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INTRODUCTION

The patent grant is a social contract.[1] Society defers for a limited time the right to make, use, or sell[2] an invention that is useful, novel, and nonobvious.[3] In exchange, the applicant provides a disclosure that teaches one of ordinary skill in the art how best to make and use that invention.[4] As a result, society trades a period of exclusivity for a defined contribution to its body of useful knowledge.[5] As more commonly

1. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 489 (1974) (stating that a patent is a public bargain of exclusive use in return for disclosure"); *see also* Mark A. Lemley, *Intellectual Property and Shrinkwrap Licenses*, 68 S. CAL. L. REV. 1239, 1276 n.166 (1995) ("Patent law has been described as a social contract in which the interests of all parties must be balanced."); Pamela Samuelson, *Creating a New Kind of Intellectual Property: Applying the Lessons of the Chip Law to Computer Programs*, 70 MINN. L. REV. 471, 511 n.195 (1985) ("It is common to see copyright and patent law described as a kind of social contract or bargain."); Jeff Kuehnle, Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*: Opening the Floodgates on Nonliteral Patent Infringement Through the Doctrine of Equivalents*, 48 BAYLOR L. REV. 589, 604 (1996) ("Patent law was created as a contract between society and an inventor . . . .").

2. *See* 35 U.S.C.A. § 271(a) (West Supp. 1996) ("[W]hoever without authority makes, uses, offers to sell, or sells any patented invention . . . during the term of the patent therefor, infringes the patent.").

3. *See* 35 U.S.C. § 154 (1994); Seymour v. Osborne, 78 U.S. 516, 533 (1870) (discussing the exclusive right granted to the inventor); Christopher S. Marchese, *Promoting the Progress of the Useful Arts by Narrowing Best Mode Disclosure Requirements in Patent Law*, 54 U. PITT. L. REV. 589, 594-95 (1993) ("Inventors who apply for patent protection and whose works qualify under the current act will obtain the exclusive right and liberty to make, use and sell their inventions . . . ."). For a discussion of the three conditions of patentability see *infra* notes 18-25 and accompanying text.

4. *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150 (1989) ("The applicant . . . who is willing to reveal to the public the substance of his discovery and 'the best mode . . . of carrying out his invention,' is granted 'the right to exclude others from making, using, or selling the invention throughout the United States.'") (citations omitted); Thomas L. Irving et al., *The Significant Federal Circuit Cases Interpreting Section 112*, 41 AM. U. L. REV. 621, 623 (1992) ("Disclosure by the inventor . . . is the consideration in the social contract between the inventor and the government.").

5. *See* United States v. Dubilier Condenser Corp., 289 U.S. 178, 186, *modified*, 289 U.S. 706 (1933) (explaining that granting a patent to an inventor "gives something of value to the community by adding to the sum of human knowledge") (citation omitted); Markman v. Westview Instruments, Inc., 116 S. Ct. 1384, 1387 (1996) (stating that the government grants inventors "'the right to exclude others from making, using, offering for sale, selling, or importing the patented inven-

stated, disclosure is the *quid pro quo* for the patent grant..[6]

Inventors rightfully seek a scope of protection consistent with their inventive contribution to the art.[7] That is, the scope of protection afforded depends upon the invention. For example, a pioneering invention is entitled to a broad scope of protection, while an incremental improvement warrants a more narrow scope.[8] Inventors working in the unpredictable arts experience peculiar problems specifying the breadth of the inventive contribution, and thus defining the proper scope of protection.[9]

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tion,' in exchange for full disclosure of an invention") (quoting 1 H. SCHWARTZ, PATENT LAW & PRACTICE 33 (2d ed. 1995)); *see also* Keuhnle, *supra* note 1, at 604 (stating that the purpose of a patent is "to ensure that the inventor receives a limited monopoly on the invention in consideration for disclosing it to the public").

As the Supreme Court explained in *Kewanee Oil Co.*:

> When a patent is granted and the information in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.

Kewanee Oil Co., 416 U.S. at 481. The GATT Implementing Legislation has changed the term of a patent such that a patent granted on an application filed on or after June 8, 1995 commences on the date of grant and expires 20 years from the application filing date, or the date from which priority is claimed. *See* Uruguay Round Agreements Act, Pub. L. No. 103-465, §§ 531-533, 108 Stat. 4809, 4882-90 (1994).

6. *See* 2 DONALD S. CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT § 7.01 (1996) ("The requirement of adequate disclosure assures that the public receives 'quid pro quo' for the limited monopoly granted to the inventor."); Brenner v. Manson, 383 U.S. 519, 534 (1966) ("The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.").

7. *See* AMERICAN BAR ASSOCIATION SECTION OF PATENT, TRADEMARK AND COPYRIGHT LAW, WHAT IS A PATENT? 1 (1981).

8. *Cf.* Stephen G. Whiteside, *Patents Claiming Genetically Engineered Inventions: A Few Thoughts on Obtaining Broad Property Rights*, 30 NEW ENG. L. REV. 1019, 1034 (1996) ("[I]nventions that represent dramatic technological advancements are given a greater range of equivalents than those that represent modification of existing inventions.").

9. *See* Mark D. Schuman, *Patent Protection for Microbiological Processes: Has* In re Argoudelis *Been Mutated?*, 1984 WIS. L. REV. 1679, 1701 (1984) (concluding that as unpredictability in an art increases, the scope of protection afforded in-

The unpredictable arts are those technological disciplines for which there is insufficient learning to explain, a priori, the effect that changed variables will have within a system.[10] Unpredictable arts might be newly emerging areas of scientific inquiry and discovery, or disciplines long recognized as defying generalization within the confines of established scientific principles.[11]

Some disciplines might not suffer from the "unpredictable" label indefinitely. An emerging technology might be deemed unpredictable only temporarily—as the emerging technology is applied, it matures and its unpredictability fades.[12] As a result, the task of describing the incremental innovations of a maturing technology increasingly becomes definite and routine.

Other disciplines are perceived to be more persistently

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ventions in that art should decrease); *see also* Garth Butterfield et al., *Biotechnology Protection and Licensing*, *in* TECHNOLOGY LICENSING & LITIGATION, at 235, 250 (PLI Litig. & Admin. Practice Course Handbook Series No. 386, 1996).

10. One commentator has made an analogous argument concerning chemical inventions:

> Special concerns arise with chemical patents because the properties of chemical compounds can be less predictable than those of mechanical inventions. When an inventor brings together old mechanical components, normally no new and unexpected result follows. In contrast, a slight change in the structure or composition of a chemical compound can have dramatic effects on its properties.

Julie A. Hokans, In re Bard*: A New Approach to Obviousness of Chemical Compounds*, 29 U.C. DAVIS L. REV. 197, 205 (1995) (citations omitted).

11. *Compare Ex parte* Old, 229 U.S.P.Q. (BNA) 196, 200 (Pat. Bd. App. & Int. 1985 1985) (classifying as unpredictable the then emerging use of hybridoma technology to create monoclonal antibodies) *with In re* Gardner, 427 F.2d 786 (C.C.P.A. 1970) (discussing pharmacology as a discipline persistently deemed unpredictable).

12. *See* Butterfield et al., *supra* note 8, at 243, 247; Allan G. Altera, *Expanding the Reissue Procedure: A Better Way To Do Business*, 1 J. INTELL. PROP. L. 185, 209 (1993). One example of an emerging technology once branded as unpredictable, but now routinely applied is the use of biotechnology, particularly hybridoma technology, to create monoclonal antibodies. *See* Edward T. Lentz, *Adequacy of Disclosures of Biotechnology Inventions*, 16 AIPLA Q.J. 314, 322 (1989) (acknowledging that the preparation of monoclonal antibodies is achievable by standard techniques, and discussing *In re* Wands, 858 F.2d 731 (Fed. Cir. 1988)).

unpredictable.[13] Contributing to the perception of unpredictability is often a real or imagined interplay of a host of unknowns and variables. As a result, it might be difficult to accurately describe the breadth of a particular contribution to the relevant art.

Within the law of patents, the unpredictable arts bring to the fore the issue of the sufficiency of a patent applicant's disclosure.[14] The issue arises when an applicant describes and claims an invention broadly amidst a paucity of supporting data or examples.[15] When the applicant has relied upon unsupported inferences or reasoning by extrapolation to generalize the invention, the United States Patent and Trademark Office ("PTO") will likely reject the applicant's claim for insufficiency of disclosure.[16]

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13. One discipline persistently perceived as "unpredictable" is pharmacology and the study of the effects of biologically active agents on the body. *See, e.g.*, *In re* Gardner, 427 F.2d 786 (C.C.P.A. 1970) (involving a patent claim of a discovery that certain already existing pharmaceutical compounds have an antidepressant effect when administered internally). Minor molecular modifications in an active agent might cause profoundly different effects when administered to a living organism. *See, e.g.*, *id.*; *cf.* John C. Todaro, *Enablement in Biotechnology Cases After* In re Goodman, 5 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1, 37 (1994) (stating that the highly competitive nature of the biotechnology industry often prompts patent applicants in that field to seek claims that are undeniably broad).

14. The literature contains no systematic analysis of insufficiency of disclosure rejections as they are applied in the unpredictable arts. Although one commentator thoroughly catalogs the PTO's various bases for rejection based upon insufficiency of disclosure, the discussion is directed more generally to the PTO's sufficiency of disclosure challenges, and the corresponding burdens of proof, without particular emphasis on the unpredictable arts or an analysis of the root causes for those rejections. *See* Edward C. Walterscheid, *Insufficient Disclosure Rejections* (pts. 1-6), 62 J. PAT. OFF. SOC'Y 217, 229, 261, 361, 387, 546 (1980).

Another commentator looks at the unique problems associated with meeting the enablement requirement in rapidly developing arts, particularly biotechnology. *See generally* Ellen P. Winner, *Enablement in Rapidly Developing Arts—Biotechnology*, 70 J. PAT. OFF. SOC'Y 608 (1988). Ms. Winner does not, however, emphasize the underlying causes of those rejections. *See generally id.*

15. *See* Karen S. Canady, *The Wright Enabling Disclosure for Biotechnology Patents*, 69 WASH. L. REV. 455, 455 (1994) ("In the competitive biotechnology industry, companies often seek broad claims to protect contemplated embodiments of their inventions that have not yet been reduced to practice.").

16. *See, e.g.*, *In re* Wright, 999 F.2d 1557 (Fed. Cir. 1993) (affirming the PTO's

The inventor's generalized description might be improper when the applicant has broadly defined the invention, based upon arbitrarily selected features common among the supporting examples, but not necessarily coincident with the inventive feature or result—that is, where the applicant defines the invention based upon superficial commonalities or reasoning by extrapolation from few examples.[17] This Article proposes that such undue generalization can result in the creation of a false inventive genus, and that the identification of such generalization will bring greater consistency to rejections for insufficient disclosure.

While courts and the PTO have rejected patent claims on grounds that incorporate the principles of the false inventive genus, the rejections are often poorly articulated as the phenomenon of the false inventive genus has not been previously identified as such. Part I introduces the policy and statutory requirements of patent disclosure, and explains the complications of disclosure in the unpredictable arts. Part II examines the evolution and present status of the sufficiency of disclosure inquiry. Part III argues that current case law, which is seemingly discordant for evaluating the sufficiency

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rejection, based on an applicant's failure to satisfy the enablement requirement of 35 U.S.C. § 112 for all but the narrowest claims in a patent application for a genetically engineered vaccine to protect against retroviruses). Such extrapolation or generalization leads to consideration of the "genus-species" relationship. *See* CHISUM, *supra* note 6, § 12.03[3], at 12-67 (addressing genus-species relationship in the context of restriction requirements). The phrase has a rather specialized use within the field of patent law. For example, genus claims are broader claims that embrace a variety of potential embodiments of the invention. *Id.* On the other hand, species claims are narrower, and are usually limited to a single embodiment or a single option for a particular variable. *Id.* As a result, the PTO might make rejections of genus claims on the grounds that such claims are supported by an insufficient number of species of examples. *See* U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2164.02 (6th ed. rev. 1 1995) [hereinafter M.P.E.P.] ("The lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and underdeveloped art."). The terms are necessarily relative, thereby prompting a degree of ambiguity. CHISUM, *supra* note 6, § 12.03[3][b], at 12-69.

17. *See supra* note 15 and accompanying text (explaining that some biotechnology companies define a patent broadly to protect yet-to-be discovered embodiments).

of disclosure for the unpredictable arts, can be reconciled under a new approach—the false inventive genus. Accordingly, this Article concludes that courts and the PTO should more particularly identify instances of suspected reliance on a false inventive genus. Challenges to the patentability or validity of a claim on such a basis will focus attention more effectively on the perceived shortcoming, thereby narrowing the issues and facilitating their proper resolution.

I. INTRODUCTION TO THE DISCLOSURE REQUIREMENT

The three pillars of patentability are Utility, Invention, and Disclosure.[18] Utility and Invention are requirements directed to the invention itself—the subject matter for which the applicant seeks an exclusive right; disclosure, on the other hand, is more a formal requirement directed to the content of the application.[19]

Congress implemented these requirements through the Patent Act of 1952 ("Patent Act"),[20] which states that a patentable invention: (1) must have some demonstrable practical use;[21] (2) must be new;[22] and (3) must be more than a

18. One commentator refers to the three white horses of patentability: "[a]n applicant for a patent must come riding on 'three white horses'; he must present a clear disclosure of his invention, his invention must transcend the skill of the art and it must be useful." S. Wolffe, *Adequacy of Disclosure as Regards Specific Embodiment and Use of Invention*, 41 J. PAT. OFF. SOC'Y 61, 61 (1959). Conceptualizing these requirements as pillars reinforces that they are requisite structural elements, without which the application for patent cannot stand.

19. *See* Bradford J. Duft, *Patent Infringement and Biotechnology*, 16 AIPLA Q.J. 339, 352 (1989) ("The invention as defined by the claims and the description of the physical embodiment of the invention are two quite different things."); *see also* 3 ERNEST BAINBRIDGE LIPSCOMB III, LIPSCOMB'S WALKER ON PATENTS § 9:1, at 11 (3d ed. 1985) ("It should be borne in mind that *patents are creatures of statute* . . . and that patent specifications, drawings, and claims must be drafted to conform and be in harmony with the statutory and Patent Office requirements.").

20. 35 U.S.C. §§ 1-376 (1994).

21. Patentable subject matter is defined as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101.

22. The Patent Act's novelty requirement precludes patentability of inventions that have been invented by others, or that have been publicly disclosed or

mere obvious alteration or improvement over what was previously known in the relevant art.[23] The Patent Act also defines the disclosure requirement.[24] This requirement does not address the merits of the invention. Rather, the disclosure requirement states what the applicant must tender in exchange for the patent grant. Disclosure is a contrivance separate from the invention; but like the invention, it can be dispositive of the application, or of the validity or enforceability of the patent.[25]

This part introduces the disclosure requirement and describes its application to the unpredictable arts. First, this part explains the policies underlying the disclosure requirement. Second, this part discusses the statutory requirements of patent disclosure. Third, this part addresses the complications of disclosure in the unpredictable arts. Finally, this part analyzes the application of the disclosure requirement to the unpredictable arts.

A. *The Policies of Disclosure*

The policies underlying the disclosure requirement are born of the constitutional mandate that Congress provide a framework for granting copyrights and patents.[26] In a rare instance in which the Founding Fathers coupled an enumerated power with a specific objective, the Constitution empowers Congress "to promote Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[27] True to the constitutional mandate, the promotion of the useful arts has been the objec-

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sold more than one year prior to the filing date of the application. 35 U.S.C. § 102.

23. The Patent Act's nonobviousness requirement demands that the subject of the grant be an inventive contribution to the art; that is, something that would not have been obvious to one of ordinary skill in the art at the time the invention was made. 35 U.S.C. § 103.

24. *See* 35 U.S.C. § 112.

25. *See, e.g.*, LIPSCOMB, *supra* note 19, § 10:17, at 234.

26. U.S. CONST. art. I, § 8, cl. 8.

27. *Id.*

tive of the various patent statutes and the body of law interpreting them.[28]

The Founding Fathers thought it equitable to reward inventors with the grant of a limited exclusive right.[29] They acknowledged society's interests by specifying that the grant of such rights be structured to promote the progress of the "useful arts."[30] In exchange for this exclusive right, Congress, beginning with the Patent Act of 1790,[31] has continually insisted upon full and fair disclosure of both the invention and the exclusive right claimed by the innovator.[32] Congress has thus implemented a patent system that balances the private interests of the inventor with the public benefits of disclosure.[33]

By requiring applicants to identify the invention for which they seek an exclusive right,[34] Congress seeks to protect the private interests of innovators by allowing them to give notice of the exclusive right, and "inform the public during the life of the patent of the limits of the monopoly asserted."[35]

Just as inventors benefit from a public disclosure of their

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28. *See generally*, CHISUM, *supra* note 6, § 7.01-.03; LIPSCOMB, *supra* note 19, § 1:8-:9.

29. *See* Canady, *supra* note 15, at 456 ("To encourage the development of technology, the federal government grants patent protection to those who invent products or processes in exchange for public disclosure of their inventions.").

30. THE FEDERALIST NO. 43 (James Madison). According to Mr. Madison:

> The utility of this power will scarcely be questioned. The copy right of authors has been solemnly adjudged in Great Britain to be a right at common law. The right to useful inventions, seems with equal reason to belong to the inventors. The public good fully coincides in both cases, with the claims of individuals.

Id.

31. Act of April 10, 1790, ch. 7, 1 Stat. 109 (repealed 1793).

32. *See* CHISUM, *supra* note 6, § 7.02.

33. *See, e.g.*, Matheson v. Campbell, 69 F. 597, 604 (C.C.S.D.N.Y. 1895) ("The consideration received from the disclosure of the discovery to the public is the foundation of the right to the monopoly of the patent."), *reh'g granted*, 77 F. 280, 281 (C.C.S.D.N.Y. 1896), *rev'd on other grounds*, 78 F. 910 (2d Cir. 1897).

34. 35 U.S.C. § 112.

35. Permutit Co. v. Graver Corp., 284 U.S. 52, 60 (1931).

exclusive right, so too does the public. First, disclosure teaches those in the relevant art how to make and use the invention, thereby enabling the public to exploit the invention at the end of the patent term.[36] Second, the disclosure requirement assures an immediate contribution to the art, so that others might make improvements and advances during the term of the patent.[37] Finally, disclosure protects the public against undue, *ad hoc* extension of the exclusive right.[38]

Consequently, through the disclosure requirement (including the presentation of particularized claims),[39] Congress assures that the public will receive *quid pro quo* for the patent grant; that is, society gains a detailed enabling disclosure, as well as fair notice of the scope of the exclusive right, and protection against undue extension of that right.[40]

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36. *See, e.g.*, *id.* (stating that the patentee must describe the invention in enough detail so that any person skilled in the art may construct and use it after the patent expires).

37. *See* Paul M. Janicke, *Patent Disclosure: Some Problems and Current Developments*, 53 J. PAT. OFF. SOC'Y 3 (1971); *see also In re* Nelson, 280 F.2d 172 (C.C.P.A. 1960), *overruled on other grounds by In re* Kirk, 376 F.2d 936, 943-46 (C.C.P.A. 1967) (discussing the level of usefulness required to be considered a contribution to the art). In *Nelson*, the court harkened back to historical texts, including PHILLIPS, THE LAW OF PATENTS FOR INVENTIONS (1837):

> There are two objects in view in making a specification. As the law grants the patentee a monopoly, and not only awards damages, but inflicts a penalty for violation of the exclusive privilege, it very equitably requires that the invention shall be so described in the specification, that every person may, by examining it, *know what the patentee claims*, and be able to distinguish what may be an infringement. The other object of the specification is to *give the public the advantage of the invention* after the expiration of the patent. . . . [W]e add to Phillips' explanation that a further public advantage from the specification is the addition it makes to technical literature immediately upon issuance of the patent, without waiting for its expiration.

280 F.2d at 181 (emphasis added).

38. *See, e.g.*, Universal Oil Prod. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484-85 (1944) ("The claim is the measure of the grant . . . [and] is required to be specific for the very purpose of protecting the public against extension of the scope of the patent.") (citation omitted).

39. *See infra* notes 51-54 and accompanying text (explaining "particularized claims").

40. *See, e.g.*, *Universal Oil*, 322 U.S. at 484. The Supreme Court explained:

> As a reward for inventions and to encourage their disclosure, the

B. *Statutory Requirements of Disclosure*

To fulfill the foregoing objectives of the patent system, Congress devised section 112 of the Patent Act ("section 112").[41] Paragraph one of section 112 very explicitly states the requirements of disclosure: that the application contain a written description of the invention sufficient to enable an artisan, skilled in the relevant art, to make and use the invention, and that it set forth the inventor's best mode[42] of putting the invention into practice.[43]

Compliance with the above is often analyzed from the perspective of three independent requirements: (1) written description; (2) enablement; and (3) best mode.[44] Satisfaction of the first requirement, a written description, would seem a rather plain and innocuous task. Nonetheless, the

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> United States offers a seventeen-year monopoly to an inventor who refrains from keeping his invention a trade secret. But the *quid pro quo* is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired; and the same precision of disclosure is likewise essential to warn the industry concerned of the precise scope of the monopoly asserted.

Id. (citations omitted); *see also* Brenner v. Manson, 383 U.S. 519, 534 (1966) ("The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.").

41. 35 U.S.C. § 112.

42. *Id.* "Best mode" refers to the patent applicant's requirement to disclose "the best mode of practicing an invention [which] refers to the component parts or ingredients or parameters that an inventor considers to work particularly well with the invention." Roy E. Hofer & L. Ann Fitzgerald, *New Rules for Old Problems: Defining Contours of the Best Mode Requirement in Patent Law*, 44 AM. U. L. REV. 2309, 2349 n.1 (1995).

43. The first paragraph of section 112 states the disclosure requirements which the application, also referred to as "the specification," must fulfill:

> The specification shall contain a *written description* of the invention, and 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.

35 U.S.C. § 112 (emphasis added).

44. *Id.*

written description is an independent, and sometimes fateful, requirement within the unpredictable arts.[45] Indeed, it has been urged that treating the call for a written description as an independent requirement, rather than as a mere modifier, is anomalous, and if appropriate at all, only so in complex chemical cases.[46]

The second requirement, enablement, is the most pregnant with ambiguity,[47] and is the birthplace of this Article. Intertwined with satisfaction of the enablement requirement is the obligation to teach one of skill in the art how-to-make and how-to-use the invention. This, too, would seem a plain and innocuous task, but for the complexity of the unpredictable arts.[48]

The third, and final, requirement of disclosure, best mode, simply obligates the applicant to disclose the invention fully, including the relevant tricks of the trade as it were, so as not to conceal within the one hand, what is seemingly revealed in the other.[49] If the inventor knows of spe-

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45. M.P.E.P., *supra* note 16, § 2161 ("The written description requirement is separate and distinct from the enablement requirement.") (citations omitted); *see also In re* DiLeone, 436 F.2d 1404, 1405 (C.C.P.A. 1971) ("[I]t is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention."); *In re* Ruschig, 379 F.2d 990 (C.C.P.A. 1967).

46. *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560 (Fed. Cir. 1991) ("To the uninitiated, it may seem anomalous that the first paragraph of [section 112] has been interpreted as requiring a separate 'description of the invention,' when the invention is, necessarily, the subject matter defined in the *claims* under consideration."); *see also In re* Barker, 559 F.2d 588, 594 (C.C.P.A. 1977) (Markey, C. J., dissenting) (stating that it is "incongruous," and "exaltive of form over substance" to conclude that the disclosure of an invention in such "clear, concise and exact terms as to enable its practice" somehow fails to meet a distinct written description requirement), *cert. denied*, 434 U.S. 1064 (1978).

47. *Cf.* Canady, *supra* note 15, at 458 ("Biotechnology companies often encounter frustration when trying to satisfy the enablement requirement.") (citation omitted).

48. *See* Lentz, *supra* note 12, at 315-16 (acknowledging that the enablement requirement presents special problems for patents disclosing and claiming biotechnology inventions); *see also* Canady, *supra* note 15, at 458 (explaining that satisfaction of the enablement requirement is much more challenging with chemical and biological inventions than with mechanical innovations).

49. *See, e.g.*, *In re* Gay, 309 F.2d 769, 772 (C.C.P.A. 1962) ("Manifestly, the sole

cific techniques, instrumentalities, or characteristics (referred to as preferred embodiments) for best putting the invention into practice, the best mode requirement mandates disclosure of that information to the public.[50]

The second paragraph of section 112 states that the specification shall conclude with one or more claims "particularly point[ing] out and distinctly claim[ing]" the subject matter which the applicant regards as his invention.[51] Claims are single sentence descriptions that specify the measure, or establish the metes and bounds, of the exclusive right.[52] In so doing, the claims define the outer limits of the exclusive right asserted, thereby putting the public on notice so as to avoid infringement.[53] Similarly, the claims commit the patentee to a particular scope of protection, thus preventing improper *ad hoc* extension of the exclusive right.[54]

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purpose of this latter requirement is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived.").

50. Marchese, *supra* note 2, at 599; *see also Gay*, 309 F.2d at 772. Because best mode rejections are not peculiar to the unpredictable arts, this Article does not discuss them further. *See* Lentz, *supra* note 12, at 315 ("The requirement to set forth the best mode of an invention seems no more often or greater a problem in cases of biotechnology inventions than in typical chemical cases."); *see also* Whiteside, *supra* note 7, at 1028 ("One particularly difficult issue presented by biotechnological inventions has been the satisfaction of the enablement requirement.").

51. 35 U.S.C. § 112.

52. *See generally* CHISUM, *supra* note 6, §§ 8.02, 8.06. According to one commentator:

> The only known (or at least acceptable) way so far to particularly point out and distinctly claim an invention in a statutory class is by means of an English sentence. This is unfortunate, because many of the problems in claim drafting stem from problems in writing English and in the meanings of words.

JOHN L. LANDIS, MECHANICS OF PATENT CLAIM DRAFTING 7 (2d ed. 1974).

53. CHISUM, *supra* note 5, § 8.03.

54. *Id.* § 8.03[1]; *see also id.* § 8.03 ("On occasion, courts, including the Supreme Court, have failed to distinguish carefully the requirement of definiteness, which claims must meet, from the requirement of enablement, which the disclosure of the specification must meet."). Except insofar as the obligation to *claim* the invention is confused with the obligation to *disclose* the invention, claims are not addressed further in this Article.

C. *Application of the Disclosure Requirement to the Unpredictable Arts*

As noted above, compliance with the disclosure requirement can be dispositive of the application, regardless of the merits of the invention.[55] The disclosure, however, can only negatively affect patentability; that is, where the specification fails to meet the requirements of section 112. This section explains the application of the disclosure requirement to the unpredictable arts. This section first introduces the commonly acknowledged complications of disclosure in the unpredictable arts. This section then examines how the courts and the PTO address those complications, and how their treatment might affect the scope of protection an applicant is ultimately granted.

1. The Complications of Disclosure in the Unpredictable Arts

a. Terminology and Language

Describing even the simplest of inventions is often a challenge—even more so with inventions that are either unpredictable or perceived as such.[56] After all, inventions are, by definition, new and non-obvious.[57] As a result, they often do not fit neatly within established theories or paradigms. This amorphism can frustrate attempts to comply with the Patent Act's mandate that disclosure be in full, clear, concise, and exact terms.[58] For example, in *Autogiro Co. of America v.*

55. *See supra* note 25 and accompanying text; *see* LIPSCOMB, *supra* note 19, § 9:1.

56. *See, e.g.*, Slimfold Mfg. Co., Inc. v. Kinkead Indust., Inc., 810 F.2d 1113, 1117 (Fed. Cir. 1987) ("'The specification and claims of a patent . . . constitute one of the most difficult legal instruments to draw with accuracy.'") (citation omitted).

57. 35 U.S.C. §§ 102-103.

58. *See, e.g.*, Lentz, *supra* note 12, at 315 ("The written description requirement is sometimes more problematic [in biotechnology,] owing to the common use in patent claims of words and phrases that may be jargon or otherwise not widely understood, or that may be subjective or functional.").

United States,[59] the United States Court of Claims[60] acknowledged the inherent difficulties of the disclosure requirement. The *Autogiro* court observed that the process of discovery necessarily precedes description of that discovery, and that language, terminology, and nomenclature necessarily lag invention.[61] For this reason, the Court of Claims would grant an applicant latitude in creating and defining the terminology of the invention.[62]

The Court of Customs and Patent Appeals ("C.C.P.A.") also acknowledged the occasional incompatibility of language and innovation.[63] In so doing, the C.C.P.A. refused to

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59. Autogiro Co. of Am. v. United States, 384 F.2d 391 (Ct. Cl. 1967).

60. The United States Court of Appeals for the Federal Circuit, which came into being in 1982, assumed the responsibilities of the United States Court of Claims and the United States Court of Customs and Patent Appeals ("C.C.P.A."). Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 5, 16, 18, 19, 25, 26, 28, 35 & 41 U.S.C.) (1982). The Federal Circuit adopted the body of law represented by the holdings of the Court of Claims and the C.C.P.A. in *South Corp. v. United States*, 690 F.2d 1368 (Fed. Cir. 1982) (*en banc*). The Federal Circuit has exclusive subject matter jurisdiction over all appeals from the federal district courts, the PTO, and the ITC arising under the patent laws of the United States. *See* 28 U.S.C. §§ 1292(c), 1295 (1994); 35 U.S.C. § 141 (1994).

61. As the court in *Autogiro* observed:

> An invention exists most importantly as a tangible structure or a series of drawings. A verbal portrayal is usually an afterthought written to satisfy the requirements of patent law. This conversion of machine to words allows for unintended idea gaps which cannot be satisfactorily filled. Often the invention is novel and words do not exist to describe it. The dictionary does not always keep abreast of the inventor. It cannot. Things are not made for the sake of words, but words for things. To overcome this lag, patent law allows the inventor to be his own lexicographer.

384 F.2d at 397 (citations omitted). The rule that an applicant is entitled to be his or her own lexicographer continues to receive explicit endorsement. *See, e.g.*, Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995) (*en banc*), *aff'd*, 116 S. Ct. 1384 (1996) (citing *Autogiro*, 384 F.2d at 397). The rule acknowledges that new terms are required to describe new discoveries. *Id.* This, too, is a long since acknowledged concept: "I am not yet so lost in lexicography as to forget that words are the daughter of earth, and that things are the sons of heaven." SAMUEL JOHNSON, *Preface to* DICTIONARY (1755), *quoted in* J. BARTLETT, BARTLETT'S FAMILIAR QUOTATIONS (16th ed. 1992).

62. *Autogiro*, 384 F.2d at 397.

63. *See, e.g.*, *In re* Fisher, 427 F.2d 833, 838 (C.C.P.A. 1970).

penalize inventors for ambiguities or inadequacies of language in a patent application.[64] Nonetheless, the inventor must thoroughly and accurately define any new terms, and must use such terms consistently throughout the specification and the claims.[65]

b. Scientific Principles

Another challenge to disclosure in the unpredictable arts arises where the principles relied upon to explain or describe the operation of an invention, are new, untested, and yet to be accepted by the scientific community.[66] In such a situation, the inventive principle itself, or at least the inventor's description of it, might be looked upon with suspicion.

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64. In *Fisher*, the court explained:

> We recognize a problem in determining differences over the prior art where the claim uses language which is now accepted and precise but which was not used in the art at the time the prior-art references were published. However, were we to require that claims speak in the language of the prior art, we would be prohibiting the use of newer and frequently more precise language of the present art.

427 F.2d at 838; *see also* Benger Labs. Ltd. v. R.K. Laros Co., 209 F. Supp. 639, 642 (E.D. Pa. 1962). As the *Benger Laboratories* court noted:

> Nothing in the law requires courts to deny a patent to the inventor of a new and useful product merely because laboratory technique has not advanced to a point where the chemical structure can be recognized and described. All that is necessary is that the patentee make as full disclosure as he reasonably can and that he describe the product with sufficient particularity that it can be identified and that those who are interested in its manufacture are enabled to determine what will and what will not infringe.

Id.

65. *See, e.g.*, Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995) (*en banc*), *aff'd*, 116 S. Ct. 1384 (1996) ("The caveat is that any special definition given to a word must be clearly defined in the specification.") (citing Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1388 (Fed. Cir. 1992)).

66. R.H. Comey Co. v. Monte Christi Corp., 17 F.2d 910, 912 (3d Cir. 1927) ("When [experimentation] is necessary, especially where, as here, it is claimed the art is new, courts will carefully appraise the adequacy of the disclosures and sustain or strike down the patent accordingly.") (citations omitted); *see also In re* Chilowsky, 229 F.2d 457, 462 (C.C.P.A. 1956) (suggesting that when the operation alleged conflicts with recognized principles or is not amenable to testing by known scientific principles, applicants will be required to demonstrate the workability and utility of the device and make clear the principles by which it operates)

Courts or the PTO might then treat the invention as unpredictable, or not amenable to generalization, and question the sufficiency of the disclosure. When the subject of a patent application is among the unpredictable arts, and the application contains claims covering subject matter beyond that illustrated in the disclosure, courts and the PTO are likely to scrutinize closely the disclosure for enablement.[67]

Unpredictable factors are more prevalent in some disciplines, thereby complicating the sufficiency of disclosure analysis and casting suspicion on broad claims to inventions within such disciplines.[68] For example, while electrical and mechanical inventions are generally considered as among the predictable arts,[69] inventions involving chemistry[70]—

67. *Cf. In re* Wright, 999 F.2d 1557 (Fed. Cir. 1993) (affirming rejection of broad generic claims in an unpredictable art, which claims were supported by only a single working example).

68. *See, e.g.*, *In re* Fisher, 427 F.2d 833 (C.C.P.A. 1970); *see also* M.P.E.P., *supra* note 16, § 2164.03.

69. *Fisher*, 427 F.2d at 839. In *Fisher*, the C.C.P.A. observed:

> In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies with the degree of unpredictability of the factors involved.

Id.; *accord Ex parte* Hitzeman, 9 U.S.P.Q.2d (BNA) 1821, 1823 (Bd. Pat. App. & Int. 1988) ("noting that a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, but that more is required in cases involving unpredictable factors, such as most chemical reactions and physiological activity); *see also* Matheson v. Campbell, 78 F. 910, 916 (2d Cir. 1897) ("[A patentee cannot] speculate on the equivalents of his claimed invention and thereby oblige the public to resort to experiments in order to determine the scope of the claims of his patent.").

70. *See, e.g.*, Schering Corp. v. Gilbert, 153 F.2d 428, 433 (2d Cir. 1946) ("[W]hile analogy is at times useful, organic chemistry is essentially an experimental science and results are often uncertain, unpredictable, and unexpected."); Naylor v. Alsop Process Co., 168 F. 911, 919 (8th Cir. 1909) ("[R]easoning by analogy in a complex field like chemistry is very much more restricted than in a simple field like mechanics."); Standard Oil Co. v. Montedison, S.p.A., 494 F. Supp. 370, 432 (D. Del. 1980) ("[I]n the notably unpredictable fields of catalysis and organic chemistry small changes can yield quite significant results").

including physiological utility or therapeutic uses of compounds,[71] living materials such as microorganisms or cultured cells,[72] and other aspects of biochemistry and genetic manipulation—are generally categorized as among the unpredictable arts.[73] Consequently, broad claims to inventions among the latter group of disciplines often receive greater scrutiny.

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71. *See, e.g.*, *Ex parte* Sudilovsky, 21 U.S.P.Q.2d (BNA) 1702, 1705 (Bd. Pat. App. & Int. 1991) (finding an invention which concerned pharmaceutical activity to be relatively unpredictable because there was no record of analogous activity for similar compounds); *see also In re* Sichert, 566 F.2d 1154 (C.C.P.A. 1977) (addressing therapeutical compositions comprising mixtures of extracts from plants of various enumerated families); *In re* Gardner, 427 F.2d 786 (C.C.P.A. 1970) (addressing pharmaceutical compositions having "antidepressant activity"); Imperial Chem. Indus. v. Mossinghoff, 223 U.S.P.Q. (BNA) 769 (D.D.C. 1984) (distinguishing enablement requirement for claimed compounds from claimed therapeutic use: disclosure requirements for claimed therapeutic use of known compounds being greater.); *Ex parte* Kranz, 19 U.S.P.Q.2d (BNA) 1216 (Bd. Pat. App. & Int. 1991) (addressing treatment of cancer); *Ex parte* Busse, 1 U.S.P.Q.2d (BNA) 1908 (Bd. Pat. App. & Int. 1986) (addressing treatment of cancer); *Ex parte* Powers, 220 U.S.P.Q. (BNA) 924 (Bd. App. 1982) ("[D]isclosure . . . lacks any information as to host, dosage level, mode or routes of administration, or how to prepare the composition for administration."); *cf. In re* Bundy, 642 F.2d 430 (C.C.P.A. 1981) (recognizing less stringent requirement for disclosure of "how to use" the invention for claims directed to compounds as compared to claims for therapeutic use); *accord* Bey v. Kollonitsch, 215 U.S.P.Q. (BNA) 454, 459 (Bd. Pat. App. & Int. 1981).

72. *See, e.g.*, *In re* Wands, 858 F.2d 731 (Fed. Cir. 1988); *Ex parte* Humphreys, 24 U.S.P.Q.2d (BNA) 1255 (Bd. Pat. App. & Int. 1992); *Ex parte* Hata, 6 U.S.P.Q.2d (BNA) 1652 (Bd. Pat. App. & Int. 1988) (deposit of microorganisms required if not shown to be "not rarely occurring"). *But see* Hybritech Inc. v. Abbott Labs., 4 U.S.P.Q.2d (BNA) 1001 (C.D. Cal. 1987), *aff'd*, 849 F.2d 1446 (Fed. Cir. 1988) (concluding it is not undue experimentation to make and screen monoclonal antibodies by hybridoma method).

73. *See, e.g.*, *In re* Goodman, 11 F.3d 1046, 1050 (Fed. Cir. 1993) (finding single example in support of claims for method for producing mammalian peptides in any plant cell insufficient enablement and acknowledging articles showing "great unpredictability in the art"); *Hitzeman*, 9 U.S.P.Q.2d at 1823 ("[T]his case involves highly unpredictable factors including unique, delicate, and unpredictable biochemical and genetic actions.") (citing examiner's Answer with approval).

This Article uses the terms "chemical inventions" and "chemical cases" to include inventions and claims involving physiological utility or therapeutic uses of compounds, living materials such as microorganisms or cultured cells, and other aspects of biochemistry and genetic manipulation.

One might view this enhanced scrutiny of the unpredictable arts as merely healthy skepticism of disciplines that trace their roots to the medieval practice of alchemy, which, despite its association with chicanery and fraud, is the forerunner of modern chemistry and pharmacology.[74] Nonetheless, it is worthwhile to examine the effect that such enhanced scrutiny might have on the scope of protection afforded an invention.

2. The Proper Inquiry: Unpredictable Factors in the Art

Rather than branding entire disciplines unpredictable, the C.C.P.A. has commented that it "would prefer to see the dichotomy which lawyers find in the chemical and mechanical cases 'denominated a dichotomy between predictable and unpredictable factors in the art.' However, we recognize that the realities of chemical cases often result in unpredictability."[75] The court's attempt to clarify this issue might be interpreted as acknowledging that not all chemical inventions are inherently unpredictable.

3. Assessing Unpredictability and Sufficiency of Disclosure

a. Standards of Disclosure and Burdens of Proof

The mere prospect that an invention might be denominated "unpredictable," thereby rendering broad claims suspect, raises a preliminary issue: whether inventions that

74. *See* N. IRVING SAX AND RICHARD J. LEWIS, SR., HAWLEY'S CONDENSED CHEMICAL DICTIONARY 31 (11th ed. 1987) (defining alchemy as: "The predecessor of chemistry practiced from as early as 500 B.C. through the 16th century. Its two principal goals were transmutation of the base metals into gold and discovery of a universal remedy. Modern chemistry grew out of alchemy by gradual stages.").

75. *In re* Bowen, 181 U.S.P.Q. (BNA) 48, 50 (C.C.P.A. 1974) (citing *In re* Cook, 439 F.2d 730, 734 (C.C.P.A. 1971)). The distinction is frequently overlooked, however. Judge Rich wrote the opinion in both *Bowen* and *Cook*, yet more recently wrote, "it is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable *art*." *In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) (emphasis added).

possess unpredictable factors are subject to a more rigorous standard of disclosure.

The Patent Office Board of Appeals has acknowledged that the sufficiency of the patent disclosure is more often called into question in chemical cases.[76] Nonetheless, the C.C.P.A. has refuted the suggestion that there is a more rigorous standard of disclosure, noting that "the patent code does not prescribe a different standard [of disclosure] between 'complex' and 'simple' cases; nor does this court apply different standards in such cases."[77] Nonetheless, the burden of proof, as to whether an applicant has satisfied that

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76. *Ex parte* Vickers, 53 U.S.P.Q. (BNA) 607, 608 (Bd. App. 1941); *see also* Nationwide Chem. Corp. v. Wright, 458 F. Supp. 828, 839 (M.D. Fla. 1976), *aff'd*, 584 F.2d 714 (5th Cir. 1978). In *Nationwide Chemical Corp.*, the court distinguished treatment of generic mechanical claims from generic claims in chemical and biological arts and acknowledged that:

> [O]ne skilled in these chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances. Thus, in so-called 'chemical' patent law practice, the claims of a patent are limited by the scope of what the disclosure reasonably teaches to one skilled in the art.

Id. Furthermore, as the *Vickers* court explained:

> [T]he rejection is that the claim is broader than the invention. This ground of rejection is frequently applied in purely chemical cases where equivalents are not obvious, but is very infrequently applied to strictly mechanical cases . . . . The reason for the distinction made between chemical and mechanical cases is because in the mechanical cases the equivalents are obvious to any mechanic."

53 U.S.P.Q. at 608.

77. *In re* Barker, 559 F.2d 588, 593 n.6 (C.C.P.A. 1977), *cert. denied*, 434 U.S. 1064 (1978) (citing *In re* Arkley, 455 F.2d 586, 589-90 (C.C.P.A. 1972)); *see also Ex parte* DesOrmeaux, 25 U.S.P.Q.2d (BNA) 2040, 2043-44 (Bd. Pat. App. & Int. 1992) ("[W]e are unaware of any distinction in law as to the enablement or description requirements of the first paragraph of [section] 112 based on whether the subject matter is chemical or non chemical."). *But see* United States v. Telectronics, Inc., 857 F.2d 778, 786 (Fed. Cir. 1988) ("*Fisher* and *Bowen* both involved chemical reactions, recognized by our predecessor court as having a high degree of unpredictability and therefore requiring an increased enablement disclosure."); Hormone Research Found. v. Genentech, Inc., 8 U.S.P.Q.2d (BNA) 1377, 1386 (N.D. Cal. 1988), *aff'd in part, vacated in part, and remanded*, 904 F.2d 1558 (Fed. Cir. 1990), *cert. dismissed*, 499 U.S. 955 (1991) ("Patents concerning chemical reactions and biological activity, like the patent in suit, generally involve unpredictable factors thus enable a narrower range of claims.").

disclosure requirement can vary. Courts have acknowledged the propriety of shifting the burden of proof, depending upon the unpredictability of an invention.[78]

b. Measuring the Sufficiency of Disclosure

The prospect that the burden of proof can shift, depending upon the perceived unpredictability within an art, raises a more challenging question: how does one reliably measure the sufficiency of disclosure in disciplines fraught with unpredictability? The proper inquiry is whether there is a reasonable correlation between the scope of enablement provided by the disclosure and the scope of the claims.[79] In other words, whether the specification contains a description of the invention that would enable one of ordinary skill in the relevant art to make and use the invention throughout the range of embodiments embraced by the claim.[80]

Confirmation that the scope of enablement correlates with the scope of the claim is not an arbitrary hurdle erected exclusively before the invention possessing unpredictable factors.[81] Rather, it is a recognition that, regardless of disci-

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78. *See infra* notes 178-85 and accompanying text (discussing the role of unpredictability in shifting the burden of proof as between the PTO and applicant); *see also In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971).

79. *See infra* note 238 and accompanying text; *see also In re* Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1981); *In re* Wands, 858 F.2d 731, 736-37 (Fed. Cir. 1988); *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) (noting that the first paragraph of section 112 requires that the scope of protection sought bear a reasonable correlation to the scope of enablement provided by the specification); *In re* Borkowski, 422 F.2d 904, 909 (C.C.P.A. 1970). As the *Borkowski* court explained:

> [I]f the 'enabling' disclosure of a specification is not commensurate in scope with the subject matter encompassed by a claim, that fact does not render the claim imprecise or indefinite or otherwise not in compliance with the *second* paragraph of § 112; rather, the claim is based on an *insufficient disclosure*. . . .

Id. (citations omitted).

80. *See, e.g.*, *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993) ("Although not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'") (citations omitted).

81. The ability to draw generalizations not expressly supported by a disclosure was addressed with characteristic eloquence by Judge Learned Hand:

pline, enablement contemplates predictability, or at least the ability to duplicate what the applicant claims to have invented.[82]

Early in the post-World War II era, the C.C.P.A. gave voice to this principle in *In re Chilowsky*.[83] *Chilowsky* involved claims directed to the use of nuclear fission to generate useful energy.[84] The PTO had rejected the claims on the grounds of inoperativeness and indefiniteness.[85] The C.C.P.A. observed, however, that neither the examiner nor the Board of Appeals had identified any specific feature shown to be, or considered to be, inoperative, but rather merely objected to the speculative nature of the disclosure.[86] Accordingly, the *Chilowsky* court concluded that the stan-

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> An inventor is, of course, not confined to the exact details of his disclosure, else his patent would be of small value. The extent to which he may generalize it depends, not only upon the surrounding pressure of the art, but the extent to which the variations which he wishes to cover in his claims, are themselves within the initiative of a journeyman in the art. For the inventor's contribution must be a sufficient guide in itself, and its extent is limited to such substitutes for any disclosed element, as the art needs no help to find. . . . An inventor must do more than give cues for future experiment. Unless he is dealing with elements whose action and reaction is known and certain, he is bound to disclose how the combination will operate. A patent is the reward of a tested contribution to the art, not of a pregnant surmise or promising hypothesis.

Leonard, Inc. v. Maxwell Motor Sales Corp., 252 F. 584, 589-90 (2d Cir. 1918) (citations omitted). Judge Hand's comments also show that this particular inquiry is not peculiar to the unpredictable arts, because the issue before the *Leonard* court was whether the disclosure supported an assertion of the claims against alleged equivalents in a mechanical invention. *See generally* Leonard, Inc. v. Maxwell Motor Sales Corp., 252 F. 584 (2d Cir. 1918).

82. *Id.*; *see also In re* Herschler, 591 F.2d 693, 701 (C.C.P.A. 1979) (saying description must provide measure of predictability for the utility described for the invention); Nationwide Chem. Corp. v. Wright, 458 F. Supp. 828, 839, *aff'd*, 584 F.2d 714 (5th Cir. 1978) ("With respect to generic claims to chemical and biological inventions, the scope of the claim is limited to what those skilled in the art could reasonably predict from the inventor's disclosure.").

83. *In re* Chilowsky, 229 F.2d 457 (C.C.P.A. 1956).

84. *Id.* at 459.

85. *Id.* at 460. The examiner had argued that in order for there to be patentability for generating power by nuclear fission, "there must be *conclusive* proof" that the disclosed reactor can be constructed and operated. *Id.* at 461.

86. *Id.* at 461.

dards by which operativeness of the invention and enablement are judged should be no different in emerging or unpredictable technologies than in other more established and predictable technologies.[87]

Nonetheless, within developing disciplines, unpredictability, alone, might be sufficient to cast doubt on the scope of enablement.[88] Still greater scrutiny—even a presumption of a lack of utility or of inoperability—is appropriate where the alleged operation is in actual conflict with recognized scientific principles,[89] or otherwise commonly acknowledged

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87. *Chilowsky*, 229 F.2d at 461-62. The *Chilowsky* court said that:

> [T]he same principles should apply in determining operativeness and sufficiency of disclosure in applications relating to nuclear fission as in other cases. There appears to be no basis in the statutes or decisions for requiring any more conclusive evidence of operativeness in one type of case than another. The character and amount of evidence needed may vary, depending on whether the alleged operation described in the application appears to accord with or to contravene established scientific principles or to depend upon principles alleged but not generally recognized; but the degree of certainty as to the ultimate fact of operativeness . . . should be the same in all cases.

Id.

88. *See In re* Marzocchi, 439 F.2d 220 (C.C.P.A. 1971). In *Marzocchi*, the court observed:

> In the field of chemistry generally, there may be times when the well known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles.

Id. at 223.

89. *Id.*; *see also In re* Chilowski, 229 F.2d at 462 ("[I]f the alleged operation seems clearly to conflict with a recognized scientific principle as, for example, where an applicant purports to have discovered a machine producing perpetual motion, the presumption of inoperativeness is so strong that very clear evidence is required to overcome it."); Newman v. Quigg, 877 F.2d 1575 (Fed. Cir. 1989) (claims for a perpetual motion machine rejected under both sections 101 and 112), *modified*, 886 F.2d 329 (Fed. Cir. 1989), *cert. denied*, 495 U.S. 932 (1990); *cf. In re* Sichert, 566 F.2d 1154, 1159 (C.C.P.A. 1977) (holding that the claimed utility, treatment of lymphatic congestion, is not "incredible"). In a corresponding footnote, the court identified a series of cases addressing the issue of whether the claimed utility was speculative, incredible, esoteric, factually misleading, or contrary to the common knowledge of persons of ordinary skill in the art. *See, e.g.*, *In re* Houghton, 433 F.2d 820, 820 (C.C.P.A. 1970) (flying machine operating on

as the "subject matter of much humbuggery and fraud."[90]

II. EVOLUTION OF THE SUFFICIENCY OF DISCLOSURE INQUIRY

The sufficiency of disclosure inquiry derives from the requirement of section 112, first paragraph that an applicant describe his or her invention.[91] More particularly, the disclosure must satisfy the written description, enablement, and how-to-make-and-use requirements.[92] The sufficiency of disclosure inquiry has occasionally suffered from the failure to distinguish the descriptive requirements of the first paragraph of section 112 from the definitional requirements of the second paragraph—as seen in rejections for undue breadth—and from the requirement that the invention be useful[93]—as seen in rejections for including inoperative embodiments. This part examines the evolution of sufficiency of disclosure rejections from those decrying undue breadth and faulting the inclusion of inoperative embodiments to the current rejections for insufficiency of disclosure alleging the need for undue experimentation.

"flapping or flutter function"); *In re* Eltgroth, 419 F.2d 918 (C.C.P.A. 1970) (control of aging process); *In re* Buting, 418 F.2d 540 (C.C.P.A. 1969) (treating cancer); *In re* Ferens, 417 F.2d 1072 (C.C.P.A. 1969) (hair restorer); *In re* Citron, 325 F.2d 254 (C.C.P.A. 1963) (treating cancer)). *Id.* at 1159 n.5.

90. *In re* Nelson, 280 F.2d 172, 180 (C.C.P.A. 1960), *overruled on other grounds by In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967). The *Nelson* court also cited *In re Oberweger*. *Id.* (citing *In re* Oberweger, 115 F.2d 826 (C.C.P.A. 1940)) ("[W]herein an invention consisting of various admixtures of such things as bone marrow, aromatic oils and alcohol was held lacking in utility for the specified purpose of growing hair.").

91. *See, e.g.*, *In re* Angstadt, 537 F.2d 498, 501 (C.C.P.A. 1976) (holding that whether the claims read on subject matter for which the specification is enabling is an issue of paragraph one of section 112).

92. The various insufficiency of disclosure rejections have been categorized elsewhere. *See generally* Walterscheid (pt. III), *supra* note 14.

93. *See, e.g.*, *In re* Frilette, 423 F.2d 1397 (C.C.P.A. 1970) (noting that rejection that claims were "too broad" confused the requirements of the first and second paragraphs of section 112, and section 101 (utility)); *see generally* CHISUM, *supra* note 6, §§ 7.02-.03, 8.03.

A. *Undue Breadth: Distinguishing the Obligation to Define from the Obligation to Describe the Invention*

In the past, the PTO has rejected patent applications for insufficiency of disclosure by alleging that the inventor's claims were unduly broad.[94] Such "undue breadth" rejections are now disfavored, as they fail to distinguish between an alleged inadequacy of the claims or the disclosure.[95]

The sufficiency of disclosure analysis has often been confounded by the failure to distinguish the obligation to define, or delineate the boundaries of the invention, from the obligation to disclose or describe the invention.[96] The applicant's definition of the invention must "particularly point out and distinctly claim" what the applicant regards as the invention.[97] Because the applicant has the obligation of defining the invention in the first instance, the application—and the sufficiency of the disclosure—must be analyzed with respect to *the invention* as claimed.[98]

1. The Claim Defines That Which Must Separately Be Described

When considering whether an application sufficiently describes an invention, one must first determine what the invention is.[99] The first paragraph of section 112 requires that the applicant enable one of skill in the art to make and

94. *See, e.g.*, *In re* Borkowski, 422 F.2d 904 (C.C.P.A. 1971); *In re* Frilette, 423 F.2d 1397 (C.C.P.A. 1970).

95. *See Borkowski*, 422 F.2d at 909; *Frilette*, 423 F.2d at 1400-01.

96. *See supra* note 106 and accompanying text.

97. The obligation to define the invention is found in the first paragraph of section 112, and obligates the applicant to define the exclusive right sought by "particularly point[ing] out and distinctly claim[ing]" that which the applicant regards as the invention. 35 U.S.C. § 112; *see supra* notes 41-54 and accompanying text (explaining the statutory requirements of disclosure). The sufficiency of the disclosure must meet the strictures of the first paragraph of section 112. *See supra* notes 41-54 and accompanying text (explaining the statutory requirements of disclosure).

98. *Angstadt*, 537 F.2d at 501-02 (citing *In re* Moore, 439 F.2d 1232, 1235 (C.C.P.A. 1971)).

99. *Id.*

use the invention; the second paragraph requires that the applicant define the scope of the invention.[100] Because an invention must first be defined in order to ascertain whether it is enabled, a proper analysis for compliance with section 112 must start with the second paragraph.[101]

The test for compliance with section 112, second paragraph, is whether the claims "set out and circumscribe a particular area with a reasonable degree of precision and particularity."[102]

If so, the applicant has satisfied the requirements of the second paragraph of section 112.[103] If, however, the "enabling" disclosure of a specification is not commensurate in scope with the subject matter encompassed by a claim, the claim is based on an insufficient disclosure, and the issue becomes one of compliance with section 112, first paragraph.[104] In such situations, it is important to distinguish the requirement of definiteness, which the claims must meet, from enablement, which the disclosure of the specification must

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100. *Id.*

101. *Id.*

102. *Id.*; *see also*, Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 874-75 (Fed. Cir. 1993). In *Miles*, the court explained:

> The "distinctly claiming" requirement means that the claims must have a clear and definite meaning when construed in the light of the complete patent document. Section 112 thus ensures definiteness of claim language.
>
> The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, [section] 112 demands no more. The degree of precision necessary for adequate claims is a function of the nature of the subject matter.

Id. (citations omitted). Put another way:

> If the scope of subject matter embraced by a claim is clear, and if the applicant has not otherwise indicated that he intends the claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention.

Borkowski, 422 F.2d at 909.

103. *Angstadt*, 537 F.2d at 501-02.

104. *Id.*

meet.[105]

2. Undue Breadth Fails to Distinguish Definitional from Descriptive Faults

The distinct requirements of the first and second paragraphs of section 112 have occasionally been muddled.[106] The result is highlighted in the debate over whether claims might properly be rejected for undue breadth.[107] Because of inherent ambiguities and resulting confusion, the undue breadth rejection was explicitly spurned by the C.C.P.A. in *In re Borkowski*.[108]

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105. *See* CHISUM, *supra* note 6, § 8.03; *see also In re* Fuetterer, 319 F.2d 259, 261 (C.C.P.A. 1963). As the *Fuetterer* court explained: "[w]e think the examiner's rejection of the instant claims as failing to *enable* the public to 'determine operable proportions' is misplaced. Such is the function of the *invention description* and not that of the claims." *Id.* (citations omitted) (emphasis in original). *But see* General Electric Co. v. United States, 572 F.2d 745 (Ct. Cl. 1978). In *General Electric*, the court noted:

> Claims 35 and 36 fail to structurally recite, in any form, transformer 81. This element is an essential element of the combination for without transformer 81, or some equivalent means, the claimed combination is inoperative. . . . Since the combination as claimed is inoperative for its claimed purpose, the patentee has failed to distinctly claim the disclosed invention as required by the second paragraph of [section] 112.

Id. at 754 (citations omitted).

106. *See generally* CHISUM, *supra* note 6, § 8.03 (discussing several Supreme Court cases confusing the distinction); Levin, *supra* note 67 (explaining that some courts confuse the first and second paragraphs of section 112). Much of the confusion can be attributed to the fact that under prior patent acts the enablement requirement and the "distinctly claiming" requirement were expressed within the same sentence. With the Patent Act of 1952, however, those requirements were expressed in separate paragraphs of section 112. *See supra* notes 20-25 and accompanying text (discussing the Patent Act of 1952). One commentator has explained:

> In the old statute, the requirement for a claim pointing out what the applicant regarded as his invention appeared as a clause in the same sentence relating to the description, which led to some confounding of the nature of the two requirements in a few decisions. In the new statute, the clause relating to the claim has been made a separate paragraph to emphasize the distinction between the description and the claim, and the language has been modified.

Federico, *Commentary on the New Patent Act*, 75 J. PAT. OFF. SOC'Y 157, 186 (1993).

107. *See, e.g.*, *In re* Borkowski, 422 F.2d 904 (C.C.P.A. 1970); *In re* Fuetterer, 319 F.2d 259 (C.C.P.A. 1963).

108. *In re* Borkowski, 422 F.2d 904, 909 (C.C.P.A. 1970).

In *Borkowski*, the examiner had rejected the claims in issue under both the first and second paragraphs of section 112; specifically, the examiner asserted that the claims were "based on an insufficient disclosure," and failed to "particularly point out and distinctly claim the invention."[109] The court suggested that the undue breadth rejection begs the question as to whether the applicant has failed to enable the invention as broadly as it is claimed, or has failed to claim clearly and with particularity that which is disclosed and presumably enabled.[110]

The C.C.P.A. has also made clear its view that undue breadth is an ambivalent rejection from which neither the applicant nor appellate tribunals can decipher the deficiency alleged.[111] Furthermore, the C.C.P.A. has observed that the undue breadth rejection might suggest inoperativeness—that embodiments within the scope of the claims lack utility—and thus an implicit rejection under section 101.[112] Accordingly, the undue breadth rejection, without more, is inappropriate and should not stand.[113] In fact, the rejection is more appropriately made based upon the first paragraph of Section 112.[114]

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109. *Id.*

110. *Id.*

111. *Frilette*, 423 F.2d at 1400-01.

112. *Id.* ("Thus, while citing [section] 112, the board's discussion of the factual grounds for the rejection indicates, as does the examiner's, a concern with alleged inoperativeness or lack of utility of embodiments embraceable within the scope of the language of the claims.").

113. *Id.* (remanding for clarification a rejection of claims under section 112 asserting claims were "too broad").

114. *See In re* Hyatt, 708 F.2d 712, 714 (Fed. Cir. 1983) ("[T]he claim is properly rejected for what used to be known as 'undue breadth,' but has since been appreciated as being, more accurately, based upon the first paragraph of [section] 112."); *see generally* M.P.E.P., *supra* note 16 (eliminating section 706.03(z) from the previous edition, which expressly provided grounds for rejecting claims for "Undue Breadth," particularly among the unpredictable arts such as those involving chemical reactions). Similarly, section 706.03(n) has also been eliminated from the most recent edition of the M.P.E.P. *See generally id.* That section, entitled "Correspondence of Claim & Disclosure" was often used by examiners in tandem with section 706.03(z) to reject claims based upon the first paragraph

Sufficiency of disclosure, then, addresses compliance with the requirements of section 112, first paragraph. Within the first paragraph, however, there are the three subsidiary requirements particularly relevant in the unpredictable arts: (1) written description, (2) enablement, and (3) how to make and use the invention.[115] Satisfaction of these requirements is often debated in conjunction with the invention's utility.[116]

B. *Inoperative Embodiments and the Utility Component of Disclosure*

Another now disfavored form of insufficiency of disclosure rejection is the allegation that the claim embraces inoperative embodiments. As with undue breadth, inoperative embodiment rejections confuse the respective requirements of the first and second paragraphs of section 112, as well as the utility requirement of section 101.[117]

The invention and the description of the invention are separate contrivances:[118] the utility requirement demands the invention *be* useful, while the disclosure requirement demands that the written description of the invention enable one of ordinary skill in the art *to make and use* the invention.[119] The inoperative embodiment rejection, like the undue breadth rejection, suffered from misguided reasoning and inherent ambiguity. The demise of both rejections was the genesis of the modern undue experimentation inquiry.

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of section 112. *See generally id.* Such rejections are now controlled by new M.P.E.P. § 706.03(c), entitled "Rejections Under 35 U.S.C. § 112, First Paragraph." Such rejections are discussed at length in M.P.E.P. Chapter 2100. *See generally id.* § 2164 (reiterating the principles and grounds formerly found in sections 706.03(n),(z)).

115. 35 U.S.C. § 112.

116. *See, e.g.*, *In re* Frilette, 423 F.2d 1401 (C.C.P.A. 1970) (noting that the first paragraph of section 112 requires "enabling" disclosure).

117. *See infra* note 125 and accompanying text.

118. *See supra* notes 20-25 and accompanying text.

119. *See supra* notes 18-25 and accompanying text.

1. Utility and Disclosure of Utility

As explained above in Part I, the subject of an application for a utility patent must be useful.[120] While the utility requirement is found in section 101, it is also embraced by section 112.[121] Indeed, the C.C.P.A. has held that compliance with section 112 contemplates satisfaction of section 101.[122]

Furthermore, in *Raytheon Co. v. Roper Corp.*,[123] the Court of Appeals for the Federal Circuit, affirming a lower court's holding that a patent application was invalid for lack of utility, confirmed that a rejection for lack of utility can properly be made under either section 101 or section 112.[124]

Nonetheless, the requirements of these two sections are

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120. *See supra* note 21 and accompanying text.

121. *See generally* M.P.E.P., *supra* note 16, § 2107(d).

122. *In re* Kirk, 376 F.2d 936, 941 (C.C.P.A. 1967). In *Kirk*, the court explained:

> [S]urely Congress intended [section] 112 to pre-suppose *full satisfaction* of the requirements of [section] 101. Necessarily, compliance with [section] 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention.

Id. at 942 (emphasis in original).

123. 724 F.2d 951 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984).

124. *Raytheon*, 724 F.2d at 956. In *Raytheon*, the court noted that:

> Because it is for the invention as claimed that enablement must exist, and because the impossible cannot be enabled, a claim containing a limitation impossible to meet may be held invalid under [section] 112. Moreover, when a claim requires a means for accomplishing an unattainable result, the claimed invention must be considered inoperative as claimed and the claim must be held invalid under either [section] 101 or [section] 112 . . . .

Id.; *see also* M.P.E.P., *supra* note 16, § 2164.07 ("Relationship of Enablement Requirement to Utility Requirement of 35 U.S.C. § 101"), § 2107.02 ("Special Considerations for Asserted Therapeutic or Pharmacologic Utilities"); U.S. PATENT & TRADEMARK OFFICE, GUIDELINES FOR CONSIDERING DISCLOSURES OF UTILITY IN DRUG CASES 567 (1968) [hereinafter PTO DRUG UTILITY GUIDELINES] (providing a historical discussion of disclosure in chemical cases); *cf.* U.S. PATENT & TRADEMARK OFFICE, *Utility Examination Guidelines*, 60 Fed. Reg. 36,263 (1995). If an applicant has not stated a utility, and the claimed invention does not have a well established utility, examiners should interpose a rejection under both sections 101 and 112. *Id.* at 36,264. This should shift the burden to the applicant to: (1) identify a utility, and (2) show support for that utility in the specification. *Id.*

distinct. The C.C.P.A. has admonished that "'utility' as required by section 101 and a showing of 'how to use' the invention as required by the first paragraph of section 112 should not be confused as has often been done by courts, including this court in *In re Bremner* . . . ."[125] Such confusion occasionally results in sufficiency of disclosure rejections based upon the *utility* requirement of section 112.[126]

The C.C.P.A. examined the distinction between section 101 and section 112 in considerable detail in *In re Nelson*.[127] The *Nelson* court noted that the utility requirement of section 101 is intended to limit the grant of patents to "useful" inventions.[128] As such, section 101 limits the granting of patents to certain classes of invention—that is, those possessing utility. It is therefore inappropriate to rely upon section 112 to object to the *kind* of utility disclosed.[129] If the invention possesses utility and the subject matter otherwise comes within the classes of patentable subject matter, the invention complies with section 101.[130] Thus, "section 112, as we view the matter, does not deal with 'utility,' in the sense in which that term is used in patent law to define a prerequisite to patentability."[131]

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125. *In re* Szwarc, 319 F.2d 277, 284 n.6 (C.C.P.A. 1963) (citing *In re* Bremner, 182 F.2d 216 (C.C.P.A. 1950)); *cf. In re* Fouche, 439 F.2d 1237, 1243 (C.C.P.A. 1971). As the *Fouche* court observed:

> It appears that the examiner and the board doubted that compositions having heterocyclic moieties would be useful at all for therapeutic purposes. While this position could have led to a rejection under [section] 101, it also leads to a rejection under the how-to-use provision of [section] 112, since if such compositions are in fact useless, appellant's specification cannot have taught how to use them.)

Id.

126. *See, e.g.*, Parker & Wasson v. Biel, 159 U.S.P.Q. (BNA) 613 (Bd. Pat. App. & Int. 1961); *see also* M.P.E.P., *supra* note 16, § 2164.07.

127. *In re* Nelson, 280 F.2d 172 (C.C.P.A. 1960), *overruled on other grounds by In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).

128. *Nelson*, 280 F.2d at 178.

129. *Id.* at 177.

130. *Id.* at 178.

131. *Id.*

2. The Written Description Requirement

The call for a written description has been interpreted as fulfilling a dual purpose in the unpredictable arts.[132] Regardless of discipline, the requirement is first a modifier explaining how the disclosure shall be effected.[133] Where the invention is rooted in the unpredictable arts, the written description has additionally been interpreted as a separate requirement by which the applicant demonstrates an appreciation for the utility and breadth of the invention.[134] Thus, the written description is an independent, and occasionally dispositive, requirement.[135] As a dispositive issue, however, it is rarely raised outside the unpredictable arts.[136]

The written description is the mechanism whereby the applicant establishes that he or she was in possession of *the invention* at the time of filing. That is, the application, taken together with the prior art, should explicitly document the

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132. *See, e.g.*, Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560-61 (Fed. Cir. 1991).

133. *Id.*

134. *Id.* at 1561.

135. *In re* Bowen, 492 F.2d 859, 864 (C.C.P.A. 1974); *see also In re* Barker, 559 F.2d 588 (C.C.P.A. 1977), *cert. denied*, 434 U.S. 1064 (1978).

136. *Cf. Barker*, 559 F.2d at 594 (Markey, Chief J., dissenting). In *Barker*, the court sustained a section 112 written description rejection in an uncomplicated mechanical case. *See generally In re* Barker, 559 F.2d 588 (C.C.P.A. 1977), *cert. denied*, 434 U.S. 1064 (1978). Judge Markey disagreed with the imposition of this "separate description requirement" in such cases. *Id.* at 594 Nonetheless, he acknowledged the propriety of such a separate description requirement in complex chemical cases. *Id.*

Unlike mechanical inventions, a description of a new composition of matter does not necessarily carry with it a description of how to make or how to use the invention, or its reasonable equivalents. *See, e.g., In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970). When this is so, it is incumbent upon applicant to show that he or she was in possession of the invention at the time of filing by demonstrating an appreciation for the utility and breadth of the invention as now claimed. *See In re* Nelson, 280 F.2d 172, 184-85 (C.C.P.A. 1960).

As a practical matter, however, the written description requirement cannot be wholly divorced from the enablement and how-to-use requirements, for if they are not met, surely the written description requirement is not met. Thus, reliance on the call for a written description as a separate requirement should be made sparingly.

utility of the invention, how to make and use the invention, and the contemplated breadth of the invention.[137]

Courts have held that an applicant can satisfy the enablement and how-to-use requirements, yet fail to comply with the written description requirement.[138] This is further confirmation that the written description requirement is distinct from the enablement or how-to-use requirements.[139]

The issue of compliance with a separate written description requirement might arise through the practice of amending claims during the course of prosecuting a patent application.[140] By way of such amendments, an applicant redefines *the invention*; in so doing, the applicant might fortuitously teach *how to use* the invention and *enable* its use, without actually disclosing that particular invention in the original application.[141] In other words, the addition of the limitation within the claim might *enable* the claimed invention, and the pre-existing disclosure might have taught *how to use* the invention, but the new limitation, if unsupported by the writ-

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137. In a mechanism that is beyond the scope of this Article, applicants may alternatively fulfill the "written description" requirement in the case of biological materials by making a deposit of the material in a recognized depository. *See generally* M.P.E.P., *supra* note 16, § 2402.

138. *See, e.g.*, *Vas-Cath*, 935 F.2d at 1561-62 (citing *In re* Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989); Utter v. Hiraga, 845 F.2d 993, 998 (Fed. Cir. 1988); *Barker*, 559 F.2d at 591; *In re* DiLeone, 436 F.2d 1404, 1405 (C.C.P.A. 1971) ("[I]t is possible for a specification to *enable* the practice of an invention as broadly as it is claimed, and still not *describe* that invention.") (emphasis in original).

139. *Vas-Cath*, 935 F.2d at 1563. In *Vas-Cath*, the Federal Circuit concluded that:

> The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; 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*.

Id. at 1563-64.

140. *See, e.g.*, *In re* Kaslow, 707 F.2d 1366, 1372 (Fed. Cir. 1983); *see also In re* Smith, 481 F.2d 910, 914 (C.C.P.A. 1973).

141. *See, e.g.*, Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) ("The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*.").

ten description of the specification as filed, might not have been appreciated as material to a description necessarily circumscribing the invention.[142]

When the original disclosure lacks supporting disclosure that is material to the disclosure of the invention, such amendments constitute an impermissible attempt to introduce *new matter* to the application.[143] This issue typically arises where a particular feature is subsequently recognized as imparting a distinct patentable advantage, or is necessary to overcome a prior art reference or other barrier to patentability. For example, an applicant might attempt to amend a claim during examination (or reissue) of the application;[144] alternatively, an applicant might claim the benefit

142. *See generally Ex parte* Grasselli, 231 U.S.P.Q. (BNA) 393 (Pat. Bd. App. & Inf. 1983), *on request for rehearing*, 231 U.S.P.Q. (BNA) 395 (Pat. Bd. App. & Inf. 1983), *aff'd*, 738 F.2d 453 (Fed. Cir. 1984) (unpublished).

143. The introduction of *new matter* into a patent application is prohibited by statute. 35 U.S.C. §§ 132, 251 (1994); *see also* M.P.E.P., *supra* note 16, § 706.03(o) (governing rejections based upon "new matter"). A brief but informative description of the term and discussion of the prohibition is found in *In re Oda*:

> 'New matter' is a technical legal term in patent law—a term of art. Its meaning has never been clearly defined for it cannot be. The term is on a par with such terms as infringement, obviousness, priority, abandonment and the like which express ultimate legal conclusions and are in the nature of labels attached to results after they have been reached by processes of reasoning grounded on analyses of factual situations. In other words, the statute gives us no help in determining what is or is not 'new matter.' We have to decide on a case-by-case basis what changes are prohibited as 'new matter' and what changes are not.

443 F.2d 1200, 1203 (C.C.P.A. 1971); *see also* CHISUM, *supra* note 6, § 7.04[1]. As this passage suggests, a determination of what constitutes *new matter* is a complex and fact specific endeavor. *See id.* While a detailed treatment of the subject is beyond the scope of this Article, it is helpful to recall the public policy objectives underlying disclosure. *See supra* notes 26-40 and accompanying text. The type of *new matter* that is proscribed by the Patent Act is that which is not otherwise available to one of ordinary skill in the art. *See* 35 U.S.C. §§ 132, 251. That is, if the subject matter sought to be introduced to the application is such that it would not have been readily available from the prior art nor obvious to one of ordinary skill in the art over the teaching of the specification taken together with the prior art, it is likely to be found to be *new matter*. *See id.* Viewed from this perspective, *new matter* is the inverse of enablement. *See infra* part II.B.2.b (discussing enablement more fully).

144. *See, e.g.*, *In re* Glass, 492 F.2d 1228, 1232 (C.C.P.A. 1974) (finding that

of the earlier filing date of a related application[145] when, in fact, the applicant introduced in a later-filed application a written description of the invention that he or she now claims.[146] This later scenario might arise when an applicant claims the benefit of an earlier priority date in the U.S. counterpart of a foreign filed application, or in a domestic continuation-in-part application.[147]

Because of the benefits and advantages conferred on an applicant as of the filing date of the application,[148] courts and the PTO measure enablement as of the filing date and strictly prohibit applicants from later introducing into the application new matter that is material to the invention.[149]

3. Enabling One to Make and Use the Invention

Beyond the formal requirement of a written description, an applicant's disclosure must *enable* one of ordinary skill in the art to *make and use* the invention.[150] Although these two facets of disclosure—enablement and how to make and use the invention— are often addressed interchangeably, they are distinct requirements.[151] The two requirements are also rightly, but sometimes confusingly, addressed when the utility of the invention is at issue.[152] This sub-section first dis-

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disclosure cannot be made sufficient while the application is pending by later publications which enable the invention).

145. The related application may be filed under either sections 119 or 120.

146. *See, e.g.*, *Glass*, 492 F.2d at 1232.

147. *See, e.g.*, *id.*

148. *See, e.g.*, *id.* (noting that the filing date becomes a date of constructive reduction to practice).

149. *See, e.g.*, *id.*; *Oda*, 443 F.2d at 1203-04; *see also* 35 U.S.C. §§ 132, 251; 37 C.F.R. § 1.118 (1996); M.P.E.P., *supra* note 16, § 608.04.

150. 35 U.S.C. § 112.

151. *See generally* CHISUM, *supra* note 6, § 7.03[5] (discussing the how-to-make requirement), § 7.03[6] (discussing the how-to-use requirement).

152. *Id.* at § 7.03[6]. As explained in the Chisum treatise:

> There is a close relation between the how-to-use aspect of the enablement requirement under [s]ection 112 and the utility requirement under [s]ection 101. If a patent claim fails to meet the utility requirement because it is not shown to be useful or operative, then it equally fails to meet the how-to-use aspect of the enablement requirement.

Id.

cusses the more particular how-to-make-and-use requirements, and second the more general enablement requirement.

a. The How-to-Make and How-to-Use Requirements

The how-to-make requirement demands that the disclosure be sufficiently complete so as to teach one of ordinary skill in the relevant art how to make the invention.[153] The requirement principally addresses the disclosure of essential starting materials to ensure public availability consistent with the objectives of the patent system.[154]

The issue of compliance with the how-to-use requirement of section 112 often arises in the context of establishing an appreciation for the utility of an invention.[155] According to the C.C.P.A., the test for compliance is what the application communicates, implicitly and explicitly, to the skilled practitioner.[156]

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153. *See generally id.* § 7.03[5].

154. *Id.* (suggesting that the application of the how-to-make requirement, in the context of the unpredictable arts, principally addresses the need for the deposit of biological materials in a public depository as a means for complying with the various requirements of the first paragraph of section 112). That subject is outside the scope of this Article, and is not addressed further.

155. *See, e.g., In re* Nelson, 280 F.2d 172 (C.C.P.A. 1960).

156. *Nelson*, 280 F.2d at 184-85. In *Nelson*, the court stated:

> [T]he test is what the application as a whole *communicates* to one skilled in the art. In some cases an applicant may, merely by naming his new instrument or material, indicate *what* its use is, as, for example, by saying he has invented a 'match,' 'hammer,' 'paint,' 'adhesive,' or 'detergent.' He may or may not have to go further in order to *enable* others to use the invention, depending on its nature and how much those of ordinary skill in the art know. In other words, compliance with the law does not necessarily require specific *recitations* of use but may be inherent in description or may result from disclosure of a sufficient number of properties to make a use obvious; and where those of ordinary skill in the art will know *how* to use, the applicant has a right to rely on such knowledge. If it will not be sufficient to enable them to use his invention, he must supply the know-how. As this court has often said before, each case must be judged on its own facts.

Id. (emphasis added).

Failure to disclose how to use the invention is an occasionally fatal infirmity in the unpredictable arts.[157] In *In re Kirk*,[158] for example, the C.C.P.A. held that the applicants had failed to disclose how to use their invention, by describing their invention merely as a new class of compounds *often possessing high biological activity*.[159] In substance, the court agreed with the examiner that what the "applicants are really saying to those in the art is take these steroids, experiment, and find what use they do have as medicines."[160] The examiner had refused to consider the applicants' affidavit showing that three of the claimed compounds do, in fact, possess specific anabolic, anti-inflammatory, or glucocorticoid activity, or usefulness as oral progestational agents.[161] The court agreed, characterizing the affidavit as "simply an ex post facto affirmation irrelevant to the issue of adequacy of the original disclosure inasmuch as it attempts to add statements of usefulness to the disclosure of the application as filed."[162]

Implicit in the *Kirk* court's reasoning is the recognition that the affidavit established that the claimed compounds possessed utility.[163] The claims were thus directed to patentable subject matter in compliance with section 101. The

157. *See, e.g.*, *In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).

158. 376 F.2d 936 (C.C.P.A. 1967).

159. 376 F.2d at 938. In *Kirk*, the court explained:

> It seems to us that the nebulous expressions 'biological activity' or 'biological properties' appearing in the specification convey no more explicit indication of the usefulness of the compounds and how to use them than did the equally obscure expression 'useful for [sic] technical and pharmaceutical purposes' unsuccessfully relied upon by the appellant in *In re* Diedrich.

Id. at 941 (citation omitted); *cf. In re* Johnson, 282 F.2d 370, 371 (C.C.P.A. 1960) (satisfying the how-to-use requirement by stating "the products of the aforesaid process are valuable as chemical intermediates for organic synthesis, for solvent uses and *for the preparation of toxic substances such as insecticides, fungicides*, etc.") (emphasis added).

160. *Kirk*, 376 F.2d at 940.

161. *Id.*

162. *Id.* at 941.

163. *See generally id.* at 940-41.

fatal infirmity, however, was the applicants' failure to include the recitation of utility in the original disclosure.[164] The proscription against adding new matter prevented the applicants from entering the information into the disclosure during examination.[165] Thus, the application, as originally filed, failed to teach how to use the invention.[166] Notwithstanding, the *Kirk* court affirmed the examiner's rejection of the claims under *both* sections 101 and 112.[167]

Kirk perpetuated the confusion between Sections 101 and 112 that the *Nelson* court had attempted to eliminate.[168] In *Nelson*, the court built upon its own precedent, *In re Bremner*,[169] which, while eschewing any "hard and fast" rule on disclosure of "utility" in a specification, held that the law required "*an assertion of utility and an indication of the use or uses intended*."[170] The *Nelson* court observed that *Bremner* had already established that "applicants' specification *has to indicate the intended use or uses*, which is a requirement distinct from the mere *possession* of 'utility.'"[171]

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164. *Id.* at 941.

165. *See* 35 U.S.C. § 132 (1994); 37 C.F.R. § 1.118 (1996); M.P.E.P., *supra* note 16, § 608.04.

166. *Kirk*, 376 F.2d at 940-41.

167. *Id.* at 941-42.

168. *Nelson*, 280 F.2d at 183.

169. 182 F.2d 216 (C.C.P.A. 1950).

170. *Nelson*, 280 F.2d at 183 (quoting *Bremner*, 182 F.2d at 217) (emphasis in original). The court clarified the precedential value of *Bremner* by explaining:

> The first law point discussed in the *Bremner* opinion was that a patent specification is required by law to assert 'utility' and the factual finding was that it did not. We find on review of the record that the court was mistaken in saying there was no assertion of utility, for the opening statement of the Bremner et al. specification was that the invention was '*new and useful*.' Upon reflection, we are now of the opinion that a *mere assertion* of utility in a specification is a meaningless formality and no more required by law than an assertion of novelty. We think it only reasonable to infer from the fact of filing an application that the applicant asserts that the invention is new and useful, for unless it is both he has no right to a patent.

Id. at 183 n.4 (emphasis added) (citations omitted).

171. *Id. But see* M.P.E.P., *supra* note 16, § 2164.07 (suggesting that section 101 requires that some use be set forth for the invention, and that the use be provable

Nelson suggests that an invention either does or does not inherently possesses utility under section 101,[172] irrespective of an applicant's compliance with the disclosure requirement.[173] It follows, then, that evidence of utility is entitled to consideration at any time; it is not subject to the proscription against the introduction of new matter.[174] If, however, the disclosure fails to describe, implicitly or explicitly, an appreciation for that utility and how to use the invention, the applicant has not complied with the first paragraph of section 112—an infirmity that cannot be corrected by an *ex post facto* (or *nunc pro tunc*) affidavit, or any other evidence extrinsic to the application.[175]

b. The Enablement Requirement

As with the how-to-make-and-use requirements, the general enablement requirement has a utility component, in that the applicant must supply others with the means or knowledge necessary to successfully exploit the invention.[176]

This Article proposes that satisfaction of the enablement requirement is properly addressed after confirming satisfaction of both the written description requirement and the how-to-use requirement. For example, the invention might possess utility (section 101); in addition, the applicant might have correctly contemplated and expressed that utility (written description); finally, the applicant also might have de-

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and not against public policy). *Nelson* characterizes the section 101 requirement as satisfied by the mere *possession* of utility regardless what is "set forth." *See Nelson*, 280 F.2d at 183.

172. *Nelson*, 280 F.2d at 183.

173. *Id.* at 184. In *Nelson*, the court acknowledged:

> Much confused thinking on this matter has resulted from a failure to separate the requirement of [s]ection 101 that an invention *be* useful from the [s]ection 112 requirement that a specification shall so explain 'the manner and process of . . . using' the invention as to 'enable any person skilled in the art . . . to . . . use the same.'

Id.

174. *See, e.g.*, *id.*

175. *Kirk*, 376 F.2d at 941.

176. *See, e.g., In re* Cook, 439 F.2d 730 (C.C.P.A. 1970).

scribed the manner in which that utility can be exploited (how-to-use). Nonetheless, the applicant must also supply the means or knowledge necessary to actually exploit the claimed invention in its entirety (enablement).[177]

i. Inoperative Embodiments

The utility/how-to-use/enablement conundrum comes to the fore in rejections alleging that the claim embraces inoperative embodiments. Extension of the invention beyond illustrated embodiments involves inductive reasoning.[178] Extrapolating from demonstrated specifics, the inventor proposes, explicitly or implicitly, a more general theory to claim the invention broadly.[179] These broader claims incorporate a generalization of the invention, or specify contemplated alternative functional components or features (what the patent practitioner refers to as "equivalents").[180] Such extrapolation is a path riddled with pitfalls. The traditions of scientific inquiry caution small, incremental steps,[181] while inventors occasionally urge large, inferential leaps.[182]

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177. *Cf. Cook*, 439 F.2d at 736 ("Section 112 requires not that the specifications merely say how to use the claimed invention, but that such teaching be true, i.e. in fact enabling.").

178. *See* Wilson Sporting Goods v. David Geoffrey & Assocs., 904 F.2d 677, 683-85 (Fed. Cir.), *cert. denied*, 498 U.S. 992 (1990).

179. *Id.*

180. *See* Valmont Indus., Inc. v. Reinke Mfg. Co., 983 F.2d 1039, 1043-45 (Fed. Cir. 1993).

181. *Cf.* REMINGTON'S PHARMACEUTICAL SCIENCES 8 (Alfonso R. Gennaro et al. eds., 1985) (extolling the fundamentals of the scientific method seen in the writings and practices of Hippocrates and followers—that is, observation and classification, rejection of unsupported theory and superstition, and a cautious generalization and induction that remained open to critical discussion and revision).

182. *See, e.g.*, Consolidated Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 472 (1895). In addressing a charge of infringement against Edison for his use of particular fibrous portions of bamboo plant in his new long lasting electric light bulbs, the court stated (despite the complainant's prior art patent teaching the use of "fibrous" material but with only narrow exemplification):

> Is the complainant entitled to a monopoly of all fibrous and textile materials for incandescent conductors? If the patentees had discovered in fibrous and textile substances a quality common to them all, or to them generally, as distinguishing them from other materials, such as minerals, etc., and such quality or characteristic adapted them peculiarly to

Inductive reasoning presents particular problems in the unpredictable arts.[183] In predictable cases, equivalents—alternative but functional features—can be envisioned *a priori*. Unpredictability is wrought by the inability to so envision such equivalents. Likewise, an applicant might be unable to draw an "obvious" equivalent from the prior art.[184] One reason for this inability might be that there is less art from which to draw; alternatively, the applicant might be unable to draw an obvious equivalent because the teachings of the relevant art are inapplicable to the peculiarities of the present invention.

Claims resulting from inductive reasoning in the unpredictable arts raise the possibility that *the invention* does not

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> incandescent conductors, such claim might not be too broad. . . . Sawyer and Man supposed they had discovered in carbonized paper the best material for an incandescent conductor. Instead of confining themselves to carbonized paper, as they might properly have done, and in fact did in their third claim, they made a broad claim for every fibrous or textile material, when in fact an examination of over 6,000 vegetable growths showed that none of them possessed the peculiar qualities that fitted them for that purpose. Was everybody, then, precluded by this broad claim from making further investigation? We think not.

Id. at 472; *see, e.g.*, Todaro, *supra* note 13, at 37 ("Applicants in the field of biotechnology often seek claims that are undeniably broad in the light of the specification.").

183. *Cf.* CHISUM, *supra* note 6, § 7.03[4][d] ("A recurring problem is whether a specification that sets forth a single or a limited number of examples can be enabling of broad claims when the subject matter concerns biological materials or reactions, which are generally considered to be unpredictable.").

184. *See* Charles L. Gholz, *Recent Developments in the C.C.P.A. Relating to the First Paragraph of 35 U.S.C. § 112 (Conclusion)*, 55 J. PAT. OFF. SOC'Y 1, 4 (1973). According to one commentator:

> It should be noted that 'obvious' in the [section] 112 sense does not mean the same things as 'obvious' in the [section] 103 sense. While the authorities are not uniform, the majority view appears to be that the 'person skilled in the art' referred to in . . . [section] 112 is *not* presumed to know all the obscure, arcane art presumed to be known by [section] 103's 'person having ordinary skill in the art.'

Id. at 20 n.152 (citation omitted). *But see* CHISUM, *supra* note 6, § 7.03[2](a), (b) ("Although few decisions consider the question explicitly, it would seem that the 'person skilled in the art" within the meaning of section 112 is the same as the person having "ordinary skill in the art' within the meaning of Section 103 on nonobviousness.").

possess the utility alleged throughout the claimed scope.[185] In the past, this possibility resulted in enablement rejections alleging that the claims would be expected to embrace inoperative embodiments.[186] As explained below, however, the proper inquiry is twofold. The first question is whether the invention possesses the specified utility throughout the scope of the claim, regardless of whether there are inoperative embodiments within that scope. The second question is whether one of ordinary skill in the relevant art could exploit that utility throughout the scope of the claim on the strength of the applicant's disclosure.

ii. Constructively Inoperative, Actually Inoperative, and the Burden of Proof

Claims have suffered enablement rejections for being either constructively or actually possessed of inoperative embodiments.[187] Those rejections would arise, for example, when an applicant claims that an invention has a particular range of application without presenting confirming data. To avoid granting broad exclusivity on the basis of unsupported statements, the PTO might challenge the application's enablement by alleging that the claims would be expected to embrace inoperative embodiments. To do so successfully, the PTO must either show that the supporting

185. *See generally* Herbert H. Goodman, *The Invalidation of Generic Claims for Inclusion of a Small Number of Inoperative Species*, 40 J. PAT. OFF. SOC'Y 745 (1958) (outlining some of the "unique problems" arising in drafting chemical claims involving inductive reasoning from limited examples).

186. *Id.*; *see also* Gholz, *supra* note 184 (addressing clarification in the "Broad-Enough-to-Read-on-Inoperative-Subject-Matter-Rejections); H. Einhorn, *The Enforceability of Patent Claims Encompassing Some Inoperative Species*, 45 J. PAT. OFF. SOC'Y 716 (1963).

187. This Article uses the term, constructively inoperative, in reference to claims which could be construed as embracing inoperative embodiments, but which such embodiments would not be selected by one of ordinary skill in the art because it would be apparent, *a priori*, that such embodiments would be inoperative; use of "actually inoperative" refers to claims embracing inoperative embodiments but where it is not possible to discern which embodiments will be inoperative, *a priori*. The significance of the distinction is discussed further below.

statements are inaccurate, or explain why the written description does not enable the invention throughout the scope of the claim.[188]

Before the C.C.P.A. had definitively resolved this issue, one commentator suggested that the likelihood of success of a challenge to the validity of a patent on the grounds of inclusion of inoperative embodiments in an infringement context was a function of equity.[189] In other words, the commentator posited that courts would strive to preclude an accused infringer from successfully asserting an inoperative-embodiments challenge when the infringer was exploiting the invention consistent with the plain teaching of the patent.[190]

Another commentator noted that "[t]he inventor gains nothing, nor is the public foreclosed, by claiming 'more than the invention' where the 'more' is inoperative subject matter."[191] Nonetheless, the commentator conceded that a claim including inoperative-embodiments might properly be held invalid "where most of the embodiments are inoperative, or where it is impossible or very difficult for one skilled in the art to determine whether a material is operative."[192]

In a span of two years, the C.C.P.A. decided four logi-

188. *See In re* Marzocchi, 439 F.2d 220, 224 (C.C.P.A. 1971) ("[I]t is incumbent upon the Patent Office, whenever a rejection on this basis [scope of enablement commensurate with scope of protection sought] is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure. . . ."); *accord Bowen*, 492 F.2d at 862 ("It is clear that even in cases involving the unpredictable world of chemistry such reasons are required."); *Ex parte* Gastambide, 189 U.S.P.Q. (BNA) 643, 645 (Bd. Pat. App. & Int. 1975) ("Proper grounds for rejection require more than unsubstantiated doubt as to the operability of the invention."); *see also* U.S. PATENT & TRADEMARK OFFICE, OVERVIEW OF LEGAL PRECEDENT GOVERNING THE UTILITY REQUIREMENT ¶ II.C (1995) [hereinafter PTO LEGAL OVERVIEW: UTILITY]).

189. *See generally* Einhorn, *supra* note 186.

190. *See generally id.*

191. Goodman, *supra* note 185, at 749.

192. *Id*; *see also* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 336 U.S. 271, 276-77 (1949) (holding that claims may be too broad "to the point of invalidity" by reason of reading on significant numbers of inoperative embodiments).

cally-connected cases that together confirm that neither the potential nor the actual existence of inoperative embodiments necessarily defeats a claim:[193] (1) *In re Skrivan*,[194] (2) *In re Cook*,[195] (3) *In re Marzocchi*,[196] and (4) *In re Fouche*.[197]

In the first decision, *In re Skrivan*, the C.C.P.A. addressed constructively inoperative embodiments. The applicant had claimed certain improvements in the "plasma-jet" process for making finely-divided metal oxides for use in pigments.[198] The PTO had rejected several of the claims under section 112 as being "unduly broad" in failing to include a limitation alleged to be necessary to operation of the process.[199] The examiner's undue breadth rejection was predicated on the applicant's failure to recite within the claim the angle at which the two reactant-containing streams were combined.[200] The *Skrivan* court observed that neither were the claims indefinite, nor had the applicant suggested that the claims defined anything other than what the applicant regarded as his invention.[201] Moreover, the *Skrivan* court

193. *See, e.g.*, *In re* Cook, 439 F.2d 730 (C.C.P.A. 1970). In *Cook*, the court observed:

> While we have held that 'the mere *possibility* of inclusion of inoperative . . . [subject matter] does not prevent *allowance* of broad claims,' when the examiner sets forth reasonable grounds in support of his conclusion that an applicant's claims may read on inoperative subject matter (other than subject matter inoperative only in the sense of *In re Skrivan*) . . . it becomes incumbent upon the applicant either to reasonably limit his claims to the approximate area where operativeness has not been challenged or to rebut the examiner's challenge either by the submission of representative evidence, or by persuasive arguments based on known laws of physics and chemistry . . . .

439 F.2d at 734-35 n.4 (citations omitted); *see also In re* Barr, 444 F.2d 588 (C.C.P.A. 1971); *In re* Fouche, 439 F.2d 1237 (C.C.P.A. 1971); *In re* Marzocchi, 439 F.2d 220 (C.C.P.A. 1971); *see generally* Gholz, *supra* note 184.

194. 427 F.2d 801 (C.C.P.A. 1970).

195. 439 F.2d 730 (C.C.P.A. 1970).

196. 439 F.2d 220 (C.C.P.A. 1971).

197. 439 F.2d 1237 (C.C.P.A. 1971).

198. *Skrivan*, 427 F.2d at 802.

199. *Id.*

200. *Id.* at 805.

201. *Id.* at 805-06.

emphasized that the disputed limitation dealt with a routine operating condition of an admittedly old aspect of the process.[202] Such limitations, the court held, must be presumed to be within the level of ordinary skill in the relevant art.[203]

In short, the *Skrivan* court held that claims that might be construed as including inoperative embodiments are not necessarily unpatentable.[204] If it would have been obvious to one skilled in the relevant art that the embodiments otherwise allowed by the claim would be inoperable, one skilled in the art would not resort to such embodiments, and the presence of such embodiments should not preclude allowability of the claim.[205]

Similarly, the C.C.P.A. has held that where such an ambiguity is not central to the invention, there is likewise little risk of encroachment on the public interest, and the claims may be allowed.[206]

The C.C.P.A. elaborated on *Skrivan* in *In re Cook*. The claims in *Cook*, directed to zoom lens assemblies, stood rejected under the first paragraph of section 112. Among other things, the claims were supported by six exemplary embodiments. The *Cook* court acknowledged that the optical design of such lens assemblies is extremely complex, involving the manipulation of more than 100 related variables.[207] The *Cook* court acknowledged that the PTO may reject claims merely because they read on "one or more inoperative species,"[208] but noted that many properly patented claims do

202. *Id.* at 806.

203. *Skrivan*, 427 F.2d at 806 ("We hold that claims need not recite such factors where one of ordinary skill in the art, to whom the specification and claims are directed, would consider them obvious.").

204. *Id.*

205. *Id.*

206. *See, e.g.*, *In re* Stephens, 529 F.2d 1343, 1345 (C.C.P.A. 1976) ("Noncritical features of the invention may be supported by a more general disclosure than those at the heart of the invention.").

207. *Cook*, 439 F.2d at 731.

208. *Id.* at 734 (citing Graver Tank & Mfg. Co. v. Linde Air Products Co., 336 U.S. 271, 276-77 (1949)).

not exclude inoperative embodiments, because one skilled in the relevant art might reasonably be presumed to appreciate those factors that would lead to inoperative embodiments.[209]

Notwithstanding its recognition that inoperative embodiments do not necessarily preclude patentability of claims, the court affirmed the PTO's rejection of Cook's claims.[210] The court characterized the examiner's rejection for insufficient disclosure under section 112 as twofold: (1) because it would take one skilled in the art many months to

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209. In *Cook*, the court explained:

> We see no reason why the Patent Office and the courts deciding infringement litigation should not 'have authority to reject a broad claim merely because it . . . [reads on a significant number of] inoperative species.'
>
> However, many patented claims read on vast numbers of inoperative embodiments in the trivial sense that they can and do omit 'factors which must be presumed to be within the level of ordinary skill in the art,' and therefore read on embodiments in which such factors *may* be included in such a manner as to make the embodiments inoperative. There is nothing wrong with this so long as it would be obvious to one of skill in the relevant art how to include those factors in such manner as to make the embodiment operative rather than inoperative.

Id. at 734-35 (alternation in original) (citations omitted); *accord In re* Geerdes, 491 F.2d 1260, 1265 (C.C.P.A. 1974) ("Of course, it is possible to argue that process claims encompass inoperative embodiments on the premise of unrealistic or vague assumptions, but that is not a valid basis for rejection."); *In re* Smythe, 480 F.2d 1376 (C.C.P.A. 1973). In *Smythe*, the court noted that:

> The use here of any particular 'liquids' which would be inoperative, such as the examples given by the board—'colored materials,' materials 'adherent to the walls of the sight tube,' and 'liquid wetting agents'—would be predictably inoperative in the invention and thus would never be selected by one skilled in the art. As we have said before, it is almost always possible to so construe a claim as to have it read on inoperative embodiments, but the alternative of requiring an applicant to be so specific in his claims "as to exclude materials known to be inoperative and [which] even those not skilled in the art would not try" would result in claims which would fail to comply with [section] 112, second paragraph, because they would be so detailed as to obscure, rather than to particularly point out and distinctly claim, the invention.

480 F.2d at 1385 (citations omitted); *see also Ex parte* Vollheim, 191 U.S.P.Q. (BNA) 407, 408 (Bd. Pat. App. & Int. 1975) ("It is not a function of the claims to specifically exclude either possible inoperative conditions or ineffective reactant proportions.").

210. *Cook*, 439 F.2d at 736 (holding that the PTO had properly rejected the claims).

design other lenses that came within the claim, and (2) because the six examples were not representative of the ranges recited in the claims.[211] Under the examiner's first rationale, the *Cook* court found for the applicants.[212] Although the applicants conceded that the claims encompassed a large number of inoperative embodiments, the court found that a person skilled in the relevant art could determine *a priori*, albeit through lengthy calculations, which embodiments would be inoperative.[213]

Under the examiner's second rationale, however, the *Cook* court ruled against the applicants.[214] The court held that the applicants had represented, at least implicitly through their application, that operative embodiments resided throughout the claimed ranges, but that the corresponding ranges found in the examples were not coextensive with the claimed ranges.[215] The court found that, when challenged on this point by the PTO, the applicants failed to provide evidence supporting the recited ranges,[216] and accordingly affirmed the examiner's rejection.[217]

The court held that although one skilled in the relevant art would have known *a priori* that certain embodiments within the claimed ranges of variables would be *inoperative*, the applicants failed to show that embodiments could be made throughout the claimed ranges that would be *operative*.[218] The court further held that the conceded existence of

211. *Id.* at 732.

212. *Id.* at 732-33.

213. *Id.* at 735; *see also* Tyler v. City of Boston, 74 U.S. 327, 330 (1868) (observing that the effects of a machine consisting of a combination of devices and subject of invention, may be calculated *a priori*, while discovery of a new substance by means of chemical combinations of known materials is empirical and discovered by experiment).

214. *Cook*, 439 F.2d at 735-36.

215. *Id.*

216. *Id.* Finally, on appeal, the applicants made the unsupported statement that they had performed calculations supporting the ranges. *Id.* at 736.

217. *Id.*

218. *Cook*, 439 F.2d at 736.

inoperative embodiments—which the PTO and the court treated as analogous to unpredictability—supported the examiner's challenge, and shifted the burden of proof to the applicants to establish the existence of operative embodiments throughout the ranges claimed.[219]

In *In re Marzocchi*, the C.C.P.A. further refined the proper allocation of the burden of proof, particularly in the context of a chemical case. In *Marzocchi*, the applicants had claimed a technique for improving the adhesion characteristics between glass fibers and vinyl polymer resins by premixing a specified "amine compound" with the polymer resin.[220] Claims six and twelve, which specified "polyethyleneamine" as the amine compound, were rejected under the first paragraph of section 112 as not enabled by the specification.[221] The PTO noted that "[t]he term is obviously generic to a considerable number of compounds."[222] The *Marzocchi* court reversed the rejection, explaining that the PTO had expressed nothing more than concern over the *breadth* of the disputed term.[223] The court held that if the specification supports the claim, and there is no reason to doubt the supporting statements made in the specification, the disclosure must be taken as enabling;[224] that is, where the specification supports the scope of the claim *ab initio*, it is incumbent upon the PTO to disprove or explain *why* it doubts the truth or accuracy of the supporting statements in the specification.[225]

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219. *See id.* (noting that "[a]ppellants asserted that they had 'made calculations which resulted in the definition of the ranges set forth in the specification,' but they never produced those calculations to substantiate the truthfulness of the teaching in their specification which the examiner challenged.").

220. *Marzocchi*, 439 F.2d at 221.

221. *Id.*

222. *Id.* at 223.

223. *Id.*

224. *Id.*

225. *Marzocchi*, 439 F.2d at 223-24. The *Marzocchi* court noted that:

> In the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially

The applicants in *Marzocchi* had complied with the written description requirement by expressly contemplating a certain breadth of the invention, constraining the PTO to put forth credible reasons to rebut such statements.[226] Because the PTO had merely expressed doubt about enablement due to the apparent *breadth* of the term, it failed to meet its burden, and the court reversed the rejection.[227]

> be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof. In any event, it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Id. (footnote omitted); *see also Ex parte* Hitzeman, 9 U.S.P.Q.2d (BNA) 1821, 1822 (Bd. Pat. App. & Int. 1988). According to the *Hitzeman* court: "[w]e are mindful that it is incumbent on the PTO, whenever a rejection on this basis is made, to advance acceptable reasoning or evidence which is inconsistent with enablement. That is, it is incumbent on the examiner to first establish a *prima facie* case of nonenablement." *Id.* (citations omitted).

226. *Marzocchi*, 439 F.2d at 224.

227. *Id.*; *see also In re* Barr, 444 F.2d 588, 589-90 (C.C.P.A. 1971). In *Barr*, the examiner had rejected claims incorporating the terms "5-pyrazolone coupler radical" and "open-chain ketomethylene coupler radical," among others. *Id.* The applicants had filed a lengthy specification including working examples for 25 different 5-pyrazolone coupler radicals. *Id.* at 595. Consistent with usage in the claims, the applicants had used the terms generically within the specification, and thus complied with the written description requirement. *Id.*

The court faulted both the Board and the examiner for failing to identify particular deficiencies whereby the working examples were inadequate to support the claimed genus. *Id.* at 596. The court noted that the PTO proffered no evidence of inoperative compounds within the scope of the claims, nor was there any evidence suggesting that "any significant group of compounds embraced by the claims are so obviously inoperative that we can take judicial notice of the fact." *Barr*, 444 F.2d at 589-90. In reversing, the *Barr* court said:

> Appellants have specifically disclosed how to make and use a large number of compounds and have asserted that other compounds, similar to the compounds specifically disclosed in certain stated respects, may be made and used in the same fashion. We see no reason, on the state of this record, to suspect that their assertion is not accurate or that appellants are not the pioneer inventors they claim to be. Appellants' application runs to 132 pages in the transcript of record, and we are not persuaded that any useful purpose would have been served by extend-

In *In re Fouche*, however, the PTO met its burden. The applicant had presented claims directed to dibenzocycloheptadiene derivatives said to be useful for antidepressant, neuroleptic, and tranquilizing properties.[228] The PTO rejected a generic claim incorporating a Markush group,[229] which expressly included both aliphatic and heterocyclic[230] substituents, under the first paragraph of section 112 for insufficiency of disclosure.[231] In rejecting the claim, the examiner urged that the specification did not enable the use of compounds having heterocyclic moieties.[232] The examiner noted that none of the working examples included heterocyclic moieties, and concluded that one of skill in the relevant art would not expect such embodiments to be operative.[233]

The court acknowledged that the specification was devoid of examples incorporating heterocyclic moieties, and that the applicant failed to provide other evidence supporting the utility of such compounds.[234] Furthermore, the court

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ing it with further working examples.

Id. at 596-97.

228. *Id.* at 1238.

229. A Markush group is a "contrived generic expression where no true generic expression exists. Example: a metal selected from the group consisting of copper, silver, and gold." LANDIS, *supra* note 52, at 528; *see also* Edward C. Walterscheid, *Markush Practice Revisited*, 61 J. PAT. OFF. SOC'Y 270 (1979).

230. Aliphatic refers to organic compounds characterized by straight or branched chain arrangement of the constituent carbon atoms; heterocyclic refers to closed ring chemical substituents having a hetero atom, such as nitrogen or oxygen, integral to the closed ring. *See* N. IRVING SAX AND RICHARD J. LEWIS, SR., HAWLEY'S CONDENSED CHEMICAL DICTIONARY (11th ed. 1987). Here, the terms are used to describe substituents attached to the molecular skeleton of the core pharmacological compound.

231. *Fouche*, 439 F.2d at 1243.

232. *Id.*

233. *Id.*

234. *Id.* The court stated that:

> [T]he inclusion of representative examples is not required to enable a person skilled in the art to use a generic invention. Nevertheless, an applicant must use *some* technique of providing teaching of how to use which is commensurate with the breadth of protection sought by the claim, unless such knowledge is already available to persons skilled in the art.

Id. (emphasis added).

relied on the fact that the PTO had cited a reference that called into question the utility of the claimed compounds when bearing heterocyclic substituents.[235] The court said that reference was sufficient to shift the burden to the appellant, and thus affirmed the rejection.[236]

C. *Undue Experimentation*

The modern enablement inquiry has supplanted the undue breadth and inoperative embodiments rejections.[237] The PTO and judicial opinions now focus on whether one skilled in the art would expect that undue experimentation would be required to practice the invention throughout its scope; in other words, whether the scope of enablement is commensurate in scope with the claim.[238] The development of this inquiry was a significant step in the evolution of the sufficiency of disclosure analysis as applied to the unpredictable arts.[239] This section traces that development.

The evolution of the undue experimentation analysis began in 1970, when the C.C.P.A. contemporaneously found fatal ambiguities in challenges based upon both undue

235. *Fouche*, 439 F.2d at 1243.

236. *Id.*

237. *See supra* parts II.A.1, II.B.2.b. As discussed above, the continued viability of the "undue breadth" rejection is questionable. *See supra* note 114 and accompanying text. *But cf.* CHISUM, *supra* note 6, § 7.03[7] (discussing undue breadth generally). Professor Chisum refers to the "three senses of undue breadth," one of which is a claim encompassing material from the prior art. *Id.* The source of such a rejection is novelty (section 102) and/or obviousness (section 103). *Id.* Consistent with the theme of this Article, use of "undue breadth" does not include that aspect.

238. *See In re* Angstadt, 190 U.S.P.Q. (BNA) 214 (C.C.P.A. 1976) (holding that the PTO bears the initial burden of establishing why a specification is not enabling, and that alleged insufficiencies of disclosure necessitate undue experimentation). One commentator has suggested that there is a dichotomy between the inquiries as to whether undue experimentation would be required or whether the scope of enablement is commensurate with the scope of the claims. Walterscheid (pt. V), *supra* note 14. The inquiries suggest different tests requiring different evidence, and, presumably, capable of yielding different results. This Article treats the inquiries as stated in the text above as coterminous.

239. *See, e.g.*, DeGeorge v. Bernier, 768 F.2d 1318 (Fed. Cir. 1985).

breadth and inoperative embodiments.[240] Although both terms subsequently faded from use, the underlying issue—how to test the scope of enablement against the scope of protection sought—remains.[241]

The evolution that occurred during that era is seen in retrospect in *In re Sichert*.[242] *Sichert* sounded the death knell for challenges based upon inoperative embodiments,[243] and confirmed the arrival of the modern inquiry.[244]

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240. *See, e.g., In re* Barr, 422 F.2d 588 (C.C.P.A. 1971) (undue breadth and inoperative embodiments); *In re* Cook, 439 F.2d 730 (C.C.P.A. 1971) (inoperative embodiments); *In re* Borkowski, 422 F.2d 904 (C.C.P.A. 1970) (concerning undue breadth); *see also In re* Mayhew, 527 F.2d 1229, 1235 (C.C.P.A. 1976) (Baldwin, J., concurring):

> Beginning in 1970, we departed from a vast line of authority which permitted the PTO to reject claims under the second paragraph of [section] 112 for 'undue breadth.' Up to that time, examiners quite frequently determined what they felt the invention was and rejected all claims which were broader than their conception of the invention, using the second paragraph of [section] 112 as the statutory basis. Most often, the examiner's conception of the invention was derived from a reading of an applicant's specification.

Id.

241. *See e.g.*, *In re* Wright, 999 F.2d 1557 (Fed. Cir. 1993).

242. 566 F.2d 1154 (C.C.P.A. 1977).

243. Having seemingly disposed of inoperative embodiments as a valid basis for rejection, *In re Sichert* was the last C.C.P.A. opinion to substantively address the issue in those terms. *But cf.* Hercules Inc. v. Exxon Corp., 497 F. Supp. 661, 682 (D. Del. 1980) ("The third description rule prevents an applicant's claim from covering inoperative as well as operative subject matter.") (citing Graver Tank & Mfg. Co. v. Linde Air Products Co., 336 U.S. 271 (1949)). The M.P.E.P. continues to address the inoperative embodiments rejection. M.P.E.P., *supra* note 16, § 2164.08(b). Nonetheless, the PTO acknowledges that the rejection is often obviated by functional language limiting the claim to operative embodiments.

244. *Sichert*, 566 F.2d at 1161. In *Sichert*, the court said:

> [The rejection] establishes a prima facie case of lack of enablement, a result that would not follow from a showing or allegation of the mere possibility of inclusion of inoperative embodiments in broad claims. Therefore, the burden shifted to appellant to show that one of ordinary skill in the art could practice the invention without *undue experimentation*.

Id. (citations omitted) (emphasis added). Thus, the *Sichert* court explicitly discounted the significance of inoperative embodiments within the ambit of the claim in favor of an examination as to whether undue experimentation would be required.

The term undue experimentation is not new to the sufficiency of disclosure analysis.[245] For example, in *Buckeye Incubator Co. v. Wolf*,[246] the court addressed alleged infringement of patents pertaining to egg hatching.[247] The defendant urged that the method claims were void for indefiniteness.[248] According to the alleged infringer, important features, such as the temperature, humidity, and velocity of air current within certain egg incubators, were not recited within the specification.[249] The alleged infringer further argued that the absence of such features in the patent's disclosure thereby created a patent that was erroneous and misleading.[250] The *Buckeye* court observed, however, that despite the discovery of certain defects in a commercialized prototype incubator, various field experts sent out by the incubator company had been able to remedy those defects.[251] The court thus denied the proposition that the patent was fatally flawed for omitting from the disclosure something known to be necessary to the practice of the invention.[252]

Buckeye presaged the modern inquiry. Its reasoning and, particularly, its use of the term *undue* (as opposed to other modifiers) placed an emphasis on the qualitative aspect of

245. *See generally* Buckeye Incubator Co. v. Wolf, 291 F. 253 (N.D. Ohio 1923).

246. 291 F. at 253.

247. *Id.*

248. *Id.* at 261. At the time *Buckeye* was decided, the controlling law was the Patent Act of 1870, Section 26 [R.S. § 4888]. That section corresponded to current section 112, but it combined in a single paragraph the disclosure requirements of the first paragraph of section 112 with the claim requirements of the second paragraph of section 112. Understandably, the court treats indefiniteness interchangeably with the requirements of disclosure.

249. *Id.*

250. *Id.*

251. *Buckeye*, 291 F. at 261.

252. *Id.* The court rejected the proposition that the patentee had omitted from his disclosures something that was known to be necessary to the practical operation of his method claims. *Id.* In actual experience, persons skilled in the art have not found these disclosures so indefinite and defective as to make the apparatus inoperative without undue experimentation. *Id.*

the experimentation required.[253] Others had suggested that the need for merely *independent* or *extensive* experimentation should nullify patentability.[254] Subsequent decisions have acknowledged the propriety of that qualitative emphasis.[255]

In 1961, the term undue experimentation was resurrected.[256] In *Locklin v. Switzer Bros.*,[257] the patent in issue was directed to resins useful in the manufacture of pigments.[258] The resin ingredients were said to include an aldehyde, a melamine, and a sulfonamide.[259] The accused infringer challenged the sufficiency of the disclosure as inadequate to support a claim for a broad class of melamine derivatives.[260] Specifically, the alleged infringer claimed that "there is no recipe given for the proportions of the entire class of melamine compounds by which one could be certain to obtain the critical result."[261] Nonetheless, the court acknowledged testimony that such a determination involved "a simple, clear test for an ordinary chemist to perform and one that does not require extensive experimentation in order that the precise critical limits be ascertained in a particular case."[262]

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253. *Id.* at 261-62.

254. *See, e.g.*, Consolidated Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 474 (1895) ("If the description be so vague and uncertain that no one can tell, except by independent experiments, how to construct the patented device, the patent is void."); Wood v. Underhill, 46 U.S. 1 (1847) (suggesting that any experimentation nullifies the patent).

255. *Cf. In re* Angstadt, 190 U.S.P.Q. (BNA) 214, 219 (C.C.P.A. 1976) ("The key word is 'undue' not 'experimentation.'").

256. Locklin v. Switzer Bros., 299 F.2d 160 (9th Cir. 1961).

257. 299 F.2d 160 (9th Cir. 1961).

258. *Id.*

259. *Id.* at 162.

260. *Id.* at 167.

261. *Id.*

262. *Locklin*, 299 F.2d at 166. Similarly, in *Minerals Separation, Ltd. v. Hyde*, the Court said:

> Equally untenable is the claim that the patent is invalid for the reason that the evidence shows that when different ores are treated preliminary tests mus[t] be made to determine the amount of oil and the extent of agitation necessary in order to obtain the best results. Such variation of treatment must be within the scope of the claims, and the certainty which the law requires in patents is not greater than is reasonable, hav-

Thus, the court held that ascertaining such specific limits in any particular case did not require extensive or undue experimentation.[263]

Subsequently, undue experimentation was invoked with increasing frequency. Nonetheless, it was not until 1970 that it rose to the level of a structured analytical tool.[264]

> ing regard to their subject matter. The composition of ores varies infinitely, each one presenting its special problem, and it is obviously impossible to specify in a patent the precise treatment which would be most successful and economical in each case. The process is one for dealing with a large class of substances and the range of treatment within the terms of the claims,while leaving something to the skill of persons applying the invention, is clearly sufficiently definite to guide those skilled in the art to its successful application, as the evidence abundantly shows. This satisfies the law.

242 U.S. 261, 270-71 (1916) (citations omitted).

263. *Locklin*, 299 F.2d at 168.

264. *See, e.g.*, *In re* Fisher, 427 F.2d 833 (C.C.P.A. 1970) (identifying the direct relationship between unpredictability and noting the likelihood that undue experimentation will be required). Previously, opinions had merely reiterated the term "undue experimentation" from PTO rejections without explaining how such a conclusion is properly made. *See, e.g.*, Merck & Co., Inc. v. Chase Chem. Co., 155 U.S.P.Q. (BNA) 139, 145 (C.C.P.A. 1967) ("It is, of course, well settled, that a patent is invalid for insufficient disclosure if, in order to practice the invention, a person skilled in the art must resort to elaborate experimentation, independent investigation, or exercise inventive skill.") (citations omitted); *In re* Long, 368 F.2d 892, 894 (C.C.P.A. 1966) ("We are of the view that the minimum amount of disilicide required to bind the oxide particles together can be determined by a skilled metallurgist without an undue amount of experimentation."); *In re* Moureu, 345 F.2d 595, 597 (C.C.P.A. 1965) ("Appellants have not placed one iota of evidence in the record to indicate that one skilled in the art would be able to use their antitubercular compounds effectively without undue experimentation . . . [leaving us] no way of knowing whether an express 'how to use' disclosure is necessary."); *In re* Corneil, 347 F.2d 557, 561 (C.C.P.A. 1965) ("[Although we] do not hold that actual performance of appellants' method would necessarily be a prerequisite to patentability . . . the fact that the method has not been performed compels recognition that other problems not yet uncovered may exist in addition to those discussed."); *In re* Gay, 309 F.2d 769, 774 (C.C.P.A. 1962) ("From the disclosure of appellant's invention as it appears in the specification alone, we feel that one skilled in the art would be enabled to make and use appellant's invention without undue experimentation . . . ."); *see also* PTO DRUG UTILITY GUIDELINES, *supra* note 124, at 568 ("It is not necessary to specify the dosage or method of use if it is obvious to one skilled in the art that such information could be obtained without *undue experimentation*.") (emphasis added).

In *In re Fisher*,[265] the PTO Board of Appeals had rejected for insufficient disclosure Fisher's claims directed to adrenocorticotrophic hormones ("ACTH") having "at least twenty-four amino acids" of a specified sequence.[266] Fisher had disclosed only certain ACTHs having thirty-nine amino acids.[267] The court concluded that this was insufficient to enable one skilled in the relevant art to make ACTHs of anything other than thirty-nine amino acids; consequently, the applicant had not enabled one of skill in the art to make ACTHs of "at least twenty-four amino acids."[268]

In re Angstadt[269] illustrates the further transformation of the enablement inquiry from its focus on inoperative embodiments to undue experimentation. In *Angstadt*, the claimed invention involved a method of catalytically converting hydrocarbons to hydroperoxides.[270] In example six of the disclosure, however, the applicants stated that they had recovered from that reaction mixture an aldehyde rather than a hydroperoxide.[271] The PTO rejected the corresponding claim based upon inoperative examples.[272] The appellate court reversed,[273] acknowledging that "many chemical processes, and catalytic processes particularly, are unpredictable,

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265. 427 F.2d 833 (C.C.P.A. 1970).

266. *Id.* at 838-39.

267. *Id.* at 839.

268. *Id.* at 836. In *Fisher*, the court said:

> [T]he parent specification does not enable one skilled in the art to make or obtain ACTHs with other than 39 amino acids in the chain, and there has been no showing that one of ordinary skill would have known how to make or obtain such other ACTH's without undue experimentation. As for appellant's conclusion that the 25th to 39th acids in the chain are unnecessary, it is one thing to make such a statement when persons skilled in the art are able to make or obtain ACTH having other than 39 amino acids; it is quite another thing when they are not able to do so.

Id.

269. 537 F.2d 498 (C.C.P.A. 1960).

270. *Id.* at 499. For definitions of chemical terminology, see SAX AND LEWIS, *supra* note 74.

271. *Angstadt*, 537 F.2d at 501.

272. *Id.* at 500-01.

273. *Id.* at 505.

and that the scope of enablement varies inversely with the degree of unpredictability involved."[274] Nonetheless, in this case, the applicants' process is "not complicated and there is no indication that special equipment or unusual reaction conditions must be provided when practicing the invention."[275] The applicants had shown that the same metal salt catalyst used in example six was operative, albeit with other starting materials.[276] The *Angstadt* court observed that it was common in the use of catalysts to perform trial runs, even if the end result was uncertain.[277] The court noted that the burden was on the PTO to give reasons why the specification is not enabling, and that a showing that the alleged insufficiencies of the disclosure necessitate *undue* experimentation is part of the PTO's initial burden.[278] Other than the applicants' failure to successfully identify hydroperoxides in the product of example six, the PTO had failed to explain why it doubted the truth or accuracy of the supporting disclosure.[279]

Angstadt is analogous to the court's treatment of the PTO's rejection in *Cook*. In *Cook*, the court observed that it would have been possible for one of skill in the relevant art to determine, *a priori*, which variables would lead to inoperative embodiments, albeit through complex and lengthy calculations.[280] Similarly, in *Angstadt*, the court concluded that it would have been routine to conduct trial runs to determine which of the catalyst/starting material combinations would be operative.[281] That is, although the determination

274. *Id.* at 502 (citations omitted).

275. *Id.* at 503.

276. *Angstadt*, 537 F.2d at 504-05.

277. *Id.* at 504 (noting that some experimentation is acceptable and that the term "experimentation" implies that the success of the activity is uncertain).

278. *Id.*

279. *Id.* (citing *In re* Armbruster, 512 F.2d 676 (C.C.P.A. 1975)); *see also In re* Marzocchi, 439 F.2d 220 (C.C.P.A. 1971).

280. *Cook*, 439 F.2d at 730.

281. *Angstadt*, 537 F.2d at 505 ("In this art the performing of trial runs using different catalysts is 'reasonable,' even if the end result is uncertain . . . .").

could not be made, *a priori*, such routine trial runs were no more burdensome than complex and lengthy calculations as required in *Cook*.[282] Accordingly, the *Angstadt* court reversed the PTO's rejection.[283]

1. Undue Experimentation and its Subsidiary Factors

Just months before *Sichert*, the C.C.P.A. decided *In re Colianni*,[284] in which Judge Miller's concurring opinion expressed collectively the various factors to be included in an undue experimentation inquiry where unpredictable factors pertain.[285] Judge Miller suggested that one should consider: (1) whether the applicant has provided sufficient direction or guidance for any experimentation, and (2) the presence or absence of working examples, (3) the nature of the invention, (4) the state of the prior art, (5) the relative skill of those in the art, (6) the unpredictability of the art, and (7) the breadth of the claims.[286] The Federal Circuit, the C.C.P.A., and the

282. *Cf.* Tyler v. City of Boston, 74 U.S. 327, 330 (1868).
283. *Angstadt*, 537 F.2d at 505.
284. 561 F.2d 220 (C.C.P.A. 1977).
285. *Id.* at 224 (Miller, J., concurring).
286. *Id.* Judge Miller wrote:

> In determining what constitutes undue experimentation, many factors are to be taken into account. The quality of any necessary experimentation would clearly be undue when 'ingenuity beyond that to be expected of one of ordinary skill in the art' is required. Judge Rich's opinion indicates that the quantity of necessary experimentation (i.e., 'a great amount of work') may be undue. However, an extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance. Other factors to be considered are the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Id. (citations omitted). The qualitative aspect of any necessary experimentation had been acknowledged earlier. *See* Matheson v. Campbell, 78 F. 910 (2d Cir. 1897). In *Matheson*, the court found insufficient disclosure in support of claims generically covering the diazotization of sulpho acids derived from coal tar to create aniline colors, notably naphthol-black. *Id.* at 916. The applicants conceded that there were as many as 500 such sulpho acids and that a great many of these would not work in the prescribed process. *Id.* The court concluded that "[s]ome future experimenter will have to make some new discovery, and invent some

PTO have embraced Judge Miller's factors (and others) when analyzing sufficiency of disclosure in disciplines perceived to be possessed of unpredictability.[287]

Ironically, Judge Miller had dissented in *Angstadt*, yet in *Colianni* he provides an artfully crafted statement that brings *Angstadt* in line with *Cook*. The majority in *Angstadt* held that the performance of trial runs was commonplace and thus reasonable.[288] *Angstadt* is thus an extension of *Cook* in that the majority was not dissuaded by the fact that one of ordinary skill in the relevant art would have had to perform trial runs of the claimed process to determine operability. One can see from the court's reasoning that it concluded that such trial runs did not require "ingenuity beyond that to be expected of one of ordinary skill in the art."[289]

The determination of what constitutes undue experimentation must be decided on the facts of each particular case; such a determination also "requires the application of a

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new process, before these other sulpho acids can be transformed into naphthol-black." *Id.*

287. *See, e.g.*, *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (identifying factors to be considered in the undue experimentation inquiry as: (1) the quantity of experimentation necessarily; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims); *Ex parte* Kung, 17 U.S.P.Q.2d (BNA) 1545, 1547 (Bd. Pat. App. & Int. 1990) (identifying as undue experimentation factors: (1) the breadth of the claims; (2) the nature of the invention; (3) the amount of direction or guidance presented; (4) the presence or absence of working examples; and (5) the unpredictability of the art); *Ex parte* Forman, 230 U.S.P.Q. (BNA) 546, 547 (Bd. Pat. App & Int. 1986); *see also In re* Stephens, 529 F.2d 1343, 1345 (C.C.P.A. 1976). In *Stephens*, the court noted:

> The test is whether there is sufficient working procedure for one skilled in the art to practice the claimed invention without undue experimentation. In addition to the presence or absence of a working example, relevant considerations are the nature of the invention, the state of the prior art, and the relative skill of those in that art.

Id. (citation omitted).

288. *Angstadt*, 537 F.2d at 504.

289. 537 F.2d 503; *see also* Minerals Separation v. Hyde, 242 U.S. 261 (1916); Buckeye Incubator, Inc. v. Wolf, 291 F. 253 (N.D. Ohio 1923); *In re* Gay 309 F.2d 769 (C.C.P.A. 1962).

standard of reasonableness, having due regard for the nature of the invention and the state of the art."[290] It is well established that a patent specification need not be a blueprint for practicing the invention.[291] Accordingly, "enablement is not precluded even if some experimentation is necessary, although the amount of experimentation must not be unduly extensive."[292]

Thus, some level of experimentation is to be tolerated, although apparently not so much that it rises to *inventive* experimentation, or that requiring ingenuity beyond one of ordinary skill in the relevant art. Experimentation requiring only routine optimization or screening is not inventive experimentation.[293]

2. Supporting the Generic Claim

As previously noted, the genus-species dichotomy has been problematic for inventors, the PTO, and the courts, particularly when addressing inventions in disciplines per-

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290. *Ex parte* Forman, 230 U.S.P.Q. (BNA) 546 (Bd. Pat. App. & Int. 1986).

291. *See, e.g.*, DeGeorge v. Bernier, 768 F.2d 1318, 1323 (Fed. Cir. 1985) (noting that patent specifications need not be as detailed as production specifications).

292. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

The Board of Patent Appeals and Interferences has explained that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Forman, 230 U.S.P.Q. at 547.

293. *See, e.g.*, *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) ("Enablement is not precluded by the necessity for some experimentation such as routine screening.") (citations omitted); *Locklin*, 299 F.2d at 166. The *Locklin* court stated:

> There is testimony to the effect that 'sufficient melamine to render the resin substantially insoluble' is a simple, clear test for an ordinary chemist to perform and one which does not require extensive experimentation in order that the precise critical limits be ascertained in a particular case. Under such circumstances, the fact that some preliminary testing is required does not render the claim invalid for vagueness.

Id. (citing Minerals Separation, Ltd. v. Hyde, 242 U.S. 261 (1916)).

ceived to be unpredictable.[294] This sub-section focuses on several cases illustrating failed attempts to support genus claims with discrete species claims.

In *Ex parte Diamond*,[295] the PTO Board of Appeals had specifically held that an applicant shall not secure exclusive rights to a broad generic invention on the basis of broad unsupported statements.[296]

In 1968, the Commissioner of Patents issued Guidelines for Considering Disclosure of Utility in Drug Cases ("Guidelines").[297] With regard to establishing *utility* of genus claims, the Guidelines clarified the rule from *Ex parte Diamond*, explaining that unsupported generalizations must be taken at face value, unless there is some basis for doubting them.[298]

In *Hercules Inc. v. Exxon Corp.*,[299] the court addressed the sufficiency of disclosure of broad genus claims, and acknowledged the principle that the specification must support the utility of claimed compounds throughout the scope

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294. *See supra* notes 55-90 (discussing application of the disclosure requirement to the unpredictable arts).

295. 123 U.S.P.Q. (BNA) 167 (Bd. Pat. App. & Int. 1959).

296. In *Diamond*, the Board of Patent Appeals and Interferences said:

> An applicant may not preempt an unduly large field by the expedient of making broad prophetic statements in the specification and claims unless the accuracy of such statements is sufficiently supported by well established chemical principles or by sufficient number of examples.

Id. at 168.

297. U.S. PATENT AND TRADEMARK OFFICE, GUIDELINES FOR CONSIDERING DISCLOSURES OF UTILITY IN DRUG CASES (1968).

298. The Guidelines stated that:

> [R]epresentative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if it would be deemed likely by one skilled in the art, in view of contemporary knowledge in the art, that the claimed genus would possess the asserted utility. Proof of utility will be required for other members of the claimed genus only in those cases where adequate reasons can be advanced by the examiner for believing that the genus as a whole does not possess the asserted utility.

PTO DRUG UTILITY GUIDELINES, *supra* note 124, at 568; *see also* M.P.E.P., *supra* note 16, § 2107.02.

299. 497 F. Supp. 661 (D. Del. 1980).

of the claim.[300] In what the court loosely characterized as an *exception* to this rule, it observed that only a few examples will suffice where the claimed compounds share a "key structural feature from which a common utility derives."[301]

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300. *Id.* at 681-82.

301. *Id.* at 682. The court suggests that there is an exception to the so-called chemical exception, which brings the court's reasoning back in line with the general rule. *Id.* The chemical exception states that, due to unpredictability, generic claims involving chemical reactions can not be supported by a limited number of examples. M.P.E.P., *supra* note 16, § 2164.03. Nonetheless, as among more predictable inventions, as where claimed compounds share key features having an acknowledged common utility, the general rule should prevail—that is, a limited number of examples can support broad generic claims. Here, the court found that there was an acknowledged common utility, and so the unpredictability giving rise to the chemical exception did not pertain. *Hercules*, 497 F. Supp. at 682.

Further, one might interpret the court's reasoning to suggest some quantifiable relationship between the number of examples and the requisite support for a genus claim from which an exception might be made. The courts have routinely spurned the proposition that there is any such relationship to be divined. *See In re* Strahilevitz, 668 F.2d 1229 (C.C.P.A. 1982); *In re* Cavallito, 282 F.2d 357, 360 (C.C.P.A. 1960) ("The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases."). In *Strahilevitz*, the court observed:

> We recognize that working examples are *desirable* in complex technologies and that detailed examples can satisfy the statutory enablement requirement . . . . Nevertheless, as acknowledged by the board, examples are not *required* to satisfy section 112, first paragraph. Therefore the examiner's statement that the 'nearly universal applicability' alleged for the invention necessitated numerous examples was erroneous.

Strahilevitz, 668 F.2d at 1232 (emphasis added) (citations omitted); *see also In re* Herschler, 591 F.2d 693, 696 (C.C.P.A. 1979) (rejecting the board's reasoning that it was "well settled law that disclosure of a species is insufficient to provide descriptive support for a generic or sub-generic claim"); *In re* Borkowski, 422 F.2d 904, 910 (C.C.P.A. 1970) ("[T]here is no magical relation between the number of representative examples and the breadth of the claims; the number and variety of examples are irrelevant if the disclosure is 'enabling' and sets forth the 'best mode contemplated.'"). *But cf. In re* Grimme, 274 F.2d 949 (C.C.P.A. 1960). The court in *Grimme* stated:

> The question as to the sufficiency of disclosure to support a generic or subgeneric claim in the field of chemistry has frequently been considered by this court and it has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. However, it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.' What constitutes 'other appropriate language' within the meaning of the cited cases will, of course, depend on

Nonetheless, the *Hercules* court correctly emphasized that the proper inquiry is whether there is a key feature common to those members of the claimed genus and associated with the utility alleged.[302] Support for the presence of the feature, or its association with the alleged utility, might be derived from either the disclosure itself, or from the prior art generally.[303] Thus, the inquiry is whether the applicant has relied upon a generic feature that is truly common to the invention, and whether that feature is recognized or shown to be associated with the invention either within the prior art or the specification.[304]

The applicant in *In re Sichert*[305] failed to establish the requisite nexus between the supposedly generic feature and the alleged inventive utility. Although the applicant described the therapeutic benefits of a drug obtained from plant extracts from various plant families,[306] his disclosure failed to establish that the drug could be extracted successfully from even a single plant from each of the enumerated families.[307]

The *Sichert* court's reasoning seized upon the applicant's reliance on general taxonomic principles to generalize the invention; the court noted that those principles have no apparent relationship with the inventive utility, which, in this case, was the presence of the drug.[308] Accordingly, the *Si-*

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the circumstances of each particular case.

Id. at 952 (citations omitted); M.P.E.P., *supra* note 16, § 2164.02 ("Working Example").

302. *Hercules*, 497 F. Supp. at 682.

303. *Id.*

304. *Id.*

305. 566 F.2d 1154 (C.C.P.A. 1977).

306. *Id.* at 1156.

307. *Id.* The C.C.P.A. quoted the board's reasoning with approval:

> We note that claim 1 recites families of plants as opposed to genuses. The taxonomy of plants is not based on drug content but on leaf form, flower type, etc. Thus, the family Solanaceae, for example, includes belladonna, petunia, hot pepper and sweet pepper. It is considered most unlikely that these varied plant types will yield the same drug extracts.

Id. at 1161.

308. *Id.*

chert court held that the applicants had failed to adequately support the generic invention, and thus affirmed the PTO's rejection.[309]

Similarly, in *In re Vaeck*,[310] the Federal Circuit employed the same reasoning to affirm a section 112 rejection of broad genus claims.[311] In *Vaeck*, the applicants claimed the use of specified genetic engineering techniques to produce insecticidal proteins.[312] Specifically, the applicants had shown how to make insecticidal *Bacillus* proteins with greater killing potential under normal conditions of use, by transfecting a particular cyanobacterium to express the proteins.[313] The applicants interposed claims for a chimeric gene capable of being expressed in Cyanobacteria cells.[314] The examiner rejected the claims, stating that: (1) cyanobacteria comprise a large and diverse group of photosynthetic bacteria, including large numbers of species in some 150 different genera, and (2) that the claims were directed to subject matter having a high degree of unpredictability, due to the fact that such organisms had only recently come under serious study.[315] The *Vaeck* court especially noted that the applicants had included only one example of a successfully transfected cyanobacterium, and that only nine genera of cyanobacteria were mentioned in the specification.[316] Because there was a great deal

309. *Sichert*, 566 F.2d at 1161.
310. 947 F.2d 488 (Fed. Cir. 1991).
311. *Id.* at 495-96
312. *Id.* at 489-90.
313. *Id.*
314. *Id.* at 490.
315. *Vaeck*, 947 F.2d at 492-93.
316. The *Vaeck* court affirmed the section 112 rejection, saying:

> [T]here must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the 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. Where as here a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be

of uncertainty and unpredictability within the discipline, and because the applicants had provided such limited supporting disclosure, the *Vaeck* court affirmed the PTO's enablement rejection.[317]

In *In re Wright*,[318] the applicant disclosed processes for producing a live, non-pathogenic vaccine against a pathogenic RNA virus.[319] The specification possessed a single working example, describing a recombinant vaccine conferring immunity in chickens against the RNA virus, Prague Avian Sarcoma Virus ("PrASV").[320] The applicant claimed: (1) processes for producing live non-pathogenic vaccines, (2) vaccines produced by those processes, and (3) methods of using claimed vaccines to protect living organisms against RNA viruses, generally, avian RNA viruses, and PrASV.[321]

The PTO rejected Wright's claims of broad and intermediate scope as non-enabled, given the breadth of the claims, the unpredictability in the relevant art, and the limited guidance provided by the specification.[322] The examiner noted that Wright's broad and intermediate claims were directed to vaccines and methods useful against pathogenic RNA viruses, generally, which included AIDS, leukemia, and sarcoma.[323] The examiner reasoned that such broad claims were not enabled by the disclosure, and that undue experimentation would be required to exploit the invention

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> greater than, for example, the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element.

Id. at 496.

317. *Id.* at 495-96.

318. 999 F.2d 1557 (Fed. Cir. 1993).

319. *Id.* at 1559.

320. *Id.*

321. *Id.* at 1559-60.

322. *Wright*, 999 F.2d at 1560. Wright's disclosure contained only a single working example—that is, conferring immunity in chickens against Prague Avian Sarcoma Virus. *Id.* Following submission of *in vivo* data supporting the efficacy of that example, the corresponding claim was allowed. *Id.* Rejections were maintained for the broader claims encompassing non-pathogenic vaccines for avian RNA viruses and for all RNA viruses. *Id.*

323. *Id.* at 1560.

throughout its scope, particularly in view of the prevailing unpredictability within the relevant art.[324]

In response, Wright argued—without supporting data—that the art was not as unpredictable as the examiner concluded, and that undue experimentation would not have been required to exploit the invention with other RNA viruses.[325] On appeal, the examiner stated that the art had not even then progressed to the stage the applicant urged as prevailing at the time of the invention, and specifically noted that the scientific community had yet to develop an effective AIDS vaccine.[326] For support, the examiner cited for the first time an intervening reference teaching that AIDS retroviruses, a subset of all RNA viruses, possessed great genetic diversity.[327] The examiner thus argued that the design and

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324. *Wright*, 999 F.2d at 1560. The examiner had previously reasoned thus:

> With respect to the claims broadly drawn to the claims of vaccines to any RNA tumor virus via recombinant techniques, it is noted that the specification does not generically teach the identification and cloning of all antigenic and pathogenic genes of all possible RNA tumor viruses, nor does the specification adequately provide means by which the antigenic genes can readily be isolated and cloned into a non-pathogenic virus absent an undue amount of further experimentation.
>
> It has not been shown *e.g.* that envelope genes are so similar in structure in different RNA tumor viruses such that the possession and cloning of the instant *env* gene would facilitate isolation and cloning of all others. . . . Note that the virus would have to be expressed on the surface of the virus so as to present the envelope protein to the host's immune system, therefore the gene would have to recombine at a point that makes the envelope protein get externalized. This is a further issue of unpredictability.

U.S. Patent Application 06/914,620, Paper No. 3 (July 1, 1988) (This application is a continuation application of U.S. Patent Application 06/469,985 filed Feb. 25, 1983).

325. *Wright*, 999 F.2d at 1562-63.

326. U.S. Patent Application 06/914,620, Paper No. 27, ("Examiner's Answer"). The Examiner's Answer is filed in the latter stages of the prosecution of a patent application. 37 C.F.R. § 1.191 (1996). It is the examiner's responsive arguments to Appellant's Brief on Appeal to the Board of Patent Appeals and Interferences. *Id.* Appellant may make an Appeal and file such a Brief only after the claim(s) have been twice rejected or for which the rejection has been made final. *Id.*

327. Thomas J. Matthews et al., *Prospects for Development of a Vaccine Against HIV*, *in* HUMAN RETROVIRUSES, CANCER, AND AIDS: APPROACHES TO PREVENTION &

production of recombinant virus vaccines against RNA tumor viruses, generally, and against avian RNA viruses would have necessitated undue experimentation.[328] The examiner's reasoning was expressly adopted by the PTO Board of Appeals,[329] and was later affirmed by the Federal Circuit.[330] Thus, *Wright* is another illustration of an applicant's failure to support generic claims with limited examples.

3. The Burden of Proof Revisited

Wright has been criticized as inconsistent with precedent, and as undermining the general objectives of the patent system.[331] The holding in *Wright* resulted, in substantial part, from a shift in the burden of proof, which in turn resulted

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THERAPY, 313-25 (1988). Wright's effective filing date was 1981.

328. *Wright*, 999 F.2d at 1560.

329. *Id.* at 1561 n.5.

330. *Id.* at 1564.

331. *See generally* Karen S. Canady, *The Wright Enabling Disclosure for Biotechnology Patents*, 69 WASH. L. REV. 455 (1994) (arguing that the court's approval of the examiner's reliance on the intervening (post filing date) reference was contrary to the rule of *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977), and that the holding unduly restricts the scope of enablement for biotechnology inventions); *cf.* Schuman, *supra* note 9, at 1699-1700. Schuman argues that the C.C.P.A. especially scrutinizes enablement in the unpredictable arts, particularly those involving microbiological inventions, and thus unduly limits the scope of protection for inventions in those disciplines. *Id.*

Schuman proffers a continuum analogy to explain the court's enablement holdings in the unpredictable arts as embodied in various holdings from *In re Fisher*, 427 F.2d 833 (C.C.P.A. 1970) and culminating in *Ex parte Jackson*, 217 U.S.P.Q. (BNA) 804 (Bd. Pat. App. & Int. 1982). *Id.* While the analogy may be appropriate, *Jackson*, like *Wright* and even *Fisher* itself, illustrates those cases wherein applicant relied upon a false inventive genus.

In *Jackson*, applicants presented claims to a process for producing a specified antibiotic by culturing microorganisms of a specified genus. 217 U.S.P.Q. at 808. Three strains within the genus were exemplified. *Id.* As in *In re Vaeck*, the C.C.P.A. observed that biological classification was inexact and arbitrary. *See supra* note 310 and accompanying text (discussing the *Vaeck* decision). What the court failed to say, but implicit in its holding, was that the selection of morphological features upon which that classification is based are arbitrary or at the very least superficial. That is, it would not have been expected by one of skill in the art that the features upon which the microorganisms were taxonomically classified were necessarily consistent with the production of an antibiotic. Thus, reliance on the taxonomic genus was unrelated to the inventive feature, and the claims failed due to reliance on a false inventive genus.

the PTO's assessment that the discipline was unpredictable. *In re Wright* is significant in that it further refined the relationship between unpredictability and the burden of proof in supporting or rejecting generic claims.

The burden is on the PTO to make a *prima facie* case that the scope of a generic claim is not commensurate with the scope of enablement provided by the disclosure. This is especially so where the PTO takes exception to the applicant's explicit representations supporting the breadth of the claims.[332] That is, the PTO must affirmatively rebut the applicant's implicit assertion that one of ordinary skill in the relevant art would appreciate the practicability of the invention, or would be able to confirm it without inventive experimentation.[333]

The PTO often seeks to meet this burden by arguing that the applicant has failed to demonstrate that *the invention* and

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332. *See, e.g.*, *In re* Bowen, 492 F.2d 859, 862 (C.C.P.A. 1974); *In re* Marzocchi, 439 F.2d 220, 224 (C.C.P.A. 1971); *Ex parte* Gastambide, 189 U.S.P.Q. (BNA) 643, 645 (Bd. Pat. App. & Int. 1974).

333. *Wright*, 999 F.2d at 1561-62. As the *Wright* court explained:

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO meets this burden, the burden then shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling.

Id.; *see also Ex parte* Gastambide, 189 U.S.P.Q. (BNA) 643 (Bd. Pat. App. & Int. 1974) (holding proper grounds for rejection require more than unsubstantiated doubt as to the operability of the invention); *cf. In re* Robins, 429 F.2d 452, 457 (C.C.P.A. 1970) (concluding that section 112 does not require that the specification convince persons skilled in the art that assertions therein are correct). *But cf. Ex parte* Sudilovsky, 21 U.S.P.Q.2d (BNA) 1702, 1705 (Bd. Pat. App. & Int. 1992) ("When a patent applicant chooses to forego exemplification and bases utility on broad terminology and general allegations, he runs the risk that unless one with ordinary skill in the art would accept the allegations as obviously valid and correct, the examiner may, properly, ask for evidence to substantiate them.") (citations omitted).

the genus are coextensive.[334] Support for that argument can be drawn from teachings in the prior art, as in *In re Fouche*,[335] or, as we learn from *Wright*, from a general assessment that the relevant art is unpredictable.[336]

Just as the sufficiency of an applicant's disclosure must be measured as of its filing date,[337] so too must support for the PTO's rejection rely upon the prevailing state of the art as of the filing date.[338] In *In re Hogan*,[339] the court struck down a rejection based upon a later development in the relevant art.[340] In *Hogan*, the applicants disclosed and claimed solid polymers made from certain olefinic monomers.[341] Subsequent to the applicants' priority date, a publication appeared disclosing that certain polymers within the claimed genus could be synthesized in an amorphous, rather than crystalline, form.[342] The examiner rejected the genus claim as not enabled, noting that while the applicants' disclosed embodiments were crystalline, the patent claims were not so limited.[343] The revelation of a crystalline/amorphous dichotomy, the examiner reasoned, rendered the claims ambiguous, and therefore unduly broad and non-enabled.[344]

The appellate court held that there was no basis on the record to question the sufficiency of the applicants' disclosure as of their filing date, absent the later publication; that is, as of the filing date, there was no reason to suspect the

334. *See, e.g.*, *In re* Vaeck, 947 F.2d 488 (Fed. Cir. 1991); *In re* Sichert, 566 F.2d 1154 (C.C.P.A. 1977).

335. *See supra* notes 228-35 and accompanying text (discussing the *Fouche* decision).

336. *See generally In re* Wright, 999 F.2d 1557 (Fed. Cir. 1993).

337. *See In re* Glass, 492 F.2d 1228 (C.C.P.A. 1974).

338. *In re* Hogan, 559 F.2d 595, 604 (C.C.P.A. 1977).

339. 559 F.2d 595 (C.C.P.A. 1977).

340. *Id.*

341. *Id.* at 597-98.

342. *Id.* at 599-600.

343. *Id.* at 600.

344. *Hogan*, 559 F.2d at 600.

polymers would be other than crystalline.[345] Thus, the examiner improperly relied upon the later publication to challenge the sufficiency of the disclosure.[346]

In *Wright*, the applicant disclosed methods for making vaccines against RNA viruses, vaccines produced thereby, and methods for protecting living organisms against RNA viruses.[347] While providing only a single example, the applicant interposed claims directed to the exemplified virus, PrASV, as well as all avian RNA viruses, and RNA viruses, generally.[348] The examiner rejected the claims of the latter two categories for lack of enablement, and, on appeal to the PTO Board of Patent Appeals and Interferences, cited an intervening reference.[349] The PTO Board of Patent Appeals and Interferences affirmed the examiner's rejection, and, on further appeal to the Court of Appeals for the Federal Circuit, the *Wright* court affirmed the PTO's rejections of the claims in the latter two categories for lack of enablement.[350]

One commentator has argued that, at the very least, Wright's claims of intermediate scope, directed to vaccines against *avian* RNA viruses, should have been allowed, and that the Federal Circuit's reliance on the intervening article contravened *Hogan*.[351]

In re Wright does not contravene *Hogan*. Rather, it stands for the proposition that the PTO need not rely on an explicit teaching or admission to assess unpredictability, and that assessment alone might be sufficient to shift the burden of proof. *Wright* thus charts a middle path between the principles espoused in *Hogan* and those of *In re Fouche*.

In *Hogan*, the court refused to allow the PTO to use an in-

345. *Id.* at 605.
346. *Id.*
347. *Wright*, 999 F.2d at 1559-60.
348. *Id.*
349. *Id.*
350. *Id.* at 1564.
351. Canady, *supra* note 331, at 258-62.

tervening reference to find unpredictability in the first instance.[352] The first indication that the applicants had not enabled the creation of olefinic polymers as broadly as had been claimed came from the reference published after the applicants' priority date.[353] Thus, the post-priority reference was essential to the examiner's *prima facie* case.[354]

In *Wright*, the court specifically held that the PTO had met its burden by setting forth a reasonable basis for doubting the applicant's broad, unsupported statements, and thus the sufficiency of the disclosure.[355] That reasoning created a prima facie case, and shifted the burden to Wright to prove otherwise.[356] The examiner's reliance on the intervening article, according to the court, merely countered the applicant's rebuttal by demonstrating that the relevant art was not even then as predictable as the applicant suggested it was at the time the application was filed.[357] The *Wright* court thus concluded that the intervening article was not needed to make a *prima facie* case of non-enablement.[358] The applicants failure to respond with "persuasive arguments, supported by suitable proofs where necessary, that the appealed claims were truly enabled" resulted in the demise of the broader claims.[359]

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352. *Hogan*, 559 F.2d at 605-06.

353. *Id.* at 605 & n.17.

354. *Id.*

355. *Wright*, 999 F.2d at 1562; *see also id.* at 1564 (addressing specifically the more narrow claims directed to avian RNA viruses); *cf. Ex parte* Sudilovsky, 21 U.S.P.Q.2d (BNA) 1702, 1705 (Bd. Pat. App. & Int. 1991) (noting that in the absence of examples or support for the proposition that one of skill would accept representations as obviously valid and correct, the PTO might properly ask for evidence to substantiate them).

356. *Wright*, 999 F.2d at 1562.

357. *Id.* at 1562-63.

358. *Id.* In *Wright*, the court held that the PTO's assessment of unpredictability merely shifted the burden to Wright to provide evidence supporting the propriety of his inventive genus. *Id.* This he failed to do. Notwithstanding, one can't help but wonder whether the result in *Wright* would have been different had the art turned out to be as predictable as Wright alleged in his disclosure. *See id.* at 1562.

359. *Wright*, 999 F.2d at 1562.

III. ADOPTION OF A NEW APPROACH—THE FALSE INVENTIVE GENUS—WOULD ENCOURAGE A MORE CONSISTENT APPLICATION OF THE SUFFICIENCY OF DISCLOSURE INQUIRY

When working within disciplines perceived to be unpredictable, the applicant is at risk of assuming the burden of proof that a generic claim is, in fact, supported by his or her disclosure.[360] That risk is increased when the PTO or the courts conclude that the applicant or the patentee has relied on a false inventive genus. This part introduces the notion of the false inventive genus, and examines its role in the sufficiency of the disclosure analysis among the unpredictable arts.

A. *The False Inventive Genus Defined*

With the demise of rejections based upon undue breadth[361] and inoperative embodiments,[362] and the ascent of the undue experimentation inquiry,[363] there remains a nagging ambiguity. Rejections alleging the need for undue experimentation, or that the scope of enablement is not commensurate in scope with the claims, beg the question.[364] Standing alone, they offer the applicant little more than a bald rebuke that he or she either did not disclose enough, or seeks to claim too much.

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360. *See supra* notes 76-78 and accompanying text (discussing generally the burden of proof generally in the context of the unpredictable arts); *supra* notes 187-236 and accompanying text (discussing the burden of proof in the context of "inoperative embodiments"); *supra* notes 331-58 and accompanying text (discussing the burden of proof in the context of "undue experimentation").

361. *See supra* notes 94-116 and accompanying text (discussing rejections based on "undue breadth").

362. *See supra* 117-236 and accompanying text (discussing rejections based on "inoperative embodiments").

363. *See supra* 237-359 and accompanying text (discussing rejections based on "undue experimentation").

364. *See* Todaro, *supra*, note 7, at 39 (arguing that the Federal Circuit's course away from reliance on the *Forman* factors for determining undue experimentation will erode predictability in the law and leave applicants guessing as to what constitutes undue experimentation).

In some instances, the implicit supporting argument is that the applicant has indulged in an impermissible generalization or has created a false inventive genus; that is, the feature or principle upon which the applicant relies to generalize the invention beyond the empirical results presented is collateral to the invention. Although not expressed as such, the objection has arisen persistently within the unpredictable arts.[365]

By identifying the creation of a false inventive genus, the PTO and the courts will more readily isolate the unsupported inference or extrapolation giving rise to the alleged insufficiency in the disclosure. In so doing, reviewing authorities will more reliably focus on the issues requiring resolution, address those issues, and thereby bring greater consistency and predictability to this area of the law.

The issues derived from reliance on a false inventive genus have arisen periodically in various contexts since at least the advent of the undue experimentation inquiry.[366] Moreover, some of the decisions discussed above address rejections founded upon an applicant's creation and reliance on a false inventive genus.

For example, in *In re Sichert*, the applicants included wide-ranging families of plants as source material for a drug.[367] The court concluded that the applicants had generalized the invention based upon taxonomic criteria not necessarily related to drug content.[368] The court affirmed the

365. *See, e.g.*, *In re* Sichert, 566 F.2d 1154 (C.C.P.A. 1977); *In re* Vaeck, 947 F.2d 488 (Fed. Cir. 1991); *In re* Wright, 999 F.2d 1557; *see also supra* notes 237-359 and accompanying text (discussing these decisions).

366. *See, e.g.*, PTO DRUG UTILITY GUIDELINES, *supra* note 124; *see also In re* Wright, 999 F.2d 1557; *In re* Vaeck, 947 F.2d 488; *In re* Sichert, 566 F.2d 1154; *see also supra* notes 237-359 and accompanying text (discussing the undue experimentation inquiry).

367. *Sichert*, 566 F.2d at 1156; *see also supra* note 305-08 and accompanying text (discussing the *Sichert* decision).

368. *Sichert*, 566 F.2d at 1162-63; *see also supra* note 305-08 and accompanying text (discussing the *Sichert* decision).

PTO Board of Appeals' conclusion that it was "most unlikely" that plant extracts from the various plant families in Sichert's generic claim possessed the desired drug.[369] Thus, Sichert had created a false inventive genus, and the court affirmed the PTO's enablement rejection of the generic claim.[370]

Similarly, the applicant in *In re Vaeck* relied on a false inventive genus. In *Vaeck*, the applicant claimed techniques for genetically manipulating cyanobacteria, generally, to produce insecticidal *Bacillus* proteins.[371] As in *Sichert*, the applicant in *Vaeck* sought to define the scope of his exclusive right by relying upon traditional taxonomic classification.[372] In rejecting the applicant's claim, the *Vaeck* court concluded that the principles upon which this taxonomic system is based are not necessarily coincident with suitability for the disclosed genetic manipulation.[373] That is, the applicant had not shown that there was a nexus between the taxonomic basis upon which cyanobacteria is classified, and the ability of the cyanobacteria to incorporate foreign DNA molecules to express the requisite insecticidal protein.[374] Thus, the court held that one of skill in the relevant art would not conclude, based upon mere commonality of gross morphological features, that these varied microorganisms could be trans-

369. *Sichert*, 566 F.2d at 1161; *see also supra* note 305-08 and accompanying text (discussing the *Sichert* decision).

370. *Sichert*, 566 F.2d at 1161; *see also supra* note 305-08 and accompanying text (discussing the *Sichert* decision).

371. *Vaeck*, 947 F.2d at 489-90; *see also supra* notes 310-16 (discussing the *Vaeck* decision).

372. *Vaeck*, 947 F.2d at 489-90; *see also supra* notes 310-16 (discussing the *Vaeck* decision).

373. *See Vaeck*, 947 F.2d at 496 ("[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."); *see also supra* notes 310-16(discussing the *Vaeck* decision).

374. *See Vaeck*, 947 F.2d at 496 ("[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."); *see also supra* notes 310-16 (discussing the *Vaeck* decision).

formed with the same chimeric gene to express insecticidal *Bacillus* proteins.[375]

Similarly, the *Wright* court's reasoning suggests that the applicant's disclosure failed to establish an acknowledged and relevant relationship between the sole exemplified recombinant PrASV, and avian retroviruses and retroviruses, generally.[376] Wright failed to persuade the PTO and the court that one of skill in the relevant art would accept as obviously valid and correct that all avian retroviruses possess the feature he had genetically manipulated in PrASV, or were susceptible to such manipulation, to create a recombinant virus capable of effecting an immunoprotective, rather than pathogenic, response.[377] Seemingly, Wright had arbitrarily chosen to genericize the invention based upon morphological features of a host, rather than demonstrably recurrent genetic features of the virus, per se.[378] This reliance on an *ad hoc* genus, coupled with a lack of supporting evidence, precipitated the downfall of the claims.[379]

Some cases involved in the inoperative embodiments imbroglio fit the same model. A few examples from the discussion above are illustrative.[380] In *Fisher*, for example, the court found fatal flaws in claims directed to an adrenocorticotrophic hormone ("ACTH") preparation.[381] The appli-

375. *See Vaeck*, 947 F.2d at 496 ("[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."); *see also supra* notes 310-16 (discussing the *Vaeck* decision).

376. *Wright*, 999 F.2d at 1562; *see also supra* notes 318-29 and accompanying text (discussing the *Wright* decision).

377. *Wright*, 999 F.2d at 1562; *see also supra* notes 318-29 and accompanying text (discussing the *Wright* decision).

378. *Wright*, 999 F.2d at 1564; *see also supra* notes 318-29 and accompanying text (discussing the *Wright* decision).

379. *Wright*, 999 F.2d at 1564; *see also supra* notes 318-29 and accompanying text (discussing the *Wright* decision).

380. *See supra* notes 178-85 and accompanying text (discussing rejections based on inoperative embodiments generally).

381. 427 F.2d at 836; *see also supra* notes 265-67 and accompanying text (discussing the *Fisher* decision).

cant's specification disclosed the ACTH amino acid sequences for hog, sheep, and beef: all were thirty-nine amino acids in length, the first twenty-four of which were identical.[382] The applicant claimed ACTHs having at least these common twenty-four amino acids in sequence, thus relying on the common sequence to genericize the invention.[383] Nonetheless, the applicant failed to show availability or activity of ACTHs of anything *other* than thirty-nine amino acids, much less those of only twenty-four amino acids.[384] Although the applicant identified a generic feature among his enabled embodiments (i.e., a particular twenty-four amino acid sequence), he improperly relied upon that feature to genericize the *invention* because it lacked a nexus with the activity relied upon for utility.[385] Accordingly, the *Fischer* court affirmed the rejection of the broad claims.[386]

Similarly, in *In re Barr*,[387] the issue on appeal involved claims to certain photographic "coupler" compounds, and, in particular, the applicants' generic terminology in claiming those compounds.[388] The examiner objected to the use of the terms, "5-pyrazolone coupler radical" and "open-chain ketomethylene coupler radical," because only a few of such radicals were exemplified in the specification.[389] The *Barr* court faulted the examiner and the PTO Board of Appeals,

382. *Fisher*, 427 F.2d at 836; *see also supra* notes 265-67 and accompanying text (discussing the *Fisher* decision).

383. *Fisher*, 427 F.2d at 835; *see also supra* notes 265-67 and accompanying text (discussing the *Fisher* decision).

384. *Fisher*, 427 F.2d at 836; *see also supra* notes 265-67 and accompanying text (discussing the *Fisher* decision).

385. *Fisher*, 427 F.2d at 838-39; *see also supra* notes 265-67 and accompanying text (discussing the *Fisher* decision).

386. *Fisher*, 427 F.2d at 840; *see also supra* notes 265-67 and accompanying text (discussing the *Fisher* decision).

387. 444 F.2d 588 (C.C.P.A. 1971); *see also supra* notes 193, 227, 240 and accompanying text (discussing the *Barr* decision).

388. *Barr*, 444 F.2d at 595; *see also supra* notes 193, 227, 240 and accompanying text (discussing the *Barr* decision).

389. *Barr*, 444 F.2d at 595; *see also supra* notes 193, 227, 240 and accompanying text (discussing the *Barr* decision).

noting that the appellants had contemplated the utility of the genus within their specification, but that neither the examiner nor the board had explained *why* that genus was suspect.[390] The PTO had failed to present reasoning or evidence questioning the appellants' use of terminology by which they defined their invention.[391] Absent such reasoning or evidence, the PTO was obligated to accept it.[392] Thus, the examiner's implicit argument—that these terms represented a false inventive genus—failed.

Finally, in *Marzocchi*, the examiner had objected to the appellants' use of the generic term "polyethyleneamine" in defining a class of adhesion enhancers in their invention.[393] The appellants had used the term consistently within the disclosure to describe the invention, and in the claims to define the scope of the invention.[394] Because the PTO failed to explain why it doubted the truth or accuracy of the appellants' supporting statements, it was obligated to accept them as true.[395] Again, what was effectively a false inventive genus argument failed.

B. *Routine Experimentation or False Inventive Genus*

An applicant is not obligated to provide examples of all conceivable embodiments of the claimed invention.[396] Nonetheless, while a specification need not be a blueprint,[397] an applicant is not entitled to usurp broad areas of technol-

390. *Barr*, 444 F.2d at 596; *see also In re* Herschler, 591 F.2d 693 (C.C.P.A. 1979); *In re* Bowen, 492 F.2d 859 (C.C.P.A. 1974).

391. *Barr*, 444 F.2d at 596; *see also supra* notes 193, 227, 240 and accompanying text (discussing the *Barr* decision).

392. *Barr*, 444 F.2d at 596; *see also supra* notes 193, 227, 240 and accompanying text (discussing the *Barr* decision).

393. 439 F.2d at 221-22; *see also supra* notes 220-26 and accompanying text.

394. 439 F.2d at 223; *see also supra* notes 220-26 and accompanying text.

395. 439 F.2d at 223; *see also supra* notes 220-26 and accompanying text.

396. *See supra* notes 204-05, 208-09 and accompanying text.

397. *See generally* Kaiser Indus. Corp. v. Jones & Laughlin Steel Corp., 181 U.S.P.Q. (BNA) 193 (W.D. Pa. 1974).

ogy by making broad, unsupported statements.[398]

The sufficiency of disclosure challenges most commonly arise where the applicant expressly contemplates broad applicability of the innovation based upon a discovery that purportedly brings predictability to a discipline,[399] but where the applicant arguably has not supported that newfound predictability with sufficient reliable scientific proof.[400] In such cases, the applicant has complied with the written description requirement,[401] and perhaps has made a prima facie case for enablement.[402] Nonetheless, if the PTO can show that the field of endeavor is notoriously unpredictable, the absence of examples or data that thoroughly correspond to the scope of the claim might operate to shift the burden back to applicant to further prove enablement.[403]

The challenge often arises from one of two perspectives—either the applicant: (1) has failed to provide a disclosure that *enables* one of skill in the art to practice the invention throughout its scope, or (2) has failed to provide a disclosure that would lead one of skill in the art to conclude that the *utility* of the claimed invention resides throughout the claimed genus.[404] Although the subtleties of the two per-

398. *See In re* Cavallito, 282 F.2d 357, 361 (C.C.P.A. 1960) ("The mere statement of an inventive concept, however, is not a sufficient basis for claiming it. Sufficient information must be given to enable those skilled in the art to practice the invention."); *see also supra* note 301 (discussing the *Cavallito* decision); *supra* notes 38-40, 54, 68 and accompanying text (explaining that full disclosure of inventors' claims protects the public against ad hoc extension of exclusive rights).

399. *See supra* notes 68-73 (discussing disclosure in the unpredictable arts).

400. *See supra* notes 68-73 (discussing disclosure in the unpredictable arts).

401. *See supra* notes 44-46 (explaining the statutory requirement of a written description); notes 132-47 (written description in the context of the unpredictable arts).

402. *See supra* notes 47-48 and accompanying text (discussing enablement generally); notes 150-76 and accompanying text (discussing enablement in the unpredictable arts).

403. *See supra* notes 187-236 and accompanying text (discussing the burden of proof in the context of "inoperative embodiments" rejections); notes 331-58 and accompanying text (discussing the burden of proof in the context of "undue experimentation" inquiry).

404. *See supra* notes 185-87 and accompanying text

spectives might differ, the essential inquiry is the same: whether the applicant provided a disclosure sufficiently thorough that one of skill in the relevant art would expect that he or she would be enabled to successfully exploit the invention throughout the claimed scope. If the applicant has arbitrarily chosen features assumed to be generic to the invention, one might conclude that one of skill in the art would not expect to be able to successfully exploit the invention throughout that genus.

The decision to grant or uphold broad generic claims in any art involves a series of subtle, qualitative inquiries in view of the prior art as a whole. For example, the PTO can be expected to consider, from the perspective of one of ordinary skill in the relevant art, whether working embodiments of the invention would be expected to reside throughout the claimed range.[405] Moreover, the issue might arise as to whether further experimentation would be required so as to exploit the invention in its entirety; if so, would one expect it to be merely routine (albeit perhaps lengthy) experimentation—which will not defeat the claim[406]—or would one ex-

405. *See supra* notes 117-236 and accompanying text (discussing rejections based on "inoperative embodiments").

406. *See supra* notes 237-359 (discussing rejections based on "undue experimentation"); *see, e.g.*, Minerals Separation v. Hyde, 242 U.S. 261 (1916); *In re* Wands, 858 F.2d 731 (Fed. Cir. 1988); *In re* Angstadt, 537 F.2d 498; *In re* Marzocchi, 439 F.2d 220; *In re* Cook, 439 F.2d 730; International Nickel Co. v. Ford Motor Co. 166 F. Supp. 551 (S.D.N.Y. 1958); *Ex parte* Mark, 12 U.S.P.Q.2d (BNA) 1904 (Bd. Pat. App. & Int. 1989). In *International Nickel Co.*, the court, quoting Judge Learned Hand, reiterated:

> It is as if a chemist were directed to add enough of an element to secure precipitation. Such a recipe would be an absolutely accurate guide to the result though the quantity varied with the temperature or atmospheric humidity. What men need is a path to the goal; they will not be curious of the country it traverses.

166 F. Supp. at 558 (quoting Burke Elec. Co. v. Independent Pneumatic Tool Co., 232 F. 145, 148 (2d Cir. 1916)). Similarly, in *Mark*, the court explained:

> The fact that a given protein may not be amenable for use in the present invention in that the cysteine residues are needed for the biological activity of the protein does not militate against a conclusion of enablement. One skilled in the art is clearly enabled to perform such work as

pect it to require ingenuity beyond that attributable to one of ordinary skill in the art—which might defeat the claim.[407] Occasionally, these determinations, and the larger question of allowability (or validity), will depend upon whether the invention is properly denominated "unpredictable." As has been stated so many times, however, there can be no general rule, and the scope of protection properly afforded depends upon the facts of each individual case.

CONCLUSION

Inventions within the unpredictable arts present unique challenges in meeting the Patent Act's disclosure requirements. Applications claiming an invention possessed of unpredictable factors will be carefully scrutinized for compliance with the utility, written description, how-to-make-and-use, and enablement requirements. Even if the applicant's disclosure facially complies with those requirements, courts or the PTO might still challenge the applicant for evidence to support enablement.

The PTO bears the burden of supporting that challenge with acceptable evidence or reasoning why it doubts the truth or accuracy of supporting statements within the disclosure. When the invention is claimed more broadly than that which is exemplified within the application, unpredictability alone might satisfy that burden. If so, the burden shifts to the applicant to prove enablement throughout the scope of

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needed to determine whether the cysteine residues of a given protein are needed for retention of biological activity.

12 U.S.P.Q.2d at 1907.

407. *See supra* notes 237-359 (discussing rejections based on "undue experimentation"); *see, e.g.*, Consolidated Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 16 S. Ct. 75 (1895); *In re* Wright, 999 F.2d 1557 (Fed. Cir. 1993); *In re* Vaeck, 947 F.2d 488 (Fed. Cir. 1991); Panzl v. Battle Island Paper Co., 138 F. 48 (2d Cir. 1905); *In re* Fouche, 439 F.2d 1237 (C.C.P.A. 1971); *In re* Schmidt, 153 U.S.P.Q. (BNA) 640 (C.C.P.A. 1967); *In re* Grant, 134 U.S.P.Q. (BNA) 248 (C.C.P.A. 1962); *In re* Cavallito, 127 U.S.P.Q. (BNA) 202 (C.C.P.A. 1960); *Ex parte* Singh, 17 U.S.P.Q.2d (BNA) 1714 (Bd. Pat. App. & Int. 1990); *Ex parte* Sizto, 9 U.S.P.Q.2d (BNA) 2081 (Bd. Pat. App. & Int. 1988).

the claim; to meet that burden, the applicant should be entitled to draw upon evidence that is extrinsic to the application itself.

When generically claiming an invention likely to be denominated unpredictable, applicants should strive to establish an explicit logical link, through carefully constructed evidence or reasoning, connecting the demonstrated operability of the invention with the basis upon which the genus has been selected. Failure to do so leaves an applicant open to a sufficiency of disclosure rejection, due to apparent reliance on a false inventive genus. By expressly identifying instances of improper reliance on a false inventive genus, the PTO will focus more effectively on the perceived shortcoming, thereby narrowing any outstanding issues and enhancing the prospects for proper and well-reasoned resolution of those issues.