

The Law of Written Description in Pharmaceutical and Biotechnology Patents

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THE CHALLENGES IN DESCRIBING INTELLECTUAL PROPERTY

LAW HAS LONG BEEN THE ARBITER of competing claims to property rights. When a property right is at stake or is asserted at or beyond the edges of well-recognized boundaries, or when aggressive tactics are employed in an attempt to take what is owned by another or the public, the law is invoked to determine the scope of that which is justly claimed.

Lawyers and other professionals spend a good deal of time trying to figure out who owns what and how much. For most of us, getting a handle on our property rights is to a large extent a straightforward matter, insofar as what we own is tangible and visible. Rights inherent in real property, evidenced in such written instruments as a deed, with its "meets and bounds," often can be verified by surveying terrain, water, or air space. Personal property rights in a tangible object, such as a ship or a diamond, are evidenced by, along with sale and title documents, possession of the thing itself, which can be seen and touched and handled. Most businesses can establish an accounting of their less tangible property rights in such "things" as cash, securities, debt, accounts receivable, hard assets, etc.

By contrast, intellectual property rights, and in particular patent rights, present unique challenges to the law's ability to demarcate reliably and consistently the degree and scope of the property that is owned. The seemingly elusive and unpredictable nature of the boundaries of the patent right derive from the fact that the right is defined exclusively by the patent document itself, specifically the claims, an enumerated set of single-sentence paragraphs that appear at the end of the specification.²

There is no physical land, air, space, water, or thing one can point to in order to define the entire scope and content of an intellectual property right. Patent claims consist primarily of words, which are always to a certain extent deficient in their ability to describe the reality of the day-to-day world accurately and reliably.³

Artists and philosophers recognize the inability to describe reality fully by using words and pictures. Consider the surrealist René Magritte's droll painting entitled "Ceci n'est pas une pipe" ("This is not a pipe"). Magritte was of course jokingly stating the obvious: this really is not a pipe but merely a painting of a pipe. His point, however, was serious. A depiction of a thing is not the thing, and no depiction or description of a thing can ever *be* the thing, no matter how hard we try to be accurate and precise or how accustomed we have be-

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² 35 USC §112 ("the [patent] specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.")

³ See *Commissioner v. National Carbide Corp.*, 167 F.2d 304, 306 (2d Cir. 1948)(Judge Learned Hand: "Such a corporation might be in some contexts a 'corporation'; but words are chameleons, which reflect the color of their environment, and in a tax statute, 'corporation' could not have been so intended.").

come to accepting asserted depictions of reality as the real thing.⁴

The challenges inherent in using words to define the scope of a “piece” of intellectual property are particularly acute. Again, in contrast to land, which is a fixed quantity on Earth (except perhaps in The Netherlands), intellectual property is in a constant state of boundless growth. It can arise at any time by virtue of almost any new creation or invention from any of the billions of minds on the planet engaged in multitudinous endeavors. The intellectual property laws are thus constantly gasping for air in an effort to keep pace with the rapidity and variation of human invention and creativity.⁵

The intellectual property arising from the development of a tangible thing or process is often mistaken by both the law and the layman for the thing itself. For example, in patent cases, some trial courts have erred in conducting an infringement analysis that compared the plaintiff’s and defendant’s competing products, instead of analyzing the defendant’s product in relation to the claims of the plaintiff’s patent.⁶ Similarly, the commercial version of an invention sometimes has been mistakenly used to describe the scope of the intellectual property in the invention.⁷

Thus, in the patent context, the patent is the “thing” that defines the intellectual property owned—not the object that one associates with the patent.

Today, the patent right is one of the most significant incentives to invest capital (i.e., spend money and other resources) on innovation because it provides an exclusive right to exploit the innovation for a specified number of years and thus creates an enhanced opportunity to recoup invested capital and reap profits.

Like most everything else, however, the patent right comes at a well-known price: in exchange for the exclusive right to the invention claimed, the patent applicant must disclose the invention in the patent document. The patent system does not grant a patent and allow the patent owner, through non-disclosure of the invention, to keep the invention a secret because this would deprive the public of the benefit of its bargain with the inventor—public disclosure of the invention and free use thereof after patent expiration.⁸

It is less well understood, however, that the mere “disclosure” of an invention in a patent application, without more, can be insufficient under U.S. Patent

law to merit or maintain a patent on that invention. Beyond disclosure, “[t]he inventor must be able to *describe the item to be patented with such clarity that the reader is assured that the inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection.*”⁹ An “inadequate patent description that merely identifies a plan to accomplish an intended

⁴ René Magritte was associated with the “Brussels Surrealists,” a quiet group of 20th Century Belgian artists and writers who, unlike the “Paris Surrealists,” sought to undermine conventional thought in a highly discreet and camouflaged manner. Magritte painted wearing a suit and tie in a corner of his living room, as opposed to a studio, and professed indifference to the quality of his works, claiming that he had “no talent, no originality, no artistic aptitude.” See Sarah Whitfield, *MAGRITTE*, The South Bank Centre (1992), p. 29. With respect to *La Pipe*, Magritte said “everything tends to make us think that there is very little connection between an object and what represents it” and “an object never fulfils the same function as its name or image.” *Id.* at Catalogue entry 67. However, while he said *La Pipe* was a mere expression of “dumb insolence,” Magritte knew *La Pipe* was provocative enough such that during the German Occupation of Belgium in 1943, he withheld its publication from an art monograph because “it might be used as a pretext to have me locked up in a madhouse.” *Id.* Magritte died in 1967, apparently of causes unrelated to his paintings.

⁵ See *Adobe Systems Inc. v. One Stop Micro, Inc.*, 84 F.Supp.2d 1086, 1092 (N.D.Ca. 2000) (dictum: “The rate of change of technology is orders of magnitude greater than the ability of intellectual property laws to keep up.”).

⁶ See *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1481–1482 (Fed. Cir. 1984). (“Infringement is not determined . . . by comparison between commercial products sold by the parties. Accused products made, sold, or used, and accused processes performed . . . *must be compared with the claims.*”)(emphasis added).

⁷ See *Oddzon Products, Inc. v. Imperial Toy Corp.*, 1991 U.S. App. LEXIS 14408 (Fed. Cir. 1991)(non precedential)(“The Koosh Ball is only a single commercial embodiment of the ‘529 patent. The ‘529 patent could cover toys other than the Koosh Ball. *The subject of this suit is Imperial’s alleged infringement of the claims, not its copying of the Koosh Ball. In making its infringement determination, the district court erred in comparing the accused device with the Koosh Ball. Instead, it must compare the accused device with the claims.*”)(emphasis added).

⁸ See *Rototron Corporation v. Lake Shore Burial Vault Co.*, 712 F.2d 1214, 1215 (7th Cir. 1983)(“the Rototron process cannot be regarded as a trade secret, because the grant of a patent automatically constitutes full disclosure of the patented process. As stated in the District Court’s opinion, ‘In order to foster invention and reward those who expand human knowledge, our nation grants a monopoly for the life of a patent in the invention or process disclosed in the claim. But the price for this reward is full disclosure’”).

⁹ *University of Rochester v. G.D. Searle & Co., Inc.*, Slip Op., 00-CV-6161L, p. 1 (W.D.N.Y. March 5, 2003)(emphasis added).

result 'is an attempt to preempt the future before it has arrived."¹⁰

Patent cases abound with complex problems. The courts are constantly grappling with difficult scientific and technologic fact patterns, arcane and sometime counterintuitive patent doctrine, extensive specifications and file histories, scientific data, literature and prior art, competing and usually conflicting expert testimony, fat deposition transcripts and exhibits, and reams of internal corporate documents and notebooks—all of which are supposed to aid a judge or jury in understanding the often prolix (if not brain-teasing) patent claim language that, following the wisdom of some ancient Patent Office officials, is required to be written in a single sentence.¹¹

Often, however, the issues in patent litigations, even the most complex, can be boiled down to a determination of how much intellectual property the patents properly claim and thus temporarily remove from the public domain. Astute courts and litigants can gain control of the relevant issues driving this determination by focusing on some simple questions, such as:

- What in fact did the inventor invent?
- How does the patent specification describe the claimed invention?
- How does the written description of the invention compare with the competing courtroom stories about what the inventor invented?

The law of written description speaks directly to, and can often help decide, these core issues and is playing a growing role in modern patent jurisprudence as it seeks to reward true invention, ward off anticompetitive business practices, and instill a measure of predictability in measuring the scope of patent claims. To a large extent, this jurisprudence is placing increasing emphasis on detailed, precise, and specific descriptions of inventions in patent documents and looking askance at *post hoc* assertions of invention held up only by slim "expert" testimony and arguments of counsel.

THE US PATENT STATUTE CONTAINS A DISTINCT WRITTEN DESCRIPTION REQUIREMENT TO ACHIEVE A CRITICAL OBJECTIVE

The written description requirement finds its basis in the first paragraph of §112 of the Patent Statute:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention*¹²

The description requirement forms an early part of U.S. patent jurisprudence. Prior to the time when the patent laws required claims, the Patent Act of 1793 required that the patent applicant "deliver a written description of his invention . . . in such full, clear and exact terms as to distinguish the same from all other things before known."¹³ The early description requirement was aimed at "put[ting] the public in possession of what the party claims as his own invention."¹⁴

Although some courts confused or combined the written description and enablement ("making and using") requirements of §112, *Vas Cath Inc. v. Mahurkar*¹⁵ established that the statute "requires a 'written description of the invention' which is separate and distinct from the enablement requirement" and which is "broader than to merely explain how to 'make and use.'"¹⁶ "Thus, this statutory language mandates satisfaction of two separate and independent requirements: an applicant must both describe the claimed invention adequately and enable its reproduction and use."¹⁷

The central role of the description requirement in the patent system was recently echoed by Circuit Judge Lourie of the Court of Appeals for the Federal Circuit in the *Enzo* cases:

The written description requirement is no less than the *quid pro quo* of our patent system, in

¹⁰ *Id.*, citing *Fiers v Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993) (emphasis added).

¹¹ See MPEP § 608.01 (m) (5th Ed., 1989). A brave soul or two has challenged the single sentence requirement, having the audacity to assert that adding a period or two might result in patent claims that make more sense or are at least more readable—but to no avail. See *Fressola v. Manbeck*, 36 U.S.P.Q. 2d 1211 (DDC 1995).

¹² 35 USC §112, 1. (emphasis added); *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996).

¹³ *Evans v. Eaton*, 20 U.S. 356 (1822).

¹⁴ *Id.*

¹⁵ *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991)

¹⁶ *Id.* 935 F.2d at 1563–1564.

¹⁷ *Amgen Inc. v. Transkaryotic Therapies, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003).

which an inventor is only entitled to claim subject matter that is adequately described to the public.¹⁸

Thus, compliance with the distinct written description requirement is part of the deal between the inventor and the government in the granting of a patent. Failure to make an “adequate description” of the invention in the patent application means that the applicant has not lived up to her end of the bargain and thus cannot obtain a patent claim that covers subject matter inadequately described.

Additionally, in the words of the *Vas Cath* court, the written description requirement simply seeks to ensure that the “[patent] specification discloses [a thing] as something appellants actually invented.”¹⁹ In other words, the purpose of the written description requirement is broader than to merely explain how to “make and use the invention”:

the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the “written description” inquiry, whatever is now claimed.²⁰

What is more important, however, is that the description requirement provides legal protection against certain activities that can harm competition on the merits and impair predictability in making R&D investments, namely, attempts to patent purported inventions not in fact invented by a patent applicant (or her assignee) and attempts to obtain patent claims that rightfully belong to competitor *via* the use of questionable strategies during the prosecution of applications in the Patent Office. “The purpose of the written description requirement is to *prevent an applicant from later asserting that he invented that which he did not.*”²¹ An adequate written description thus “guards against the inventor’s overreaching by later claiming that which he did not invent, by insisting that he recount his invention *in such detail that his future claims can be determined to be encompassed within his original creation.*”²²

ASSESSMENT OF THE ADEQUACY OF A WRITTEN DESCRIPTION

“Possession” plus descriptive means

The general inquiry in determining whether the written description requirement has been met is

whether the description in the application “clearly allows persons of ordinary skill in the art to recognize that the applicant has in fact invented what is claimed.”²³ The relevant inquiry has been almost uniformly characterized as an effort to determine whether one of ordinary skill in the field of the invention would have recognized that the inventor was “in possession” of the invention.²⁴

Notwithstanding the wealth of precedent reciting (and supposedly applying) the “possession test,” the Federal Circuit announced in *Enzo I* that “possession of the invention” is not so much the test for the written description requirement as it is a statement of “a *purpose*” of the requirement.²⁵

In the words of Judge Lourie, the description requirement is satisfied, not only by a recognition that the inventor was in possession of the invention, but also “by the patentee’s disclosure of ‘such *descriptive means* as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.’”²⁶ Mere recognition of the inventor’s possession of the invention is not enough by itself to establish a sufficient description in the patent document:

Application of the written description requirement, however, is not subsumed by the “possession” inquiry. A showing of “possession” is secondary to the *statutory mandate* that

¹⁸ *Enzo Biochem, Inc. v. Gen-Probe Incorporated*, 285 F.3d 1013, 1019 (Fed. Cir. 2002) (“*Enzo I*”), *reversed and remanded*, *Enzo Biochem, Inc. v. Gen-Probe Incorporated*, 296 F.3d 1316, (Fed. Cir. 2002) (“*Enzo II*”) (“Such description is the *quid pro quo* of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.”)

¹⁹ *Id.*, 955 F.2d at 1561 citing *In re Rushig*, 379 F.2d 990 (CCPA 1967).

²⁰ *Id.*, 935 F.2d at 1563–64.

²¹ *Amgen Inc. v. TKT*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (emphasis added).

²² *Vas-Cath, supra*, 935 F.2d at 1561 (emphasis added).

²³ *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

²⁴ See e.g., *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996) (the written description requirement is met “[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention”); *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (the test for sufficiency of support is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession [of the invention] at the time of the later claimed subject matter”).

²⁵ *Enzo I, supra*, 285 F.3d at 1020–1021 (emphasis in original).

²⁶ *Id.*, citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

'[t]he specification shall contain a written description of the invention,' and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention.²⁷

A vain example of trying to claim an invention without adequately describing it is language in the specification that simply parrots the claim language. This tactic was rejected by *Regents of the University of California v. Eli Lilly & Co.*²⁸

In sum, while the Federal Circuit has avoided setting a rigid test for judging the adequacy of a written description, it has made clear that more than possession of the invention is required; i.e., the use of "descriptive means": words, structures, figures, diagrams, formulas, etc., that "fully set forth" the claimed invention.

Fact questions and precedents

Not surprisingly, given the broad inquiry subsumed by the description requirement, the issue of compliance in a given case is a question of fact.²⁹ Because written description is a fact issue, precedent is often said to be of limited value: each specification must be read on a "case-by-case basis."³⁰

However, notwithstanding the fact-based nature of written description cases, there are instances wherein the written description on its face "is so deficient that it fails to satisfy the written description requirement as a matter of law."³¹ The issue of written description may be decided by the district court judge on summary judgment, thus obviating a trial on the fact issues.³²

Despite the fact that each written description challenge must be assessed on its own facts, as opposed to the straight application of case precedent, a number of well-settled principles have emerged, and the trial courts frequently cite them to guide, and sometimes to drive, their decisions on whether the description requirement has been met. It is useful to keep a few examples of these in mind:

1. An invention does not have to be described *in ipsius verbis* or *in haec verba* in order to satisfy the description requirement of §112.³³
2. While an *ipsius verbis* recitation of the invention is not required and "the applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed,"³⁴ the disclo-

sure must at least "reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question."³⁵

3. The focus of the description inquiry is on what is claimed.³⁶ To meet the written description requirement, the specification must describe every element or limitation of the claimed invention: "While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. . . . The invention is, for purposes of the written description inquiry, *whatever is now claimed.*"³⁷
4. A claimed invention which is no more than an "obvious variant" of that described in the specification is not supported by an adequate written description. Thus, while a specification need not describe "the claimed subject matter in exactly

²⁷ *Enzo I*, 285 F.3d at 1021 (emphasis in original).

²⁸ *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997) ("The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity."). See also *Enzo I*, 285 F.3d at 1013, 1020 ("The appearance of the words of the claim in the specification or as an original claim does not necessarily satisfy that requirement.").

²⁹ *Vas-Cath*, *supra*, 935 F.2d at 1562, citing *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976); *In re Smith*, 458 F.2d 1389, 1395 (CCPA 1972), and *In re DiLeone*, 436 F.2d 1404 (CCPA 1971).

³⁰ *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000), citing *Vas Cath*, *supra*, 935 F.2d at 1562 (noting that the CCPA in *Driscoll*, 562 F.2d 1245, 1250 (CCPA 1977), has gone so far as to say that "the precedential value of cases in this area is extremely limited.").

³¹ See *Enzo I*, 285 F.3d. at 1025-1026 (Judge Dyk, dissenting), citing *Eli Lilly*, *supra*.

³² See *University of Rochester*, *supra*, at pp. 6-7, citing *TurboCare v. General Electric Co.*, 264 F.3d 1111, 1120 (Fed. Cir. 2001) (affirming summary judgment of invalidity for failure to meet the written description requirement).

³³ *Purdue Pharma*, *supra*, 230 F.3d 1323; *In re Wertheim*, 191 U.S.P.Q. 90, 98 (CCPA 1976).

³⁴ *In re Alton*, *supra*, 76 F.3d at 1172.

³⁵ *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). Note, however, that in *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998), Judge Lourie stated this guideline with more stringency: "the patent specification 'must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" *Id.*, citing *In re Gosteli*, 872 F.2d 1008 (Fed. Cir. 1989) (emphasis added).

³⁶ *Amgen v. TKT*, *supra*, 314 F.3d at 1333.

³⁷ *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571-1572 (Fed. Cir. 1997) (emphasis added). See also *University of Rochester*, *supra*, at 7-8.

the same terms as used in the claims, it must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention . . . is not sufficient."³⁸

5. A patent claim that meets the enablement standard of §112 because the specification teaches how to make and use the claimed invention may nonetheless be held invalid if not supported by an adequate description of the claimed invention.³⁹
6. Satisfaction of the description "requirement is measured by the understanding of the ordinary skilled artisan"⁴⁰ as of the filing date of the patent application.⁴¹
7. It is in general improper to use hindsight to confer an adequate description onto a patent specification where no such description is reasonably or clearly found in the specification in the first instance; i.e., as of the time it was filed.⁴²
8. While it is not necessary that every species in a genus be described in order to describe the genus adequately,⁴³ a description of a species does not always constitute a description of the genus of which it is a part."⁴⁴

PHARMACEUTICAL CHEMICAL AND FORMULATION CASES

Trail blazing vs. hindsight picking and choosing

Although written description issues have arisen in virtually every type of patent litigation, there is a concentration of such cases originating in the pharmaceutical and chemical arts. These cases are often directed to thorny issues raised by a party's attempt to capture a patent claim covering a valuable product or technology already issued to a competitor. The cases have also been generated in the context of interference proceedings and during the prosecution of patent applications, wherein the claims of an issued patent are copied for the purpose of provoking an interference between the patent and the application. Written description issues have also arisen when an applicant during prosecution, or a patentee during litigation, has sought to obtain the benefit date of an earlier-filed application for later-filed claims to, for example, avert invalidating prior art that postdates the earlier application.

The decisions in these cases have recognized that "[w]hen a party . . . seeks the benefit of an earlier-

filed United States patent application, the earlier application must meet the requirements of 35 USC §120 and 35 USC §112 ¶1" (written description and enablement) for the subject matter of the patent claim or the interference count.⁴⁵ The courts have thus had ample opportunity to write a substantial body of case law directed to both the description and enablement issues.

The detailed articulation of the modern policies and guidelines on the description requirement began in the 1960s with cases involving the claiming of chemical compounds. In a line of cases beginning with the 1967 CCPA decision, *In re Ruschig, supra*, the courts have invalidated and affirmed the rejection of patent claims to a chemical species (a single specific compound) or subgenus (small group of related compounds) where the specification "disclosed" such chemical compounds only as part of a large genus, "laundry list," or "shotgun" disclosure of compounds.

In these cases, the courts have carefully scrutinized the patent application or specification in light of the claim at issue in an effort to determine whether the applicant actually invented the specific compounds claimed or whether she was working backward by combining disparate portions of the specification in an attempt to justify a new claim to a chemical compound that was not within her possession at the time of her invention. In such cases, the courts have sought to deter a litigant's use of hindsight to bootstrap a construction of a patent specification that would arguably "describe" specific compounds the patentee merely wished she had invented and described in the application at the time it was filed.

At times, it may be transparent that the applicant or litigant, as the case may be, is overreaching in an

³⁸ *Lockwood v. American Airlines, Inc., supra*, 107 F.3d at 1572.

³⁹ *In re DeLeone*, 436 F.2d 1404 (CCPA 1971).

⁴⁰ *Amgen Inc. v. TKT, supra*, 314 F.3d 1330

⁴¹ *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996).

⁴² *Fujikawa*, 93 F.3d 1559, 1570 (Fed. Cir. 1996); *In re Ruschig*, 379 F.2d 990, 995 (CCPA 1967); *Rohm and Haas Co. v. Mobil Oil Corp.*, 718 F.Supp. 274 (D. Del. 1989), *aff'd*, 895 F.2d 1421 (Fed. Cir. 1990).

⁴³ *Utter v. Hiraga*, 845 F.2d 993 (Fed. Cir. 1988)

⁴⁴ *Lockwood, supra*, 107 F.3d at 1568.

⁴⁵ See e.g., *Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998) and *Fiers v. Revel*, 984 F.2d 1164, 1169-1170 (Fed. Cir. 1993).

