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Articles

FORMALISM AND PATENT CLAIM DRAFTING: THE STATUS OF DE FACTO INDEPENDENT CLAIMS UNDER THE FOURTH PARAGRAPH OF 35 U.S.C. § 112

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*264 I. Introduction

In his 1990 article regarding the status of American patent law, Giles S. Rich, the former Chief Judge for the United States Court of Appeals for the Federal Circuit, famously said "the name of the game is the claim."[1] What Judge Rich meant was that patent claims define what a patentee may legally exclude others from making, using, or selling.[2] It is the claims that provide the public with notice of the patentee's invention and permit the public to determine the scope of the patentee's exclusive right.[3] For these reasons, claims are the first part of a patent application that patent examiners read during patent prosecution,[4] and claims are the primary concern of judges and attorneys during patent litigation.[5] Since the claims define the scope of protection for a patentee, a claim drafter must carefully select each word that he or she uses.

***265** Patent claims are drafted in either independent or dependent form. Generally, an independent claim stands alone (i.e., the claim defines the invention without reference to another claim), whereas a dependent claim refers back to a previous claim for a broad definition of the invention and then provides a narrowing limitation on some aspect thereof.[6] When claim drafters prepare claims for a patent application, they must comply with the formal requirements prescribed by 35 U.S.C. § 112 (USC 112).[7] The statute's fourth paragraph provides: "[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."[8] However, the statute does not define the requirements for an independent claim. Therefore, this article questions whether a claim that does not "incorporate by reference all the limitations of the claim to which it refers"[9] may be construed as an independent claim.

In the chemical arts,[10] a claim drafter may choose to describe a new compound by its chemical structure, formula, name, properties, the process by which it is made, or some combination thereof.[11] The most common methods for drafting a claim drawn to a new compound are to define the compound by its chemical name or structure.[12] Those familiar with chemical nomenclature know that it is tedious to write out the name of a chemical compound.[13] Even when a chemical structure is ***266** provided in a patent, chemical nomenclature may still be confusing for courts.[14] Complicating the matter is the fact that there are different nomenclature systems and that compounds are routinely assigned common or trade names.[15] For example, morphine is the common name for (5a,6a)-7,8-didehydro-4,5-epoxy-17-methylmorphinan-3,6-diol, acetaminophen is the common name for N-(4-hydroxyphenyl)acetamide, and ibuprofen is the common name for a-methyl-4-(2-methylpropyl)benzene-acetic acid.[16]

Considering the complexity of chemical names, there is a chance of a typographical error when a claim draftsman needs to retype a chemical name in multiple claims. In all likelihood such concerns resulted in the development of what are known as "shorthand claim references." These references refer to instances in which a chemical name is written in an independent claim and subsequent claims then refer back to the prior claim instead of retyping the awkward chemical name.[17] The following hypothetical claim 2 is illustrative of a shorthand reference:

1. A compound selected from the group of N-(4-hydroxyphenyl)acetamide, a-methyl-4-(2-methylpropyl)benzene-acetic acid, a-methyl-4-(2-methylpropyl)benzene-acetic acid, and (5a,6a)-7,8-dihehydro-4,5-epoxy-17-methylmorphinan-3,6-diol.

2. A pharmaceutical composition comprising a compound of claim 1.

Since there is no definition of independent claim in either the patent statutes or the patent regulations, a question arises as to whether claim 2 should be construed as an independent claim, written with a shorthand reference to claim 1, or a dependent claim because of its reference to claim 1. If claim 2 is a dependent claim because of the reference to claim 1, then the next question is whether claim 2 is ***267** written in proper dependent form. This question would require an analysis of the claim

under the fourth paragraph of 35 U.S.C. § 112 (USC 112, P 4).[18] Alternatively, if claim 2 is construed as an independent claim merely having a shorthand claim reference--a de facto independent claim--then an analysis of the claim under USC 112, P 4 is not necessary. It has been routine for patent practitioners to use claims such as claim 2 and just as routine for patent examiners or judges to construe those claims as de facto independent claims. Accordingly, Judge Rich would ask: "Is it not obvious that we are dealing with a simple question of definition?"[19]

Prior to the appellate decision in Pfizer, Inc. v. Ranbaxy Labs. Ltd.,[20] when a patent claim was invalidated under USC 112, P 4 for the first time,[21] claim drafters in the chemical arts were implicitly authorized by the holdings of the United States Patent and Trademark Office (USPTO) Board of Patent Appeals and Interferences (BPAI) to exploit shorthand claim references without concern.[22] However, the claim interpretations in Pfizer and subsequent cases provide that claim 2 should be construed as a dependent claim and analyzed for validity under USC 112, P 4.

This article examines the confusion that arises when claims are drafted with a shorthand reference and reviews the history and jurisprudence of USC 112, P 4. The decisions of the federal courts and the holdings of the BPAI suggest that claim drafters should discontinue the use of shorthand references and avoid the common mistakes that have resulted in unpatentable or invalid claims. The court and BPAI decisions also illustrate that shorthand references are used outside of the chemical context; for instance, they are used in biotechnology, engineering, and design patents.

This article proposes that the USPTO should revise the Code of Federal Regulations (CFR) rule for patent claims[23] to provide a formal definition of independent claim in a way that is consistent with the law.[24] Logically, independent and dependent claims should have contrary definitions, such that a dependent claim necessarily refers back to a previous claim to define the invention, and an independent ***268** claim must define the invention without a reference to another claim. Similarly, the Manual of Patent Examining Procedure (MPEP)[25] should be revised in a manner that is consistent with the holdings of Pfizer and subsequent cases. The proposed revisions would facilitate consistent and predictable claim interpretations during patent prosecution and litigation--the wish of all interested parties.

Part II of this article provides an overview of the formal requirements for patent claims under USC 112 and 37 C.F.R. § 1.75 (CFR 1.75).[26] Part II includes a historical context for the holding in Pfizer and provides an explanation as to how administrative acquiescence to the use of shorthand references allowed the definition of independent and dependent claims to be conflated. Lastly, Part II discusses patents in the context of the pharmaceutical industry and the role of formalism in patent law. Part III presents some of the common mistakes made by claim drafters that have resulted in unpatentability or invalidity holdings under USC 112, P 4 by the BPAI and federal courts since Pfizer. Part IV articulates the limitations imposed by the doctrine of necessity on claims that incorporate by reference subject matter from the written description (commonly referred to as the specification). Additionally, Part IV proposes a rule that would resolve the conflating definitions for independent claim and dependent claim and discusses the likely arguments in opposition of the proposed rule. Next, Part V demonstrates, with hypothetical claims, how the proposed rule would facilitate consistent and predictable claim interpretations and why the rule would simplify the doctrine of claim differentiation. Finally, Part VI provides a summary of the article's main thesis, findings, and suggestions.

II. Background and History of Claims in Patent Law[27]

There have been numerous revisions to the patent laws since the first patent bill was enacted in 1790. For instance, one revision replaced a patent registration system with a patent examination system,[28] and another revision eliminated the requirement that a patent applicant produce a model of his or her invention for inspection. ***269** [29] With respect to the modern era of patent law, the revisions in the nineteenth century are the most significant because they made a claim a formal requirement of a patent application.[30]

A. The Formal Requirement of Claims

1. Statutory Requirement

The Patent Act of 1836 was significant to the origin of patent claims because it required patent applicants to "particularly specify and point out the part, improvement, or combination which he claims as his own invention or discovery."[31] The statute resulted in what is referred to as central claiming, where the patent claim merely recited the gist of the invention.[32] In

this style of claim drafting, patentees often set forth the phrase substantially as described to indicate that the reader must refer back to the written description in order to ascertain the patentee's invention.[33]

The Patent Act of 1870[34] resulted in the demise of central claiming and the evolution of peripheral claiming, in which the claim sets forth "all circumstances under which the discovered process operates, or all variations of the patentee's material creation."[35] In other words, claim drafters must set forth a boundary in a claim that delineates "the metes and bounds of the subject matter that will be protected ***270** by the patent grant."[36] As a result of this revision, a claim drafter was no longer permitted to point out the part of the invention, but instead must "particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery."[37] The revisions implemented in the Patent Act of 1870 created a patent statute that resembles the current version of 35 U.S.C. § 112, P 2 (USC 112, P 2), the statutory provision that formally mandates that the specification conclude with one or more claims.[38]

In the period from 1870 to 1952, Congress passed over sixty acts relating to patents, but the amendatory and supplemental enactments did not substantially change the 1870 Patent Act.[39] However, the 1952 Patent Act completely rewrote the patent statutes. In the 1952 Act, USC 112 was revised from one paragraph to three paragraphs, in which the clause relating to the claims in the original paragraph was separated from the clause relating to the description in order to clarify their significance.[40] Additionally, the last paragraph of USC 112 was added to permit functional claiming.[41]

Claim drafters began using a plurality of independent claims in order to define their exclusive right in the nineteenth century, but the use of dependent claims did not emerge until the early twentieth century.[42] Several years later, the Patent Act of 1965 codified what claim drafters had already been practicing. In fact, the original MPEP contained a section drawn to dependent claims.[43] In 1965, the second paragraph of USC 112 was revised to include the following: "A claim may be written in independent or dependent form, and if in dependent form, it shall be construed to include all the limitations of the claim incorporated by reference into ***271** the dependent claim."[44] That revision resembles the third paragraph and the second sentence of the fourth paragraph of the current statute.

In 1975, USC 112 was amended to its current form in order to carry into effect certain provisions of the Patent Cooperation Treaty and to take account of the multiple dependent claim practice introduced by the Treaty.[45] As a result of the revision, the second paragraph became the current third, fourth, and fifth paragraphs, and the third paragraph became the current sixth paragraph.[46]

In its current form, the third paragraph of USC 112 authorizes claim drafters to use dependent claims, whereas USC 112, P 4 mandates requirements and interpretation methods for dependent claims:
A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.[47]

A discussion of USC 112, P 4 is omitted from most patent law literature.[48] This article provides the recent jurisprudence of USC 112, P 4 in the realm of patent ***272** prosecution,[49] as well as in litigation scenarios in which an alleged patent infringer asserts a defense that the claim infringed is invalid.[50]

2. Regulatory Requirement

In addition to the requirements set forth in USC 112, patent claims must also comply with CFR 1.75.[51] Briefly, the language of subsection (c) parallels the language of the third through fifth paragraphs of USC 112,[52] whereas subsection (g) suggests a general format for multiple claims: the broadest claim should be presented first and all dependent claims should be grouped together, following the broad claim.[53]

Interestingly, subsection (c) states that a multiple dependent claim, or any claim that depends from a multiple dependent claim, will be considered to be that number of claims to which direct reference is made in that claim for fee calculation purposes.[54] The phrase for fee calculation purposes implies that a multiple dependent claim will be considered one way for determining the patent applicant's fees, but it may be construed differently with respect to patentability. As stated in the MPEP: "The initial acceptance of a claim as a dependent claim does not . . . preclude a subsequent holding by the examiner

that a claim is not a proper dependent claim."[55] In a similar manner, the amendment to CFR 1.75, subsection (b)--as promulgated on August 21, 2007--was amended as set out below:

(b) . . . A dependent claim must contain a reference to a claim previously set forth in the same application, incorporate by reference all the limitations of the previous claim to which such dependent claim refers, and specify a further limitation of the subject matter of the previous claim. . . .

(2) A claim that refers to another claim but does not incorporate by reference all of the limitations of the claim to which such claim refers will be treated as an independent claim for fee calculation purposes under § 1.16 (or § 1.492) and for purposes of paragraph (b) of this section. A claim that refers to a claim of a different statutory class of invention will also be treated as an independent claim for ***273** fee calculation purposes under § 1.16 (or § 1.492) and for purposes of paragraph (b) of this section.[56]

Had the district court not issued an injunction of the aforementioned rule in Tafas v. Dudas,[57] the regulations would have expressly permitted the use of de facto independent claims: claims that refer to another claim, but are construed as independent claims because they do not incorporate by reference all of the limitations of the claim upon which they refer. In effect, this rule change would not have altered current practice, but due to the injunction there remains an issue as to whether such claims are valid under USC 112, P 4. Nevertheless, the rule change begs the question of whether it is necessary to have two definitions for an independent claim: one that allows a reference to another claim and one that requires the claim to be complete in of itself (i.e., without reference to another claim).

B. The Missing Definition for Independent Claim

During patent prosecution, an examiner's interpretation of whether a claim is an independent or dependent claim is important for the determination of patentability under USC 112. Construing a claim as independent or dependent is also a critical component of claim interpretation during Markman hearings,[58] in which claim construction is completed by the litigants and the court prior to trial.[59] Each claim is an independent intellectual property right with respect to the other claims in a patent; therefore, it is often the practice of the court to invalidate only those claims that fail to adhere to the statutory requirements and not the entire patent.[60]

A definition of dependent claim has been provided in USC 112 and CFR 1.75.[61] Also, the MPEP offers the infringement test[62] as a means for determining ***274** whether a claim is a proper dependent claim. However, independent claim has not been defined in USC 112 or CFR 1.75 and the MPEP does not offer a test for determining whether a claim is properly independent.

Without a definition of independent claim, the format used by the claim drafter may provide insight into the proper construction.[63] A claim usually contains three parts: a preamble, a transition phrase, and a body.[64] Generally, a claim in dependent form will recite a preamble that is parallel to the preamble of the claim in which it refers. For example, if independent claim 1 recites: "A compound of the formula (I) . . .", then dependent claim 2 might state: "The compound according to claim 1 . . . ." Although not dispositive, the preamble may provide contextual evidence for the determination of whether a claim is independent or dependent.

Some commentators assert that "[t]he status of a claim as a dependent claim is signified by reference, in its preamble, to the claim number on which the instant claim depends coupled with a statement that the limitations recited in the body of the instant dependent claim are in addition to those recited in the claims on which the instant claim depends."[65] However, the requirement that a claim reference be in the preamble is unfounded. There is nothing in either USC 112 or CFR 1.75 that requires a claim reference to be in the preamble. In fact, the MPEP expressly states, "there is no set statutory form for claims."[66] Further, in Landis on Mechanics of Patent Claim Drafting, Faber states that "the statement of dependency upon a prior claim need not be in the preamble."[67] So, although the context ***275** of a claim reference may be helpful to claim construction, only a definition or legal test would control the determination of whether a claim is independent or dependent.

Surprisingly, the original MPEP included a definition for independent claim, but subsequent revisions of the MPEP omitted the following, "Claims are independent or dependent. An independent claim is complete in itself without reference to another claim. A dependent claim refers to and modifies another claim."[68]

The majority of patent literature is in agreement with the original MPEP definition of independent claim and the contrary relationship between independent and dependent claims. As the name suggests, "[a]n independent claim stands alone, includes all its necessary limitations, and is not dependent upon and does not include limitations from any other claim to make it complete."[69] However, some commentators disagree. They suggest that a claim may make reference to another claim and still be characterized as an independent claim.[70] In short, because USC 112 and CFR 1.75 are silent on the matter, two definitions of independent claim have emerged:

• An independent claim is complete in itself without reference to another claim.

• An independent claim may incorporate by reference the subject matter of another claim.

***276** As a matter of classical logic,[71] there is an incompatibility between the two definitions. Taken together, the definitions are contradictory; therefore, they both cannot be true. This article proposes a definition for independent claim that would reduce ambiguity in claim construction, eliminate one of the contradictory definitions, and restore the contrary relationship between independent and dependent claims.

C. Administrative Deference to Shorthand Claim References

The jurisprudence of USC 112, P 4 reinforces the unsettling facts that there are contradictory definitions for independent claim and that dependent and independent claims are false contraries. In Ex parte Moelands,[72] a patent examiner rejected claims 9, 11, and 20 under USC 112, P 4 as being in improper dependent form for failing to further limit the subject matter of a previous claim.[73] Claim 11 was representative of the issues in the case:

> 11. A data transmission system comprising: at least two of the data transmission stations of claim 10; a clock bus interconnecting the clock terminals of the stations; and means which maintain the clock bus at the second voltage level in the absence of forcing by the stations.[74]

In the decision, the BPAI addressed the threshold requirement necessary for a claim to be characterized as a dependent claim:

***277** We also note that 35 U.S.C. 112, fourth paragraph, initially merely requires that a dependent claim contain "a reference" to a claim previously set forth. It is clear to us that the claims at issue here do comply with this statutory requirement.

. . . .

The fourth paragraph of 35 U.S.C. 112, also mandates that "a claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." Claims 9, 11 and 20 do include at least every limitation of the claims from which they respectively depend. Furthermore, a system which would infringe the plural stations of claims 9, 11 and 20 would certainly infringe the single station of claims 7 and 8, 10, 18 or 18 and 19.[75]

The Ex parte Moelands majority opinion is illustrative of two points: first, the examiner, appellants, and BPAI each construed claim 11 as a dependent claim because it referenced a preceding claim; and second, a claim reference to a preceding claim need not be in the claim preamble. Nevertheless, the BPAI concluded that the rejected claims (including claim 11) met the statutory requirements of USC 112, P 4 and passed the infringement test.[76]

Of note is the fact that the dissenting patent judge construed Claims 9, 11, and 20 as independent claims because the claims failed to further limit the subject matter of the claim in which they referenced. The dissent is set out below:

> In my view the change in § 112 which resulted in the fourth paragraph language in question here codified the provision of Rule 75(c) that requires a dependent claim to further limit another claim. The only exception that I am aware of to this requirement is in regard to product by process claims. The claims in issue clearly do not further limit or restrict the subject matter of the claims from which they refer back to. I view the questioned claims as wholly independent claims which refer back to and incorporate the subject matter of previous claims by reference. This is merely a shorthand form of claim drafting which eliminates the need for repeating the defined elements set forth in the referenced claims in much the same manner as tabular data, reference numerals or figures from a drawing are incorporated by reference into

claims. The fourth paragraph of the statute does not apply when viewing the claims in this light.[77]

Next they examined the use of shorthand claim references, and found them proper, in Ex parte Porter.[78] During the prosecution of Porter's patent application, ***278** the examiner rejected claim 6 under USC 112, P 4 as not being a proper dependent claim. Claim 6 is set out below:

> 6. A method for unloading non-packed, non-bridging and packed, bridging flowable particle catalyst and bead material from the opened end of a reactor tube which comprises utilizing the nozzle of claim 7.[79]

In contrast to the previous case, the BPAI, in an expanded panel, construed claim 6 of Ex parte Porter to be an independent claim. The BPAI explained:

The manner in which claim 6 has been drafted has been an acceptable format for years. The format of claim 6 apparently is used more often in chemically related applications . . .

. . . .

While claim 6 could be construed as an independent claim, drafted in a short-hand format to avoid rewriting the particulars of the nozzle recited in claim 7, for fee calculation purposes the Office initially treats all claims that refer to another claim as a dependent claim. . . .

. . . .

Our decision herein, when considered with ex parte Moelands should make it clear that we do regard a claim that incorporates by reference all of the subject matter of another claim, that is, the claim is not broader in any respect, to be in compliance with the fourth paragraph of 35 USC § 112.[80]

It is apparent from these BPAI decisions that whether or not the claims on appeal complied with USC 112, P 4 was only part of the issue. In each case there was a threshold issue as to whether such claims were dependent at all. Although the BPAI claim constructions were contradictory, the decision in Ex parte Porter garners greater precedential value because it was rendered by an expanded panel, is more recent, and has been endorsed by the USPTO.[81] However, most of the precedential value in Ex parte Porter was undercut by the Federal Circuit's 2006 decision in Pfizer v. Ranbaxy.[82]

***279 D. Pfizer v. Ranbaxy: Shorthand Claim Reference Renders Claim Invalid**

Pfizer v. Ranbaxy has become the seminal case for the invalidation of a claim under USC 112, P 4. In the decision, the Federal Circuit relied on dicta from Curtiss-Wright Flow Control Corp. v. Velan Inc. to support their conclusion of invalidity.[83] The Federal Circuit suggested that any provision of USC 112 may substantiate an invalidation defense in an infringement suit.[84] A few months later, Ranbaxy, a generic drug company, successfully argued that claim 6 in Pfizer's U.S. Patent 5,273,995 was invalid for failing to further limit the referenced claim 2, which did not include salts.[85] Claim 6 is set out below:

> 6. The hemicalcium salt of the compound of claim 2.[86]

Prior to the appeal, the district court recognized that there was a drafting problem with claim 6, but stated that there was no precedent for invalidating a claim under USC 112, P 4.[87] The Federal Circuit's opinion in Curtiss-Wright was issued after the district court opinion, but before the Pfizer v. Ranbaxy appeal.[88] There, the court said:

We recognize that the patentee was attempting to claim what might otherwise have been patentable subject matter. Indeed, claim 6 could have been properly drafted either as dependent from claim 1 or as an independent claim--i.e., "the hemicalcium salt of atorvastatin acid." But, we "should not rewrite claims to preserve validity."

. . . .

***280** Although the district court was reluctant to find the fourth paragraph of § 112 to be an invalidating provision, doing so

does not exalt form over substance. Rather, it is consistent with the overall statutory scheme that requires applicants to satisfy certain requirements before obtaining a patent, some of which are more procedural or technical than others.[89]

In Pfizer, the Federal Circuit was bound by precedent not to rewrite claim 6 in order to preserve its validity.[90] Further, the court was unable to apply the statutory presumption of validity because the claim was not indefinite.[91] Of note is the fact that both the Federal Circuit and the district court construed claim 6 as a dependent claim because of the reference to claim 2.[92] In other words, the courts construed claim 6 in accord with the construction of claim 11 in Ex parte Moelands, but in contrast with the construction of claim 6 in Ex parte Porter.

Some commentators have criticized the Federal Circuit's opinion in Pfizer, lamenting: "there is no legal or logical reason for considering claim 6 to be a dependent claim at all."[93] On the contrary, when Chief Judge Michel opined that invalidating a claim under USC 112, P 4 "does not exalt form over substance,"[94] he meant something utterly logical: the provision, USC 112, P 4, exalts form over convenience.

E. Pharmaceutical Patents, the Federal Circuit, and Formalism

The decision in Pfizer invalidated a claim protecting the active ingredient in the drug Lipitor®, a drug that the district court referred to as "the largest selling pharmaceutical in history."[95] In 2006, Lipitor® earned $12.9 billion in revenue, which was nearly three times more than their next leading drug (Norvasc®).[96] Fortunately ***281** for Pfizer, the court determined that the other claims protecting Lipitor® remained valid.[97] Nevertheless, it is alarming that a formal requirement in the Patent Act may have adversely affected the $12 billion per year blockbuster drug.

Through their empirical research, Professors Bessen and Meurer have determined that chemical patents are substantially more valuable than the patents in other industries.[98] The findings of their research suggest that the chemical and pharmaceutical industries benefit more from their patents as compared to other industries because the cost of litigation is several times larger than the profits received from patents in the latter industries.[99] Yet, the relationship is reciprocal: the industry that benefits the most from patents is also the industry that would not exist without patents.[100] In the pharmaceutical industry, the inventions cannot be protected by trade secret because the results of clinical studies are published.[101] Further, without the exclusive protection afforded by patents, the incentive for pharmaceutical companies to invest in expensive and risky research would disappear. The term of patent protection encourages innovation and provides a patentee a period of time to develop and market a new drug, and the opportunity to recoup the expenses of research and development.[102]

Researchers in the chemical industries attribute the success of their patents to the clear standards that can be applied to assess a chemical patent's validity and the fact that boundaries are more easily defined in such patents.[103] Even so, Professors ***282** Bessen and Meurer concluded that patent quality has declined in recent years: "Patents that are of low quality because they are vaguely worded, overly abstract, of uncertain scope, or that contain strategically hidden claims."[104] They assert that such problems with patent claim drafting have been exacerbated by the Federal Circuit's struggle to find the best approach for interpreting claims.[105] In their view, the patent system is reliant on the function that patent claims perform: patent notice.[106] As a solution, the commentators recommended that the Federal Circuit yield more deference to the interpretative tasks of the USPTO and establish limits on how patent claims may be drafted.[107]

Broadly, the suggestions expressed in Patent Failure straddle the fence between two competing camps. In one camp, commentators have criticized a pattern of judicial hyperactivity in the Federal Circuit's jurisprudence, which means the court engaged in a form of appellate review that "usurps elements of the decision-making process that are supposed to be the province of the lower courts, administrative bodies, or even litigants."[108] Gayoso and Feit, critics of the Pfizer decision, fall into this camp.[109] They noted the fact that there is no formal definition of independent claim.[110] Without a formal definition, they considered it unnecessary that the Federal Circuit construed claim 6 as a dependent claim when the BPAI had previously opined that such claims had been recognized as an acceptable format for independent claims.[111] Further, they argued that "it is difficult to imagine any public policy that is promoted by the Federal Circuit's decision in Pfizer v. Ranbaxy. It is equally difficult to imagine any public policy that is harmed by considering claims in the form of claim 6 to be valid independent claims."[112]

Commentators in the other camp argue that formalism is a policy that facilitates the goals of patent law. Professor Thomas observed that "the Federal Circuit has embraced an increasingly formal jurisprudence."[113] He predicted that the trend would

continue and that the goals of formalism are certainty and predictability:

> ***283** U.S. patent law is in many ways becoming more certain. The Federal Circuit's ongoing pursuit of doctrinal stability has led to maximalist decision making that has specified considerable legal rules in advance of their application. As we assess the court's movement into adjudicative rules formalism, we would do well to remember that the goals of certainty and predictability rank high among the list of legal aspirations.[114]

Accordingly, it is arguable that the result in Pfizer was foreseeable. Professor Thomas explained that the USPTO has battled several difficulties in the administration of patent applications over the past decade: an increase in the number of applications filed per year; an increase in the pendency of such applications; applications have become more complex; there is a steady rumble of poor patent quality; and a diverted revenue stream by Congress that prohibits the USPTO from addressing such difficulties.[115] Furthermore, the following perception persists in regard to the USPTO: "The patent-examining corps consists of many hundreds of examiners, many with 'full signatory' authority that effectively allows them to serve as one-person patent offices. The presence of many different decision makers, and the absence of centralized oversight of patentability determinations, further suggests the desirability of rules over standards."[116] In view of such troubles faced by the USPTO, it was not unimaginable that the Federal Circuit would seek to clarify an area of ambiguity: namely, de facto independent claims.

It shall not be forgotten that "the name of the game is the claim."[117] As pointed out in Part II.A.1, patent practice in the United States existed from 1790-1870 before claims were statutorily required. With consideration of the fact that "claims are themselves highly formal entities,"[118] the invalidation of claim 6 in Pfizer was not surprising in view of the Federal Circuit's pursuit of formalism.

III. Application of 35 USC § 112, Fourth Paragraph After Pfizer v. Ranbaxy

It should be apparent from the background section that USC 112, P 4 requires that a proper dependent claim: 1) refer to preceding claim; 2) specify a further limitation of the subject matter in the preceding claim; and 3) be construed to incorporate by reference all of the limitations set forth in the preceding claim. Since the Federal Circuit's decision in Pfizer, alleged infringers have been utilizing USC 112, ***284** P 4 as an invalidation defense. Furthermore, the BPAI has found the same provision serviceable for rendering claims in a patent application unpatentable.

A. Invalidation of Claims by Federal Judges

In Intamin v. Magnetar, the plaintiff filed suit against Magnetar for the infringement of their patented braking system (used for amusement devices; e.g., a rollercoaster).[119] The district court invalidated dependent claim 10 in US Patent 6,062,350.[120] Claim 10 is set out below:

> 10. The braking device of claim 1 wherein said energizing portion is configured for attachment to said fixed device part, and said conductive portion is configured for attachment to said movable device part.[121]

After summary judgment for the plaintiff, but prior to the final decision, the case was appealed to the Federal Circuit.[122] The Federal Circuit was only required to construe the meaning of claim 1, but Intamin argued that court's claim construction of claim 1 would render claim 10 improper.[123] For this reason, Intamin argued that the court should construe claim 1 as to include the embodiment of claim 10.[124] The Federal Circuit disagreed: "Because claim 1 requires the conductive portion to reach the length of the fixed device part and claim 10 places the conductive portion on the passenger car, claim 10 is an improper dependent claim."[125] On remand, claim 10 was invalidated because it "eliminates the element of a conducting rail attached to or extending the length of the fixed device part."[126] In other words, when claim 10 eliminated a limitation of claim 1, the claim was invalid for failing to incorporate by reference all of the limitations of the preceding claim that it referenced.[127]

If the harm of invalidation is great and USC 112, P 4 is more procedural than substantive, then a litigator would likely argue that a court should construe claims in a manner that would preserve the validity of such claims. That is precisely what happened in Nike v. Adidas.[128]

***285** Nike sued Adidas for infringement of its patent (US 6,487,796).[129] In the Markman order, the district court acknowledged the maxim "[a] claim should be interpreted, if practicable, so as to give it effect rather than to have it fail," but reasoned that a court cannot correct a claim during claim construction.[130] Adidas argued that claim 16 was in violation of USC 112, P 4, for failing to further limit the subject matter in claim 9, and was therefore invalid.[131] Claim 16 is set out below:

> 16. The article of footwear of claim 9, wherein said heel plate underlies at least a portion of an arch of the foot and substantially all of the heel.[132]

The problem with the claim 16 reference to said heel plate is that claim 9 does not recite heel plate. Therefore, claim 16 recites the definite said without an antecedent basis for the subject matter of reference. In response, Nike argued that the term said was an error and should be interpreted as a,[133] which means one or more.[134] According to Nike, "the specification and claims make ample references to 'heel plate' so a substitution of 'a' for 'said' is not subject to reasonable debate."[135]

The court was unconvinced that such an error would be harmless, and reasoned that correcting said as if it were a typographical error would be akin to substituting "claim 8" for "claim 9."[136] The court concluded: "If changing '9' to '8' makes as much sense as replacing 'said' with 'a,' then Nike's proposed correction is 'subject to reasonable debate.' Claim 16 cannot be corrected in claim construction."[137]

Of note is the fact that the MPEP proposes that claims lacking proper antecedent basis are indefinite under USC 112, P 2.[138] The MPEP states the following:

> ***286** A claim is indefinite when it contains words or phrases whose meaning is unclear. The lack of clarity could arise where a claim refers to "said lever" or "the lever," where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference.[139]

Yet, MPEP § 2173.05(e) provides the following stipulation: "the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite."[140] The typographical error in dependent claim 16, at issue in Nike v. Adidas, provides such an example. There, the defendant was arguably foreclosed from asserting that claim 16 was indefinite because the meaning of said heel plate was apparent from the context provided by the specification and other claims. In that case, Adidas asserted the correct argument against the validity of claim 16; specifically, Adidas argued that the dependent claim was drafted improperly and should be rendered invalid under USC 112, P 4.

Although not all dependent claims that are rendered improper under USC 112, P 4 are also indefinite under USC 112, P 2, there are situations where a dependent claim would be construed as both improper and indefinite. For instance, a dependent claim that is inconsistent with the independent claim from which it depends may also be invalid under both paragraphs of USC 112.

In Konvin v. Extech, the defendant argued that dependent claims 5 and 21 of Konvin's patent (US 6,164,024) were indefinite under USC 112, P 2 because of their inconsistencies with the independent claims 1 and 15, from which they depend, respectively.[141] The district court noted:

> Though parties making this type of argument ordinarily argue that improper dependent claims violate 35 U.S.C. 112, P 4, . . . the Court can also imagine a dependent claim that violates § 112, P 2. A claim, like the one in Allen, that does not adequately notify the public regarding the patentee's right to exclude because it contains an internal contradiction presumably would fall into this category.[142]

After the court examined the claims, it concluded that claim 5 properly narrowed the subject matter of claim 1, but because "claims 21 [sic] cannot both incorporate the elements of claim 15 and recite a clip with an 'upwardly, opening channel,' claim 21 does not adequately notify the public of Konvin's right to exclude. ***287** For this reason, no jury reasonably could find that claim 21 is valid under 35 U.S.C. § 112, P 2."[143] The failure of dependent claim 21 to incorporate by reference all of the limitations set forth in claim 15 would have rendered the claim invalid under USC 112, P 4 as well, had the defendant made that argument.

In sum, the Intamin, Nike, and Konvin cases examined dependent claims that were drafted in a traditional dependent format, i.e., the reference to the preceding claim was in the claim preamble. Although those cases reinforce the soundness of invalidating an improper dependent claim under USC 112, P 4, none required the courts to interpret a claim having shorthand drafting language, i.e., the reference to the preceding claim is not in the claim preamble. However, in Monsanto v. Syngenta, the Federal Circuit noted that dependent claim 4 in US patent 5,538,880 was in a "somewhat unusual format."[144] Claim 4 is set out below:

> 4. A process comprising obtaining progeny from a fertile transgenic plant obtained by the process of claim 1 which comprise said DNA.[145]

The district court construed claim 4 as a dependent claim, wherein claim 4 added a fourth step of obtaining progeny by the process of claim 1.[146] On appeal, the Federal Circuit characterized Monsanto's argument as follows:

According to Monsanto, claim 4 is by itself a single-step process (process of obtaining progeny). Under Monsanto's construction, the dependent language refers instead to the novel starting material (a fertile transgenic plant previously obtained using the claim 1 process) of the new process in claim 4. To bolster its point, Monsanto draws attention to the form of claim 4, which differs a bit from the customary dependent claim format (i.e., "the process of claim 1 further comprising . . .").[147]

Before the Federal Circuit examined the validity of claim 4, the court set forth the rule of USC 112, P 4 and cautioned that a claim is not independent or dependent based on form alone:

> To establish whether a claim is dependent upon another, this court examines if the new claim both refers to an earlier claim and further limits that referent. . . . A ***288** claim's status as dependent or independent depends on the substance of the claim in light of the language of § 112, P 4, and not the form alone.[148]

The analysis provided by the court in regard to the validity of claim 4 under USC 112, P 4 was straight-forward,[149] but the court's comment on a "claim's status" signaled that the substance of the claim must be considered in the determination of whether a claim is dependent or independent. The court said, "[t]he claim might have used express language to clarify that it only invoked the product of the process in claim 1 as a starting material, but did not do so. Instead, the claim language reads claim 1 into claim 4."[150] The court explained:

> Although in a somewhat unusual format, claim 4 is dependent from claim 1 because it only stands if all three steps recited in claim 1 have been performed. In other words, the additional fourth step of obtaining progeny depends on the performance of the process comprising the three steps recited in claim 1 for obtaining a fertile transgenic plant. Claim 4 contains each element of a dependent claim.[151]

Based on the Federal Circuit's analysis, it becomes apparent that if a claim has been drafted with a reference to a preceding claim, then there will be a presumption that the claim is dependent. However, that presumption is rebuttable when the substance incorporated by the reference is unnecessary for the claim to stand alone. In this case, Monsanto was unable to rebut the presumption and successfully argue that claim 4 was a de facto independent claim because the limitation added by claim 4 only had meaning when the court read the limitations of claim 1 into claim 4.

The approach advocated by the Federal Circuit infuses flexibility into the construction of claims drafted with a shorthand reference, but it remains unclear how a claim could have meaning without reading the language of a preceding claim into the referent claim.

B. Rejection of Claims by Administrative Patent Judges

Since Pfizer, the BPAI has employed USC 112, P 4 to render various claims unpatentable. In Ex parte Esser, the BPAI examined chemical compound claims.[152] ***289** The BPAI found dependent claims 74-76 and 78-80 unpatentable because the variable R may be, inter alia, halogen, whereas the preceding independent claim 21 limited the variable R to the specific halogens: fluorine, bromine, and iodine (i.e., no chlorine or astatine).[153] A dependent claim that does not include all of the limitations of the claim from which it is dependent fails to comply with USC 112, P 4. In this case, because halogen is a genus that is broader than any of its species, the dependent claims 74-76 and 78-80 failed to include the limitations recited in

the referenced claim 21.[154]

The BPAI decision in Ex parte Hsu presented another case in which an indefiniteness analysis under USC 112, P 2 incorporated the USC 112, P 4 analysis of Pfizer.[155] In the inventor's patent application, independent claim 25 and dependent claim 45 recited:
25. A process for cleaning a microelectronic substrate . . . with an aqueous cleaning composition . . . wherein the aqueous cleaning composition consisting of . . . .

. . . .

45. A process of claim 25 wherein the cleaning composition comprises . . . .[156]

It is settled law that the transitional phrase "consisting of" is closed language, whereas "comprising" is open-ended language that does not restrict the scope of the claim to the subsequently enumerated limitations.[157] For this reason, the BPAI concluded that dependent claim 45 recited a composition that allowed for the inclusion of other, unspecified ingredients.[158] Because claim 45 was construed as broader in scope than its preceding independent claim 25, it necessarily failed to incorporate by reference all the limitations of the previous claim, as required by USC 112, P 4.[159] The BPAI concluded that there was no reason to issue a patent with such language and "transfer to potential competitors and Federal Courts the chore of having to figure out the claims."[160] During examination, a claim should be amended to clear up even minor ambiguities, whereas in litigation a claim enjoys a presumption of validity.[161] As a result, the BPAI concluded that "[a] 'comprising' ***290** dependent claim cannot open the scope of a 'consisting of' independent claim without causing potential confusion," and maintained the examiner's rejection under USC 112, P 2.[162]

Finally, in Ex parte Avizienis, the BPAI agreed with the patent examiner in regard to an interpretation of the word such.[163] In this case, claim 1 recited: "Apparatus for deterring failure of a computing system; said apparatus comprising . . ."; and claim 4 recited: "The apparatus of claim 1, further comprising: such computing system."[164] The BPAI rendered claim 4 unpatentable under USC 112, P 4. The holding is set out below:

> [W]e agree with the Examiner that using "such" (instead of "said" or "the") does not further limit the antecedent claim element in the parent claim. Instead, we conclude that the use of "such" actually broadens what has been previously claimed, because "such computing system" (claim 4) could be reasonably read on a different computing system (perhaps a similar computing system) than the particular "computing system" originally introduced in the preamble of claim 1.[165]

Unfortunately, the Ex parte Esser, Ex parte Hsu, and Ex parte Avizienis appeals did not present the BPAI with an opportunity to construe a shorthand claim reference because all of the dependent claims examined had been drafted in traditional dependent form. Still, the decision in Ex parte Hsu was consistent with the district courts' holdings in Nike and Konvin. Those cases collectively illustrate that a dependent claim that fails to incorporate by reference the limitations of a preceding ***291** claim or add a further limitation to the subject matter thereof--the requirements of USC 112, P 4-- may concurrently be rendered indefinite under USC 112, P 2.

C. Objection of Claims by Patent Examiners

A patent examiner is a quasi-judicial employee.[166] This means that an examiner is required to apply legal principles, such as novelty or obviousness, but is not allowed to change the law. In other words, an examiner must interpret and examine the claims of a patent application in a manner that is consistent with the procedures and case law set out in the MPEP.[167] As identified supra,[168] the MPEP puts forward the infringement test as the means for an examiner to determine the patentability of dependent claims under USC 112, P 4.[169] With respect to the treatment of improper dependent claims, MPEP § 608.01(n) states:

> Where a claim in dependent form is not considered to be a proper dependent claim under 37 CFR 1.75(c), the examiner should object to such claim under 37 CFR 1.75(c) and require cancellation of such improper dependent claim or rewriting of such improper dependent claim in independent form.[170]

In Ex parte Avizienis, the BPAI sustained the examiner's rejection of several claims (including claim 4) under USC 112, P 4. Interestingly, the BPAI relied on the Pfizer decision and withheld any discussion of Ex parte Porter, which recited the following:

> We note that the above-referenced section of M.P.E.P. Section 608.01(n) suggests that where an examiner considers a claim to be an improper dependent claim, the examiner should require cancellation of that claim. Such requirement, in our opinion, properly treats a claim considered to be an improper dependent claim as an administerial function or formal matter wherein the examiner's ruling can be challenged by way of petition under 37 CFR Section 1.181 rather than by appeal under 37 CRF Section 1.191.[171]

In its current form, the MPEP has not been revised in a manner that is consistent with Pfizer or the recent BPAI decisions. In each of those cases, a judge invalidated or rejected (rendered unpatentable) one or more dependent claims that failed ***292** to comply with the formal requirements of USC 112, P 4. The inconsistency is that an examiner must object to improper dependent claims, whereas the BPAI has rejected such claims.

IV. Incorporation by Reference and the Doctrine of Necessity[172]

A traditional dependent claim further defines an earlier claim, whereas some dependent claims and de facto independent claims are defined by an earlier claim.[173] Claim drafters have also referenced various parts of the specification, including tables, figures, and/or other data (e.g., sequence listings).[174] The judicial doctrine of necessity governs the permissible use of such references and is insightful for the determination of whether the use of de facto independent claims should be permitted.

A. Claims Referencing the Specification, Drawings, and Data

Intuitively, an independent claim should stand alone. In fact, this is what the patent and claim drafting manuals specify.[175] Further, this was the position of the BPAI in Ex parte Fressola.[176] In that appeal, the BPAI examined claim 42, which the examiner rejected under USC 112, P 4.[177] Claim 42 is set out below:

> 42. A system for the display of stereographic three-dimensional images of celestial objects as disclosed in the specification and drawings herein.[178]

The BPAI reasoned that because the specification and claims are separate statutory requirements, "[a] claim which refers to the specification defeats the purpose of a claim. The limited exceptions which permit incorporation by reference do not apply because the system can be described in words without reference to the specification ***293** and drawings."[179] The rule of this case is cited in MPEP § 2173.05(s), which is set out below:

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table [of properties] "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience."

Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims.[180]

In the biotechnology arts, the doctrine of necessity permits an applicant to reference biological materials in the disclosure of the specification.[181] A basic canon of claim construction is that claims must be read in light of the specification.[182] If an examiner determines that access to a biological material is necessary for the determination of patentability, then the claims may be rejected under 35 U.S.C. § 112.[183] As a result, references to biological identifiers (i.e., "sequence listings") are permitted in claims. MPEP § 2402 states:

> Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. Courts have recognized the necessity and desirability of permitting an applicant for a patent to supplement the written

> disclosure in an application with a deposit of biological material which is essential to meet some requirement of the statute with respect to the claimed invention.[184]

***294** The rule in Ex parte Fressola is practical and exemplifies a pro-patent policy--a patent applicant should not be foreclosed from the rights and protections that patents provide merely because of the inherent limitations of language. The flexibility of the rule of necessity provides a shield to claim drafters, who often need to describe complex inventions, and a sword to patent examiners and judges, who need to enforce the statutory requirement that claims particularly point out and distinctly claim the subject matter of the invention.

B. Proposed Amendments for the Rule on Claims and the MPEP

The rule of necessity, as articulated in Ex parte Fressola, provides a reasonable standard that is generally applicable to all claims. This article proposes amendments to CFR 1.75 and the MPEP that incorporate the rule of necessity, and it is suggested that the amendments will facilitate consistent and predictable claim construction.

The amendment to CFR 1.75 consists of a formal definition of "independent claim." As a rule, the definition reestablishes the logical, contrary relationship between independent and dependent claims. Additionally, the definition abolishes de facto independent claims, eliminating the illogical, contradictory relationship between independent and de facto independent claims. The proposed rule for CFR 1.75 adopts the definitions provided by the original MPEP and should be an added as 37 CFR § 1.75(j). The new rule is set out below:

> (j) Claims are independent or dependent. An independent claim is complete in itself without reference to another claim. A dependent claim refers to and modifies another claim.

The proposed revisions to the MPEP address inconsistencies between §§ 608.01 and 2173.05 and the recent jurisprudence of USC 112, P 4. The first proposed amendment is a revision to MPEP § 2173.05(f), in which the following paragraphs should be inserted before the current language that discusses references to another claim (in the context of indefiniteness under USC 112, P 2). The revision is set out below:
2173.05(f) Reference to Limitations in Another Claim

37 CFR § 1.75(j) Claims are independent or dependent. An independent claim is complete in itself without reference to another claim. A dependent claim refers to and modifies another claim.

A claim that refers to another claim shall be construed as a dependent claim. A claim that refers to an earlier claim and does not comply with the statutory requirements of 35 U.S.C. § 112, P 4 or any other provision of this section is unpatentable. In Pfizer, Inc. v. Ranbaxy Laboratories Ltd., 457 F.3d 1284, 1292 79 U.S.P.Q.2d 1583 (Fed. Cir. 2006), the Federal Circuit construed the following claim as a dependent claim: "The hemicalcium salt of the compound of claim 2." The court invalidated the claim because it failed to further limit the subject matter of claim 2, the claim upon which it depended. An examiner that determines ***295** that a dependent claim is improper under 35 U.S.C. § 112, P 4 should reject the dependent claim and require an appropriate correction.

The second proposed amendment is a revision to MPEP § 2173.05(e), in which the following paragraphs should be inserted after the current language that discusses antecedent basis (also in the context of indefiniteness under USC 112, P 2). The revision is set out below:
2173.05(e) Lack of Antecedent Basis

A dependent claim is improper if it fails to specify a further limitation of the subject matter in a preceding claim, or if the claim fails to incorporate by reference all of the limitations set forth in the preceding claim (35 U.S.C. 112, fourth paragraph). A situation arises in dependent claims that refer to "said heel plate," where neither the claim nor the earlier claim upon which the claim is dependent from contains an earlier recitation or limitation of a "heel plate." A claim that lacks antecedent basis in this manner is improper because it fails to further limit the subject matter in an earlier claim. Nike, Inc. v. Adidas Am. Inc., No. 9:06-CV-43, 2006 WL 3751181 (E.D. Tex. Dec. 18, 2006).

The third proposed amendment is a revision to MPEP § 608.01(n), Part II. The revisions are set out below:
II. Treatment of Improper DEPENDENT Claims

Where a claim in dependent form is not considered to be a proper dependent claim under 37 CFR 1.75(c) or (j), the examiner should <<strikethrough>>object<<end strikethrough>> reject such claim under 37 CFR 1.75(c) and (j) and require cancellation of such improper dependent claim or rewriting of such improper dependent claim in proper independent form. See << strikethrough>>Ex parte Porter, 25 USPQ2d 1144, 1147 (Bd. of Pat. App. & Inter. 1992) (A claim determined to be an improper dependent claim should be treated as a formal matter, in that the claim should be objected to and applicant should be required to cancel the claim (or replace the improper dependent claim with an independent claim) rather than treated by a rejection of the claim under 35 U.S.C. 112, fourth paragraph.)<<end strikethrough>> Pfizer, Inc. v. Ranbaxy Laboratories Ltd., 457 F.3d 1284, 1292 79 U.S.P.Q.2d 1583 (Fed. Cir. 2006) ("Although the district court was reluctant to find the fourth paragraph of § 112 to be an invalidating provision, doing so does not exalt form over substance. Rather, it is consistent with the overall statutory scheme that requires applicants to satisfy certain requirements before obtaining a patent, some of which are more procedural or technical than others."). The applicant may thereupon amend the claims to place them in proper dependent form, or may redraft them as independent claims, upon payment of any necessary additional fee.

<<strikethrough>>Note, that although 37 CFR 1.75(c) requires the dependent claim to further limit a preceding claim, this rule does not apply to product-by-process claims.<<end strikethrough>>

The fourth and final proposed amendment is the elimination of the infringement test set forth in MPEP § 608.01(n), Part III. In view of the proposed rule, the infringement test is superfluous.

***296** In sum, the proposed amendments to CFR 1.75 and the MPEP clarify the relationship between independent and dependent claims, and will facilitate consistent claim constructions for those claims that reference a preceding claim or the limitations therein.

C. Arguments in Opposition to the Proposed Amendments

Admittedly, the proposed rule and revisions to the MPEP are likely to have critics. Patent claims are presumed to be valid[185] and the proposed definition would likely render any claims having a shorthand reference invalid under USC 112, P 4, if challenged in litigation. The rule proposal is essentially a codification of the Federal Circuit's claim interpretation of claim 6 in Pfizer. Critics of the Pfizer decision argue that a purpose of USC 112, P 4 is to expedite patent prosecution: dependent claims are generally shorter in length and functionally narrow a broader independent claim.[186] For this reason, dependent claims are easier to examine.[187] In fact, the PTO encourages the use of dependent claims by charging lower filing fees than for independent claims.[188] Additionally, critics of the Pfizer decision argue that courts, when faced with a situation where a claim may be construed as either independent or as an improper dependent claim, should not rigidly apply USC 112, P 4, but construe the claim in a manner that will preserve its validity.[189]

Another likely critic to the proposed rule and revisions to the MPEP is the USPTO. The MPEP is illustrative of the agency's policy, and the following MPEP quotations are in conflict with the proposed rule:
[A]lthough 37 CFR 1.75(c) requires the dependent claim to further limit a preceding claim, this rule does not apply to product-by-process claims . . .

. . . .

[A] dependent claim which is otherwise proper might relate to a separate invention which would require a separate search or be separately classified from the claim on which it depends would not render it an improper dependent claim

. . . .

***297** [T]hat the independent and dependent claims are in different statutory classes does not, in itself, render the latter improper.[190]

Finally, it has been customary in patent claim drafting to reference other claims in shorthand form. The use of shorthand references is a convenient means for incorporating limitations from earlier claims, and the use of such references allows for shorter claims that are easier to read. The proposed rule would render the use of shorthand references impermissible and dependent claims would have to be rewritten into independent form. As a result, a patent applicant would have to pay higher fees for the additional independent claims.[191]

Prosecution history estoppel (estoppel) is also a concern for patentees and patent applicants. Estoppel can occur in various ways, including when some subject matter in a claim, as originally filed, was redacted from the claim during prosecution.[192] Courts have established a rebuttable presumption that amendments made during prosecution were made for patentability reasons, and that the subject matter that was redacted has been surrendered.[193] Thus, when an amendment converts a dependent claim into an independent claim during prosecution, estoppel will potentially foreclose a patentee from asserting infringement under the doctrine of equivalents.[194]

For patent applications filed after the proposed rule, if enacted, there would not be a concern for estoppel because patent applicants are permitted to submit preliminary amendments prior to the examination of an application.[195] However, for issued patents and applications currently in prosecution, there would be a concern that a claim amendment would jeopardize the scope of protection that a patent offers. In Honeywell International Inc. v. Hamilton Sundstrand Corp., the Federal Circuit made clear that converting dependent claims into independent claims is a real risk:

> ***298** [T]he fact that the scope of the rewritten claim has remained unchanged will not preclude the application of prosecution history estoppel if, by canceling the original independent claim and rewriting the dependent claims into independent form, the scope of subject matter claimed in the independent claim has been narrowed to secure the patent.[196]

It is true that the implementation of the proposed rule may be adverse to the validity of many patent claims; however, if those patent claims were to be challenged for invalidity, then the patentee faces the risk of losing patent protection regardless.

One way of rectifying any minor errors in a patent claim before an assertion of invalidity is through a certificate of correction.[197] Upon payment of a fee, the USPTO will "issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination."[198] An amendment that merely rewrites a dependent claim into an independent claim that includes the subject matter that was previously incorporated by reference would likely qualify as a mistake "of minor character" and not require re-examination.[199]

In Honeywell, Judge Newman's dissenting opinion correctly articulates the relationship between estoppel and USC 112, P 4:

> When a dependent claim is placed in independent form, it simply states explicitly what was previously incorporated by reference. . . . Restating a dependent claim in independent form does not change its content or scope; the claim is of identical content and scope before and after it is rewritten.[200]

***299** In Honeywell, "[a]ll of the asserted independent claims were originally dependent claims that were rewritten into their present independent form during prosecution. The broader original independent claims were cancelled."[201] Since all of the referenced claims in Honeywell were cancelled, they were subject to estoppel. However, those facts are distinct from the scenario that the rule proposed in this article foresees. In the situation that claims, either dependent or de facto independent, need to be amended in order to comply with USC 112, P 4, the earlier claim need not be cancelled. It is likely that such claims were drafted with the intent of presenting claims of varying scope. Thus, the replacement of the shorthand reference with the actual subject matter previously incorporated by reference will still result in claims of varying scope. In other words, when the original independent claim is not cancelled, estoppel should not be applicable.

One of the concerns that would result from more independent claims is the increase in filing fees for patent applicants.[202] Although not ideal for applicants, former Federal Circuit Chief Judge Michel expressly called for higher fees.[203] Other than potentially higher fees and the risk of estoppel, the arguments in opposition to the proposed rule are drawn to convenience. An administrative policy based on convenience rather than formalism is not proper. Rather, a policy that facilitates consistency and predictability is sound, and the rule proposed in this article seeks to promote those ends. Further, the proposed rule articulates a logical relationship between ***300** dependent and independent claims. As a result, the plain meaning of USC 112, P 4 need not be strained by the existence of de facto independent claims.

V. Application of the Proposed Rule in Practice

As defined by the proposed rule in Part IV, an independent claim is complete in itself without reference to another claim. Application of the rule to the following hypothetical claims makes claim interpretation, in regard to form, an easy and predictable exercise. Consider the following hypothetical claims:

1. A compound selected from the group of N-(4-hydroxyphenyl)acetamide, a-methyl-4-(2-methylpropyl)benzene-acetic acid, a-methyl-4-(2-methylpropyl)benzene-acetic acid, and (5a,6a)-7,8-dihehydro-4,5-epoxy-17-methylmorphinan-3,6-diol.

2. The compound of claim 1 that is a-methyl-4-(2-methylpropyl)benzene-acetic acid.

3. The compound of claim 1 that is N-(4-hydroxyphenyl)acetamide.

4. A pharmaceutical composition comprising a compound of claim 1.

5. A pharmaceutical composition comprising (5a,6a)-7,8-dihehydro-4,5-epoxy-17-methylmorphinan-3,6-diol.

6. A pharmaceutical composition comprising the compound of claims 2 or 3.

7. A chemical process of preparing a compound comprising the reaction of p-aminophenol with acetic anhydride.

8. The product produced by the process in claim 7.

9. The product produced by a chemical process comprising the reaction of p-aminophenol with acetic anhydride.

10. A method of treating pain in a patient in need thereof comprising administering a physiologically effective dose of a pharmaceutical composition of N-(4-hydroxyphenyl)acetamide.

11. A method of treating inflammation in a patient in need thereof comprising administering a physiologically effective dose of the composition in claim 5 or 6.

12. A method of treating inflammation in a patient in need thereof comprising administering a physiologically effective dose of the compound in claim 2.

There are four statutory classes of inventions: processes, machines, manufactures, and compositions of matter.[204] Patent applications in the chemical arts generally contain product and process claims.[205] In chemical applications, a product ***301** claim is a composition of matter and a process claim is either a method of preparing a product or a method of using a product. The product claims generally set forth the definition of the chemical compounds, whereas composition and method claims generally refer back to the product claims for limitations of the compound. Although patent applications in the chemical arts are usually subject to a restriction requirement,[206] an examiner may examine claims from various statutory classes.[207]

The hypothetical claims 1-6 are product claims, in which claims 1-3 are compound claims and claims 4-6 are composition claims. Claims 8 and 9 are product-by-process claims. Claims 7 and 10-12 are process claims, in which claim 7 provides a method of making a compound and claims 10-12 provide methods for using the compound. Claims 2 and 3 have been drafted in a traditional dependent format, whereas claims 4, 6, 8, 11, and 12 use shorthand references to previous claims. Claims 6 and 11 refer to more than one preceding claim and are referred to as multiple dependent claims.

A. Claims Referencing Claims of the Same Statutory Class

Dependent claims 2 and 3 are proper dependent claims under USC 112, P 4 because they refer to an earlier claim and add a further limitation to the subject matter therein (claim 1 is a genus of three compounds and claims 2 and 3 are each drawn to one species in the genus).

Dependent claims 4 and 6 are improper dependent claims because the claims fail to further limit the subject matter of claims 2 or 3. Claims 4 and 6 use the open-ended transition phrase comprising, whereas claims 2 and 3 use closed language that restricts the subject matter to a compound. Therefore, claims 4 and 6 open the scope and allow for the inclusion of other, unspecified ingredients.

***302 B. Claims Referencing Claims of a Different Statutory Class**

Dependent claims 11 and 12 are of a different statutory class than the claims in which they are dependent from; that is, claims 5, 6, and 2. Claim 11 is a multiple dependent claim and is discussed below. Claim 12 is an improper dependent claim because it fails to further limit the subject matter of claim 2. Claim 2 is drawn to a particular chemical compound and cannot be further limited; thus, claim 12 should be rewritten to replace "the compound of claim 2" with the chemical name, a-methyl-4-(2-methylpropyl)benzene-acetic acid.

C. Claim Referencing in Product-by-Process Claims

A product-by-process claim is a claim that defines a product by the process in which the product is made.[208] This format of drafting developed as a means for claiming new products that had not been fully characterized. In other words, a product's chemical structure was unascertainable. The USPTO and courts have allowed such claims because an inventor would be unable to protect his discovery otherwise. Product-by-process claims evolved in a manner that is consistent with the doctrine of necessity, as described in Part IV.

In In re Thorpe, the Federal Circuit explained: "Product-by-process claims are not specifically discussed in the patent statute. The practice and governing law have developed in response to the need to enable an applicant to claim an otherwise patentable product that resists definition by other than the process by which it is made."[209]

Admittedly, it appears that product-by-process claims no longer are restricted to those instances of necessity. In Smithkline Beecham Corp. v. Apotex Corp., the Federal Circuit stated: "Today, however, product-by-process claims are used by inventors even if the invention could have been described independent of the ***303** process."[210] Although this change of policy creates more flexibility to applicants, it provides more ambiguity to patent examiners and judges.

The rule proposed in this article would eliminate dependent product-by-process claims, because the definition of independent claim would not permit a product claim to further limit a process claim. For example, consider hypothetical claims 7-9. Claim 7 is a process claim and claims 8 and 9 are product-by-process claims. Claim 8 is dependent on claim 7 and is improper for failing to further define the synthetic process. However, claim 9 is independent and does not refer back to another claim. For this reason, claim 9 would be a proper product-by-process claim in view of the Federal Circuit's policy and demonstrates that the proposed rule in this article is not overly rigid.

D. Claim Referencing in Multiple Dependent Claims

A claim that refers back, in the alternative, to more than one preceding independent or dependent claims is called a multiple dependent claim.[211] While USC 112, P 4 is the statutory provision that defines dependent claims, the fifth paragraph of USC 112 provides a similar definition for multiple dependent claims:

> A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.[212]

The MPEP states that "a multiple dependent claim must be considered in the same manner as a plurality of single dependent claims."[213] Therefore, a multiple dependent claim must: 1) refer to the preceding claim; 2) specify a further limitation of the subject matter in the preceding claim; and 3) be construed to incorporate by reference all of the limitations set forth in the preceding claim. However, the fifth paragraph of USC 112 adds another requirement: 4) a multiple dependent claim shall not serve as a basis for any other multiple dependent claim.

The rule proposed in this article would also facilitate consistent and predictable claim constructions of multiple dependent claims. Multiple dependent claim drafting has been used internationally for decades. When such international patent applications are subsequently filed in the United States, a question arises: are multiple dependent claims that have a shorthand reference to a preceding claim independent ***304** or dependent? If the rule proposed in this article were adopted, then the inquiry would end if the examined claim has a reference to another claim. A claim referencing another claim is a dependent claim, and if the claim refers to multiple claims, then the claim must adhere to the requirements of the fifth paragraph of USC 112.

In practice, it is easy to see that hypothetical claims 6 and 11 refer back to multiple claims. Claim 6 was discussed in part B, supra. Claim 11 refers back to claim 6, which is itself a multiple dependent claim. For this reason, the claim is improper under the fifth paragraph of USC 112, requiring that "a multiple dependent claim shall not serve as a basis for any other multiple dependent claim."[214]

E. Claim Construction and the Doctrine of Claim Differentiation

Courts apply many canons of claim construction, but in Professor Lemley's opinion: "the doctrine of claim differentiation is the canon that has arguably had the most significant impact on claim construction."[215] In theory, no two claims in the same patent should be of identical scope.[216] Claim differentiation, stated most broadly, is the "'presumption that each claim in a patent has a different scope.'"[217] More specifically, and most relevant to this article, claim differentiation "refers to the presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim. . . . Thus, the claim differentiation tool works best in the relationship between independent and dependent claims."[218]

***305** In effect, claim differentiation generally results in broad construction of patent claims, and may at times expand the scope of a claim beyond what the patent supports. Lemley investigated the use of claim differentiation in federal courts and discovered that the doctrine sometimes "lead courts astray."[219] For example, Lemley discusses the Federal Circuit's interpretation in Phillips v. AWH, where "the court interpreted a claim to encompass an embodiment of an invention that would not achieve the purpose of the invention."[220] In order to guide courts from inappropriate claim constructions based on claim differentiation, Lemley proposed several guidelines.

The first guideline suggests that "courts should not use the doctrine unless the claims in question are in an independent-dependent relationship."[221] He explained that interpreting an independent claim in a manner that results in an identical construction as for a dependent claim defeats the purpose of having a dependent claim.[222] In Liebel-Flarsheim Co. v. Medrad, Inc., the Federal Circuit explained, "the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim."[223] This presumption parallels the statutory requirements of USC 112, P 4. However, without a definition for independent claim, informed minds may disagree as to whether a claim is independent or dependent.

The rule proposed in this article buttresses Lemley's guideline and the judicial presumptions of claim differentiation because it eliminates de facto independent claims. As a result, the determination of whether a claim is dependent or independent is simplified, and the courts will be more likely to construe claims in an independent-dependent relationship with differing scope without the concern that the claims are arguably both independent.

VI. Conclusion

This article investigated the confusion that arises when claims are drafted with shorthand references, and reviewed the history and jurisprudence of USC 112, P 4. It was determined that the patent system has allowed claim drafters to use de facto independent claims--claims that refer back to a preceding claim like a dependent claim, but are construed as independent claims--and that such claims have resulted in inconsistent claim constructions by patent examiners and judges.

As a means to end the ambiguity that arises with the use of de facto independent claims, this article proposed a formal definition for independent claim that will ***306** assist in the claim construction of all claim formats. The definition does not exalt form over substance, but it does exalt form over convenience. It is proposed that formalism in claim drafting will facilitate consistent and predictable claim interpretations during patent prosecution and litigation, and will protect

multi-billion dollar investments like Lipitor®.

Footnotes

[a1] Patent Examiner, U.S. Patent & Trademark Office, Technology Center 1600 (Biotechnology, Organic Chemistry and Pharmaceuticals), Alexandria, VA; Ph.D. (Organic Chemistry), North Carolina State University, 2003; B.S. (Chemistry), St. Lawrence University, 1998; J.D. candidate, The Columbus School of Law at The Catholic University of America, 2012. I gratefully acknowledge A.G. Harmon, Professor, The Columbus School of Law, for his incredible help. All errors herein are mine. The views in this article are those of the author and do not necessarily reflect the views of the United States Patent and Trademark Office.

[1] Giles S. Rich, The Extent of the Protection and Interpretation of Claims--American Perspectives, 21 Int'l Rev. Indus. Prop. & Copyright L. 497, 499 (1990). Prior to an international meeting between European and American judges in 1990, regarding the problems of European and American patent law, Judge Rich published his perspective on American claim interpretation.

[2] 35 U.S.C. §154(d) (2006).

[3] Rich, supra note 1, at 501.

[4] U.S. Patent & Trademark Office, Manual of Patent Examining Procedure §704 (8th ed., Rev. 8, July 2010) [hereinafter MPEP].

[5] See, e.g., Markman v. Westview Instruments, Inc., 52 F.3d 967, 990 (Fed. Cir. 1995) (Mayer, J., concurring) ("Anyone who wants to know what a patent protects must first read its claims, for they are the measure of its scope.") (citing Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 339 (1961)), aff'd, 517 U.S. 370 (1996). Many trials begin after a claim interpretation hearing, also known as a Markman hearing. Janice M. Mueller, Patent Law 344-45 (3d ed. 2009). Following the hearing, the court will issue a Markman order that sets forth the manner in which each claim will be construed for the remainder of the case. Id. However, there is no uniform procedure and some courts conduct the Markman hearing at other times; for instance, after a motion for summary judgment. Id. at 344.

[6] Mueller, supra note 5, at 84.

[7] 35 U.S.C. §112 (2006).

[8] Id.

[9] Id.

[10] The chemical arts include inventions from various industries, such as pharmaceuticals, herbicides, cosmetics, polymers, fuels, inks, explosives, material science, etc. See U.S. Patent & Trademark Office, Classes Within the U.S. Classification System II 1-2 (2009), http:// www.uspto.gov/web/offices/opc/documents/classescombined.pdf (listing items included in Group 1: Chemical and Related Arts).

[11] Combinations include product-by-process and "fingerprint" claims. See, e.g., Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1287, 1291-92 (Fed. Cir. 2009) (discussing both styles of claim drafting). A product-by-process is usually drafted such that the claim has a product preamble followed by limitations that define the product by the process in which it was made. Black's Law Dictionary 1160 (8th ed. 2004). A fingerprint claim is drafted as to describe a new chemical compound by its inherent properties because the exact structure of the compound is unknown or hard to distinguish as compared to a known form. Id.

[12] In re Baranauckas, 228 F.2d 413, 415 (C.C.P.A. 1955).

[13] In 1919, the International Union of Pure and Applied Chemistry (IUPAC) was formed by chemists from industry and academia for the international standardization of chemical nomenclature, weights, measures, and symbols. About IUPAC, International Union of Pure and Applied Chemistry, http:// old.iupac.org/general/about.html (last visited July 1, 2010). However, even with the promulgation of the international rules, the name of a particular chemical will vary among different resources (e.g., Chemical Abstracts, text books, ChemDraw® chemical drawing & naming software, or the Merck Index).

[14] See William D. Marsillo, How Chemical Nomenclature Confused the Courts, 6 U. Balt. Intell. Prop. L.J. 29, 30-31 (1997) (examining "the difficulty courts have had in maintaining a consistent jurisprudence in the area of chemical patents that have a genus species relationship"). A genus structure depicts a substantial core feature that several chemical species share and variables are attached to the core in order to account for species' differences. See id. (discussing the relationship between genus and species). In regard to chemical nomenclature: "Determining a chemical's name is dependent on the arrangement of different atoms, bonds, and side-groups ...." Id. at 40.

[15] Information on Chemical Nomenclature, University of Pennsylvania Libraries, http://gethelp.library.upenn.edu/guides/scitech/chemnom.html (last updated Dec. 13, 2007); see also Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1353 n.1 (Fed. Cir. 2007) ("Besylate is referred to in the art interchangeably as benzene sulphonate, benzenesulphonate, or benzene sulfonate.").

[16] The Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals 9, 839, 1074 (12th ed. 1996). Compare the above pain medicines with the chemical name for paclitaxel, an anti-cancer therapeutic: [2aR-[2aa, 4b,4ab,6b,9a(aR*,bS*),11a,12a,12aa,12ba]]-b-(benzoylamino)-a-hydroxybenzene-propanoic acid 6,12b-bis(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a, 5,6,9,10,11,12,12a,12b-dodecahydro-4,11-dihydroxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester. Id. at 1200.

[17] The same is true for chemical structures, which are just as tedious to repeat in subsequent claims. However, for simplicity, this article is limited to examples with chemical names.

[18] 35 U.S.C. §112 (2006).

[19] Giles S. Rich, Are Letters Patent Grants of Monopoly?, 15 W. New Eng. L. Rev. 239, 241 (1993). Judge Rich further noted that "[i]f the patent right is not a changeling, there must be two definitions of monopoly, one which includes patents and one which excludes them. The fact is there are two definitions." Id. In a similar manner, there are two definitions of independent claim, one which allows for a reference to another claim and one that requires the claim to stand alone. See infra Part II.C.

[20] 457 F.3d 1284 (Fed. Cir. 2006).

[21] Id. at 1292.

[22] For an explanation of implicit authorization, see infra Part II.C.

[23] 37 C.F.R. §1.75 (2009).

[24] See 35 U.S.C. §2(b)(2) (2006) (stating that the USPTO "may establish regulations, not inconsistent with law").

[25] The MPEP is the Patent Office's official "set of instructions to the examining corps." In re Kaghan, 387 F.2d 398, 401 (C.C.P.A.

1967). Although "[t]he MPEP does not have the force and effect of law ... it is entitled to judicial notice as the agency's official interpretation of statutes or regulations." Refac Int'l, Ltd. v. Lotus Dev. Corp., 81 F.3d 1576, 1584 n.2 (Fed. Cir. 1996).

[26] 37 C.F.R. §1.75 (2009).

[27] Patent law on the North American continent extends back to 1641, when the state of Massachusetts granted Samuel Winslow a limited monopoly right for his novel method of making salt. E.g., U.S. Dep't of Commerce, The Story of the United States Patent Office iv (1972); see also Robert C. Kahrl, Patent Claim Construction §2.03[B], at 2-15 (2008) ("In 1641, the General Court of Massachusetts Bay adopted the first colonial legislation with any resemblance to a patent act."). Patent law became federal law after the U.S. Constitution was ratified by the colonies and the first patent act was signed by the President in 1790. Kahrl, supra, §2.03[D], at 2-18-2-19.

[28] Kahrl, supra note 27, §2.03[D], at 2-20.

[29] Id. §2.03[F], 2-30.

[30] Id. §1.01, 1-3.

[31] Patent Act of 1836, ch. 357, §6, 5 Stat. 117, 119 (emphasis added). The 1836 Patent Act codified what patent practitioners had "almost universally" been doing for years. N.J. Brumbaugh, History and Purpose of Claims in United States Patent Law, 14 J. Pat. Off. Soc'y 273, 276 (1932); see also Karl B. Lutz, Evolution of the Claims of U. S. Patents, 20 J. Pat. Off. Soc'y 134, 143 (1938) ("This addition to the statute had no immediate effect on the form or substance of claims because it was understood as merely codifying the existing law which had been developed by the courts.").

[32] See Craig Allen Nard, Legal Forms and the Common Law of Patents, 90 B.U. L. Rev. 51, 71 (2010) (noting that "claim practice under the 1836 [Patent] Act was characterized by ... central claim drafting").

[33] Kahrl, supra note 27, §2.04[B], at 2-43. Kahrl also noted that although "[t]he Patent Act of 1836 first mentions the concept of the patent claim ... the Patent Act of 1836 cannot be said to have fundamentally changed the patent system, but rather to have reflected a trend in patent practice and judicial expectations that improved the functional efficiency of the patent." Id. §2.04[A], at 2-36 to 2-37; see also Amy L. Landers, Understanding Patent Law 47 (2008) ("Applicants began to include claims that summarized the most important features of an invention and used words such as 'substantially as set forth' in the patent."); see also Mueller, supra note 5, at 66 ("Claims were first mentioned in the U.S. Patent Act of 1836, but not mandated by statute until 1870. Prior to these enactments, patent applicants disclosed their invention to the world by means of a written description.").

[34] Patent Act of 1870, ch. 23, 16 Stat. 198, 201. The Act of July 8, 1870 also contained a provision authorizing the Commissioner of Patents to "make rules and regulations, not inconsistent with law, concerning the conduct of proceedings in the Patent Office." U.S. Dep't of Commerce, supra note 27, at 15.

[35] Kahrl, supra note 27, §2.04[B], at 2-42.

[36] MPEP, supra note 4, §2171 .

[37] Patent Act of 1870, ch. 230, §26, 16 Stat. 198, 201 (emphasis added); Landers, supra note 33, at 48; Mueller, supra note 5, at 66; Kahrl, supra note 27, §2.03[G], at 2-32; but see Kahrl, supra note 27, §2.04[A], at 2-35 ("[A] student might conclude that the claim was bolstered to its present status as the ultimate determinant of a patent through the successive changes of the patent acts. In truth, the prominence of the patent claim arose first as patent practitioners voluntarily used the patent claim to define their invention, and then as a requirement established by court opinions.").

[38] Compare Patent Act of 1870, ch. 230, §26, 16 Stat. 198, 201, with 35 U.S.C. §112 (2006).

[39] P.J. Federico, Commentary on the New Patent Act, 75 J. Pat. & Trademark Off. Soc'y 161, 166 (1993).

[40] See id. at 186 ("In the old statute the requirement for a claim pointing out what the applicant regarded as his invention appeared as a clause in the same sentence relating to the description, which led to some confounding of the nature of the two requirements in a few decisions.... The possible existence of more than one claim in a patent is recognized in the new language.").

[41] Id. Currently, this is the sixth paragraph of 35 U.S.C. §112 (2006).

[42] 1 R. Carl Moy, Moy's Walker on Patents §4:102 (4th ed. 2009).

[43] U.S. Patent & Trademark Office, Manual of Patent Examining Procedure §8-9-16 (1948-1949) [hereinafter Original Manual of Patent Examining Procedure], available at http://www.uspto.gov/web/offices/pac/mpep/old/mpep_ E0R0.htm (last visited Nov. 12, 2010).

[44] Act of July 24, 1965, Pub. L. No. 89-83, §9, 79 Stat. 261.

[45] Act of Nov. 14, 1975, Pub. L. No. 94-131, §§7, 10, 89 Stat. 685 (Patent Cooperation Treaty).

[46] Previously, 35 U.S.C. §112 stated: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. A claim may be written in independent or dependent form, and if in dependent form, it shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim." 35 U.S.C. §112 (1964), amended by Act of July 24, 1965, Pub. L. No. 89-83, §9, 79 Stat. 261. The first paragraph remained unchanged.

[47] 35 U.S.C. §112 (2006) (emphasis added). For the language of the fifth paragraph, see infra Part V.C.

[48] The following make either no reference or a passing reference to the formal requirements of the fourth paragraph of 35 U.S.C. §112: Robert C. Faber, Landis on Mechanics of Patent Claim Drafting (5th ed. 2006); Ernest B. Lipscomb III, Patent Claims (3d ed. 2008); John Gladstone Mills et al., Patent Law Fundamentals §14:32 (2d ed. 2010) [hereinafter Patent Law Fundamentals]; John G. Mills III et al., Patent Law Basics §14:18 (2009) [hereinafter Patent Law Basics]; 1 Moy, supra note 42, §4:102; Mueller, supra note 6; Jeffrey G. Sheldon, How to Write a Patent Application (Supp. 2004); Jane E. Lehman et al., 60 Am. Jur. 2d Patents §371 (2010); Jay P. Lessler et al., Drafting Claims for Chemical, Pharmaceutical, and Biotechnology Patent Applications, 942 PLI/Pat 163, PLI Order No. 14964 (2008); see also MPEP, supra note 4, Ch. 2100 (discussing the requirements of the first and second paragraphs of 35 U.S.C. §112 in §2174 and, directly thereafter, the requirements of the sixth paragraph in §2181).

[49] For an informative discussion of patent prosecution (or examination), see George Elliott, Basics of US Patents and the Patent System, 9 AAPS J. E317, 318 (2007) (explaining "[t]he basic process of examining an application").

[50] Although this article focuses on the fourth paragraph of 35 U.S.C. §112, the same analysis applies to the fifth paragraph. The author was unable to find case law regarding the fifth paragraph of 35 U.S.C. §112.

[51] 37 C.F.R. §1.75 (2009).

[52] Compare 35 U.S.C. §112 (2006), with 37 C.F.R. §1.75 (2009).

[53] 37 C.F.R. §1.75 (2009).

[54] Id.

[55] MPEP, supra note 4, §608.01(n).

[56] 72 Fed. Reg. 46,716, 46,836 (Aug. 21, 2007). The USPTO promulgated a series of rule changes in 2007, concurrently with the change to the rule on claims. See 72 Fed. Reg. 46,716 (Aug. 21, 2007) (entitling them "Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications"). The revisions to 37 C.F.R. §1.75, subsections (b) and (c), were published in 72 Fed. Reg. 46,836 (Aug. 21, 2007) and were to become effective on November 1, 2007. However, a preliminary injunction was granted Oct. 31, 2007, in Tafas v. Dudas, 511 F. Supp. 2d 652, 656 (E.D. Va. 2007).

[57] 511 F. Supp. 2d 652 (E.D. Va. 2007); see also 74 Fed. Reg. 52,686, 52,688-89 (Oct. 14, 2009) (redacting the amendments to 37 CFR §1.75(b) & (c)).

[58] See supra note 5 (discussing Markman hearings).

[59] For further discussion of the interpretation of patent claims, see generally The Markman Subcommittee, The Interpretation of Patent Claims, 32 AIPLA Q.J. 1, 4-75 (2004) (analyzing claim interpretation).

[60] 35 U.S.C. §282 (2006).

[61] See 35 U.S.C. §112 (2006) ("[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."); 37 CFR §1.75(c) (2009) ("One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application.... Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim."). The promulgated-but-enjoined 37 C.F.R. §1.75(b) presented a revised definition of dependent claim, but the revision would not have materially changed the meaning. See supra Part I.A.2.

[62] See MPEP, supra note 4, §608.01(n) ("The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph) or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim.... The test for a proper dependent claim under the fourth paragraph of 35 U.S.C. 112 is whether the dependent claim includes every limitation of the claim from which it depends. The test is not whether the claims differ in scope.").

[63] See Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1362 (Fed. Cir. 2004) ("A preamble may provide context for claim construction.").

[64] Thomas D. Brainard, Patent Claim Construction: A Graphic Look, 82 J. Pat. Off. Soc'y 670, 676 (2000); see also MPEP, supra note 4, §2111.02 (discussing the effect of the preamble); Id. §2111.03 (discussing transitional phrases). Claims are usually drafted such that the subject matter considered essential to the invention is provided in the claim body, with the caveat that the preamble may be construed to include a limitation of the invention. The Federal Circuit espoused: "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999).

[65] Patent Law Fundamentals, supra note 48, §14:32 (emphasis added).

[66] MPEP, supra note 4, §608.01(m).

[67] Faber, supra note 48, §2:9, at 2-23.

[68] Compare Original Manual of Patent Examining Procedure, supra note 43, §8-9-16 (including the quoted text), with MPEP, supra note 4 (omitting the quote text).

[69] Faber, supra note 48, §2:10, at 2-38; see also 1 Moy, supra note 42, §4:102 ("As the name implies, independent claims are free-standing. The scope of an independent claim can therefore be determined, at least in theory, by referring to that claim only and not to any other claims in the patent. Dependent claims, in contrast, incorporate the contents of a preceding claim by reference. The scope of a dependent claim cannot be ascertained without referring to the claim from which it depends."); Sheldon, supra note 48, §7:4, at 7-47 ("An independent claim stands alone and includes only the limitations recited in the claim itself; it is not dependent upon any other claim to make it complete.").

[70] Tony A. Gayoso & Irving N. Feit, Can a Patent Claim that Refers to Another Claim be Independent?, 89 J. Pat. & Trademark Off. Soc'y 740, 746-47 (2007) (proposing that "[c]laims that refer to subject matter in other claims, but that are within the scope of the subject matter of the other claim ... may be considered to be proper independent claims that merely incorporate subject matter by reference from another claim"); Jeffrey A. Lefstin, The Formal Structure of Patent Law and the Limits of Enablement, 23 Berkeley Tech. L.J. 1141, 1179 (2008) ("35 U.S.C. §112 simply requires that dependent claims add a further limitation to subject matter already claimed and are construed to include all the limitations of the independent claim. It does not require that independent claims encompass all the subject matter defined by the dependent claim, nor does it require that any claim making reference to another claim be construed as a dependent claim.") (emphasis added).

[71] Admittedly, logic is not necessarily persuasive in legal argument. See, e.g., Oliver Wendell Holmes, The Common Law 1 (1881) ("The life of the law has not been logic: it has been experience."); David N. Hayes, The Language and Logic of Law: A Case Study, 35 U. Miami L. Rev. 183, 185 (1981) ("Strict logical consequence is the subject of theories of formal reasoning. Legal argument, however, is not a matter of strict logical consequence."); Steven D. Jamar, This Article has No Footnotes: An Essay on RFRA and the Limits of Logic in Law, 27 Stetson L. Rev. 559, 560 (1997) ("Logic has a favored place in the law, but it is not its only or even its most important structural element. As so eloquently expressed by Justice Holmes well more than a century ago, what the rules of law are or should be owes more to history and human experience than to formal logic."); contra, Kevin W. Saunders, What Logic Can and Cannot Tell Us About Law, 73 Notre Dame L. Rev. 667, 677-80 (1997) ("Most of the informal fallacies face similar questions in application to law, but what of more formal logic? Here there would seem to be less reason to distinguish law from other fields. If logic has recognized certain forms of argument as valid, and a legal argument goes beyond or contradicts one of those forms, that would appear to be a solid reason for calling the validity of the argument into question. Here logic may be of service to the law, by identifying problems with arguments. Even here, however, it must be recognized that sometimes the seeming difference in logic may be nothing more than a linguistic difficulty, and that the law has come to the proper solution. Logic can also help law in finding the best language to express the rules adopted by legal institutions.....Logic can also be of service to the law in the drafting of statutes. Layman Allen and others have discussed logical form in that area and have attempted to identify the sources of ambiguity in statutes. Much of the ambiguity in statutes, and in other statements of the law, results from the misuse of logical connectives or the failure to recognize that it is unclear how portions of a complex proposition are to be combined.").

[72] No. 616-61, 1987 Pat. App. LEXIS 27 (B.P.A.I. Jan. 30, 1987).

[73] Id. at *1.

[74] Id. at *2.

[75] Id. at *3-4.

[76] MPEP, supra note 4, §608.01(n). The BPAI acknowledged that the "Senate Report 94-215 is silent regarding the legislative history of the language that became 35 U.S.C. 112, fourth paragraph," that their majority opinion was consistent with the Manual of Patent Examining Procedure, §608.01(n). Ex parte Moelands, 1987 Pat. App. LEXIS 27, at *4. Therefore, the claims at issue were proper. Id.

[77] Ex parte Moelands, 1987 Pat. App. LEXIS 27, at *8-9 (emphasis added).

[78] Ex Parte Porter, No. 92-1668, 1992 Pat. App. LEXIS 27, at *1 (B.P.A.I. Sept. 29, 1992).

[79] Id. at *2.

[80] Id. at *8-10 (citations omitted).

[81] MPEP, supra note 4, §608.01(n). The Manual of Patent Examining Procedure includes the body of caselaw that is consistent with the legal positions of the USPTO.

[82] Pfizer Inc. v. Ranbaxy Labs. Ltd., 457 F.3d 1284, 1292 (Fed. Cir. 2006). In the litigation, there were two US patents contested: 4,681,893 (expired) and 5,273,995 (due to expire June 28, 2011). The patent status of any drug is listed in the Food and Drug Administration's Orange Book, available at www.accessdata.fda.gov/scripts/cder/ob/docs/querynewobpat.cfm (last visited June 26, 2010).

[83] Pfizer, 457 F.3d at 1291-92 (citing Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380 (Fed. Cir. 2006)). Although the suggestion is technically dicta, the premise has statutory support. 35 U.S.C. §282 expressly states: "Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title."

[84] Id. at 1292.

[85] Court Voids One of Two Lipitor Patents, 22 No. 7 Andrews Pharmaceutical Litig. Rep. 5, Aug. 30, 2006; Mary Ann Liebert, Pfizer Maintains One Lipitor Patent, 25 Biotechnology L. Rep. 570, Oct. 2006, at 571 (providings a quick history of the case and analysis of the court.) (Claim 2 recites the chemical name for Lipitor®.); U.S. Patent No. 5,273,995 col.16 l.16 to col.17 l.2 (filed Feb. 26, 1991).

[86] Pfizer Inc. v. Ranbazy Labs. Ltd., 405 F. Supp. 2d 495, 507 (D. Del. 2005), vacated, 457 F.3d 1284 (Fed. Cir. 2006).

[87] Pfizer Inc. v. Ranbaxy Labs. Ltd., 405 F. Supp. 2d 495, 508-09 (2005), vacated, 457 F.3d 1284 (Fed. Cir. 2006). The court would have been "required to declare an issued claim invalid because of the failure to adhere to the drafting technicalities for dependent claims." Id. at 508. Relying on legislative history and the approach taken by the USPTO in the Manual of Patent Examining Procedure, the court was "not persuaded that the law of invalidity should be extended to reach Section 112, paragraph 4." Id. at 509.

[88] Pfizer, 457 F.3d at 1291-92 ("It is true that at the time the district court wrote its opinion, there was no applicable Federal Circuit precedent. More recently, however, we have suggested that a violation of §112, P 4 renders a patent invalid just as violations of other paragraphs of §112 would.").

[89] Id. at 1292 (citations omitted) (emphasis added) (quoting Nazomi Commc'ns, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1368 (Fed. Cir. 2005)).

[90] Nazomi Commc'ns, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1368 (Fed. Cir. 2005); see also Rembrandt Data Techs., LP v.

AOL, LLC, 673 F. Supp. 2d 420, 426 (E.D. Va. 2009) ("The editing of patent claims is generally disfavored, and the Federal Circuit has announced that, '[t]his court ... repeatedly and consistently has recognized that courts may not redraft claims, whether to make them operable or to sustain their validity.' ... Courts in patent infringement suites may however correct obvious clerical errors.") (citations omitted) (quoting Chef Am., Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004)).

91 Phillips v. AWH Corp., 415 F.3d 1303, 1327 (Fed. Cir. 2005) (en banc) (acknowledging the maxim of construing claims so as to preserve their validity, but explaining "we have limited the maxim to cases in which 'the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.'" (quoting Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911 (Fed. Cir. 2004))).

92 Pfizer, 457 F.3d at 1291; Pfizer, 405 F. Supp. 2d at 507.

93 Gayoso & Feit, supra note 70, at 744.

94 Pfizer, 456 F.3d at 1292.

95 Pfizer, 405 F. Supp. 2d at 500.

96 Pfizer Inc. 2006 Financial Report 16 (2006); available at www.pfizer.com/investors/financial_reports/financial_reports.jsp (follow "2006 Financial Report" hyperlink); see also Pfizer Inc. 2009 Financial Report 21 ($11.4 billion in revenue); 21 ($12.4 billion in revenue); Pfizer Inc. 2007 Financial Report 21 ($12.7 billion in revenue); Pfizer Inc. 2005 Financial Report 13 ($12.2 billion in revenue); Pfizer Inc. 2004 Financial Report 10 ($10.8 billion in revenue).

97 Pfizer, 457 F.3d at 1286.

98 James Bessen & Michael J. Meurer, Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators At Risk 106-07 (2008); see also Dan L. Burk & Mark A. Lemley, Is Patent Law Technology Specific?, 17 Berkeley Tech. L.J. 1155, 1156 (2002) ("As a practical matter, it appears that while patent law is technology-neutral in theory, it is technology-specific in application.").

99 Bessen & Meurer, supra note 98, at 142.

100 Andrew A. Phillips, Comment, Strengthen Pharmaceutical Patent Rights: Lowering the Cost of Prescription Drugs by Stopping the Reckless Patent Litigation Abuse of Generic Companies, 13 Conn. Ins. L.J. 397, 405-06 (2006-2007) ("It is widely believed that without the protection of patents, all research and development of new drugs by these companies would cease to exist.... In the pharmaceutical industry, an innovator could pour large amounts of money into developing and bringing to market a new drug, and without patent protection, lose that entire investment to a competitor who merely copied the innovator's invention.").

101 Id. at 417.

102 Id. at 406 ("Pharmaceutical companies spend on average $897 million to develop a new prescription drug. Thousands of compounds are investigated for every one that makes it to human testing. Of those compounds that make it to human testing, only one in five will eventually gain approval of the Food and Drug Administration (FDA), and make it to market. In addition, the patent is issued years before the pharmaceutical companies can actually sell the product in the marketplace. For example, the average development time of a drug went from 8.1 years in the 1960s to 14.2 years in the 1990s.").

103 Bessen & Meurer, supra note 98, at 107.

[104] Id. at 163.

[105] Id. at 237.

[106] Id. at 236.

[107] Id. at 237-38.

[108] William C. Rooklidge & Matthew F. Weil, Judicial Hyperactivity: The Federal Circuit's Discomfort with its Appellate Role, 15 Berkeley Tech. L.J. 725, 727 (2000). They conclude that "the Federal Circuit, like any other appellate court, should strive to confine its decision-making procedures to those traditionally associated with an appellate court, and leave patent searching, innovative advocacy and fact-finding to others." Id. at 752.

[109] Gayoso & Feit, supra note 70, at 743.

[110] Id. at 743.

[111] Id. at 745.

[112] Id. at 746.

[113] John R. Thomas, Formalism at the Federal Circuit, 52 Am. U. L. Rev. 771, 774 (2003).

[114] Id. at 810.

[115] Id. at 803.

[116] Id. at 796.

[117] Rich, supra note 1, at 499.

[118] Jeffrey A. Lefstin, The Formal Structure of Patent Law and the Limits of Enablement, 23 Berkeley Tech. L.J. 1141, 1145 (2008). He states further that "[t]he most fundamental change in patent law during this period concerned the mode by which patentee's rights were defined.... an inventor's rights came to be defined not by what the inventor actually made or disclosed, but by formal 'claims' that specified the precise boundaries of the inventor's exclusive right." Id. at 1143.

[119] Intamin, Ltd. v. Magnetar Techs. Corp., 623 F. Supp. 2d 1055, 1058 (C.D. Cal. 2009).

[120] Id. at 1059.

[121] U.S. Patent No. 6,062,350 col.9 l.22-25 (filed Apr. 12, 1996).

[122] Intamin, Ltd. v. Magnetar Techs. Corp., 483 F.3d 1328, 1337 (Fed. Cir. 2007).

[123] Id.

[124] Id.

[125] Id.

[126] Intamin, 623 F. Supp. 2d at 1066 (emphasis added).

[127] Id.

[128] Nike, Inc. v. Adidas Am. Inc., No. 9:06-CV-43, 2006 WL 3751181 (E.D. Tex. Dec. 18, 2006).

[129] Id. at *1.

[130] Id. at *3, 10.

[131] Id. at *9.

[132] Id. (emphasis added).

[133] Id. at *10.

[134] See, e.g., Silicon Graphics, Inc. v. ATI Techs., Inc., 607 F.3d 784, 790 (Fed. Cir. 2010) ("The use of the indefinite article 'a' in the claim, when coupled with the list of processes provided in the specification, makes it clear that the claims' references to 'a rasterization process' means 'one or more rasterization processes.'").

[135] Nike, 2006 WL 3751181, at *10.

[136] Id.

[137] Id. (citations omitted) (applying the standard from Hoffer v. Microsoft Corp., 405 F.3d 1326, 1331 (Fed. Cir. 2005)) ("When a harmless error in a patent is not subject to reasonable debate, it can be corrected by the court, as for other legal documents.").

[138] MPEP, supra note 4, §2173.05(e).

[139] Id.

[140] Id.

[141] Konvin Assocs. v. Extech/Exterior Techs., No. 04 C 2544, 2006 WL 2460589, at *3-4 (N.D. Ill. Aug. 21, 2006).

[142] Id. at *4 (citations omitted).

[143] Id. at *5 (emphasis added).

[144] Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1358 (Fed. Cir. 2007) ("Although in a somewhat unusual format, claim 4 is dependent from claim 1 because it only stands if all three steps recited in claim 1 have been performed. In other words, the additional fourth step of obtaining progeny depends on the performance of the process comprising the three steps recited in claim 1 for obtaining a fertile transgenic plant. Claim 4 contains each element of a dependent claim.").

[145] Id. at 1355.

[146] Id. at 1357.

[147] Id.

[148] Id. (emphasis added).

[149] The panel determined that although claim 4 contained a preamble that was clearly different from the preamble in claim 1, claim 4 still referred back to "the process of claim 1." The court determined that claim 4 "expressly recites the process of claim 1 ... Claim 4 thus incorporates the format specified by the statute for dependent claims ... [and] the claim language reads claim 1 into claim 4." Id. at 1358.

[150] Monsato, 503 F.3d at 1357 (emphasis added).

[151] Id. at 1358.

[152] Ex parte Esser, Appeal 2006-3252, 2007 WL 2823697, at *12 (B.P.A.I. Sept. 27, 2007).

[153] Id. at *13.

[154] Id.

[155] Ex parte Chien-Pin Sherman Hsu, Appeal 2009-2630, 2009 WL 1155614, at *12 (B.P.A.I. Apr. 28, 2009).

[156] Id. at *4,*11 (emphasis added).

[157] Id. at *11-12 (citing Ex parte Davis, 80 U.S.P.Q. 448 (B.P.A.I. 1948)).

[158] Id. at *12.

[159] Id.

[160] Id.

[161] Ex parte Chien-Pin, 2009 WL 1155614, at *11. The BPAI acknowledged the Federal Circuit's statement that the "essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous." Id. (citing In re Zletz, 893 F.2d 319, 322 (Fed. Cir. 1989)). Further, the BPAI cited Exxon Research & Engineering Co. v. United States, where the Federal Circuit said that a different standard for indefiniteness may be appropriate during prosecution than in litigation. Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1384 (Fed. Cir. 2001).

[162] Ex parte Chien-Pin, 2009 WL 1155614, at *12.

[163] Ex parte Avizienis, Appeal 2009-003592, 2009 WL 3519744, at *5 (B.P.A.I. Oct. 29, 2009).

[164] U.S. Patent Application No. 2002/0046365 A1 (filed June 20, 2001). On appeal, claim 4 was in its original form, but claim 1 was amended prior to appeal. However, the differences in claim 1 are insignificant for the purposes of this article.

[165] Ex parte Avizienis, 2009 WL 3519744, at *5. The BPAI interpretation of "such" is not reconcilable with the interpretation given in Jeffrey G. Sheldon's How to Write a Patent Application, which considers the term "such" to be equivalent to other the definite terms "said" or "the." See Sheldon, supra note 48, §6.6.3, at 6-113 (stating that "the definite articles 'the,' 'said,' and 'such' cannot be used unless the following noun has already been introduced in the claim.... If the claim is a dependent claim, the antecedent basis can be found in the dependent claim or any claim upon which the claim is dependent, since a dependent claim incorporates by reference all of the claims from which it depends."). Further, with respect to the second paragraph of 35 U.S.C. §112, §2173.02 in the Manual of Patent Examining Procedure states: "The mere use of the phrase 'such as' in the claim does not by itself render the claim indefinite. Office policy is not to employ per se rules to make technical rejections." MPEP, supra note 4, §2173.02.

[166] See, e.g., W. Elec. Co. v. Piezo Tech., Inc., 860 F.2d 428, 431 (Fed. Cir. 1988) (stating that "patent examiners are quasi-judicial officials").

[167] The Manual of Patent Examining Procedure, as the name suggests, is an examining manual that contains examining procedures. Additionally, the Manual of Patent Examining Procedure includes the body of case law that is consistent with the legal positions of the USPTO. See supra note 25.

[168] See supra Part II.B. and Part II.C.

[169] See supra note 62.

[170] MPEP, supra note 4, §608.01(n).

[171] Ex parte Porter, Appeal No. 92-1668, 1992 WL 3920605, at *4 (B.P.A.I. Sept. 29, 1992).

[172] MPEP, supra note 4, §2173.05(s). "Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table 'is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience."' Ex parte Fressola, 27 U.S.P.Q.2d 1608, 1609 (B.P.A.I. 1993) (citations omitted) (emphasis added).

[173] See MPEP, supra note 4, §2173.05(f) ("A claim which makes reference to a preceding claim to define a limitation is an acceptable claim construction which should not necessarily be rejected as improper or confusing under 35 U.S.C. 112, second paragraph."); see also Faber, supra note 48, §2:9, at 2-34 ("The typical dependent claim further defines the earlier claim rather than being defined by it. But both types are acceptable.").

[174] See MPEP, supra note 4, §2422.03 (discussing the requirements for a sequence listing and sequence identifiers).

[175] See supra note 69 and accompanying text (citing manuals that stand for the idea that independent claims should stand alone).

[176] Appeal No. 93-0828, 1993 Pat. App. LEXIS 3, at *3-4 (B.P.A.I. Mar. 11, 1993); see also MPEP, supra note 4, §2173.05(s) ("Where possible, claims are to be complete in themselves.").

[177] Ex parte Fressola, 1993 Pat. App. LEXIS 3, at *13.

[178] Id. at *2 (emphasis added).

[179] Id. at *15-16.

[180] MPEP, supra note 4, §2173.05(s) (emphasis added) (citing Ex parte Fressola, Appeal No. 93-0828, 1993 Pat. App. LEXIS 3 (B.P.A.I. Mar. 11, 1993)).

[181] See MPEP, supra note 4, §2406.01 (describing the allowance of biological material).

[182] See, e.g. In re Fout, 675 F.2d 297, 300 (C.C.P.A. 1982) ("Claims must always be read in light of the specification.").

[183] MPEP, supra note 4, §2411.01.

[184] MPEP, supra note 4, §2402 (emphasis added); see also id. §2422.03 ("The rules do not alter, in any way, the requirements of 35 U.S.C. 112. The implementation of the rules has had no effect on disclosure and/or claiming requirements. The rules, in general, or the use of sequence identifiers throughout the specification and claims, specifically, should not raise any issues under 35 U.S.C. 112, first or second paragraphs. The use of sequence identification numbers (SEQ ID NO:X) only provides a shorthand way for applicants to discuss and claim their inventions. These identification numbers do not in any way restrict the manner in which an invention can be claimed." (emphasis added)).

[185] 35 U.S.C. §282 (2006).

[186] Gayoso & Feit, supra note 70, at 746.

[187] Gayoso & Feit, supra note 70, at 746; see also Faber, supra note 48, §2:9, at 2-27 ("The main advantage of dependent claims, of course, is that they require far less time to examine ....").

[188] See Faber, supra note 48, §2:9, at 2-27 ("[T]he filing fee for a dependent claim, when the number of claims exceeds a maximum number (in 2008, twenty claims) is a small fraction of the filing fee for an independent claim that exceeds a maximum number of independent claims ...."); see also Honeywell Int'l Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1148 (Fed. Cir. 2004) (Newman, J., dissenting) ("The use of dependent claims is encouraged by the patent examining authority as an aid in examination. Its value during examination is reflected in the significantly lower fee charged for examination of dependent claims.").

[189] Gayoso & Feit, supra note 70, at 746.

[190] MPEP, supra note 4, §608.01(n).

[191] See 35 U.S.C. §41 (2006) (discussing filing fees).

[192] For an analysis of the relationship between the doctrine of equivalents and prosecution history estoppel, see generally Douglas Lichtman, Rethinking Prosecution History Estoppel, 71 U. Chi. L. Rev. 151 (2004).

[193] Honeywell Int'l Inc. v. Hamilton Sundstrand Corp., 370 F.3d 1131, 1141 (Fed. Cir. 2004) ("A presumption of surrender therefore arises if rewriting the dependent claims into independent form, along with canceling the original independent claims, constitutes a narrowing amendment." (emphasis added)).

[194] See, e.g., Landers, supra note 28, at 295 ("Infringement under the doctrine of equivalents does not require the one-to-one correspondence that is necessary to a finding of literal infringement. Rather, infringement under doctrine of equivalents may exist where an accused device or process includes every claim limitation or its equivalent. Under this doctrine, a claim limitation may be met by an element of an accursed device or process that is insubstantially different from the claim's literal limitation." (emphasis added)).

[195] 37 C.F.R. §1.115 (2009).

[196] Honeywell, 370 F.3d at 1142 (emphasis added).

[197] 35 U.S.C. §255 (2006); 37 C.F.R. §§1.322, 1.323 (2009) (discussing certificates of correction for mistakes made by the PTO and applicants).

[198] 35 U.S.C. §255 (2006).

[199] Id.

[200] Honeywell, 370 F.3d at 1146-47 (Newman, J., dissenting). On the contrary, the amendment of an independent claim into a dependent claim will not result in the conclusion that the amendment was formal and not substantive. In Zircon Corp. v. The Stanley Works, 713 F. Supp. 2d 881, (N.D. Cal. 2010), a district court examined claim 21 of U.S. Patent No. 7,116,091 (filed Mar. 4, 2004) for validity under USC 112, P 4. In Zircon, claim 21 was amended during prosecution "to make it dependent on claim 1, thereby surrendering original claim 21's broader 'comparing' language in favor of the narrower 'commuting a ratio' term." Zircon, 713 F. Supp. 2d at 15. Due to the amendment, "claim 21 as drafted does not contain a further limitation of claims 10 and 19, and instead contains a limitation of non-overlapping scope." Id. at 9. Because of the statutory language of USC 112, P 4, the construction of the independent claim should be read more broadly than its dependent claim. The court concluded that "the statute does not mandate that the limitations in claims 10 and 19 must be read more broadly than drafted to sustain the validity of claim 21." Id. at 8. In sum, the amendment to claim 21 rendered its construction to be narrower than its corresponding independent claims 10 and 19; Zircon was unable to rebut the presumption that the amendment was made for reasons of patentability; Zircon was barred from using the doctrine of equivalents; and, therefore, the court granted summary judgment of non-infringement to the defendant on the basis of prosecution history estoppel. Id. at 16-17.

[201] Honeywell, 370 F.3d at 1146-47 (Newman, J., dissenting) (emphasis added).

[202] See id. at 1153 ("Patent applications will cost more, since independent claims carry a heavier fee than dependent ones.").

[203] Paul R. Michel, Fellow Citizens: Be On Guard, 92 J. Pat. & Trademark Off. Soc'y 135, 137 (2010). Judge Michel explained:
The gears of our patent system seem seized up: public inaction is discouraging private investment. Obviously we need to strengthen and speed both examinations and litigations, but doing so requires public investment. Although the PTO should remain financed by user fees, it needs a transfusion of public money to overcome its dysfunction. It needs thousand[s] of additional examiners, salary increases to retain experienced examiners, new computer systems and space to house an expanded work force. (At present, many employees, although lacking extensive experience, work at home where adequate supervision is more difficult and applicant interviews are problematic.) Thus, even if Congress raised fees, which it should, resolving the current crisis requires a large infusion of public money. And it is needed soon. Deferral will have corrosive consequences that cannot be undone. Therefore, I suggest an immediate capital investment of one billion dollars. It could be spent over the next several fiscal years, but it must be appropriated immediately.
Id. (emphasis added).

[204] 35 U.S.C. §101 (2006). The term "process" is defined in 35 U.S.C. §100(b) to mean "process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."

[205] MPEP, supra note 4, §608.01(b).

[206] See generally 37 C.F.R. §1.142 (2009) (describing the restriction requirement). A restriction requirement identifies and separates patentably distinct inventions. Id. Thus, a claim drawn to a chemical compound is a patentably distinct invention as compared to a method of using that chemical. This is simple to understand: the inventive effort required for a chemist to synthesize a useful chemical is distinct from the inventive effort required for a clinician to determine the dosage, safety, and efficacy in order to treat a disease in a human patient. Similarly, a different inventive effort is required for a chemist to formulate a chemical into a pill, tablet, or liquid preparation in order to deliver the drug to the biological target. In this respect, patent claims drawn to a composition comprised of an old drug may be issued under the "improvement" clause of 35 U.S.C. §101. Over the period from 1993 to 2008, restriction requirements grew from about 1.5% to over 50% for patent applications in the biotech practice groups. Shine S. Tu et al., Squeezing More Patent Protection from a Smaller Budget Without Compromising Quality, 2 No. 2 Landslide 37, Nov./Dec. 2009, at 38. Note, however, this number may or may not include the chemical groups: both groups are in the same technology center. Nevertheless, the percentage of restrictions in the chemical groups is high.

[207] E.g., MPEP, supra note 4, §2173.05(p) (giving an example of a claim utilizing both a product and process).

[208] MPEP, supra note 4, §2113. For further discussion of product-by-process claims, see Eric P. Mirabel, Product-by-Process Claims: A Practical Perspective, 68 J. Pat. & Trademark Off. Soc'y 3, 3 (1986) (discussing product by process claims); 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, 529-31 (1960) (discussing the evolution of product-by-process claims); Gary Newson, Comment, Product-By-Process Patent Claims: Arguing for a Return to Necessity and a Reduction in the Scope of Protection, 40 Ariz. St. L.J. 327, 328 (2008) (suggesting "the use of product-by-process claims for patents should be discontinued except in rare cases where the invention cannot be sufficiently described due to limits in our understanding of current technology").
Occurring more frequently are fingerprint claims, which are used to describe a compound by its properties when its exact structure is unknown or in order to distinguish a new form of a compound from a known form. See Faber, supra note 48, §6:4, at 6-13 (explaining that fingerprint claims occur "where a new composition has been produced ... but where the differences from previous forms cannot be explained in terms of physical or chemical structure."); MPEP, supra note 4, §2173.05(t) ("A compound of unknown structure may be claimed by a combination of physical and chemical characteristics.").

[209] In re Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985) (emphasis added).

[210] Smithkline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1315 (Fed. Cir. 2006).

[211] MPEP, supra note 4, §608.01(n).

[212] 35 U.S.C. §112 (2006); see also 37 C.F.R. §1.75(c) (2009) (describing dependent and multiple dependent claims).

[213] MPEP, supra note 4, §608.01(n).

[214] 35 U.S.C. §112 (2006).

[215] Mark A. Lemley, The Limits of Claim Differentiation, 22 Berkeley Tech. L.J. 1389, 1391 (2007) (explaining that "claim differentiation is based on the presumption that patent applicants almost always write multiple claims in an effort to get several different tries at capturing their invention in words."); see also Nexans, Inc. v. General Cable Techs. Corp., 630 F. Supp. 2d 499, 503-05 (E.D. Pa. 2008) (explaining the canons of claim construction and the doctrine of claim differentiation). Further, in Nexans, the court explained the following principles: "Claims are often written in a hierarchy, with independent claims as the broadest claims and a series of dependent claims having more narrow scope." Id. at 503 (citing 35 U.S.C. §112 (2006)). "The doctrine of claim differentiation creates a presumption that, where a dependent claim is more specific than the independent claim from which it depends, the independent claim must be broader and not limited to the specifics of the dependent claim." Id. "As a general rule, the presence of a dependent claim that adds a particular limitation creates a presumption that the limitation in question is not part of the independent claim." Id. at 504 (citing Wenger Mfg., Inc. v. Coating Mach. Sys., Inc., 239 F.3d 1225, 1233 (Fed. Cir. 2001)). "Moreover, if 'some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad whether to avoid invalidity or to escape infringement.'" Id. (quoting Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1054-55 (Fed. Cir. 1988)).

[216] See 37 C.F.R. §1.75(b) (2009) ("More than one claim may be presented provided they differ substantially from each other and are not unduly multiplied.").

[217] Curtiss-Wright Flow Control Corp. v. Velan Inc., 438 F.3d 1374, 1380 (Fed. Cir. 2006) (quoting Versa Corp. v. Ag-Bag Int'l Ltd., 392 F.3d 1325, 1330 (Fed. Cir. 2004)).

[218] Id. (citation omitted).

[219] Lemley, supra note 215, at 1393.

[220] Id.

[221] Id. at 1396.

[222] Id.

[223] Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004).