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ENABLING DNA AND PROTEIN COMPOSITION CLAIMS: WHY CLAIMING BIOLOGICAL EQUIVALENTS ENCOURAGES INNOVATION

Kenneth G. Chahine[*]

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I. INTRODUCTION

Our patent system is based on a fundamental principle: the governmental grant of a limited monopoly encourages inventors to be creative and disclose their laudable ideas to the public. These disclosures then stimulate other inventors to improve the patented technology in an attempt to secure their own limited monopoly on an improved invention. In the process, the constitutional goal of promoting the progress of the useful arts is fostered.[1] The success of the patent system, therefore, depends largely on the scope of protection patentees receive for their invention. Narrow protection renders a patent useless by allowing others to avoid infringement easily, without a concomitant contribution to the art. Conversely, overly broad patent protection stymies innovation; it discourages others from improving previously patented technologies due to a fear that even significant improvements will fall within the literal scope of the patented claims and thus infringe.

Currently, biotechnology companies are receiving narrow patent protection for newly discovered DNA molecules and proteins.[2] The problem

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[1] U.S. CONST. art. I, § 8. ("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.")

[2] Proteins are substances which play many roles in living organisms, including regulatory functions. In humans, for example, the amount of sugar in a person's bloodstream is regulated by the protein insulin.

Proteins are polymers made up of subunits called amino acids. There are 20 amino acids. The protein's biological activity is dictated by the particular arrangement of the amino acids. The arrangement of the amino acids is referred to as the amino acid sequence or protein sequence. A useful analogy is to think of amino acids as letters in the alphabet which form different words depending on how they are arranged. Although the words "DAD" and "ADD" (analogous to a protein) are comprised of the same letters (analogous to the amino acids), the meaning conveyed by the words changes depending on how the letters are arranged.

In the cell, a molecule called deoxyribonucleic acid, or DNA, carries all the information required to make all the proteins of the body. DNA is a polymer of molecules called nucleotides. The information carried by a DNA molecule is stored in the particular arrangement of the nucleotides. The arrangement of the nucleotides is referred to as the nucleotide sequence or DNA sequence. A "gene" is an arrangement of nucleotides that contains the information necessary to make a single protein.

stems in part from the inherent structural organization and chemical properties of DNA molecules and proteins. It is well known in the art of molecular biology,[3] for example, that modifications which slightly alter the structure of a protein generally will not affect the protein's biological activity. Thus, in order for patentees to adequately protect their inventions adequately, the claims must cover more than the specific amino acid sequence of the protein. The number of possible modifications, however, is enormous; one cannot expect to make and test them all. Patentees, therefore, are placed in an awkward predicament: they must limit the claims to the specific nucleotide or amino acid sequence of the DNA molecule or protein, or have the claims rejected for lack of enabling disclosure under the first paragraph of 35 U.S.C. section 112.[4]

In an attempt to obtain broader patent protection, patentees are drafting claims that cover not only the newly discovered protein, but also those protein modifications that retain the same biological activity as the newly discovered protein. The Patent and Trademark Office ("PTO") and the Federal Circuit have consistently held, however, that claims encompassing biological equivalents are not enabled. The rationale of the PTO and the

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In a process called translation, a cell makes a protein using the information stored in the gene as a template in much the same way that a house is built using an architect's blueprints as a template. Three nucleotides (a codon) within a DNA molecule specify for a specific amino acid. For example, the codon CCA "tells" the cell to insert the amino acid proline, the codon AGA tells the cell to insert the amino acid arginine, and so forth. Thus, knowing the DNA sequence of a gene allows one to accurately predict the amino acid sequence of the corresponding protein. *See infra* Part IV.A.

Because of the special relationship between DNA and proteins, patents ultimately seeking to protect a protein may claim the DNA sequence which codes for the protein, the amino acid sequence of the protein, or both. Depending on the discussion, one of these claiming strategies may be emphasized. It is understood, however, that the analysis applies equally to all three claiming strategies. *See generally* JAMES D. WATSON ET AL., MOLECULAR BIOLOGY OF THE GENE (1987) [hereinafter WATSON ET AL.].

[3] Molecular biology is the study of organisms at the DNA and protein level. MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS 1288 (5th ed. 1994) [hereinafter SCIENTIFIC DICTIONARY].

[4] 35 U.S.C. § 112 (1996).

Federal Circuit is that the art of molecular biology is unpredictable. They argue that a patentee cannot teach one skilled in the art exactly which protein modification will retain biological activity and which will not.[5] As such, the claims are not enabled under a traditional enablement analysis.

Although the reasoning of the PTO and the Federal Circuit initially appears sound, when analyzed in light of the skill in the art and the policy underlying the enablement doctrine, this reasoning becomes questionable. This article will first show that although determining which protein modifications will yield a protein with similar biological activity is not absolutely predictable, it is not as unpredictable as the PTO and the Federal Circuit suggest. Using the scientific theory of natural selection, this article will demonstrate how one skilled in the art can reasonably predict which protein modifications will retain biological activity and which ones will lose biological activity. Second, the article will show that although protein composition claims that are limited by functional language may not satisfy the traditional enablement analysis, they fulfill the underlying purpose of the enablement doctrine.[6] Limiting a protein composition claim to the native[7]

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[5] *See infra* Part III.

[6] Under 35 U.S.C. § 112, para. 6, an element in a combination claim may be expressed as a means for performing a specific function. The scope of "means-plus-function" limitations extends to "the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, para. 6 (1996). The exact scope of functional language that does not use the "means for" expression is unclear. *See* Paul M. Janicke, *The Crisis in Patent Coverage: Defining Scope of an Invention by Function*, 8 HARV. J.L. & TECH. 155, 188 (1994). The PTO's new guideline for examiners states that the words "means for" are unnecessary in order for the claim limitation to fall within the scope of the sixth paragraph of §112, and thus their scope is equivalent to means-plus-function limitations. *See* Charles E. Van Horn, *PTO Notice on Means or Step Plus Function Limitation Under 35 U.S.C. Section 112, 6th Paragraph*, 47 PAT. TRADEMARK & COPYRIGHT J. (BNA) 571 (1994). In any event, functional limitations, like all other claim limitations, must be read in light of the specification in order to properly define the scope of the claim. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 982-83, 34 U.S.P.Q.2d (BNA) 1321, 1332 (Fed. Cir. 1995) (in banc), *aff'd*, 116 S. Ct. 1384 (1996).

In this article, the author assumes that functional language is always used in combination with a structure such as a DNA molecule or protein (i.e., not a single means claim). The author further assumes that, like all other claim limitations, the scope of functional language is defined by the structure (i.e., the DNA or protein sequence) and the acts described

amino acid sequence of the protein and modifications of that sequence exhibiting similar biological activity, strikes a sensible balance between the patentee's need to claim the invention generically and the public's goal of encouraging innovation. The scope of claims limited to biological function, when properly defined, is narrower than the scope of protection afforded many chemical composition claims. By excluding protein modifications which may be similar in structure yet superior in biological activity, the resulting claims encourage others in the field to design around the claimed protein, thus promoting the progress of the useful arts.

II. ENABLEMENT

In addition to the requirement that an invention be new, useful, and nonobvious, a patent application must fully disclose the invention and describe to one skilled in the art how to make and use the invention. This requirement dates back to the original Patent Act of 1790, which required that the patent specification:

> be so particular . . . [as] to enable a workman or other person skilled in the art of manufacture, whereof it is a branch, or wherewith it may be nearest connected, to make, construct or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term.[8]

The current standard for enablement is set forth in the first paragraph of section 112 of the 1952 Patent Act which similarly states:

> 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

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(i.e., biological function) in the specification.

[7] The term "native" refers to DNA molecules and proteins as they exist in nature.

[8] Patent Act of 1790, ch. 7, § 2, 1 Stat. 111 (repealed 1793).

> with which it is most nearly connected, to make and use the same . . . .[9]

Although not explicitly stated in the statute, courts have required that the specification of a patent teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.[10] Courts have also suggested certain factors for determining whether a claimed invention is enabled. Those factors, referred to as the *Wands*[11] factors, include the relative skill of those in the art; the state of the prior art; the amount of guidance provided by the specification; the number of working examples provided by the specification; the nature of the invention; the unpredictability of the art; the amount of experimentation required to practice the claimed invention; and the breadth of the claimed invention.[12] The cumulative application of these factors, and not the reliance on any one, determines whether a claimed invention is enabled; moreover, the factors are "illustrative, not mandatory."[13]

An applicant's disclosure must rise above an invitation to experiment,[14] but it need not rise to the level of a "blueprint."[15] The only requirement is a "reasonable expectation of success."[16] Further, nothing more than "objective" enablement is required by the first paragraph of

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[9] 35 U.S.C. § 112 (1996).

[10] *See In re* Wright, 99 F.2d 1557, 27 U.S.P.Q.2d (BNA) 1510 (Fed. Cir. 1993).

[11] *In re* Wands, 858 F.2d 731, 8 U.S.P.Q.2d (BNA) 1400 (Fed. Cir. 1988); *see also Ex parte* Forman, 230 U.S.P.Q. (BNA) 546 (Bd. Pat. App. & Int'f 1986).

[12] *See In re* Wands, 858 F.2d at 737, 8 U.S.P.Q.2d (BNA) at 1404.

[13] Amgen v. Chugai, 927 F.2d 1200, 1213, 18 U.S.P.Q.2d (BNA) 1026, 1027 (Fed. Cir. 1991).

[14] *See In re* Wright, 99 F.2d at 1562, 27 U.S.P.Q.2d (BNA) at 1514.

[15] *See* Staehelin v. Secher, 24 U.S.P.Q.2d (BNA) 1513, 1515 (Bd. Pat. App. & Int'f 1992).

[16] *In re* Wright, 99 F.2d 1557, 1564, 27 U.S.P.Q.2d (BNA) 1510, 1515 (Fed. Cir. 1993).

section 112.[17] The scope of the claims may be enabled "through broad terminology or illustrative examples."[18]

The PTO bears the burden of proof. A specification purporting to teach one how to make and use the subject matter of the patent application "*must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support."[19]

A. *The Specification Must Enable One Skilled In The Art*

Section 112 requires that the specification enable one skilled in the art to make and use the claimed invention.[20] "A patent specification is not addressed to judges or lawyers, but to those skilled in the art; it must be comprehensible to them, even though the unskilled may not be able to gather from it how to use the invention, and even if it is 'all Greek' to the unskilled."[21] A properly enabled specification, therefore, assumes

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[17] *See id.* at 1562, 27 U.S.P.Q.2d (BNA) at 1513.

[18] *Id.*

[19] Fiers v. Revel, 984 F.2d 1164, 25 U.S.P.Q.2d (BNA) 1601 (Fed. Cir. 1993) (quoting *In re* Marzocchi, 439 F.2d 220, 223, 169 U.S.P.Q. (BNA) 367, 369 (C.C.P.A. 1971)).

[20] *See* 35 U.S.C. § 112 (1996).

[21] Gould v. Mossinghoff, 229 U.S.P.Q. (BNA) 1, 14 (D.D.C. 1985), *aff'd in part, vacated in part, and remanded sub nom,* Gould v. Quigg, 822 F.2d 1074, 3 U.S.P.Q.2d (BNA) 1302 (Fed. Cir. 1987).

familiarity with the subject matter and merely describes the invention.[22] Indeed, the specification preferably omits what is well known in the art.[23]

B. *The Predictability Of The Art*

The scope of enablement is directly proportional to the predictability of the art.[24] The mechanical and electrical arts are considered predictable and the chemical and biochemical arts are considered unpredictable.[25] As the Court of Customs and Patent Appeals stated in *In re Fisher*:

> In cases dealing with 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 predicated 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 inversely with the degree of unpredictability of the factors involved.[26]

Although this statement was made over a quarter of a century ago, the sentiments the court articulated have not changed--at least with respect to biotechnology. Despite the fact that the court in *In re Fisher*, and again in *In*

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[22] In *Webster Loom Co. v. Higgins*, 105 U.S. 580 (1881), Webster claimed an improvement in looms for weaving pile fabrics. The Supreme Court upheld the patent over the defendant's objection that the specification was not enabling. After establishing that the proper standard was that of the hypothetical person of skill in the art, the Court stated that the inventor "may begin [describing the invention] at the point where the invention begins, and describes what he has made that is new, and what it replaces of the old. That which is common and well known is as if it were written out in the patent and delineated in the drawing." *Id.* at 590.

[23] *See* Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384-85, 231 U.S.P.Q. (BNA) 81, 94 (Fed. Cir. 1986).

[24] *See In re* Fisher, 427 F.2d 833, 839, 166 U.S.P.Q. (BNA) 18, 24 (C.C.P.A. 1970).

[25] *See id.*

[26] *Id.*

re Cook,[27] indicated a preference to speak in terms of unpredictable factors rather than to refer to an entire art as unpredictable, later cases continue to categorize whole arts as predictable or unpredictable.[28] However, other factors, such as the level of skill in the art and the amount of guidance in the specification, offset the unpredictability of the art.

C. *The Quantity Of Experimentation Necessary*

Historically, courts have not required the disclosure of every embodiment that fell within a patent's scope.[29] The length of the specification that would be necessary to describe every embodiment, alone, would render such a requirement unreasonable for generic claims. As discussed above, the patentee need only objectively teach one skilled in the art how to derive, with a reasonable expectation of success, all the embodiments that fall within the claimed invention. The need for some experimentation to practice the claimed invention is not fatal. In *Minerals Separation, Ltd. v. Hyde*,[30] the Supreme Court addressed the adequacy of the disclosure in the case of a froth flotation process for ore separation which required some experimentation to practice the claimed invention. The Court responded to the argument that the claims were invalid for want of enablement as follows:

> 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 must 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

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[27] 439 F.2d 730, 733, 169 U.S.P.Q. (BNA) 298, 301 (C.C.P.A. 1971).

[28] *See Ex parte* Forman, 230 U.S.P.Q. (BNA) 546, 548 (Bd. Pat. App. & Int'f 1981) ("[E]xperiments in genetic engineering produce, at best, unpredictable results."); *see also In re* Hitzeman, 9 U.S.P.Q.2d (BNA) 1821, 1823 (Bd. Pat. App. & Int'f 1988) (citing *In re* Fisher, 427 F.2d 833, 166 U.S.P.Q. (BNA) 18 (C.C.P.A. 1970)); *In re* Wands, 99 F.2d 1557, 8 U.S.P.Q.2d (BNA) 1510 (Fed. Cir. 1993) (Newman, J., dissenting) (quoting *Ex parte* Forman).

[29] *See* Deering v. Winona Harvester Works, 155 U.S. 286, 302 (1894).

[30] 242 U.S. 261 (1916).

> law requires in patents is not greater than is reasonable, having regard to their subject matter. . . . The process, . . . 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. . . . This satisfies the law.[31]

More recently, the Federal Circuit stated that "[a]lthough the statute [35 U.S.C. § 112] does not say so, enablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation.' . . . That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'"[32] Although there is no dispute that some experimentation does not render the claims invalid, exactly how much experimentation is "undue" is unclear. This is a factor that must be evaluated on the particular facts of each case.[33]

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[31] *Id.* at 270-71; *see also* The Incandescent Lamp Patent, 159 U.S. 465 (1895) ("If the description is so vague and uncertain that no one can tell, except by independent experimentation, how to construct the patented device, the patent is void.")

[32] *In re* Vaeck, 947 F.2d 488, 494-95, 20 U.S.P.Q.2d (BNA) 1438, 1444 (Fed. Cir. 1991).

[33] *See In re* Wands, 858 F.2d 731, 8 U.S.P.Q.2d (BNA) 1400 (Fed. Cir. 1988). In *In re Wands*, the claimed invention was for "immunoassay methods for the detection of hepatitis B surface antigen ["HBsAG"] by using high-affinity monoclonal antibodies of the IgM isotype." *Id.* at 733, 8 U.S.P.Q.2d (BNA) at 1401. The specification taught a process for immunizing mice against HbsAG and producing monoclonal antibodies from lymphocytes isolated from the immunized mice. The method yielded both IgG and IgM high-affinity monoclonal antibodies. A process using the IgM isotypes, which usually are not favored for immunoassay, was claimed because the IgM isotypes were found to have "unexpectedly high sensitivity and specificity." *Id.* at 734, 8 U.S.P.Q.2d (BNA) at 1402. Wands submitted a declaration under 37 C.F.R. § 1.132, demonstrating that the process could be practiced reproducibly. The data demonstrated that 6 out of 10 fusions yielded hybridoma cell lines which produced antibodies specific for HBsAg. Of those, 143 "high-binders" were isolated. *See id.* at 738, 8 U.S.P.Q.2d (BNA) at 1405. Nine of the 143 were subjected to further analysis. Of those nine, four had affinitiessuitable for practicing the claimed invention (i.e., 10^9 M^{-1}).

The PTO rejected the claims for [illegible]

D. *The Breadth Of The Claims*

Consistent with the general principle that the claims of the patent define the invention for the purposes of patentability and infringement, what must be enabled is the claimed invention.[34] As discussed above, the patentee is not limited to the specific embodiments disclosed in the patent application. Claims covering more than what the specification objectively teaches,

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arguing that "since the stored cell lines were not completely tested, there was no proof that any of them could produce IgM antibodies with a binding affinity constant of at least 10^9 M^{-1}." *Id.* Thus, only 4 out of 143 hybridomas, or 2.8% were *proved* to fall within the claims. *Id.* Wands argued that because only 9 of the 143 were actually tested, and 4 of those fell within the scope of the claims, the success rate was 44%. *See id.* at 79, 8 U.S.P.Q.2d (BNA) at 1405. The majority of the court agreed that the remaining 134 hybridomas that were untested should not be written off as failures: "The PTO's position leads to the absurd conclusion that the more hybridomas an applicant makes and saves without testing, the less predictable the applicant's results become." *Id.* at 740, 8 U.S.P.Q.2d (BNA) at 1406.

In her dissenting opinion, Judge Newman sided with the PTO contending that Wands had failed to enable the breadth of the generic claims. *See id.* at 741, 8 U.S.P.Q.2d (BNA) at 1407 (Newman, J., dissenting). In response to Wands' statistical analysis that it would have been highly unlikely to choose the only 4 antibodies with high affinity out of 143 hybridomas, Judge Newman responded:

> Wands did not . . . prove the right point. The question is whether Wands, by testing nine out of 143 (the Commissioner points out that the randomness of the sample was not established), and finding that 4 out of the 9 had the desired properties, has provided sufficient experimental support for the breadth of the requested claims in the context that 'experiments in genetic engineering produce, at best, unpredictable results . . .'

Id. (quoting *Ex Parte* Forman, 230 U.S.P.Q. (BNA) 546, 547 (Bd. Pat. App. & Int'f 1986). According to Judge Newman, the experimentation required to determine the affinity of the remaining antibodies was undue. *See id.*

[34] *See* 35 U.S.C. § 112 (1996) ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."); *see also In re* Wright, 99 F.2d 1557, 1561, 27 U.S.P.Q.2d (BNA) 1510, 1513 (Fed. Cir. 1993) ("[T]he specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention.")

however, are rejected or invalidated for "undue breadth."[35] The concept of undue breadth was made famous by the Telegraph Case of *O'Reilly v. Morse*.[36] Morse's eighth claim read:

> Eighth. I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, *however developed*, for making or printing intelligible characters, signs, or letters, *at any distance*, being a new application of that power of which I claim to be the first inventor or discoverer.[37]

The Supreme Court did not find it difficult to declare that the scope of Morse's eighth claim far exceeded the teachings of the specification, which surely did not teach *all* methods of electro-magnetic communication. The Court's major concern was that such broad patent protection would preempt the entire field and discourage innovation:

> If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in a plaintiff's specification. His invention may be less complicated--less liable to get out of order--less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee. [38]

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[35] *See* O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853).

[36] *Id.*

[37] *Id.* at 64 (emphasis added).

[38] *Id.* at 68.

Morse's claim is referred to as a "single means" claim because it recites only a desired function with no limitations on how that function is to be achieved, such as with a telegraph.[39]

Similarly, the scope of the claims must not unduly read on inoperative subject matter.[40] In *In re Cavallito*,[41] the applicant's generic claims covered bis-quaternary ammonium substituted alkanes used as hypotensive agents. The applicant identified 30 members of the class which were operative, yet claimed several hundred thousand possible compounds. The Court of Customs and Patent Appeals ("C.C.P.A.") responded that an applicant seeking to claim such a large group of compounds must provide "reasonable assurance that all or substantially all of them are useful. . . . An applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a select few are useful and a general suggestion of a similar utility in the others."[42] However, claims reading mainly on operative species, but including inoperative species, are enabled if the inoperative species can be identified by one skilled in the art without undue experimentation.[43]

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[39] *See supra* note 6. Not all claims that recite a function are objectionable, however. The sixth paragraph of § 112 of the Patent Act specifically sanctions functional language used in a claim for a combination. *See* 35 U.S.C. § 112 para. 6 (1996).

[40] *See generally* 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.03[7][c] (1995); 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 4, 15-27 (1973); Einhorn, *The Enforceability of Patent Claims Encompassing Some Inoperative Species*, 45 J. PAT. OFF. SOC'Y 716 (1963); Herbert H. Goodman, *The Invalidation of Generic Claims by Inclusion of a Small Number of Inoperative Species*, 40 J. PAT. OFF. SOC'Y 745 (1958). A rejection may also be maintained under 35 U.S.C. § 101 for lack of utility.

[41] 282 F.2d 357, 127 U.S.P.Q. (BNA) 202 (C.C.P.A. 1960).

[42] *Id.* at 361, 127 U.S.P.Q. (BNA) at 205; *see also In re* Corkill, 771 F.2d 1496, 1501, 226 U.S.P.Q. 1005, 1009 (Fed. Cir. 1985) (stating that claims covering a substantial number of inoperative members are properly rejected for non-enablement).

[43] *See* Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1575-77, 224 U.S.P.Q. (BNA) 409, 414 (Fed. Cir. 1984) ("Even if some of the claimed combinations are inoperative, the claims are not necessarily invalid. However, if . . . the number of inoperative combinations

While the scope of an invention cannot cover all future developments in the art, courts have suggested that truly unique or pioneering inventions should be treated more leniently. In *In re Fisher*,[44] often cited for this proposition, the inventor was the first to develop a long desired adrenocorticotrophic hormones ("ACTH") preparation with a potency exceeding fifty percent of "International Standard" and which contained relatively low content of undesirable products. The applicant claimed all preparations of ACTH with a potency above one hundred percent of "International Units."[45] The C.C.P.A. recognized the importance of the contribution, stating:

> It is apparent that such an inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings. Such improvements, while unobvious from his teachings, are still within his contributions, since the improvement was made possible by his work.[46]

After suggesting that the inventor was entitled to broad patent protection, however, the court rejected the claims for undue breadth. The court stated, "[i]t is equally apparent, however, that [the inventor] must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. § 112,"[47] requiring claims to bear a reasonable correlation to the scope of enablement. It is difficult to reconcile how an inventor can be permitted to dominate future inventions without expanding the claims beyond what the specification objectively teaches. So long as claims must bear a reasonable

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becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid."); Horton v. Stevens, 7 U.S.P.Q.2d (BNA) 1245, 1247 (Bd. Pat. App. & Int'f 1988) ("The mere fact that a claim embraces undisclosed or inoperative species or embodiments does not necessarily render it unduly broad.")

[44]427 F.2d 833, 166 U.S.P.Q. (BNA) 18 (C.C.P.A. 1970).

[45]*See id.*

[46]*Id.* at 839, 166 U.S.P.Q. (BNA) at 24.

[47] *Id.*

correlation with the disclosure, any future domination is a direct result of the broad applicability of the invention not judicial remuneration.[48]

III. CASE LAW

There have been few cases dealing directly with the enablement of DNA composition claims that code for a native protein and biological equivalents. In each case, the patentees have employed slightly different claiming strategies in an attempt to claim the invention generically without running afoul of an enablement rejection. In *Ex parte Hudson*,[49] for example, the applicant's claim on appeal was to the gene that coded for porcine relaxin and modifications thereof. Claim 32 read:

> Claim 32. An isolated gene, double stranded DNA fragment, or DNA transfer vector as claimed . . . which has been modified by one or more of the procedures selected from the group consisting of:
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> (a) deletion of one or more natural codons;
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> (b) addition of further codons to a natural sequence; or
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> (c) replacement of one or more of the natural codons by codons which code for amino acids other than those coded

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[48] Remuneration for pioneering inventions often occurs as a result of successful infringement litigation under the judicially created doctrine of equivalents. *See* Graver Tank & Mfg. Co. v. Linde Air Prod., 339 U.S. 605, 85 U.S.P.Q. (BNA) 328 (1950). Thus, in some instances, the doctrine of equivalents may afford a patentee broader patent scope. The doctrine of equivalents, however, is deemed not to be an adequate remedy for DNA and protein composition claims because the doctrine itself is unpredictable as to the legal standard used and how it is applied to inventions. Recently, the Federal Circuit sitting *in banc* in *Hilton Davis Chem. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 35 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 1995), *rev'd by*, 117 S. Ct. 1014 (1996), *on remand to* 114 F.3d 1161, 43 U.S.P.Q.2d (BNA) 1152 (Fed. Cir. 1997) had a difficult time agreeing on the legal standard of the doctrine, with 5 out of 12 judges dissenting in 3 separate dissenting opinions.

[49] 18 U.S.P.Q.2d (BNA) 1322 (Bd. Pat. App. & Int'f 1990).

> by the natural codons; with the proviso that the thus modified gene, DNA sequence or transfer vector still encodes peptides with porcine relaxin activity.[50]

Claim 32 was rejected under section 112 for lack of enabling disclosure. The examiner initially took the position that section 112 required the applicant "to determine *all* of the modified DNA sequences which would code for peptides with porcine relaxin activity."[51] The Board of Patent Appeals and Interferences ("the Board") did not agree with the examiner's position that all claimed modifications must be tested.[52] Nevertheless, the Board agreed with the examiner that the specification at issue failed to teach one skilled in the art how to determine which modifications would retain biological activity.[53]

The applicants contended that one skilled in the art could determine, without undue experimentation, which modification would retain relaxin activity. In support of their position, the applicants relied on three articles[54] that compared the DNA sequence of porcine relaxin to the DNA sequences of insulin and relaxins of other species.[55] Based on the comparison, the applicants argued that one skilled in the art could predict modifications that would retain biological activity. The Board acknowledged that "[e]xpression of relaxin activity in the relaxins of different species through a common receptor binding region . . . might indicate that the non-common sequences

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[50] *Id.* at 1323.

[51] *Id.* (emphasis added).

[52] *See id.*

[53] *See id.*

[54] *See id.* The articles were: Dodson et al., *Rat relaxin: insulin-like fold predicts a likely receptor binding region*, 4 INT'L J. BIOL. MACROMOL. 399 (1982); Isaacs, *Relaxin and its structural relationship to insulin*, 271 NATURE 278 (1978); Blundell et al., *Biology of relaxin and its role in the human*, PROC. OF THE 1ST INT'L CONF ON HUM. RELAXIN 14 (1983).

[55] *See infra* Part IV.B (discussing how these predictions are made by one

could be relatively freely modified. . . ."[56] According to the Board, however, this would not "unequivocally establish that fact."[57]

In *Ex parte Maizel*,[58] the invention concerned the protein B-cell growth factor ("BCGF"). BCGF has the ability to stimulate the growth of B-cells in culture. Applicants did not claim the protein itself, but rather claimed the DNA sequence which coded for the protein in combination with a vector.[59] Representative claim one read:

> 1. A recombinant DNA vector comprising a DNA sequence which encodes a protein exhibiting a molecular weight between about 8 and about 14 kilodaltons upon gel exclusion chromatography, said protein having an amino acid sequence which includes the non B-galactosidase-derived sequence of the amino acids displayed in Figure 4, or a biologically functional equivalent thereof, and having a BCGF biological activity characterized by an ability to stimulate the incorporation of thymidine into DNA of BCGF-dependent B-cells, or an ability to stimulate the comitogenesis of anti-u activated B-cells, when said protein is cocultured in effective concentrations with said respective B-cells in vitro.[60]

The Board began by noting that the applicants' claim covered "any" DNA which encoded the BCGF protein or a "biologically functional equivalent" having BCGF-like activity.[61] The claim, the Board said, was analogous to a single means claim because it defined the DNA molecule's function, rather than its structure. As such, the claims were not

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[56] *See Ex parte* Hudson, 18 U.S.P.Q. 2d (BNA) at 1323-24.

[57] *Id.* The Board apparently also found that some of the prior art data was contradictory.

[58] 27 U.S.P.Q.2d (BNA) 1662 (Bd. Pat. App. & Int'f 1992).

[59] *See id.* at 1664.

[60] *Id.* at 1663-64.

[61] *Id.* at 1665.

commensurate with the scope of the disclosure.[62] As support, the Board cited a long passage from the Supreme Court in *O'Reilly v. Morse*[63] to the effect that such a broad claim would encompass future inventions which the public could not enjoy without the permission of the patentee.[64]

Applicants argued that the phrase "biologically functional equivalent" was limited "to proteins having amino acid substitutions wherein the substituted acids have similar hydrophobicity and charge characteristics such that the substitutions are 'conservative' and do not modify the basic functional characteristics of the BCGF protein."[65] The Board responded that the specification of the patent broadly defined "biologically functional equivalent" to encompass any protein that had the biological activity of BCGF regardless of its structure.[66] Moreover, the applicants' specification described several proteins that exhibited BCGF-activity which, according to the Board, fell within the scope of the claims.[67]

Earlier, in *Amgen Inc. v. Chugai Pharmaceutical Co.*,[68] the Federal Circuit used similar language to invalidate Amgen's composition claims directed to the native DNA sequence for the human erythropoietin ("EPO")[69] gene. Claim seven was a generic claim which covered all the DNA sequences that produced a protein that was sufficiently similar to the native EPO amino acid sequence to be biologically active. Claim seven read:

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[62] *See id.*

[63] 56 U.S. (15 How.) 62, 113 (1853).

[64] *See Maizel*, 27 U.S.P.Q.2d (BNA) at 1665.

[65] *Id.*; *see also infra* Part IV.B (discussing conservative amino acid substitutions).

[66] *See Maizel*, 27 U.S.P.Q.2d (BNA) at 1665.

[67] *See id.*

[68] 97 F.2d 1200, 18 U.S.P.Q.2d (BNA) 1016 (Fed. Cir. 1991).

[69] EPO stimulates the production of red blood cells. *See id.* at 1203, 18 U.S.P.Q.2d (BNA) at 1018.

> 7. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake.[70]

In support of the claim, Amgen included "extensive statements in the specification concerning all the analogs of the EPO gene that [could] be made."[71] In addition, Amgen had prepared a few analogs of the EPO gene.[72]

The district court rejected the claims as not enabled by the specification. The district court calculated that more than 3600 different EPO analogs could be made by substituting a single amino acid at various positions of the EPO gene, and more than a million analogs by substituting three amino acids in the EPO gene.[73] The Federal Circuit stated that the district court had correctly invalidated the claims for lack of enabling disclosure, but found that the district court incorrectly focused on the biological activity of the protein rather than the structure.[74] The court stated:

> [I]t is not necessary that a patent applicant test all the embodiments of his invention; what is necessary is that he provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims. For DNA sequences, that means disclosing how

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[70] *Id.* at 1204, 18 U.S.P.Q.2d (BNA) at 1019.

[71] *Id.* at 1213, 18 U.S.P.Q.2d (BNA) at 1027.

[72] *See id.*

[73] *See id.* at 1213, 18 U.S.P.Q.2d (BNA) at 1026.

[74] *See* Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213, 18 U.S.P.Q.2d (BNA) 1016, 1027 (Fed. Cir. 1991).

> to make and use enough sequences to justify the grant of the claims sought.[75]

With respect to Amgen's claim seven, the court stated:

> Considering the structural complexity of the EPO gene, the manifold possibilities for change in its structure, with attendant uncertainty as to what utility will be possessed by these analogs, we consider that more is needed concerning identifying the various analogs that are within the scope of the claim, methods for making them, and structural requirements for producing compounds with EPO-like activity. It is not sufficient, having made the gene and a handful of analogs whose activity has not been clearly ascertained, to claim all possible genetic sequences that have EPO-like activity.[76]

Accordingly, the court invalidated claim seven for failing to teach one skilled in the art the full scope of the claimed invention.[77]

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[75] *Id.* (citation omitted).

[76] *Id.* at 1214, 18 U.S.P.Q.2d (BNA) at 1028.

[77] *See id.* In *Ex parte* Ishizaka, 24 U.S.P.Q.2d (BNA) 1621, 1625-26 (Bd. Pat. App. & Int'f 1992), applicants claimed the DNA sequence and modifications of the protein glycosylation inhibiting factor ("GIF"). Claims one and two read:

> 1. A nucleic acid capable of encoding a polypeptide exhibiting glycosylation inhibiting factor activity, the nucleic acid having a sequence of nucleotides effectively homologous to the nucleotide sequence defined by the formula:
> CGT-CAC . . . [remaining nucleotide sequence] . . . TAA-AAA.
> 2. The nucleotide sequence of claim 1 wherein said polypeptide exhibits human glycosylation inhibiting factor activity. [sic] and wherein said sequence of nucleotides is at least seventy percent (70%) homologous to said nucleotide sequence defined by said formula.

During prosecution, the examiner rejected the claims as obvious under §

Since *Amgen*, the Federal Circuit has not changed its view. In *In re Deuel*,[78] the applicant isolated two DNA molecules[79] that code for heparin-binding growth factors ("HBGF").[80] Based on the DNA sequences, Deuel determined the amino acid sequence of the proteins. Representative claim four read:

> 4. A purified and isolated DNA sequence consisting of a sequence encoding human heparin binding growth factor of 168 amino acids having the following amino acid sequence:
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> Met Gln Ala . . . [remainder of 168 amino acid sequence].[81]

The PTO did not reject the claim for lack of enablement. However, the Federal Circuit, in dictum, questioned whether the claims were enabled: "[b]ecause Deuel's patent application does not describe how to obtain any DNA except the disclosed cDNA molecules, claim 4 . . . may be considered to be inadequately supported by the disclosure of the application."[82] The

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103, but did not reject the claims for lack of enablement. On appeal, the Board pursuant to 37 C.F.R. § 1.196(b), rejected claims one and two as not complying with the first paragraph of 35 U.S.C. § 112. The Board merely quoted language from the Federal Circuit in *Amgen* to the effect that the claims were not enabled because applicants had not taught one skilled in the art to make and use a sufficient number of members from the generic class claimed to justify a grant of the claims sought.

[78] 51 F.3d 1552, 34 U.S.P.Q.2d (BNA) 1210 (Fed. Cir. 1995).

[79] Deuel actually isolated the complementary DNA ("cDNA") molecules. The difference between a DNA molecule and a cDNA molecule is not relevant to this discussion. For an explanation refer to the "Background" section of the *Deuel* opinion. *See id.* at 1554-55, 34 U.S.P.Q.2d (BNA) at 1211-12.

[80] Heparin-binding growth factors stimulate growth and thus are useful for accelerating the healing process of wounds. *See id.* at 1554, 34 U.S.P.Q.2d (BNA) at 1211.

[81] *Id.* at 1555, 34 U.S.P.Q.2d (BNA) at 1212.

[82] *Id.* at 1560, 34 U.S.P.Q.2d (BNA) at 1216.

court then suggested that the PTO should review the enablement of the claim in light of the precedent of *Amgen*.[83]

IV. ANALYSIS

The theme that emerges from these cases is that, given the unpredictability of the art of molecular biology, the patentee cannot teach one skilled in the art which protein modifications will retain a particular biological activity. Accordingly, the claims are not enabled. The holdings, however, are conclusory; there is no meaningful discussion of the skill in the art, the predictability or unpredictability of determining which protein modification would retain biological activity, or why the scope of the claims violates the underlying policy of the enablement doctrine. In fact, in *Amgen* the Federal Circuit avoided discussing these factors by stating that the *Wands* factors were "illustrative, not mandatory."[84] Whether part of the *Wands* factors, or otherwise, courts should not substitute their judgment for that of one skilled in the art. Nor should courts ignore the impact the breadth of claims will have on the progress of the useful arts; the very purpose of the enablement requirement. The analytical framework of the *Wands* factors, properly applied, would permit broader claims while simultaneously encouraging innovation.

A. *Skill In The Art, Examples And Guidance*

In *Amgen*, the Federal Circuit expressed concern that the specification failed to teach one skilled in the art "methods for making" other DNA molecules.[85] Later in *Deuel*, the same court reiterated its concern that the specification failed to teach how to make DNA molecules other than the ones disclosed in the patent application.[86] A specification, however, preferably excludes what is well known in the art. One skilled in the art can determine, with certainty, every DNA sequence which codes for a particular protein. This is best understood by way of example: assume that the amino acid

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[83] *See id.*; *Amgen*, 927 F.2d 1200, 18 U.S.P.Q.2d (BNA) 1016.

[84] *Amgen*, 927 F.2d at 1213, 18 U.S.P.Q.2d (BNA) at 1027.

[85] *See id.* at 1214, 18 U.S.P.Q.2d (BNA) at 1028.

[86] *See In re* Deuel, 51 F.3d 1552, 1560, 34 U.S.P.Q.2d (BNA) 1210, 1216 (Fed. Cir. 1995).

sequence of a peptide[87] is methionine (Met) - glutamine (Gln) - alanine (Ala). Using the genetic code,[88] one skilled in the art, indeed even one with no skill in the art, could determine which set, or sets of three nucleotides (called a

[87] Proteins comprised of only a few amino acids are referred to as peptides. *See* SCIENTIFIC DICTIONARY, *supra* note 3, at 1469.

[88] The genetic code:

UUU] Phenylalanine UUC	UCU] UCC] Serine	UAU] Tyrosine UAC	UGU] Cysteine UGC
UUA] Leucine UUG	UCA] UCG	UAA] Stop UAG	UGA Stop UGG Tryptophan
CUU] CUC] Leucine CUA] CUG	CUU] CCC] Proline CCA] CCG	CAU] Histidine CAC CAA] Glutamine CAG	CGU] CGC] Arginine CGA] CGG
AUU] AUC Isoleucine] AUA AUG Methionine	ACU] ACC] Threonine ACA] ACG	AAU] Asparagine AAC AAA] Lysine AAG	AGU] Serine AGC AGA] Arginine AGG
GUU] GUC] Valine GUA] GUG	GCU] GCC] Alanine GCA] GCG	GAU] Aspartate GAC GAA] Glutamate GAG	GGU] GGC] Glycine GGA] GGG

On the left side of each column are all the sixty-four codons combinations that can be made with three nucleotides. On the right are the respective amino acids which are specified by the codons on the left. Brackets indicate codons which code for the same amino acid. "Stop" indicates those codons which terminate the translation of the protein. *See, e.g.*, WATSON ET AL., *supra* note 2.

codon), code for the above peptide. The genetic code is redundant. That is, there are sixty-four codons and only twenty amino acids. Up to six different codons can code for a single amino acid.[89] This means that many DNA sequences can code for the same peptide. All the possible DNA sequences that code for the peptide in this example are listed below:

Amino acid sequence:	MET - GLN - ALA
DNA nucleotide sequence:	ATG - CAA - GCT
	ATG - CAA - GCC
	ATG - CAA - GCA
	ATG - CAA - GCG
	ATG - CAG - GCT
	ATG - CAG - GCC
	ATG - CAG - GCA
	ATG - CAG - GCG

Moreover, making any of the recombinant DNA molecules[90] that code for a particular protein is routine in the art of molecular biology. Commonly, a technique known as "site-directed mutagenesis" is employed. In fact, many biotechnology companies offer site-directed mutagenesis kits which include the needed reagents and detailed instructions on how to make DNA modifications. Thus, using the amino acid sequence of the peptide and the genetic code, one skilled in the art can determine and make all the DNA

[89] Leucine is one such amino acid. *See* SCIENTIFIC DICTIONARY, *supra* note 3, at 1131.

[90] A recombinant DNA is a DNA molecule whose nucleotide sequence has been modified by in vitro manipulation (i.e., humanly-engineered). A recombinant protein is a protein whose amino acid sequence has been modified by in vitro manipulation, usually using recombinant DNA as a template. SCIENTIFIC DICTIONARY, *supra* note 3, at 1664.

sequences that code for a particular protein. No guidance in the specification or examples of any kind is required.

Of course, the number of DNA molecules that code for an entire protein, typically made up of several hundred amino acids, is enormous. This should not detract from the fact that one skilled in the art could easily determine and make them all. The aid of a computer and automated synthesizers makes the task even easier. It is difficult, therefore, to comprehend the Federal Circuit's concern in *In re Deuel* that the applicant had not explained how to make any other DNA sequences that coded for the native amino acid sequence of the claimed HBGF protein[91] when all the DNA sequences that code for HBGF can be determined easily by one skilled in the art without any experimentation. Moreover, contrary to the court's assertion,[92] the precedents in *Amgen* do not support the court's decision because *Amgen* addresses a fundamentally different enablement question: whether the specification enabled one skilled in the art to determine which *amino acid* modifications would yield an EPO protein with a similar biological activity as the native EPO protein.[93]

B. *Unpredictability And Experimentation Required*

As discussed above, all the DNA sequences that code for the amino acid sequence of a protein can be determined with certainty. Determining which amino acid modifications will retain biological activity is not absolutely predictable. However, such determinations are not as unpredictable as some opinions might suggest. Using well known theories, one skilled in the art can reasonably predict which protein modification will likely retain biological activity and which modification will not.

Protein modifications can be subdivided into four general classes: substitutions, additions, deletions, and post translational modifications. This discussion is limited to amino acid substitutions, which is what the case law has heretofore generally addressed. Substitutions refer to the replacement

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[91] *See In re* Deuel, 51 F.3d 1552, 1560, 34 U.S.P.Q. 2d (BNA) 1210, 1216 (Fed. Cir. 1995).

[92] *See id.*

[93] The author is cognizant that the *Deuel* and *Amgen* opinions were written by the same judge.

of one or more of a protein's amino acids with a different amino acid. Generally, amino acid substitutions do not significantly alter the protein's function,[94] particularly when the substitute is a similar[95] amino acid. Similar amino acids are amino acids that, because of size, charge, polarity and conformation, are more readily substituted without significantly affecting the structure and function of the protein.[96]

Amino acids can be freely substituted because only a limited number of amino acids directly participate in the protein's biological activity, for example through binding to its substrate or binding to another protein. The vast majority of the amino acids participate in defining the protein's three-dimensional structure. All amino acids, of course, work in concert to ultimately confer biological activity to the protein. Any significant change in the amino acid sequence of a protein is liable to destroy the protein's biological activity. However, proteins generally can tolerate modifications of amino acids that participate only in maintaining its three-dimensional structure better than they can tolerate modifications of amino acids that are directly responsible for the protein's biological activity.[97]

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[94] WATSON ET AL., *supra* note 2 at 227 ("Evidence now indicates that amino acid replacements in many parts of a polypeptide chain can occur without seriously modifying catalytic activity.")

[95]Replacements with similar amino acids are often referred to in the art as "conservative substitutions." SCIENTIFIC DICTIONARY, *supra* note 3, at 442.

[96] For example, the non-polar amino acids Glycine, Alanine, Valine, Isoleucine, and Leucine; the non-polar aromatic amino acids Phenylalanine, Tryptophan, and Tyrosine; the neutral polar amino acids Serine, Threonine, Cysteine, Glutamine, Asparagine, and Methionine; the negatively charged amino acids Lysine, Arginine, and Histidine; the positively charged amino acids Aspartate and Glutamate, represent groups of conservative amino acids. Any one can be substituted for another of the same group. *See generally* WATSON ET AL., *supra* note 2.

[97] More specifically, the backbone of all twenty amino acids are identical (NH_2 -CH - COOH), with the exception of proline and histidine. What differs between amino acids is the functional (R) groups which are attached to the backbone. The biological activity of a protein is usually the result of very specific interactions between the functional (R) groups of a few amino acids with the substrate. On the other hand, the three-dimensional structure of the protein is primarily stabilized by hydrogen bonds formed from atoms on the backbone of the amino acid. Thus,

Nevertheless, it is not always clear from looking at the sequence of the protein which amino acids are primarily involved in the protein's biological activity and which are primarily involved in the protein's three-dimensional structure. In cases where the protein belongs to a class of proteins never before studied or sequenced, there is no dependable way to determine which amino acids are critical to the protein's function except for trial-and-error experimentation. However, such unstudied or unsequenced proteins are becoming increasingly rare. Often, a protein, or at least domains within a protein, belong to a family of proteins that have been previously studied and sequenced. In such cases, nature will have already performed the trial-and-error experimentation. This is the theory of natural selection that stems from Darwin's theory of evolution. Based on this theory, living things emerged from a similar ancestry. Consequently, different organisms perform similar functions using similar biological processes. Fortunately, the proteins of different organisms that perform similar biological functions are similar but not identical. Thus, by comparing the amino acid sequences of similar proteins from different organisms, one skilled in the art can predict which regions of the protein are vital for biological activity and which ones are not.

An example will demonstrate how one skilled in the art can determine which regions of the protein are critical to biological activity. Assume that a DNA sequence that codes for a protein is isolated from human cells. A computer generated comparison of the protein sequence against all known protein sequences reveals four other sequences that are similar.[98] A small portion of the computer generated amino acid alignment looks as following:[99]

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which stabilizes the protein's three-dimensional structure because the backbone of most amino acids is identical. Typically, only amino acids like proline, which has a secondary amino group, and aromatic amino acids, which are bulky, significantly disrupt the protein's three-dimensional structure. *See generally* WATSON ET AL., *supra* note 2.

[98] Computer comparisons of DNA and protein molecules can be performed in a matter of seconds at the National Institute of Health via the internet.

[99] The sequence below is an actual sequence comparison of cyclic GMP-dependent protein kinases which have been implicated in the regulation of smooth muscle contraction and platelet aggregation. *See* Michael D. Uhler, *Cloning and Expression of a Novel Cyclic GMP-dependent Protein Kinase*

		* * * * * *
hCGKIb (human)	E L E L D Q K D E L	L N K G H D I S A D
mCGKII (mouse)	K Q T V . A I A E L	L N K G H D F S V D
bCGKIa (cow)	E K R L S E K E E E	L N K G H D I S A D
DrCGKI (fruit fly)	K K K L Y S L P E Q	L N K G H D R A V D
DrCGKII(fruit fly)	R G S A A G C A G T	L N R G H D I S A D

One skilled in the art would immediately appreciate that over millions of years of evolution (from the fruit fly to the human) a certain amino acid pattern has developed. At certain positions some amino acids are identical in all the species (indicated by an asterisk above the amino acid). Other amino acids have been replaced only by amino acids that have similar structures and chemical properties (shaded). Others have been replaced by amino acids that have different structures and chemical properties (not shaded). As explained above, the theory of natural selection holds that amino acids of the protein, which have been conserved over millions of years, are important to the protein's biological function. Any species that acquired a non-similar amino acid mutation at a position important for the protein's biological function would not have survived or would have been placed at a distinct disadvantage. Over time, the species carrying that particular mutation would have become extinct or been replaced by another species carrying a more favorable amino acid sequence. By comparing the amino acid sequences of proteins from the same family, one skilled in the art can reasonably predict which amino acids can be substituted without significantly affecting the biological function of the protein. Accordingly, one skilled in the art is not completely ignorant as to which modifications will affect the protein's biological activity and which ones will not.

This was the argument unsuccessfully advanced by the patentees in *Ex parte Hudson*.[100] In *Hudson*, the prior art compared the claimed porcine relaxin with insulin and relaxin from other species.[101] The comparison revealed which region was likely to be important for biological activity. The Board initially acknowledged that this protein comparison "might indicate that the non-common sequences could be relatively freely modified."[102] The Board pointed out, however, that such a comparison did not "unequivocally" establish which amino acids could be modified without loosing biological activity.[103] Apparently, the Board believed that enablement requires absolute predictability. By contrast, the law requires nothing more than a "reasonable expectation of success."[104] Based on the comparison data, one skilled in the art could reasonably determine, without undue experimentation, which members of the claimed group retain activity. One skilled in the art could merely run a computer comparison, make the modification using site-directed mutagenesis, and test the modified protein for biological activity.

The C.C.P.A.'s analysis in *In re Angstadt*[105] is pertinent to this discussion. In *Angstadt* the claims were for a "method of catalytically oxidizing secondary or tertiary alkylaromatic hydrocarbons to form a reaction mixture comprising the corresponding hydroperoxides."[106] The method employed an organometalic complex[107] as a catalyst. In the specification, the applicant stated that "certain" of the metals used in the organometalic complex were particularly effective as catalysts, but conceded

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[100] 18 U.S.P.Q. 2d (BNA) 1322 (Bd. Pat. App. & Int'f 1990).

[101] *See id.*

[102] *Id.* at 1324.

[103] *Id.*

[104] *See In re* Wright, 999 F.2d 1557, 1564, 27 U.S.P.Q.2d (BNA) 1510, 1515 (Fed. Cir. 1993).

[105] 537 F.2d 498, 190 U.S.P.Q. (BNA) 214 (C.C.P.A. 1976).

[106] *Id.* at 499, 190 U.S.P.Q. (BNA) at 215.

[107] The organometalic complex formed had the formula "$Mx_n(HAPA)_m$, wherein HAPA is a hexaalkylphosphoramide, MX is a metal salt, m is an integer of from 1 to 8, and n is an integer of from 1 to 4." *Id.*

that not all of the metals yielded hydroperoxides.[108] Nevertheless, the applicant claimed all transition metal cations.[109] The PTO rejected the claims under 35 U.S.C. Section 112, contending that not all transition metal cations were operative and, given the unpredictability of the art, the specification did not teach one skilled in the art how to discern the operative from the inoperative metals without undue experimentation.[110]

The C.C.P.A. disagreed, stating "that applicants are *not* required to disclose *every* species encompassed by their claims even in an unpredictable art."[111] The applicant had disclosed forty operative examples using various metals.[112] If one skilled in the art wished to make or use a transition metal not included within the examples, "he would merely read applicants' specification for directions how to make and use the catalyst complex to oxidize the alkylaromatic hydrocarbons, and could then determine whether hydroperoxides are, in fact, formed."[113] The key word, the court said, in an enablement determination is "'undue' not 'experimentation.'"[114]

This same reasoning should also apply to protein modifications. Admittedly, the number of potential embodiments falling within the scope of the claims is much greater than the number of possible catalysts in *Angstadt*. Nevertheless, there is no difference in the quality of experimentation that is required. One skilled in the art could readily determine which members retain biological activity using routine techniques in the art of molecular biology. As the *Manual of Patent Examining Procedure*

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[108] *See id.* at 500, 190 U.S.P.Q. (BNA) at 216.

[109] *See id.*

[110] *See id.* at 500-01, 190 U.S.P.Q. (BNA) at 216-17.

[111] *In re* Angstadt, 537 F.2d 498, 503, 190 U.S.P.Q. (BNA) 214, 218 (C.C.P.A. 1976).

[112] *See id.*

[113] *Id. See also In re* Marzocchi, 439 F.2d 220, 224, 169 U.S.P.Q. (BNA) 367, 370 (C.C.P.A. 1971) (holding that one skilled in the art could, without undue experimentation, ascertain the inoperative species covered by the claims).

[114] *In re* Angstadt, 537 F.2d at 504, 190 U.S.P.Q. (BNA) at 218

points out, the fact that experimentation may be complex or extensive does not necessarily constitute undue experimentation, so long as the experimentation is routine to one skilled in the art.[115]

C. *The Breadth Of The Claims*

Restricting the scope of DNA and protein composition claims by function rather than structure does not fit the traditional enablement test. The PTO and the Federal Circuit insist that the patentee explain how to make and use, without undue experimentation, a sufficient number of claimed compositions to justify the scope of the claims sought.[116] When applied to the mechanical, electrical and chemical arts, this subtest generally promotes the purpose of the enablement requirement. With new technologies, however, come new claiming strategies unique to the needs of the art. When this occurs, courts must reevaluate the enablement subtest in light of the new claiming strategies to ensure that the purpose of the enablement doctrine is being served.

Markush claims are a perfect example of a claiming strategy that developed to meet the needs of the chemical art.[117] Initially, the PTO adopted a policy against the use of Markush claims. The Commissioner, in *Ex parte Reid*,[118] stated that "the objection to an alternative claim is its uncertainty--the difficulty or impossibility of determining the precise limits of the alleged invention."[119] Later it was realized that the claims were not uncertain and that there was nothing wrong with claiming something in the alternative.[120] Markush groups merely provided inventors an adequate way to claim their invention.

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[115] *See* U.S. DEPARTMENT OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2164.01 (1995).

[116] *See supra* Part III.

[117] *See Ex parte* Markush, 1925 C.D. 126, 340 O.G. 839 (Comm'r Pat. 1924).

[118] 1879 C.D. 70, 15 O.G. 882 (Comm'r Pat. 1879).

[119] *See id. See also* Carr v. Rice, 5 F. Cas. 139, 140 (No. 2439) (C.C. S.D. N.Y. 1858). ("The third claim is good for nothing, on account of its uncertainty. Nothing is claimed absolutely, as the whole is in the alternative.")

[120] *Ex parte* Markush, 1925 C.D. 126, 340 O.G. 839 (Comm'r Pat. 1924).

Claims concerning DNA and proteins suffer the same problems that chemical composition claims suffered earlier this century. Traditional claiming strategies do not adequately protect the invention. Limiting the claims to the specific nucleotide or amino acid sequence of the DNA or protein is unacceptable because then one skilled in the art could very easily avoid literal infringement. Furthermore, the number of possible protein modifications is so large that making and testing them all would be impossible. Patentees, therefore, have developed a strategy of claiming only those protein modifications that retain biological activity.[121] This new claiming strategy does not bode well for the traditional test for enablement because, according to the PTO and the Federal Circuit, the patentee cannot predict exactly which protein modification will retain biological activity. This response is remarkably similar to that given in the first Markush claim.[122] It should not be overlooked, however, that properly limiting DNA and protein composition claims to modifications that exhibit a similar biological function advances the purpose of the enablement requirement.

Recall that the reason for insisting that the patentee disclose a reasonable number of species that fall within the claim is to ensure that the claim does not cover future inventions to which the patentee did not significantly contribute. Claims may encompass future inventions by covering inoperative compounds. The term "inoperative" is somewhat misleading, however. Inoperative species are of no use, and thus there is no incentive to disclose them in the first place. The fear is that the inoperative subject matter will in fact be *operative* for another purpose under conditions that the patentee has not addressed. This becomes a serious concern in composition claims because the claims cover all possible uses for all compositions within their scope. Thus, a claim that covers an unreasonable number of inoperative species may literally read on a future invention claiming one of the inoperative species for a wholly different purpose. Since the first inventor contributed nothing to the second invention, the first inventor should not be permitted to dominate it.

A second way a claim can encompass future inventions is if it is written so broadly that it covers significant improvements of the invention.

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[121] *See supra* Part III.

[122] *See Markush*, 1925 C.D. at 126, 340 O.G. at 839

This was the case in *O'Reilly*,[123] where the single means claim covered all future methods of electro-magnetic transmissions. Similar to the concerns regarding inoperative compounds, the fear is that the inventor will dominate future inventions. Consequently, others will be discouraged from developing new technologies because they will literally infringe.[124]

The traditional rule that a patentee must demonstrate that a reasonable number of species within the scope of the claims are useful and function in the same way, decreases the probability that the claims will cover inoperative compounds or that they will read on future inventions. However, the rule does not completely allay these concerns. The composition claims could still literally read on inoperative compounds, which may later be discovered to be useful for an entirely different purpose, because only a reasonable number of species must be tested. The claims may also read on unforeseen improvements. Although in both of these cases the second inventor could still obtain a patent for the new use or unforeseen improvement,[125] the second inventor cannot practice the invention without infringing the first inventor's patent claims.

If, on the other hand, the composition claims are limited to the particular function, they will literally exclude the inoperative species from the scope of the claims because the species do not perform the claimed function.[126] Likewise, improvements that provide a protein with significantly better biological properties fall outside the claimed invention. Indeed, any modification of the protein, however slight, that yields a significantly better function or biological property does not infringe. Sickle cell anemia is an example of a disease caused by a single amino acid change in the blood protein hemaglobin that dramatically alters the protein's

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[123] O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853).

[124] In limited exceptions, the alleged infringer may invoke the reverse doctrine of equivalents. *See* SRI Int'l v. Matsushita Elec. Co. of Am., 775 F.2d 1107, 227 U.S.P.Q. (BNA) 577 (Fed. Cir. 1985).

[125] *See In re* Soni, 54 F.3d 746, 34 U.S.P.Q.2d (BNA) 1684 (Fed. Cir. 1995).

[126] *See supra* note 6 (defining the scope of functional language).

biological activity.[127] Thus, despite the fact that the protein is greater than ninety-nine percent identical to the native protein, it would fall outside the claim because it does not meet the functional limitation. The scope of the claim, therefore, certainly does not resemble a single means claim, as some suggest. On the contrary, the scope of the invention is narrow. Limiting the scope of the DNA composition claim to the particular function of the protein for which it codes imposes a better fit between the scope of the claim and the scope of the disclosure than does the current standard, which is based on the disclosure of a reasonable number of embodiments.

Given that claims limited by functional language exclude inoperative species and significant improvements from their scope, from a patent standpoint, why is it important to know all the protein modifications that possess an identical or similar biological activity to the native protein? There appear to be no reasons, and the PTO and the Federal Circuit have not provided any. In *Amgen*, the court reasoned that there were "attendant uncertaint[ies] as to what utility will be possessed by . . . [the claimed but untested] analogs."[128] If the court used the term "utility" to distinguish between operative (useful) and inoperative (not useful) compounds, as the C.C.P.A. did in *In re Cavallito*,[129] then the concern appears unfounded because the claims specifically exclude inoperative species. If, on the other hand, the court meant "utility" in the section 101 sense,[130] the concern is again misplaced because all the protein modifications must have the same biological activity as the native protein and thus are useful for the same purpose as the native protein. Finally, if the court's concern was that in the future other utilities may be discovered for a modified protein, the reasoning is once again misplaced. Any new use for a modified protein will likely be possessed by the native protein because they are biologically similar. If the modified protein possesses an additional property not possessed by the native protein, the remedy is a new use patent, because the patentee is

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[127] Sickle hemoglobin has a valine (Val) at position 6 of the β chain, while normal hemoglobin has a glutamic acid (Glu). STRYER, BIOCHEMISTRY 92 (2d ed. 1981).

[128] Amgen v. Chugai, 927 F.2d 1200, 1214, 18 U.S.P.Q.2d (BNA) 1016, 1028 (Fed. Cir. 1991).

[129] 282 F.2d 357, 127 U.S.P.Q. (BNA) 202 (C.C.P.A. 1960).

[130] 35 U.S.C. § 101 (1986).

entitled to all the uses to which the invention can be put so long as the inventor discloses one utility in the patent. The same situation occurs in all other arts.

Unquestionably, any modification made by a competitor during the course of designing around the invention, which possesses a similar biological activity, will infringe. Assuming this discourages others from discovering which modifications will retain a similar biological activity, the public loses nothing. The public gains nothing by knowing that certain modifications of the same protein possess the same biological activity. The only discoveries that the public should encourage, and be willing to grant a limited monopoly for, are those that *improve* on the biological activity or properties of the claimed protein. As discussed above, these discoveries fall outside the scope of the claims. Accordingly, the incentive to discover is greater for composition claims limited to a particular function than for chemical composition claims, which merely assume that all species within the claims behave similarly.

In contrast, if the patentee's claims were limited to the native DNA or protein sequence, the patent would be useless. One skilled in the art could avoid infringement by merely designing a different sequence that would code for a modified protein with nearly identical biological activity. This would destroy any incentive to be the first to discover and disclose a protein's sequence. More important, it would promote complacency. A competitor would have no incentive to design around and improve an invention if it could easily avoid infringement and successfully compete in the same market. Thus, the public would lose at both ends. It is absurd, therefore, to hold that a claim is not enabled because all the operative members cannot be identified, when such a disclosure is irrelevant and the scope of the claims promotes the progress of science by creating greater incentives to discover and disclose.

One potential problem is that naturally occurring proteins that are discovered later may fall within the scope of the claimed modification. The solution is to add a further limitation requiring the modifications be recombinant.[131] This would exclude all naturally occurring compounds with similar structure and biological activity. However, it could be persuasively argued that even natural proteins with a similar biological activity should

[131] *See supra* note 90 (definition of recombinant).

properly fall within the scope of the claim if the protein is the first member of a protein family to be discovered. This is particularly true given recent Federal Circuit decisions in the area of obviousness, which have made it exceedingly easy to obtain patent protection for naturally occurring DNA sequences.[132] Otherwise, a competitor will simply isolate the corresponding protein from a related species, which has similar biological activity such as a baboon or a monkey, and avoid infringement. For example, diabetes in humans was originally treated using insulin isolated from pigs.[133]

A more compelling reason for permitting subsequent natural proteins to fall within the scope of the claims is that after the first member of a protein family is isolated, subsequent members are isolated at only a fraction of the time and cost.[134] Hence, subsequent inventors who discover other members of the protein family will actually be indebted to the first inventor and should accordingly be required to obtain a license.[135] This will help the first inventor defer some of the large research and development costs and encourage others to discover pioneering new proteins.

A compromise would be to allow a patentee to claim all of the modifications that code for proteins with similar biological activity and that are substantially homologous[136] to the native protein. This strategy was

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[132] *See In re* Deuel, 34 U.S.P.Q.2d (BNA) at 1213 ("What cannot be contemplated or conceived cannot be obvious.")

[133] *See* PETER C.E. MOODY & ANTHONY J. WILKINSON, PROTEIN ENGINEERING 61-62 (D. Rickwood ed. 1990).

[134] The theory of natural selection holds that proteins that perform similar functions will have similar amino acid sequences. *See* ANATOLY BEZKOROVAINY & MAX E. RAFELSON, JR., CONCISE BIOCHEMISTRY 64 (1996). Thus, once one member of a protein family is isolated, other members can be isolated using techniques well known in the art, such as library screening, which takes advantage of the similarities in sequence. *See* R.W. OLD & S.B. PRIMROSE, PRINCIPLES OF GENE MANIPULATION 129 (N.G. Carr ed. 1994).

[135] *See infra* note 46 and accompanying text.

[136] Homology is defined as the degree of identity between the nucleotide or amino acid sequences of two DNA molecules or proteins. SCIENTIFIC DICTIONARY, *supra* note 3, at 949. For example, in *Amgen* the baboon and

unsuccessfully attempted in *Ex parte Ishizaka*,[137] where the claim was limited to modifications that exhibited a certain biological activity and were at least seventy percent homologous.[138] The compromise would protect an inventor who isolates a human gene, for example, against a competitor who isolates a human allele[139] or the corresponding protein from a baboon or monkey, whose proteins are usually highly homologous and function like the human counterpart. However, the corresponding protein isolated from a mouse or rat may only be sixty to sixty-five percent homologous and would thus fall outside the scope of the claims. Therefore, using homology as a claim limitation, would protect the patentee against competitors who would merely isolate the corresponding protein from a closely related species, and it would simultaneously protect the public against the unlikely event that a highly divergent protein with a similar biological activity would be subject to the control of the patentee.

V. CONCLUSION

Generic DNA and protein composition claims that limit the scope of protection to modifications exhibiting similar biological activity of the resulting protein should not be rejected for lack of enablement under the first paragraph of section 112. The PTO and the Federal Circuit continue to reject the claims because the art is unpredictable and the applicant cannot predict precisely which DNA sequences will code for a protein that retains biological activity. However, the unpredictability of the art of molecular biology is much lower, and the skill in the art much higher, than the court is willing to acknowledge. The PTO and the Federal Circuit assess enablement from the vantage point of a lay person rather than one skilled in the art. Moreover,

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that nine out of ten nucleotides were identical. Amgen v. Chugai, 927 F.2d 1200, 18 U.S.P.Q.2d (BNA) 1016 (Fed. Cir. 1991).

[137] 24 U.S.P.Q.2d (BNA) 1621 (Bd. Pat. App. & Int'f 1992).

[138] *See supra* note 77.

[139] An allele is an alternate form of the same gene that codes for a protein with identical or nearly identical biological activity. SCIENTIFIC DICTIONARY, *supra* note 3, at 65. Alleles arise out of random mutations. Subpopulations of humans, for example, carry different alleles of the same gene with no physical manifestations. Other alleles, such as the one that causes sickle cell anemia, are the cause of disease. SCIENTIFIC DICTIONARY, *supra* note 3, at 65.

the PTO's and the Federal Circuit's contention that the scope of the claims resembles a single means claim is unsubstantiated. The scope of the claims is far narrower than most chemical composition claims that have been granted since the original Patent Act. By limiting the scope of the claims to a particular biological function, the claims do not cover inoperative species or improvements that exhibit significantly better biological activity. As such, the scope of the claims promotes the purpose of the patent system by encouraging innovation and disclosure.

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THE PATENTING OF EXTINCT ORGANISMS: REVIVAL OF LOST ARTS

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I. INTRODUCTION

The biotechnological arts, perhaps more than other industrial arts, have challenged traditional applications of U.S. patent law. Congress, the judiciary, and the Patent and Trademark Office ("PTO") have accommodated these challenges while attempting to maintain the traditional goals of the U.S. patent system. In particular, the *Diamond v. Chakrabarty*[1] decision, holding a genetically engineered microorganism to be a patentable subject matter, helped fuel the biotechnological revolution.[2] This decision by no means resolved the issues surrounding the patenting of biological materials. Rather, it opened the door to additional legal challenges that would continue to arise with further advances in biotechnology.

One of these scientific advances is the ability to generate whole organisms from somatic (non-reproductive) cells of embryos and adult organisms. This scientific revolution in the ability to manipulate living cells and organisms parallels the revolution of the last twenty-five years in the biochemical manipulation of DNA.[3] The breakthrough in cloning Dolly the sheep brought this technology to the forefront of public attention.[4] Behind the scenes, however, lay many other breakthroughs in the manipulation of cells and tissues. Advances in the ability to regenerate whole organisms from single cells, to clone animals, to produce interspecies chimeric animals, and to perform interspecies embryo implantation serve as the technological foundation for new approaches to animal husbandry and the genetic improvement of agriculturally valuable plants and animals.

These technologies will also permit society to recover some of the losses suffered as a consequence of modern agricultural practices and the severe depletion of the world's ecosystems. Preserved biological specimens

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[1]447 U.S. 303, 206 U.S.P.Q. (BNA) 193 (1980).

[2]*See* U.S. CONGRESS, OFFICE OF TECHNOLOGICAL ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE 8 (1989) [hereinafter PATENTING LIFE].

[3]*See* U.S. CONGRESS, OFFICE OF TECHNOLOGICAL ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: U.S. INVESTMENT IN BIOTECHNOLOGY 161-67, 194-98 (1988).

[4]*See* Rick Weiss, *Scottish Scientists Clone Adult Sheep*, WASH. POST, Feb. 24, 1997, at A1 [hereinafter Weiss I].

from endangered or extinct[5] organisms serve as a repository from which biotechnologists will revive or regenerate some of these plants and animals. Such organisms are not only tropical plants and animals whose commercial value remains unexploited. Rare varieties of domesticated plants and animals of known agricultural utility also become extinct every year.

Ambergene Corporation claims to have already revived 1,500 prehistoric microorganisms preserved in chunks of amber.[6] Their recently issued patent broadly claims "an isolated viable culture of a microorganism obtained from within a naturally occurring resin."[7] To the extent that these microorganisms differ from known microorganisms, patent claims to pure cultures of microorganisms raise no new legal issues because the patenting of newly isolated microorganisms is now routine.[8]

By contrast, patent claims to higher plants and animals revived or regenerated from preserved biological materials raise new legal challenges. Accordingly, this article assesses the patentability of regenerated higher organisms following their extinction in nature. The article focuses on utility patents because they provide the patentee with broader rights to new plants than those available under a plant patent or Plant Variety Protection Act certificate.[9] Moreover, utility patents are the only intellectual property protection available for animals.[10]

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[5]In this article, the term "extinct" refers to organisms, species or varieties, that no longer exist in a domesticated or free-living form capable of replication or procreation by natural processes. Thus, for example, an organism represented on earth by only biological materials such as isolated tissue, cells, DNA, seeds, or spores preserved in a repository would be extinct under this definition.

[6]*See* Madeleine Nash, *Return of the Living Dead*, TIME, May 29, 1995, at 55; Raúl J. Cano & Monica K. Borucki, *Revival and Identification of Bacterial Spores in 25- to 40-Million-Year-Old Dominican Amber*, 268 SCI. 1060 (1995).

[7]U.S. Patent No. 5,593,883.

[8]*See* KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT 17-18 (1995).

[9]*See* Nicholas J. Seay, *Protecting the Seeds of Innovation: Patenting Plants*, 16 AIPLA Q.J. 418, 433-35 (1989); PATENTING LIFE, *supra* note 2, at 9-10.

[10]*See* PATENTING LIFE, *supra* note 2, at 9-10.

Several unique issues arise in assessing the patentability of regenerated organisms. The threshold issue is whether such organisms represent statutory subject matter. More than other biotechnological arts, regenerated organisms straddle the boundary between products of nature and statutory subject matter made by humans. Case law does not provide a bright line rule but does provide guidance for determining which regenerated organisms constitute statutory subject matter.

A key issue is whether an organism's previous existence in nature serves as prior art to defeat the novelty and nonobviousness of the regenerated organism. The statutory analysis and case law in other biotechnological arts suggest that a regenerated organism is potentially novel and nonobvious when no biological materials remain on earth that give rise to the organism in an obvious manner. The "lost art" doctrine, a judicial doctrine applied for the first time to this new art, also bolsters this conclusion.

This article discusses how the patentability requirements of statutory subject matter, utility, novelty, and nonobviousness are readily adaptable to the art of regenerating formerly extinct organisms. The ability to patent regenerated organisms while complying with these statutory requirements provides an appropriate incentive for inventors and ensures that the public is not deprived of subject matter already in the public domain.

II. REGENERATING EXTINCT ORGANISMS

A. *Preservation Of Biological Materials*

Wild plants and animals are an important commercial resource.[11] Pharmacologists discover useful new medicinal agents in extracts from

[11]*See* Philip Abelson, *Medicine from Plants (Editorial)*, 247 SCI. 513 (1990); Constance Holden, *Entomologists Wane as Insects Wax*, 246 SCI. 754 (1989); June Starr & Kenneth C. Hardy, *Not by Seeds Alone: The Biodiversity Treaty and the Role for Native Agriculture*, 12 STAN. ENVTL. L.J. 85, 91-92 (1993); Curt Suplee, *Earth's Biotic Wealth Faces "Unprecedented" Threat*, WASH. POST, Nov. 20, 1995, at A3 [hereinafter Suplee I] ("In 1993, about 80% of the 150 top prescription drugs in the United States" were modeled upon or

plants[12] and animals.[13] Historically, people on every continent have developed agriculturally valuable crops by domesticating wild varieties.[14] Plant and animal breeders still value these wild varieties as a natural repository of agriculturally useful genetic traits.[15] Breeders use traditional cross breeding techniques to transfer economically valuable traits such as high yield, and resistance to disease, drought, and salinity from these wild organisms into domesticated crops and animals.[16] These techniques require that a particular wild organism be closely related to the domesticated organism receiving the trait so that the two organisms can be cross bred. Modern molecular biology techniques, however, overcome this species barrier by permitting genes to be transferred between unrelated species.[17]

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[12]*See* Alison Mack, *Biotechnology Turns to Ancient Remedies in Quest for Sources of New Therapies*, THE SCIENTIST, Jan. 6, 1997, at 1; Kathleen Day, *Rain Forest Remedies, More Drug Companies Turning to Tribal Healers for Medicines*, WASH. POST, Sept. 19, 1995, at E1; Abelson, *supra* note 11.

[13]*See* Elyse Tanouye, *Scientists Go Back to Folk Remedies, Find Ideas for Future*, WALL ST. J., Feb. 16, 1993, at B6. Magainin Pharmaceuticals isolated the antibiotic squalamine from dogfish shark and is testing an antibiotic from frog skin. *See id.* Bristol-Myers Squibb discovered the drug capoten in snake venom. *See id.* Bat plasminogen activator and hirudin, a leech enzyme, may be useful in preventing blood clot formation in humans. *See* Curt Suplee, *Medicine: Going to Bat Against Heart Attacks*, WASH. POST, July 15, 1991, at A2.

[14]*See, e.g.*, Gabriel Escobar, *Andean Heirlooms: Is There a Global Future in Peru's Weird Tubers?*, WASH. POST, Jan. 10, 1996, at E1; Starr & Hardy, *supra* note 11, at 96-98.

[15]*See* Starr & Hardy, *supra* note 11, at 96-98; Boyce Rensberger, *A Rescue Mission for Dying Breeds: U.N. Program Targets Farm Animals*, WASH. POST, Feb. 3, 1992, at A3; Steven D. Tanksley & Susan R. McCouch, *Seed Banks and Molecular Maps: Unlocking Genetic Potential from the Wild*, 277 SCI. 1063 (1997).

[16]*See* Starr & Hardy, *supra* note 11, at 96-98; Rensberger, *supra* note 15; NATIONAL RESEARCH COUNCIL, MANAGING GLOBAL GENETIC RESOURCES: AGRICULTURAL CROP ISSUES AND POLICIES 119-20 (1993) [hereinafter AGRICULTURAL CROP ISSUES]. The Department of Agriculture estimates that genetic materials from seed banks have been the source of crop improvements worth one billion dollars annually. *See* Paul Raeburn, *The Last Harvest*, POPULAR SCI., May 1, 1996, at 70.

[17]*See* PATENTING LIFE, *supra* note 2, at 93-97.

Thus, wild organisms will constitute an even more important source of genetic material as techniques for gene transfer are perfected.

The destruction of the tropical rain forest and other ecologically sensitive habitats has led and will continue to lead to the extinction of many species.[18] This raises great concern, in part because important plants and animals will be lost before scientists have had the opportunity to evaluate their commercially valuable characteristics.[19] Tomorrow's cure for a dreaded disease or genetic trait to increase crop production may lie undiscovered in an organism facing extinction.

Even varieties of domesticated plants and animals face extinction or have already become extinct. Over time, traditional varieties and breeds carrying important genetic traits have been lost, as farmers abandon them in favor of more modern, high-yield varieties and breeds.[20] These modern varieties generate more income for farmers in the short term but may be inferior in the long term because they often lack disease resistance or the ability to adapt to changing local environments.[21]

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[18]*See* COLIN TUDGE, LAST ANIMALS AT THE ZOO 33-36 (1992). Biologist Edward O. Wilson estimates that 27,000 species in tropical rain forests become extinct each year. *See id.* Moreover, these rates are expected to rise in the foreseeable future. *See id.* By the year 2000, 14% of tropical plant species could be extinct. In the next 50 years, one-fourth of the world's known 250,000 plant species may become extinct. *See id. See also* Eric Christensen, *Genetic Ark: A Proposal to Preserve Genetic Diversity for Future Generations*, 12 STAN. L. REV. 279, 281-82 (1987). The IUCN-World Conservation Union's 1996 "Red List" lists 5205 endangered species representing 25% of the world's mammals, 11% of birds, 20% of reptiles, 25% of amphibians, and 34% of fish. *See* Rick Weiss, *One-Fourth of Mammalian Species Face Extinction*, WASH. POST, Oct. 4, 1996, at A3.

[19]Of the estimated 14 million species on earth, only 1.75 million have been described. *See* Suplee I, *supra* note 11.

[20]*See* AGRICULTURAL CROP ISSUES, *supra* note 16, at 32-36. A 1982 survey of European livestock classified as endangered one-third of the 700 distinct breeds of cattle, goats, horses, pigs and sheep. *See* NATIONAL RESEARCH COUNCIL, MANAGING GLOBAL GENETIC RESOURCES, LIVESTOCK 29 (1993) [hereinafter LIVESTOCK]. In Europe, nine breeds of cattle, 54 breeds of pigs, and 30 breeds of sheep have become extinct recently. *Id.* at 144, 152, 158.

Attempts to save these endangered organisms and their genetic resources include habitat preservation,[22] raising endangered animals in parks or zoos[23] and endangered fish in aquaria,[24] growing endangered plants in botanical gardens, and preserving biological materials in repositories.[25] These repositories of plant and animal cells, tissues, and DNA are more formally known as seed banks[26] or germplasm collections.[27] Stored seeds and buds from some plants remain viable in cold storage for long periods of time.[28] Animal semen, ova (egg cells), and embryos from some species, as well as other cells isolated from plants and animals, can be cryopreserved by freezing small samples at extremely low temperatures in liquid nitrogen.[29]

With the extinction of entire species or varieties, germplasm repositories and seed banks will provide valuable sources of genetic material

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[22]*See* TUDGE, *supra* note 18, at 40-45.

[23]*See* Joan O'C. Hamilton, *A Zoo Changes Its Stripes*, BUS. WK., June 5, 1995, at 28B.

[24]*See* TUDGE, *supra* note 18, at 137-38.

[25]*See* AGRICULTURAL CROP ISSUES, *supra* note 16, at 85-92; LIVESTOCK, *supra* note 20, at 121-22; Starr & Hardy, *supra* note 11, at 99-100.

[26]*See* Starr & Hardy, *supra* note 11, at 99.

[27]*See* Boyce Rensberger, *Apple Hunt Bears Fruit in the Earth's Original Orchards*, WASH. POST, Oct. 23, 1995, at A3; Christensen, *supra* note 18; J.D. Ballou, *Potential Contribution of Genetic Diversity and Conservation of Endangered Species in Captivity*, 29 CRYOBIOLOGY 19 (1992); NATIONAL RESEARCH COUNCIL, MANAGING GLOBAL GENETIC RESOURCES: THE U.S. NATIONAL PLANT GERMPLASM SYSTEM 21-25 (1991)[hereinafter NATIONAL PLANT GERMPLASM SYSTEM]. A network of state and federal facilities in the U.S., known as the National Plant Germplasm System, contains more than 380,000 germplasm accessions representing more than 8700 species. *See id.* at 44.

[28]*See* AGRICULTURAL CROP ISSUES, *supra* note 16, at 192-93.

[29]*See* LIVESTOCK, *supra* note 20, at 57-58, 87-91; NATIONAL PLANT GERMPLASM SYSTEM, *supra* note 27, at 24-25; Gregory Benford, *Saving the "Library of Life,"* 89 PROC. OF THE NAT'L ACAD. SCI. 11,098, 11,099-11,100 (1992).

from which to regenerate these organisms. Some techniques currently exist to regenerate organisms from preserved biological materials, and the field continues to advance rapidly.[30] Progress is made species by species. Organisms vary considerably in their biochemical properties and tolerance to laboratory manipulation.[31] Successful storage and regeneration methods, perfected in one species, must often be modified significantly before applying them successfully to other species, even those closely related.

Successful long-term storage of biological materials sometimes requires periodic manipulation of the samples. For example, stored seeds maintain their viability for only a defined period of time. Their long-term preservation requires replanting and preparation of fresh seed for storage at regular intervals.[32]

Many varieties of plants, some recently extinct in the wild, are stored at the National Seed Storage Laboratory in Colorado.[33] Most of these seeds are still viable and can be germinated using routine techniques. Other seeds, however, are no longer viable because the laboratory does not have adequate resources to replant them periodically.[34] The number of seeds in this latter category grows annually with the loss of their important genetic resources.[35]

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[30]*See* TUDGE, *supra* note 18, at 169-92 (describing the "frozen zoo").

[31]For example, cattle and sheep embryos more readily tolerate cryopreservation than those of swine and poultry. *See* LIVESTOCK, *supra* note 20, at 90. Seeds vary greatly in their ability to germinate following cold storage. *See* NATIONAL PLANT GERMPLASM SYSTEM, *supra* note 27, at 24-25. Even plants within the same family vary in their adaptability to cell culture. *See* AGRICULTURAL CROP ISSUES, *supra* note 16, at 191.

[32]*See* Raeburn, *supra* note 16.

[33]*See id.*

[34]*See id.* Seeds in cold storage retain their viability between several years and several decades. *See id.* For example, nearly all of the Laboratory's 5000 to 10,000 tropical corn varieties collected in the last 40 years are at risk of losing viability. *See id.*

B. *Cloning And Regeneration Technologies*

Recent technological advances allow scientists to regenerate whole organisms from biological materials. For some species, whole organisms can be regenerated from single cells. A number of crop plants, including tobacco, carrot, rice, and corn, fall into this category.[36] Frogs, sheep, monkeys, pigs, and cows have been cloned or regenerated by transferring a nucleus from a single adult or embryonic cell to an anucleated ovum, an egg cell with its own nucleus removed.[37]

Advances in animal husbandry allow non-endangered species to play a role in the effort to rehabilitate endangered species. Frozen embryos of endangered species have been successfully thawed and transferred into receptive females of related, but non-endangered species. The surrogate mothers give birth and raise the endangered animal as their own.[38] Similar techniques may be applied to the regeneration of extinct organisms where there is insufficient time or insurmountable technological barriers to accomplish surrogate parenting prior to a species' extinction.

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[36]*See* Charles S. Gasser & Robert T. Fraley, *Genetically Engineered Plants for Crop Improvement*, 244 SCI. 1293, 1294 (1989); TUDGE, *supra* note 18, at 190.

[37]*See* J.B. Gurdon, *The Birth of Cloning*, THE BIRTH OF CLONING, Sept.- Oct. 1997, at 26, 30 (reporting that adult frogs were cloned from tad pole cells in the 1960's and that tadpoles were cloned from adult frog cells in the 1970's); Rick Weiss, *Researchers Fuse Cells in Lab to Clone Sheep, Unlimited Production Envisioned*, WASH. POST, March 7, 1996, at A1 (sheep cloned from embryonic cells); Weiss I, *supra* note 4 (sheep cloned from adult cells); Rick Weiss & John Schwartz, *Monkeys Cloned for First Time, Oregon Scientists Created Primates from Embryos Not Adult Cells*, WASH. POST, Mar. 2, 1997, at A4 (monkeys cloned from embryo cells); Rick Weiss, *Animals in U.S. and Europe Now Pregnant with Clones*, WASH. POST, June 28, 1997, at A1 (reports of cloning pigs); Rick Weiss, *Cow Eggs Play Role in Cloning Effort, With Bit of a Pig's Ear, Embryo Starts to Grow*, WASH. POST, Jan. 19, 1998, at A1 (pig, rat, sheep and monkey embryos cloned by transferring a cell nucleus from the various species into a nucleated cow eggs); Carey Goldberg & Gina Kolata, *Scientists Announce Births of Cows Cloned in New Way*, N.Y. TIMES, Jan. 21, 1998, at A14.

[38]*See* TUDGE, *supra* note 18, at 185-86. An eland antelope has successfully given birth to an implanted bongo antelope embryo, a Holstein cow to a guar, and a domestic cat to an Indian desert cat. *See id.*

Techniques for producing chimeras also show promise for the regeneration of extinct animals. Chimeras are organisms consisting of cells derived from more than one fertilized ovum from either the same or a closely related species.[39] For example, scientists could obtain embryonic cells of an extinct animal from either a frozen embryo or an embryo produced *in vitro* from combining preserved semen and ova. They could then inject these embryonic cells into an embryo of a related living species to form a chimeric embryo. After implantation of the embryo in the uterus of the related living species, the embryo's tissues and organs would develop from one or both of the species. Chimeric organisms that contain testes or ovaries derived from the embryonic cells of the extinct species would prove valuable in breeding offspring that are homogenous in containing only tissues of the extinct organism.

Another promising regeneration approach involves germ-line transplantation. Scientists have recently reported the ability to freeze sperm-producing cells, thaw and subsequently implant them into another species.[40] After removal of the sperm producing cells from an unrelated living animal, scientists could transplant previously frozen sperm-producing cells from an extinct animal into this animal. Its semen would then contain sperm of the formerly extinct animal and could be used to fertilize frozen ova of the extinct species. Alternatively, the organism could mate with a female that has had an analogous transplant, if and when ovary transplant technology becomes available.[41]

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[39]*See* TUDGE, *supra* note 18, at 186-87 (describing techniques used to create sheep-goat chimeras). Chimeric animals can be made by combining cells from two or more early embryos of the same or related species into one embryo or by injecting cells from one embryo into the early embryo of another. *See* BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 1058-59 (3d ed., 1994). The chimeric embryo is then implanted into the uterus of a foster mother where it develops naturally. *See id.*

[40]*See* Curt Suplee, *Animal Researchers Transplant Sperm-Producing Cells from Species to Species: A Type of Test-Tube Immortality Is Achieved*, WASH. POST, May 30, 1996, at A4. Transplantation of testes between species is inherently more successful than other organ transplantation because the testis is an immunologically privileged site--it is relatively isolated from an organism's immune defenses. *See id.*

[41]*See generally id.* Scientists have successfully cultured mouse ovarian tissue from which they removed mature follicles, fertilized them with

Naturally preserved biological materials may also serve as a source of materials from which to regenerate species. Archeologists sometimes recover seeds from ancient sites.[42] Chinese scientists have successfully sprouted 1,288 year old lotus seeds and 2000 year old tomato seeds.[43] Eggs of a small crustacean lay buried in a New England pond bottom for 350 years before scientists hatched them.[44] In addition to microorganisms, amber has entombed plant parts and small animals for millions of years.[45] Fragments of DNA have been sequenced from a fossilized bee, termite, weevil, and tree leaf preserved in amber for years--ranging from 25 to over 100 million years.[46] Scientists have also cloned DNA from naturally preserved carcasses of extinct species such as the ice-age mammoth, the moa, an extinct flightless bird from New Zealand that became extinct 350 years ago, and the quagga, a relative of the zebra that became extinct only 100

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but with an overall low success rate. Ovarian tissue has been removed from sheep ovaries, frozen and later successfully reimplanted in the same ewe. Transplantation of ovaries is inherently more difficult because, unlike testes, ovaries do not occupy an immunologically privileged site. Thus, without immunosuppressive therapy, tissue-type mismatched individuals reject transplanted ovaries like other transplanted organs. *See* John Travis, *Brave New Egg*, DISCOVER, Apr. 1997, at 76, 78, 80.

[42]*See, e.g.*, Abraham Rabinovich, *Kinnert's Lows are High Times for History*, JERUSALEM POST, Apr. 26, 1991, at 1, *available in* WESTLAW, Magsplus database, 1991 WL 3507046.

[43]*See Botany: Enzyme Fed Ancient Seeds' Longevity*, WASH. POST, Nov. 20, 1995, at A2; *2,000-Year-Old Seeds Sprout Tomato Buds*, CHI. TRIB., Mar. 3, 1985, at 5.

[44]*See The Big Sleep*, DISCOVER, Dec. 1995, at 26.

[45]*See* David Grimaldi, *Captured in Amber*, 274 SCI. AMER., Apr. 1996, at 85-87. *See generally* GEORGE POINAR & ROBERTA POINAR, THE QUEST FOR LIFE IN AMBER (1994).

[46]*See* POINAR & POINAR, *supra* note 45, at 142-47. Recent research suggests that DNA will not survive chemically intact for more than 50,000 years unless it is sealed water tight in amber, in which case it appears to remain intact for tens of millions of years. *See* Hendrick N. Poinar, et al., *Amino Acid Racemization and the Preservation of Ancient DNA*, 272 SCI. 864 (1996); Robert F. Service, *Just How Old is That DNA Anyway?*, 272 SCI. 810 (1996).

years ago.[47] But, contrary to the Jurassic Park scenario,[48] the technology does not yet exist--and may never exist--to regenerate extinct species fully from naturally preserved DNA alone.[49]

Although no patents have yet issued claiming a previously extinct higher organism, the time is ripe for inventors to attempt to patent such an invention. Inventors have access to biological materials from endangered or extinct organisms and techniques with which to regenerate them. Strong scientific and economic incentives to commercialize plants and animals with medical or agricultural value serve as the impetus for filing such claims. Inventors are certainly motivated to obtain the broadest patent coverage available. They are unlikely to limit their claims to only novel genes and proteins obtained from regenerated organisms and techniques for obtaining them when they can support claims to the entire organism. The question remains as to what extent these organisms are patentable. The following analysis explores this issue and defines the boundaries of patentability for regenerated organisms.

III. PATENTABILITY OF FORMERLY EXTINCT ORGANISMS

Patent applications claiming living organisms, like all others, must claim statutory subject matter and must satisfy the requirements for patentability, including utility, novelty, and nonobviousness.[50] The PTO and courts have routinely applied these criteria to living organisms[51] since the

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[47]*See* POINAR & POINAR, *supra* note 45, at 70-71; *see also* Tabitha M. Powledge & Mark Rose, *The Great DNA Hunt*, ARCHEOLOGY, Sept.-Oct. 1996, at 37-38 (arguing that DNA cannot survive more than 100,000 years).

[48]*See* JURASSIC PARK (MCA 1993) and THE LOST WORLD--JURASSIC PARK (MCA 1997), directed by Steven Spielberg, based on MICHAEL CRIGHTON, JURASSIC PARK (1990).

[49]*See* POINAR & POINAR, *supra* note 45, at 156-57; Maxine F. Singer, *No You Can't Make Dinosaurs*, WASH. POST, July 7, 1993, at A21.

[50]*See* 35 U.S.C.A. §§ 101-03 (West Supp. 1996).

[51]*See Animals--Patentability*, 1077 Off. Gaz. Pat. Office 24 (Apr. 21, 1987). In 1987, the Commissioner issued a notice that the PTO would consider "nonnaturally occurring, nonhuman multicellular living organisms

Supreme Court held in *Diamond v. Chakrabarty*[52] that a genetically engineered bacterium is statutory subject matter as a composition of matter under section 101.[53]

A. *Subject Matter*

The analysis of statutory subject matter in the case of living organisms and "products of nature" is easily confused with the analysis of novelty. An organism found in nature does not constitute statutory subject matter because it results from natural processes unaided by humans. At the same time, an organism found in nature lacks novelty because it already exists in the public domain. Some courts have combined these issues in ruling that particular products of nature do not constitute statutory subject

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including animals, to be patentable subject matter." *Id.; see also,* U.S. DEPARTMENT OF COMMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2105 (6th ed., rev. July 1996) [hereinafter M.P.E.P.]. The first patent claiming a mammal issued in 1988 for the "Harvard Onco-mouse." U.S. Patent No. 4,736,866. As of October 1996, the PTO had issued 29 animal patents--23 mice, one rabbit, one rat, one sheep, one bird, one fish, and one worm. Over 1200 applications claiming animals were pending, and 32 were allowed. *See* John Doll, Director of Group 1800, PTO, Address at the AIPLA Annual Meeting (Oct. 24, 1996). In 1996, 69 patents issued claiming corn (maize) hybrid or inbred plants. Search of WESTLAW, Patents-90 database (Feb. 7, 1997); *see generally* Michael D. Davis, *The Patenting of Products of Nature,* 21 RUTGERS COMPUTER & TECH. L.J. 293 (1995).

[52]447 U.S. 303, 206 U.S.P.Q. (BNA) 193 (1980).

[53]*See id.* at 310, 206 U.S.P.Q. (BNA) at 197.

matter while actually determining they lack novelty or nonobviousness.[54] Novelty, however, is not relevant to an analysis of statutory subject matter.[55]

In declaring anything "made by man" potentially patentable,[56] the *Chakrabarty* Court focused on the application of human effort to distinguish non-patentable "products of nature" from patentable living organisms.[57] For example, purified strains of bacteria, although technically not "made by man," constitute statutory subject matter[58] because the process of purification requires a microbiologist's ingenuity to devise laboratory conditions in

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[54]*See In re* Bergy, 596 F.2d 952, 959-60, 201 U.S.P.Q. (BNA) 352, 362 (C.C.P.A. 1979), *judgment as to Bergy vacated and case remanded with directions to dismiss the appeal as moot sub nom.*, Diamond v. Chakrabarty, 444 U.S. 1028 (1980). The *Chakrabarty* Court blends the subject matter and novelty analysis in making the observation that the genetically engineered microorganism was previously an "unknown natural phenomenon." *Chakrabarty*, 447 U.S. at 309-10, 206 U.S.P.Q. (BNA) at 197 ("[Chakrabarty's] claim is not to a hitherto unknown natural phenomenon, but to a nonnatur-ally occurring manufacture or composition of matter--a product of human ingenuity 'having a distinctive name, character [and] use.'" (citing Hartranft v. Wiegman, 121 U.S. 609, 615 (1887)); *see* 1 IVER P. COOPER, BIOTECHNOLOGY AND THE LAW § 3.02 (1997).

[55]*See* Diamond v. Dieher, 450 U.S. 175, 188-89, 209 U.S.P.Q. (BNA) 1, 9 (1981). One year after *Chakrabarty*, the Court clarified this analysis, holding that novelty is not relevant to the subject matter analysis. *See id.*; *see also Bergy*, 596 F.2d at 962-64, 201 U.S.P.Q. (BNA) at 362-63 ("Prior art is irrelevant to the determination of statutory subject matter under § 101. . . . The question here . . . is: are the inventions claimed of a *kind* contemplated by Congress *if* . . . they turn out to be new, useful, and unobvious. . . .").

[56]*See Chakrabarty*, 447 U.S. at 309, 206 U.S.P.Q. (BNA) at 197 ("Congress intended statutory subject matter to 'include anything under the sun that is made by man.'").

[57]*See id.* at 313, 206 U.S.P.Q. (BNA) at 199 ("[T]he relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."); *see also* Karl Bozicevic, *Distinguishing "Products of Nature" from Products Derived from Nature*, 69 J. PAT. & TRADEMARK OFF. SOC'Y 415 (1987).

[58]*See Bergy*, 563 F.2d at 1035, 195 U.S.P.Q. (BNA) at 348 (arguing that a biologically pure strain of a microorganism is not a "product of nature" since it does not exist in nature in that form).

which to isolate and culture the microorganisms.[59] In addition, claims directed to a purified microorganism do not embrace organisms found in nature, which do not result from an inventor's ingenuity.[60]

In contrast, naturally occurring higher plants and animals are large enough that their identification and isolation does not require a scientist's ingenuity in developing experimental culture conditions. A higher organism constitutes statutory subject matter only when the organism itself results from the application of human ingenuity and effort, rather than from the routine cultivation of a free-living organism.[61] Thus, plant varieties[62] and animals strains[63] created through human experimentation constitute statutory subject matter. In addition, claims to such living organisms can be crafted so as to avoid non-statutory subject matter, such as naturally occurring organisms.[64]

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[59]*See id.* at 972, 201 U.S.P.Q. (BNA) at 370; *see also* 1 COOPER, *supra* note 54, § 1.01[1].

[60]*See* 1 COOPER, *supra* note 54, § 3.04.

[61]*See Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1426-27 (Bd. Pat. App. & Int. 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988); *Ex parte* Hibberd, 227 U.S.P.Q. (BNA) 443, 444 (Bd. Pat. App. & Int. 1985).

[62]*See Hibberd*, 227 U.S.P.Q. (BNA) at 444 ("man made plant life" (hybrid corn plants and seeds) is patentable).

[63]*See Allen*, 2 U.S.P.Q.2d (BNA) at 1427 (finding that polyploid oysters, which "do not occur naturally," are statutory subject matter). In *Allen*, the examiner did not satisfy the burden of showing that the claimed oysters occurred naturally. *See id.* It did not seem relevant to the court that they might have existed in nature some time in the past. The mere possibility of an occasional or rare event in nature giving rise to a product identical to that claimed in an application does not necessarily defeat its patentability. *See* 1 COOPER, *supra* note 54, § 4.02[1].

[64]In general, "products of nature," such as organisms, genes and proteins, must be distinguished from their natural forms to be patentable. *See* Bozicevic, *supra* note 57, at 426. Thus, claims to genes are usually directed to the isolated, cloned, or purified forms. *See Ex parte* D, 27 U.S.P.Q.2d (BNA) 1067, 1068 (Bd. Pat. App. & Int. 1993)(explaining that claims to DNA sequences must distinguish the naturally occurring gene); *see also* Amgen v. Chugai Pharmaceutical Co., Ltd., 13 U.S.P.Q.2d (BNA) 1737, 1759 (D. Mass. 1989) (explaining that claims must be made to the purified and isolated DNA sequence encoding human erythropoietin as opposed to the natural DNA sequence).

Regenerated organisms straddle the boundary between statutory subject matter and products of nature, but most lie on the statutory side of that boundary. Case law and issued patents provide examples of only patentable higher organisms that differ from organisms known to exist in nature.[65] The law, however, does not require proof of absolute novelty for a living organism to constitute statutory subject matter.[66]

Regenerated higher organisms constitute statutory subject matter when they exist primarily as a result of human ingenuity.[67] The courts have not given clear guidance for determining whether sufficient human ingenuity has been provided beyond the requirement that the organisms be "made by man" and not be "preexisting and merely plucked from the earth."[68] The standard does not appear to be high, however, since human manipulation of primarily biological processes, such as the application of pressure to developing oyster embryos,[69] or traditional plant breeding,[70] can result in statutory subject matter. In this respect, it is irrelevant that regenerated organisms would be governed by natural processes.[71]

Naturally preserved biological materials, such as seeds and spores, constitute products of nature even if the organism from which they were derived is otherwise extinct.[72] These materials are merely "plucked from the

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[65]*See supra* notes 51, 52, and 61.

[66]*See supra* note 63; *see infra* note 163.

[67]*See supra* notes 56-64.

[68]*Bergy*, 563 F.2d at 1036, 195 U.S.P.Q. (BNA) at 349.

[69]*See Allen*, 2 U.S.P.Q.2d (BNA) at 1425.

[70]*See supra* note 51. *See also* U.S. Patent No. 5,589,605, entitled "Hybrid Corn with a Genetic Complement Producing Increased Yield, Seedling Vigor, Early Stand, Stalk Strength and Low Harvest Moisture"; U.S. Patent No. 4,686,318, entitled "Kiwifruit Plant" (claiming fruit and propagating material from a newly identified, spontaneously arising cultivar of kiwifruit).

[71]For example, in *Allen*, the Board of Appeals did not find it relevant that Allen's generation of the polyploid oysters by hydrostatic pressure was governed by the laws of nature. *See Allen*, 2 U.S.P.Q.2d (BNA) at 1427.

[72]*See* Diamond v. Chakrabarty, 447 U.S. 303, 309, 206 U.S.P.Q. (BNA) 193, 197 (1980) ("[A] new plant found in the wild is not patentable subject

earth." Thus, if one discovers a viable seed from an extinct plant, plants it in soil, and tends to it so that it sprouts and matures, this plant is a product of nature because there is little or no innovation involved in bringing it into existence.

Artificially preserved biological materials constitute statutory subject matter when their existence or form results primarily from inventive activity. To the extent that the materials would have existed in nature in a similar form, such as a seed lying in a drawer under ambient conditions, they are products of nature. Whereas, the application of inventive methods of preservation transforms products of nature into statutory subject matter when these methods extend the viability or the form of the materials beyond that which they would have had in nature. Thus, cells preserved in a special medium in liquid nitrogen are no longer products of nature.

Even if the starting materials used in a regeneration process are products of nature, the process of regenerating an organism from the starting materials may itself involve sufficient inventive activity for the regenerated organism to constitute statutory subject matter. When the process of preservation or regeneration of an organism occurs under controlled conditions such that it would not exist but for human ingenuity, the regenerated organism is statutory subject matter. In this respect, the organism would not differ from the isolated microorganisms in *Bergy*,[73] the polyploid oysters in *Allen*,[74] and the corn varieties in *Hibberd*.[75]

A regenerated organism can constitute statutory subject matter, whether or not similar living organisms still exist in nature, because novelty is distinct from statutory subject matter.[76] Of course, if similar organisms still exist in nature, the regenerated organism would not be patentable because it lacks novelty.[77]

It would also be difficult to construct claims that distinguish the regenerated organism from those found in nature such that the claims do not

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[73]563 F.2d 1031, 195 U.S.P.Q. (BNA) 344 (C.C.P.A. 1977).

[74]2 U.S.P.Q.2d (BNA) at 1425.

[75]227 U.S.P.Q. (BNA) at 443.

[76]*See supra* notes 54-55 and accompanying text.

[77]*See infra* Part III.C (Novelty).

read on products of nature. Moreover, the regenerated organism would not be commercially valuable if one could find similar organisms in nature.[78] Therefore, the only relevant discussion of statutory subject matter for regenerated organisms necessarily involves those organisms that are otherwise extinct.

B. *Utility*

A patentable invention must also be useful.[79] The applicant claiming a regenerated organism must assert at least one particular use of the invention that is credible to a "person of ordinary skill in the art."[80] Since this use must be more than a scientific curiosity or research tool,[81] an assertion that the organism is a valuable source of genetic material for cross-breeding or genetic engineering research experiments probably would not meet the applicant's burden of showing utility. Instead, the applicant would have to show that the organism has "real-world" value.[82] The organism, for example, may have commercial value as breeding stock for animal or plant breeders.[83] Other possible commercial uses include agricultural (a source of food, wool,

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[78]If the naturally occurring organism were difficult to obtain or reproduce, then a method of regenerating the organism might have value.

[79]37 U.S.C. § 101 (1994).

[80] *See In re* Brana, 51 F.3d 1560, 1566, 34 U.S.P.Q. (BNA) 1436, 1441 (Fed. Cir. 1995) (placing the burden on the PTO to show that one of ordinary skill in the art would "reasonably doubt" the asserted utility); *In re* Jolles, 628 F.2d 1322, 1326-27, 206 U.S.P.Q. (BNA) 885, 889-90 (C.C.P.A. 1980)(suggesting that the asserted utility cannot be "incredible"); Patent and Trademark Office Utility Patent Examination Guidelines, 60 Fed. Reg. 36,263, 36,264 (1995). The examiner must make a prima facie showing of no utility to reject claims for lack of utility. The applicant then bears the burden of rebutting the examiner's rejection. *See id.* at 36,265.

[81]*See* Brenner v. Manson, 383 U.S. 519, 534-35, 148 U.S.P.Q. (BNA) 689, 695 (1966)(explaining that utility requires the demonstration of a specific benefit; an object of research is not inherently "useful").

[82]*See* Nelson v. Bowler, 626 F.2d 853, 856, 206 U.S.P.Q. (BNA) 881, 883 (C.C.P.A. 1980) (requiring that one skilled in the art must be able to use the invention "in a manner which provides some immediate benefit to the public").

[83]*See In re* Magerlein, 602 F.2d 366, 202 U.S.P.Q. (BNA) 473 (C.C.P.A. 1979) (approving that intermediates in the production of improved series of

fur, or other by-products), pharmaceutical (a source of particular drugs or biologicals), or domestic (a pet animal or house plant).

An applicant may have difficulty establishing a utility for more speculative assertions because the asserted utility must be credible to one skilled in the art. In particular, an assertion of pharmaceutical utility, such as ingesting a plant to treat a disease, may require support from an appropriate experimental model system.[84] The utility requirement would therefore limit the applicant's claims to organisms whose utility can clearly be demonstrated.

Some scientists will regenerate organisms with the primary goal of restoring ecological environments and maintaining biodiversity. While this utility differs from the utility of traditional inventions by not constituting a commercial product or service, it does constitute a valuable contribution to society. The difficulty in complying with the utility requirement, however, lies in the fact that one species alone is unlikely to restore an ecological environment. The species represents only one thread in a larger interdependent web of organisms. If this ecological benefit cannot be described in concrete terms as a "real-world value," the PTO may find the asserted utility to be too speculative.

Thus, when the applicant asserts as a utility the restoration of an ecological environment, she should be prepared to provide concrete evidence of a particular benefit to the environment and subsequently to the public. This utility obstacle, however, may not be of great concern to scientists whose goal in regenerating an extinct organism is strictly to reintroduce a species into its natural habitat. These scientists are less likely to be interested in obtaining and enforcing intellectual property rights.

C. *Novelty*

Three provisions of the novelty requirement are particularly relevant to regenerated organisms.[85] They relate to acts that occur before the invention is made, that is, before the organism is regenerated. First, public

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[84]*See Brana*, 51 F.3d at 1566, 34 U.S.P.Q.2d (BNA) at 1441.

[85]Other provisions of section 102 such as the statutory bar will not be the focus of this analysis because they relate primarily to loss of the inventor's right to a patent and do not raise issues unique to this art.

knowledge or use of the invention in this country or a printed publication anywhere in the world describing the invention prior to the applicant's invention date can defeat the patent.[86] Second, a person cannot patent an invention that was invented by someone else.[87] Third, a later inventor may not obtain a patent if the same invention was previously made in this country by someone who did not abandon, suppress, or conceal it.[88]

Claims to a regenerated organism challenge conventional applications of the novelty requirement. The key to the analysis is to determine precisely what types of prior art anticipate a regenerated organism.[89] In general, prior art, including knowledge and use, must be available to the person of ordinary skill in the art.[90] A single prior art reference anticipates an invention only if it is substantially identical to the invention[91] and enables a person of ordinary skill in the art to possess the invention.[92]

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[86]*See* 35 U.S.C. § 102(a) (1994).

[87]*See* 35 U.S.C. § 102(f) (1994).

[88]*See* 35 U.S.C. § 102(g) (1994).

[89]*See* 35 U.S.C. §§ 161-64 (1994)(setting forth plant patent requirements); *see also* M.P.E.P., *supra* note 51, § 1600; Deposit of Biological Materials for Patent Purposes, 54 Fed. Reg. 34,864 (1989)(listing biological materials deposit guidelines).

[90]*See* Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453, 223 U.S.P.Q. (BNA) 603, 614 (Fed. Cir. 1984); *see also* Lamb-Weston, Inc. v. McCain Foods, Ltd., 78 F.3d 540, 548-49, 37 U.S.P.Q.2d (BNA) 1856, 1863 (Fed. Cir. 1996) (Newman, J., dissenting) (arguing that the majority erroneously invoked §102(f) prior art to provide the motivation to combine references under § 103 and stating that "secret or abandoned knowledge is not prior art" except under § 102(e) where the filing date of a patent that ultimately issues is the effective date of the prior art).

[91]*See* Structural Rubber Prods., Co. v. Park Rubber Co., 749 F.2d 707, 716, 223 U.S.P.Q. (BNA) 1264, 1270-71 (Fed. Cir. 1984).

[92]*See In re* Donohue, 766 F.2d 531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985)(citing *In re* Borst 345 F.2d 851, 855, 145 U.S.P.Q. (BNA) 554, 557 (C.C.P.A. 1965)) ("Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention."); Van Heusen Prods., Inc. v. Earl & Wilson, 300 F. 922, 930 (S.D.N.Y. 1924) (mandating that an anticipatory reference "must tell you how you can get with certainty the result you are after"); *cf. In re* Wiggins, 488 F.2d 538, 542, 179

A living organism is unique subject matter because a written description, photograph, or awareness of public use alone does not enable one to recreate it.[93] In order to reproduce the invention, one must obtain a sample of the living organism such as a microorganism culture, cell line, seed, or living animal. Thus, an enabling reference must describe the manner in which one can obtain either the living organism or a biological sample that gives rise to the organism without undue experimentation.[94]

Regenerated organisms raise unique issues in that sources of anticipatory prior art for these inventions lose their ability over time to enable the invention. A printed publication describing an organism before it became extinct is relevant prior art, but it is not anticipatory because it no longer teaches how or where to obtain the organism. Similarly, public knowledge or use of the organism in the United States prior to its extinction does not enable one to obtain it today.

Biological materials other than the mature or adult organism itself serve as anticipatory prior art if they allow one skilled in the art to possess

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U.S.P.Q. (BNA) 421, 424 (C.C.P.A. 1973) (noting prior art reference need not give every detail to be enabling to one skilled in the art). Biological materials are enabling under 35 U.S.C. § 112 if they are readily available and can be used to generate the invention "without undue experimentation." *See* 37 C.F.R. § 1.802 (1996).

[93]*See* 1 COOPER, *supra* note 54, § 4.05[1].

[94]*See In re* Lundak, 773 F.2d 1216, 1218, 227 U.S.P.Q. (BNA) 90, 92 (Fed. Cir. 1985) (clarifying that written description of human cell line is not enabling without a deposit when cell line is not "known and readily available" to the public); *In re* Mancy, 499 F.2d 1289, 1293, 168 U.S.P.Q. (BNA) 303, 305 (C.C.P.A. 1974) (noting that process of using a new organism is not obvious in light of reference describing the organism unless that organism were available from a public depository); *In re* LeGrice, 301 F.2d 929, 939, 133 U.S.P.Q. (BNA) 365, 374 (C.C.P.A. 1962) (explaining that a description of a patented rose is not § 102(b) prior art for utility or plant patents because it does not enable one to obtain or create the rose); *Ex parte* Rinehart, 10 U.S.P.Q.2d 1719, 1720 (Bd. Pat. App. & Int. 1985) (enablement of a marine tunicate was satisfied by a description of its precise geographic location); *Ex parte* Argoudelis, 157 U.S.P.Q. 437, 440 (Pat. Off. Bd. App. 1967), *rev'd*, 434 F.2d 1390, 168 U.S.P.Q. (BNA) 99 (C.C.P.A. 1970) (explaining that reference disclosing cultivation of an actinomyces fungus strain to produce an antibiotic identical to that claimed is not anticipatory because it does not enable one to obtain the microorganism).

the regenerated organism.[95] Seeds, plant spores, and any independently viable form of the organism found in nature fall into this category.[96] By obtaining one form, a person of ordinary skill in the art can possess the other developmental forms without significant human experimentation.

By contrast, other biological materials such as DNA, semen, ova, cell cultures, and tissues do not constitute anticipatory prior art for regenerated organisms given the current state of technology. From this standpoint, it does not matter whether the materials are frozen cell cultures, stored with the expectation of future revival, or a desiccated carcass, preserved by natural processes and discovered accidentally. None of these materials alone are substantially identical to the independently viable form of a regenerated organism or allow one of ordinary skill in the art to possess the entire organism without undue experimentation.[97]

Frozen animal embryos fall in the middle of this spectrum in that they possess some attributes of plant seeds but, from a technological perspective, are more similar to animal tissues. Like a plant seed, an embryo constitutes a life stage of the organism with the potential to develop into an adult. Embryos, however, are more comparable to cells and tissues in that they cannot independently give rise to an adult form. In order to mature, isolated embryos require implantation into a natural or artificial womb.[98] This process involves not only other sources of prior art, but may also involve undue experimentation when, for example, all adult females of that species are extinct, and the identification of other surrogate species for embryo implantation requires undue experimentation.

As the science of embryo storage and implantation advances, however, the generation of an adult organism from an embryo may some

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[95]*See* Kate H. Murâshige, *Section 102-103 Issues in Biotechnology Patent Prosecution*, 16 AIPLA Q.J. 294 (1988).

[96]*See Ex parte* Thompson, 24 U.S.P.Q.2d (BNA) 1618, 1621 (Bd. Pat. App. & Int. 1992) (finding that advertisement for commercially available seeds is an enabling disclosure for a cotton cultivar of the same species).

[97]However, the combination of these biological materials with other prior art may make the invention obvious. *See infra* Section III.E (Nonobviousness).

[98]*See* Michael Specter & Gina Kolata, *After Decades and Many Missteps,*

day be as routine as obtaining a mature plant from a seed. Until then, publicly known sources of DNA, semen, ova, cells, and tissues, as well as frozen embryos, constitute relevant prior art but do not anticipate regenerated organisms. The only biological materials that are likely to anticipate a regenerated organism are viable seeds and spores described in a printed publication or the public knowledge or use of the materials in the United States to the extent that the materials are available to the public at the time the invention is made.[99]

Many endangered organisms are known or used by local peoples outside the United States, especially in tropical rain forests, but yet remain uncharacterized by Western scientists.[100] In order to tap this storehouse of knowledge, Western scientists study traditional medicine practices of local healers for indications of plants and animals with pharmaceutical potential.[101] Biological materials collected during these surveys and stored in a repository could later be used to regenerate an organism following its extinction. To the extent that these materials are publicly available when the organism is regenerated, either through a publication anywhere in the world or public knowledge or use in the United States, they would serve as prior art under section 102(a).

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[99]An applicant may also employ product-by-process claims to distinctly claim organisms regenerated by a particular process or from particular starting materials, such as frozen semen and ova. *See* 1 DONALD CHISUM, PATENTS § 8.05[3] (1994). Note, however, that product-by-process claims are inherently weaker than strict product claims. *See generally* Donald R. Holland, *Can Product-by-Process Patents Provide the Protection Needed for Proteins Made by Recombinant DNA Technology?*, 74 J. PAT. & TRADEMARK OFF. SOC'Y 903 (1992). The novelty analysis for a product-by-process remains the same as that of the product alone. The scope of anticipatory prior art is not limited by the claimed process. *See* Scripps Clinic v. Genentech, Inc., 927 F.2d 1565, 1583, 18 U.S.P.Q.2d (BNA) 1001, 1015 (Fed. Cir. 1991); *In re* Thorpe, 777 F.2d 695, 227 U.S.P.Q. (BNA) 964 (Fed. Cir. 1985). Once patented, however, claims to a product-by-process are only infringed by the same product made by the same process. *See* Atlantic Thermoplastics Co., Inc. v. Faytex Corp., 970 F.2d 834, 846-47, 23 U.S.P.Q.2d (BNA) 1481 (Fed. Cir. 1992). *But see Scripps Clinic*, 927 F.2d at 1583, 18 U.S.P.Q.2d (BNA) at 1015.

[100]*See* Day, *supra* note 12.

[101]*See id.*

At archeological digs, seeds discovered by paleobiologists from otherwise extinct species or varieties of plants[102] may constitute prior art under section 102(a). Such seeds anticipate the mature plant if they can be germinated without undue experimentation and are available to the public through a printed publication anywhere in the world or by public knowledge or use in the United States. For example, a cataloged manuscript in a library describing the location of viable seeds at the site of an archeological dig and the oral tradition of a Native American community in the United States as to the location of ancient seeds would each constitute anticipatory prior art under 102(a).

While section 102(a) would not defeat a patent for a regenerated organism from non-public sources of biological materials or from knowledge or use outside the United States, other subsections of 102 would limit the patentability of organisms regenerated from such materials. Under section 102(f), an applicant cannot obtain a patent for an invention that the applicant did not invent.[103] A showing that the applicant derived the invention from another requires evidence that the invention was conceived previously by another and that the complete conception was communicated to the applicant.[104] An organism that previously existed in nature was in a sense conceived and reduced to practice by natural forces. When the would-be inventor obtains a sample of a biological material, whether secret or not, that gives rise to the mature organism in a direct or obvious manner, the complete conception is in effect communicated to him. He derives the invention from the previously "invented" natural materials. Thus, section 102(f) defeats any patent claiming regenerated organisms when the regeneration is obvious to one of ordinary skill in the art.[105]

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[102]*See supra* notes 42-43 and accompanying text.

[103]*See* 35 U.S.C. § 102(f) (1994).

[104]*See* New England Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 883, 23 U.S.P.Q.2d (BNA) 1622, 1626 (Fed. Cir. 1992) ("To invalidate a patent for derivation of invention, a party must demonstrate that the named inventor . . . acquired knowledge of the claimed invention from another, or at least so much of the claimed invention as would have made it obvious to one of ordinary skill in the art."); Pentech Int'l v. Hayduchok, 18 U.S.P.Q.2d (BNA) 1337, 1343 (S.D.N.Y. 1990) (citing Amax Fly Ash Corp. v. U.S., 514 F.2d 1041, 1047, 182 U.S.P.Q. (BNA) 210, 214 (Cl. Ct. 1975)).

Section 102(g) defeats a patent to a second inventor if the first inventor reduced the invention to practice in this country and did not abandon, suppress, or conceal it.[106] At least while the organism was living, nature had reduced it to practice and did not suppress, conceal, or abandon the invention.[107] If living materials, such as seeds, which readily give rise to the mature organism, still exist somewhere, the organism is not fully suppressed, concealed, or abandoned.

Section 102(g) is ineffective against an organism that existed--was reduced to practice--exclusively in another country. However, if viable samples of the organism are first brought into the United States, the receipt date constitutes a date of conception in this country.[108] If one secretly stores the biological materials in the United States for any extended period of time, then this delay in reducing the invention to practice would constitute abandonment, suppression, or concealment under section 102(g).[109] In this manner, section 102(g) operates to prevent one who regenerates an organism from viable biological materials from obtaining a patent when the organism previously existed in the United States or the materials are brought into the United States and stored.

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[106]*See* 35 U.S.C. § 102(g) (1994). In addition to resolving priority disputes between inventors, this section can also be invoked as a defense to an infringement action. *See, e.g.*, Hybritech, Inc. v. Monoclonal Antibodies, Inc., 623 F. Supp. 1344, 227 U.S.P.Q. (BNA) 215 (N.D. Cal. 1985), *rev'd*, 802 F.2d 1367, 231 U.S.P.Q. (BNA) 81 (Fed. Cir. 1986).

[107]The previous invention need not be patented for section 102(g) to defeat the later invention. *See* E.I. duPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1437, 7 U.S.P.Q.2d (BNA) 1129, 1134 (Fed. Cir. 1988).

[108]*See* Fiers v. Sugano, 984 F.2d 1164, 25 U.S.P.Q.2d (BNA) 1601 (Fed. Cir. 1993); Kate H. Murashige, *The Hilmer Doctrine, Self-Collision, Novelty, and the Definition of Prior Art*, 26 J. MARSHALL L. REV. 549, 554 & n.20 (1993). However, a complete conception may require the inventor to contemplate a utility. *See* D'Amico v. Brown, 155 U.S.P.Q. (BNA) 534, 537 (Bd. Pat. App. & Int. 1967) (suggesting that a contemplated utility is required for conception); *cf.* Rey-Bellet v. Engelhardt, 493 F.2d 1380, 1385, 181 U.S.P.Q. (BNA) 453, 456 (C.C.P.A. 1974) (noting that utility requirement for a complete conception is an "open question").

[109]*See* Shindelar v. Holdeman, 628 F.2d 1337, 207 U.S.P.Q. (BNA) 112 (C.C.P.A. 1980).

A unique issue for this art is whether an organism is considered suppressed, concealed, or abandoned when it becomes extinct in the wild and no viable biological materials remain that readily give rise to the organism. In the abstract, the question is whether an invention, once publicly known and used, can be withdrawn from the public domain such that previous knowledge and use of it no longer constitute prior art to defeat a later invention.

Patented inventions, even years after the patent issues, are presumed enabled, operational, and available to the public.[110] Even if the patent is shown to be inoperative as described in the patent, claims in a new patent must distinguish the older issued claims.[111] Thus, it does not appear that at least a patented invention can be withdrawn from consideration as prior art. There is reason, however, to treat an unpatented invention differently. The judicial doctrine of lost art addresses this very issue.

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[110] *See* Western States Mach. Co. v. S.S. Hepworth Co., 147 F.2d 345, 350, 64 U.S.P.Q. (BNA) 141, 143 (2d Cir. 1945); *In re* Crosby, 157 F.2d 198, 200, 71 U.S.P.Q. (BNA) 73, 75 (C.C.P.A. 1975); *see* M.P.E.P., *supra* note 51, § 716.07 (stating that the appellant must rebut the presumption of operability by a preponderance of the evidence).

[111] *See In re* Lurelli Guild, 204 F.2d 700, 704, 98 U.S.P.Q. (BNA) 68, 71 (C.C.P.A. 1953); *Crosby*, 157 F.2d at 200, 71 U.S.P.Q. (BNA) at 175. *But see Western States Mach.*, 147 F.2d at 350, 64 U.S.P.Q. (BNA) at 143 (reiterating that patents are presumed operational, but for patents to be disregarded "there must be substantial proof that they are not")(*citing* Dashiell v.

D. *The Lost Art Doctrine*

1. The Historical Context

The novelty and statutory bar requirements serve to reward the first inventor who ultimately makes an invention known to the public by diligently filing an application no more than one year after a public disclosure.[112] However, the statute makes an exception for public disclosures by knowledge and use or sale in another country and for abandonment, suppression, and concealment of an invention.[113] The legislative intent of the patent statute was to award an inventor with a patent unless the U.S. public had already received the benefit of the invention through public disclosure.[114] Disclosures by knowledge and use "in remote places" were not considered reasonably accessible to the U.S. public.[115] Therefore, a later inventor may be rewarded with a patent when he is first to confer a benefit to the U.S. public by disclosing the invention in an accessible manner.[116]

The judicial doctrine of "lost art" draws upon the same rationale and policy as the statutory exception for inaccessible prior use abroad.[117] In *Gayler v. Wilder*,[118] the Supreme Court affirmed for the first time that prior public knowledge and use of an invention does not defeat a patent to a

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[112]*See* ROBERT P. MERGES, PATENT LAW AND POLICY 162-64 (1992).

[113]*See* 35 U.S.C. § 102(a), (b), (g) (1994).

[114]*See* Gayler v. Wilder, 51 U.S. (10 How.) 477, 497 (1850); *see also* Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453-54, 223 U.S.P.Q. (BNA) 603, 614 (Fed. Cir. 1984) (citing Graham v. John Deere Co., 383 U.S. 1, 6, 148 U.S.P.Q. (BNA) 459, 462 (1966)).

[115]*Gayler*, 51 U.S. (10 How.) at 497. Although the argument for geographic inaccessibility has been criticized, it remains good law. *See* William C. Rooklidge, *The On Sale and Public Use Bars to Patentability: The Policies Reexamined*, THE FED. CIRCUIT BAR J. 7, 23-31 (1991).

[116]*See Gayler*, 51 U.S. (10 How.) at 497.

[117]*See* 1 CHISUM, *supra* note 100, § 3.05[1][b]; Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 341-42 (1992) (explaining that the novelty requirement is seldom taken to "its logical abstraction").

[118]51 U.S. (10 How.) 477 (1850).

second independent inventor when the first invention is completely lost.[119] Prior knowledge and use must exist in a manner accessible to the public in order to defeat a patent.[120] When an earlier invention is inaccessible, a later, independent inventor restores to the public the benefit of the invention.[121]

In *Gayler*, Conner invented a fire-proof safe about 1830 and used it publicly at his place of business for about eight years, after which time he gave the only embodiment to a third party and lost track of it.[122] Fitzgerald independently invented the same safe in 1830, but he continued to test it for six years before filing a patent application. Fitzgerald's patent finally issued in 1843, seven years after filing,[123] and Benjamin Wilder, the "exclusive" licensee of the Fitzgerald patent in New York, brought suit against Charles Gayler for infringement.[124] The Court held that the lower court had given an appropriate instruction to the jury regarding the lost art doctrine as it related to the defense of prior invention by another.[125] The judge had instructed the jury to find the Fitzgerald patent valid if they found Conner to be *an* original,

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[119]*See id.* at 497-98. Judge Nelson, Southern District of New York, first announced this doctrine in 1848 in a suit sustaining the validity of this same patent. *See* Rich v. Lippincott, 20 F. 672, 676 n.2 (C.C.W.D. Pa. 1853) (citing *Fire Proof Safe Case: Crandale Rich & Co. v. Lippincott & Barr*, 26 J. OF THE FRANKLIN INST. 10 (1853)).

[120]*See Gayler*, 51 U.S. (10 How.) at 497.

[121]*See id.*

[122]*See id.* at 489; *see also Rich*, 20 F. at 672 (discussing fire proof safe invention and related litigation).

[123]*See Gayler*, 51 U.S. (10 How.) at 478, 483-84.

[124]*See id.* at 477-78, 482. In addition to arguing prior invention by another, the defense unsuccessfully maintained that the assignment of the patent right during the pendency of the patent application was ineffectual and that plaintiff Wilder lacked standing to bring suit because he had licensed his exclusive rights in the State of New York to another. *See id.* at 492-95. In fact, the license was not exclusive because Wilder had reserved for himself the right to sell the invention in some parts of New York. *See id.*

though not necessarily *the* original, inventor and the Conner invention to have been lost and forgotten before Fitzgerald's invention.[126]

The *Gayler* Court stirred controversy by affirming a less than ideal application of the lost art doctrine. The jury was allowed to rely on subjective evidence of short-term, and potentially temporary, loss of the invention.[127] If Conner had forgotten how to make his safe, his loss of memory would have had to occur after Fitzgerald's independent invention.[128] Conner's memory loss was not absolute, because knowledge of Fitzgerald's invention jogged Conner's recollection of his own earlier invention.[129] Moreover, the location and use of the only embodiment of the invention was unknown, not necessarily destroyed.[130] The jury would thus have had to rely heavily on the subjective testimony of the second inventor that he did not acquire and remember useful information from those who witnessed the invention.[131]

The Supreme Court's only other discussion of the doctrine came twenty-three years later in 1873 in *Coffin v. Ogden*.[132] The Court ruled in favor of the accused infringer who had argued that he was the first inventor and had used the invention publicly.[133] In discussing the defense of prior invention of another, the Court held that prior use by one person is sufficient to invalidate a later patent.[134] Without deciding the validity of the lost art doctrine, the *Coffin* Court cast doubt on at least the *Gayler* Court's application of the doctrine. In particular, the Court questioned the limitation that the

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[126]*See id.* at 496, 498 ("For if the Conner safe had passed away from the memory of Conner himself, and of those who had seen it, and the safe itself had disappeared, the knowledge of the improvement was as completely lost as if it had never been discovered.").

[127]*See id.* at 498.

[128]*See id.*

[129]*See id.* ("[The invention] was not the less new and unknown because Conner's safe was recalled to his memory by the success of Fitzgerald's.").

[130]*See id.* at 495-96.

[131]*See id.* at 501-02 (McLean, J., dissenting).

[132]*See* Coffin v. Ogden, 85 U.S. (18 Wall.) 120 (1873).

[133]*See id.* at 120-21, 125.

[134]*See id.* at 124.

Gayler Court had placed on the defense of prior invention by another, namely, that the later inventor would be entitled to a patent as long as the invention were no longer in the memory of the first inventor.[135]

Since then, a few courts have discussed the lost art doctrine in the context of the defense of prior invention in actions for infringement or during interference proceedings. None, however, has found a prior public use in this country to have been so completely abandoned and unavailable to the public that it no longer constituted prior art. Some courts have noted the *Coffin* Court's doubts.[136] Yet others have lent their support to the doctrine without question.[137]

The Court of Customs and Patent Appeals discussed the history of the defense of prior invention of another and traced the *Gayler* lost art holding to the current section 102(g).[138] This court has also cited *Gayler* in

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[135]*See id.* at 125. ("Whether the proposition expressed by the proviso ['provided Conner's safe and its mode of construction were still in the memory of Conner before they were recalled by Fritzgerald's patent'] is a sound one, it is not necessary in this case to consider"); *see also* 1 CHISUM, *supra* note 100, § 3.05[1][c].

[136]*See e.g.*, Dalby v. Lynes, 64 F. 376, 379 (C.C.D. Mass. 1894) (finding a patent invalid because prior use was not forgotten or abandoned); Buser v. Novelty Tufting Machine, 151 F. 478, 493-96 (6th Cir. 1907) (noting that even though the invention's use was abandoned, prior commercial use should be recognized because such use was not forgotten); Van Heusen Prods., Inc. v. Earl & Wilson, 300 F. 922, 930-31 (S.D.N.Y. 1924) (suggesting that a prior patent that might by chance produce the invention at issue is similar to a lost art and thus does not constitute anticipatory prior art).

[137]*See, e.g.*, Dunlop Holdings Ltd. v. Ram Golf Corp., 524 F.2d 33, 35-36, 188 U.S.P.Q. (BNA) 481, 483 (7th Cir. 1975)(referring to the lost art doctrine as settled law and finding the patent invalidated by prior commercial use by another that amounted to non-informing public use but not secret use); Monaco v. Hoffman, 189 F. Supp. 474, 477-78, 127 U.S.P.Q. (BNA) 516, 518-19 (D.D.C. 1960), *aff'd*, 293 F.2d 883, 130 U.S.P.Q. (BNA) 97 (D.C. Cir. 1961)(finding prior knowledge and use in a foreign country not anticipatory); Converse v. Matthews, 58 F. 246, 249 (C.C.D. Mass. 1893) (finding patent valid because of insufficient proof of prior use).

[138]*See In re* Bass, 474 F.2d 1276, 1299-1300, 177 U.S.P.Q. (BNA) 178, 195-96 (C.C.P.A. 1973) (Baldwin, J., concurring), *superseded by* 35 U.S.C. § 103 (1994) *as stated in* Oddzon Prods., Inc. v. Just Toys, Inc., 43 U.S.P.Q.2d

holding that only prior knowledge that is available to the public can invalidate a patent claim.[139]

The Court of Appeals for the Federal Circuit has not addressed directly the lost art doctrine. It has, however, supported the basic premise of the lost art doctrine without actually invoking it by name in holding that an invention is not suppressed or concealed when the knowledge gained by the public "insure[s] its preservation in the public domain."[140]

These courts differ in opinion more with respect to the appropriate application of the doctrine rather than its general validity. In essence, they confirm the *Gayler* Court's basic holding that prior art must be available to the public to defeat a later invention.[141] Thus, courts concur with the majority opinion in *Gayler* but take into consideration Judge Daniel's caveats. While Judge Daniel objected to the specific application of the lost art doctrine in *Gayler*, he affirmed its application to arts "lost for centuries."[142] Courts lend greater support to the application of the lost art doctrine when they can

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[139]*See In re* Schlittler, 234 F.2d 882, 887, 110 U.S.P.Q. (BNA) 304, 307 (C.C.P.A. 1956), *overruled by* In re Borst, 345 F.2d 851, 145 U.S.P.Q. (BNA) 554 (C.C.P.A. 1965); *see also* Connecticut Valley Enter., Inc. v. United States, 348 F.2d 949, 952, 146 U.S.P.Q. (BNA) 404, 406 (Ct. Cl. 1965).

[140]Checkpoint Systems, Inc. v. United States Int'l Trade Comm'n, 54 F.3d 756, 762, 35 U.S.P.Q.2d (BNA) 1042, 1047 (Fed. Cir. 1995) (quoting Palmer v. Dudzik, 481 F.2d 1377, 1387, 178 U.S.P.Q. (BNA) 608, 616 (C.C.P.A. 1973)).

[141]*See, e.g.*, Kimberly-Clark v. Johnson & Johnson, 745 F.2d 1437, 1453, 223 U.S.P.Q. (BNA) 603, 614 (Fed. Cir. 1984) ("That is the real meaning of 'prior art' in legal theory--it is knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in the art.").

[142]*Gayler v. Wilder*, 51 U.S. (10 How.) 477, 508 (1850) (Daniel, J., dissenting).

be more certain that the art is truly lost.[143] However, certainty of loss does not always require that the art be lost for a long period of time.

Commentators vary in their assessments of the lost art doctrine but generally support it. Chisum mentions the Court's mixed reception to the doctrine of lost art and concludes that the *Coffin* Court doubted whether prior knowledge and use by another must be public in order to invalidate a later patent.[144] Walker also cites the doubts of the *Coffin* Court but overall affirms the validity of the lost art doctrine where the "prior knowledge should have completely disappeared and must have been so far forgotten that its inventor, if living, or others who may have witnessed its use would not be able to recall it to memory and reproduce it without re-inventing the subsequent invention."[145] In an era much closer in time to the *Gayler* and *Coffin* decisions, Robinson explained the doctrine without mentioning any controversy or lack of support for it.[146] More recent reviewers argue that rent dissipation theory supports the lost art doctrine.[147] Overall, the skeptical comments by the Court in *Coffin*, the lack of cases on point, and the concern about potential weaknesses in the *Gayler* Court's application of the doctrine, such as verifying memory loss, may explain the mixed reception to the doctrine. While few inventors invoke the lost art doctrine, it nevertheless appears to remain valid.

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[143] *See, e.g., Monaco v. Hoffman*, 189 F. Supp. 474, 477, 127 U.S.P.Q. (BNA) 516, 518 (D.D.C. 1960), *aff'd*, 293 F.2d 883, 130 U.S.P.Q. (BNA) 97 (D.C. Cir. 1961)(supporting the application of the lost art doctrine to the rediscovery of "arts that have been *extinct* or forgotten *for ages*"); *see also Converse v. Matthews*, 58 F. 246, 249 (C.C.D. Mass. 1893) ("There is no equity or public policy which requires that one should be deprived of his just reward who revived a lost art, whether buried for ages, or for only a few years, although with the latter there is of course more necessity for making sure that the revival was not suggested by the knowledge of what had apparently disappeared.").

[144] *See* 1 CHISUM, *supra* note 100, § 3.05[1]c.

[145] 1 ERNEST B. LIPSCOMB III, LIPSCOMB'S WALKER ON PATENTS § 4:15 (1984) [hereinafter WALKER].

[146] 1 W. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 323 (1890)("[T]he length of time lost . . . [is] of no consequence, provided only that it be actually lost out of the practical knowledge of the public.").

The definition of "completely lost" constitutes the critical element in the application of the lost art doctrine. Walker's definition requires that the inventor and witnesses to the invention not be able to reproduce it without re-inventing it.[148] This is consistent with the Federal Circuit's definition of prior art as knowledge that is available to the public.[149] In other words, an earlier invention no longer constitutes prior art when its inventor and the public have been fully deprived of enabling knowledge of the first invention--when its re-creation requires re-invention.

The application of the lost art doctrine must also address the concerns raised by the *Gayler* dissents.[150] These concerns relate to certainty of the loss of the invention. First, a reliance on memory loss of the first inventor or witnesses to the first invention raises the specter of fraudulent claims--that the second inventor actually learned of the invention from the first inventor or the witnesses.[151] Second, application of the doctrine should be reserved for inventions that have been "irretrievably swept from the earth."[152] The lost art doctrine thus should apply only to inventions that are totally lost and not merely hidden or misplaced.

Defining the standard in this manner is consistent with the provisions of section 102. If an invention constitutes the revival of a lost art, prior publications, knowledge and use are no longer enabling, the inventor did not derive the invention from another, and the invention is not available to the public from a previous inventor who abandoned, suppressed, or concealed it.[153] Thus, application of the lost art doctrine ensures that a second inventor receives the reward of patent rights only for an invention that was otherwise unavailable to the public at the time of the invention.

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[148]*See* 1 WALKER, *supra* note 145, § 4:15.

[149]*See* Kimberly-Clark v. Johnson & Johnson, 745 F.2d 1437, 1453, 223 U.S.P.Q. (BNA) 603, 614 (Fed. Cir. 1984).

[150]*See* Gayler v. Wilder, 51 U.S. (10 How.) 477, 498-509 (1850) (McLean and Daniel, JJ., dissenting).

[151]*See id.* at 502 (McLean, J., dissenting).

[152]*Id.* at 507-08 (Daniel, J., dissenting).

[153]*See supra* Part III.C (Novelty).

2. Extinct Organisms As Lost Arts

Extinct organisms satisfy both the legal requirements and policy considerations of the lost art doctrine. The inventor who regenerates an extinct organism--one that is totally lost--confers knowledge and use of an important resource to the public that it would not otherwise enjoy.[154] Moreover, equity and public policy dictate that an inventor who provides a benefit to the public by reviving an extinct organism should not be deprived of his just reward.[155]

An extinct organism qualifies as a lost art when the organism is so completely lost that no one of ordinary skill in the art can reproduce it without re-inventing it.[156] Nature, the first inventor, no longer provides the invention to the public. The prior art is no longer enabling, whether it be the fossilized record of an organism that became extinct millennia ago or previous knowledge and printed descriptions of an organism that recently became extinct. Such an organism would no longer be free living, and there would be no published reports or public knowledge that make it obvious to one of ordinary skill in the art how to regenerate or obtain the organism from biological materials.

In the case of stored biological materials, the lost art analysis involves similar challenges as those noted in the traditional novelty analysis.[157] Namely, when do particular biological materials serve as anticipatory prior art and subsequently defeat the classification of the regenerated organism as a lost art?

Under Walker's definition, the lost art doctrine requires persons who witnessed the invention not be able to reproduce it without re-inventing it--they should not rely on their own memory.[158] One who secrets away

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[154]*See Gayler*, 51 U.S. (10 How.) at 497 ("[The discoverer of a lost art] would not literally be the first and original inventor. But he would be the first to confer on the public the benefit of the invention. He would discover what is unknown, and communicate knowledge which the public had not the means of obtaining without his invention.").

[155]*See* Converse v. Matthews, 58 F. 246, 249 (C.C.D. Mass. 1893).

[156]*See* 1 WALKER, *supra* note 145, § 4:15.

[157]*See supra* Part III.C (Novelty).

biological materials that readily give rise to the organism relies on nature's own biological memory of the organism to reproduce it. This does not constitute an invention because the organism is not really lost. The means of obtaining the organism by regeneration is obvious. In a sense, the organism is just misplaced, hidden, or derived from the original inventor. An organism "regenerated" in such an obvious manner is also a product of nature or derived from nature.[159]

Organisms that have become extinct recently raise the question as to the legal standard for declaring an organism lost. Scientists define an organism as extinct when it has not been seen *in the wild* for more than fifty years and all captive organisms have died.[160] This scientific criterion for extinction certainly constitutes a lost art.

Perhaps this standard it too strict. A proposed new standard would designate an organism as extinct when there is "no reasonable doubt" that the last organism has died.[161] This standard is even higher than the preponderance of the evidence standard that applies to the presumption of operability of patented inventions.[162] Normally, the examiner should reject a claim only if the invention is anticipated by prior art.[163] The applicant would then have the burden of overcoming the examiner's *prima facie* case by submitting declarations from experts claiming that the prior art is no longer enabling.[164] Such declarations would provide evidence of the inability

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[159]*See supra* Parts III.A (Subject Matter) and III.C (Novelty).

[160]*See* Stephen R. Edwards, *Conserving Biodiversity Resources for Our Future*, *in* THE TRUE STATE OF THE PLANET 212, 217 (Ronald Bailey ed., 1995).

[161]*Id.* at 240.

[162]*See* M.P.E.P., *supra* note 51, § 716.07.

[163]*See id.* § 706. The Board of Appeals has made it clear that the examiner has the burden of showing that claimed organisms occur naturally without the "intervention of man." *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1427 (Bd. Pat. App. & Int. 1987) ("The examiner has presented no evidence that the claimed polyploid oysters occur naturally without the intervention of man . .. ."). The examiner would have to show that the oysters currently exist or occasionally arise spontaneously in nature. If they exist, no one knows about it or they are so rare that no one can find them. *See also* MERGES, *supra* note 112, 187-92 (discussing inherency doctrine).

[164]*See* M.P.E.P., *supra* note 51, § 706.

to locate viable organisms in nature or in captivity, including the inventor's biological starting material. Thus, a scientific determination of extinction under this standard would satisfy the requirements for rebutting the examiner's *prima facie* case for anticipation.

The application of the lost art doctrine to extinct organisms is more appropriate than the application of the lost art doctrine to the safe in *Gayler*.[165] This new application of the doctrine is not saddled with the criticisms voiced by the *Gayler* dissent.[166] When one defines "lost" in this context as regeneration of an extinct organism from nonenabling biological materials, the second inventor could not have "learned" of the invention from the first inventor, nature. Unlike the *Gayler* invention, the inventor of a regenerated organism would not be able to rely on memory of the earlier invention, an extinct organism. The first invention would have been irretrievably lost because the organism or enabling biological materials derived from it would not be known to exist anywhere in the world. The second inventor would have performed an inventive act and could not have relied on a secret stash of materials that readily give rise to mature forms of the organism.

What happens if an inventor satisfies this standard during prosecution, the PTO allows her patent, but the organism turns out not to be extinct?[167] This situation is analogous to finding an anticipatory reference for an invention claimed in an issued patent.[168] An issued patent is presumed valid and can only be defeated by clear and convincing evidence to the contrary.[169] In a suit for infringement, clear and convincing evidence of the

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[165]*See* Gayler v. Wilder, 51 U.S. (10 How.) 477, 502, 507-08 (McLean and Daniel, JJ., dissenting); *supra* notes 152-53 and accompanying text.

[166]*See id.*

[167]*See, e.g., Science: Prehistoric Tree, Anyone?*, TIME, Dec. 26, 1994, at 40 (discovery of a species of pine tree in Australia thought to be extinct for more than 65 million years); *Rare Violet Assumed Extinct Rediscovered in Okinawa*, JAPAN SCIENCE SCAN, Dec. 12, 1994, *available in* WESTLAW, Allnews database, 1994 WL 2689415; Carl Zimmer, *Shell Game*, DISCOVER, Jan. 1997, at 72 (discovery of living gulf snapping turtle, thought to have been extinct for more than 20,000 years).

[168]*See, e.g., supra* notes 110-11.

[169]*See* 35 U.S.C. § 282 (1994); Perkin-Elmer Corp. v. Computervision Corp.,

organism's continued existence, either in nature or stored in a repository, would invalidate the application of the lost art doctrine and consequently invalidate the patent due to lack of novelty.

The *Gayler* dissent's desire to limit the lost art doctrine to long-lost arts[170] should not prevent the application of the doctrine to recently extinct organisms. The concern in *Gayler* and lower court cases relates more to ensuring the totality of the loss than to the amount of time per se.[171] The reliance on objective criteria for extinction rather than testimony of memory loss overcomes the weaknesses in the *Gayler* application of the lost art doctrine. Limiting the doctrine to organisms thought to have become extinct ages ago does not eliminate the possibility that the organism still survives somewhere in nature. The standard for invoking the lost art doctrine for extinct organisms should thus be the appropriate standard of proof[172] of extinction as opposed to the amount of time that the organism has been extinct.

Assessing whether an organism is "lost" becomes more challenging when the applicant claims a previously extinct variety while other varieties of the same species survive or when the regenerated organism differs from the parent organism as a result of the regeneration process.[173] A similar issue arises during the prosecution of plant patents.[174] The burden would rest on the applicant to demonstrate that the regenerated variety has at least one distinctive characteristic that distinguishes it from extant varieties. The PTO would limit allowable claims to organisms with these characteristics. The issue of distinguishing varieties becomes even more significant in assessing the obviousness of inventions.

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[170]*See Gayler*, 51 U.S. (10 How.) at 508 (Daniel, J., dissenting).

[171]*See supra* notes 142-43 and accompanying text.

[172]The standards are a preponderance of evidence to rebut the examiner's prima facie case of anticipation or obviousness during prosecution and clear and convincing evidence after the patent issues. *See* M.P.E.P., *supra* note 51, §§ 2121, 2142; *supra* notes 110-11 and accompanying text.

[173] For example, Dolly the sheep has chromosomes from the doneor cell nucleus and some DNA (mitochondrial) from the egg cell into which the nucleus was injected. Philip Kitcher, *Whose Self is it, Anyway?*, THE SCIENCES, Sept-Oct. 1997, at 58, 59.

[174]*See* 35 U.S.C. §§ 161-64 (1997); M.P.E.P., *supra* note 51, § 1600.

E. *Nonobviousness*

The "subject matter as a whole" of a patentable invention must not be "obvious at the time the invention was made to a person having ordinary skill in the art."[175] *Graham v. John Deere*[176] defined four criteria to be weighed in this analysis: scope and content of the prior art, differences between the prior art and the claims at issue, the level of skill in the art, and relevant secondary considerations such as commercial success, long felt need, and failure of others.[177]

In assessing the obviousness of an invention, the scope of prior art under this analysis is the same as that under the section 102 novelty analysis.[178] The combined prior art references are then compared to the invention as a whole without the benefit of hindsight,[179] but only if the prior

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[175]35 U.S.C.A. § 103 (West Supp. 1997).

[176]383 U.S. 1, 148 U.S.P.Q. (BNA) 459 (1966).

[177]*See id.* at 17-18, 148 U.S.P.Q. (BNA) at 467.

[178]*See* In re Wertheim, 646 F.2d 527, 532, 209 U.S.P.Q. (BNA) 554, 560 (C.C.P.A. 1981). There are two exceptions to this generalization. Relevant prior art references must be derived from an analogous art. *See In re* Deminski, 796 F.2d 436, 442, 230 U.S.P.Q. (BNA) 313, 315 (Fed. Cir. 1986) (describing a two-fold test for nonanalogous art: whether the reference is "within the field of the inventor's endeavor," and, if not, "whether the reference is reasonably pertinent to the particular problem with which the inventor was involved"). In addition, references qualifying only as sections 102(f) and (g) prior art cannot be used to defeat a patent if they describe subject matter assigned to the same entity as the claimed invention. *See* 35 U.S.C.A. § 103(a), ¶ 2 (West Supp. 1996); Kimberly Clark Corp. v. Procter & Gamble Distrib. Co., 973 F.2d 911, 917, 23 U.S.P.Q.2d (BNA) 1921, 1926 (Fed. Cir. 1992) (discussing the purpose of this amendment to section 103). Judge Newman argues that section 102(f) prior art is irrelevant to an obviousness analysis. *See* Lamb-Weston, Inc. v. McCain Foods, Inc., 78 F.3d 540, 548-49, 37 U.S.P.Q.2d (BNA) 1856, 1863 (Fed. Cir. 1996) (Newman, J., dissenting). The majority in that decision cites contrary authorities but does not reach the issue. *See id.* at 544 & n.*, 37 U.S.P.Q.2d (BNA) at 1860 & n*.

[179]*See* Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 U.S.P.Q.

art teaches or suggests that the particular references be combined.[180] Few specific rules can be formulated because the analysis is highly fact based.[181]

A regenerated organism is obvious only if (1) the prior art suggests to scientists that they should regenerate the organism from known biological starting materials, and (2) the prior art reveals that scientists would have a reasonable expectation of success in accomplishing this task.[182] As long as some aspect of the regeneration, either the methods or the starting materials, are unknown to a person of ordinary skill in the art, the regenerated organism is potentially nonobvious. For example, a regenerated organism may be nonobvious if the inventor generated it by applying a known technique to a novel and nonobvious biological material even if the application of the technique to the materials would be obvious in hindsight.[183] The prior art cannot teach the application of a readily adaptable technique to a material that was unknown at the time.[184]

If, on the other hand, the materials are known but the prior art does not adequately enable the invention, the invention is nonobvious. When the prior art suggests the use of a technique for regeneration or the starting biological materials but does not clearly teach how to perform the technique or how to obtain the materials, the regenerated organism is not obvious

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[180]*See* Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1050-51, 5 U.S.P.Q.2d (BNA) 1434, 1439 (Fed. Cir. 1988).

[181]*See In re* Brouwer, 77 F.3d 422, 425, 37 U.S.P.Q.2d (BNA) 1663, 1665 (Fed. Cir. 1996). Recent legislative changes to section 103 also allow an applicant to claim certain biotechnological processes in the same application as associated claims to novel and nonobvious compositions of matter even if the processes would otherwise be obvious. *See* Biotechnological Process Patents Act of 1995, Pub. L. No. 104-41, 109 Stat. 351 (to be codified at 35 U.S.C. § 103).

[182]See *In re* Vaeck, 947 F.2d 488, 493, 20 U.S.P.Q.2d (BNA) 1438, 1442 (Fed. Cir. 1991)(evaluating the obviousness of recombinant cyanobacteria).

[183]*See In re* Ochiai, 71 F.3d 1565, 1569-70, 37 U.S.P.Q.2d (BNA) 1127, 1131 (Fed. Cir. 1995) (finding that claims to a process for making a nonobvious chemical product from a nonobvious starting chemical are patentable even though the prior art teaches the use of this process with "similar" chemicals).

[184]*See id.*

because the prior art is defective as a nonenabled teaching.[185] The suggestion in the prior art to regenerate the organism may simply be an invitation to try.[186] Similarly, when the prior art does not suggest the application of a known method of regeneration to known materials, the resulting organism may still be nonobvious.[187] For the organism to be obvious, the references must provide a reasonable expectation of success by specifically suggesting how to modify known materials using known techniques to regenerate the organism and by providing evidence that such modification could be accomplished successfully.[188] Such references serve to establish a *prima facie* case of obviousness that the applicant may be able to overcome with objective evidence to the contrary, including evidence of long felt need and failure of others, the "secondary considerations."[189] Other statutory

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[185]*See Vaeck*, 947 F.2d at 493, 20 U.S.P.Q. (BNA) at 1442 (holding that expression of a protein in cyanobacteria was not obvious in light of prior art describing the expression of a protein in bacteria, a separate family of unicellular organisms); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380, 231 U.S.P.Q. (BNA) 81, 91 (Fed. Cir. 1986) (noting that prior art suggested the claimed assay but did not teach how to perform it).

[186]*See In re* O'Farrell, 853 F.2d 894, 902, 7 U.S.P.Q.2d (BNA) 1673, 1680 (Fed. Cir. 1988).

[187]*See In re* Brouwer, 77 F.3d 422, 425, 37 U.S.P.Q.2d (BNA) 1663, 1665 (Fed. Cir. 1996) (finding that claims to a process of reacting known starting materials to produce a nonobvious product is patentable even though the basic chemical method was known, noting that the prior art did not suggest the use of the reactant in this process or how to obtain the product by this process); BURCHFIEL, supra note 8, at 27-30 (discussing the *Ochiai* and *Brouwer* decisions).

[188]*See Vaeck*, 947 F.2d at 494-95, 20 U.S.P.Q.2d (BNA) at 1443-44 (finding no reasonable expectation of success in producing recombinant cyanobacteria); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1208, 18 U.S.P.Q.2d (BNA) 1016, 1022 (Fed. Cir. 1991) (finding no reasonable expectation of success in cloning the erythropoietin gene); *O'Farrell*, 853 F.2d at 903-04, 7 U.S.P.Q.2d (BNA) at 1681 (observing that the genetic engineering method of producing proteins was obvious over prior art which suggested reasonable expectation of success); *Ex parte* Obukowicz, 27 U.S.P.Q.2d (BNA) 1063, 1065 (Bd. Pat. App. & Int. 1993) (explaining that general guidance suggesting approaches for genetically engineering a particular bacterium is just "an invitation to scientists to explore a new technology that seems promising").

[189]*See In re* Piasecki, 745 F.2d 1468, 1472, 223 U.S.P.Q. (BNA) 785, 788 (Fed.

requirements, however, may limit the application of these principles when the regeneration effort constitutes derivation of the invention from nature.[190]

A suggestion in the prior art to apply techniques used with one variety to another closely related variety or species is, as in *Allen*, more likely to provide a reasonable expectation of success.[191] Conversely, the further the organism diverges genetically from a given species to another, as in *Vaeck*, the less likely techniques can be adapted in any predictable manner.[192] For example, techniques for the *in vitro* fertilization of animals and for the regeneration of plants from cell culture often must be fine tuned to the biological idiosyncracies of each species. Scientists adapting the technique from one species to another may often find the results unpredictable and difficult to obtain.[193] Such failure of others to adapt a technique serves as a secondary consideration to suggest that the invention is nonobvious.

Current case law and PTO regulations in the biotechnological arts provide adequate guidance to evaluate the nonobviousness of regenerated organisms. In the coming years, numerous regenerated organisms likely may fulfill this statutory criterion along with the other requirements for patentability. The application of these requirements to regenerated organisms requires only minor adjustments to precedent established in other biotechnological arts. This fine tuning should also be performed in light of the policies and goals of the patent system. Doing so will ensure the appropriate balance of incentives and equities to both inventors and the public at large.

IV. FURTHERING THE GOALS OF THE PATENT SYSTEM

The patenting of regenerated, formerly extinct organisms ultimately furthers the goals of the patent system. One goal is to induce the discovery of new inventions by granting inventors the right to exclude others from making, selling, or using the invention for a limited period of time.[194] But at

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[190] *See infra* Part IV (Furthering the Goals of the Patent System).

[191] *Ex Parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1427 (1987).

[192] *See Vaeck*, 947 F.2d at 493, 20 U.S.P.Q. (BNA) at 1442.

[193] *See supra* note 31 and accompanying text.

[194] *See* Eli Lilly & Co. v. Premo Pharm. Labs., Inc., 630 F.2d 120, 137, 207 U.S.P.Q. (BNA) 719, 735 (3d Cir. 1980).

the same time, Congress intended to maximize the benefit to society and minimize any potential harm by not permitting inventors to remove from the public domain anything to which the public already has access.[195] In addition, equitable principles compel the award of a patent to an inventor who has conferred the benefit of a lost art to the public.[196]

Since the loss of domestic plants and animals and the extinction of wild organisms is a serious concern, both scientifically and economically, the United States should promote the regeneration of extinct organisms. The public benefits from the recovery of formerly extinct organisms that serve as sources of pharmaceuticals, agriculturally valuable crops and animals, as well as new genetic materials to improve existing domesticated species. The ability to regenerate organisms in the future requires planning and foresight in the present to preserve biological materials with the expectation that they may be regenerated should preservation efforts fail. The high cost of searching tropical locations for organisms, storage of the biological materials, and the development of new regeneration methods requires a strong economic incentive, particularly if it is to be performed by private industry.

The ability to obtain broad claims to entire organisms rather than narrower claims to their biochemical components or to methods of regenerating or using them provides a strong incentive for pioneers in this art. The patent system provides such an incentive in other arts by awarding composition of matter claims to the first inventor who demonstrates at least one new utility. Later inventors who identify new uses can only claim new methods of use.[197] This incentive should be equally available to inventors who regenerate organisms as to inventors in other arts.

If the method of using a regenerated organism is not patentable, such as growing the organism as a farm crop, then the only patent incentive available is a claim to the organism itself. In this respect, the incentive is similar to that for most genetically engineered plants and animals. While claims to the process of regeneration, if available, would be valuable to an inventor, claims to the final product may be even more valuable intellectual

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[195] *See* Gayler v. Wilder, 51 U.S. (10 How.) 477, 497 (1850); *see also supra* notes 113-17 and accompanying text.

[196] *See* Converse v. Matthews, 58 F. 246, 249 (C.C.D. Mass. 1893).

property.[198] Once the organism is regenerated, production and use of the organism may not necessarily infringe the patented regeneration technique; whereas, use of the organism will certainly infringe claims to the organism itself. Thus, the prospect of future patent rights to regenerated organisms should serve as an appropriate incentive for inventors to invest their time and money in this effort.

These incentives are tempered by the patent system's established safeguards to ensure against the inequity of rewarding inventors with exclusive rights to technologies already in the public domain. The system should reward only inventors who benefit society with the disclosure of novel and nonobvious regenerated organisms. Organisms revived by routine, foreseeable means or using anticipatory biological materials should not be patentable.

It is thus important to ensure that there are no legal opportunities to obtain a patent for activity in this new art that would deprive the public of something to which they already have access. Section 102(a) bars the award of a patent when prior art references allow a person of ordinary skill in the art to obtain the invention by obvious means.[199] This section, however, does not bar a patent in light of prior knowledge and use abroad.[200] Section 102(g) bars a patent to a later inventor when an earlier inventor has not abandoned, suppressed, or concealed the invention. An invention is abandoned, suppressed, or concealed--it is a lost art--only if one of ordinary skill in the art is unable to obtain it from known biological materials in an obvious manner.[201] As in section 102(a), section 102(g) only applies to activity in the United States. It is does not defeat a patent when a prior inventor makes and maintains the invention abroad without abandoning, suppressing, or concealing it.[202]

These "loop holes" for foreign knowledge and use are disconcerting in light of the *Brouwer* and *Ochiai* decisions, which would not bar an inventor from obtaining a patent for a novel product by applying a known technique

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[198] *See* supra note 99.

[199] *See supra* notes 93-95, 141 and accompanying text.

[200] *See* 35 U.S.C. § 102(a) (1994).

[201] *See supra* Part III.D (The Lost Art Doctrine).

[202] *See* 35 U.S.C. § 102(a), (g) (1994).

to a biological starting material.[203] For example, under this rationale an inventor might be able to obtain a patent for a plant that is otherwise extinct by planting and sprouting a preserved seed in soil, as long as the seed was only known from prior knowledge and use abroad.

Fortunately, Section 102(f) eliminates this inequity by invalidating a patent to a would-be inventor who derives the invention from another anywhere in the world by obtaining a sufficient amount of the invention "as would make it obvious to one of ordinary skill in the art."[204] In addition, an organism derived from unmodified natural materials, known or unknown, would likely constitute a product of nature[205] and would not constitute a lost art.[206] Thus, the novelty and nonobviousness requirements appear to exclude patents to regenerated organisms when the inventor derives the invention from nature, even when the source of the biological materials is unknown to the public at large.

This conclusion may appear to conflict with the Federal Circuit's opinions in *Brouwer* and *Ochiai*.[207] However, these cases cannot be interpreted to overrule previous precedent and the statutory requirements of sections 101 and 102(f). *Brouwer* and *Ochiai* should not apply to situations where the biological starting materials are essentially unaltered from their natural state. These decisions involved claims to chemical processes in which the products were novel and nonobvious, but the prior art did not teach how to obtain these products by otherwise known processes.[208] A derived organism differs from the *Ochiai* and *Brouwer* inventions in that such

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[203] *See supra* notes 182-86 and accompanying text.

[204] 35 U.S.C. § 102(f) (1994); *see* New England Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 883, 23 U.S.P.Q.2d (BNA) 1622, 1626 (Fed. Cir. 1992); *supra* note 106 and accompanying text.

[205] *See supra* Part III.A (Subject Matter).

[206] *See supra* Part III.D.2 (Extinct Organisms as Lost Arts).

[207] *See supra* notes 181-86 and accompanying text.

[208] *See In re* Ochiai, 71 F.3d 1565, 1569-70, 37 U.S.P.Q.2d (BNA) 1127, 1131 (Fed. Cir. 1995); *In re* Brouwer, 77 F.3d 422, 425, 37 U.S.P.Q.2d (BNA) 1663,

an organism is not statutory subject matter[209] and is not novel and nonobvious.[210]

In addition, previous holdings that biological materials are novel when the prior art does not teach where to obtain them[211] must be distinguished from the analysis of derived inventions.[212] Under the novelty analysis, the prior art is viewed from a third-party perspective as that which is available to the public. By contrast, the derivation analysis takes into account the inventor's actual source of materials, the means of regenerating the organism from these materials, and whether a person of ordinary skill in the art would find it obvious to manipulate the same materials in the same manner. Thus, whether a source of materials is known to the public and constitutes 102(a) prior art is relevant to the nonobvious analysis of *Brouwer* and *Ochiai.* It is not relevant, however, to determining whether the invention was derived from another.

Even if the patent system properly rewards only those who make inventive contributions to society, there are those who would object to the patenting of regenerated organisms on the basis of public policy. One might speculate that the prospect of obtaining a patent for regenerated organisms would inspire some individuals to hasten the extinction of an endangered species. There are several reasons why this remote possibility should not impact any decision to issue patent claims to regenerated organisms. There are already many economic incentives, more concrete than inchoate patent rights, for individuals to engage in habitat destruction and other activities that hasten the extinction of organisms. In addition, the authority and ability to prohibit such destructive acts lies outside the PTO, with other federal and state agencies. Finally, if the means of regeneration were obvious at the time of the extinction, the organism regenerated after the extinction event is not likely to be patentable. An individual contributing to the demise of a species with the intent of obtaining future patent rights would have to gamble that a regeneration technique would be available to him at a later date and would result in a patentable invention. This possibility appears to be so speculative

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[209] *See supra* Part III.A (Subject Matter).

[210] *See supra* notes 91-93 and accompanying text and Parts III.C (Novelty) and III.D.2 (Extinct Organisms As Lost Arts).

[211] *See supra* note 90 and accompanying text.

[212] *See supra* notes 100-02 and accompanying text.

that it is not likely to motivate any inventor. Overall, the prospect that these patents would encourage constructive activities is much greater than the prospect that they would encourage destructive activities.

There are those who would question the ethics of allowing patents to issue for regenerated organisms. While this controversy applies to all currently patentable life forms, particularly transgenic animals,[213] its extension to organisms that previously were unpatentable "products of nature" is likely to inflame the debate further. In the case of organisms that became extinct in modern times, however, there is less support for the argument that patenting new life forms encourages the attending risks of genetic research and subsequent release of these organisms. Here, the opposite is true. The patenting of regenerated organisms ultimately encourages the revival and reintroduction of native species into the wild. Ultimately, the process of regulating attendant risks of new technologies "involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives" not the PTO.[214]

V. CONCLUSION

Technologies are now available to regenerate some organisms from preserved biological materials following their extinction. New technologies will certainly arise in the near future to permit scientists to regenerate a wider range of species from diverse biological materials. The rapid rate of species extinction world-wide combined with ongoing attempts to preserve materials from endangered species means that many organisms are likely to fall within this class in the next decade. Attempts to patent regenerated organisms will present the patent bar with new challenges to the traditional patentability criteria.

While public policy and equitable principles mitigate against rewarding those whose only "inventive" act is to store viable biological materials, these same principles justify the award of patent rights to those

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[213]*See* Reid G. Adler, *Controlling the Applications of Biotechnology: A Critical Analysis of the Proposed Moratorium on Animal Patenting*, 1 HARV. J.L. & TECH. 1, 15 (1988); Richard Stone, *Religious Leaders Oppose Patenting Genes and Animals*, 268 SCI. 1126 (1995); *see also* BURCHFIEL, *supra* note 8, at 43-45.

[214]Diamond v. Chakrabarty, 447 U.S. 303, 317, 206 U.S.P.Q. (BNA) 193, 200

who do make significant inventive contributions in regenerating extinct organisms. In particular, the preexistence of an organism should not defeat a later patent after the organism becomes extinct when the only biological materials remaining after the extinction do not inherently give rise to the organism.

Like all inventions, these organisms must constitute statutory subject matter and fulfill the other requirements of patentability including utility, novelty, and nonobviousness. An extinct organism is only patentable as a lost art when it is "irretrievably" lost from the earth, that is when its regeneration involves undue experimentation or unpredictable results. Not all regenerated organisms will satisfy these criteria, but a subset most likely will.

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FUTURE MEETINGS calendar

1998

April 16-18	LICENSING EXECUTIVE SOCIETY, LES (USA & CANADA) Spring Meeting, The Westin Bayshore, Vancouver, British Columbia (703-836-3106)
April 22-24	AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, Spring Meeting, Minneapolis Hilton & Towers, Minneapolis, Minnesota (703-415-0780)
May 9-13	INTERNATIONAL TRADEMARK ASSOCIATION, Copley Connection and Hynes Convention Center, Boston, Massachusetts (Call Membership Services, (212) 768-9887)
June 21-24	ASSOCIATION OF CORPORATE PATENT COUNSEL, The Inn at Semi-AH-Moo, Blaine, Washington (near Vancouver, B.C.) (Contact: Allen Richmond, Secretary, (918) 661-0512, Fax (918) 661-8739)
June 24-28	ABA-IPL SECTION, ABA - IPL1998 Summer IPL Conference, Colonial Williamsburg, Virginia (312-988-5639)
June 25-27	LICENSING EXECUTIVE SOCIETY, LES (USA & CANADA) Summer Meeting, Boston Marriott Long Wharf Hotel, Boston, Massachusettes (703-836-3106)
July 31-August 5	ABA-IPL SECTION, 1998 Annual Meeting, Toronto, Ontario, Canada (312-988-5639)
October 1-3	PATENT AND TRADEMARK INSTITUTE OF CANADA, 72nd Annual General Meeting, Hotel Newfoundland, St. JohnÆs, Newfoundland, Canada (613-234-0516)
October 1-3	HOUSTON INTELLECTUAL PROPERTY LAW ASSOCIATION & UNIVERSITY OF HOUSTON, 14th Annual Institute of Intellectual Property Law, The San Luis Resort and Conference Center, Galveston Island, Texas (713-547-2234)
October 15-17	AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, Annual Meeting, Crystal Gateway Marriott Hotel, Arlington, Virginia (703-415-0780)
October 25-28	LICENSING EXECUTIVE SOCIETY, LES (USA & CANADA) Annual Meeting, Fountainbleau Hilton, Miami Beach, Florida (703-836-3106)

1999

January 30-February 2	ABA-IPL SECTION, ABA - IPL 1999 Midwinter Meeting, Hyatt Regency Grand Cypress (tentative), Orlando, Florida (312-988-5639)
February 3-6	AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, Mid-Winter Meeting, Walt Disney World Swan (Westin), Orlando, Florida (703-415-0780)

February 7-10	ASSOCIATION OF CORPORATE PATENT COUNSEL, Ritz Carlton, Palm Beach, Florida (Contact: Allen Richmond, Secretary, (918) 661-0512, Fax (918) 661-8739)
April 12-13	ABA-IPL SECTION, ABA - IPL 1999 Spring CLE Meeting, Omni Shoreham Hotel, Washington, D.C. (312-988-5639)
May 22-26	INTERNATIONAL TRADEMARK ASSOCIATION, Washington State Convention and Trade Center, Seattle, Washington (Call Membership Services, (212) 768-9887)
June 20-23	ASSOCIATION OF CORPORATE PATENT COUNSEL, Silverado Country Club, Napa Valley, California (Contact: Allen Richmond, Secretary, (918) 661-0512, Fax (918) 661-8739)
June 23-27	ABA-IPL SECTION, ABA - IPL 1999 Summer IPL Conference, Sheraton Palace, San Francisco, California (312-988-5639)
August 6-11	ABA-IPL SECTION, 1999 Annual Meeting, Atlanta, Georgia (312-988-5639)
October 21-23	AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, Annual Meeting, Crystal Gateway Marriott Hotel, Arlington, Virginia (703-415-0780)
October 23-30	LICENSING EXECUTIVE SOCIETY, LES (USA & CANADA) Annual Meeting, Marriott River Center, San Antonio, Texas (703-836-3106)

2000

April 29-May 3	INTERNATIONAL TRADEMARK ASSOCIATION, Denver Convention Center, Denver, Colorado (Call Membership Services, (212) 768-9887)
September 9-16	LICENSING EXECUTIVE SOCIETY, LES (USA & CANADA) Annual Meeting, Sheraton Center, Toronto, Canada (703-836-3106)
October 19-21	AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, Annual Meeting, Crystal Gateway Marriott Hotel, Arlington, Virginia (703-415-0780)

2001

May 5-9	INTERNATIONAL TRADEMARK ASSOCIATION, San Francisco Marriott & Mascone Convention Center, San Francisco, California (Call Membership Services, (212) 768-9887)
May 9-11	AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, Spring Meeting, Sheraton Palace, San Francisco, California (703-415-0780)

2002

January 23-26	AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, Mid-Winter Meeting, La Pointe Hilton on South Mt., Phoenix, Arizona (703-415-0780)