# THE FORMAL STRUCTURE OF PATENT LAW AND THE LIMITS OF ENABLEMENT

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*American patent law underwent a revolution in the late 19th century. 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 property right. At the same time, as legal formalism swept American law in general, patent law became committed to a highly formal and abstract system modeled upon logical principles of science.*

*These themes have been revived in patent law over the last 25 years under the guidance of the Court of Appeals for the Federal Circuit. However, as the court has attempted to systematize patent law along formal lines, bitter disputes have arisen between its judges concerning the relationship between the inventor's disclosure and patent scope.*

*These developments are not coincidental. The question of patent scope is contested today because the shift to a formal claiming system left patent law without a coherent doctrine to define the permissible scope of the patentee's rights. The doctrine most commonly thought to limit patentees' rights – the enablement doctrine – is incapable by itself of providing satisfactory limits on patent scope. This deficiency arises because all patent claims are of infinite scope, and the enablement doctrine provides no coherent method to constrain the reach of an infinite set.*

*This Article argues that the written description doctrine provides the necessary means to constrain the scope of patent claims. Critics of the doctrine have argued that the written description doctrine is not rooted in statute, became obsolete with the advent of modern claim practice, or is a doctrine specific to biotechnology and genetic sequence patents. These criticisms arise from a misapprehension of the nature of the written description doctrine. The written description doctrine is properly conceived as a*

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*doctrine of logical definition. Once the true nature of the doctrine is recognized, the essential role of written description doctrine in defining patent scope becomes clear.*

## INTRODUCTION: THE NEW FORMALISM AND THE LAW OF ENABLEMENT

Modern patent law has recapitulated the circumstances of its birth. American patent law was systematically consolidated between the Civil War and the end of the 19th century,[2] the period when the American legal mind was captivated by the highly formal system of thought described as classical legal orthodoxy.[3] That system's emphasis on generalization, abstraction, and categorization extended to nearly all fields of American law.[4] But the past several decades have seen the second great period of formalism in American patent law. By formalism I do not mean solely that the substantive doctrines of patent law have gravitated towards the classical ideal of bright-line rules in place of looser standards, although scholars have identified such trends in the patent jurisprudence both of the Supreme Court and the Court of Appeals for the Federal Circuit.[5] I mean instead that the courts have become committed to a highly formal conception of the patent itself; it is the legal structure of the patent system that has become formal, not just its particular doctrines.[6]

As an intellectual structure, classical legal orthodoxy was characterized primarily by:

- A strong commitment to the existence of abstract legal categories, and the clear differentiation of one category from another.

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[2] *See* Samuel Oddi, *Regeneration in American Patent Law: Statutory Subject Matter*, 46 IDEA 491, 520-34 (2006).

[3] *See* Thomas C. Grey, *Langdell's Orthodoxy*, 45 U. PITT. L. REV. 1,2 (1983).

[4] *See* Horwitz*, at 11-31

[5] *See* Timothy R. Holbrook, *The Supreme Court's Complicity in Federal Circuit Formalism*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1 (2003); John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771 (2003). The Federal Circuit since 1982 has been vested with nearly complete and exclusive appellate jurisdiction over questions of patent law.

[6] *See* Grey, *supra* note 3, at 11-12 (distinguishing between a preference for rules over standards, and a commitment to analytically deriving those rules from top-level principles). According to Grey, late 19th-century classical legal orthodoxy was committed to formalism at both levels. *Id.*

- The desire for bottom-level legal rules to be derived analytically from a few basic top-level categories and higher principles, akin to Euclid's derivation of the whole of geometry from five fundamental axioms. Inherent in this process was the condensation of legal rules, previously scattered among functional categories or forms of action, around a few key principles such as (for tort) negligence and fault, or (for contract) offer, acceptance, and consideration.
- A preference for objective rules over vague standards. If not motivated by the ascendant business community's demand for legal predictability, this preference met the community's needs for clear legal rules on which investment decisions could be predicated.

Modern patent law has been organized along similar lines. The defining characteristic of patent law today is the claim, that portion of the patent delineating exactly the subject matter over which the inventor is entitled to exclude others from manufacture, use, or sale. Claims are the sole measure of the invention; all questions of patent infringement, validity, and inventorship, are resolved by reference to the subject matter defined by the claim. The claim, "the invention", and "the patent" are essentially synonymous.[7] Modern claims are themselves highly formal entities. They recite a set of characteristics, or properties, that exclusively define the subject matter encompassed by the patent. The more properties or characteristics the claim recites, the smaller the scope of the subject matter thus defined;[8] most patents contained ordered, hierarchical pyramids of claims in which more and more properties are recited to define successively smaller slices of subject matter.

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[7] Patents typically carry more than one claim, each of which technically defines an "invention." Though the essential synonymy of invention and claim was well-established by the time of the 1952 Patent Act, it is interesting to note that the equivalence of the invention and claim is never explicitly demanded by the Act itself. The Act's substantive validity and infringement provisions speak of "the invention" rather than "a claim"; § 112 of the Act merely requires the patentee to conclude the specification with one or more claims distinctly pointing out what he regards as his invention.

[8] This structure corresponds to the concepts of intension and extension prevalent in classical logic and deriving ultimately from Aristotle; as the intension (meaning) of a definition grows richer, the extension (the number of objects to which it applies) becomes smaller. *See* WILLIAM T. PARRY & EDWARD A. HACKER, ARISTOTELIAN LOGIC 65-67 (1991)

Though claims have been the primary measure of the inventor's rights since the mid-19th century, the Federal Circuit's jurisprudence has driven towards a new ideal in which the patentee has an absolute entitlement to all things within the boundaries defined by the claims, and – with the possible exception of developments unforeseeable at the time of patenting[9] – no rights over any things outside the literal boundaries of the claim. In the law of infringement, the court has worked towards a regime in which *any* use of subject matter falling within the claims is an act of infringement, regardless of its extent or purpose.[10] Conversely, with its hostility to the doctrine of equivalents, the court has tried to prevent patentees from asserting infringement against subject matter lying outside the literal scope of the claims.[11] With respect to patent validity, questions of novelty have been reduced to exact rules of inclusion or exclusion within the boundaries of the claim, in derogation of the more nuanced approach of earlier times.[12]

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[9] *See Johnson & Johnston*, 285 F.3d at 1056 (Rader, J., concurring) (arguing that doctrine of equivalents should not extend to "subject matter that the patent drafter reasonably could have foreseen during the application process and included in the claims."). Judge Rader's argument that foreseeability ought to be the sole principle underlying the doctrine of equivalents recalls the classical program of systematizing unruly legal regimes around central organizing principles.

[10] The court has essentially denied the existence of a common-law experimental use exemption or an exception for 'de minimis' infringement, *see* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002), and (before being reversed by the Supreme Court) accorded narrow scope to the statutory exemption for activities directed to approval of generic drugs mandated by the Hatch-Waxman Act, *see* Integra Lifesicence I, Ltd. V. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003), *rev'd*, 545 U.S. 193 (2005). The Federal Circuit's rule that permanent injunctions would issue upon proof of infringement absent exceptional circumstances, was another example of the absolutist strain in the law of infringement. The Supreme Court limited that rule in *Ebay v. MercExchange*, holding that injunctions should issue only upon satisfaction of the traditional tests for equitable relief. **

[11] In *Johnson & Johnston Associates Inc. v. R.E. Service Co., Inc.*, 285 F.3d 1046 (Fed. Cir. 2002), the court has held that any subject matter disclosed in the patent's specification but not explicitly claimed is abandoned to the public and cannot be reached under the doctrine of equivalents. The court also attempted to impose a strict regime of prosecution history estoppel in which any subject once within the claims during prosecution, but not within the final claims, was surrendered and beyond the reach the doctrine of equivalents. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558 (Fed. Cir. 2000), *rev'd* **. The Supreme Court tempered the Federal Circuit's absolute rule by specifying conditions under which the patentee could rebut a presumption of surrender.

[12] In assessing whether an invention has been anticipated by a disclosure in the prior art, the court has held that *any* prior use or sale of subject matter falling within the scope of the claims invalidates the claim, regardless of whether the use or even existence of the subject matter was known at the time. *See* Schering Corp. v. Geneva Pharms., 339 F.3d 1373, 1377-80 (Fed. Cir. 2003). Earlier case law, which the Federal Circuit in *Schering* characterized as dicta, had suggested that prior accidental or unknown existence of subject matter within the scope of the claims might not render the patent invalid. ** Other developments towards a regime of absolute novelty include expanding the range of so-called "secret prior art" that can destroy patentability despite the absence of publication or actual public knowledge. **. Of course, the benchmark for bright-line rules of public use was laid down during the heyday of classical legal

In addition to the substantive doctrines of patent law being reduced to formal questions of inclusion or exclusion with respect to claim scope, the Federal Circuit has since its founding maintained a rigid conceptual separation between the substantive doctrines themselves. The questions of patent infringement and patent validity are both binary determinations; the patent is infringed or not, and it is valid or invalid. The determination that the patent is valid is made independently of the infringement inquiry and without reference to the allegedly infringing device. In particular, the question of patent scope – whether the patentee is entitled to assert exclusive rights over a broad range of subject matter – is resolved independently from the question of whether the patentee is entitled to assert exclusive rights over the particular subject matter practiced by the accused infringer.[13] Formally, it is no defense that the accused infringer is practicing something which was in the public domain before the patent,[14] nor is it a defense that the accused technology is beyond what the patentee's disclosure enabled. Once the determination of validity *vel non* is made, there is no formal relationship

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orthodoxy, when the Supreme Court held that corset springs were in "public use" when their inventor gave his "intimate friend" a single pair to wear within her corset. *Egbert***

[13] Historically, patent law *did* have the ability to take into account the relationship between these inquiries via the so-called "reverse doctrine of equivalents," which permitted accused subject matter to escape infringement even though it fell within the literal boundaries of the patent's claims. This doctrine permitted a court to assess infringement in light not only of the degree to which the claimed invention represented an advance over the prior art, but the marginal advance and functional similarity of the accused subject matter as well. *See, e.g.,* Boyden Power-Brake Co. v. Westinghouse, 170 U.S. 537 (1898). However, the Federal Circuit has suggested that the doctrine was essentially destroyed by the 1952 Patent Act, and has never affirmed a finding of noninfringement under the reverse doctrine of equivalents. *See Tate Access Floors*, 279 F.3d at 1368. But the disappearance of the reverse doctrine of equivalents has little to do with the passage of the 1952 Act, which largely codified common-law patent doctrine. The reverse doctrine of equivalents is untenable in modern patent law because it is premised on the existence of "the invention" and 'the claims" as separate entities, or at least on the significance of that distinction. *See Boyden Power-Brake*, 170 U.S. at 568 ("The patentee may bring the defendant within the letter of his claims, but if the latter has so far changed the principle of the device that *the claims of the patent, literally construed, have ceased to represent his actual invention*, he is as little subject to be adjudged an infringer as one who has violated the letter of a statute has to be convicted, when he has done nothing in conflict with its spirit and intent." (emphasis added). Such a distinction is incompatible with the modern synonymy of claim and invention.

[14] *See* Tate Access Floors, Inc. v. Interface Arch. Res., Inc., 279 F.3d 1357, 1365-66 (Fed. Cir. 2002) (refusing to accept 'practicing the prior art' as a defense to literal infringement). However, infringement under the doctrine of equivalents is explicitly limited by the scope of the prior art. *See* Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677 (Fed. Cir. 1990)

between what the patentee is asserting rights over (the accused subject matter) and either the patentee's disclosure, or the prior art.[15]

The program of condensing patent law into a rigorously defined system centered around the claim has not proceeded without interruption. The Supreme Court in particular has resisted the Federal Circuit's tendencies toward an absolutist or minimalist model of patent infringement.[16] But there can be little doubt that the vision of patent law as a set of conceptually differentiated, binary determinations founded on the abstract concept of the claim would have been received favorably by classical legal theorists,[17] as would the Federal Circuit's desire to provide certain and predictable patent law upon

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[15] The questions of validity, claim scope, and infringement are still connected *in practice* by the question of claim interpretation. The parties in suit tailor their claim interpretations to suit their arguments on infringement and validity; a broader claim is more likely to be infringed but less likely to be valid, and vice versa. Moreover, one of the maxims of claim interpretation is that claims should be construed, if possible, to preserve their validity. Thus, as a matter of interpretation, claim scope is determined with an eye towards the arguments raised in connection with infringement and invalidity. If, however, the claims are textually clear and unambiguous, there is no room for interpretive discretion, and the validity and infringement determinations proceed as entirely disconnected inquiries. *Amgen We might regard clarity in claim scope as the sine qua none of the formalist program: if claim scope is not certain, then that uncertainty limits the precision of patent determinations no matter how closely the substantive doctrines adhere to the boundaries of the claims. Two trends in the Federal Circuit's claim construction jurisprudence – the emphasis on dictionaries as a source of meaning (e.g., Texas Digital*), and the suggestion that claim construction should proceed by an ordered algorithm (e.g., Vitronics*) – may be viewed as attempts to formalize claim interpretation as well. However, the Federal Circuit put an end to these trends in its en banc decision in Phillips, de-emphasizing the role of dictionaries and denying the existence of any rigid structure to the claim construction process. One might well consider the formalist program futile if the boundaries of claims cannot be determined with precision. However, as an *intellectual* structure, the claim system is still conceptually ordered if a single principle governs the outcome of claim construction. Thus, the principle of *Phillips* – that claim terms mean what an ordinary artisan in the field of the invention would think them to mean after having read the patent specification and prosecution history – provides a conceptually ordered unity to claim interpretation regardless of whether the outcome in individual cases is determinate or not. *Phillips* clearly reflects the aspirations of classical legal thinkers: a single unifying principle from which the bottom-level rules of the regime may be derived.

[16] The court has restored some of the ground lost by the doctrine of equivalents; broadened the scope of the statutory exemption for generic drug approval under the Hatch-Waxman Act, and emphasized that the grant of injunctive relief is subject to the traditional principles of equitable discretion. *** One might also view the Supreme Court's *KSR* decision – which declared that the Federal Circuit's "teaching, suggestion, or motivation" test for combining prior art references was but one of several permissible ways to demonstrate obviousness – as rejecting the notion that obviousness can be condensed around a single unifying principle.

[17] Horwitz describes how classical legal thinking was dominated not only by the tendency to draw bright-line classifications of legal phenomena, but also by the tendency to structure legal inquiries as binary questions of inclusion or exclusion from those abstract categories. *See* Horwitz, *supra* note 4, at 17-18. Twentieth century legal thinking, according to Horwitz, was more receptive to balancing tests. *Id.* at 131. One could, for example, conceive of a patent system in which the question of infringement might depend on the degree to which a patent was novel and non-obvious, rather than being an entirely separate question once the statutory thresholds of novelty and non-obviousness have been met.

which investment decisions may be based.[18] So too would classical legal theorists endorse the efforts by some Federal Circuit judges to condense complex bodies of patent law around single unifying principles, such as the notion that the subject matter requirement of § 102 may be reduced to the question of whether an invention yields a "useful, concrete, and tangible result."[19] And just as classical legal theorists sought to order law as a system of rules formally derivable from a minimum set of higher-order principles, the vision behind the formalist program seems to be of a patent law which the rules of infringement and validity can essentially be derived from a few simple axioms. We might in fact represent the formalist ideals of patent eligibility, patent validity, and patent infringement by three axioms, along the lines of:

> *All things useful may be claimed;*
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> *No claim may have within its boundaries any thing existing in, or obvious from, the prior art; and*
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> *All things within the boundaries of the claim infringe, and no thing outside those boundaries infringes.*

These three axioms are insufficient to derive a conceptually ordered system of patent law, because we have not yet defined an axiom of permissible claim scope. Patent law gauges how broadly the inventor is entitled to claim by reference to what the inventor

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[18] *See, e.g.,* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558, 577-78 (Fed. Cir. 2000) (en banc), *rev'd* ___ (justifying limitations on doctrine of equivalents as stimulating investment in improvements by competitors); Aerojet-General Corp. v. Machine Tool Works, Oerlikon-Buehrle Ltd., 895 F.2d 736, 744 (Fed. Cir. 1990) (en banc) ("The availability of a clear, stable, uniform basis for evaluating matters of patent validity/invalidity and infringement/noninfringement renders more predictable the outcome of contemplated litigation, facilitates effective business planning, and adds confidence to investment in innovative new products and technology."), *overruled by* Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc., 535 U.S. 826 (2002).

[19] State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1375 (Fed. Cir. 1998). *** Judge Linn v. Gajarsa in Comiskey/Nuijten. *See* In re Nuijten, 500 F.3d 1346, 1354 (Fed. Cir. 2007) (refusing to read *State Street* "as a holding that the four statutory categories are rendered irrelevant, non-limiting, or subsumed into an overarching question about patentable utility."). *See* Thomas, supra note **, at 771 ("It is difficult to imagine a more simple rule governing patent-eligible subject matter."). *See also* In re Bilksi, 2008 WL 417680 (Fed. Cir. Feb. 15, 2008) (granting *en banc* review to consider overruling *State Street* and other aspects of the subject matter requirement). The same desire to condense law around a single principle – so attractive to classical legal theorists – motivates the notion that the complex cloud of restrictions on the doctrine of equivalents may be reduced to the question of whether the alleged equivalent was foreseeable. *See* Johnson & Johnston Associates Inc. v. R.E. Service Co., Inc, 285 F.3d 1046, 1056-59 (en banc)* (Rader, J., concurring) *Festo*, 344 F.3d 1359, 1374-77 (Fed. Cir. 2003) (en banc) (Rader, J., concurring).

discloses about the invention in the patent's specification; the statutory expression of this *quid pro quo* is defined by the first paragraph of 35 U.S.C. § 112:

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

The Federal Circuit has interpreted the first paragraph § 112 to contain, in addition to the requirement that the inventor disclose the 'best mode' of practicing his invention, two separate requirements that define the relationship between the inventor's disclosure and the permissible scope of patent claims. One is the uncontroversial requirement that the disclosure enable one of ordinary skill in the art to make and use the claimed subject matter without undue experimentation. The other is the requirement that the disclosure, independent of the claims, also contain a 'written description' of the claimed subject matter.

Whether there ought to be a claim scope doctrine beyond enablement has been highly controversial, ever since the Federal Circuit articulated the modern doctrine to restrict recombinant DNA claims in *Regents of the University of California v. Eli Lilly*. Since *Lilly*, a minority of judges on the court have vigorously denied the existence or utility of a separate written description requirement in § 112, arguing that enablement alone should define the scope of the patentee's claims.[20] Though a majority of the Federal Circuit remains opposed to revisiting *Lilly en banc*,[21] a wealth of scholarly commentary has sympathized with the minority position, arguing that the written description doctrine is a dangerous and unnecessary graft onto the traditional law of claim scope.

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[20] To the extent they concede that a written description requirement is necessary to prevent patentees from adding unsupported claims to existing applications, they believe that such a function is more properly found in § 132 of the Patent Act, which forbids patentees from adding new matter to the specification by amendment. Throughout this Article, I refer to arguments for and against written description as arguments for the position that written description plus enablement limit the scope of originally filed claims, or for the position that enablement alone limits the scope of original claims. One's position on best mode is peripheral to this question. The inventor need only disclose *the* best mode of carrying out the claimed invention, if he subjectively has a preferred mode. Best mode is therefore not a doctrine of claim scope as enablement and written description are.

[21] *See* Lizardtech, Inc. v. Earth Resource Mapping, Inc., 433 F.3d 1373 (Fed. Cir. 2006) (denying *en banc* review); *id.* at 1376-81 (Rader, J., dissenting from denial of rehearing)

If we reflect upon the program of systematizing patent law into a classically ordered formal system, then it becomes clear that the elimination of the written description requirement is an essential element of that program. Obviously, any formal description of patent law requires at least one axiom of permissible claim scope. But why should the formalist conception of patent law entail that enablement be the only doctrine of claim scope? One answer is simply guilt by association. Those judges of the Federal Circuit who have consistently opposed the *Lilly* doctrine are also those who have authored some of the most notable articulations of the formalist program. But the intellectual connection between the attack on written description and the desire for a classically ordered system of patent law is far deeper. Classical legal theorists sought to condense scattered rules and doctrines around core principles such as 'fault' or 'will'.[22] Likewise, the modern classicists of patent law would condense the disclosure doctrine around enablement alone, relegating not only written description, but best mode as well, to peripheral roles.[23] Classical legal theorists sought unification of the law, preferring a generalized category of 'contract' over separate bodies of law devoted to particular industries or relationships.[24] So too, modern critics who view the written description as a doctrine peculiar to chemistry and biotechnology cases assail the doctrine on the grounds that patent law ought not to be technology-specific. Classical legal theorists sought certainty in the law in part to provide stability for business expectations;[25] modern theorists criticize the *Lilly* written description inquiry as one that yields no certain results in scope inquiries.[26]

Yet it would be wrong to argue that those who oppose written description do so merely because they share the intellectual aspirations of classical legal theorists. The

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[22] *See* Horwitz, * at 13.

[23] Judge Rader has argued that a separate best mode requirement is largely unnecessary. *See* Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306, 1325 (Fed. Cir. 2006) (Rader, J., concurring). ("Because informed patent applicants know to avoid best mode problems, this § 112 requirement is invariably little more than a trap for the uninformed applicant-usually a university or independent inventor without corporate legal resources. Because the best mode requirement is a trap for the unwary, the Federal Circuit has wisely followed the statutory "scope of the claimed invention" rule to confine the reach of this snare."). Likewise, Judge Linn * (Teleflex)

[24] *See* Wiecek*, 102-3.

[25] *See* Gordon, in Gelson (ed.), at 92. Modern historians have distanced themselves from the position that classical legal thought was intended by its architects to fortify the emerging capitalist class. *See id.;**

[26] Holbrook, possession, 162*

more sophisticated of them seek to excise written from the formal structure of patent law because they view it as an obsolete relic of an earlier patent law: a patent law without claims. When the earliest United States patent statutes demanded that the patent specification include "a written description of the invention," patents did not include claims defining the scope of inventors' rights. Early judicial interpretations of the patent statute therefore required that the specification not only enable practice of the invention so as to satisfy the quid pro quo of the patent system, but also define the invention so as to put the public on notice of infringement, and to permit courts to assess the novelty of the invention.[27] The description of the invention in the specification therefore served the function of modern claims. Claims evolved gradually over the course of the 19th century, their first incarnations being formal statements of the invention's novelty rather than definitions of the scope of the inventor's rights.[28] But the claim evolved to represent the subject matter against which the patentee could claim infringement – initially 'central' claims, which defined an embodiment around which judges determined the actual scope of patent rights, then later as modern 'peripheral' claims, which themselves define the boundaries of the patent right.

In modern practice the claim is 'the invention,' and the set of properties recited by the claim solely defines both the subject matter over which the patentee may assert infringement, and the subject matter which may invalidate the patent if known or obvious from the prior art. For those who doubt a modern role for the written description doctrine, claims have entirely supplanted the notice function once performed by the specification's description of the invention.[29] On this view, written description as articulated by *Lilly* is an atavism of the time before claims, and has no role in limiting the

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[27] *See* Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 434-35 (1822)

[28] *See* Lutz*, at 147. This practice may seem puzzling today, but we must remember that the notion that the patentee has exclusive rights to a set of things bearing the properties recited by the claim is a relatively recent development. In the early 19th century, the patentee was required to show what was *novel* about the invention. A patentee could not describe as his invention, for example, a clock with a novel mainspring, because the other components of the clock would be 'old' and the patentee would be accused of claiming the old and the new together. Claims defined the novel feature or principle of the invention, not necessarily an actual embodiment, and therefore ensured that the patent would not be held invalid for lack of novelty.

[29] *See* Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 977 (Rader, J., dissenting from the denial of rehearing en banc) ("In later enactments, this function was assigned to claims, leaving enablement as the only purpose of the 'written description' language.").

permissible scope of modern peripheral claims.[30] The function of the description in the specification is to fulfill the *quid pro quo* of the patent system: to disclose the invention to the public, so that the public may practice the invention upon expiration of the inventor's exclusive right. That is the function of the enablement doctrine and of enablement alone. To complete the process of systematizing patent law into a conceptually ordered system grounded upon the peripheral claim, it is necessary to discard remnants of the pre-claim system such as the written description doctrine. Thus, for those who would deny the doctrine of written description, the conceptual ordering of patent law can be largely achieved by adding only one more formal axiom to the set described above:

> *The maximum permissible boundaries of the claim are what the patentee has enabled in the specification.*

My object in this Article is to evaluate critically the formalist conception of patent law. By identifying the modern patent program as 'formalist' or 'classical,' I do not suggest that it represents an obsolete or futile endeavor. The decay of the classical system of legal thought may have come more from its political assumptions than from its epistemological ones, and it is not my intention here to evaluate whether the epistemological criticisms leveled at classical legal thought negate the possibility of a conceptually ordered patent system. My interest is in whether the formalist program can succeed on its own terms in formulating a conceptually ordered patent system, and whether the written description doctrine is necessary to such a system. My evaluation asks whether patent law can be reduced to a set of uniform principles centered on a formal and hierarchical model of claim scope. In particular, I wish to assess whether the doctrine of enablement can satisfactorily limit claim scope in our modern peripheral claiming system, or whether additional constraints – such as a written description doctrine – are necessary to limit claim scope based on the inventor's disclosure. My approach is in part formal, attempting to ascertain whether a theoretically coherent doctrine of claim scope is possible within the confines of the peripheral claiming system.

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[30] Again, because the Court of Customs and Patent Appeals grounded the 'new matter' rejection of new claims in a continuation application in part in § 112, those who feel bound to respect the CCPA's precedent concede that the 'written description' language of § 112 serves that important role. *See supra* note 20.

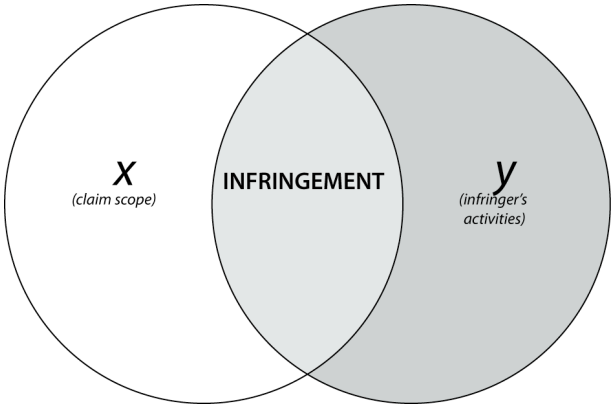
However, because gaps in the formal structure have significant implications for what a patentee is entitled to claim, most of the theoretical difficulties I highlight have implications for the policy goals of the patent system. In Part I, I consider how the various doctrines of patent law may be expressed as formal statements of inclusion or exclusion from claim scope. I show that enablement, in contrast to other doctrines, cannot be expressed as a truth function defined in terms of claim scope. In Part II, I detail the characteristics of enablement that make it incapable in its present form of adequately constraining claim scope, and evaluate proposals for modifying enablement to account for these problems. In Part III, I revisit the doctrine of written description and argue for a hitherto unrecognized role as a doctrine of *definition*. Once the written description doctrine is recognized as a doctrine of definition, it becomes clear that it serves a necessary function in defining the scope of patentable inventions in a peripheral claiming system.

## I. PATENT LAW AS A FORMAL SYSTEM

Nearly all the doctrines of patent law can be described as a precise relationship between the legal inquiry and the subject matter within the claim's boundaries. These doctrines may be posed almost as mathematical set-functions whose truth value is described in terms of the claimed subject matter. Take a claim reciting particular properties, and call the set of all possible things or events characterized by those properties as *x*. In general, a patent is infringed by the manufacture, use or sale, of anything possessing all the properties recited by the patent claims. We may easily represent the question of patent infringement in terms of the members of *x*:

> *Let y be the set of all things the accused infringer has made, used, sold, or offered to sell within the United States. The claim is infringed if and only if x and y intersect.*

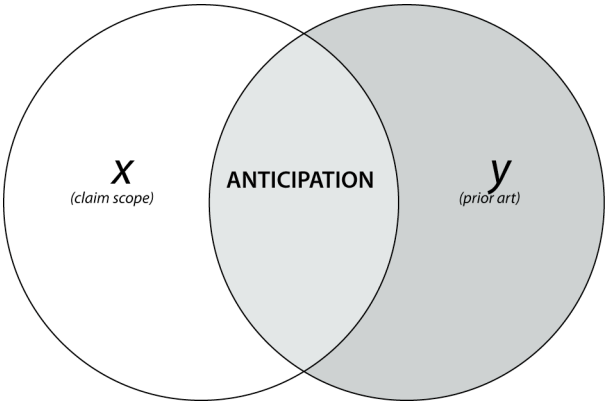
We might diagram this rendition of the infringement inquiry as follows:




Can the statutory requirements of patent validity be expressed in similar terms? Consider first the requirement of § 102, which denies patentability if the invention was known or used by others prior to the date of invention. If the invention is synonymous with the claims, then we can express the requirement of novelty as a simple intersection between the subject matter of the claim and the prior art:

> *Let y be the set of all things known and used, or patented or described in a printed publication, prior to the date of invention (the prior art). The claim is novel if and only if there is no intersection between x and y.*

Thus, the claim is anticipated if there is any overlap between the claim scope and the prior art:




Certainly the test of novelty may be uncertain because the scope of the claim – the set of things *x* having the properties recited by the claim – may be uncertain. In practice, claims may be precise or vague, and the more vague the claim the more uncertain the test of novelty. But practically every inquiry in patent law shares this uncertainty. My aim is not to show that particular doctrines in patent law are certain or uncertain in practice. It is to illustrate where uncertainty lies in the various doctrines of patent law, and, more importantly, to distinguish between the fundamental *kinds* of uncertainty inherent in the

doctrines. Uncertainty in claim scope means that the set *x* may be difficult to define. However, once we have defined *x* to whatever degree we think satisfactory or practical, the underlying formal structure of the novelty inquiry is precise. Likewise, the set of prior art *y* may be uncertain because the standard of whether a thing is "known or used" is not precise.[31] But once a satisfactory definition of set *y* is achieved, the dependence of the novelty inquiry on sets *x* and *y* is clear.

The requirement of § 103 that the claimed subject matter be non-obvious may also be framed as a relationship between the set of prior art and the set of things encompassed by the claim:[32]

> *Let y again be the set of all things known and used prior to the date of the invention. The claim is obvious if, for any y or set of y, the difference between any y and any x would be obvious to one of ordinary skill in the art.*
>
> or:
>
> *Let y' be the set of all things for which the difference between any y' and any y or set of y would be obvious to one of ordinary skill in the art. The claim is obvious if and only if x and y' intersect.*

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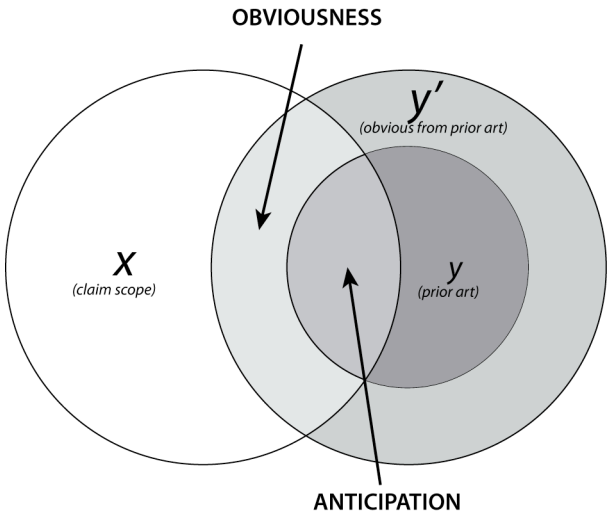
[31] For example, the question of whether subject matter was "known or used" if the property defining the subject matter was not perceived at the time has divided the Federal Circuit. *See* Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research, 304 F.3d 1221, 1229-31 (Fed. Cir. 2002) (holding that inherent feature of transgenic mouse was not disclosed by reference suggesting method of making mouse); *id.* (Dyk, J., dissenting) (arguing that reference inherently disclosed feature that would be present if method performed). *See also* Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research, 314 F.3d 1299 (Fed. Cir. 2002) (order granting rehearing en banc); Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051 (Fed Cir. 2003) (deciding case on enablement rather than inherency grounds).

[32] This point was shown by the Supreme Court's *KSR* decision, which explicitly defined the non-obviousness inquiry in terms of the set of things encompassed by the claim. *See* KSR Intern. Co. v. Teleflex Inc., 127 S.Ct. 1727, 1742 (2007) ("What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103."). The Court many years earlier in *Graham* made definition of the set of prior art the first factual inquiry under § 103. *See Graham* ("Under § 103, the scope and content of the prior art are to be determined.")




Again, the reader may object that this is not a precise relationship at all. The transformation between *y*, the prior art, and *y*', the set of all things obvious in light of the prior art, is vague and indeterminate. True, there has never been a certain test of whether the difference between a *y* and a *y*' would be obvious to one of ordinary skill in the art, and the test has become even less certain after the Supreme Court's opinion in *KSR v. Teleflex*.[33] But this kind of uncertainty has nothing to do with the scope of the claim in question. The uncertainty lies in how far the penumbra of obvious objects *y*' extends from the boundaries of the prior art objects *y*. Once we develop or posit a determinate method of defining the extent of this penumbra, then the structure of the non-obviousness inquiry is identical to the novelty inquiry: we simply ask whether claim scope *x* and penumbra *y*' intersect, rather than claim scope *x* and prior art *y*.

Similarly, for the doctrine of utility – the requirement of § 101[34] that the invention be "useful" – we may define a straightforward relationship between the validity inquiry

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[33] Prior to *KSR*, the Federal Circuit required as an element of obviousness a teaching, suggestion, or motivation for the artisan to combine or modify the prior art and arrive at the claimed subject matter. Under this so-called "TSM test," the set of obvious subject matter *y*' might have been defined more precisely: something is a member of *y*' if there exists a teaching, suggestion, or motivation connecting the putative member with a member of *y*. *See also* Holbrook, *supra* note ___, at 172.

[34] As far as the requirement that the invention be within the class of statutory subject matter defined by § 101, the Court of Customs and Patent Appeals assumed, without deciding, that a claim reading on both statutory and non-statutory subject matter would be invalid under § 101. *See* In re Mahony, 421 F.3d 742, 746 (C.C.P.A. 1970). This interpretation may be difficult to sustain. Any open claim may be construed to include some form of non-statutory subject matter, because adding additional elements to subject matter meeting the limitations of the claim does not remove that subject matter from the scope of

and the scope of the claim. As a general matter, if an applicant or patentee establishes the utility of a species encompassed by the claim, then the utility of the claim is established.[35] Therefore, if we can agree on a satisfactory standard of whether a particular thing is or is not useful, the question of whether a claim satisfies the utility requirement generally reduces to the question of whether any member of the set *x* possesses the quality of utility.[36]

In contrast, the disclosure requirements of § 112 *cannot* be reduced to an inquiry defined strictly in terms of the claim scope. Consider the enablement aspect of § 112, which according to the reductionist position, is the only disclosure doctrine necessary to define the proper scope of allowable claims. Section 112 frames the enablement inquiry as whether one of ordinary skill in the art can "make and use" the invention, a standard which the Federal Circuit has explained requires that the ordinary artisan be able to make and use the invention without "undue experimentation." Let us define as *y* the set of all things which the skilled artisan, equipped with the teachings of the patent and the knowledge of the art, could make and use without undue experimentation. We cannot express enablement as a simple intersection as we could for §§ 101, 102 and 103. Simply because an inventor has enabled *something* within the scope of the claims, he is not necessarily entitled to *everything* within the scope of the claims. The proposition:

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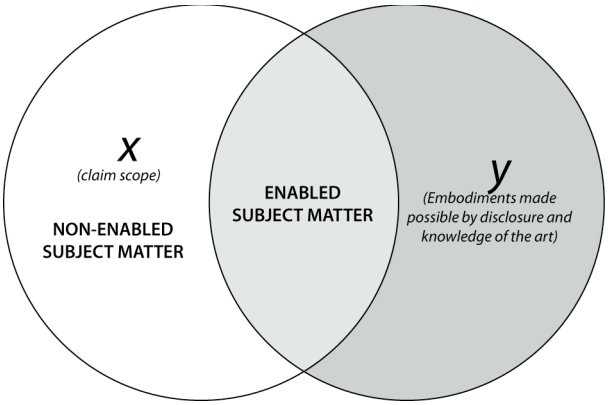
the claim. The Federal Circuit may resolve the question in *In re Bilski*, as one of the questions posed for en banc review was whether claims that contain both mental and physical steps are eligible subject matter under § 101. *See* In re Bilksi, 2008 WL 417680 (Fed. Cir. Feb. 15, 2008) (order granting en banc review).

[35] *See* United States Patent and Trademark Office, MANUAL OF PATENT EXAMINING PROCEDURE § 2107.02. ("Where an applicant has established utility for a species that falls within an identified genus of compounds, and presents a generic claim covering the genus, as a general matter, that claim should be treated as being sufficient under 35 U.S.C. 101.").

[36] The question becomes more complicated if some members of *x* possess the quality of utility, and some do not. In contrast with novelty and non-obviousness – for which the claim is invalid if any species encompassed by the claim lacks those qualities – a claim may still meet the utility requirement of § 101 even if some members of the set *x* are not useful. At least in recent case law, this question of "inoperative embodiments" has been treated nor as a matter of utility *per se*, as a matter of compliance with the enablement requirement of § 112: so long as one of ordinary skill in the art can distinguish between the operative and inoperative embodiments without "undue experimentation," then one of skill in the art can "make and use" the invention in accordance with the first paragraph of §112. *See* Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1576-77 (Fed. Cir. 1984) (holding that claim encompassing inoperative embodiments may be enabled if one of ordinary skill can distinguish inoperative embodiments without undue experimentation). We might express this doctrine as follows:

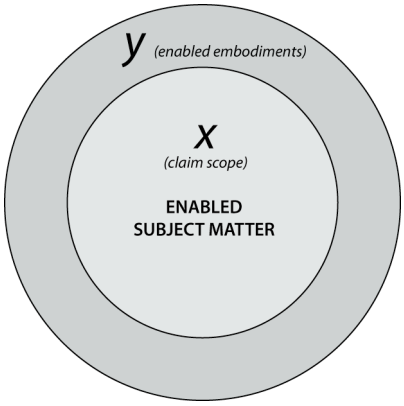
> *Let x' be the members of x which are operative, and let x'' be the members of x which are not operative. The claim is valid if and only if one of ordinary skill in the art can identify members of x' without undue experimentation.*

*The claim is enabled if x and y intersect*




is false, because enablement of some members of *x* does not necessarily imply that the full claim scope is enabled. Nor is it the case that the inventor must enable *all* things falling within the scope of the patent claim. The proposition

*The claim is enabled only if all members of x are also members of y*




is false, because an inventor need not – and in most instances can not – enable all things falling within the scope of his claim. I shall discuss the reasons why, and the implications thereof, shortly. What is important to note is that the uncertainty inherent in the disclosure requirement of § 112 is qualitatively different from the uncertainties inherent in other doctrines of patent law. Questions of infringement and novelty, once the predicate facts have been established,[37] are completely determinate provided that the scope of the claims is precise. Non-obviousness is also determinate if, in addition to

[37] *I.e.*, whether the accused subject matter or the prior art actually has the properties recited by the claim.

precise claim scope, we can determine whether a specific thing *y'* falling within the scope of the claims would or would not have been obvious to one of ordinary skill in the art. Not so for the disclosure requirement. Even if we have a perfect technique for construing claims, and a perfect test of whether one of ordinary skill in the art could make and use a particular thing *y*, we cannot necessarily determine whether or not the claim meets the enablement requirement of § 112. There is certain relationship between validity and claim scope even if the theory of claim construction or the underlying substantive doctrine of enablement is further refined.

## II. THE LIMITS OF ENABLEMENT

The inability to formulate a doctrine of enablement in terms of claim scope is no mere quirk of the law of enablement, but neither is it a necessary property of a patent system. Rather, it is an inherent and necessary property of the particular claim system that has been at the heart of the United States patent system for a century, and more recently abroad. It arises because we have condensed three formerly separate concepts in patent law – the invention, the claim, and the scope of the inventor's exclusive rights – into a unitary conception founded exclusively upon the claim. The implication of this deficiency is that patent law is not capable of reduction to a formal set-theoretic system. In turn, the inability to reduce patent law to a formal system means that the attempt to squeeze out the last remnant of the pre-claim[38] conception of patent law – the written description doctrine – cannot succeed if patent law is to remain a coherent system.

### A. All the World's a Genus: The Problem of Infinite Scope

Why is it that we cannot formulate a formally coherent doctrine of enablement within the structure of modern patent law? We cannot because modern patent law must reconcile two apparently contradictory principles:

[38] Or at least pre-central claim.

*The claim completely and exclusively*[39] *defines the class of things over which the inventor may exercise his rights.*

*All patent claims are of infinite scope.*

The first principle is familiar; the second may be less so. It is an essential characteristic of all patent claims that, they cover a set of entities rather than a single entity; otherwise claims could not be infringed, save perhaps by the use of the physical entity that the inventor constructed. But the set of entities covered by a claim, despite being bounded by the language of the claim and the various doctrines of patent law, must be infinite in scope. This conclusion follows not from legal doctrine, but from the ontological nature of patent claims themselves.

The distinction between "genus" claims – claims covering a class of entities characterized by a common property – and "species" claims – claims covering only a single entity – is familiar in chemical and biotechnological practice. An inventor might synthesize a novel molecule with antibiotic properties, and file a claim defining the specific structure of the molecule that she synthesized. However, because molecules with minor modifications to the chemical backbone may share the antibiotic property, inventors typically also draft a claim to a genus of related molecules sharing the same backbone but varying in the atoms or groups attached to the backbone. Likewise, because multiple DNA molecules can encode the same polypeptide,[40] an inventor discovering a novel protein will typically claim the genus of all DNA molecules encoding that protein.

What is not often appreciated is that essentially all patent claims – not just those defining chemical and biotechnological inventions – are genus claims. Modern patent claims define the scope of the inventor's rights by reciting *properties*; all things having those properties fall within the scope of a patent's claims.[41] Regardless of form, such

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[39] The doctrine of equivalents of course renders this statement not literally true if we take "define" to mean literal claim scope only. The argument is the same whether we consider literal claim scope only or literal claim scope plus equivalents; if the point is that all claims are infinite then the extension of those claims by the doctrine of equivalents is a relatively trivial matter.

[40] Due to the degeneracy of the genetic code.

[41] In metaphysical terms, the patent claim is thereby synonymous with the extension of the properties, or class. "A *class* is often thought of as the extension of a property (or concept), the collection of all those things. . . which have that property or fall under that concept." JAEGWON KIM & ERNEST SOSA (eds.), A COMPANION TO METAPHYSICS 86 (1996).

claims define an infinite number of existing and possible objects.[42] Consider a simple claim to a chair having four legs:

> *1. An object for supporting a human body, comprising*
>
> *a substantially flat surface sized to accommodate a human posterior, and*
>
> *four legs supporting said surface.*

This claim is unremarkable and, supposing the inventor to be the first to conceive of the idea of a chair with four legs, we would not think this claim poses any issue of adequate disclosure. Yet this claim, even more so than the typical chemistry or biotechnology claim, covers an infinite variety of embodiments. This claim, like most claims, is written in the so-called 'open' format – employing the word "comprising."[43] Such claims are construed to cover all things which possess, at a minimum the recited properties. Subject matter with *additional* properties or elements still falls within the scope of the claim, so long as it retains those properties recited by the claim. Thus chairs made of all sorts of materials, chairs including contoured backrests, chairs with roller wheels, etc. are all within the claim so long as they possess the recited flat surface and four legs.[44]

Supposing the inventor to have disclosed the basic structure of the chair, we would have little difficulty concluding that claim 1 satisfies the enablement requirement of § 112. The inventor is entitled to assert exclusive rights over all chairs which include a flat surface and four legs. If the inventor has enabled those of skill in the art to make and

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[42] It might be possible in theory to draft claims limited to a particular instantiation of those properties. One might, for example, claim a chair with the property that "said chair being resident in Room 380 of 200 McAllister Street, San Francisco, on November 21, 2007." Obviously such claims are lacking in practice, their commercial utility being slight. This particular example would raise the interesting question of whether subject matter defined by temporal or spatial limitations would infringe if, having met those conditions at some point, ceased to meet them at a later point. The example is trivial but the general question is not. *See* Novartis Corp. v. Ben Venue Labs., Inc., 271 F.3d 1043, 1049 n.5 (Fed. Cir. 2001) (discussing theory of transitory infringement by chemical intermediate).

[43] There are more narrow patent claims drafted with the phrase 'consisting of' instead of 'comprising'; such "closed" claims extend only to subject matter possessing the recited elements and no others. Closed claims are quite rare and are generally employed only when the invention lies in the elimination of an element or step necessary in the prior art. Somewhat more common are 'hybrid' claims employing the language 'consisting essentially of,' which are open to the addition of elements that do not materially change the properties of the claimed subject matter.

[44] Indeed, chairs with five or more legs (but not three) would also fall within the scope of the claim, because they possess the recited four legs in addition to their others. *See* Gilette Co. v. Energizer Holdings, 405 F.3d 1367 (Fed. Cir. 2005) (holding that four-bladed razor infringed claims reciting "a razor comprising ... a group of first, second, and third blades.").

use the genus of chairs defined by claim 1, then by definition claims dependent on claim 1 – claims reciting additional properties and thereby defining subsets of claim 1 – are also enabled. Yet manifestly the inventor has not disclosed information sufficient to make and use all subsets of claim 1. Consider the claims:

> 2. *The object of claim 1, wherein the legs and surface are composed of neutronium.*[45]
>
> 3. *The object of claim 1, wherein the object further comprises a portable fusion reactor.*

Claim 2 defines a set of chairs composed of a material that cannot now (nor possibly ever) be made on this planet.[46] Claim 3 defines a set of chairs including a portable fusion power source, a technology that might be possible in the future but certainly is not available today. Clearly, the inventor's disclosure did not enable one of ordinary skill in the art to make chairs of neutronium or including fusion reactors. Yet, because of the hierarchical structure of patent claims, the sets of chairs defined by claims 2 and 3 are subsets of the set of chairs defined by claim 1.

These claims are by statute proper dependent claims, and if the inventor has satisfied the enablement requirement of § 112 with respect to claim 1, then he has done so for claims 2 and 3 as well.[47] Even if we are accustomed to the notion that the inventor need not enable all embodiments within the scope of a claim for the claim to be enabled, claims 2 and 3 are curious. Either the inventor is entitled to claims 2 and 3, or there must

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[45] A material of unimaginable density found only in neutron stars, where gravitation has forced protons and electrons to combine.

[46] Claim 2 would presumably be a proper dependent claim even if claim 1 was written in closed format. Claim 3 would not, because the addition of a fusion reactor would be an additional element. Note that additional elements make claims narrower, not broader. If we are truly committed to the hierarchical claim structure, it is not entirely clear that the distinction between open and closed claims can be sustained. Consider a closed claim defining a chair "consisting of a seat and four legs." From a purely ontological viewpoint, there is no distinction between narrowing the set by adding the property "composed of wood," and narrowing the set by adding the property "having a backrest." Yet the chair composed of wood would infringe the closed claim, and the chair including a backrest would not.

[47] *See, e.g.*, Ex Parte Forstova, 2002 WL 3234992 (Bd. Pat. App. & Interf. 2002) ("We first express our concern about the anomalous situation confronting us where dependent claims 2-5 are rejected as being non-enabled while claim 1, the independent claim from which these claims directly or indirectly depend, is not rejected. It has long been held that a claim must be enabled throughout its scope. . . As a matter of logic, assuming claims 2-5 are proper dependent claims and we see no reason why they are not, the examiner's decision that claims 2-5 are non-enabled necessarily means that claim 1 is non-enabled.").

be some limitation on permissible claim scope beyond the enablement doctrine as currently conceived.[48]

This paradox may be more significant than is first supposed. Today the chair claim clearly lacks novelty over known chairs. But claims 2 and 3 are certainly novel and non-obvious, because no prior art discloses or makes obvious the limitations added by claims 2 and 3; claims 2 and 3 may therefore be patentable where claim 1 is not. A real-world manifestation of this pattern appeared in *Amgen Inc. v. Hoechst Marion Roussel, Inc*. Several of the patents in *Amgen* claimed a "non-naturally occurring erythropoietin [EPO] glycoprotein." Because naturally occurring EPO was known in the prior art, addition of the "non-naturally occurring" limitation made the claims novel and potentially non-obvious over the prior art. The patentee's disclosure of one method of making non-naturally occurring EPO was held to enable the claim – a claim which was construed to over *all* non-naturally occurring EPO, whether made by the patentee's synthetic process or not. By adding a novelty-imparting limitation to a broad genus, the patentee was able to lay claim to all subsequent synthetic EPO molecules without having to enable the sub-genera of molecules made by different synthetic processes. Although the broader claim is more useful commercially, as with claims 2 and 3 it is difficult to understand in terms of enablement alone why Amgen could not have explicitly claimed synthetic methods of producing EPO that were not yet possible when it filed its application, given that the broader category of synthetic EPO was enabled.[49]

Likewise, the Board of Patent Appeals and Interferences has reversed enablement rejections of claims directed to technology useful for gene therapy, notwithstanding that gene therapy is not yet clinically viable. In *Ex parte Forstova*,[50] claims to a method of

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[48] One might object that claims 2 and 3 lack utility as demanded by 35 U.S.C. § 101. If by utility we mean the requirement that inventions confer some tangible benefit upon society, then we can easily remedy the lack of utility by changing the hypothetical to less outlandish objects that might become more useful by being composed of neutronium or including fusion reactors; such objects, if possible to create, would confer benefit upon society. Likewise, if we are concerned about the prohibition against inventions that violate known laws of physics, we could choose examples that are beyond current technology yet more plausible than the ones given.

[49] Claims defining subject matter very far afield from the embodiments the inventor created may allow the inventor to circumvent certain limitations on the licensing of patent claims. *See* Robin Jacob, *Objectionable Narrowness of Claim, in* DONALD S. CHISUM, CRAIG ALLEN NARD, HERBERT F. SCHWARTZ, PAULINE NEWMAN & F. SCOTT KIEF, PRINCIPLES OF PATENT LAW (2d ed. 2001).

[50] *Forstova*, *supra* note ___.

transferring DNA into a host cell with a papovavirus capsid protein were allowed, despite the examiner's rejection that applications of the method to clinical gene therapy were not enabled. Because the claims were directed to a method of gene transfer rather than clinical gene therapy, the Board held that alleged difficulties in clinical gene therapy did not preclude enablement of the claim. But given the Board's reasoning that enablement of a narrower claim is logically predicated on enablement of the broader claim, a dependent claim explicitly directed to clinical gene therapy ought to have been enabled as well. If so, the attachment of "non-enabled limitations" to broader enabled claims provides a means to circumvent the rule that an inventor cannot claim an improvement or additional feature on a base technology if the base technology itself is not enabled.[51] If the non-enabled base technology is itself attached as a limitation to a broader enabled claim, then the problem of enablement is circumvented.

Note that the claim is infinite regardless of *when* its scope is assessed. As in *Amgen*, we are often concerned with the problem of claim scope in the context of after-arising technology: a later inventor develops a marvelous new back-supporting chair, and we question whether the original inventor ought to be entitled to assert patent rights over chairs that did not exist or could not exist at the time the inventor filed for a patent. The question of after-arising technology is important in allocating the proper incentives for innovation between earlier and later inventors. However, the scope questions that arise in the context of after-arising technology are merely subsets of the more general problem of infinite claim scope. There are an infinite number of variations on the simple chair that can be constructed with contemporary technology – variations in material, proportions, decoration, etc. – and are within the scope of the claim. It seems self-evident that without a coherent conception of claim scope with respect to *present-day* embodiments of the invention, we cannot hope to achieve a coherent conception of claim scope as applied to *future* embodiments of the invention.

The difficulties with current enablement doctrine, even when exotic technologies are not at issue, are evident from the Federal Circuit's recent enablement jurisprudence. The court has held claims on fairly conventional technologies invalid for lack of

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[51] *See* Gould v. Hellwarth, 472 F.2d 1383, 1386 (C.C.P.A. 1973) (holding that improvement on laser could not be patented absent disclosure enabling construction of laser).

enablement under § 112, holding that the disclosure must enable the "full scope" of the patent claims.[52] The court has not defined "full scope" means, other than to indicate that §112 requires "reasonable enablement,"[53] and to suggest that failure to enable "a significant portion of the subject matter encompassed"[54] by the claims renders the claims invalid under § 112. Due to the infinite scope of patent claims, a patentee certainly cannot enable every embodiment falling within the "full scope" of the claims, though it is not clear if the Federal Circuit's recent jurisprudence recognizes this basic principle.[55]

What *is* clear is that reconciliation of enablement doctrine with a formal conception of patent law is difficult, perhaps impossible, without resort to disclosure doctrines beyond enablement. As an illustration, take the Federal Circuit's decision in *AK Steel Corp. v. Sollac & Ungine*,[56] the case that inaugurated the current "full scope of enablement" line of authority. The patents at issue in *AK Steel* were compositions of matter: aluminum-coated stainless steel strips, made by an improved process of hot-dipping the steel strips in a coating solution.[57] Standard industry coating solutions (known as "Type 1" coatings) had included about 10% silicon. The inventors had

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[52] *See* Sitrick v. Dreamworks, LLC, 516 F.3d 993 (Fed. Cir. 2008); Pharm. Resources, Inc. v. Roxane Labs., Inc., 2007 WL 3151692 (Fed. Cir. Oct. 26, 2007); Automotive Technologies Intern., Inc. v. BMW of North America, Inc., 501 F.3d 1274 (Fed. Cir. 2007); Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371 (Fed. Cir. 2007); AK Steel Corp. v. Sollac & Ungine, 344 F.3d 1234 (Fed. Cir. 2003).

[53] *AK Steel,* 344 F.3d at 1244.

[54] *Id.* at 1245

[55] With respect to the "full scope" requirement, the court in *AK Steel* stated: "That is not to say that the specification itself must necessarily *describe* how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending on the predictability of the art." *Id.* at 1244 (emphasis added). This language can be read to suggest that while the specification need not *describe* every embodiment within the scope of the claims, it must enable one of skill in the art to practice every embodiment within the scope of the claims without undue experimentation. Historically, case law been clear that the specification need not disclose every embodiment within the scope of the claims, but has usually done so in the context of whether one of skill in the art would have to experiment unduly to identify operable species within the claimed parameters. The question of whether each embodiment within the claims must be embodied within the claims has not been addressed directly, but a rigid requirement would run counter to the sentiments expressed in the historical case law. *See, e.g.,* In re Angstadt, 537 F.2d 498 (C.C.P.A. 1976). Interestingly, such precedent essentially rejects the synonymy of the claimed invention and the scope of the inventor's legal rights. *See id.* at 504 ("By calling the claimed "invention" the "scope of protection sought" the dissent obscures the problem and frustrates the intended operation of the patent system. Depriving inventors of claims which adequately protect them and limiting them to claims which practically invite appropriation of the invention while avoiding infringement inevitably has the effect of suppressing disclosure."). *See also infra* Part III (discussing conflation of invention, claim, and legal right).

[56] 344 F.3d 1234 (Fed. Cir. 2003).

[57] *See id.* at 1236-37.

discovered that the inclusion of silicon inhibited the coating process. The patent specifications therefore stated that pure coating solutions with little or no silicon (known as "Type 2" coatings) were preferred for their invention. However, the patent issued with an independent claim that did not limit the amount of silicon the coating solution:

> 1. A ferrous base ferritic strip continuously hot dip coated with a coating metal, comprising:
>
> *. . . the coating metal including aluminum or aluminum alloys . . .*[58]

as well as a dependent claim explicitly reciting coating solutions with substantial amounts of silicon:

> 3. The strip of claim 1 wherein *the aluminum coating metal contains up to about 10% by weight silicon.*[59]

Thus, the patent claimed, in an independent claim, a broad genus not defined by any particular silicon content, and in a dependent claim, a narrower genus that encompassed the "Type 1" coating explicitly advised against by the disclosure.[60]

The patentee asserted the patent against a defendant whose stainless steel strips were coated with a solution containing about 8% silicon.[61] In light of evidence that one of ordinary skill in the art could not practice the invention using a coating solution with about 10% silicon, the Federal Circuit held that *both* independent claim 1 and dependent claim 3 were invalid for lack of enablement.[62]

What I wish to highlight is that the outcome in *AK Steel* was essentially dictated by a formalist conception of patent law, and of patent claim structure in particular. Consider the alternative courses the court could have taken. The Federal Circuit's own case law had long suggested that a claim encompassing 'inoperative embodiments' would not be invalid for lack of enablement, so long as one of ordinary skill in the art could

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[58] U.S. Patent No. 5,066,549.

[59] *Id.*

[60] In the infringement suit, both the district court and the Federal Circuit construed the dependent claim to include Type 1 coatings with substantial silicon. *AK Steel*, 344 F.3d at 1240-43. The Federal Circuit held that, despite the maxim that claims are to be construed in order to preserve their validity, the clear literal word of the claim, and the prosecution history of the '549 patent, demanded that the claim be construed to cover coating solutions with about 10% silicon.

[61] *AK Steel*, 344 F.3d at 1238.

[62] *Id.* at 1245. Other claims in the '549 patent were essentially parallel to claims 1 and 3, and met the same fate.

identify the inoperative embodiments without undue experimentation.[63] One of skill in the art would certainly not have to experiment unduly to exclude the high-silicon embodiments that fell within the claims, since the disclosure quite simply instructs him to avoid them.[64] The court's opinion does not refer to the 'inoperative embodiments' doctrine, perhaps with good reason.[65] If enablement were the only disclosure requirement of § 112, then the logical conclusion of the 'inoperative embodiments' doctrine would be that the patentee may draft a claim of the form:

*1. Everything.*

and have no issues with § 112, so long as the specification directs one of skill in the art to confine himself to one or two embodiments enabled by the disclosure.[66]

The second alternative would have been to construe at least claim 1 to exclude high-silicon coatings, given that the specification explicitly disclaimed such embodiments. Such a construction would not only comport with the maxim that claims are interpreted in light of the specification, but would also avoid the invalidation of claim 1 for lack of enablement. Why did the court not choose this course? In part, the court's decision was driven by a formalist 'plain meaning' principle of interpretation. The claim recited a coating containing 'aluminum or aluminum alloys,' and no claim language limited its silicon content. Notwithstanding the principle that claims ought to be construed to preserve their validity, the court would not apply that principle absent any lexical ambiguity in the claim language.[67]

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[63] *See Atlas Powder,* 750 F.2d at 1576-77; *In re Cook*, 439 F.2d 730, 735 (C.C.P.A. 1971).

[64] *See* In re Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) ("[T]he disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility.").

[65] It also may be that the inoperative embodiments doctrine was not argued by the litigants, as there is no mention of the doctrine in the district court's lengthy opinion. *See* AK Steel Corp. v. Sollac & Ugine, 234 F. Supp. 2d 711 (S.D. Ohio 2002).

[66] Of course prior art also limits claim scope; *see infra* Part II.B. To be fair, the *Atlas Powder* doctrine could be read more narrowly. *Atlas Powder* states that "Of course, if the number of inoperative combinations becomes significant, and *in effect* forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid." *Atlas Powder*, 750 F.2d 1576-77 (emphasis added). One could interpret this passage to mean that a large number of inoperative embodiments is equivalent to undue experimentation, even if one of skill in the art could easily identify and exclude the inoperative embodiments.

[67] *See AK Steel,*, 344 F.3d at 1243. *See also* MBO Labs., Inc. v. Becton, Dickinson & Co., 474 F.3d 1323, 1332 (Fed. Cir. 2007) ("[V]alidity construction should be used as a last resort, not a first principle. . . .").

But more important than the 'plain language' principle was the Federal Circuit's focus on the hierarchical structure of patent claims. According to the court, claim 1 *must* encompass coatings with up to 10% silicon, because claim 3, which depended from claim 1, explicitly recited "up to about 10% silicon." In the court's view, because claim 3 depended from claim 1, claim 3 must define a sub-genus *entirely contained* within the scope of claim 1. Given that claim 3 clearly encompassed high-silicon coatings, the supra-genus defined by claim 1 must encompass them as well.[68] This line of reasoning is predicated on a formal, hierarchical view of claim structure: every dependent claim, because it merely adds limitations to another claim, must constitute a sub-genus of its parent claim. The subject matter encompassed by every independent claim must therefore be a superset of the subject matter encompassed by its dependent claims.

Such a view of claim structure has an impeccable pedigree. It simply recapitulates Aristotle's scheme of categorization, in which all things that exist may be classified in a hierarchical structure of genus and sub-genus.[69] It is not, however, required by the patent statutes. 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.[70] 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. *A priori*, one could conceive of dependent claims that included all the limitations of an independent claim but whose subject matter was not entirely included within the independent claim, or one could conceive of claims that incorporate the limitations of other claims without being dependent on those claims. In fact, decisions of the PTO's Board of Patent Appeals and Interferences have in the past considered the possibility that a claim referring to another claim might be treated as an independent claim, and that the reference to another claim is only a shorthand form of drafting.[71] But an intrinsic commitment to the hierarchical conception of claim structure foreclosed this route for the

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[68] *AK Steel*, 344 F.3d at 1242.

[69] *See infra* Part III.C.

[70] 35 U.S.C. § 112, para. 4

[71] *See* Ex parte Porter, 25 USPQ2d 1144, 1147 (BPAI 1992); Ex parte Moelands, 3 USPQ2d 1474, 1476-77 (BPAI 1987) (Spencer, dissenting in part, and Lovell, concurring in the result).

Federal Circuit in *AK Steel*, leaving the court with no choice but to conclude that the independent claims encompassed the subject matter defined by the dependent claims.

After defining the patent's scope according to a formal conception of claim structure, the *AK Steel* court proceeded to determine enablement of the claims, and it is at this point we see the uncomfortable interface between the formal structure of patent law and the enablement doctrine. The evidence showed that the patent's specification did not enable one of ordinary skill in the art to use high-silicon "Type 1" coating solutions in the manufacture of the claimed steel strips. Having construed the independent claims to encompass Type 1 coating solutions, the court held those claims invalid because "the specification does not enable a significant portion of the subject matter" claimed by the patent.[72] But why were the Type 1 coatings a "significant portion" of the claimed subject matter? As we have seen, all claims are infinite. While there were an infinity of non-enabled Type 1 compositions within the scope of the claims, there were also an infinity of enabled Type 2 (low-silicon) compositions within the scope of the claims. It is not apparent from first principles why the first set ought to be more significant than the second, especially given that there were also an infinity of non-enabled *Type 2* compositions within the scope of the claims.[73]

Of course, the non-enablement of Type 1 embodiments was significant in *AK Steel* because the accused infringer practiced a Type 1 embodiment. But whether the accused subject matter is enabled by the disclosure is ostensibly irrelevant to the question of enablement;[74] certainly under the formal conception of patent law, enablement is a function solely of the claim and the disclosure, and not dependent on whom the patentee sues. Perhaps the "full scope of enablement" doctrine can be expressed in terms of some complex calculus of infinities, in which the relative proportions of enabled and non-

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[72] *AK Steel*, 344 F.3d at 1246.

[73] E.g., Type 2 coatings dipped at extreme temperatures, or with immiscible materials, etc. Of course, one of ordinary skill in the art would certainly know to avoid these embodiments. But one of ordinary skill in the art would also know to avoid the Type 1 embodiments, given the specification's explicit teachings.

[74] *See, e.g.,* Durel Corp. v. Osram Sylvania Inc., 256 F.3d 1298, 1306 (Fed. Cir. 2001) ("The dispositive question of enablement does not turn on whether the accused product is enabled.").

enabled subject matter are assessed.[75] But the outcomes in cases contemporary with *AK Steel* – cases in which the presence of significant non-enabled subject matter within the claims did not negate enablement[76] – suggests that as currently practiced the doctrine is no more than a license to selectively invalidate claims when the patentee asserts them against particular technologies, based on which non-enabled subject matter is brought to the court's attention. Such a function may or may not be desirable on policy grounds, but it certainly cannot be squared with the formal model of patent scope.[77]

### B. Can Enablement Limit Claim Scope?

The preceding section contended that a coherent doctrine of enablement is not compatible within a formalist conception of the patent system; or, alternatively, that the formalist conception of patent law cannot be coherent given our current doctrine of enablement. We might not be too concerned if issues of formal coherence were the only difficulties with relying on enablement as our sole disclosure doctrine. In this section, I argue that the inability of current enablement doctrine to grapple with the problem of infinite scope is not only a problem of formal coherence, but also has important consequences for the basic substantive question of the extent of the patentee's entitlement.

The limits on a patent's scope essentially derive from only two sources: the prior art at the time of the invention, and the inventor's disclosure.[78] If we take the reductionism of the formalist conception at face value, these limits can be embodied in only two doctrines: non-obviousness, and enablement. Non-obviousness, because it

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[75] Of course if we discard the purely hierarchical view of enablement, cases like *AK Steel* may become formally coherent; the independent claim may be enabled notwithstanding the existence of non-enabled dependent claims.

[76] *See, e.g., Amgen*, 314 F.3d at 1334 – 1336.

[77] *AK Steel* could well have been a trivial case if it had been resolved on written description grounds. The invention was described by the specification as employing low-silicon coatings – not merely as a particular embodiment, but as a general property of the invention. Should the claims still be construed to define a genus of coatings without limitation to silicon content, then they do not correspond with the specification's fixation of the invention within the definitional hierarchy. *See infra* Part III.

[78] I assume for this discussion that there are no questions of subject matter eligibility or compliance with the technical requirements of the law.

functions as a superset of novelty,[79] embodies the all limitations imposed by the prior art. Enablement limits claim scope based on the inventor's disclosure; at least nominally, this limitation embodies the quid pro quo of the patent system that an inventor's exclusive rights be commensurate with the benefits conferred on society by his disclosure.[80] Ever since *Lilly*, considerable controversy has revolved around the question of whether an additional disclosure requirement – the "written description" aspect of § 112 – is necessary to properly circumscribe claim scope. Subsidiary to this controversy has been the question of whether the written description requirement is confined to chemistry and biotechnology or is applicable to other arts as well.

The problem, I believe, can be boiled down to a very simple hypothetical. Suppose a patentee to file an essentially empty disclosure, with the following claim:

> *4. All material objects which are enabled by the prior art, excluding those which are known or obvious in light of the prior art.*[81]

where "enabled" here means that the material object can be made and used without undue experimentation given the current state of the art. Such a claim seems absurd. But why, exactly would it not be patentable? By its own terms, it only encompasses subject matter that is novel, non-obvious and enabled as proscribed by statute.[82] Of course, most things obvious in light of the prior art are enabled by the prior art, and so this claim encompasses only the set of objects defined by the difference between the set of enabled objects and the set of obvious objects. *If* the standards of non-obviousness and enablement were identical, then this difference would be the empty set and the claim would cover nothing. Any object which was enabled by the prior art would also be obvious in light of the prior art, and hence unpatentable. However, the standards of

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[79] There are some technical limitations to this principle. Subject matter which is in public use may anticipate a claim even if its existence or properties were unknown to those skilled in the art. Formally, such unknown subject matter might not be regarded as obvious. *See, e.g.,* TorPharm, Inc. v. Ranbaxy Pharms., Inc., 336 F.3d 1322, 1327 (Fed. Cir. 2003) (discussing anticipation and obviousness in the absence of disclosure).

[80] *But see* Holbrook, *supra* note ___, at 131-46 (arguing against disclosure function).

[81] I limit these hypothetical claims to material objects for simplicity and to avoid issues of patentable subject matter under § 101, but the principles are applicable to claims for methods and other intangibles as well.

[82] One might challenge the claim on the ground that the subject matter is not "useful" as required by § 101, or the related ground that claim encompasses such a large number of inoperative embodiments that it is rendered non-enabled under § 112.

enablement and non-obviousness are symmetrical neither in theory nor in practice.[83] Most notably, the judicial standard for enablement – that the ordinary artisan ought to be able to make and use the invention without "undue experimentation" – invokes the effort required to produce the invention given the state of the art. In contrast, the statutory standard for non-obviousness under § 103 explicitly discourages inquiry into the inventive effort, declaring that "[p]atentability shall not be negatived by the manner in which the invention would be made."[84] Therefore, if only the doctrines of enablement and non-obviousness constrain patent scope, claim 4 defines patentable subject matter.

One might object that such a claim is indefinite for not "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention" as required by § 112, ¶ 2. But are the metes and bounds of the claim indistinct? One of ordinary skill in the art can certainly decide whether putative subject matter is a material object or not. Perhaps the skilled artisan cannot readily determine whether a given object is enabled or obvious given the current state of the art. Yet then the objection to claim 4 is premised entirely on the uncertainty in our current doctrines of enablement and non-obviousness. If we posit readily ascertainable standards of enablement and non-obviousness, then it becomes untenable to argue that one or ordinary skill in the art cannot ascertain the scope of the claim.

Claim 4 shows us that, at least at the formal level, the doctrines of enablement and non-obviousness provide only incomplete limits on the scope of the patentee's claims. In particular, there is no necessary relation between the inventor's disclosure and the scope of the rights granted to the inventor in the absence of additional disclosure requirements. There are three basic responses to claim 4 possible within our current mode of defining the limits of the patentee's rights. The first is to simply concede that the patentee is entitled to the full scope of claim 4. The second is to modify our doctrines of enablement or non-obviousness to eliminate the sliver of subject matter lying between the two

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[83] Before the notions of obviousness and enablement were clearly differentiated, the standard may have been more symmetrical. Writing in 1873, Curtis states that a specification will render the patent void if it "create[s] a necessity for the exercise of *inventive power* on the part of the person who has undertaken to apply the description." George Curtis, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS (4th ed. 1873) § 256. However, Curtis's discussion is mostly centered around undue experimentation as the standard for adequacy of the specification.

[84] 35 U.S.C. § 103(a).

doctrines. The third – as was the case in *Lilly* – is to invoke a separate limitation on the scope of the patentee's rights, which for all intents and purposes may be the written description doctrine.

The first response to the problem posed by claim 4 is to declare that it is not a problem. No one files patent applications with empty disclosures. But we can make claim 4 more realistic by modifying it slightly. Let us suppose the applicant files an application with some disclosure, and the following claim:

> 5. *All material objects which are enabled by the combination of my disclosure and the prior art, excluding those which are known or obvious in light of the prior art.*

Claim 5 represents a more plausible situation than claim 4, but does not resolve the question of scope; all things that were within the scope of claim 4 are within the scope of claim 5.

Still, claims 4 and 5 may not be problematic at all. One might argue that at any given point in time, all inventions that are enabled by current technology will be quickly disclosed, either by being claimed in another patent application or otherwise made known to the public.[85] Therefore, the sliver of claimable subject matter lying in the gap between enabled and obvious subject matter will not exist in the absence of new information contributed by the inventor. We will encounter problems only when decisions of the courts have legally cemented the standards of enablement or non-obviousness rather than let them flow with technological advance. If the standards of enablement and non-obviousness have become too far decoupled, then a minimal disclosure by an inventor may render a large swath of subject matter enabled but also non-obvious. On this view, the scope problem in cases like *Eli Lilly* arises ultimately[86] from the Federal Circuit's decision in *In re Deuel*, which held that a novel chemical entity claimed by structure could not be obvious in the absence of information in the prior art that would suggest the

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[85] This argument is parallel to the one advanced by Judge Rader, who argued that inventions enabled by a technological disclosure will inevitably be disclosed and claimed in a patent application. *See* Univ. of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1312 (Fed Cir. 2004) (Rader, J, dissenting from denial of rehearing en banc).

[86] Obviousness itself was not litigated in *Lilly*.

claimed structure itself.[87] By decoupling the standard of non-obviousness from considerations such as the ease of obtaining the chemical entity, the Federal Circuit drew the boundaries of non-obviousness such that all of the incipient information about genetic sequences fell into the gap between enablement and obviousness. Subsequent tightening of the written description and utility standards by the courts or the Patent Office has been an attempt to limit the subject matter otherwise made patentable by the divergence of the enablement and non-obviousness standards.

But there remain significant difficulties with the argument that only in unusual circumstances will patentable subject matter lie in the gap between enablement and non-obviousness. For one, the scope of inventions defined by claim 4 is decidedly non-trivial. Consider patents on simple mechanical inventions. Such inventions, not involving any radical technological advance, have been enabled by the state of the art for years. *Yet they were not made*, presumably because they were not obvious. Likewise, there exist many inventions in which the inventive activity consists of recognizing a problem; once the problem is recognized, the solution is well within the technological capabilities of the art without further contribution from the inventor.[88] Perhaps inventions that do not open up new technological possibilities ought not to be patentable; Justice Douglas so argued in his concurrence in *Great A&P*,[89] and the Supreme Court recently reminded us that *Great A&P* remains good law.[90] Yet if we continue to grant patents on inventions that are

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[87] *Eli Lilly*, though not litigated along these lines, provides representative facts. The patentee in *Lilly* had discovered and disclosed the cDNA molecule encoding rat insulin. In addition to claiming the rat insulin DNA, the patentee also claimed human insulin DNA, whose sequence was not yet known at the time of filing, and the broader genus of vertebrate insulin DNA molecules. Contemporary Federal Circuit precedent – *In re Deuel* – suggested that at the claimed species of human insulin DNA would be non-obvious absent prior art suggesting the structure of the claimed molecule, though arguably the genus claim could be obvious under *Deuel* if the structure of insulin polypeptides were known. Although the enablement issue was not directly litigated in *Lilly*, it is arguable that under the prevailing enablement standard the isolation of human insulin DNA by sequence homology from the rat molecule would not require undue experimentation. Human insulin DNA was therefore – more by case law than by technology – within the zone of things enabled but not obvious in light of prior art. Both the district court and the Federal Circuit relied upon the written description doctrine to invalidate the claim.

[88] *See, e.g.,* In re Sponnoble, 405 F.2d 578, 585 (C.C.P.A. 1969) ("It should not be necessary for this court to point out that a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified.")

[89] 340 U.S. 147, 154-55 (Douglas, J., concurring) ("The invention, to justify a patent, had to serve the ends of science-to push back the frontiers of chemistry, physics, and the like; to make a distinctive contribution to scientific knowledge. . . . The Constitution never sanctioned the patenting of gadgets.")

[90] *See* KSR Intern. Co. v. Teleflex Inc.,, 127 S.Ct. 1727, 1739 (2007) (emphasizing that cases like *Great A&P* remain good law).

possible with current technology, we must preserve a zone of patentability between subject matter that is currently enabled and subject matter that is currently non-obvious. It follows that the standards of enablement and non-obviousness ought not to be perfectly symmetrical, and that prior inventors cannot be entitled *a priori* to all things enabled by their disclosures in combination with the prior art.

### C. Rethinking Enablement

Even if we believe that non-obviousness and enablement ought to be symmetric – or even if we think the questions of formal structure posed by claims 4 and 5 are trivial – it is not clear that enablement and non-obviousness, at least in their current form, can properly constrain the scope of patent claims. As I have noted above, the scope of the inventor's possible rights is not synonymous with the scope of things enabled by the inventor; not only is the boundary between enabled claim and non-enabled claim indeterminate in practice, but there is no defined relationship between the intellectual framework of the enablement inquiry (could one of ordinary skill make and use a *thing*) and the legal framework (could one of ordinary skill make and use *the claimed invention*).[91] This uncertainty would seem to make enablement, at least as the doctrine is currently conceived, a fragile foundation on which to place the full burden of determining permissible claim scope.[92]

Enablement and non-obviousness may also have practical disadvantages as tools to constrain claim scope. As compared to written description, both enablement and non-obviousness are fact-intensive inquiries, requiring evidence of what one of ordinary skill

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[91] *See infra* Part III.C, on the distinction between thing and invention.

[92] *Amgen* may be instructive here as well. In *Amgen*, the patentee, who had been the first to synthesize human erythropoietin, asserted claims to essentially all synthetic erythropoietin molecules regardless of how they were synthesized. Had the patentee sought claims explicitly directed to "A method of producing synthetic EPO," the enablement requirement would likely have dictated that the claims be limited to the method of synthesis disclosed by the patentee. But because the claims were drafted with a source limitation – "non-naturally occurring" – rather than an explicit reference to the process of producing EPO, the claims were considered "composition" claims for which a patentee need disclose only a single method of making to claim the composition no matter how made. The point is not whether the patentee in *Amgen* deserved broad claims. The point is that the indeterminate relationship between claim scope and disclosure characteristic of the enablement doctrine makes the entire scope question highly sensitive to fine point of the law of enablement.

in the art could or could not accomplish[93] given the start of the art. These inquiries may require extensive expert testimony and may not be amenable to early judicial intervention. Written description, in contrast, is a question of what the patent specification discloses. No less than most other inquiries in patent law, this question is resolved from the perspective of one of ordinary skill in the art. Nevertheless, the underlying question in written description – what information is conveyed by the patent specification – may be more capable of judicial resolution than questions about the behavior or thought processes of technological artisans.[94] To the extent that we desire more judicial control over patent scope,[95] written description is a more appealing doctrine than enablement or non-obviousness.

### 1. Converging Enablement and Non-Obviousness

These considerations aside, can the doctrines of non-obviousness or enablement be modified to constrain a patentee's rights without resort to a doctrine like written description? If we think that claim 4 fairly represents the problem – that the standards of non-obviousness and enablement are not symmetric – then perhaps convergence of the two doctrines will solve our problems. The non-zero scope of claim 4 arises because the standards for enablement and non-obviousness are not symmetric. If the set of subject

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[93] Or perhaps would or would not accomplish, in the case of non-obviousness.

[94] This argument is not supported by the current standards of appellate review. Enablement and non-obviousness are treated as issues of law with underlying factual components, whereas written description is treated as an issue of fact. However, in practice, the nature of the inquiry – content of a text versus the mindset or capability of one of ordinary skill in the art – may well be more important than the nominal standard of appellate review. The current "factual" state of written description is somewhat ironic. It derives from the Court of Customs and Patent Appeals statement in *In re Ruschig*: "[W]e doubt that the rejection is truly based on section 112, at least on the parts relied on by appellants. If based on section 112, it is on the requirement thereof that "The specification shall contain a written description of the invention * * *." (Emphasis ours.) We have a specification which describes appellants' invention. The issue here is in no wise a question of its compliance with section 112, it is a question of fact : Is the compound of claim 13 described therein?" *See In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976) (quoting *Ruschig* for proposition that written description requirement is issue of fact). Moreover, the Court of Customs and Patent Appeals was not particularly deferential to the PTO on issues of fact. *See* In re Zurko, 142 F.3d 1447, 1454-55 (Fed. Cir. 1998) (*rev'd*, ____) (discussing C.C.P.A. review of Patent Office decisions).

[95] The advantages of judicial resolution of scope issues in the context of validity are similar to those posed by judicial resolution of claim interpretation issues: early decision of scope issues by summary judgment, and uniformity from centralized appellate review. Obviously, the current standards of review at least nominally impede these advantages.

matter enabled by the prior art is the same as the set of subject matter made obvious by the prior art, then the scope of a claim like claim 4 is non-existent.[96]

We might define obviousness in terms of enablement: *All things enabled by the prior art are obvious*. However, while this symmetry would eliminate the scope of claim 4, it would also eliminate the category of inventions discussed above: the inventions which are feasible with current technology but have not yet been invented. Unless we are willing to exclude all such inventions from patentability, non-obviousness cannot be defined solely in terms of enablement.

Perhaps we can instead define enablement in terms of obviousness: *All things obvious from the prior art and the inventor's disclosure are enabled*. On this formulation, the inventor is entitled to claim all things which are obvious from the combination of the prior art and his disclosure. Since things obvious from the prior art alone are unpatentable, the inventor's rights are defined in terms of what we might call "marginal obviousness": those things which were not obvious from the prior art alone, but are obvious once the inventor's disclosure is considered.[97] This solution has considerable formal appeal: though non-obviousness is not a certain inquiry, this formulation makes it possible to it is possible to describe claim scope in a qualitatively (but not quantitatively) precise way. The inventor is entitled to a halo of subject matter surrounding his or her disclosure, the extent of that halo being determined by what is obvious or not based on the disclosure and the prior art. Under this formulation, the inventor is entitled to a claim akin to the following:

> 6. *All material objects which are obvious in light of the combination of my disclosure and the prior art, excluding those which are known or obvious in light of the prior art.*

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[96] *See also* Holbrook, *supra* note ____, at 169-73 (arguing that standards of non-obviousness and enablement ought to converge on possession).

[97] This is in part the approach advocated by Professor Feldman, though she does not label it as such. Professor Feldman proposes that, for instances in which the inventor did not disclose an accused embodiment but such an embodiment is information knowable at the time of the invention, the scope of the patentee's rights should depend on whether the step from the disclosure to the accused subject matter is routine or "requires creativity, imagination or experimentation to derive." Robin Feldman, *The Inventor's Contribution*, 9 U.C.L.A. J. OF L. & TECH. 1, 35 (2005). She describes this inquiry as having "the indirect effect of measuring the inventive leap of the accused product." Id. at 39. Measuring the level of mental or inventive activity required to create something seems very firmly rooted in the non-obviousness inquiry, though here framed in terms of the inventor's disclosure rather than the prior art alone.

What claim 6 defines is, in essence, a central claiming system, in which the inventor describes a core and the scope of his rights extends in a diminishing penumbra around the core. A central-like system may, in fact, be the only solution to the problems of scope I have raised.[98] If we wish to adhere to our peripheral claiming system, however, we must declare claim 6 to be indefinite under 35 U.S.C. § 112, and encourage the inventor to draft peripheral claims that approximate claim 6 in scope. It is not certain that claim 6 can be dismissed as indefinite: if one of ordinary skill in the art can recognize what is obvious and what is not obvious, then it appears that one of ordinary skill in the art can ascertain the boundaries of claim 6. If one of skill in the art cannot recognize what it is obvious and what is not, then patent law seems headed for some difficulties, given that it is the one of ordinary skill in the art who decides whether subject matter is obvious or not under 35 U.S.C. § 103.[99]

Formal questions of claim structure aside, defining permissible claim scope along the lines of claim 6 carries significant policy implications. By its terms, claim 6 excludes from patent scope all technological developments occurring after the date of the invention, except those which are obvious in light of current technologies. Some commentators have advocated this result, proposing that the inventor's rights be fixed in terms of the state of the art at the time the invention was made.[100] However, while this limitation might be viewed as appropriate for technologies following discontinuous patterns of technological improvement,[101] it is more difficult to justify for technologies characterized by continuous and cumulative development. For ordinary technologies, few would agree that any non-obvious improvement upon a patented invention should escape infringement altogether. But whether or not one regards this as the optimal result

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[98] *See infra* Part III.C.

[99] This conundrum may highlight the difficulty in employing the perspective of one of ordinary skill in the art – logically employed to make technological judgments such as non-obviousness – to decide essentially legal matters concerning the definition of the patentee's exclusive rights. In this light, we may question whether the notion that claims ought to be interpreted from the perspective of one of ordinary skill in the art is truly tenable.

[100] *See* Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CAL. L. REV. 1, 40-41 (2005).

[101] Feldman proposes this rule in the context of "uncertain arts" such as biotechnology. Id. The cases may be viewed as instances in which new technologies allowed the accomplishment of old results by radically different means. The true effect of "uncertainty" may be that technology proceeds erratically, with unpredictable leaps that open or revisit large areas of subject matter, and give new meanings to old words within the lifetime of a patent.

on policy grounds, making enablement and non-obviousness symmetrical excludes future technologies from patent protection. To achieve a coherent scope doctrine within the confines of the peripheral claiming system, we must consider other modifications of the enablement doctrine or look beyond it altogether.

**2. "Enablement Plus"**

In fact, enablement has already been modified. Certain aspects of existing enablement law, while difficult to square with the nominal conception of enablement as a "make and use" requirement, can best be explained as responses to the problem of untethered claim scope epitomized by claim 4. I suspect the underlying objection to claim 4, and to a lesser extent 5 and 6, is not that the scope of protection conferred by those claims is not calibrated to the policy goals of patent law. The underlying objection is that the scope of the claim has little or nothing to do with *what the inventor actually invented*. Two aspects of enablement doctrine embody the requirement of a nexus to what the inventor actually made or disclosed – a consideration irrelevant to the question of whether one of ordinary skill in the art could make and use the invention without undue experimentation, but relevant to an underlying concern that the inventor be entitled to claim only that which he invented.

Consider the principle that if a feature described by the disclosure as critical for the invention is not recited in the claim, the claim is invalid for lack of enablement.[102] Whether or not a feature described by the patentee as critical appears as a limitation in the claim is not relevant to whether one of ordinary skill in the art could make or use the invention defined by the claim. But is relevant to the question of whether the claim is connected to what the inventor actually invented. This principle, though little applied in recent years,[103] shows that current enablement doctrine incorporates limitations on claim

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[102] *See* In re Mayhew, 527 F.2d 1229, 1233 (C.C.P.A. 1976)

[103] No subsequent majority opinion of the Court of Customs and Patent Appeals or the Federal Circuit has relied upon *Mayhew*. However, the *Mayhew* principle remains enshrined in the MPEP [§ 2164.08(c)], and the PTO and the Board of Patent Appeals and Interferences have relied upon *Mayhew* to reject claims failing to recite elements described by the inventor as essential. *See, e.g.*, Ex parte Zacharias, 2002 WL 32346094 (BPAI). Arguably, *Mayhew* has been misinterpreted; the specification's emphasis on the omitted feature may only have been evidence tending to show that the broader claim lacking the feature was not enabled.

scope beyond the requirement that the disclosure teach how to make and use the invention without undue experimentation.[104]

More recently, the Federal Circuit has held that the novel aspect of a claimed invention must be enabled by a specific disclosure in the specification, rather than by mere resort to the knowledge of one skilled in the art. In *Automotive Technologies v. BMW*,[105] the Federal Circuit upheld a verdict of lack of enablement because the patent's specification disclosed only mechanical side impact sensors, and not electronic side sensors. Dismissing the patentee's argument that the knowledge of one of skill in the art could supply the information required to construct electronic side sensors, the court held that "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute enablement."[106] Under the formal model of patent scope, in which the claim limitations define the category of subject matter to which the patentee is entitled, the "novel aspects" of the invention have no significance whatsoever for enablement. Either the specification enables one of ordinary skill in the art to make and use the subject matter defined by the claim limitations or it does not; which aspects of the invention are novel is relevant only to questions of novelty or non-obviousness. Clearly a requirement that disclosure specifically enable the novel aspects of the invention cannot be explained under a conception of claim scope in which the inventor is entitled to claim all that his specification enables one of ordinary

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[104] Judge Baldwin of the C.C.P.A., concurring in *Mayhew*, regarded the case not as a failure to meet the enablement requirement of § 112, ¶ 1, but as a failure to meet the requirement of ¶ 2 that the claims define what "the applicant regards as his invention" – that is, a connection between the claim and the inventor's subjective view of the invention. *Mayhew*, 1237-39 (Baldwin, J, concurring). For those critics of the written description doctrine who object that the doctrine lacks statutory foundation, the requirement that claims correspond to what the inventor regards as his invention would seem to provide more than adequate basis. However, the Court of Customs and Patent Appeals, with considerable internal debate, seems to have established that whether the claims define what the inventor regards as his invention is a *subjective* question, answerable only by extrinsic evidence of the inventor's intent, and not the specification. *See* In re Ehhreich, 590 F.2d 902, 906-07 (C.C.P.A 1979); *id.* at 910 (Baldwin, J, concurring); In re Cormany, 476 F.2d 998, 1002-03 (C.C.P.A. 1973) (Baldwin, J., concurring, and Lane, J., concurring); In re Prater, 415 F.2d 1393 (C.C.P.A. 1969). The Federal Circuit, do doubt reluctant to endorse a validity doctrine dependent on the inventor's subjective view of his invention, has attempted to confine doctrine by the somewhat implausible notion that the statutory requirement is applicable only during prosecution, and not in infringement litigation. *See* Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1377-79 (Fed. Cir. 2000).

[105] 501 F.3d 1272 (Fed. Cir. 2007)

[106] Id. at 1283 (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 103 F.3d 1361, 1366 (Fed. Cir. 1997)).

skill in the art to make and use. It can be explained only as a limitation of the inventor's rights to subject matter actually invented by the patentee.

The holding of *BMW* would modify the enablement standard to eliminate the scope of claim 4; the novel and non-obvious subject matter falling within the scope of the claim would be non-enabled because it does not appear in the (empty) disclosure. The Federal Circuit has thus apprehended that the "make and use" aspect of enablement does not satisfactorily constrain claim scope. Whether the additional limits placed on claim scope should be a matter of enablement is open to question. The *BMW* opinion emerged from the Federal Circuit without outward controversy, presumably because it framed the requirement for disclosure in terms of enablement rather than written description.[107] But a requirement that claimed subject matter be explicitly disclosed in the specification, though perhaps masquerading as "enablement plus", would seem to be nothing more than written description by another name.[108]

**3. Possession**

An alternative conception of enablement has been proposed by Professor Holbrook. Holbrook identifies possession of the invention as the central touchstone of patent law.[109] Arguing that patent disclosures rarely serve the teaching function traditionally associated with enablement,[110] Holbrook argues that enablement is rather the best evidence of possession; if the inventor has physically created the invention or provided an enabling description of how to do so, possession of the invention has been decisively proven.[111] Accordingly, there is no need to lodge a separate possession requirement in the doctrine of written description, where it has previously resided.

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[107] The panel of the Federal Circuit that decided *BMW* included Judge Lourie, the most vocal proponent of applying the written description requirement to originally-filed claims, and Judge Rader, its most ardent opponent. The district court had held certain of the claims invalid under written description as well. The Federal Circuit took great pains to avoid having to decide the written description issue, which no doubt would have fractured the panel's unanimity. Id. at nn. 1-2.

[108] In the context of a written description priority determination, the Federal Circuit in *Vas-Cath* denied that the 'novel or important' aspects of the invention held any special significance.

[109] *See generally* Holbrook, *supra* note ___.

[110] The implication of Holbrook's argument is that the question of whether the patentee has enabled those of ordinary skill in the art to make and use the invention has little relevance in determining patent scope.

[111] *See id*. at 147.

Can the notion of possession make enablement into a doctrine that is both coherent and an appropriate limitation on claim scope? It depends, of course, on what we mean when we say the inventor "possessed the invention." As I have discussed above, if enablement is to be the *sole* measure of possession, then under the current standard of enablement, the inventor is "in possession" of an infinite variety of things, some relating to his disclosure and many more not. Broad claims like claims 4 and 5 are permissible under such a notion, because the inventor is in possession of all that he or she enabled. If the broad claim is enabled, then the inventor is in possession of all the species and sub-genera that fall under the broader claim, notwithstanding that they may incorporate information unknown at the time of the invention. Conversely, if enablement itself is defined in terms of possession,[112] then – like the patentee is unable to assert patent rights against any later-developed technology, except perhaps through the doctrine of equivalents.[113]

Unless we are to take a very literal view of possession – that the inventor possesses only those physical entities he or she actually created, or exactly described in the specification – possession cannot by itself serve as a coherent limitation on claim scope. Take the textbook case of *Vas-Cath v. Mahurkar* – a case, because it deals with priority issues, is generally accepted as canonical by those who view the application of the doctrine to originally filed claims as heretical. The patentee in *Vas-Cath* had filed a design patent depicting, in drawings, a new design of a double-lumen catheter. The patentee later filed a utility patent claiming the catheter. The claims of the utility patent recited a catheter with narrowed end, the narrowed end having a diameter between 50% and 100% of the remainder of the catheter. Because of a question of intervening prior art,[114] the patentee had to establish that the utility application was entitled to claim priority from the design patent – meaning that the design patent had to satisfy the written description patent with respect to the invention defined by the claims of the later-filed

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[112] Professor Holbrook's proposal seems to partake both of the notion that enablement demonstrates possession, and that possession defines enablement. The common factual predicate is the inventor's physical creation of the invention or the creation of an enabling disclosure. *See id.*

[113] Id. at 158.

[114] Which was the patentee's own Canadian design patent.

utility patent. The Federal Circuit framed the question in terms of whether the inventor "possessed" the later-claimed invention:

> the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*. . . . [T]he proper test is whether the drawings conveyed with reasonable clarity to those of ordinary skill that [the patentee] had in fact invented the catheter recited in those claims, having (among several other limitations) a return lumen diameter substantially less than 1.0 but substantially greater than 0.5 times the diameter of the combined lumens.

But what, exactly, did the patentee possess or invent? The invention is what is claimed. The claims defined a *genus* of catheters, with an infinite variety of measurements and materials. The genus is constrained by the ratio of diameters defined by the claims, but like all patent claims, is an infinite genus. One could perhaps decide whether the patentee's drawings enabled one of ordinary skill in the art to make and use the genus of catheters, but is it a meaningful question to ask whether the patentee "possessed" the genus?

In my view, the question of "possession of the invention" is simply not a meaningful inquiry under our current claiming system. In the peripheral claiming system, "the invention" is a bundle of properties recited by the claims, defining the perimeter of the patentee's legal right to exclude. It is not syntactically sensible to ask whether an inventor "invented" or "possessed" an abstract bundle of properties defining a legally cognizable right. Inventors create ideas and things, not abstract legal entities or infinite sets of subject matter.[115] One can of course make the ultimate *legal* determination that the inventor 'invented' or 'possessed' the abstract rights defined by the claim, but one cannot ask the question as a factual predicate to that ultimate legal determination.

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[115] Judge Rich – who was the author of *Vas-Cath* – himself recognized the disconnection between what the inventor actually did and the legal conception of the invention as defined by the claims: "Claims are frequently a far cry from what the inventor invented. In a suit, claims are construed to find out what the patentee can exclude the defendant from doing. CLAIMS ARE CONSTRUED TO DETERMINE THE SCOPE OF THE RIGHT TO EXCLUDE, regardless of what the inventor invented." Janice Mueller, *A Rich Legacy*, 14 BERK. TECH. L. J. 895, 899-900 (1999) (quoting e-mail from Judge Giles Rich) (caps in original). *See also* Holbrook, *supra* note ___, at 146 ("The invention is not necessarily a particular embodiment necessarily but more the idea of the invention.").

It was not always so. Prior to the full development of the peripheral claiming system, claims were not entities that defined a category of subject matter by listing its properties. Rather, claims were directly drawn to the inventive principle itself, and established not the inventor's right to exclude but his right to the grant of a patent. Even after claiming assumed primary importance, "the invention," and "the claims" were distinct concepts in American patent law.[116] One could sensibly discuss "the invention" in terms of the inventor's physical or mental creation, entirely apart from the question of the scope of the inventor's legal rights. Under such a regime, questions of whether the inventor physically possessed an embodiment of the invention, or whether the inventor mentally possessed the idea behind the invention, are sensible questions. But once the concepts of "invention" and "claim" became essentially synonymous in patent law, the notion of "possessing the invention" became a logical impossibility.

## III. WRITTEN DESCRIPTION REVISITED

### A. A Doctrine of Definition

It is not clear if the formal or normative problems of patent scope can in the end be addressed under our peripheral claiming system.[117] Yet what is clear is that the enablement doctrine alone, whether conceived of as "make-and-use" or as possession, does not provide sufficient limits on patent scope in the peripheral claiming system. If there is an answer, it lies in the written description doctrine.

The idea that the disclosure limits originally filed claims, independently of the enablement requirement, was not invented by the Federal Circuit in *Lilly* in 1997, nor by

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[116] *See infra* Part III.C.

[117] Commentators who advocate modification of the enablement requirement, and the elimination of written description as a limit on originally filed claims, arrive ultimately at a rejection of the formal peripheral claiming concept, though they do not describe it as such. The foundation of the formal system is that claim scope, validity, and infringement are all independent entities; though claims are construed to preserve their validity, the scope of the claim is in theory fixed and the question of whether accused subject matter falls within the patent's claims is resolved without reference to the question of whether the patentee's disclosure enables that particular embodiment. Professor Holbrook, however, concludes that (as a matter of claim construction) "[i]n order to literally infringe the patent, the patent would have to enable *the accused device*, thus showing that the patentee had placed the PHOSITA in possession of it." Holbrook, *supra* note ___, at 158 (emphasis added). Likewise, Professor Feldman would frame the inquiry as "the leap that it will take to get from what the inventor actually disclosed to the product that the inventor is trying to reach." Feldman, *supra* note ___, at 40. She recognizes that this approach departs from the traditional notion that patent scope is determined without reference to the allegedly infringing material. Id.

the Court of Customs and Patent Appeals in 1967 in *Ruschig*. In his monumental and influential 1890 treatise on patent law, William Robinson unmistakably distinguished between the written description, enablement, and best mode requirements that we recognize in § 112 today:

> According to the statutes, the Description must contain full explanations of *three* different subjects: *the invention itself*; the manner of making it; and the mode of putting it into practical use. . . .[118]

And though the notion of defining the invention by the disclosure originated when American patent law did not require claims, neither is the written description requirement an obsolete relic of the time before claiming. At the time Robinson was writing, claims were required by the Act of 1870, and had been common practice long before. The notion that claims were distinct from the disclosure, and defined the boundaries of the patentee's legal rights, was well-developed and abundantly attested by Robinson and other treatise-writers.[119] Robinson quite clearly recognized that the claim defined the inventor's legal right, but also quite clearly asserted that claims could not embrace subject matter not described by the specification, even if such subject matter was within the knowledge of one skilled in the art:

> Features of the invention not delineated in the Description cannot be inserted in the Claim, even though a mechanic in endeavoring to construct or employ the invention would inevitably discover them.[120]

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[118] 2 William C. Robinson, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 484 (1890) (emphases added). The mode of putting in the invention into practical use was the inventor's best mode. *See id*. § 486 ("The mode explained must be the best within the knowledge of the applicant. . ."). As compared to § 112 of the current patent statute, the Act of 1870 differed primarily by requiring that "in case of a machine, [the inventor] shall explain the principle thereof, and the best mode in which he has contemplated applying that principle so as to distinguish it from other inventions. . . ." Patent Act of 1870 § 26 (R.S. § 4888).

[119] A caveat to this argument is that omnibus claims, claiming the invention "substantially as described" in the disclosure, were still permissible, though the practice of claiming by essential properties was established by this time. *Id*. § 511.

[120] *Id*. §515 . Robinson may not have been on the firmest ground for this statement. He cites as authority *Needham v. Washburn*, 17 F. Cas. 1276 (C.C.D. Mass. 1874), and *Kelleher v. Darling*, 14 F. Cas. 1223 (C.C.D. Me. 1878). *Kelleher* concerned new matter in a reissue, though the court did reason by analogy that a claim reciting that feature in the original patent would have been invalid for failure to comply with the written description statute, notwithstanding the ability of one skilled in the art to discover the feature. *Kelleher*, 14 F. Cas. at 228. *Needham* did concern an original claim, and the court stated: "Much reason exists for holding, that the second feature of the claim is invalid, because not embraced in the description of the method or process used by the complainant, as required by the act of congress. . . .". *Needham*, 17 F. Cas at 1279. But the court declined to rest its holding entirely on that ground, because the claimed feature was the omission of a welding flux employed by the prior art process. *Id*. Both cases were

So the doctrine of written description is not new. Nor, as many commentators have maintained, is it a special biotechnology rule requiring nucleotide-by-nucleotide disclosure of DNA molecules. Neither is it a rigid rule limiting patentees to disclosed embodiments alone. It is instead nothing more than a general requirement that the applicant for a patent *define the invention* according to traditional principles of logic. Consider the language of *Lilly*:

> A description of a genus of cDNAs may be achieved by means of a *recitation of a representative number* of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a *recitation of structural features common to the members of the genus*, which features constitute a substantial portion of the genus.[121]

The Federal Circuit demanded that the claimed genus – in this instance, a genus of DNA molecules – be described either by disclosure of a representative number of species in the genus, or by disclosure of properties that are common to members of the genus. These two modes correspond precisely to the two modes of *definition* articulated in formal logic. Recitation of the features or properties of a genus corresponds to definition by intension, or definition *per genus et differentiam*. In this classical mode of definition, a thing is defined by specifying the proximate genus to which it belongs, and those properties which differentiate it from other members of the genus.[122] *Lilly*'s other mode – enumeration of a representative number of members of the genus – corresponds to definition by extension, or definition by type. Definition by type proceeds by designating some individual or group of individuals as central or typical members of the genus, and determining membership in the genus by degree of resemblance.[123]

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decided by Justice Clifford riding the First Circuit. But the point is not whether Robinson's assertion was decisively settled law at the time; the point is that a notion of a description requirement beyond enablement and applicable to original claims was current.

[121] Lilly (emphasis added). A "cDNA", or complementary DNA molecule, is a synthetic DNA molecule produced by reverse transcription of a messenger RNA encoding a protein such as human insulin.

[122] *See, e.g.,* 1 Peter Coffey, THE SCIENCE OF LOGIC, 94 (1912) ("In order, therefore, to define any object of thought, we must find out and indicated its *proximate genus* – the next highest class into which it *naturally* falls – and the attribute or group of attributes which distinguishes it from other *cognate species* of the same *genus*.") (footnote omitted).

[123] *See id.* at 98. In linguistics the notion of a family gathered around a type is often attributed to Wittgenstein, but the idea was in circulation well before. See John Neville Keynes, STUDIES AND EXERCISES IN FORMAL LOGIC 34 (1884). Note that in some respects the intensional and extensional modes of definition also correspond to the peripheral and central modes of patent claiming. The topic of definition in patent law and its implication for the structure and interpretation of claims deserves far fuller treatment than can be accorded here.

The Federal Circuit clearly understood itself to be promulgating a doctrine of definition in *Eli Lilly*. Holding that the inventors had not sufficiently described the genus of DNA molecules encoding mammalian insulins by the phrase "mammalian insulin cDNA," the standard the court employed was one of definition:

> It does not specifically *define* any of the genes that fall within its definition. It does not *define* any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.[124]

By expressing the written description doctrine as a doctrine of definition, the Federal Circuit provided, at least in theory, both a coherent rationale and a coherent test for application of the written description doctrine. Had *Eli Lilly*'s lead been followed, the true role of the written description doctrine, and how it differs from that of enablement, might have become clear.

**B. Losing the Path**

Unfortunately, since *Eli Lilly*, the written description doctrine has gravitated back to the quixotic notion of 'possession."[125] This trend is evident in the evolution of the PTO's guidelines on assessing patent applications for compliance with the written description requirement. The initial *Guidelines*, issued in response to *Eli Lilly,* explained the doctrine of written description in terms of possession. However, the *Guidelines* also framed written description as a doctrine of definition as articulated in *Eli Lilly*. For generic claims, the *Guidelines* suggested that the specification must allow "one skilled in the art [to] readily envision a sufficient number of members of the claimed genus to provide written description support for the genus."[126] In other words, the written

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[124] *Eli Lilly*, 119 F.3d at 1568 (emphases added). The theme of *mental* process – visualization or recognition - in the doctrine of written description seems to have derived from *Amgen v. Chugai Pharmaceutical Co*. 927 F.2d 1200 (Fed. Cir. 1991). *Amgen* was an infringement action in which the question of priority of invention for a DNA molecule encoding erythropoeitin was in dispute. As set forth by 35 U.S.C. § 102(g), an inventor may initially establish priority by demonstrating earlier conception of the invention. Conception in patent law is an entirely mental act, though it must be demonstrated by some objective disclosure. The court in *Amgen* held that an inventor who had failed "to envision the detailed chemical structure of the gene so as to distinguish it from other materials" could not establish conception until he had actually isolated the claimed DNA molecule. *See also* Fiers v. Revel, 984 F.3d 1164, 1168-69 (Fed. Cir. 1993) (discussing *Amgen*).

[125] The notion of possession may well have utility in other contexts; the point is that possession is not sensible in the context of written description.

[126] *Interim Guidelines*, 63 Fed. Reg. 32639, 32641 (Jun. 15, 1998) (citing *Lilly*).

description inquiry was to proceed by asking whether the inventor had conveyed enough information for one of ordinary skill in the art to define the genus by its intension. Likewise, satisfying the requirement by disclosure of common characteristics was judged by whether one of skill in the art could "reasonably predict sufficient identifying characteristics of the other members of the genus and, thus establish possession of the genus."[127]

However, in subsequent revisions of the *Guidelines*, the PTO eliminated the definitional aspect of the written description doctrine and focused entirely on the notion of possession. The result was an essentially tautological expression of the doctrine:

> To satisfy the written description doctrine, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations.[128]

In other words, one describes the invention by showing possession, and one shows possession by describing the invention. With respect to genus claims, the revised *Guidelines* discarded the notion that the specification must convey enough information to permit one of skill in the art to envision or predict characteristics of members of the genus. Rather, the question was whether "the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed."[129] It may be difficult enough to understand how one may 'possess' a genus of inventions, which are at least discrete objects or processes. It seems even more difficult to understand how one may 'possess' attributes or features of the genus: I may possess a thing such as a red ball, and perhaps somehow a genus of red balls, but by what means do we assess whether I possess 'red'?[130]

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[127] Id. at 32642.

[128] *Revised Interim Guidelines*, 64 Fed. Reg. 71427, 71434 (Dec. 21, 1999). The final revision of the *Guidelines* added that 'describing the claimed invention with all of its limitations' could be achieved by "using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the claimed invention." *Guidelines*, 66 Fed. Reg. 1099, 1104 (Jan. 5, 2001).

[129] *Revised Interim Guidelines*, 64 Fed. Reg. at 71436; *Guidelines*, 66 Fed. Reg. at 1106.

[130] By framing the inquiry as whether the inventor showed possession of *properties* of the genus, the Patent Office seems to have committed itself to a form of metaphysical realism, the position descending from Plato that universals have an independent and objective existence outside of the particulars that instantiate them.

Further muddying the nature of the doctrine, the revised *Guidelines* added that possession could be shown if the specification described an actual reduction to practice, or sufficiently disclosed to indicate that the invention was 'ready for patenting.' These standards were imported from the Supreme Court's opinion *Pfaff v. Wells*, a case deciding at what point of development inventions could be considered "on sale" for purposes of novelty. The relevance of the *Pfaff* standard to the written description doctrine is hard to fathom. In order to encourage prompt filing of patent applications, the *Pfaff* standard was set to trigger the on-sale bar no earlier than the point when the inventor could patent the invention; if the invention was not yet ready for patenting then the law ought not to penalize the inventor who fails to file that early. But the *Pfaff* standard was designed to identify the point in time at which the inventor *could* describe the invention to satisfy the standard of § 112, not to determine whether the inventor *did* describe the invention within the meaning of § 112. More importantly, the *Pfaff* inquiry, a tool for assessing whether the statutory bar to patenting has been triggered, is utterly unhelpful for a doctrine of claim scope. As explained above, the statutory bar (like other provisions of § 102) is triggered by *any* overlap between the set defined by the claim and the set of prior art. If any one embodiment of the claimed invention was sold and was ready for patenting under the *Pfaff* standard, then the claim is invalid under § 102(b). But the disclosure requirements of § 112 are not satisfied merely by some intersection between what was described and what is claimed. Satisfaction of the *Pfaff* standard may show that the inventor described *something* within the scope of the claims, but that sheds little light on whether the inventor described the set of all things encompassed by the claim.

The Federal Circuit has endorsed the PTO's *Guidelines*,[131] while simultaneously emphasizing that a patent specification may demonstrate 'possession' but still fail to

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[131] *See* Enzo Biochem, Inc. v. Gen_probe Inc., 323 F.3d 956, 964 ("We are persuaded by the Guidelines on this point and adopt the PTO's applicable standard for determining compliance with the written description requirement."). Formally, the court's endorsement of the *Guidelines* might be read to extend only to the point addressed in that section of the *Enzo* opinion – the use of correlated structural and functional properties to describe claimed subject matter. Id. However, the *Enzo* court's remand instructions explicitly directed the district court to judge the broader questions whether the genus was adequately described according to the *Guidelines*. Id. at 967-68.

provide a written description of the invention.[132] Yet in the same breath the court phrased the written description inquiry as whether the applicant has "demonstrate[d] possession of the generic scope of the claims."[133] And in subsequent opinions, the court has continued to assess the adequacy of support for a generic claim by asking whether the written description demonstrates that "the patentee possessed the full scope of the invention."[134]

**C. Anchoring the Definitional Hierarchy**

The possession inquiry, at least as currently constituted, cannot support or explain how written description functions as a limitation on claim scope. But once we recognize written description as a method of logical definition, then its function in determining claim scope becomes perfectly clear. The system of definition in classical logic postulated hierarchical trees or chains of categories, each category being differentiated from the category above it by some necessary and essential characteristic property.[135] In the classical example, a human is defined and distinguished from all other things by successively narrower genera, until we reach the level of the individual person:

Objects
Material Objects
Living Objects
Animals
Humans
(Socrates)

We could construct a similar chain focusing on the rat insulin DNA molecule at issue in *Lilly*:

DNA

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[132] Id. at 969 (explaining that possession is ancillary to the statutory requirement of written description).

[133] Id. at 966.

[134] *See* LizardTech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005). *See also* University of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1307 (Fed. Cir. 2004) (Lourie, J., concurring in the denial of rehearing en banc) ("[T]he issue may still remain in a given case, especially with regard to generic claims, whether an original claim conveys that one has possession of and thus has invented species sufficient to constitute the genus.").

[135] This scheme is generally known as the Tree of Porphyry, as it was set out explicitly in Porphyry's *Isagogue*, a commentary on Aristotle's *Categories*.

Vertebrate DNA

Vertebrate insulin DNA

Mammalian insulin DNA

Rat insulin DNA

(Particular variant of rat insulin DNA)

The written description requirement anchors claim scope to a particular level within the chain of definition. The inventor who has discovered and disclosed only rat insulin DNA is not entitled to claim higher categories, such as "vertebrate insulin DNA," because the inventor has defined the genus neither by properties that distinguish it from other genera, nor by a set of types by which the genus can be recognized by degree of resemblance. Nor is the inventor entitled to claim a particular variant of rat insulin DNA, unless the differentia – in this case, the structural distinction between the variant and the type – of that species can be derived from the inventor's disclosure.

By anchoring claim scope within the hierarchy of definitional genera, written description deals directly with the question of claim scope and has the potential to resolve formal questions of claim scope in a way that enablement cannot. If written description was necessary solely to rationalize the formal structure of claiming, that would be little reason to maintain the doctrine. But of course the question of properly locating a patent's scope within the definitional hierarchy is critical to the policies of the patent system. In its traditional role in chemical practice, the written description doctrine prevented the inventor of a broader genus from reaching down the definitional chain to claim enabled but undisclosed members of that genus. Such function is necessary if we are to preserve the incentive for later inventors to develop improved or otherwise favorable members of the known genus.[136] If we instead held that description of the genus necessarily described every member of the genus, patents on favorable members of the genus would either be unobtainable or the property of the inventor of the genus.[137] To use the example based on

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[136] Such members of the genus must still be non-obvious over the genus in order to be patentable.

[137] If the generic disclosure sufficed to disclose the members of the genus, then the patentee would be entitled to claim them as they were described in his original specification. If not claimed by the patentee, they would be thereafter be unpatentable, having been made "prior art" by the provisions of § 102. This balance further illustrates the necessity of the written description doctrine. Given that all things enabled by a disclosure do not become prior art, it would be curious to conclude that a species enabled but

*Lilly*, suppose that particular synthetic variations of the rat insulin gene have properties making them more valuable than ordinary rat insulin. By forbidding the patentee who has disclosed the structure of rat insulin DNA from claiming those improved variants, we allow inventors who subsequently discover improved variants to patent them.[138]

Likewise, written description limits the inventor from reaching too far upwards on the definitional chain. This, according to some commentators, is the novel and heretical aspect of *Lilly*; but once the role of written description is seen as properly locating claim scope in the definitional hierarchy, then restrictions on upward reach seem as reasonable as restrictions on downward reach. Here too the goal must be to preserve incentives for later inventors but the doctrine has more bite: no one[139] is entitled to a patent on the broader genus such as "mammalian insulin DNA", though patents on cognate genera (such as "human insulin DNA") are still available. And if the original inventor has indeed enabled the broader genus,[140] there would seem to be little difficulty in the inventor accumulating the information necessary to define the genus under the written description doctrine. The argument that the inventor who has enabled the broader claim ought to be entitled to it regardless of his ability to describe it seems to carry the seeds of its own destruction: if accumulating the information needed to describe the genus is difficult and time-consuming, though 'enabled,' then perhaps enablement is doing a poor job of implementing the quid pro quo of the patent system.[141]

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not described by the specification is always disclosed for purposes of § 112 – the patentee's right to claim it – but not for purposes of § 102 – a subsequent inventor's right to claim it.

[138] Such variants would still infringe the generic inventor's patent, of course. Nonetheless, patents on a favorable embodiment are valuable, though less valuable than they would be in the absence of the generic patent.

[139] The disclosure of a species anticipates the broader genus. This doctrine is necessary to prevent the generic inventor from removing species from the public domain.

[140] Assuming we have a coherent way to answer this question.

[141] This argument in some ways resembles the one made by Kitch's prospect theory: that even once the point of patentability has been reached (here, enablement of the genus) significant investments may be necessary to identify commercially useful embodiments of the genus. Edmund W. Kitch, *The Nature and Function of the Patent System,* 20 J.L. & ECON. 265 (1977). Kitch's solution was to grant the original inventor a broad patent, enabling him to coordinate the process of commercial development. Critics who doubt the ability of patentees to coordinate development would deny the broad patent to maximize incentives for others to develop commercial embodiments. If those critics are correct, then the inventor who 'enables a genus' should not necessarily obtain a patent covering the entire genus.

Phrasing the scope problem in terms of the definitional hierarchy makes the *Lilly* upward-limiting aspect of the written description doctrine a natural extension of the traditional downward-limiting aspect of the doctrine. Likewise, once we understand that all claims are genus claims, we can understand that (1) the doctrine of written description is applicable to all categories of inventions, not just biotechnological inventions, and (2) satisfaction of the requirement is usually a matter of course for categories like simple mechanical inventions. The genus of "chairs with four legs" is much larger, and more variable, then a genus like "mammalian insulin DNA."[142] Yet, one of ordinary skill in the art, if presented with a disclosure embodying the novel inventive idea of placing four legs on a seating surface, would readily be able to grasp the concept of the genus of all chairs with four legs, and envision any given member of the genus.[143] Viewed in this light, the application of the written description doctrine to 'ordinary' inventions should be uncontroversial.

Take the case of *Gentry Gallery*, viewed by many commentators as a prime example of the written description requirement run amok. The disclosure of the patent in *Gentry* described a sofa with two reclining seats, controls for the recliners being located on a console between the seats. The Federal Circuit held that a claim which did not fix the location of the controls on the console was invalid for failure to satisfy the written description requirement, because the patent disclosed only controls mounted on the console.

Had the court treated the problem as one of broader and narrower genera, the claims might have been held valid. The question would have been whether the disclosure of a narrower genus – sofas with controls mounted on a console – would have permitted one of ordinary skill in the art to envision the broader genus of sofas with controls

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[142] We may postulate an infinite variety of dimensions, materials, decorative qualities, etc. for chairs. In contrast, there are 4,000 to 5,000 mammalian species; if the insulin gene is different in each species then there are at most 4,000 to 5,000 mammalian insulin genes. Of course one can postulate an infinite number of DNA molecules that encode a mammalian insulin polypeptide, by adding non-coding sequences or varying the sequence of the insulin polypeptide, but such changes in DNA sequence are qualitatively much simpler than the transformations that can be imagined of chairs.

[143] This is not the same as being able to make and use any member of the genus. One of skill in the art can envision a chair made of neutronium, and perhaps predict its properties, but cannot make and use one. Even if the fashioning of furniture from neutronium is known in the art, actually making a chair from neutronium may require unforeseeable advancements that by definition could not have been envisioned by one of ordinary skill in the art.

mounted elsewhere on the sofa. If locating the controls on the console was not necessary for the function of the sofa, then one of ordinary skill in the art would likely have been able to envision a genus of sofas with controls located elsewhere than the console. If the sofa arts are a predictable arts, then based on the properties of the sofa with console-mounted controls, one skilled in the sofa arts would likely have been able to predict the properties of sofas belonging to the broader genus. *Gentry Gallery* therefore represents not an aberrant application of a biotechnology doctrine to a mechanical patent, but a failure to recognize that the principles of genus and species explicit in chemical and biotechnological practice are inherent in every category of invention.

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The problems posed by the necessity to define a genus did not arise prior to the development of the peripheral claiming system in its modern form. It is well-appreciated that the United States formerly followed a central system, in which the patentee described an embodiment of the invention and infringement was assessed by comparison between what the inventor had made or described and the accused subject matter. What is perhaps less appreciated is that in their original form, claims did not define subject matter at all. Early claims defined only the novel *inventive principle* the inventor had created, not a category of objects or processes. Indeed, in early practice, a claim defining the structure of an operative machine with a novel inventive feature– as modern claims do – was invalid, for the inventor had included old features over which he had no rights along with the new and inventive feature to which he was entitled.

Under this regime – which German patent law retained until the late 20th century[144] – questions of claim scope, non-obviousness, and infringement were resolved as an integrated inquiry. The inventive principle contributed by the inventor was assessed in light of prior art, and claim scope and infringement determined according to whether they embodied the inventive principle disclosed by the inventor. Under such a system, it is not necessary to define *ex ante* a category of objects over which the inventor may exercise exclusive rights. The disadvantage of such a regime, of course, is that a patent

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[144] Germany retained a central claiming system until 1973, when it joined the European Patent Convention. *See* Heinz Winkler, *The Scope of Patent Protection: Past, Present, and Future*,10 INT'L REV. OF INDUS. PROP. & COPYRIGHT LAW 296 (1979).

has no definite bounds, and the public cannot be certain what is infringing and what is not.[145] Hence the development of the modern American system of claiming, in which claims recite properties precisely defining a set of objects or processes over which the patentee asserts exclusive rights. As the notions of invention, claim and legal right converged, the concepts of scope, infringement, and non-obviousness crystallized into distinct doctrines. But in fixating upon a system where legal rights were precisely delineated by a system of claims that defined not what the inventor had created, but to what he was entitled, patent law lost at least two advantages of the central claiming system. It lost the ability to integrate information about patent validity and the technological advance represented by the invention into the infringement inquiry, and it lost the ability to define the inventor's *permissible* entitlement in a theoretically rigorous manner. But the need to tether claim scope to the invention itself remains. So long as that need remains, the written description requirement will remain a necessary aspect of patent law.

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[145] It must be noted that this uncertainty did not seem to impede technological development in Germany, which retained its central claiming system until it joined the European Patent Convention. However, the German economy, at least prior to World War II, was characterized by industrial concentration and infrequent litigation, rather than vigorous competition and commonplace litigation. *See* Heinrich Kronstein, *The Dynamics of German Cartels and Patents*, 9 U. CHI. L. REV. 643 (1942). These characteristics may have blunted any chilling effect of uncertain patent scope.