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The *Wright* Enabling Disclosure for Biotechnology Patents

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Abstract: The disclosure in a patent specification must enable others to make and use the claimed invention. 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. In *In re Wright,* the Federal Circuit recently challenged this approach when it upheld the rejection, for lack of enablement, of all but the narrowest claims to a vaccine genetically engineered to protect against retroviruses. This decision unreasonably elevates the established standard for enablement by limiting biotechnological patent protection to only those embodiments of a claimed invention whose success can be demonstrated by working examples. This Note critiques that decision and proposes a limited policy-based approach to guide consistent determinations of enablement for patent claims.

Dr. Stephen E. Wright used recombinant DNA technology to develop a vaccine against an RNA virus that causes tumors in chickens. Wright applied for a patent on his strategy for genetically engineering vaccines against RNA viruses. His patent application included claims covering the specific vaccine he had developed, vaccines against other avian tumor viruses, and vaccines against pathogenic RNA viruses in general, which include the AIDS and leukemia viruses. The patent examiner rejected, for lack of enablement, all of Wright's claims except those limited to the single chicken tumor virus Wright described in his patent application. The Board of Patent Appeals and Interferences and the Court of Appeals for the Federal Circuit affirmed the rejection. This decision suggests that biotechnology inventors may be limited to very narrow patent protection.

This Note explores the requirement for enabling disclosure in biotechnology patents. Part I summarizes the enablement requirement and discusses problems this requirement raises for biotechnology patents. In parts II and III, the Note examines *In re Wright,*[1] arguing that the court failed to provide an adequate basis for rejecting Wright's intermediate claims. Part IV discusses the need for consistency and clarity in determining enablement for biotechnology patents and proposes a limited policy-based standard to address this need.

1. 999 F.2d 1557 (Fed. Cir. 1993).

I. PATENTS AND THE ENABLEMENT REQUIREMENT

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.[2] Patents protect intellectual property by allowing inventors to exclude others from making and using their inventions for 17 years from the date the patent issues.[3] During a patent's life, the holder has several options for exercising this right. The patent holder may: exclude competitors from marketing the invention, license to one or more others the right to make or use the invention in exchange for royalty payments, or do nothing with the invention. Meanwhile, from the time the patent issues, the public has access to a detailed description of the invention.

For an invention to be patentable, it must be novel, useful, and nonobvious.[4] The inventor must also satisfy an enablement requirement by providing a detailed specification[5] of the invention sufficient to enable those of ordinary skill in the art[6] to practice the invention without undue experimentation, along with a description of the best mode for carrying out the invention.[7] If a disclosure is found to be non-enabling, the examiner at the Patent and Trademark Office (PTO) need not reject the

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2. Congress has the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8. The patent system is codified in 35 U.S.C. §§ 1–376 (1988).

3. 35 U.S.C. § 154 (1988).

4. 35 U.S.C. §§ 101–103 (1988).

5. The specification contains background information, a summary of the invention, and a detailed description of the process of making and using one or more embodiments of the claimed invention. U.S. Department of Commerce, Patent and Trademark Office, *Manual of Patent Examining Procedure* § 608.01 (1992).

6. "Art" refers to the relevant technology and derives from the clause of the U.S. Constitution cited *supra* note 2.

7. The enablement requirement appears in section 112:

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

35 U.S.C. § 112 para. 1 (1988). The best mode requirement raised in the final clause will not be addressed in this Note. For a discussion of the best mode requirement, see Christopher S. Marchese, *Promoting the Progress of the Useful Arts by Narrowing the Best Mode Disclosure Requirements in Patent Law*, 54 U. Pitt. L. Rev. 589 (1993).

entire patent application, but may reject only those claims[8] that are not enabled by the specification. In determining whether a claim is enabled, the examiner considers only the state of the art as of the application filing date and not developments arising during the pendency of the application.[9] Thus, the applicant is not required to anticipate future developments when drafting the specification. When rejecting a claim for non-enablement, the examiner bears the initial burden of providing a reasonable explanation for doubting the adequacy of the disclosure.[10] Once this burden has been met by the examiner, the burden shifts to the applicant, who may provide evidence that the disclosure does in fact enable the invention as claimed.[11]

The extent of disclosure necessary to satisfy the enablement requirement varies with the art, and is determined by consideration of several identified factors.[12] The application of these factors to biotechnology raises concerns about balancing the need to adequately reward inventors for their disclosures against the need to encourage other inventors to bring subsequent technological advances into the public domain.

A. Ease of Compliance with the Enablement Requirement Varies with the Technology

Satisfying the enablement requirement is relatively straightforward for some technologies. For example, the specification for the invention of chopsticks would contain a description of two sticks of a given range of sizes, how sticks of appropriate dimensions could be made, and how the sticks would be positioned in the hand to be used for eating. Even if the claims were broad enough to include chopsticks with pointed and rounded tips, as well as other possible combinations of features, the above specification would be sufficiently enabling for the ordinary utensil manufacturer to produce the invention as claimed. The specifications for complex machinery can be similarly straightforward

8. A patent application consists of claims and a specification. The claims define the scope of the patent protection sought, while the specification describes the claimed invention. *Manual of Patent Examining Procedure, supra* note 5, § 608.01.

9. *In re* Hogan, 559 F.2d 595, 607 (C.C.P.A. 1977), *followed in* Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1568 (Fed. Cir. 1990), *cert. dismissed,* 499 U.S. 955 (1991).

10. *In re* Marzocchi, 439 F.2d 220, 223–24 (C.C.P.A. 1971), *followed in* Weil v. Fritz, 601 F.2d 551, 555 (C.C.P.A. 1979).

11. *Marzocchi,* 439 F.2d at 223–24.

12. *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

because of the mechanical nature of the technology, which makes use of well-understood scientific principles.

With chemical and biological inventions, however, satisfying the enablement requirement is often more challenging. For example, an inventor may produce a potion to make hair grow on the scalp by culturing cells that secrete a hormone which, when combined with a particular oil-based medium, promotes hair growth. The patent claim may be broad enough to include combining the cellular secretions with any oil-based medium. If the ordinary manufacturer of hair potions would have to experiment extensively with each of a large number of oil-based media in order to determine which would be suitable vehicles for use of the hormone, then the enablement requirement is not satisfied. Alternatively, if the manufacturer need use only routine testing procedures to screen a number of oil-based media, then the applicant has satisfied the enablement requirement.

Biotechnology companies[13] often encounter frustration when trying to satisfy the enablement requirement. This frustration arises when an inventor develops a strategy for solving a class of problems, but has yet to demonstrate success in all applications within that class. Although the strategy may seem logical enough that one would expect it to succeed wherever applied, the unpredictability of biology raises doubts about this expectation. Difficulties arise because trial and error is normally required before a biologist can know which applications of a given strategy will succeed. Thus, it is difficult to distinguish between claimed inventions that solve an entire class of problems and those whose applicability is more limited.

B. Several Factors Determine Satisfaction of the Enablement Requirement

When evaluating satisfaction of the enablement requirement, the examiner's objective is to determine whether one of ordinary skill in the art could practice the invention without engaging in undue experimentation.[14] The question is whether one of ordinary skill in the art would have a reasonable expectation of success when setting out to practice the claimed invention by following the description in the patent

13. Although inventors may seek patent protection and encounter the same frustrations, biotechnology companies are most often in this position because inventors typically assign their patent rights to their employers.

14. Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1571 (Fed. Cir. 1991); *see also Wands*, 858 F.2d at 737.

specification. The examiner applies a standard of reasonableness to the consideration of undue experimentation, taking into account the nature of the invention and the state of the art.[15]

The PTO and the courts consider eight factors when determining whether the experimentation required to practice an invention according to the specification is unduly extensive. The factors, as identified in *Ex parte Forman,*[16] are: the breadth of the claims, the unpredictability of the art, the amount of experimentation necessary, the extent of guidance presented, the presence of working examples, the nature of the invention, the state of the prior art, and the relative skill of those in that art. Claim breadth and unpredictability of the art serve as threshold factors. The remaining factors are often considered in combination, such that the presence of one may obviate the need to consider others.

1. Unpredictability of the Art and Breadth of Claims Serve as Threshold Factors

The court (or PTO) will not consider the other *Forman* factors unless the claims are broad and the art is unpredictable.[17] If the claims are narrow enough to encompass only the examples described in the specification, the examiner will presume compliance with the enablement requirement.[18] Furthermore, if the art is predictable,[19] all of the other factors are much less relevant. Those who will practice the invention will avoid a large amount of experimentation because the predictability of the technology will guide them. The ability to predict the outcome reduces the need for guidance, additional examples, and a high level of skill. If the art has reached a state of predictability, then the state of the art is sufficiently advanced, and the nature of the invention will be less

15. Ansul Co. v. Uniroyal, Inc., 448 F.2d 872, 878 (2d Cir. 1971), *cert. denied,* 404 U.S. 1018 (1972).

16. 230 U.S.P.Q. (BNA) 546, 547 (Bd. Pat. App. & Int., 1986); *Wands,* 858 F.2d at 737 (adopting the factors identified in *Forman*).

17. *In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971) (acknowledging in dicta that unpredictability of the art can be enough to create a reasonable doubt regarding enablement).

18. *Id.*

19. Courts and commentators have suggested that entire arts should not be categorized as predictable or unpredictable when the better course would be to evaluate the predictability of the process or element at issue. *In re* Cook, 439 F.2d 730, 734 (C.C.P.A. 1971). *See also* Ellen P. Winner, *Enablement in Rapidly Developing Arts—Biotechnology,* 70 J. Pat. & Trademark Off. Soc'y 608, 609 (1988). This Note uses "art" to refer to classes of inventions and not the entire field of biotechnology.

problematic. Thus, the *Forman* factors-based analysis of enablement primarily arises in the less predictable chemical and biological arts.[20]

2. *The* Forman *Factors are Often Applied in Combination*

All of the undue experimentation factors need not be reviewed in each case.[21] Individual cases often address two or three of the *Forman* factors in combination. For example, the quantity of experimentation can be offset by the nature of the experimentation. If the required experimentation is routine, a large amount is permissible. The Federal Circuit recognized this offset principle in *In re Wands*.[22] *Wands* concerned a patent for the production of monoclonal antibodies[23] to detect hepatitis B surface antigen. In order to practice this invention as broadly as it was claimed, a person skilled in the art would have to screen as many as 134 hybridomas.[24] While the Board of Patent Appeals and Interferences considered this amount of experimentation undue, the Federal Circuit disagreed, pointing out that it is the nature of monoclonal antibody work to screen a number of hybridomas to find one producing a desired antibody.[25] Thus, the *Wands* court considered one of the *Forman* factors, the nature of monoclonal antibody technology, in determining whether a second factor, quantity of experiments, was indicative of undue experimentation.

Similarly, the courts have considered other *Forman* undue experimentation factors in combination. For example, *In re Vaeck*[26] held

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20. Donald S. Chisum, *Intellectual Property Law: United States* § 2D[3][a] (1992); *In re* Wands, 858 F.2d 731, 736–40 (Fed. Cir. 1988) (applying *Forman* factors to biological invention); *Ex parte* Forman, 230 U.S.P.Q. (BNA) 546, 548 (Bd. Pat. App. & Int., 1986) (noting that "experiments in genetic engineering produce, at best, unpredictable results"); *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) (noting, with reference to chemical and biological arts, "the scope of enablement obviously varies inversely with the degree of unpredictability").

21. Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1213 (Fed. Cir.) (noting that it is not necessary for the court to review all the factors as they are "illustrative, not mandatory"), *cert. denied,* 112 S. Ct. 169 (1991).

22. 858 F.2d at 737.

23. Monoclonal antibodies bind to single antigenic sites or epitopes, distinguishing them from polyclonal antisera, which are far less specific because they contain numerous antibodies recognizing a variety of antigenic sites.

24. A hybridoma results from the fusion of an antibody-producing lymphocyte with an immortal myeloma cell. The resulting hybrid cell will produce the same antibody the lymphocyte produced and will perpetually divide and survive *in vitro*. Following fusion, the hybridomas are screened to determine the characteristics of the antibodies produced.

25. *Wands,* 858 F.2d at 740.

26. 947 F.2d 488, 496 (Fed. Cir. 1991).

that, where the claims are broad enough to cover species not described in the specification, then illustrative examples and guidance in selecting useful species are required. In so holding, *Vaeck* cited the relatively undeveloped state of the art regarding the biology of the genera of bacteria involved and the limited guidance provided in the specification.[27]

C. *Problems Raised by Biotechnology Patents*

Patenting biotechnological inventions raises two difficulties that are not encountered in more established fields. First, the biotechnology patent applicant struggles with the conflicting demands of the nonobviousness and enablement requirements with respect to the predictability of the art. Second, because the technology is developing rapidly, the patent applicant seeks claims broad enough to cover modifications of the invention enabled by future technical advances.[28] Without assurance that developments in the near future will not render a patent worthless, companies will not invest in the research and development necessary to bring a product to market.[29] The need for broad protection, however, must be weighed against policy considerations favoring limited claim scope.

1. *The Nonobviousness and Enablement Requirements Present Conflicting Demands*

The applicant for a biotechnological patent faces the difficulty of characterizing the field of the invention as unpredictable for purposes of meeting the nonobviousness requirement and as predictable for satisfying the enablement requirement. In order to be patentable, the invention must be nonobvious. Because biotechnology inventions are often recombinant versions of known proteins, it is the unpredictable aspects of applying recombinant DNA technology that make these inventions nonobvious and patentable.[30] On the other hand, if the art is considered unpredictable, claims covering modifications of the examples provided are difficult to enable. This tension is especially prevalent in the fields of

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27. *Id.* at 495.

28. Discussed in Winner, *supra* note 19, at 615.

29. U.S. Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis* 383 (1984).

30. Kate H. Murashige, *Section 102/103 Issues in Biotechnology Patent Prosecution,* 16 AIPLA Q.J. 294, 297–98 (1988–89).

recombinant DNA and monoclonal antibodies, where the general strategies are well-established, but application of these strategies to new proteins often requires some modification of previous methods.[31]

2. *The Need for Broad Claims Conflicts with Policy Considerations Favoring Limited Protection*

Case law concerning biotechnology patents reflects the tension between the need for broad claims to meaningfully reward valuable (often medically significant) advances and the concern that granting broad claims will hinder further advances or disproportionately reward those who make small, but timely, contributions. Economically viable biotechnology patents must be broad enough in scope to prevent competitors from being able to invent around the patent.[32] If the claims are too narrow, competitors can use materials or methods not covered by the claims to achieve essentially the same result without infringing the patent. This is more likely to occur in rapidly developing fields, such as biotechnology, where developments not anticipated by a patent application often arise shortly after the patent is filed.

Biotechnology, however, is characterized by what Professors Robert Merges and Richard Nelson[33] call science-based technical advances. These are advances which build on recent scientific developments that reveal technological opportunities for industry.[34] Merges and Nelson have identified three situations in which science-based inventions should be limited to narrower claims because much of the background contribution comes from basic science research. First, narrower claims may be justified where many are working toward the same objective, and only the first to achieve that objective will get the patent. A second situation warranting narrow protection is one in which a new development has been anticipated, and the first to make it operational has made a relatively small contribution. Third, narrow claims are appropriate when the invention is a great commercial success, but is merely a successful practical application of principles generally known by scientists.[35]

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31. *Id.* at 297–300.

32. Thomas G. Wiseman, *Biotechnology Patent Practice—A Primer,* 16 AIPLA Q.J. 394, 402 (1989); *Commercial Biotechnology: An International Analysis, supra* note 29, at 388–90.

33. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope,* 90 Colum. L. Rev. 839, 883 (1990).

34. *Id.*

35. *Id.* at 884.

The litigation concerning human growth hormone (hGH) exemplifies the tension between the need for broad claims and the concern over disproportionately rewarding contributions of limited value. In *Hormone Research Foundation v. Genentech,*[36] the dispute concerned Hormone Research Foundation's (HRF's) patent on synthetic hGH.[37] HRF sued Genentech for infringement of its patent because Genentech was producing hGH by a recombinant DNA technique. HRF's patent did not anticipate the ability to produce hGH by recombinant DNA methods, but it covered the same product. At the time the HRF patent application was filed, the inventor erroneously indicated in the application that he had identified the structure of natural hGH. HRF's hGH consisted of a 190 amino acid sequence, while Genentech's hGH contained 192 amino acids. Genentech defended the alleged infringement by asserting that its product did not have the same structure as that claimed in the HRF patent. The district court granted Genentech's motion for summary judgment on the grounds that 1) its products did not infringe the HRF patent, and 2) HRF's claims were invalid for nonenablement. The Federal Circuit agreed that Genentech had not literally infringed the HRF patent, but remanded the case for determination of factual issues concerning the judgment of noninfringement and invalidity.[38]

This case raises questions of who deserves broad protection for their contribution of useful biotechnology. Before HRF developed the synthetic production of hGH, this hormone could be obtained only by extraction from the pituitary glands of human cadavers.[39] HRF's contribution of synthetic hGH was, therefore, a valuable breakthrough for the treatment of dwarfism and other growth hormone deficiencies. HRF did not, however, anticipate the later developments of recombinant DNA technology. As the Federal Circuit noted, the production of purer and more potent forms of the compound through the use of later-developed technology does not necessarily indicate that the original patent specification did not enable the production of the purer forms.[40] One could argue that the original inventor should not be punished for a few inaccuracies in the sequence in favor of one who makes a small, albeit significant, improvement on his method, and who escapes

36. 904 F.2d 1558 (Fed. Cir. 1990), *cert. dismissed,* 499 U.S. 955 (1991).

37. If the amino acid sequence for a given protein is known, that protein can be synthesized chemically by assembling the necessary amino acids in the proper sequence. This was how HRF was making hGH at the time the patent was filed. *Id.* at 1560.

38. *Id.* at 1569.

39. *Id.* at 1560 n.1.

40. *Id.* at 1568.

infringement by the good fortune of the original inventor's minor error. On the other hand, the development of a more potent hGH should not be hindered by an overly broad patent issued to the first to invent synthetic hGH, especially when the original patent disclosed an erroneous amino acid sequence.

In re Wright reflects this tension between conflicting policy considerations in patent law. One concern is that those who disclose their inventions to the public deserve patent protection broad enough to make disclosure worthwhile.[41] A contrary concern is that patent protection, especially in science-based disciplines like biotechnology, should be conservative in scope so as to encourage others to continue research and development without fear of infringing existing patents.[42] Wright developed a vaccine strategy clearly worthy of patent protection. The question is what scope of patent protection appropriately rewards this type of moderately significant invention without hindering development of vaccines needed to protect against other RNA viruses.

II. *IN RE WRIGHT*

Dr. Stephen E. Wright used recombinant DNA techniques to develop a vaccine against an avian RNA tumor virus and applied for patent protection covering the use of his strategy to make vaccines against RNA viruses.[43] Wright's application included broad, intermediate, and narrow claims. The broad claims covered vaccines against RNA viruses in general.[44] The intermediate claims were limited to vaccines against avian RNA tumor viruses. The only claims the PTO allowed were his narrowest, those limited to the one vaccine he had demonstrated as successful against one avian RNA tumor virus.

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41. Yusing Ko, *An Economic Analysis of Biotechnology Patent Protection,* 102 Yale L.J. 777, 791–92 (1992).

42. *Id.* at 793–94.

43. *In re* Wright, 999 F.2d 1557, 1559 (Fed. Cir. 1993).

44. RNA viruses include a wide variety of virus classes, all of which use RNA (rather than DNA) for their genetic material. Retroviruses are one class of RNA virus so named for their ability to use an enzyme (reverse transcriptase) to make DNA from their RNA.. RNA tumor viruses are retroviruses that cause tumors. Not all retroviruses are tumor viruses (for example, the AIDS and leukemia viruses). *See generally RNA Tumor Viruses* (Robin Weiss et al. eds., 1982).

A. *Recombinant DNA Technology*

Recombinant DNA technology involves engineering the production of proteins or cells with particular functions by taking advantage of the means by which living organisms naturally produce proteins. The strategy is to put the DNA coding for a desired protein into a host cell by a process known as transformation or transfection. Transfected host cells can serve as factories to produce large quantities of the protein. This approach has been used to produce human insulin and human growth hormone, both of which were previously obtainable only by extraction from cadavers.[45] Alternatively, the objective may be to engineer a cell with a particular combination of properties by changing the proteins synthesized within the cell.

One general approach can be outlined as follows.[46] First, the researcher isolates the DNA encoding the desired protein. Then this DNA is linked to the DNA of a bacterium or virus capable of infecting the host cell.[47] The foreign DNA integrates into the host cell genome, and the transfected cells then carry and express[48] the foreign gene. By selecting genes that code for useful features, and omitting genes that code for unwanted characteristics, one can construct a cell ideally suited for a particular purpose. One example is a live vaccine containing the viral particles necessary to protect against disease, but lacking the pathogenic gene regions responsible for the risks of exposure to a natural virus.

B. *Wright's Invention*

Using recombinant DNA techniques, Wright developed a vaccine effective at immunizing chickens against a tumor virus, Prague avian sarcoma virus (PrASV).[49] His strategy involved two major steps. First, he isolated the gene that codes for envelope A protein, a PrASV

45. Walter L. Miller, *Use of Recombinant DNA Technology for the Production of Polypeptides*, 118 Advances in Experimental Med. & Biology 153, 168–69 (1979).

46. For a more detailed explanation of recombinant DNA techniques, see James D. Watson et al., *Recombinant DNA: A Short Course* (1983).

47. Restriction enzymes, which cut DNA at sites containing specific nucleic acid sequences, are used to cut out desired pieces of DNA. Other enzymes (DNA ligase) are used to splice two segments of DNA.

48. When a cell makes the protein coded for by a particular gene, the gene is said to be expressed.

49. *In re* Wright, 999 F.2d 1557, 1559 (Fed. Cir. 1993).

antigen.[50] He then transfected chicken embryo cells with the antigenic genes, and infected the cells with a similar but nononcogenic[51] virus, 0-type Rous Associated Virus (RAV-0). The cells were then incubated to allow time for the genetic material of the RAV-0 to recombine with the envelope gene, and for the recombined virus to replicate. Wright subsequently purified the vaccine so that it contained only the desired recombinant virus particles. In this manner, he created a version of the virus, called RAV-Ac^n, that lacked the ability to induce tumor formation but provoked an immune response to PrASV.

C. *The Rejection of Wright's Claims*

The PTO examiner allowed only the claims specific to the RAV-Ac^n vaccine and the process for making RAV-Ac^n or a similar viral vaccine containing the same antigenic gene and non-oncogenic virus.[52] The examiner rejected the broader claims covering vaccines, or the process for making vaccines, for other pathogenic RNA viruses by creating a genome coding for antigenicity without pathogenicity.[53] She also

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50. An antigen is a protein that stimulates an immune response. Antibodies generated as part of the immune response recognize and bind to antigens on the foreign material, in this case, the tumor virus. Antigen recognition is the means by which the immune system knows which cells to destroy.

51. Oncogenicity refers to the ability to induce tumor formation.

52. The allowed claims were:

Claim 13 A live, non-pathogenic vaccine for a pathogenic RNA virus, comprising an immunologically effective amount of a viral, antigenic, genomic expression having an antigenic determinant region of the RNA virus, but no pathogenic properties, the viral, antigenic, genomic expression being the RAV-Ac^n virus.

Claim 14 A vaccine according to claim 13, wherein the vaccine has been purified by selection for the expression of the antigenic genome.

Claim 43 A process for producing a live, non-pathogenic, recombinant vaccine conferring immunity against the PrASV avian tumor virus in chickens, comprising inserting the PrASV env A gene into a RAV-O virus by marker rescue such that said PrASV env A gene replaces the endogenous envelope gene of the RAV-O virus; and selecting for the recombinant in C/E cells.

Claim 44 A live, non-pathogenic, recombinant vaccine conferring immunity against the PrASV avian tumor virus in chickens, in which vaccine the PrASV env A gene has been inserted into a RAV-O virus by marker rescue to replace the endogenous envelope gene of the RAV-O virus, and the recombinant has been selected for in C/E cells.

Wright, 999 F.2d at 1559.

53. Two of the rejected claims were:

Claim 1 A process for producing a live non-pathogenic vaccine for a pathogenic RNA virus, comprising the steps of identifying the antigenic and pathogenic gene regions of said virus; performing gene alteration to produce a genome which codes for the antigenicity of the virus, but does not have its pathogenicity; and obtaining an expression of the gene.

rejected intermediate claims limited to vaccines against avian tumor viruses. Wright's single success, the examiner argued, did not demonstrate sufficient probability that other recombinant RNA viruses could be made without undue experimentation.[54]

The examiner considered Wright's most generic claims too broad because many of them could include any and all live, non-pathogenic vaccines, and processes for making these vaccines, which would protect any living organism from any RNA virus.[55] She recognized that these claims were broad enough to include vaccines against leukemia viruses, tumor viruses, and AIDS viruses.[56] The examiner pointed out that scientists have been unable to develop an AIDS vaccine for humans despite the considerable amount of time and money devoted to that effort.[57] Referring to a 1988 article concerning AIDS vaccine development,[58] the examiner noted the diversity of AIDS virus genes in general and of their envelope proteins in particular.[59] Wright's claims were too broad because they required extrapolation of one virus envelope gene's immunogenicity to that of another virus envelope gene. Such an extrapolation has not been possible between divergent immunodeficiency viruses.[60]

The Board of Patent Appeals and Interferences affirmed the examiner's rejection.[61] The board agreed with the examiner that the rejected claims lacked enabling disclosure because of their breadth and the lack of evidence supporting an expectation of success in producing an effective vaccine using the claimed process.[62] The board also noted that the examiner allowed the narrowest claims only after Wright

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Claim 11 A live, non-pathogenic vaccine for a pathogenic RNA virus, comprising an immunologically effective amount of a viral antigenic, genomic expression having an antigenic determinant region of the RNA virus, but no pathogenic properties.

Id. at 1559–60.

54. *Id.* at 1560.

55. *Id.*

56. *Id.* Human immunodeficiency virus (HIV) is an RNA virus thought to play a causative role in AIDS. Wright's broader claims would encompass any pathogenic RNA virus, including HIV.

57. *Id.*

58. Thomas J. Matthews et al., *Prospects for Development of a Vaccine Against HIV* in *Human Retroviruses, Cancer, and AIDS: Approaches to Prevention and Therapy* 313 (Dani Bolognesi ed., 1988).

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

60. *Id; see also* Matthews, *supra* note 58, at 317.

61. *Wright*, 999 F.2d at 1561.

62. *Id.* at 1560.

submitted evidence of the vaccine's efficacy *in vivo*.[63] Although Wright had shown that his strategy was successful in constructing a recombinant virus with the desired characteristics and that this virus could provoke an immune response, the examiner did not consider the invention enabled until Wright submitted evidence of immunoprotection in chickens.[64]

The Federal Circuit affirmed, essentially by citing the examiner's answer.[65] The court noted the inclusion of AIDS vaccines within the claims to demonstrate the unpredictability of the art as well as the breadth of the claims.[66] The court approved of the examiner's reliance upon a 1988 article[67] in support of her position that, as of February 1983,[68] the physiological activity of RNA viruses was so unpredictable that one of ordinary skill in the art would not have had a reasonable expectation that any living organism could be immunized against any pathogenic RNA virus by inoculation with a live virus containing the antigenic portion, but not the pathogenic portion, of the RNA virus.

Wright argued that the art is not so unpredictable that his specification was not enabling.[69] Wright supported this argument with his subsequent success in constructing a recombinant vaccine using a different envelope gene and following his disclosed invention.[70] He also cited papers published by others in 1990–92 showing successful application of his strategy to construct vaccines effective at protecting chimpanzees and goats from immunodeficiency viruses.[71] The court disregarded these successes because they addressed the current state of the art rather than the state of the art in February of 1983.[72] In dicta, the court also noted that these few successes were not sufficient to rebut the examiner's determination of undue experimentation.[73]

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63. *In vivo* refers to in the living organism.

64. *Wright*, 999 F.2d at 1561.

65. *Id.* at 1562–63.

66. *Id.* at 1562.

67. Matthews, *supra* note 58.

68. Wright filed his patent application on February 25, 1983. *Wright*, 999 F.2d at 1558, n.1.

69. *Id.* at 1562.

70. *Id.*

71. *Id.* n.7.

72. *Id.* at 1562–63.

73. *Id.* at 1563. Unfortunately, the court did not elaborate on this point and it remains unclear what would have been sufficient. For example, the dicta imply that if these successful examples had been included in the original specification, the court still might have considered them insufficient to support claims beyond those limited to the RAV-Ac^{n} vaccine. Yet, it is difficult to see how working examples could be insufficient to enable the corresponding claims. The burden would be on the examiner to show why the examples would not be enabling.

III. ANALYSIS OF *WRIGHT*

Although the court reached an appropriate result with respect to Wright's broadest claims, it improperly considered post-filing-date evidence to support its finding of non-enablement. With respect to Wright's claims limited to avian tumor virus vaccines, the PTO failed to meet its burden of providing a reasonable basis for concluding that these intermediate claims were not enabled. The Federal Circuit emphasized the breadth of Wright's most generic claims in affirming the examiner's finding of non-enablement, while relying on faulty reasoning to support its finding that Wright had not enabled the claims limited to what the court recognized as a narrow group.[74] The frequent reference to the inclusion of AIDS vaccines suggests a concern with reserving broad patent protection for those whose inventions bring a significant breakthrough. This policy consideration justifies the rejection of Wright's broader claims, but it does not adequately support the rejection of his intermediate claims. By suggesting that Wright needed working examples to enable all embodiments of his claimed invention, the court elevated the enablement standard and set a confusing precedent.

A. The Court Improperly Considered Post-Filing-Date Evidence

The court erroneously upheld the examiner's reliance on post-filing-date developments to demonstrate the unpredictability of the art.[75] While later publications may be used as evidence of the state of the art existing on the filing date,[76] the *Wright* court stretches this to include using the later state of the art as evidence of the state of the art on the filing date. This is not the same as citing a post-filing date publication that refers to the state of the art as of the filing date. The examiner used the late date

74. *Id.* at 1564.

75. This was done even though the court refused to permit the applicant to cite developments occurring after the filing date to support the predictability of the art and the enablement provided in the disclosure. Yet the court explicitly stated in *Hogan* that "Courts should not treat the same legal question, enablement under § 112, in one manner with respect to the applicant and in a different manner with respect to the examiner." *In re* Hogan, 559 F.2d 595, 604–05 (C.C.P.A. 1977) (holding that enablement must be determined as of the filing date, and not on the basis of evidence arising later). The Court of Customs and Patent Appeals suggested in *Marzocchi,* however, that references supporting the accuracy of the disclosure as enabling need not necessarily pre-date the filing. *In re* Marzocchi, 439 F.2d 220, 223 n.4 (C.C.P.A. 1971). This dictum suggests that Wright should have been permitted to offer his 1985 data to demonstrate the enablement provided by his patent specification, provided that these data were developed through application of the 1983 state of the art.

76. *Hogan,* 559 F.2d at 605.

of the Matthews publication as evidence that the art of producing vaccines for retroviruses was still unpredictable five years after the filing date of Wright's application.[77] The Federal Circuit agreed that the 1988 article illustrates that "the art is not even today as predictable as Wright has suggested that it was back in 1983."[78] This statement reflects the erroneous assumption that an art becomes more predictable with time. It is true that developments occurring after the filing date can make the art more predictable as the properties of a biological system become better understood.[79] In some fields, however, new discoveries and difficulties advancing the art can reveal that the biological system is highly variable and less predictable than was once believed. This is true with the race to develop an effective AIDS vaccine.[80] The *Wright* court erred when it presumed that, because immunodeficiency viruses were known to be highly variable in 1988, it must have been known in 1983 that RNA viruses were so unpredictable that a vaccine strategy effective against one would not be expected to work with another. The 1988 article on AIDS viruses, however, does not describe the state of the art existing in 1983. The first publications suggesting that AIDS could be caused by a retrovirus were not even published until May 1983, three months after Wright filed his patent application.[81]

Reference to the unpredictability of an element unknown as of the filing date does not offer a reasonable basis for claim rejection on grounds of nonenablement. *In re Hogan* drew a distinction between permissible and impermissible uses of a later publication to demonstrate non-enablement.[82] It is permissible to use a later publication as evidence

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

78. *Id.* at 1563.

79. Murashige, *supra* note 30, at 299–300 (implying that, in the monoclonal antibody field, the art has become so predictable that it is difficult to patent new inventions).

80. Peter Newmark, *Receding Hopes of AIDS Vaccines,* 333 Nature 699 (1988) (noting difficulty in developing AIDS vaccine, more than for any other virus, and listing numerous reasons for this difficulty, one of which is genomic variability); George M. Shaw et al., *Molecular Characterization of Human T-Cell Leukemia (Lymphotropic) Virus Type III in the Acquired Immune Deficiency Syndrome,* 226 Science 1165, 1167–68 (1984) (contrasting novel data on genomic diversity of AIDS virus with genomic conservation of related viruses).

81. M. Essex et al., *Antibodies to Cell Membrane Antigens Associated with Human T-Cell Leukemia Virus in Patients with AIDS,* 220 Science 859 (May 20, 1983); Edward P. Gelmann et al., *Proviral DNA of a Retrovirus, Human T-Cell Leukemia Virus, in Two Patients with AIDS,* 220 Science 862 (May 20, 1983); Robert C. Gallo et al., *Isolation of Human T-Cell Leukemia Virus in Acquired Immune Deficiency Syndrome (AIDS),* 220 Science 867 (May 20, 1983); F. Barré-Sinoussi et al., *Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS),* 220 Science 868 (May 20, 1983).

82. *In re* Hogan, 559 F.2d 595, 605 (C.C.P.A. 1977).

that, as of the filing date, the invention could not be practiced as claimed without undue experimentation. But using a later publication to demonstrate art-related facts that did not exist on the filing date is impermissible.[83] In *Hogan,* a claim covering amorphous polymers was rejected because the use of amorphous polymers was not enabled by the specification. Amorphous polymers, however, were not discovered until nine years after Hogan's application filing date. In reversing the claim rejection, the court pointed out that "[t]o now say that appellants should have disclosed in 1953 the amorphous form which on this record did not exist until 1962, would be to impose an impossible burden on inventors and thus on the patent system."[84] Likewise, it would have placed an impossible burden on Wright to have required him to enable the application of his claimed vaccine strategy to an unusually variable class of retroviruses before that class of viruses had been discovered.[85]

B. The Court's Rejection of the Intermediate Claims was Based on Faulty Reasoning and Elevated the Enablement Standard

The *Wright* opinion focused heavily on the broadest claims, which covered recombinant vaccines protecting against any RNA virus.[86] The court gave less attention to the intermediate claims, also rejected for non-enablement, which were restricted to vaccines against avian tumor viruses. In *Wright,* the court illogically equated variability between breeds of chickens with variability among viruses to support rejection of the intermediate claims. This was not a reasonable basis for claim rejection and, if taken literally, elevates the standard for enablement such that Wright's narrowest claims should have been rejected as well.

1. The Court's Rejection of the Intermediate Claims was Based on Faulty Reasoning

The court drew support for its assertion of unpredictability in the art of avian RNA tumor viruses from a 1985 paper co-authored by Wright.[87]

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83. *Id.*

84. *Id.* at 606.

85. It would have been appropriate, however, to use publications demonstrating the variability among the many types of RNA viruses known at the time of Wright's filing date.

86. *In re* Wright, 999 F.2d 1557, 1562–63 (Fed. Cir. 1993).

87. The unpublished paper, *Avian Retroviral Recombinant Expressing Foreign Envelope Delays Tumor Formation of ASV-A-Induced Sarcoma,* was co-authored by David Bennett, and was attached to a November 1985 declaration by Wright. *Id.* at 1564.

This paper stated that one breed of chickens did not respond well immunologically and that future experiments would include other breeds of chickens. According to the court, this "suggests that, even as late as 1985, the genetic diversity existing among chickens alone required efficacy testing even among the members of this narrow group."[88] The court illogically used this evidence of variability between different breeds of chickens as evidence of variability among avian RNA viruses.[89]

In fact, in 1983, RNA tumor viruses were considered so genetically similar that the preface of a large compendium on the subject indicated that most of its material could be considered generally applicable to all RNA tumor viruses.[90] The introductory chapter of this compendium pointed out the remarkable uniformity of RNA tumor virus genomes despite the diversity of their pathological mechanisms.[91] Wright's intermediate claims were limited to avian RNA tumor viruses, the subset of RNA tumor viruses that has been studied since 1911.[92] It is not clear, therefore, why the court considered the narrow class of avian RNA tumor viruses to have the same problems of unpredictability as all classes of RNA viruses.

If the court was asserting that there was so much variability among avian tumor viruses that a vaccine strategy effective against one virus could not be expected to be effective against another, then the court should have supported its statement with evidence directly related to this assertion. Instead, the court discussed only variability between chicken breeds. The fact that one breed of chickens is less responsive to a vaccine against a single virus does not mean that there is so much variability among avian viruses that the strategy used to make the vaccine against one virus would not be effective against other viruses of the same type.

Taken to its logical conclusion, the court's reasoning suggests that even Wright's narrowest claims should have been rejected. In particular, claim 43 specifically covers a process for producing a "vaccine conferring immunity against the PrASV avian tumor virus in chickens."[93]

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88. *Id.*

89. The court concluded: "Accordingly, we see no error in the Board's finding that one skilled in the art would not have believed as early as February of 1983 that the success of Wright's one example could be extrapolated with a reasonable expectation of success to all avian RNA viruses." *Id.*

90. *RNA Tumor Viruses, supra* note 44, at viii.

91. *Id.* at 2–3.

92. *Id.* at 3.

93. *See supra* note 52.

If the court believed that the genetic diversity among chickens requires efficacy testing for all breeds of this narrow group, then claim 43 should have been rejected as non-enabled. To enable claim 43 in accordance with the Federal Circuit's reasoning, Wright would have had to submit evidence that his recombinant PrASV vaccine provokes an effective immune response in all breeds of chickens. This would be inconsistent with existing precedent[94] and would place an unfair burden on patent applicants.

2. *The Court Elevated the Enablement Standard*

The court was not persuaded by Wright's argument that the scientific literature indicated predictability in the area of avian RNA tumor viruses. Instead, the court cited Wright's declaration, in which he stated that he waited for results of *in vivo* tests before applying for the patent. The court used this declaration as evidence that *in vivo* testing is necessary to enable the application of Wright's invention to other avian viruses, without citing other evidence that *in vivo* testing was required. Thus, the court implied that an applicant should refrain from providing too much data supporting enablement, lest that amount of data be required for other embodiments of the invention.

By suggesting that Wright needed to perform *in vivo* efficacy tests for each vaccine and each animal species covered by his claims, the court set an extraordinarily high standard for biotechnological inventions and contradicted well-established precedents.[95] Essentially, the court elevated the standard for an enabling disclosure from a reasonable expectation of success to a demonstrated success. *Wright* could be interpreted as holding that the specification must enable one of ordinary skill in the art to practice the invention without any experimentation, rather than without undue experimentation. If so, then a patent

94. *In re* Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) ("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* Wands, 858 F.2d 731, 740 (Fed. Cir. 1988) (specification enabled claim to methods using a generic class of antibodies even though applicant deposited only one hybridoma cell line that secreted a specific antibody); United States v. Telectronics, Inc., 857 F.2d 778, 786 (Fed. Cir. 1988) (specification disclosing a method of electrically stimulating fractured bone with stainless steel electrodes to promote healing was enabling for the use of other electrode materials not described in the specification), *cert. denied,* 490 U.S. 1046 (1989); Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576–77 (Fed. Cir. 1984) (patent specification was enabling where it listed elements that could form thousands of products, not all of which would be operative, and holding that the use of prophetic examples does not necessarily make a specification non-enabling).

95. See cases cited *supra* note 94.

specification would have to provide evidence that each embodiment of a claimed invention will succeed.

C. *Implicit Policy Considerations Influenced* Wright

As acknowledged in *Hogan,* enablement questions ultimately reflect the concern that the scope of patent protection should match the applicant's contribution to the art.[96] In light of this policy, it is reasonable that Wright's broadest claims were rejected. Wright's contribution of a vaccine protecting chickens against a tumor virus does not warrant patent protection for vaccines against all of the many other types of RNA viruses. This concern does not provide an adequate basis, however, for denying him patent protection for vaccines against other avian RNA tumor viruses.

The court's restriction of Wright's patent to exclude the broadest claims is consistent with Merges and Nelson's scheme for inventions relying heavily on basic science.[97] Scientists have been searching for effective vaccines against RNA viruses for some time, with the effort significantly enhanced by recombinant DNA technology.[98] A 1980 publication discusses the general strategy of using recombinant DNA technology to construct other types of viral vaccines bearing the antigenic sites while lacking the pathogenic properties.[99] While Wright may have been the first to develop a specific and effective retroviral vaccine, many others have been working on the same problem and could be close to finding a more effective vaccine strategy for protection against AIDS. When so many scientists must spend years of effort gradually working toward a solution to a problem as great as the spread of AIDS, it is unreasonable to grant broad patent protection to the first to develop one vaccine effective at protecting chickens from a tumor virus.

The court expressed its concern with disproportionately rewarding Wright's contribution when it suggested that, if Wright's viral vaccine strategy enabled his broader claims, then an effective AIDS vaccine would have been developed by the time this case was decided. The court showed little faith that Wright's invention could improve the prospects for developing an effective AIDS vaccine, despite Wright's attempt to

96. *In re* Hogan, 559 F.2d 595, 605–06 (C.C.P.A. 1977).

97. *See supra* notes 33–35 and accompanying text.

98. B.P. Marmion, *Prospects for New Viral Vaccines,* 290 Phil. Transactions of the Royal Soc'y of London—Biology 395 (1980).

99. *Id.*

demonstrate that his invention had already been successful in making effective recombinant AIDS vaccines for chimpanzees and goats.[100] These developments were dismissed because they occurred after the filing date.[101] While claims broad enough to include all RNA viruses, or even all retroviruses, would disproportionately reward Wright for his invention, it is not clear that this same policy argument can be applied to the claims limited to avian RNA tumor viruses. The Merges and Nelson arguments for narrow patent scope justify rejecting claims covering an entire field (for example, all retroviruses), but do not require restricting patent protection to those embodiments actually reduced to practice. Avian RNA tumor viruses are a relatively restricted and homogeneous class of viruses, and a patent claim limited to this class would present an appropriate middle ground between disproportionately broad protection and an overly narrow patent.

D. Wright *Creates Problems for Inventors and Sets a Confusing Precedent*

As a result of *Wright,* biotechnology companies may be reluctant to disclose their inventions through patents because they would risk public disclosure of their trade secrets without receiving adequate protection to support their investment in research and development. Simply postponing patent filing until more working examples have been developed would cause two problems for such companies. First, the applicant would risk losing patent rights in foreign countries that grant patents with priority to those who file first,[102] and require filing within a year of filing in the United States.[103] Second, the state of the art may advance so much that the invention is no longer patentable because it has become obvious. Not only must the specification enable others practicing the invention to have a reasonable expectation of success, but this same reasonable expectation of success must not derive from the prior art. If the prior art is found to enable the invention, then the patent application is rejected for nonobviousness. Thus, further developments

100. *In re* Wright, 999 F.2d 1557, 1562–63 (Fed. Cir. 1993).

101. *Id.*

102. Charles R.B. Macedo, *First-to-File: Is American Adoption of the International Standard in Patent Law Worth the Price?,* 18 AIPLA Q.J. 193, 202 (1990).

103. The Paris Convention permits residents and nationals of member countries to claim the priority right of a previous filing date in another member country for patent applications filed within 12 months of the first filing. Paris Convention for the Protection of Industrial Property, March 20, 1883, art. 4, 21 U.S.T. 1583, 1631–32 (as revised at Stockholm on July 14, 1967).

in the art of recombinant viral vaccines could have rendered Wright's invention obvious and, therefore, unpatentable.

Because *Wright* also does not provide a clear and reasonable basis for finding the intermediate claims non-enabled, it sends a confusing message to biotechnology inventors and their attorneys. The rejection of Wright's intermediate claims suggests that the unpredictability of biological systems may be so great that claims to biotechnology inventions are not enabled unless each conceivable embodiment of the claims has been reduced to actual practice. Such a rule would render patent protection worthless for biotechnological inventions. Competitors could easily practice around a patented process by applying the method to another species, or by making minor modifications to the process. While such a restrictive policy was not explicit in *Wright,* and would be inconsistent with legal precedent,[104] the ambiguity remains. A clarification of the standards of enablement, particularly as they apply to biotechnology, is therefore needed.

IV. GUIDELINES FOR EVALUATION OF ENABLING DISCLOSURE

In order to provide clarity and consistency, the PTO should refrain from policy-based decisions, and follow established precedents. When the PTO does make policy-based decisions, the policy should be explicit so that applicants may address the policy concerns. Concern for commensurability of the scope of enablement with the scope of claims can guide application of the enablement standard, and yield patent protection proportionate to the value of the inventor's contribution. This and other valid concerns can be addressed through application of the *Forman* factors, thereby incorporating policy concerns while adhering to precedent. An evaluation of Wright's patent application under this approach would support the rejection of the broader claims, but lead to allowance of the intermediate claims.

Consistency and clarity of the law are important when patent protection is concerned.[105] Cooperative inventors deserve to know what is expected in a specification's disclosure so they can address these

104. *See* Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1213 (Fed. Cir.), *cert. denied,* 112 S. Ct. 169 (1991); see also cases cited *supra* note 94.

105. Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1543 (Fed. Cir. 1987) (Newman, J., dissenting) (referring to consistent application of the doctrine of equivalents: "If courts are not to hinder the progress of technological advance, certainty and predictability are as important in the application of equitable as of legal principles.").

expectations in their patent applications. Those who invest in developing and marketing new inventions, especially in biotechnology, make decisions of great financial importance based on the expected patentability of an invention.[106] If the requirements for patentability change or remain nebulous, investors may find the risk of losing patent rights unacceptably high.[107] The purpose of the patent system, to promote progress in the useful arts, is lost if progress is hindered by uncertainty of legal protection for inventions.[108]

Clarity and consistency require the PTO and the courts to base claim rejections on sound reasoning. If a claim is considered non-enabled due to unpredictability of the art, there must be a causal link between that aspect of the art that is unpredictable and the non-enabled aspect of the claim. In *Wright,* the court pointed to variability of immunologic responses between chicken breeds to show that application of Wright's vaccine strategy to other viruses was not enabled. This logical fallacy confuses the enablement standard.

A general theme of the enablement requirement is that the enablement must correspond in scope to the claims.[109] This does not mean that the disclosure must describe every embodiment covered by the claims.[110] In some instances, it is sufficient that the specification discloses an inventive concept.[111] In the less predictable arts, however, the adequacy of disclosure should be addressed through analysis of the *Forman* factors. Valid policy concerns can be accommodated by this approach.

One valid concern is proportionately rewarding useful technological contributions. A realistically proportionate reward takes into account the consequences of restricting claim scope. If the patent application concerns a pioneering invention, the inventor may be more deserving of broad claims yet be less able to be specific about various embodiments of the invention. When a significant contribution deserves broad protection, a relatively limited disclosure may be regarded as enabling.[112]

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106. Eugene L. Bernard, *Government Patent Policy,* 3 Int'l Conf. on Genetic Engineering 8, 9–11 (Melissa Keenberg ed., 1981).

107. *See* Marchese, *supra* note 7, at 619–25 (discussing increased transaction costs and disincentive to invent created by uncertainty in patent disclosure requirements).

108. Reid G. Adler, *Biotechnology as an Intellectual Property,* 224 Science 357, 361 (1984).

109. *See* Thomas L. Irving et al., *The Significant Federal Circuit Cases Interpreting Section 112,* 41 Am. U. L. Rev. 621, 637–46 (1992).

110. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1213 (Fed. Cir.), *cert. denied,* 112 S. Ct. 169 (1991).

111. *See* Merges & Nelson, *supra* note 33, at 846.

112. Winner, *supra* note 19, at 610.

Conversely, if an inventor has simply taken the next logical step based on a large body of established background information developed by the scientific community, broad claims may not be justified.[113] Under these circumstances, the greater foundation of background information should make it possible for the inventor to provide guidance enabling each embodiment of the claimed invention. Most cases, however, fall between these two extremes, and restriction to the narrowest claims would leave an inventor without meaningful protection despite the value of the inventor's contribution to progress in the art. While it is true that basic science research provides much of the background information necessary to the development of biotechnology products, the work of basic scientists falls far short of bringing useful products to the public. Basic scientists, by definition, seek an understanding of the fundamentals, not of practical applications. In biotechnology, a considerable amount of research and development is necessary to turn the fruits of basic research into useful products. The recommendations of Merges and Nelson raise valid arguments for narrow patent protection, but only in limited situations.

A second valid concern is preventing broad claims from hindering further advances in the art. The *Wright* court appeared to be influenced by such a policy when it pointed out that Wright's broad claims would include an AIDS vaccine.[114] The court noted the scientific community's inability to develop an AIDS vaccine despite all the time, resources, and scientists devoted to that effort.[115] The implication was that permitting Wright's broad claims would discourage development of a much-needed AIDS vaccine because use of it would infringe Wright's patent.[116]

When the examiners and the courts are concerned that allowing claims would hinder further advances in an art, explicit statements to that effect would clarify the hazy line between enablement and non-enablement. When the PTO rejects a claim for lack of enablement, the basis for that rejection must be clear so that the patent applicant has the opportunity to offer appropriate evidence to overcome the rejection. For example, if an examiner purports to reject a claim for non-enablement because of variability among species, when in fact the rejection is influenced by a concern about hindering further advances, the applicant may not have a

113. Merges & Nelson, *supra* note 33, at 884.

114. *In re* Wright, 999 F.2d 1557, 1562 (Fed. Cir. 1993).

115. *Id.* at 1563.

116. Such an infringement could be defended under the reverse doctrine of equivalents. *See* Donald S. Chisum, 4 *Patents* § 18.04[4] (1992).

fair opportunity to rebut the examiner's rejection. No amount of evidence may be found sufficient to rebut the PTO's rejection because the applicant has not addressed the PTO's true concern. When a PTO rejection for non-enablement is based on policy grounds, that basis must be explicit so that the applicant may rebut with evidence that the policy is not violated.

In summary, policy concerns are best accommodated by: 1) explicitly acknowledging policy as it influences patent decisions by the PTO and courts, 2) confining policy factors to those related to the purposes of the patent system (incentive to disclose inventions and promote progress), and 3) using a *Forman* factors analysis to ensure commensurability of scope of protection with scope of enablement. This does not require changing existing law, but merely calls for consistency with established precedents and the objectives of the patent system. In this way, existing patent law can accommodate the need of biotechnology companies for patent protection broad enough to make research and development economically viable.

V. CONCLUSION

Biotechnology companies require enough breadth in their patent claims to make investment in technology and patent protection worthwhile. The court set a confusing and unwarranted precedent when it upheld the rejection of Wright's claims to recombinant vaccines against avian tumor viruses. The rejection relied upon a misapplication of *In re Hogan* and faulty reasoning to conclude that avian tumor viruses are too unpredictable to permit claims not fully supported by working examples. The uncertainty regarding adequate enabling disclosure in biotechnology patents can be cleared by explicit acknowledgment of any policy concerns influencing the PTO, and by consistent application of existing law. To ensure commensurability between the scope of enablement and the scope of patent claims, the PTO should consider the value of allowed claims relative to the value of the inventor's disclosure. The PTO must strike a balance between providing meaningful patent protection for needed biotechnological inventions and encouraging subsequent advancement of the technology.