue here is only whether such a claim is infringed by products made by processes other than the one claimed. This court holds that it is not.

The jurisprudence of the Court of Customs and Patent Appeals—a court with virtually no jurisdiction to address infringement litigation—can shed little light on the enforcement of the only claim limitations that an applicant chooses to define
the invention. Indeed, this court's venerable predecessor expressed its ambivalence towards the relevant infringement analysis:

“The policy of the Patent Office in permitting product-by-process type claims to define a patentable product, where necessary, has developed with full cognizance of the fact that in infringement suits some courts have construed such claims as covering only a product made by the particular process set forth in the claim and not to the product per se.”

*In re Bridgeford*, 357 F.2d 679, 683 n. 5 (CCPA 1966). The reference to "some courts" in this prior citation, as this court notes en banc, includes the United States Supreme Court and every circuit court to consider the question, including this circuit. See also Jon S. Saxe & Julian S. Levitt, *Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice*, 42 J. Pat. Off. Soc'y 528, 530 (1960) ("[P]roduct-by-process claims have met with a most strict interpretation in the courts in infringement proceedings.... [T]he courts uniformly hold that only a product produced by the claim-designated process may be held to infringe the claim.") (citing *Gen. Elec. Co.*, 304 U.S. 364 and *BASF*, 111 U.S. at 310).

Product-by-process claims, especially for those rare situations when products were difficult or impossible to describe, historically presented a concern that the Patent Office might deny all product protection to such claims. See *In re Butler*, 37 F.2d 623 (CCPA 1930) ("Process claims are valuable, and appellant thinks he is entitled to them; but it is submitted that he should not be limited to control of the process when the article which that process produces is new and useful."). In the modern context, however, if an inventor invents a product whose structure is either not fully known or too complex to analyze (the subject of this case—a product defined by sophisticated PXRD technology—suggests that these concerns may no longer in reality exist), this court clarifies that the inventor is absolutely free to use process steps to define this product. The patent will issue subject to the ordinary requirements of patentability. The inventor will not be denied protection. Because the inventor chose to claim the product in terms of its process, however, that definition also governs the enforcement of the bounds of the patent right. This court cannot simply ignore as verbiage the only definition supplied by the inventor.

This court's rule regarding the proper treatment of product-by-process claims in infringement litigation carries its own simple logic. Assume a hypothetical chemical compound defined by process terms. The inventor declines to state any structures or characteristics of this compound. The inventor of this compound obtains a product-by-process claim: "Compound X, obtained by process Y."
Enforcing this claim without reference to its defining terms would mean that an alleged infringer who produces compound X by process Z is still liable for infringement. But how would the courts ascertain that the alleged infringer's compound is really the same as the patented compound? After all, the patent holder has just informed the public and claimed the new product solely in terms of a single process. Furthermore, what analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes? If the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed. Why also would the courts deny others the right to freely practice process Z that may produce a better product in a better way?

In sum, it is both unnecessary and logically unsound to create a rule that the process limitations of a product-by-process claim should not be enforced in some exceptional instance when the structure of the claimed product is unknown and the product can be defined only by reference to a process by which it can be made. Such a rule would expand the protection of the patent beyond the subject matter that the inventor has "particularly point[ed] out and distinctly claim[ed]" as his invention, 35 U.S.C. § 112 ¶ 6.

Thus, the Eastern District of Virginia correctly applied the rule that the recited process steps limit the product-by-process claims 2-5 for any infringement analysis.

* * *
NEWMAN, J., Joined by MAYER, LOURIE, JJ., dissenting from en banc § III.A.2.

The court today acts en banc to overturn a century of precedent and practice, and holds that a new product that is difficult to describe without reference to how it was made, but that is nonetheless a new and unobvious product, cannot be protected as a product if its description is aided by reference to how it was made. Heretofore a new product whose structure was not fully known or not readily described could be patented as a product by including in the product description sufficient reference to how it can be made, to distinguish the new product from prior art products. Patentability was determined as a product, independent of any process reference in the claim, and validity and infringement were based on the product itself. This expedient for patenting products whose structure was not fully known at the time of filing the patent application has been called the "rule of necessity." It was pragmatic, fair, and just, for it attuned patent law and practice to the realities of invention.

Today the court rejects this expedient and discards this practice, ruling that all claims containing a process term under the rule of necessity now must be construed, for purposes of infringement, as limited to use of any process term that was used to assist in defining the product. That is, such a product is not patented as a product, however it is produced, but is limited to the process by which it was obtained. This is a new restraint on patents for new products, particularly today's complex chemical and biological products whose structure may be difficult to analyze with precision. It is a change of law with unknown consequences for patent-based innovation.

The court acts sua sponte, without explanation of what policy is intended to be served by this change, without consideration of the technologies that may be adversely affected by elimination of this expedient, without notice to those whose property rights may be diminished. In so doing, the court departs from statute, precedent, and practice. This change is as unnecessary as it is flawed, gratuitously affecting inventions past, present, and future. I respectfully dissent.

DISCUSSION

For most product inventions, the process by which the product was made, whether or not the process is itself a patentable invention, is not stated in the
product claims. However, as the variety and complexity of invention and technology have increased, various forms of product claims with process terms have been used in specific circumstances, depending on the nature of the invention.1 The form here at issue relates to product claims for new and unobvious products whose structure is not fully known, and for which process parameters are used to aid in defining the product. This claiming expedient has been recognized since at least 1891.

The court today overrules this expedient for all circumstances, brooking no exception. Acting en banc for the purpose, the court rules that if any process term or descriptive aspect is included in a product claim to aid in distinguishing a new product, the claim cannot be infringed by the identical product unless the same process aspect is used in making the accused product. The court holds that it is irrelevant whether the product is new or was known, irrelevant whether the product could have been fully described by its structure at the time of the patent application, irrelevant whether the particular invention is a new product or is actually a process. The court adopts a simplistic universal rule, thereby targeting a small but significant class of inventions. The effect of this decision on innovation in complex fields of science and technology is unknown to the court, for we have had no advice on the consequences of this change of law. My dissent is directed as much to the court's procedure, as to the substance of the court's decision.

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II

PRECEDENT AND PRACTICE

The court's opinion does not mention the long-established precedent that it is overturning. This is not a simple conflict between isolated rulings of the Federal Circuit; it is a change of law and practice with roots in century-old decisions. I start with this precedent, for the expedient of what came to be called the "rule of necessity" originated in the recognition, by the courts and the Patent Office, that not all new products could be fully described by their structure, due to the state of scientific knowledge or available analytical techniques. It was also recognized, over a century ago, that sufficient distinction from prior art products could sometimes be achieved by reference to how the product was made. Thus the courts and patent administrators established the exception that permitted inclusion in a product claim of sufficient recitation of how the product was made, to aid in identifying the product and distinguishing it from the prior art. This claim form
was loosely called a "product-by-process" form, although that term includes a
variety of situations, see n. 1 supra,[*], having diverse legal consequences. The
only form here at issue is that in which the product is new and its structure is not
fully or readily known, such that its definition as a product is aided by referring to
how it was made. Since before 1891, this has been an accepted way to claim
products as products, recognizing that this is an exception to the general rule that
new products are claimed without reference to the process by which they are
produced.

This exception was discussed in 1891 in Ex parte Painter, the Commissioner
of Patents explaining that when there is entitlement to a patent on a new article of
manufacture, it can be claimed by reference to the process of producing it, when
the inventor lacks other language to "define and discriminate" the invention:

“It requires no argument to establish the proposition that as a rule a claim for
an article of manufacture should not be defined by the process of producing that
article. On the other hand, when a man has made an invention his right to a patent
for it, or his right to a claim properly defining it, is not to be determined by the
limitations of the English language. When the case arises that an article of
manufacture is a new thing, a useful thing, and embodies invention, and that article
cannot be properly defined and discriminated from prior art otherwise than by
reference to the process of producing it, a case is presented which constitutes an
exception to the rule.”

1891 C.D. 200, 200-01 (Comm'r Pat. 1891). The Commissioner cited, as an earlier
example of this exception, the claim in Globe Nail Co. v. U.S. Horse Nail Co., 19
F. 819 (C.C.D.Mass.1884) (sustaining validity of claim directed to horse-shoe nail
claimed by reference to its process of manufacture, and finding it infringed by the
accused nail having only a "trivial and unsubstantial variation" from the claimed
product). In contrast, where the patent application made clear that the product
could be described by its structure, the Patent Office ruled that the exception did
not apply. See, e.g., Ex parte Scheckner, 1903 C.D. 315, 315-16 (Comm'r
Pat.1903) (sustaining rejection of claim directed to an etched printing-plate that
"specifies certain steps by means of which the etching is accomplished" because
other claims "define the plate in terms of its structure").

[*]Note 1: “As discussed by Eric P. Mirabel, Product-By-Process Claims: A Practical
Perspective, 68 J. Pat. & Trademark Off. Soc'y 3, 3-4 (1986), the various forms of product-by-
process claims include "true" product-by-process claims, product claims with a process
limitation, product claims with a process-derived structural element, and product claims with
functional terms.”
This expedient has been discussed in various judicial decisions. In all cases the issue has not been whether this expedient was available, for its availability was not challenged; the issue was simply its application to the particular facts. For example, at a time when it heard direct appeals from Patent Office rulings, the D.C. Circuit remarked on this "only exception" to the general rule of product claiming, stating:

“It is a well-settled rule of patent law that claims for a product which is defined by the process of producing it will not be allowed; and the only exception to this rule seems to be in cases where the product involves invention and cannot be defined except by the process used in its creation. In extreme cases of this character, the product may be allowed; but that is not this case, especially in view of the broad claims allowed appellant in his copending application....”

In re Brown, 29 F.2d 873, 874 (D.C.Cir. 1928) (emphasis added).

The Court of Customs and Patent Appeals discussed precedent involving claims for processes and products in various factual situations, and summarized that:

“Where it is possible to define a product by its characteristics, the practice is clearly settled that this should be done. Where, however, the product is novel and involves invention and cannot be defined except by the steps of the process involved in its creation, there are cases holding that such a claim may be allowed, and it has been sustained by a Court.”

In re Butler, 17 C.C.P.A. 810, 37 F.2d 623, 626 (1930) (emphasis added) (quoting Ex Parte Feisenmeier, 1922 C.D. 18 (Comm'r Pat.1922)). The CCPA then found this rule inapplicable to the facts of Butler's invention, explaining that "the record at bar does not meet this requirement [that the product was new]." Id.

In In re Lifton, 189 F.2d 261 (CCPA 1951), the CCPA again commented on this exception for product claims, stating that when "proper article claims" were possible they must be used, with the exception of when such claims are "impossible":

“This court has uniformly held that a claim for an article must define the article by its structure and not by the process of making it. The one exception to this rule, where the invention is the article and it is impossible to otherwise define it, is clearly ruled out in the present case because appellant has demonstrated the
possibility of proper article claims by including several devoid of process limitations.”

Id. at 263 (emphasis added, citations omitted). The court again recognized "the one exception," holding once again that it does not apply when the product can be described independently of the process of making it.

These inquiries into the facts warranting application of the exception demonstrate that the rule of necessity was seldom applied, but was nonetheless recognized both by the courts and the Patent Office. Decisions of the Patent Office Board of Appeals illustrate the practice. See, e.g., Ex parte Pfenning, 65 U.S.P.Q. 577 (Pat.Off. Bd.App.1945) (allowing claim "directed to a product which results from the method of claim 9" in light of applicant's argument that "it is impossible in the instant case to define the product adequately in terms of the elements which compose it or in terms of its physical characteristics"); Ex parte Lessig, 57 U.S.P.Q. 129 (Pat.Off.Bd.App. 1943) (allowing claim for a "product containing vulcanized rubber" strongly adhered to fibers which "has been prepared by the process of claim 4" because "it is not possible to otherwise distinguish over the art of record").

Commentators have explained that this claiming practice became of increasing importance as the complex sciences blossomed. See, e.g., Mark D. Passler, Product-by-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act, 49 U. Miami L.Rev. 233, 233 n. 3 (1994) ("Such claims are often used by companies to patent complex drug or chemical products whose structure is not completely understood and, therefore, can only be accurately described by the process through which it is made."). It is well known that the full structure of some chemical and biological products is not always known at the time the patent application is filed. Indeed, it is a tenet of the scientific method that explanation and theory tend to follow, not precede, the observation of a development in the science.

The CCPA continued to recognize the use of process terms to aid in describing new products—the form of claim sometimes called a "pure" product-by-process claim, see n. 1 supra — and repeatedly ruled that such claims are properly viewed as product, not process, claims. The court also disallowed such claims where the product itself was not novel and unobvious. The court confirmed that such a claim, when justified for a novel and unobvious product, is properly construed as encompassing the full scope of a product claim. For example, in In re Bridgeford, 357 F.2d 679 (CCPA 1966), the court again explained that a new
product may be defined by the process of making it if there is no other way to
describe the product, stressing that "the invention so defined is a product and not a
process," id. at 682. The Bridgeford court relied on this view of the scope of the
product-by-process claims in a related patent, and held unpatentable for double
patenting claims that defined the "product per se." Id. at 680. The court explained
that product-by-process claims are true product claims, and overruled the
suggestion in In re Freeman, 166 F.2d 178, 181 (CCPA 1948), that product-by-
process claims are "dependen[t] ... on process limitations" and therefore
coextensive with process claims. Bridgeford, 357 F.2d at 683 n. 6 ("While there is
some language in Freeman to support the contention that a product-by-process type
claim differs only `in scope' from a process type claim and they therefore `are
directed to a single invention,' (166 F.2d at 181) so far as this is inconsistent with
our holding here it must be overruled.").

My colleagues misstate the holding of Bridgeford, for Bridgeford directly
contravenes today's holding. In Bridgeford the CCPA noted that "some courts"
have construed claims with process steps as limited to the recited process, id. at
683 n. 5, apparently without inquiring whether the rule of necessity justified full
product scope for the invention at issue. The CCPA's observation that patents are
construed inconsistently in other courts cannot be taken, as apparently do my
colleagues, as error by the CCPA. To the contrary, the inconsistency among courts
led eventually to consolidation.[Footnote 2] Again in In re Brown, 459 F.2d 531
(CCPA 1972), the CCPA explained that product-by-process claims are product
claims, not process claims, and that the patentability of the product must be
established independently of the process by which it is identified. See id. at 535
("[I]n spite of the fact that the claim may recite only process limitations, it is the
patentability of the product claimed and not of the recited process steps which must
be established.").

Other decisions discussing application of this expedient to claims directed to
complex new products include In re Pilkington, 411 F.2d 1345, 1349 (CCPA 1969)
("While we are satisfied that the references of record do not anticipate appellant's
glass or demonstrate that it would be obvious, the differences between that glass
and the glass of the prior art do not appear to us to be particularly susceptible to
definition by the conventional recitation of properties or structure.")., and In re

[Footnote 2] The Hruska Commission Report, which informed the debate that eventually led to the
formation of our court, described the varying attitudes towards patents held by the regional
courts of appeal and the variations in patent rulings among the circuits. See Commission on
Revision of the Federal Court Appellate System Structure and Internal Procedures:
“Patent rights over a chemical product are typically independent of the process by which the product is made, and are particularly valuable because of this fact. This independence is normally accomplished by defining the product in terms of its structural features alone, with no reference in the claims to process steps whatsoever. The state of chemical technology, however, is sometimes too limited for a structural description of this type to be made. The structure of some chemicals, especially those including elaborate polymer chains, cannot be accurately determined. The same chemicals, however, may be both economically valuable and technologically reproducible, in the sense that they can be reliably made by subjecting a particular set of raw materials to a particular set of process steps. ***

“The law reacted to these difficulties by making it easier to obtain traditional product protection over this special class of chemicals. The inventor was allowed to describe such a chemical in terms of how one gained possession of it, that is, by way of the process steps by which it was made. Once he did so, the law preserved to the inventor the fullest measure of product-only protection that it could; it treated the process recitations as proxies for the direct recitations of structure that could not be made. Such a claim was therefore equivalent to one stated in terms of structure only. It would broadly dominate all methods by which the chemical could be made or used. At the same time, it carried the same dangers of running afoul of the art: it would be anticipated if the chemical had been produced previously, even if by a method other than what the inventor disclosed.”


The en banc court appears to misunderstand this precedent, for my colleagues now state that "binding case law" of the Court of Customs and Patent Appeals and the Court of Claims mandates a single rule for all claims that contain any process terms, whether the product is novel or known, citing In re Hughes, 496 F.2d 1216 (CCPA 1974), for this proposition. However, Hughes does not state this proposition; Hughes stands for the contrary proposition. In Hughes the question
was the patentability of claims directed to "shakes" as are used in roofing, as follows:

“12. Shakes manufactured from a shake bolt by the process of making a plurality of cuts into and across the shake bolt to an extent to establish predetermined tip lengths, and splitting the weather end portions of the shakes from the bolt by starting the splits at the inner ends of the cuts and continuing the splits to the end of the bolt.”

This claim had been rejected as an improper product-by-process claim, on the ground that the product could be described without including process steps. The Hughes court acknowledged the general rule against product-by-process claiming, but also explained the "proper exception to the general rule" as first set forth in Painter, as follows:

“[T]he Commissioner of Patents enunciated the general rule that a product should not be defined in terms of the process of making it. In Painter, a proper exception to the general rule was found on the ground that the product could not be properly defined and discriminated from the prior art otherwise than by reference to the process of producing it. This basic rule and the exception have been recognized and followed continuously by the Patent Office and the Courts.”

Hughes, 496 F.2d at 1218 (quoting approvingly the Solicitor's argument). The court reaffirmed that "in spite of the fact that a product-by-process claim may recite only process limitations, `it is the product which is covered by the claim and not the recited process steps.'" Id. Contrary to my colleagues' statement, Hughes did not eliminate this form of claim, or change its role as a product claim. Indeed, the Hughes court applied the exception and reversed the Board's rejection of a product-by-process claim, stating:

“We agree with appellant that the [general] rule should not be applied to the situation before us. We have been shown no true product claim which describes appellant's invention, in the words of the solicitor, "in terms of structure or physical characteristics." When an applicant seeks to describe his invention by a product-by-process claim because he finds that his invention is incapable of description solely by structure or physical characteristics, it is incumbent upon the Patent Office to indicate where, or how, the applicant's invention is, or may be, so described.”
Id. at 1219. My colleagues could hardly have selected less apt support for their construction of product-by-process claims, for Hughes explicitly states that such claims are for the product, not the process.

In addition to misstating precedent of the CCPA, the en banc court also mischaracterizes the decisions of our predecessor the Court of Claims, stating that the Court of Claims' decisions support today's ruling. The court cites *Tri-Wall Containers v. United States*, 408 F.2d 748 (Ct. Cl. 1969), for this purpose. That citation, too, is mysterious, for in *Tri-Wall Containers* the court found that the claimed product was not "new" because it had been on sale for more than the permitted period, although the product that was on sale had been made by a different process than the process stated in the claim. The Court of Claims stated that the evidence showed that "the prior art product and the claimed product are structurally identical," id. at 751, and explained that a known product cannot be patented by including process terms in the claim:

"It is well established that a product claimed as made by a new process is not patentable unless the product itself is new. The *Wood-Paper Patent*, 90 U.S. (23 Wall.) 566, 596 (1874), *Cochrane v. Badische Anilin & Soda Fabrik* ["BASF"], 111 U.S. 293, 311 (1884) ***

"More recent cases point out that the addition of a method step in a product claim, which product is not patentably distinguishable from the prior art, cannot impart patentability to the old product. *Jungersen v. Baden*, 69 F.Supp. 922, 928 (S.D.N.Y.1947), *aff’d*, 166 F.2d 807 (2d Cir.1948), *aff’d*, 335 U.S. 560 (1949); *In re Stephens*, 345 F.2d 1020 ,1023 (CCPA 1965)."

*Tri-Wall Containers*, 408 F.2d at 750-51. This case applied the standard rule that old products cannot be patented—it contains no statement limiting the scope of claims that include process aspects to aid in describing new products. The Supreme Court cases cited in *Tri-Wall* are all directed to new processes for making old products—these are the same cases that the en banc court today incorrectly applies to new products, as I discuss post.

Contrary to my colleagues' statement, CCPA and Court of Claims precedent do not support today's en banc thesis. Our predecessor courts understood the complexity of patenting, and the CCPA consistently implemented the expedient whereby process terms contributed to the description of complex new products of incompletely known structure. These courts recognized the independence of
product claims for new products, and did not limit such claims to the specific process steps that were used to aid in describing the product. [footnote 3]

With the advent of the Federal Circuit, this court continued to apply these principles. In In re Thorpe, 777 F.2d 695 (Fed. Cir. 1985), the court explained that product-by-process claims are anticipated when the product existed in the prior art, even if the product was made by a different process. My colleagues are mistaken in stating that Thorpe held that all such claims are to be construed as process claims, even when the product is new and the rule of necessity justifies this mode of describing the invention. In Thorpe the product was not new; it was a known color developer for carbonless paper copy systems, and this court held that the PTO correctly rejected the claim to "the product of the process of claim 1," explaining that since the product was old it could not be claimed as a product, whether or not process steps are recited in the claim.

The facts of Thorpe did not concern the exception and expedient where process terms are invoked to describe a new product of complex structure. This exception is rarely invoked. The general rule requiring claims to have a process-free definition of the structure of a new product accommodates most inventions. Some recent exceptions are seen in emerging aspects of biotechnology. For example, in Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F.Supp. 94 (D.Mass. 1989), aff'd in relevant part, 927 F.2d 1200 (Fed.Cir. 1991), the district court considered the following claim:


Our predecessor's legal and scholarly distinction in the field of patent law, and the high regard in which Congress and the innovation communities held the jurisprudence of the CCPA were a critical foundation for formation of the Federal Circuit and its charge to reinvigorate the role of the patent system in service to the nation's technological innovation. See 125 Cong. Rec. 23,462 (1979) (statement of Sen. DeConcini) ("It is a reflection of high esteem which Congress has for the sitting judges of the Court of Claims and Court of Customs and Patent Appeals that these judges will become the first judges of the new Court of the Federal Circuit.").
“4. A procaryotic or eucaryotic host cell transformed or transfected with a DNA sequence according to claim 1, 2 or 3 in a manner allowing the host cell to express erythropoietin.”

Id. at 108. The district court found claim 4 "ambiguous," explaining that while it is directed to a new product—this host cell—the words "transformed or transfected" appear to invoke a process. The district court recognized that "[i]n the traditional patent framework, a product is wholly separate and distinct from a process." Id. at 107. The court observed that "[a] product patent gives the patentee the right to restrict the use and sale of the product regardless of how and by whom it was manufactured," while "[a] process patentee's power extends only to those products made by the patented process." Id. (quoting United States v. Studiengesellschaft Kohle, 670 F.2d 1122, 1127-28 (D.C.Cir. 1981)). The district court, affirmed by the Federal Circuit, found this claim to be valid and infringed as a product claim, and although many issues and arguments were present in this litigation, the applicability of the venerable rule of necessity was not at issue.

In Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565 (Fed.Cir.1991), the Federal Circuit addressed the interpretation and scope of claims exemplified by claim 13:

13. Highly purified and concentrated VIII:C prepared in accordance with the method of claim 1.

Claim 1 set forth the method referred to in claim 13, as follows:

1. An improved method of preparing Factor VIII procoagulant activity protein [VIII:C] comprising the steps of

(a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP,

(b) eluting the VIII:C,

(c) adsorbing the VIII:C obtained in step (b) in another adsorption to concentrate and further purify same,

(d) eluting the adsorbed VIII:C, and

(e) recovering highly purified and concentrated VIII:C.
Abbott Laboratories v. Sandoz, page 18

It was not disputed that the product was a new product, that the "highly purified and concentrated" blood clotting Factor VIII:C had not previously been obtained, and that a complete structural identification of Factor VIII:C was not available. The defendant Genentech had made its commercial Factor VIII:C not by the method set forth in claim 1, but by using a sample of the Scripps product to "clone" Factor VIII:C protein using recombinant DNA techniques. One question presented in the case was whether claims such as claim 13 were infringed by the same product produced by a different method, or whether such claims were infringed only if the accused infringer used the process of claim 1.

Scripps stressed that its product was novel and enabled and was patentable as a product, although the full structure of Factor VIII:C was not available at that stage of the science. The court addressed whether claims exemplified by claim 13, properly construed, were product claims, or whether they were limited to the specific processes in the process claims to which they referred. This court held that the claims were product claims. The court held that since claims are construed the same way for infringement as for validity, the question was whether the Genentech product was the same as the claimed product, not whether they were produced by the same process. The court remanded to the district court for this factual determination. Scripps, 927 F.2d at 1584.

After Scripps was decided, a panel of this court decided an appeal concerning plastic innersoles for shoes. In Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834 (Fed.Cir.1992), the claims at issue were represented by:

“Claim 24. The product produced by the method of claim 1.”

In turn, claim 1 was as follows:

“1. In a method of manufacturing a shock-absorbing, molded innersole for insertion in footwear, which method comprises:

(a) introducing an expandable, polyurethane into a mold; and

(b) recovering from the mold an innersole which comprises a contoured heel and arch section composed of a substantially open-celled polyurethane foam material, the improvement which comprises:

(i) placing an elastomeric insert material into the mold, the insert material having greater shock-absorbing properties and being less resilient than the molded, open-celled polyurethane foam material, and the insert material having sufficient
surface tack to remain in the placed position in the mold on the introduction of the expandable polyurethane material so as to permit the expandable polyurethane material to expand about the insert material without displacement of the insert material; and

(ii) recovering a molded innersole with the insert material having a tacky surface forming a part of the exposed bottom surface of the recovered innersole.”

The panel held that a claim in the form of claim 24 always requires use of the referenced method, and that it is irrelevant whether the product was new or known. The court stated that the rule of necessity, as applied in Scripps, is contrary to Supreme Court rulings. The panel stated that the decision in Scripps is incorrect. A majority of the Federal Circuit declined to resolve the conflict en banc, resulting in several further opinions. E.g., Atlantic Thermoplastics Co. v. Faytex Corp., 974 F.2d 1279 (Fed.Cir.1992) (dissents of Chief Judge Nies and Judges Rich, Newman, and Lourie from denial of rehearing en banc). Judge Rich wrote:

“[T]his whole excursion was unnecessary because the patentee admitted that claim 24, the product-by-process claim, was limited to the process. The claim read: "The molded innersole produced by the method of claim 1." There was, therefore, no occasion to review the law to determine how the claim should be construed.... We are not here to provide restatements of the law. Such restatements should not be made without an opportunity for all affected parties to be heard from. The affected parties here are not the vendors of inner soles but largely the entire chemical industry, particularly the pharmaceutical manufacturers.”

Id. at 1280 (Rich, J., dissenting from denial of rehearing en banc).

Most trial courts continued to recognize the rule of necessity. For example, in Trustees of Columbia University v. Roche Diagnostics GmbH, 126 F.Supp.2d 16 (D.Mass.2000), the district court considered claims such as the following.

72. A eukaryotic cell into which foreign DNA I has been inserted in accordance with the process of claim 54.

The court referred to the Scripps/Atlantic conflict, concluded that the earlier panel decision controlled under the Federal Circuit's rule, see Newell Companies, Inc. v. Kenney Manufacturing Co., 864 F.2d 757, 765 (Fed.Cir.1988) ("This court has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned in banc."), and applied
the Scripps ruling, holding that the new cell was not limited by the process by which it was made.

The PTO also continued to apply the rule of necessity. In instructing examiners that products should whenever possible be described without reference to how they were made, the PTO continued to point out the exception that patentability as a product is not foreclosed when independent description is not available. The Manual of Patent Examining Procedure (MPEP) instructs the examiner to consider the structure implied by any process steps in the claim:

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.

MPEP § 2113 (8th ed., July 2008 rev.). This has been the practice since at least Ex parte Painter in 1891. I am surprised at the en banc court's casual misstatement about "the treatment of product-by-process claims throughout the years by the PTO," maj. op. at 1293, for the statement is directly contrary to the treatment of such claims throughout the years by the PTO.

The en banc court's insistence that one universal rule should now be applied is contrary to the entire body of decisional law, including the Supreme Court cases cited by my colleagues. As I next discuss, in most of the cited cases the product was not a new product and thus was not patentable as a product, whether or not any process term was included in the claim. The Court consistently held that when the product was old and only the process was a patentable invention, a claim for the "product of that process" could not cover the old product made by a different process. That is, and has always been, the law. I comment briefly on the Court's cases that my colleagues misinterpret and misapply:

Cochrane v. BASF

The en banc opinion relies primarily on Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884) ("BASF"), even though my colleagues acknowledge that the product in that case was the well-known dye alizarine. The patent before the Court was a reissue patent that claimed artificial alizarine in the following way:
Artificial alizarine, produced by either of the methods herein described, or by any other method which will produce a like result.

The Court held that since alizarine was a known product, the claim was limited to the patentee's two processes, stating:

“It was an old article. While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time, in contradistinction from being eliminated from the madder root. Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared, artificially, for the first time, from anthracite, if it was set forth as alizarine, a well-known substance. *Wood-Paper Patent*, 23 Wall. 566, (1874). There was therefore no foundation for reissue No. 4,321, for the product, because, on the description given, no patent for the product could have been taken out originally.”

111 U.S. at 311-12, 4 S.Ct. 455. The Court accordingly limited the claim to the two processes described in the patent, and in the portion of BASF quoted by my colleagues, the Court discussed the proofs needed to show infringement:

“[U]nless it is shown that the process of [the specification] was followed to produce the defendants' article, or unless it is shown that the article could not be produced by any other process, the defendants' article cannot be identified as the product of the process of [the specification]. Nothing of the kind is shown.”

Id. at 310. The Court did not state, or imply, despite my colleagues' contrary theory, that a claim to a new and complex product that is of necessity defined and distinguished by the process by which it was made, can never be infringed unless that specific process is practiced. There was no issue in BASF of a product that could not be defined without reference to how it was made. The BASF Court, providing guidance, remarked on the importance of independent description of a patented product, in the following sentence cited by my colleagues:

“Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.”

Id. at 310. This statement is indeed the general rule, as stated by the Patent Commissioner several years later in Ex parte Painter. However, BASF did not present the situation for which the expedient of necessity was created, for as the
Court stated, the invention was "a process for preparing alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine, to be prepared, however, by the new process, which process is to be the subject of the patent, and is the process of preparing the known product alizarine from anthracine." Id. at 308-09.

This was not an instance of a new product describable only in terms of its process of manufacture. The BASF decision lends no support to today's en banc rule that every product claim that mentions a process step is always restricted to that process, with no exception, no expedient, no preservation of the distinctions among forms of claim based on the nature of the invention.

**The Goodyear Dental cases**

The en banc court also states that its new ruling is supported by two cases relating to a patent on the use of vulcanized rubber to form a plate for holding dentures, *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. (3 Otto) 486 (1876), and *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. (12 Otto) 222 (1880). Review of these cases reveals no support for the en banc court's statement of their holdings. The claim at issue was:

“The plate of hard rubber or vulcanite, or its equivalent, for holding artificial teeth, or teeth and gums, substantially as described.”

*Davis*, 102 U.S. (12 Otto) at 223. The claim was written in the then-standard format of incorporating the description in the specification through the phrase "substantially as described." This was not a product-by-process or product-of-the-process claim at all, for the claim contains no process distinction or limitation, but simply refers to the description in the specification. Nonetheless, the en banc majority appears to state that these cases mean that the Supreme Court requires that all claims for products whose method of production is set forth in the specification—as is required by the description and enablement requirement—cannot be infringed unless that method is used.

That is not what the Goodyear Dental cases said. The Court referred to the position of Goodyear Dental Vulcanite that its patent covered all dental plates made of vulcanized rubber, and held, upon reviewing the specification and the prior art, that the process of manufacture was what distinguished this dental plate from the prior art dental plates, and concluded: "The invention, then, is a product or manufacture made in a defined manner. It is not a product alone, separated from
the process by which it is created." *Smith*, 93 U.S. (3 Otto) at 493. Were the claim not limited to this process, the Court concluded that the claim would not have been patentable. See *id.* at 492 (holding that if the patent were for a "mere substitution of vulcanite for other materials, which had previously been employed as a base for artificial sets of teeth" then it "constituted no invention"). Four years later, considering the same patent in *Davis*, the Court emphasized that the claim was limited to use of vulcanized rubber or its equivalent, and held that since the accused infringer made its dental plate with celluloid, there could not be infringement. See 102 U.S. (12 Otto) at 228-30.

The court today cites these cases as definitive of the interpretation of claims with process elements, although the only process referent is the phrase "substantially as described." This flawed reasoning was disposed of in 1890 in the classic Robinson on Patents, and until now has not reappeared:

“In stating Claims certain phrases are frequently employed to which a special importance seems to be attached by applicants. Among these are the phrase "substantially as described" and others of the same meaning. These phrases import the same thing when used in a Claim as when elsewhere employed. They are neither necessary nor technical. The reference they make to the Description is always implied, and relates only to the essential features of the invention as therein delineated. They add nothing, therefore, to the certainty of the Claim, nor do they detract from it unless the claimant carelessly inserts them as a substitute for a more clear and definite statement of his invention.”

II W.C. Robinson, Robinson on Patents 517 (1890) (footnotes omitted).

**Merrill v. Yeomans**

My colleagues also rely on *Merrill v. Yeomans*, 94 U.S. (4 Otto) 568 (1877). Again, the relevance is remote. The Merrill Court explained that the issue was the "correct construction of plaintiff’s patent," *id.* at 569, construing the following claim:

“[T]he above-described new manufacture of the deodorized heavy hydrocarbon oils, suitable for lubricating and other purposes, free from the characteristic odors of hydrocarbon oils, and having a slight smell like fatty oil, from hydrocarbon oils, by treating them substantially as hereinbefore described.”
Abbott Laboratories v. Sandoz, page 24

Id. at 570. The Court examined the specification to determine what was invented, and found that the invention was directed solely to a process, not to a product. The Court then concluded that the claim's usage "new manufacture" referred to the manufacturing process, and not to the product. The claim was thus a process claim, and no "product-by-process" issue was presented. The Court concluded that the defendant's oil, which was made by a different process, did not infringe.

The Merrill Court discussed its practice of looking to the patent application and interpreting the claim in light of what was "really invented":

"[W]here it appears that a valuable invention has really been made, this court, giving full effect to all that is found in the application on which the Patent Office acted, will uphold that which was really invented, and which comes within any fair interpretation of the patentee's assertion of claim."

Id. at 573. This approach is inimical to the en banc court's theory that it is irrelevant what the patentee describes as his invention, and that if a process step is mentioned in the claim or "substantially described" in the specification, the claim always requires performance of that step. Although the Court in Merrill was not confronted with a situation of indescribable product or necessity bred of complexity—indeed no product at all was claimed—neither did the Court hold that every product invention must be limited by the process that produced the product.

The Wood Paper Patent case

The list of Supreme Court cases relied on by my colleagues continues with The Wood-Paper Patent, 90 U.S. (23 Wall.) 566, 596 (1874), where claims with the standard "substantially as described" language were construed in two reissue patents relating to the pulping of wood to make paper. The Court explained that one reissue patent was for "a product or manufacture, and not for the process by which the product may be obtained," and the other "for a process and not for its product." Id. at 593. The Court examined the prior art and concluded that the claim for the product could not be sustained, because the product produced by the inventor's new pulping process was not new:

"Paper-pulp obtained from various vegetable substances was in common use before the original patent was granted to Watt & Burgess, and whatever may be said of their process for obtaining it, the product was in no sense new. The reissued patent, No. 1448, is, therefore, void for want of novelty in the manufacture patented."
Id. at 596. The Court then discussed the reissue patent for the "process and not for its product," and held this reissue void because it claimed a different invention than in the original patent. The Court also discussed several other patents directed to boilers used to produce paper-pulp, and to a process for bleaching straw. Nothing in this case concerns the product-by-process issue on which the court is today acting.

I cannot discern why the en banc court relies on The Wood-Paper Patent case as invalidating Scripps, and the court has not attempted to explain.

Plummer v. Sargent

The en banc court also relies on Plummer v. Sargent, 120 U.S. 442 (1887), which again provides no support for my colleagues' thesis. This case again illustrates the Court's practice of reviewing what the patentee stated he invented as set forth in the specification in light of the prior art. The claim in Plummer was for a "new manufacture," "substantially as described":

“What I claim and desire to procure by letters patent is the new manufacture hereinabove described, consisting of iron ornamented in imitation of bronze by the application of oil and heat, substantially as described.”

Id. at 445. The trial court had found non-infringement because the defendant had used a prior art process for bronzing iron. This prior process was work of F.W. Brocksieper, an employee of the defendant's predecessor company. The Supreme Court affirmed, stating that the claims were limited to the process described in the specification:

“It seems necessarily to follow from this view either that the Tucker patents are void by reason of anticipation practiced by Brocksieper, or that the patented process and product must be restricted to exactly what is described....”

Id. at 449. The Court thus limited the claims to the process described by the patentee, not because of any rule about limiting a product to how it was made in the specification, but to sustain validity of the patent in view of the Brocksieper prior art. The decision in Plummer is unrelated to any rule of claim construction based on whether process terms are included in the claim.

These nineteenth-century cases do not relate to the en banc court's new universal rule of claim construction, whereby all product claims having process terms are treated as process claims, whatever the nature of the product, whatever
the need for process descriptors, or any other factor that precedent shows to be relevant to the exception that is here at issue as to the use of and construction of such claims. Nor do any more recent Court cases.

General Electric v. Wabash

My colleagues also cite General Electric Co. v. Wabash Appliance Corp., 304 U.S. 364 (1938), although the relevance of this case is, again, not apparent, for it involved no product-by-process claims, but rather claims that recite the properties of the product. A typical claim is claim 25, which describes an electric lamp filament composed of tungsten grains of a size and shape that prevents sagging of the filament:

“25. A filament for electric incandescent lamps or other devices, composed substantially of tungsten and made up mainly of a number of comparatively large grains of such size and contour as to prevent substantial sagging and offsetting during a normal or commercially useful life for such a lamp or other device.”

Id. at 368. The Court held this claim "invalid on its face" for failing to provide a "distinct and definite statement of what he claims to be new, and to be his invention." Id. at 369. The Court stated that the description of the grains as "of such size and contour as to prevent substantial sagging and offsetting" was "inadequate as a description of the structural characteristics of the grains." Id. at 370. The Court also criticized the use of functional language in the claim, stating that such terms were too indefinite to provide clear guidance. Id. at 371. There was no issue of whether process steps in the claims were regarded as limiting, for there were no process steps in the claims. Instead, the Court stated that even the implicit inclusion of process steps could not save the claim, because the description of the process in the specification was inadequate:

“Even assuming that definiteness may be imparted to the product claim by that part of the specification which purportedly details only a method of making the product, the description of the Pacz process is likewise silent as to the nature of the filament product.”

58 S.Ct. 899. The Court held the patent invalid for lack of a "distinct and definite" description of the invention, for the court "doubted whether one who discovers or invents a product he knows to be new will ever find it impossible to describe some aspect of its novelty." Id. Whatever the inadequacies in the Pacz description of his invention, the Court's optimistic view of scientific capability cannot be deemed to
have barred all recourse to the rule of necessity when it is warranted, or to have voided the ensuing seventy-one years of Patent Office and judicial recognition of this pragmatic expedient.

No Supreme Court case discussed the problems of complexity and structural analysis that warrant this expedient, or created a legal solution to these problems. It is inappropriate, unsupported by law or precedent, and contrary to the purposes of patent systems, for this court now to rule that such products cannot be patented as products.

Regional circuit decisions

My colleagues also rely on some decisions of the regional circuits preceding this court's formation, announcing that "our sister circuits also followed the general rule that the defining process terms limit product-by-process claims," and citing two cases, one decided in 1915 and one in 1977. These cases do not support the en banc court's opinion, and raised no issue of an expedient based on necessity.

In Hide-Ite Leather Co. v. Fiber Products Co., 226 F. 34 (1st Cir.1915), the appeal was of two process claims for making leatherboard, and a product claim for leatherboard "made from pulp" and reciting the second step in the process claims plus the reference "substantially as described." The accused infringer did not use

[footnote 4] It is curious to observe this en banc court extolling decisions of the regional circuits as authoritative, while it disregards the decisions of our predecessor courts and of this court. This court was created to remove patent law questions from the regional circuit courts. See H.R. Rep. 96-1300, at 20 (1980) ("Directing patent appeals to the new court will have the beneficial effect of removing these unusually complex, technically difficult, and time-consuming cases from the dockets of the regional courts of appeals.... [T]he central purpose is to reduce the widespread lack of uniformity and uncertainty of legal doctrine that exist in the administration of patent law."); see also Federal Courts Improvement Act of 1979: Hearings Before the Subcomm. on Improvements in Judicial Machinery of the Comm. on the Judiciary, U.S. Senate, 96th Cong. 197 (1979) (statement of Hon. Henry J. Friendly) ("What is needed is a group of judges, some but not all patent lawyers, with scientific training and interest, aided both by law clerks of similar bent and by a staff of experts in a variety of technologies, such as the Court of Customs and Patent Appeals has had for years and the courts of appeals in the very nature of things, cannot..."). To cite two regional circuit decisions, while jettisoning the precedents of the court uniquely qualified to address patent questions and selected to supplant the regional circuits, is puzzling.
the same first step of the process. The court found that the invention was for a process, not a product, and therefore that the product claim was not infringed.

My colleagues also cite *Paeco, Inc. v. Applied Moldings, Inc.*, 562 F.2d 870, 876 (3d Cir.1977), in which the court used the specification to resolve an ambiguity in the language of a product claim relating to "replica wooden beams" made of foamed urethane. The court reviewed whether ambiguous claim language required a closed or open mold, for this determined the question of anticipation based on a prior art reference that used an open mold. Thus the court stated that the manufacturing process described in the specification was "of paramount importance," and construed the claim in light of that process as requiring a closed mold, thus preserving the claim's validity as against the prior art that used an open mold. The sentence quoted by my colleagues out of its context, does not relate to the en banc court's new rule concerning process terms in product claims, and the Paeco case raised no question of whether the product was capable of description apart from the process.

In addition to these two cases inaptly cited by the en banc court, other regional circuit decisions also contradict this court's new thesis. In *Dunn Wire-Cut Lug Brick Co. v. Toronto Fire Clay Co.*, 259 F. 258 (6th Cir.1919), the court stated: "Certain it is, in view of the weight of authority and the latest decisions, that the inventor of a new and useful product or article of manufacture may have a patent which covers it and gives a monopoly upon it regardless of great variations in the method of making." Id. at 261.

In *Buono v. Yankee Maid Dress Corp.*, 77 F.2d 274 (2d Cir.1935) (L.Hand, J.), the court held invalid a product claim for a kind of "blind stitch" used in sewing, because the invention lay only in the process of producing the stitch, which itself "was not new." Id. at 279. While the stitch had not been claimed as the product of a particular machine or process, the court remarked on the conceivability of patenting such a product "merely as the product of a machine or process, even though it were anticipated if made in other ways," id., observing that such a claim might serve a useful purpose in protecting against products that were produced by the same machine or process abroad and then imported. Of such a claim, wherein the product itself was anticipated but the process was new, the court stated "it would in that case not be infringed by anything but the product of the ... process." Id. This routine statement of established law does not mean that when the product is itself new and useful and unobvious, it cannot be claimed as a product but must be tied to the machine that made it.
Judge Hand emphasized that this example related only to situations where the product itself was not new. The opinion explained that to be claimed as a product, the product "must be new as such, that is, regardless of the process or machine which makes it; and it must stand upon its own invention, again independently of the machine or process which makes it." Id. This was also the CCPA's view of product claims, providing the precedent carried forward to, and binding upon the Federal Circuit. [Footnote 5]

III

THE EN BANC RULING

Defying precedent, the en banc court adopts for all situations "the basic rule that the process terms limit product-by-process claims," maj. op. at 1293, whether the product is novel or known, and whether or not the new product could not have been fully described by its structure alone. The court eliminates the long-accepted expedient for new products whose structure is not fully known. While the Scripps decision is the only decision that is mentioned as "expressly overruled," maj. op. at 1293, Scripps is only one of many cases now discarded.

The en banc majority's response to the dissenters is to state that "the inventor is absolutely free to use process steps to define this product" if its "structure is either not fully known or too complex to analyze," maj. op. at 1294, but to eliminate the premise that the inventor thereby obtains a product claim, not a process claim. According to the majority, a patentee can continue to obtain product claims using process descriptors, but such product claims are treated as process claims for infringement. The applicant would still have to demonstrate patentability of the new product as a product (independent of the process), while enforcement of the patent against an identical product would be limited to the infringer's use of the process steps used as a descriptor. For the first time, claims are construed differently for validity and for infringement.

[Footnote 5] There has been extensive commentary on this class of claim. See, e.g., Jon S. Saxe & Julian S. Levitt, Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice, 42 J. Pat. Off. Soc'y 528, 559 (1960) ("Except in the chemical arts, a claim to a product must be in terms of the product's objective physical and chemical characteristics; but where these are unknown or impossible to express, a claim may define a product in terms of the process by which it is made. This product-by-process exception is to be distinguished from the use of process terminology as descriptive of a state of being."); Brian S. Tomko, Scripps or Atlantic: The Federal Circuit Squares Off Over the Scope of Product-by-Process Patents, 60 Brook. L.Rev. 1693, 1696 (1995) (the Atlantic decision "pared the scope of a product-by-process patent to that of a glorified process patent").
It has been an inviolate rule that patent claims are construed the same way for validity and for infringement. See, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1330 (Fed.Cir.2003) ("It is axiomatic that claims are construed the same way for both invalidity and infringement."); Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed.Cir.2001) ("Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1363 (Fed.Cir.1998) ("Claims must be interpreted the same way for determining infringement as was done to sustain their validity."); Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir.1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."); Beachcombers, International, Inc. v. WildeWood Creative Products, Inc., 31 F.3d 1154, 1163 (Fed.Cir.1994) ("We have already interpreted the claims for purposes of assessing their validity. The same claim interpretation of course applies to the infringement analysis."); Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1583 (Fed. Cir.1991) ("claims must be construed the same way for validity and for infringement"); SmithKline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 882 (Fed.Cir.1988) ("The claims of the '970 patent measure the invention at issue; thus, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); see also 5A Chisum on Patents § 18.01 (2007) ("A fundamental tenet of patent law is that a claim must be interpreted consistently for purposes of infringement and validity."); id. § 18.03[2][h] (collecting cases).

As interpreted for validity, the claims obtained under the expedient of necessity are product claims, and are subject to the requirements of novelty, unobviousness, and all other requirements for new products, independent of how the products can be made. My colleagues hold that these are product claims for validity, but process claims for infringement. Departure from the rule that forbids such deviation requires sound reason, and fuller exploration than the cursory brush-off dispensed by my colleagues.

I do agree with my colleagues that their logic is "simple." Maj. op. at 1294. However, today's inventions are not simple. The needs of inventions of the past and present, and more so the future, are not simple. The public interest in invention and development of today's complex sciences, is not simple. The en banc court's "simple" hypothetical about "compound X, obtained by process Y," is simply irrelevant to the issues we must resolve. Scientists know that it is often easier to show that two products are the same, than to decipher their chemical or biological
structure; for example, in the case at bar, comparing the X-ray diffraction patterns
and absorption spectra could show that the products are the same, although their
exact crystal structure is undefined. However, my colleagues announce that the
only way to establish whether the accused compound is the same as the patented
compound is by inquiring whether they were prepared by the same method. Maj.
op. at 1293-94 ("[W]hat analytical tools can confirm that the alleged infringer's
compound is in fact infringing, other than a comparison of the claimed and accused
infringing processes?"). That question has many answers, now stated to be
irrelevant.

While the section of this opinion decided by the en banc court is largely
directed to its reversal of precedent, the implementation of its ruling remains with
the original panel. The panel decision enlarges the en banc ruling, further binding
this court. The claims at issue state processes by which the new crystal form is
"obtainable," although the specification states that other methods might be used.
The panel rules that a claim "cannot capture a product obtained by or obtainable by
processes other than those explicitly recited in the claims." maj. op. at 1295,
finding authority in BASF, which I have discussed ante. My colleagues thus
continue to misapply the Court's ruling in BASF, where the Court stated repeatedly
that the product in that case was a known product. BASF, 111 U.S. at 311 ("It was
an old article."). In BASF the Court responded to the patentee's argument that it
was entitled to cover all artificial alizarine made by any process, by observing that
the patentee had not shown how the infringing and patented products "can be
recognized," id. at 310, 4 S.Ct. 455, an aspect at the opposite pole from the case at
bar, where the patentee provided elaborate details as to how the patented and
accused crystal forms can be recognized.

The panel also states that "the applicant's statement in the file wrapper that
`the method of preparation ... is not considered the heart of the present invention'
should not be afforded undue gravitas." Maj. op. at 1296. This too is an aberration
of precedent, and is contrary to the many rulings of the Supreme Court and this
court that afford due gravitas to the applicant's statement of what has been
invented. See, e.g., BASF, 111 U.S. at 308, 4 S.Ct. 455 ("It is very plain that the
specification of the original patent, No. 95,465, states the invention to be a process
for preparing alizarine, not as a new substance prepared for the first time, but as the
substance already known as alizarine, to be prepared, however, by the new process,
which process is to be the subject of the patent...."); Plummer v. Sargent, 120 U.S.
at 443, 7 S.Ct. 640 (quoting specification of companion patent, where inventor
stated "My invention consists in a process of covering iron with a very thin coating
of oil, and then subjecting it to heat, the effect of which is to leave upon the iron a
firm film, which is very durable, and gives the iron a highly ornamental appearance, like that of bronze"). The Federal Circuit's emphasis on the importance of the specification has been repeatedly stated. E.g., *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed.Cir.2005) (en banc) ("[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." (internal quotation marks omitted)).

The en banc court appears to misjudge the implications of its ruling, for the court states that it is now making available to "others the right to freely practice process Z [a different process] that may produce a better product in a better way." Maj. op. at 1294. If others can indeed make a better product, this expedient presents no impediment. That is not the issue of this case. The issue is the right to make the same product, by making a process change that does not change the product. By now assuring that right, the exclusionary value of the claim to a new product is lost.

The purpose of the rule of necessity is to allow inventors of complex new products to obtain the patent scope to which their invention is entitled—the scope of the novel product they invented, no more and no less. The majority's change of law simply imposes unfairness as well as legal error on patent-supported advances.

SUMMARY

Precedent establishes that the correct construction of claims that recite process steps depends, like all claim construction, on what has been invented. No single rule fits all inventions. The construer must view the claims in light of the description of the invention in the specification, the prior art, and the prosecution history. In the complex law and practice of patents and inventions, the special expedient here of concern arises when the precise structure of a new product is not known from the information available when the patent application was filed. The law has enabled and endorsed this expedient of describing a product in order to claim it as a product, whereby validity and infringement are determined as a product, independent of any process term that was used to aid in defining the product. This expedient does not enlarge patent scope; it simply permits patenting what has been invented. A narrow but clear body of law has evolved to accommodate this need of complex technologies. This entire body of law is today overturned, sua sponte and without a hearing, without any participation of those affected, without identification of the intended benefits. I respectfully dissent from the en banc court's rulings, as well as the procedure by which they were reached.
LOURIE, J., dissenting from en banc Section III. A. 2.

I respectfully dissent from the court's en banc holding in Section III. A. 2 that product-by-process claims always require use of the recited process in order to be infringed.

I agree that there is substantial Supreme Court precedent that holds that product-by-process claims require use of the recited process for there to be infringement. However, many of those cases applied overly broad language to fact situations involving old products or used vague language that makes it difficult to determine whether the products were old or new. Clearly, however, when a product is old, a product-by-process claim cannot be interpreted as a claim to the product made by any means. The product is old and unpatentable per se. BASF in fact involved an old product. See Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 311, 4 S.Ct. 455, 28 L.Ed. 433 (1884) ("It was an old article.").

There is arguably a different situation that should apply to chemical-biological products today than to mechanical products of more than a century ago. When a product is new and the inventor claims it by a process of preparation, I fail to see why the product-by-process claim should not be interpreted as a product claim that can be infringed even when the product is made by means other than that recited in the claim. Supreme Court precedent dealing with old products, while utilizing broad language, does not foreclose that possibility. The Court years ago did not have occasion to consider today's innovations or decide whether a distinction should be made between a new chemical-biological product and an old product made by a new process.

And there may be differing results depending upon the exact wording of a claim at issue. For example, a claim reading "when made by" might only be infringed when the recited process is used by the accused, as it is situational. On the other hand, a claim reading "obtainable by" refers to capability, so it might not require use of the process to infringe. "Obtained by" is ambiguous. Bright lines have their uses, but judging should take account of differing circumstances. In addition, of course, in order to sustain any claim for infringement, a patent owner must prove that an accused product is the same as that covered by an asserted claim. If the reason a product was claimed by its process was that its structure was unknown, then, if, at the time infringement is asserted, there still is no means to ascertain structurally whether the accused product is the same as that claimed, the infringement claim fails. However, that should not mean that a new product
claimed by a process of preparation cannot ever be infringed when made by another process.

It may be that with today's analytical techniques there is little need for product-by-process claims. After all, claim 1 of the Abbott patent is a claim to a compound, not only by name, but also by certain of its characteristics. A claim to a product defined by its characteristics or properties surely is a proper claim.

However, product-by-process issues still seem to come before us and I would make a distinction between old products and new products in interpreting product-by-process claims. Accordingly, I respectfully dissent from the court's en banc holding.
PRODUCT-BY-PROCESS CLAIMS

MANUAL OF PATENT EXAMINING PROCEDURE

9th ed. 2014 (as downloaded June 9, 2015)

MPEP § 2113 Product-by-Process Claims [R-08.2012] page 1
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MPEP § 2113 Product-by-Process Claims [R-08.2012]

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).
Furthermore, "[b]ecause validity is determined based on the requirements of patentability, a patent is invalid if a product made by the process recited in a product-by-process claim is anticipated by or obvious from prior art products, even if those prior art products are made by different processes." Amgen Inc. v. F. Hoffman-La Roche Ltd., 580 F.3d 1340, 1370 n 14, 92 USPQ2d 1289, 1312, n 14 (Fed. Cir. 2009). However, in the context of an infringement analysis, a product-by-process claim is only infringed by a product made by the process recited in the claim. Id. at 1370 ("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.").

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding “interbonded by interfusion” to limit structure of the claimed composite and noting that terms such as “welded,” “intermixed,” “ground in place,” “press fitted,” and “etched” are capable of construction as structural limitations.)

**ONCE A PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS FOUND AND A 35 U.S.C. 102/103 REJECTION MADE, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBLVIOUS DIFFERENCE**

“The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature” than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.
In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite which, after ion exchange to remove alkali metal, appeared to be “essentially free of alkali metal.” The court upheld the rejection because the applicant had not come forward with any evidence that the prior art was not “essentially free of alkali metal” and therefore a different and unobvious product.).

Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (The prior art disclosed human nerve growth factor (b-NGF) isolated from human placental tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different.).

THE USE OF 35 U.S.C. 102/103 REJECTIONS FOR PRODUCT-BY-PROCESS CLAIMS HAS BEEN APPROVED BY THE COURTS

“[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Office personnel should note that reliance on the alternative grounds of 35 U.S.C. 102 or 35 U.S.C. 103 does not eliminate the need to explain both the anticipation and obviousness aspects of the rejections.
MPEP § 2173.05(p) Claim Directed to Product-By-Process or Product and Process

There are many situations where claims are permissively drafted to include a reference to more than one statutory class of invention.

I. PRODUCT-BY-PROCESS

A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. In re Luck, 476 F.2d 650, 177 USPQ 523 (CCPA 1973); In re Pilkington, 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); In re Steppan, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967). A claim to a device, apparatus, manufacture, or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph, so long as it is clear that the claim is directed to the product and not the process.

An applicant may present claims of varying scope even if it is necessary to describe the claimed product in product-by-process terms. Ex parte Pantzer, 176 USPQ 141 (Bd. App. 1972).

II. PRODUCT AND PROCESS IN THE SAME CLAIM

A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph. See In re Katz Interactive Call Processing Patent Litigation, 639 F.3d 1303, 97 USPQ2d 1737 (Fed. Cir. 2011). In Katz, a claim directed to “[a] system with an interface means for providing automated voice messages…to certain of said individual callers, wherein said certain of said individual callers digitally enter data” was determined to be indefinite because the italicized claim limitation is not directed to the system, but rather to actions of the individual callers, which creates confusion as to when direct infringement occurs.
Katz, 639 F.3d at 1318 (citing IPXL Holdings v. Amazon.com, Inc., 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005), in which a system claim that recited “an input means” and required a user to use the input means was found to be indefinite because it was unclear “whether infringement … occurs when one creates a system that allows the user [to use the input means], or whether infringement occurs when the user actually uses the input means.”); Ex parte Lyell, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) (claim directed to an automatic transmission workstand and the method of using it held ambiguous and properly rejected under 35 U.S.C. 112, second paragraph).