Maintaining Competition in Copying: Narrowing the Scope of Gene Patents

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Patents claiming naturally occurring gene sequences are generally, if not grudgingly, accepted as part of today's patent landscape. This Article does not question the existence of these patents but instead questions their breadth. Naturally occurring gene sequences are not like other inventions because they are copied from nature. Applying patent law's own originality requirement, this Article argues that these claims must be narrower than currently assumed. Gene discovery is much like cartography. Both are created by copying from nature. For maps and charts, copyright affords very narrow scope to these low authorship works; a cartographer can claim little more than her specific rendition of some coastline (i.e., her specific map). By analogy, patent claims to low inventorship works like gene discovery must be similarly narrow; they can cover the specific version of the gene sequence created by the inventor but little else. Furthermore, such narrow claims are consistent with patent law's own drive to foster economic efficiency through competition. Broad claims to gene discoveries foreclose such benefits. By narrowing these claims as mandated by the originality requirement, gene patents can benefit from the cost savings afforded by competition.

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INTRODUCTION

At one time, it may have been plausible to separate basic scientists from inventors. Basic scientists were natural philosophers; they did not concern themselves with inventing and commercializing technology. In that world, patent law had little need to understand or articulate precisely the relationship between science and technology.

Whether such a world ever existed is debatable. Today's world of innovation certainly does not fit that mold, nor can it be neatly divided into separate realms of science and technology. Basic science and commercial technology have been drawing themselves into an ever-tightening spiral. New basic science leads to new technology, and new technology leads to new basic science.[1] A modern researcher may be a traditional university scientist in the morning, then the chief researcher at her biotech start-up in the afternoon. For this complex, intermingled environment, patent law must provide guidance. Patent law must define the limits and scope of patent protection.[2] As technology advances with an ever-quickening pace, is patent law agile enough to keep up?

One area that exemplifies this deep melding of basic science and technology is the area of research tools.[3] Research tools comprise the methods and materials used in basic research.[4] As their name suggests, they are at the center of this confluence of science and technology. They are at once utilitarian tools yet they are also essential to basic science.[5] How should the patent system treat research tools?

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[1] *See* Peter Yun-hyoung Lee, *Inverting the Logic of Scientific Discovery*, 19 HARV. J.L. & TECH. 79, 81 (2005).

[2] *See* John H. Barton, *Rational Limits on Genomic Patents*, 18 NATURE BIOTECHNOLOGY 805, 805 (2000) ("Genomics and informatics are pushing the patent system into uncharted areas . . . . Unless these guidelines are developed well, the system may hurt innovation more than it helps it.").

[3] *See* Janice M. Mueller, *No "Dilletante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 10 (2001) (defining research tools).

[4] *See id.* (describing research tools "in its broadest sense as 'embracing the full range of resources that scientists use in the laboratory'"); *see also* Donald Ware, *Research Tool Patents: Judicial Remedies*, 30 AIPLA Q.J. 267, 282-87 (2002).

[5] *See, e.g.*, Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("Phenomena of nature, though just discovered . . . are not patentable, as they are the basic tools of scientific and technological work.").

Within the overall research tool debate, one of the most visible and controversial topics has been the patenting of gene discoveries.[6] It is here that patent law has proven awkward. The patenting of gene discoveries has been an ongoing, unresolved flashpoint in patent law for more than twenty years.[7] These patents have fueled heated debate between legal commentators, scientists, and now even best-selling fiction authors.[8] Despite the protests, the Patent and Trademark Office ("PTO") continues to issue these patents and the courts continue to uphold their validity.[9]

Patent law initially appears plodding in part because only two mutually exclusive solutions seem viable: gene patents are fully patentable like traditional inventions, or they are not patentable at all. These stark extremes seem ill-suited to account for the complex nature of modern gene research. The meager number of solutions is, in part, doctrinally driven. Most of the debate has focused on what constitutes patentable subject matter. However, this inherently limits the debate as this gatekeeping requirement generally only admits two outcomes — the subject matter is patentable, or it is not.[10] But this is

[6] For this Article a gene discovery is defined as a purified and isolated naturally occurring gene sequence. *See, e.g.*, U.S. Patent No. 4,703,008 col.2 ll.1-3 (filed Nov. 30, 1984) (claiming "[a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin"). It does not include an intentionally modified gene sequence, or a method of using a gene sequence, or a method of finding a gene sequence. For more discussion of purifying and isolating a naturally occurring gene sequence, see *infra* Part I.A.

[7] *Compare* Arti K. Rai, *Regulating Science Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U.L. REV. 77, 104-109 (1999) (opposing patentability of gene discoveries), *with* F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science — A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691, 699-700 (2001) (arguing gene discoveries should be patentable).

[8] *See, e.g.*, MICHAEL CRICHTON, NEXT (2006); Michael Crichton, *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, at A2.

[9] *See* Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239, 239 (2005) (finding nearly 20% of human genome is now patented).

[10] I am not only concerned that currently patentable subject matter focuses on only two solutions to this important problem. I am also concerned that the terminology of the rule itself is too unstable and vague. The distinction defined by *Diamond v. Chakrabarty* between a "product of nature" and a "product of human ingenuity" has some common sense appeal. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980). But the exact policy rationales that support these distinctions are vague. *See* Eileen Kane, *Patent Ineligibility: Maintaining a Scientific Public Domain*, 80 ST. JOHN'S L. REV. 519, 545 (2006) ("Rationales for the exclusion of the laws of nature, natural phenomena and abstract ideas cannot be described with precision."). Furthermore, the meaning of these terms can shift all too easily. Already 50 years ago, Justice Frankfurter presciently warned that, "[i]t only confuses the issue . . . to

just as well, as the policy debate has also only provided these same two opposing choices.

The supporters of gene patents argue that full patent protection is necessary to provide the incentives to invent and commercialize gene discoveries.[11] As stated by John J. Doll, the Commissioner of Patents, "It is only with the patenting of DNA technology that some companies, particularly small ones, can raise sufficient venture capital to bring beneficial products to the marketplace or fund further research."[12] Often drawing on real property rhetoric, their position is clear: absent the legal incentives provided by patent law, these valuable genetic discoveries will not be created. This view assumes that because the patent system is effective at encouraging traditional inventions, it must also be effective at encouraging gene discoveries.[13] Thus far, courts have generally followed this view and, as a result, gene discoveries are fully patentable and are treated like traditional inventions.

In contrast, those that oppose patent claims covering gene discoveries favor a public, open mode of innovation.[14] They fear that gene patents "may paradoxically hinder, rather than accelerate, the

introduce such terms as 'the work of nature' and the 'law of nature.' For these terms are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed 'the work of nature.'" Funk Bros. Seed v. Kalo Inoculant Co., 333 U.S. 127, 134-35 (1947) (Frankfurter, J., concurring). The Federal Circuit more recently quoted this passage in *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1062 (Fed. Cir. 1992). Similarly, the other term, product of human ingenuity, is equally problematic. Every discovery can be characterized as a product of human ingenuity. This all-important boundary of patentable subject matter is uncomfortably vague. The 100% natural orange juice that I drank this morning certainly is advertised to be a healthy "product of nature," but at the same time, nature does not squeeze oranges into juice, people do. Freshly squeezed orange juice, from that perspective, is a product of human ingenuity. Along similar lines, it is difficult to categorize gene discoveries as they, like my morning juice, are arguably both products of nature and products of human ingenuity.

[11] See *supra* note 6 (defining gene discoveries); *infra* note 12.

[12] John J. Doll, *The Patenting of DNA*, 280 SCI. 689, 690 (1998) ("Without the incentive of patents, there would be less investment in DNA research, and scientists might not disclose their new DNA products to the public."); Kieff, *supra* note 7, at 698-99 ("[P]atents should be available for subject matter such as living organisms, gene fragments, computer software, and financial services . . . . Protection is necessary to permit recovery of commercialization costs in markets such as these precisely because they are characterized by a particularly large difference between average cost and marginal cost.").

[13] For this Article, a traditional invention refers to the core subject matter of patent law such as a new mouse trap or a new synthetic chemical.

[14] *See* Rai, *supra* note 7, at 136.

biomedical research enterprise."[15] Emphasizing the benefits of an unfettered public domain, they caution that the existing institutions of basic science will become tangled in an unproductive legal web of patent rights.[16] From this perspective, many recommended keeping gene discoveries outside the clutches of the patent system.[17]

Both as a policy and doctrinal matter, the debate need not be so polarized. Patent law is more adaptable than it may initially appear. It can craft a better tailored solution. This Article moves beyond the question of patentable subject matter and instead examines the critical issue of claim scope, a tool that allows nearly infinite control in fine-tuning the patent right.[18] This Article assumes that gene discoveries are patentable subject matter while carefully limiting how broadly these discoveries can be claimed.

Ultimately, this Article concludes that gene patent claims should be interpreted quite narrowly.[19] They should still protect the patentee

[15] Arti K. Rai & Rebecca Eisenberg, *The Public and the Private in Biopharmaceutical Research*, *in* BIOPHARMACEUTICAL RESEARCH 158-59 (2001), *available at* http://www.law.duke.edu/pd/papers/raieisen.pdf.

[16] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 701 (1998) (warning broad, overlapping exclusionary patent rights "may lead paradoxically to fewer useful products for improving human health").

[17] *See* James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 LAW & CONTEMP. PROBS. 33, 37 (2003) ("In stories about stem cell and gene sequence patents, critics have mused darkly about the way in which the state is handing over monopoly power to a few individuals and corporations, potentially introducing bottlenecks and coordination costs that slow down innovation.").

[18] Others in patent law have also suggested looking to claim scope as the proper question for gene discoveries. *See, e.g.*, Michael D. Davis, *The Patenting of Products of Nature*, 21 RUTGERS COMPUTER & TECH L.J. 293, 336 (1995) (arguing "[a]n optimal policy would be one that is generous in granting patents, . . .yet restrained in determining the scope of protection granted for those patents so as not to stifle others from developing competing products."); Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 838 (2001) (arguing "the importance of multiple research paths to biomedical research . . . counsel in favor of relatively narrow upstream rights"); Frederic M. Scherer, *The Economics of Human Gene Patents*, 77 ACAD. MED. 1348, 1348 (2002). Note that patentable subject matter and claim scope are related. If claim scope shrinks to zero, then the claim scope decision effectively becomes a limit on patentable subject matter. This concern has also been noted in copyright. *See* Jane C. Ginsburg, *Creation and Commercial Value: Copyright Protection of Works of Information*, 90 COLUM. L. REV. 1865, 1868 (1990) ("Settling the appropriate subject matter of copyright protection will not resolve all questions" and that important questions remain as to claim scope).

[19] This Article is specifically focused on composition of matter claims directed at naturally occurring gene sequences. *See* 35 U.S.C. § 101 (2000) (listing types of patentable subject matter). Only those claims are directly addressed by the analysis in

against outright copying, but the narrower claims allow for competition from independent second-arriving researchers. Narrower claims maintain a positive incentive to undertake the initial costs of gene discovery, while simultaneously allowing competition to reduce many of the social costs currently associated with broad gene patent claims.[20]

Doctrinally, this proposed interpretation does not require a large-scale overhaul of patent law. Nor does it require a sui generis exception for gene patents. Instead, this Article relies on patent law's own long-standing (but often overlooked) constitutional originality requirement. Although often subsumed within patent law's requirement of novelty,[21] originality itself is a constitutional requirement of patent law and, for gene discoveries, it has substantial impact.[22] Originality simply requires that the claimed subject matter be independently created and not copied.[23] In the present discussion,

this Article. In contrast, if a gene researcher takes a naturally occurring gene sequence and intentionally modifies it for some useful purpose, this modification would be more like a traditional invention and not a gene discovery — that new gene sequence would be original. Likewise, if a researcher obtains a gene sequence and then invents some use for that gene sequence, the analysis here will not directly interfere with attempts to broadly claim the method of using that gene sequence. In short, this proposal is rather modest. Much of the protection that is now housed in the broad claims to the gene sequence could be achieved by method of use claims or process claims. Of course, care must be exercised so that these method claims also do not become too broad. But note that all of these other claims may be vulnerable to a claim of nonobviousness. 35 U.S.C. § 103 (2000); 35 U.S.C. § 102 (2000). *See* OddzOn Prods. v. Just Toys, 122 F.3d 1396, 1403-04 (Fed. Cir. 1997) (holding prior art under § 102(f) can be used in obviousness analysis under § 103).

[20] *See infra* Part III.

[21] For a discussion of the difference between novelty and copyright's view of originality, see JOYCE ET AL., COPYRIGHT LAW 84 (7th ed. 2006).

[22] *See generally* Oskar Liivak, *The Forgotten Originality Requirement: A Constitutional Hurdle for Gene Patents*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 261 (2005) (establishing existence of originality requirement in patent law and arguing that broad gene patents are invalid because of it).

[23] Importantly, as used here, originality does not require some modicum of creativity as required currently in copyright after *Feist Publications v. Rural Telephone Service Co.*, 499 U.S. 340, 346 (1991). Most commentators agree that originality must mean independent creation, but many question the additional requirement of a modicum of creativity from *Feist*. Professor Paul Heald has stated that "[t]he Trade-Mark Cases do tell us that the Constitution requires originality as a prerequisite to copyright protection; however it does little to dispel the possibility that creations owing their existence to perspiration rather than inspiration might conceivably be defined as 'original.'" *See* Paul J. Heald, *The Vices of Originality*, 1991 SUP. CT. REV. 143, 149 (1991). In discussing copyright in maps, he states "it hardly seems conceivable that the Court [in *Feist*] would completely deny protection to a type of work mentioned specifically by Congress in 1790 as being one of the three objects of

originality plays an important role because gene discoveries are essentially copied from nature.

To understand originality and its impact on works copied from nature, patent law can turn to the experience of its sister field of copyright. Copyright has long held originality as one its central pillars and it has developed an extensive analytical framework for discussing originality. Most importantly, copyright acknowledges the low levels of originality in works that are copied from nature.

Copyright has developed a sliding scale of protection relating to originality.[24] Jane Ginsburg has characterized the distinction as one between works of high authorship, such as novels and plays and works of low authorship, such as maps, nautical charts, and factual compilations.[25] Copyright allows only narrow protection for low authorship works, while allowing broader scope for high authorship works.[26] In particular, maps and charts have been copyrightable since the very first copyright act in 1790,[27] but the scope of copyright in these maps has always been very thin.[28] A copyright in a map protects against outright piracy of the map, but little else.

In applying originality, patent law can learn from copyright's experience. Patent law must acknowledge that not all inventions are created equal. There are fundamental differences between works of low inventorship and works of high inventorship.[29] Gene discovery is

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the first copyright act." *Id.* at 163. Thus, for this Article, originality in patent law requires only independent creation and bars copying as this is the "lowest common denominator" of all definitions of originality. *See* Diane Leenheer Zimmerman, *It's an Original! (?): In Pursuit of Copyright's Elusive Essence*, 28 COLUM. J.L. & ARTS 187, 210 n.151 (2004). And, if for no other reason, patent law should be hesitant to adopt *Feist*'s full standard of originality and its search for a "minimal creative spark," *Feist*, 499 U.S. at 363, because such a standard dangerously harkens back to the problematic requirement of invention and its "flash of creative genius" test. Cuno Eng'g Corp. v. Automatic Devices Corp., 314 U.S. 84, 91 (1941).

[24] *See* JOYCE ET AL., *supra* note 21, at 121 ("[T]he scope of copyright protection . . . is a function of a work's originality.").

[25] Ginsburg, *supra* note 18, at 1870 ("We have now, as we have long had, two kinds of copyright: in high authorship works, such as novels and narrative histories, copyright protects the authorial presence within the work; in low authorship works, such as telephone directories and compilations of stock quotations, copyright protects the labor and resources invested in the work's creation.").

[26] *Id.*

[27] Act of May 31, 1790, ch. 15, § 1, 1 Stat. 124, 124.

[28] *See* Ginsburg, *supra* note 18, at 1870.

[29] Recently Professor Rochelle Dreyfuss discussed gene patents along similar lines, contrasting gene patents with traditional inventions because gene patents are "unique works." Rochelle Cooper Dreyfuss, *Unique Works/Unique Challenges at the Intellectual Property/Competition Law Interface*, *in* EUROPEAN COMPETITION LAW ANNUAL 2005: THE

a work of low inventorship and patent protection for gene discoveries, like its cartographic counterpart, should be relatively thin.[30] In fact, in the closely related area of plant patents, patent law already provides only narrow claim scope to inventions low in inventorship.[31]

As a policy matter, limiting claim scope according to originality makes good sense. By comparing the social costs of broad and narrow claims to gene discoveries, this Article establishes that granting broad claims to gene discoveries is unnecessarily more costly than granting narrow claims. Narrower claims still provide the legal protection necessary to induce the costly investment in gene discovery, but they do so with lower social costs. These policy considerations counsel for adopting narrower claims for gene discoveries.

The policy analysis, comparing both broad and narrow claims, proceeds by highlighting the benefits of competition within patent law. The patent system encourages competition between inventors by allowing "designing around" or "inventing around" existing patents.[32] This feature of the patent system encourages other inventors to create new, non-infringing inventions that compete with existing incumbent inventions. More generally, the patent system encourages competition by granting patents to specific inventions (i.e., one inventive solution among many to a given problem) rather than to the problem itself. By allowing for and encouraging competition between inventions, the patent system reduces many of the principal social costs associated with the patent system. In other words, care must be taken to limit

INTERACTION BETWEEN COMPETITION LAW AND INTELLECTUAL PROPERTY LAW 2 (Isabela Atanasiu & Claus Dieter Ehlermann eds., 2005), *available at* http://ssrn.com/abstract=763688.

[30] *See infra* Part I.A. Although this Article certainly looks to copyright for some general direction in applying originality, this Article cautions against adopting too much of copyright's admittedly complicated doctrine in this area. As described by Paul Heald, "[T]he body of [copyright] law concerning scope of copyright protection afforded works of 'low authorship' . . . is a morass of elusive and manipulable doctrine and counterdoctrine." Heald, *supra* note 23, at 151. Thus this Article relies upon copyright only for two generally uncontroversial concepts. First, originality is used as a limitation on claim scope. Highly original works are afforded a greater scope of protection than works of low originality. This Article argues that a similar sliding scale should be employed by patent law. Second, copyright's experience with maps shows that even where copying is central to the endeavor, something original, and therefore copyrightable, flows from the copying, namely the cartographer's map. Similarly, though a gene discoverer copies from nature, there will be something original that is created and therefore patentable — the researcher's specific version of the gene sequence.

[31] *See infra* Part I.D.

[32] *See infra* Part II.B.

the breadth of an inventor's patent claim in order to avoid blocking subsequent competition.[33]

Currently claims to gene discoveries are just as broad as claims to traditional inventions. Because of this, it is hard to imagine that claim scope in gene discoveries is too broad while it is reasonable for most traditional inventions. Yet, therein lies the problem; gene discoveries are not like traditional inventions and patent law cannot treat them as identical. Activities that inherently require copying, such as gene discovery, are highly constrained in a way that high inventorship activities are not. For example, when two people successfully map an island, they end up with nearly identical maps. This is a general result — activities low in originality create closely related, if not identical, solutions. All solutions are packed closely together; consequently, the solution space for gene discovery is small. There is precious little room within that solution space for both broad patent claims and subsequent competition.

In contrast to low inventorship activities, when two people independently set out to invent the next mouse trap or to pen the next great American novel, they will not necessarily end up with the same mousetrap design or the same novel.[34] The solution space for high inventorship activities is much larger. The broad claims used for traditional inventions still leave room for others because the landscape of traditional inventions is, as a general rule, more open.

As all solutions to low inventorship works are nearly identical, the broad claims currently used for gene discoveries necessarily block all competition, thus incurring higher social costs. A sliding scale of claim scope based on originality acknowledges the important differences between high and low inventorship works. For gene discoveries, patent claims must necessarily be narrower if gene patents are to allow for competition.

In this Article, these arguments are further expanded. Part I explores patent law's constitutional requirement of originality and

[33] *See infra* Part II.B.

[34] Surely, the maps will be different in some regards, but nonetheless they must share many similar characteristics. Contrast this with two people who independently create a method or device to catch mice. Those two might come up with the exact same solution and they often do. *See* Samson Vermont, *Independent Invention as a Defense to Patent Infringement*, 105 MICH. L. REV. 475, 478-79 (2006). But, importantly, they are not compelled to come up with the same solution. In the mapping example the similarity is caused not by coincidence, as in the mouse trap case, but rather the similarity is caused by the fundamental properties of the problem at hand. For maps and for gene discovery, we expect people to go copy the same object from nature, inevitably ending up with very similar solutions.

how it mandates limiting claim scope for gene discoveries. Part II explores the policy relationship between originality, claim scope, and competition in patent law. Respectively, these two sections show that the current broad patent claims afforded to gene discoveries are doctrinally invalid and imprudent as a policy matter. Then Part III initiates the discussion toward fixing this misstep. Rather than concluding that gene patents are per se invalid, this Article concludes that courts must interpret claims to gene discoveries narrowly. Guided by the originality requirement, this Article proposes a specific narrowing interpretation for claims to gene discoveries. Currently, courts interpret the typical gene patent claim to cover "all copies of the purified and isolated gene sequence that codes for protein X."[35] This is like granting the first surveyor of Long Island the exclusive rights in her map and the right to bar all subsequent maps of Long Island made by anyone else. Such a claim inherently blocks competition.

The suggested narrower claim interpretation covers only "*copies* of the patentee's version of the gene sequence that codes for protein X." This claim is in line with originality. It is analogous to copyright's treatment of maps whereby the first surveyor of an island receives only exclusive rights in her specific map. This narrower construction provides the patentee with protection against piracy while still allowing for competition from independent second-arriving researchers. The proposal grants gene patents a scope that is commensurate with, and analogous to, Justice Oliver Wendell Holmes's famous statement that "[o]thers are free to copy the original. They are not free to copy the copy."[36]

I. PATENT LAW'S REQUIREMENT OF ORIGINALITY

Gene discoveries are different from traditional inventions and they should not be treated in an identical manner. Doctrinally, the difference between the two is one of inventorship and originality. This Article argues that the broad claims currently granted to gene discoveries extend too far and cover subject matter that is not original to the gene discoverer.

In making this argument, this Article first establishes that, as a scientific matter, gene discoveries are created by copying from nature.

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[35] *Accord* U.S. Patent No. 4,703,008 col.2 ll.1-3 (filed Nov. 30, 1984) (claiming "[a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin").

[36] Bleistein v. Donaldson Lithographing Co., 188 U.S. 239, 249 (1903).

Then, in order to show that this is relevant for patent law, this Article shows that originality is a constitutional requirement that mandates narrow claim scope for inventions low in originality. Because current patent law doctrine has not explicitly applied originality in this broader context,[37] this Article turns to patent law's sister field of copyright for help. Based in part on the experience of copyright, this Article concludes that gene patent claims, like claims to maps in copyright, should reach no further than the particular version of the gene sequence made by the gene researcher.

Lastly, this part returns to patent law itself to explore an example where patent law already limits claim scope in the face of questions regarding originality and inventorship. This Article explores the 1930 Plant Patent Act, which explicitly allows patents on newly created varieties of plants, but importantly, grants these inventions only very narrow claim scope. In fact, as with maps, the scope of protection is limited to the particular version of the plant created by the plant discoverer. The Plant Patent Act provides an important example where patent law already has tuned claim scope in low inventorship works.

A. Gene Discoveries are Copied from Nature

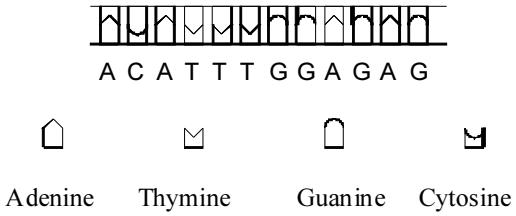
As explained in a standard cell biology textbook, because it is the blueprint for life, "[a] gene carries biological information in a form that must be precisely copied and transmitted from each cell to all of its progeny. The implications of the discovery of the DNA helix in 1952 were profound because the structure immediately suggested how information transfer [from generation to generation] could be accomplished."[38] Chemically, DNA exists as a long two-stranded

[37] In years past, patent law relied on a broadly applied natural products doctrine. This requirement barred patents claiming natural products and it was the typical way in which courts disposed of these types of cases. As a result, patent law never had to, nor had the opportunity to, acknowledge the always existing, but somewhat latent, aspect of originality. Today, the product of nature doctrine has been largely marginalized and does little to block any patenting. *See* Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 162 (4th Cir. 1958); *see also* Liivak, *supra* note 22, at 272. Because there are reasons to doubt the value and stability of the canonical distinction between products of human ingenuity and products of nature, *see* Diamond v. Chakrabarty, 447 U.S. 303, 309, 313 (1980), this Article does not advocate simply resurrecting the moribund products of nature doctrine. Rather a broader, and more comprehensive, interpretation of originality can and must play an important role. Originality can produce a nuanced result that allows some patenting in the gray areas by allowing only very thin protection.

[38] BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 99-102 (3d ed. 1994).

molecule that is twisted into the famous double helical conformation. Akin to rungs of a ladder, the two strands of the helix are spanned by pairs of four different chemicals, known as bases: adenine, cytosine, guanine, and thymine. As represented in Figure 1, each rung of the ladder is made up of two bases. Each base can only pair with one other base — its complementary pair.[39]

Figure 1. The molecular structure of DNA.[40]



The pairing is shown here by a characteristic bump, representing the differences in chemical structure of each base, that allows only its matching partner to fit, or chemically bond, with that base. Adenine pairs with thymine and guanine pairs with cytosine.[41] This matching fit between the respective bases "generates the complementary base-pairing" that is central to DNA's role as the keeper of genetic information.[42] It is the order of the base pairs along the strand of DNA that is the genetic code.[43]

[39] *Id.* at 98. Note that for simplicity of viewing, Figure 1 does not show the molecule in its double helix formation.

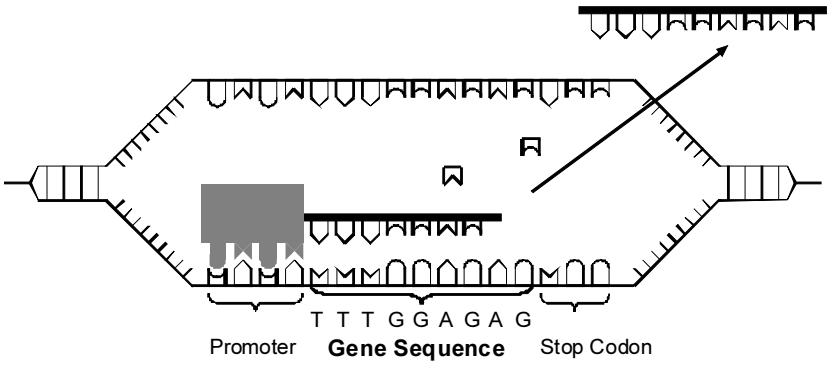
[40] Figures 1-3 are original creations of the author.

[41] ALBERTS ET AL., *supra* note 38, at 101.

[42] *Id.* at 101-02 ("As a direct consequence of the base-pairing mechanism, it becomes evident that DNA carries information by means of the linear sequence of its nucleotides. Each nucleotide . . . can be considered a letter in a four-letter alphabet that is used to write out biological messages in a linear 'ticker-tape' form.").

[43] *Id.*

Figure 2. From genes to mRNA: DNA acts as template for messenger RNA (mRNA).



The primary purpose of this ticker tape of biological information is to store and maintain the blueprints for constructing all the proteins in our bodies.[44] Generally, the blueprint for each protein is stored as a gene. Figure 2 shows a gene in a highly stylized form.[45] A gene is made of three parts: the promoter, the gene sequence itself, and stop codons. The promoter is a specific sequence in the genetic code that essentially announces that a blueprint for a protein follows. The ticker tape of nucleotides that is the actual gene sequence follows the promoter. At the end of the gene sequence is a stop codon. This is a specific genetic sequence that announces the end of the blueprint for the particular protein.

When a cell determines that it needs to construct a particular protein, the base pairs of the DNA section that houses the relevant gene are unzipped, as shown in Figure 2. An enzyme, RNA polymerase, attaches to the promoter sequence and uses the gene sequence as a template to construct a molecule known as messenger RNA ("mRNA"). The mRNA continues to grow until the stop codon is reached. This signals that the full gene has now been copied and the resulting copy of the gene (the mRNA) is released. Visually, it is as if the cell poured plaster or rubber over the characteristic bumps of the gene sequence to create the mRNA molecule; the mRNA is a perfect, reverse copy of the DNA sequence.[46] Once the RNA

[44] *Id.* at 104.

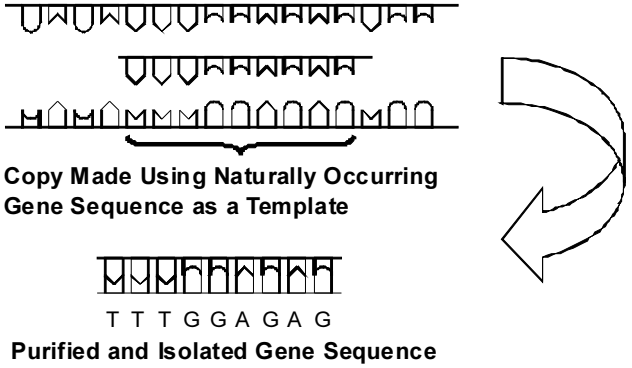
[45] *Id.* at 223-26.

[46] *See supra* Fig. 2.

polymerase has successfully constructed the mRNA, the original DNA strand is zipped back together for safe storage. As the name messenger RNA implies, the mRNA acts as a messenger. It is a copy of the DNA sequence of the protein. Once it is produced, it is transported to another location in the cell (the ribosome) where this copy is used in the actual construction of the desired protein.[47]

The technical language used is accurate and important. It describes the native DNA strand as the template for constructing the mRNA.[48]

Figure 3. Gene discovery.



Gene discoverers use exactly this technique of copying by using a naturally occurring template. There are generally two ways to produce these patented purified and isolated gene sequences. In the first method, a gene researcher takes the native DNA from a target organism and creates what is called a genomic library.[49] The researcher searches that library and finds the location of the desired

[47] The whole scheme is analogous to a master set of blueprints for various machine parts that are housed safely at the head office. When the machine shop needs to make a specific part, the head office finds the correct blueprint, makes a copy, and then sends that copied blueprint to the machine shop to guide the construction of the needed part.

[48] ALBERTS ET AL., *supra* note 38, at 101-02. Even modern dictionaries include the template notion of biochemical copying. THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1848 (3d ed. 1992) [hereinafter AMERICAN HERITAGE] (defining "template" as "[a] molecule of a nucleic acid, such as DNA, that serves as a pattern or mold for the synthesis of a macromolecule, as of RNA.").

[49] *See* ALBERTS ET AL., *supra* note 38, at 309-10.

gene sequence.[50] As shown in Figure 3, once the naturally occurring gene sequence is located, the gene discoverer uses the same copying techniques used by the organism to make a copy of that naturally occurring sequence.[51]

In a related method, researchers create what is known as a complementary DNA library. In this case, the researcher collects the expressed mRNA from an organism and then makes DNA copies of those molecules.[52] To find the gene of interest, the researcher then searches that library for the desired gene sequence.

In either case, a naturally occurring molecule is used as a template in making what will ultimately be the patented purified and isolated gene sequence. Again, the naturally occurring gene sequence is the template that determines the structure of the gene researcher's product. It is this resulting molecule — a copy of the naturally occurring DNA sequence — that is currently claimed by gene patents.[53] Again the technical language is instructive. This technique is described as DNA cloning, the central process of which is copying.[54]

Patent law has yet to contend with the fact that the resulting purified and isolated DNA molecules at the heart of these patents are the result of copying a naturally occurring molecule. The gene discoverer uses a naturally occurring DNA molecule as the template for making their patented purified and isolated gene sequence. The remainder of this Article explores the doctrinal and policy implications that flow from understanding gene discovery as copying

[50] *Id.* at 308-18.

[51] *See supra* pp. 188-91.

[52] *See* ALBERTS ET AL., *supra* note 38, at 309-10.

[53] Until now, the biggest obstacles for gene patents have been their novelty and their classification as patentable subject matter. As human DNA has existed well before the gene discoverer arrived, how can these molecules be novel? The answer, though unpersuasive to many, is that the actual molecule produced and claimed by the gene discoverer is new in a strict sense of the word. Gene sequences exist naturally as part of a much bigger molecule. There is no doubt that this much bigger molecule would be unpatentable. But gene discoverers argue that their purified and isolated gene sequences are distinct from the overall DNA molecule. As described by one of the leading cases in this area: "The invention claimed is not . . . the DNA sequence encoding [a protein] since that is a nonpatentable natural phenomenon 'free to all men and reserved exclusively to none.' Rather, the invention as claimed in claim 2 of the patent is the 'purified and isolated' DNA sequence encoding [the protein]." Amgen, Inc. v. Chugai Pharm. Co., No. 87-2617-Y, 1989 U.S. Dist. LEXIS 16110, at *88-89 (D. Mass. Dec. 11, 1989). Along similar lines, these discoveries have been classified as patentable subject matter because the specific molecules that they are claiming are arguably "products of human ingenuity" and therefore patentable.

[54] *See* ALBERTS ET AL., *supra* note 38, at 308; AMERICAN HERITAGE, *supra* note 48, at 359 (defining "cloning" as "making identical copies of a DNA sequence").

and cloning. Specifically, this Article applies patent law's own originality requirement to block broad patent claims directed at inventions copied from nature.

B. The Constitutional Originality Requirement in Patent Law

Originality is a concept that, though underutilized, is deeply rooted in patent law.[55] As early as 1804, the courts made it clear that "if it appears that the plaintiff was not the *original* inventor, . . . he is not entitled to a patent."[56] The Patent Act of 1836 required a patent applicant to make an oath that the applicant was in fact the "*original* and first" inventor.[57] In 1850, Justice Peter Daniel wrote that "[e]very law . . . has emphatically demanded *originality* and priority as indispensable prerequisites to patent privileges, and every aspirant to such privileges is expressly required to swear to these prerequisites, as well as to establish them."[58]

In 1879 the Supreme Court explicitly acknowledged the originality requirement's fundamental role by constitutionally limiting both patent and copyright law to original works in the *Trade-Mark Cases*.[59] At issue was the constitutionality of the Trademark Act. Prior to that case, lower courts had based Congress's authority to pass the Trademark Act on the Patent and Copyright Clause.[60] But after reviewing the language of the Clause, the Supreme Court held it could not authorize trademark legislation.[61] The Court held that both patents and copyrights required originality, but trademarks lacked originality.[62] The Supreme Court held that:

> Any attempt, however, to identify the essential characteristics of a trade-mark with inventions and discoveries in the arts and

[55] This description of the legal basis for originality in patent law is adapted from Liivak, *supra* note 22.

[56] Reutgen v. Kanowrs, 20 F. Cas. 555, 556 (C.C.D. Pa. 1804) (No. 11,710) (emphasis added); *see also* Dawson v. Follen, 7 F. Cas. 216, 216 (C.C.D. Pa. 1808) (No. 3670) ("[T]o entitle the plaintiff to recover, [the jury] must be satisfied that [the patentee] was the original inventor . . . .").

[57] Patent Act of 1836 § 6, ch. 357, 5 Stat. 117, 119 (1836) (current version at 35 U.S.C. § 115 (2000)) (emphasis added).

[58] Gayler v. Wilder, 51 U.S. (10 How.) 477, 509 (1850) (Daniel, J., dissenting) (emphasis added).

[59] *In re* Trade-Mark Cases, 100 U.S. 82, 93-94 (1879).

[60] *Id.* at 91-92.

[61] *Id.* at 99.

[62] *Id.* at 93-94.

> sciences, or with the writings of authors, will show that the effort is surrounded with insurmountable difficulties.
>
> The ordinary trade-mark has no necessary relation to invention or discovery. . . . [W]hen under the act of Congress it is sought to establish [trademark] by registration, neither originality, invention, discovery, science, nor art is in any way essential to the right conferred by that act. If we should endeavor to classify it under the head of writings of authors, the objections are equally strong. In this, *as in regard to inventions*, *originality is required*.[63]

Thus, the Court held that congressional authority under the Patent and Copyright Clause is limited to original acts.[64] Though the Supreme Court decided the *Trade-Mark Cases* more than 125 years ago, the Court has recently emphasized the decision's continued vitality. In the 1992 case of *Feist Publications v. Rural Telephone Services*, the Court held: "The originality requirement articulated in the *Trade-Mark Cases* . . . remains the touchstone . . . ."[65]

Although originality, especially after the *Trade-Mark Cases*, has been a central pillar of copyright law, it has been inexplicably unexplored in patent law. Only a few commentators have appreciated that the *Trade-Mark Cases* directly apply to patent law.[66] The current version of the long-lived treatise *Walker on Patents* states that "[in view of the *Trade-Mark Cases*] . . . it appears that Congress's authority under the intellectual property clause is limited to the protection of subject matter that is original to the grantee."[67] Similarly, in a recent scholarly discussion on the scope of the Patent and Copyright Clause, Thomas Nachbar explains that the *Trade-Mark Cases* require that both patented and copyrighted works "originate with the party claiming the right."[68] Other commentators have alluded to a constitutional

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

[64] *See* Edward C. Walterscheid, *Within the Limits of the Constitutional Grant: Constitutional Limitations on the Patent Power*, 9 J. INTELL. PROP. L. 291, 318 n.119 (2002) (stating that "[T]he present patent statute defining originality as an essential component of novelty for purposes of patentability would likely in an appropriate circumstance be judicially treated as constitutionally required.").

[65] Feist Publ'ns v. Rural Tel. Serv. Co., 499 U.S. 340, 347 (1991).

[66] *See* R. CARL MOY, MOY'S WALKER ON PATENTS § 1:15 (4th ed. 2003); Thomas B. Nachbar, *Intellectual Property and Constitutional Norms*, 104 COLUM. L. REV. 272, 281 (2004) ("As used in the Intellectual Property Clause, the words 'Writings' and 'Discoveries' both imply that the Article being protected be original . . . .").

[67] MOY, *supra* note 66, § 1:15.

[68] Nachbar, *supra* note 66, at 281.

connection between the language in *Feist* and gene patents in particular, but those commentaries have focused on the copyright side of *Feist*.[69]

As a constitutional limit, originality plays an important role in defining the scope of the patent system and patent law needs to reckon with its import.[70] For this Article, the originality requirement provides an important but specific role: as a constitutional requirement, originality mandates the proper statutory interpretation of the existing patent laws.[71]

The patent statute already has a cognizable locus for originality in the inventorship requirement. "The most common [modern] attribution of the originality requirement is to [35 U.S.C. §] 102(f),"[72] the novelty provision of the Patent Act, which states that "[a] person shall be entitled to a patent unless . . . he did not himself invent the subject matter sought to be patented . . . ."[73] The focus of the statute is on originality and inventorship. The patentee must be the inventor of the claimed invention.[74] Nothing in the statute distinguishes

[69] *See, e.g.*, Barton, *supra* note 2, at 805 (discussing originality in context of copyright law); Linda J. Demaine & Aaron Xavier Fellmuth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 374 (2002) (discussing originality in context of copyright law).

[70] For example, patent law must determine whether originality and the other limits of the Patent and Copyright Clause unilaterally constrain congressional action or whether Congress can simply turn to the Commerce Clause. This is an open and actively litigated question. Many believe that the limits in the Patent and Copyright Clause must limit Congress's power under the Commerce Clause because "to do otherwise would render the [Patent and Copyright] clause superfluous and its well-defined limits null." Nachbar, *supra* note 66, at 274. Commentators like Nachbar do not agree. *Id.*

There is also confusion in the courts. *See also* William Patry, *The Enumerated Powers Doctrine and Intellectual Property: An Imminent Constitutional Collision*, 67 GEO. WASH. L. REV. 359, 360-61 (1999); Malla Pollack, *Unconstitutional Incontestability? The Intersection of the Intellectual Property and Commerce Clauses of the Constitution: Beyond A Critique of* Shakespeare Co. v. Silstar Corp., 18 SEATTLE U. L. REV. 259, 270 (1995). *Compare* United States v. Moghadam, 175 F.3d 1269, 1278 (11th Cir. 1999) (holding Patent and Copyright Clause does not limit congressional action), *with* United States v. Martignon, 346 F. Supp. 2d 413, 419 (S.D.N.Y. 2004) (holding Patent and Copyright Clause imposed constraints on congressional action). *But see* United States v. Martignon, 492 F.3d 140, 153 (2d Cir. 2007) (vacating and remanding district court opinion).

[71] The current patent statute was explicitly enacted under the powers granted by the Patent and Copyright Clause. *See* S. REP. NO. 82-1979 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2396.

[72] MOY, *supra* note 66, § 8:2.

[73] 35 U.S.C. § 102(f) (2000).

[74] *Id.*

between copying from another person and copying from another source.[75] In short, the plain text of the statute requires broad applicability of the originality requirement. If the patentee did not invent the subject matter, then he cannot obtain a patent claim on that subject matter. The patentee can only claim as much as he invented himself.

Despite the plain language of the statute, some authorities have interpreted this provision too narrowly. They apply this provision only where a patentee has derived the subject matter of the patent from another person.[76] In the standard gene discovery context, there are generally no arguments that the patentee derived the invention from another person. Under such a narrow interpretation, § 102(f) seemingly has little relevance for gene discovery patents.

However, this view of originality and § 102(f) is too narrow because it ignores the plain meaning and the constitutional foundations of this provision. The patent laws, as with all statutes, must be interpreted where possible to avoid any doubts as to their constitutionality.[77]

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[75] *See* 1 DONALD CHISUM, CHISUM ON PATENTS, § 2.01 (2004) ("The requirement of originality bars issuance of a patent for a conception *derived from any source or person* other than the person or persons named as the inventorship entity in the patent application." (emphasis added)); MOY, *supra* note 66, § 8:2 ("The cases [evaluating § 102(f)] consider this provision to reserve patenting to the person who actually created the subject matter under consideration."); *see also* Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1381 (Fed. Cir. 2000).

[76] Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp. 2d 199, 241 (D. Del. 1999) ("'To invalidate a patent for derivation of invention [under § 102(f)], 'a party must demonstrate that the named inventor in the patent 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.'" (quoting New England Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 883 (Fed. Cir. 1992)) (emphasis added)); *see also* Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1576 (Fed. Cir. 1997) ("To show derivation [under 35 U.S.C. § 102(f)], the party asserting invalidity must prove both prior conception of the invention by another and communication of that conception to the patentee."); *Ex parte* Billottet, 192 U.S.P.Q. (BNA) 413, 415-16 (Bd. Patent. Appeals & Interferences 1976) ("Paragraph (f) [of 35 U.S.C. § 102] was . . . applicable in the situation where an applicant has derived an invention from another.").

[77] *See* Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs, 531 U.S. 159, 173 (2001) ("[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress."); 5 RONALD D. ROTUNDA & JOHN E. NOWAK, TREATISE ON CONSTITUTIONAL LAW § 23.10, at 248 (3d ed. 1999) ("As Justice Holmes once said: 'A statute must be construed, if fairly possible, so as to avoid not only the conclusion that it is unconstitutional but also grave doubts upon that score.' This doctrine, sometimes called the 'Constitutional Doubt,' is a canon of construction that is followed out of

Thus, in order to follow the plain language of the statue and to avoid any doubts as to its constitutionality, a court must interpret § 102(f) to bar not only copying from another person but also copying from any other source.[78] When viewed in this broader context, originality and § 102(f) have a dramatic impact on gene discovery patents.

C. Copyright: Limiting Claim Scope in Low Authorship Works

What exactly does it mean to have copied the subject matter from nature? If gene discoveries are copied from nature, are they completely unpatentable? This is a rather subtle question. In this context, patent law can learn from copyright law. Patent law can especially benefit from copyright's experience with maps. A cartographer, like a gene discoverer, uses the existing landscape as a template for her map. As with gene discovery, cartography is inherently a process of copying from nature.

Originality is one of the two central pillars of copyright law. Although copyright's requirement of originality has varied in strength over time,[79] it has always meant at the very least that copyright cannot extend to subject matter copied from another person or from another source. It has always barred copying and required independent creation.[80] Most importantly, originality in copyright limits the scope of the copyright for works that have been copied from nature. Copyright distinguishes between works of high authorship, like novels, and works of low authorship, like maps, nautical charts, and factual compilations.[81] The difference between the two is originality.

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respect for Congress, which the Court assumes legislates in light of the constitutional limitations." (quoting United States v. Jin Fuey Moy, 241 U.S. 394, 401 (1916))); *see also* Jones v. United States, 529 U.S. 848, 857 (2000); Almendarez-Torres v. United States, 523 U.S. 224, 237-38 (1998).

[78] Even if one were to argue that the narrower interpretation of § 102(f) must be maintained due to stare decisis, courts may revisit a long-standing statutory interpretation if a constitutional issue is at stake. *See* Erie R.R. Co. v. Tompkins, 304 U.S. 64, 77-78 (1938). As the Supreme Court stated in *Erie Railroad Co. v. Tompkins*: "If only a question of statutory construction were involved, we should not be prepared to abandon a doctrine so widely applied throughout nearly a century. But the unconstitutionality of the course pursued has now been made clear, and compels us to do so." *Id.*

[79] *See* Zimmerman, *supra* note 23, at 200-06.

[80] *Id.* at 200 n.151 (stating that independent creation and barring copying are "lowest common denominator" of all definitions of originality); *see also* Ginsburg, *supra* note 18, at 1874.

[81] *See* Ginsburg, *supra* note 18, at 1870.

Works of low authorship have copyright protection, but only very narrow protection.[82] Originality, as applied in copyright, can be best seen in cases dealing with maps from the nineteenth century.[83] During that time, originality in copyright was a very simple requirement: "No matter how banal the subject matter, if the author's work resulted from original efforts, rather than from copying preexisting sources, the author was entitled to a copyright."[84] In 1879, copyright scholar Eaton Drone stated the cleanest definition for this minimal originality requirement: "[T]he true test of originality is whether the production is the result of independent labor or of copying."[85] This was a very low threshold to overcome.

But, as Professor Jane Ginsburg emphasized, the relative ease with which originality could be satisfied

> [i]s somewhat misleading. It is correct in asserting the existence of early United States copyright protection for laboriously gathered factual material. Yet is incorrect to the extent that it may suggest substantial *scope* to the copyright coverage of fact-based works. . . .
>
> In fact, the scope of copyright was initially rather modest. The first author might forbid the second comer's copying from the first production, but he could not prohibit a second comer from creating a competing work — if the competitor acquired the same information from primary sources.[86]

Justice Joseph Story highlighted exactly such thin protection in the 1845 opinion in *Emerson v. Davies*. [87] Thus, the United States has

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[82] *See* Feist Publ'ns v. Rural Tel. Serv. Co., 499 U.S. 340, 348 (1991) ("[C]opyright protection may extend only to those components of a work that are original to the author.").

[83] *See* Zimmerman, *supra* note 23, at 202 (describing Justice Story's standard for originality from *Emerson v. Davies,* 8 F. Cas. 615, 619 (C.C.D. Mass. 1845) (No. 4436), as minimalist standard).

[84] Ginsburg, *supra* note 18, at 1874.

[85] EATON S. DRONE, A TREATISE OF THE LAW OF PROPERTY IN INTELLECTUAL PRODUCTIONS IN GREAT BRITAIN AND THE UNITED STATES 208 (1879).

[86] Ginsburg, *supra* note 18, at 1876.

[87] Emerson v. Davies, 8 F. Cas. 615, 619 (C.C.D. Mass. 1845) (No. 4436) ("A man has a right to the copyright of a map of a state or country, which he has surveyed or caused to be compiled from existing materials, at his own expense, or skill, or labor, or money. Another man may publish another map of the same state or country, by using the like means or materials, and the like skill, labor and expense. But then he has no right to publish a map taken substantially and designedly from the map of the other person, without any such exercise of skill, or labor, or expense.").

historically granted copyrights to low authorship works but it has kept that protection quite minimal.[88] This treatment makes sense. The protection extends only to the subject matter that was created by the cartographer. The copyright in a map protects the map itself and little more. The cartographer did not create the physical appearance of the mapped subject matter, but she did create her rendition of it.[89]

Patent law can learn from this scheme for gene discoveries.[90] Just like a cartographer, a gene discoverer copies his result from nature.[91] Based on the example of copyright in maps, gene discoveries can be patented. The gene discoverer can say that they created their particular version or copy of the gene sequence. But, like cartographers, gene discoverers can claim little original invention beyond that. The scope of patent claims in gene discoveries should be thin. To be consistent with the requirement of originality, patent claims should cover no more than the specific copy of the gene sequence created by the patentee. Adopting such a position would not be entirely new for patent law. In fact, plant patents have always had very limited scope since their inception in 1930.

D. Plant Patents: Limiting Claim Scope in Low Inventorship Works

Plant patents offer a useful example of patentable non-traditional subject matter with very thin claim scope. The patent system grants plant patents under the 1930 Plant Patent Act and the Plant Variety Protection Act.[92] The House Report that accompanied the 1930 Plant

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[88] Act of May 31, 1790 § 1, ch. 15, 1 Stat. 124, 124; *see also* David Wolf, *Is There Any Copyright Protection for Maps After* Feist*?*, 39 J. COPYRIGHT SOC'Y 224, 224 n.1 (1992).

[89] *See* Ginsburg, *supra* note 18, at 1876; Wolf, *supra* note 88, at 227.

[90] In many different instances, the human genome project has been called "mapping" the genome. This usage is not accidental. Mapping is one of the closest analogies to the process of sequencing the human genome. *See*, *e.g.*, Genome Mapping: A Guide to the Genetic Highway We Call the Human Genome, http://www.ncbi.nlm.nih.gov/About/primer/mapping.html (last visited Oct. 30, 2007) (making comparison between genome maps and physical maps for pedagogical reasons).

[91] It is common usage to describe the isolated naturally occurring gene sequences as being created by using "templates" isolated from the target genome. Even the patents that claim naturally occurring gene sequences suggest the claimed subject matter has been copied from nature. Many refer to the cloned or copied DNA sequence. In U.S. Patent No. 4,703,008 col.14 ll.30-31 (filed Nov. 30, 1984), the patentee describes "the isolation of clones containing EPO-encoding DNA." A*ccord id.* col.21 ll.24-26 (referring to gene sequence of interest as "clones.").

[92] Plant Variety Protection Act, 7 U.S.C. §§ 2321-2582 (2000); Plant Patent Act, 35 U.S.C. §§ 161-164 (2000).

Patent Act stated the bill's purpose was "to afford agriculture . . . the same opportunity to participate in the benefits of the patent system as has been given industry, and thus assist in placing agriculture on a basis of economic equality with industry."[93]

Although Congress clearly intended to extend a type of patent protection to plant breeders, it also tried to draw a rather sharp line that would limit the extent of the new protection. A plant as found in nature was not patentable. Instead, the Plant Patent Act required at least a minimal amount of cultivation of the plant; it required that the plant be "asexually reproduced prior to the application for patent."[94] Asexual reproduction is cloning, and cloning is copying.[95] Despite its current status as a term for futuristic biotechnology, in the case of plant patents, cloning is nothing more than the time-honored techniques of the plant breeder: cutting, grafting, and budding.

The Senate and House reports make clear that Congress believed it enacted the bill within the power granted under the Patent and Copyright Clause of the Constitution.[96] Nonetheless, perhaps sensing that they were nearing a constitutional limit, both reports go out of their way to answer what they perceived to be "[t]he only question" — "Is the new variety a discovery and is the originator or discoverer an inventor?"[97] In other words, the reports considered whether a patent granted under the Plant Patent Act would be constitutional recognizing that "doubt is only as to the one word, 'inventors.'"[98]

In searching for inventorship in plant breeding, Congress appreciated that they were nearing the limits of their authority. As the Commissioner of Patents later wrote: "From the language used in the reports it seems clear that serious doubts were entertained by the committees as to whether a patent could properly be granted merely on the basis of finding a new plant."[99] To support their broad definition of the term "inventor," the report explicitly compared the definition of inventor with that of its sister term "author" from copyright. The report noted that as to copyright, "authors" had been broadly construed to allow copyright in maps, and therefore Congress broadly construed "inventors" to allow patent protection to extend to

[93] H.R. REP. NO. 71-1129, at 2 (1930); *see also* S. REP. NO. 71-315, at 1 (1930) (noting Senate report has nearly identical language to House Report).

[94] H.R. REP. NO. 71-1129, at 6.

[95] *See* AMERICAN HERITAGE, *supra* note 48, at 359.

[96] H.R. REP. NO. 71-1129, at 7; S. REP. NO. 71-315, at 6.

[97] H.R. REP. NO. 71-1129, at 7; S. REP. NO. 71-315, at 6.

[98] H.R. REP. NO. 71-1129, at 10; S. REP. NO. 71-315, at 9.

[99] H.R. REP. NO. 83-1455, at 4 (1954); S REP. NO. 83-1937, at 4 (1954).

asexually reproduced plant breeds.[100] But just as with copyright, Congress did not grant these patents very broad scope: "[P]lant patents cover a single plant and its asexually reproduced progeny."[101] Thus, as suggested by the Supreme Court, plant patents "have very limited coverage."[102] Infringement of a plant patent occurs only upon a successful showing that the infringer physically copied the protected variety. In other words, the scope of plant patents is quite thin.[103] The patented plants are cloned from naturally occurring plants. Thus, although the patentee did create its specific cloned version, plant patent protection extends only to that specific cloned version of the plant.[104] This means that "independent creation" is inherently a defense in plant patent cases.[105] The scope of plant patents is consistent with the requirement of originality. This provides an example where Congress openly worried about inventorship and decided to grant patents, albeit limited in scope.[106]

II. THE SOCIAL COST OF BROAD GENE PATENTS

Establishing that broad claims in gene patents are doctrinally problematic is only half the puzzle. Just as importantly, the following establishes that treating traditional inventions and gene discoveries identically is bad policy. To understand the difference, this Article

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[100] S. REP. NO. 71-315, at 8-9 ("An indication of the construction that the courts are likely to place on the word 'inventor' in the constitutional provision can be found in their construction of the words 'author' and 'writings' in the same paragraph . . . . Under the [Patent and Copyright Clause] the original [copyright] act . . . allowed copyright of maps and charts as well as books . . . . It might well be doubted whether map makers, chart makers . . . were 'authors' . . . but the constitutionality of this legislation has been sustained from the beginning. . . . The word 'discovery' aptly describes the situation when a new and distinct variety of plant is found and 'inventors' is certainly as elastic a word as 'authors.'").

[101] 8-24 CHISUM, *supra* note 75, § 24-02; *see also* Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560, 1564-67 (Fed. Cir. 1995).

[102] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 133 (2001).

[103] *Id.*

[104] *See id.*

[105] Imazio Nursery Inc. v. Dania Greenhouses, 69 F.3d 1560, 1570 (Fed. Cir. 1995) ("The statute requires asexual reproduction of the patented plant for there to be infringement. It is necessarily a defense to plant patent infringement that the alleged infringing plant is not an asexual reproduction of the patented plant. Part of this proof could be, thus, that the defendant independently developed the allegedly infringing plant."); *see also* 8-24 CHISUM, *supra* note 75, § 24-02.

[106] Note that the Plant Variety Protection Act also grants only very narrow protection.

first looks to the social costs of the patent system as applied to traditional inventions.

This Article assumes that, as applied to traditional inventions, the current patent system operates relatively efficiently. This Article describes how patent law takes advantage of a number of competitive, efficiency-inducing features.[107] Specifically, patents block certain types of competition: blatant copying and piracy. In fact, they must block such activities in order to work. But patents do allow for other forms of competition. The patent system allows and encourages "designing around" or "inventing around" existing patents.[108] This can occur because a traditional patentable invention is generally but one solution among many to a particular technical problem.[109] A patent that claims one of those varied solutions blocks socially undesirable forms of competition (i.e., direct piracy). However, it still allows others to invent, patent, and ultimately compete in the marketplace with their own, different patentable solution. By blocking piracy, yet still allowing a limited form of competition, the patent system has crafted a property right that protects inventors while also allowing for the benefits of competition. This competition within patent law reduces a number of the social costs typically associated with the patent system: deadweight losses due to monopoly, the dynamic costs of improvers, and the costs due to rent seeking.[110] The economic benefit of these multiple competitors as opposed to a single patent holder is very closely related to the benefits of imperfect competition as seen in the theories of monopolistic competition and product differentiation (as compared to a single monopolist).[111] It is important to emphasize that the analysis below does not conclude that this competition makes the patent system cost-free. Rather, the

[107] The Supreme Court has made clear that "free competition" is "the baseline" for the patent system. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 156 (1989).

[108] Slimfold Mfg. Co. v. Kinkead Indus., 932 F.2d 1453, 1457 (Fed. Cir. 1991); *see also* Craig A. Nard, *A Theory of Claim Interpretation*, 14 HARV. J.L. & TECH. 1, 40-41 (2000) ("The practice of designing-around extant patents creates viable substitutes and advances, resulting in competition among patented technologies. The public clearly benefits from such activity.").

[109] *See infra* Part II.A.

[110] *See infra* note 128 and accompanying text.

[111] *See* DENNIS W. CARLTON & JEFFREY M. PERLOFF, MODERN INDUSTRIAL ORGANIZATION 281- 317 (2d ed. 1994); EDWARD HASTINGS CHAMBERLIN, THE THEORY OF MONOPOLISTIC COMPETITION 56-70 (8th ed. 1962); F.M. SCHERER & DAVID ROSS, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 15-29 (3d ed. 1990). For an application of these theories to copyright, see Christopher S. Yoo, *Copyright and Product Differentiation*, 79 N.Y.U. L. REV. 212, 277-303 (2005).

comparative analysis simply concludes that the social costs of a patent system with competition are lower than the social costs of a patent system without it.

Having looked at the benefits of competition in the patent system as applied to traditional inventions, this Article investigates the efficiency of the patent system as applied to broad claims covering gene discoveries.[112] When applied in this area, this Article concludes that there are critical problems. In this arena, because of the broad claims, the efficiency-inducing features are missing. Gene discoveries are different from traditional inventions. Rather than being one of many solutions, a gene discovery is, by the very nature of the problem, very nearly the one and only solution.[113] As there is only one way to accurately draw a particular map, there is very nearly only one sequence for a particular gene. Because of this property, a broad patent claim to a gene sequence becomes not just a barrier to direct piracy, but a complete barrier to nearly all competition. In these cases, there will not be any competition because a broad claim leaves no room for non-infringing solutions to the problem. Therefore, the cost-reducing features available for traditional inventions are not present. Without competitive entry, patents broadly claiming gene discoveries are socially more costly than patents claiming traditional subject matter. They have higher monopoly dead-weight loss costs, higher dynamic costs, and higher rent seeking costs. This calls into question the current treatment whereby patent law treats gene discoveries as it does traditional inventions. In fact, this establishes that broad claims to gene discoveries represent a demonstrably worse bargain for society than patents on traditional inventions.

A. Originality, Copying, and the Variety of Solutions

To appreciate the differences between traditional inventions and gene discoveries, consider that traditional inventions are solutions to technical problems. Their utility and value resides in the fact that they solve some technical problem. We want to know "how to" do something and the inventor supplies that solution: the "know how." Generally, there are many solutions to technical problems; after all, recalling an adage of questionable origins, there are many ways to skin a cat. For example, to solve the problem of a headache there are a number of competing compounds: aspirin, acetaminophen,

[112] *See infra* Part II.C.

[113] *See supra* Part I.A.

ibuprofen, codeine, etc.[114] Each solution will achieve the general result, but we have the luxury of deciding which particular solution best suits our needs.

In contrast, gene discoveries are different. They generally do not give us know how in the same sense. Instead they answer "what is" something or, as described in the philosophy literature, gene discoveries give us "know that" as opposed to "know how."[115] When we ask the question, "What is the human gene sequence that codes for some specific protein?" we don't expect there to be multiple answers. This is quite different from a traditional invention and its typical "know how" problem. Gene discovery is more akin to cartography than solving traditional technical problems. As opposed to multiple

[114] Consider other examples where there are a large number of competing compounds. For the treatment of high blood pressure, there are many different types of medicines that can be administered, including the broad categories of ACE inhibitors, angiotensin II receptor blockers, beta blockers, and calcium channel blockers. *See* High Blood Pressure Treatment, http://www.medicinenet.com/script/main/art.asp?articlekey=16095 (search for "High Blood Pressure Treatment") (last visited Oct. 30, 2007). ACE inhibitors block the actions of the angiotensin-converting enzyme; they include the drugs captopril (Capoten), benazepril (Lotensin), enalapril (Vasotec), lisinopril (Prinivil, Zestril), fosinopril (Monopril), ramipril (Altace), perindopril (Aceon), quinapril (Accupril), moexipril (Univasc), and trandolapril (Mavik). *See id.* Angiotensin receptor blockers block the action of angiotensin II; they include candesartan (ATACAND), eprosartan (TEVETAN), irbesartan (AVAPRO), telmisartan (MYCARDIS), valsartan (DIOVAN), and losartan (COZAAR). *See id.* Beta blockers block beta-adrenergic substances and thus relieve stress on the heart. *See id.* They include acebutolol (Sectral), atenolol (Tenormin), bisoprolol (Zebeta), metoprolol (Lopressor, Lopressor LA, Toprol XL), nadolol (Corgard) and timolol (Blocadren). *See id.* Calcium channel blockers block calcium uptake and thereby dilate the arteries. *See id.* They include nisoldipine (Sular), nifedipine (Adalat, Procardia), nicardipine (Cardene), bepridil (Vascor), isradipine (Dynacirc), nimodipine (Nimotop), felodipine (Plendil), amlodipine (Norvasc), diltiazem (Cardizem), and verapamil (Calan, Isoptin). *See id.*

For another example, consider cholesterol-lowering drugs known as statins. These include lovastatin (Mevacor), simvastatin (Zocor), pravastatin (Pravachol), atorvastatin (Lipitor), fluvastatin (Lescol), and rosuvastatin (Crestor). *See* Omudhome Ogbru, *Statins*, MEDICINENET.COM, Jan. 21, 2007, http://www.medicinenet.com/statins/article.htm. These are but two examples where a particular technical problem has a large number of different competing solutions.

[115] This distinction is often attributed to philosopher Gilbert Ryle. *See* GILBERT RYLE, THE CONCEPT OF MIND 32 (1969). Modern commentary in philosophy has begun to question the clarity of the dichotomy between "knowing how" and "knowing that." *See* Paul Snowdon, *Knowing How and Knowing That: A Distinction Reconsidered*, 104 PROC. ARISTOTELIAN SOC'Y 1, 1 (2003). As used in this Article, the know how and know that distinction is only used as a way to orient the discussion rather than to delineate a clear boundary. The delineation is instead drawn by the originality requirement and its focus on copying.

headache remedies, we don't expect there to be multiple, differing maps of some region.[116] Instead, we expect that there is a single answer and that there should not be factual discrepancies between maps. We expect all accurate cartographers to create essentially identical maps.

Because of this difference, encouraging solutions to traditional inventions is quite different from encouraging solutions to descriptive scientific results like gene discoveries. The relevant difference is in the multiplicity or variety of solutions available. For traditional inventions, there are generally a variety of differing solutions while, for descriptive scientific results, there is, roughly speaking, only one solution.[117] As this Article will explore below, this difference is central to the social costs of encouraging solutions in these two areas. But first, this difference needs to be explored a bit more. Why are there multiple chemical compounds that alleviate headaches while there is only one compound that is the purified and isolated gene sequence for some specific protein?

In trying to answer this question, this Article returns to the requirement of originality. Originality is relevant in this present policy discussion because it helps define where we might expect multiple solutions to a problem and where we might expect very few solutions to a given problem. The availability of multiple solutions is related to the amount and nature of copying that is involved in producing an item. In cases where a problem is inherently solved by substantial copying, solutions to that problem will be closely related. If copying plays no part in solving some problem, then we could expect a far greater variety of solutions.

For more than a century, copyright has recognized that, with regard to mapping, "there are certain common objects of information that must, if described correctly, be described in the same words."[118] Thus, "a cartographer who dealt with the same subject matter as his predecessor should create a map identical to his predecessor's, assuming he had done an equally good job."[119] Thus, two competing maps may have differences in the way in which the information is portrayed, but certainly, if they are both competent surveyors, the two maps should be identical (or at least not contradictory) as to their

[116] More precisely, you expect that maps made by different people will not contradict each other.

[117] *See* Heald, *supra* note 23, at 150 ("The closer a map depicts a precise physical reality, the better it is.").

[118] Kelly v. Morris, (1866) 1 L.R.Eq. 697, 701 (U.K.).

[119] Wolf, *supra* note 88, at 227.

information content.[120] Judge Learned Hand described that "if each [map] be faithful, identity is inevitable, because each seeks only to set down the same facts in precisely the same relations to each other. So far as each is successful, each will be exactly the same."[121] In short, though there can be some variability in their end products, surveyors are constrained to produce very similar products.[122]

A very similar analysis applies when contrasting gene discoveries and traditional inventions. The discovery of a naturally occurring gene sequence is produced by copying.[123] The value of the work resides in making faithful copies of something from nature.[124] Because of this, gene discoveries are highly constrained. As with a map, each researcher that sequences the same gene will end up with sequences that are very similar to each other.[125] In contrast, a traditional invention is not generally made or defined by copying. Traditional inventors can potentially create a far larger set of solutions.

Having established this difference between traditional inventions and gene discoveries, this Article turns to explain why this difference has a large impact on the social costs of encouraging these two types of research via a patent system. Relatively broad claims generally pose little problem for traditional inventions because there are multiple, varied solutions that allow for competition. In contrast, for low

[120] A user-friendly map that is inaccurate is relatively useless, while an accurate yet user-unfriendly map still has substantial value. *See* Ginsburg, *supra* note 18, at 1869 (noting arrangement of information "may bear little, if any, connection to the work's central importance as a source of information"). In recent years there has been a new focus on gene discoveries as sources of information. *See, e.g.*, Eileen H. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 745 (2004).

[121] *See* Fred Fisher, Inc. v. Dillingham, 298 F. 145, 151 (S.D.N.Y. 1924).

[122] John S. Wiley, *Copyright at the School of Patent*, 58 U. CHI. L. REV. 119, 135 (1991) ("Since its inception, American copyright law has protected works whose quality largely depends on the *absence* of variation between subject and rendition. For instance, the Copyright Act of 1790 protected maps and charts. The last thing navigators want is variation . . . .").

[123] *See supra* Part I.A.

[124] Where a researcher makes other scientific findings that are valuable, like finding that a specific gene sequence can be used in treating some disease, then the researcher can patent that method of using the gene sequence — that is, a solution to a know how problem.

[125] Note, for example, the language used in the controversial patent dealing with the gene BRCA1 that has been correlated to breast cancer. In U.S. Patent No. 5,747,282 col. 19 ll.44-47 (filed Nov. 19, 1998), the patentee described that "[t]he nucleic acids of the present invention will possess a sequence which is either derived from or substantially similar to a natural BRCAl-encoding gene or one having substantial homology with a natural BRCA1 encoding gene or a portion thereof."

inventorship activities like gene discoveries, broad claims leave no room for competition and the patent system incurs greater social costs.

B. Traditional Inventions: Benefiting from Competitive Efficiencies

The patent system exists to solve the problem of piracy that plagues many types of inventions.[126] In a regime of completely free competition, inventors will likely not invest resources to develop new inventions because copyists could easily pirate the invention. As the copyists only need to recoup the presumably low reproduction costs, they could undercut the original inventor. This rationale justifies the granting of exclusive rights to the extent necessary to protect inventors from the fear of pirates.[127]

But as patent law tries to solve this problem, it introduces other social costs. The three most noted of these secondary costs are generally referred to as the "monopoly dead weight loss costs," "dynamic innovation costs," and "rent seeking costs."[128] These costs are often the focus of arguments against the patent system.[129] First is the dead weight loss, which is most often associated with patents as monopolies.[130] By definition, patents allow the patentee to price above marginal cost.[131] Only by pricing above marginal cost can the patentee hope to recover the fixed costs of research and development. However, as a consequence of pricing above marginal cost, some argue that there is a social cost, because there exist consumers who would buy the product at or near marginal cost, but not at the higher price. This unsatisfied consumer demand is the dead weight loss caused by

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[126] Mark A. Lemley, *Ex Ante versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 129-30 (2004).

[127] Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1031 (2005) ("[F]ree competition is the norm. Intellectual property rights are an exception to that norm, and they are granted only when — and only to the extent that — they are necessary to encourage invention.").

[128] *See* Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 249 (1994); *see also* Lemley, *supra* note 127, at 1058-59. Lemley's accounting gives a more detailed list. He includes administrative costs which, though important, are not directly discussed here. *See infra* Part III.C.

[129] *See* Dam, *supra* note 128, at 249.

[130] *Id.* at 247-48.

[131] Marginal cost is the incremental cost required to produce each additional new unit. *See* CARLTON & PERLOFF, *supra* note 111, at 51. For most patented items, the marginal cost is generally assumed to be low. For example, compared to the huge research and development costs and FDA approval costs, the marginal cost of making one more pill of ibuprofen is generally assumed to be nearly negligible.

the exclusionary rights of the patent.[132] Second is the social cost associated with inhibiting future developments. As all invention is based in part on previous inventions, the grant of exclusive patent rights may retard the creation of new improvements.[133] Third is the social cost of wasteful racing to invent. In trying to win the patent race, inventors "dissipate any social surplus associated with an invention."[134]

These are the costs of the patent system.[135] The patent system, however, attempts to reduce these costs. A prime feature that allows the reduction of these costs is the competition between inventors. An example of this competition can be seen when others invent around or design around an existing patent's claims.[136] Although patent law curbs blatant piracy and, therefore, blocks a particular form of competition, it encourages other beneficial forms of competition.

Designing around and inventing around have been recognized as important competition-inducing features by the courts. The Supreme Court has noted the difference between "the intentional copyist making minor changes to lower the risk of legal action" with "the incremental innovator designing around the claims, yet seeking to capture as much as is permissible of the patented advance."[137] Further, the Federal Circuit has emphasized the importance of designing around.[138] Moreover, the Federal Circuit has emphasized

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[132] *See* Lemley, *supra* note 127, at 1059 ("[S]ome consumers who are not willing to pay more than it costs to make a copy of a work will be denied access to that work.").

[133] *See* Cincinnati Car Co. v. N.Y. Rapid Transit Corp., 66 F.2d 592, 593 (2d Cir. 1933) ("It is of course possible to imagine an invention for a machine, or composition, or process, which is a complete innovation, emerging, full grown, like Athene, from its parent's head . . . . Such inventions are however mythological. All have a background in the past, and are additions to the existing stock of knowledge which infringing Articles embody along with the invention."); Lemley, *supra* note 127, at 1060 ("Inventions are not created in a vacuum. They build on existing technology and ideas."). Lemley has referred to this as the "dynamic cost." *See id.*

[134] John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 440 (2005); *see also* Yoram Barzel, *Optimal Timing of Innovations*, 50 REV. ECON. & STAT. 348, 348 (1968); Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 306 (1992).

[135] For now, this Article ignores administrative costs. *See infra* Part III.C.

[136] State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1235-36 (Fed. Cir. 1985); *see also* Nuno Pires de Carvalho, *The Problem of Gene Patents*, 3 WASH. U. GLOBAL STUD. L. REV. 701, 733 (2004).

[137] Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 36 (1997); *see also* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1161 n.27 (2002).

[138] Slimfold Mfg. Co. v. Kinkead Indus., 932 F.2d 1453, 1457 (Fed. Cir. 1991) ("Designing around patents is, in fact, one of the ways in which the patent system

that designing around promotes technological progress by encouraging beneficial competition.[139] As stated by a former U.S. Assistant Commissioner for Patents, the granting of a patent "stimulate[s] others to invent around it, to improve upon it, to find a different way to do the same thing, and it spurs competition rather than restricts competition."[140] In short, a patent is a barrier to direct entry, but not a barrier to competition.

Recently, there has been a renewed interest in the compatibility of competition and patent law.[141] There is renewed confidence that limited competition leads to efficient design of the patent system.[142]

works to the advantage of the public in promoting progress in the useful arts, its constitutional purpose. Inherent in our claim-based patent system is also the principle that the protected invention is what the claims say it is, and thus that infringement can be avoided by avoiding the language of the claims.").

[139] *State Indus., Inc,* 751 F.2d at 1235-36 ("Conduct such as . . . keeping track of a competitor's products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made and is supposed to benefit the consumer. One of the benefits of a patent system is its so called 'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace.").

[140] *Patents and the Constitution: Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 100th Cong. 27 (1987) (testimony of Rene D. Tegtmeyer, Assistant Comm'r for Patents); *see also* Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT'L L. 1, 8 (2001). For claims that approach the boundary between basic scientific knowledge and invention, the Supreme Court has limited claim scope. Where a patentee claims broadly in this region, the doctrine of preemption ensures that designing around is still possible. This was recently highlighted in the amicus brief submitted in the Supreme Court case *Laboratory Corp. of America Holdings v. Metabolite Laboratories*, 126 S. Ct. 2921 (2006). The Solicitor General, quoting the Supreme Court in *Gottschalk v. Benson*, 409 U.S. 63 (1972), argued that it "[i]s also well established, however, that a patent applicant cannot validly patent a process that comprises every 'substantial practical application' of a law of nature, because such a patent 'would wholly preempt the [law of nature] and in practical effect would be a patent on the [law of nature] itself." Brief for the United States as Amicus Curiae Supporting Respondents at 20, *Laboratory Corp. of America Holdings,* 126 S. Ct. 2921 (2006) (No. 04-607) (quoting *Gottschalk*, 409 U.S. at 72). In other words, claims always leave enough behind so that in theory a competitor can search for a way to design around.

[141] *See* FEDERAL TRADE COMM., TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 1 (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf; Jessica Litman, *Breakfast with Batman: The Public Interest in the Advertising Age*, 108 YALE L.J. 1717, 1729 (1999) ("If competition is still the American way of doing business, then before we give out exclusive control of some coin of competition, we need, or should need, a justification.").

[142] *See* Yoo, *supra* note 111, at 224-25 ("The differentiated products approach, in contrast, makes far more modest demands of the government. It requires only that

This Article embraces that view.[143] This Article now turns to each of the three principal social costs and describes how the patent system as applied to traditional inventions minimizes each of these costs.[144]

1. Dead Weight Loss

The first social cost is the monopoly dead weight loss. There is a long controversial history of referring to patents as monopolies.[145] As the exclusive rights of a patent have been assumed to grant monopoly power on the inventor, patents have been assumed to incur social dead weight loss.[146] A modern view has started to uncouple this reflexive tendency to think of a patent as a monopoly.[147] Despite this more sophisticated view, many still are concerned that the patent system allows pricing above marginal cost.[148] Though it is certainly true that

the government facilitate entry, depending instead upon market forces to bring revenues into balance with fixed costs."); *see also* Lemley, *supra* note 126, at 149 ("[I]f we rely on the decisionmaking of one company rather than the aggregate decisions of the market as a whole — we give up the very discipline that guarantees us the decisions it makes will be the right ones.").

[143] This Article remains a positive analysis of patent law, specifically a positive analysis of the social cost reduction that is enabled by allowing competition from designing around. The picture that emerges from the positive analysis seems tailor-made for a "new" normative vision of the patent system. The analysis immediately suggests that patent law should use the economic theories of monopolistic competition and product differentiation as normative models for measuring the efficiency of the patent system. The description of the theory of patent law based on these concepts from industrial organization is underway. For a related analysis in copyright, see Yoo, *supra* note 111, at 277-303.

[144] *See* Dam, *supra* note 128, at 248 (discussing how patent system minimizes costs).

[145] *See id.* at 249 (arguing that "it became conventional to say that a patent is a monopoly" from 1930s to 1970s).

[146] *See* Arnold Plant, *The Economic Theory Concerning Patents for Inventions*, 1 ECONOMICA 30, 31-32 (1934).

[147] *See* 1 HERBERT HOVENKAMP ET. AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 1.3 (Aspen 2003) ("[I]ntellectual property rights do not ipso facto confer monopoly power. While they do permit product differentiation, and sometimes give the owner power over price, there is a vast difference between an exclusive right and the sort of economic monopoly that is the concern of antitrust law."); *see also* Dam, *supra* note 128, at 251 ("[T]he R & D that led to the invention might never have occurred in the absence of the incentive of patentability.").

[148] *See* John F. Duffy, *The Marginal Cost Controversy in Intellectual Property*, 71 U. CHI. L. REV. 37, 38-39 (2004) (criticizing proposals to enforce marginal cost pricing in realm of patents); *see also* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 379-80 (2003) ("To argue that economic welfare would be even higher if all firms had access to the innovation at zero cost

patents enable an inventor to price the invention above marginal cost, this alone does not mean that the patent system has failed. By definition, patents must allow inventors to price above marginal cost. Otherwise, they could not possibly recoup their fixed research and development costs.[149] After all, absent the ability to price above marginal cost, the patented item may not have been invented in the first place.[150] In most cases, we need not be alarmed that price is being set above the marginal cost.[151]

Nevertheless, having considered the marginal cost problem does not mean that patents could not incur some static dead weight losses. A patent holder who has fixed research and development costs must price the invention at or above the average cost in order to break even.[152] Absent any competition, the patent holder would be unfettered and could price above the average cost, likely at the monopoly price. In such a situation, the price set by the patentee is higher than needed to encourage the inventor to initially undertake the research (i.e., higher-than-average cost). In this case, there will be unsatisfied consumers who would have purchased at the average cost but not at the monopoly price. It is hard to argue that there is no dead weight loss in this example.

The patent system minimizes the potential for dead weight loss by competition between solutions. The patent system encourages

ignores the fact that the innovation might not be developed if the innovator did not receive a property right in the innovation.").

[149] *See* Lemley, *supra* note 127, at 1059-60; *see also* Lemley, *supra* note 126, at 136 n.25 ("[I]ntellectual property rights must confer some power to raise prices above the marginal cost of production if they are to serve their acknowledged primary purpose of encouraging creation.").

[150] *See* Dam, *supra* note 128, at 251. This highlights that generally patent law should only extend to subject matter that requires the protection of the patent laws.

[151] There are cases where such pricing leads to compelling cases of inequity, but this need not necessarily implicate a failing of the patent system. Consider the supply of vital healthcare like AIDS drugs for people that cannot afford them. *See* Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY. TECH. L.J. 1031, 1032-35 (2005). In solving such a crisis, we need not choose between disrupting the above-marginal-cost pricing of the patent system and the plight of the afflicted. These compelling cases can be solved by turning to a government's powers like its police powers or takings. In many countries, the AIDS crisis is at such epidemic levels that it could easily be declared a disaster on par with other natural disasters. We allow government intrusions into private property to aid those afflicted in the context of natural disasters. Examples in the intellectual property realm should be no different.

[152] Average costs include the marginal costs of making each copy and initial fixed costs. *See* CARLTON & PERLOFF, *supra* note 111, at 52.

competition among these solutions.[153] In so doing the patent system reduces the dead weight losses incurred from pricing above average cost.[154] Potential or actual competition helps to drive the price down to average cost. If the patentee is the first to arrive in some new technological market, then he can start pricing the invention at the monopoly price. In part, these early abnormal profits are the first-mover advantage.[155] This high return attracts competitive entrants.[156] The entrants, after completing their own research and development, will have their own fixed costs and can enter the market by pricing their product at or above their average cost. In the long term, with such competitive entry, competition drives all patentees to pricing at or near average cost.[157] By keeping the long-term equilibrium price near average cost, this competitive mechanism reduces the overall dead weight loss.[158] If prices were lower, patentees could not recoup their fixed costs.[159]

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[153] *See supra* notes 136-42 and accompanying text.

[154] *See* CARLTON & PERLOFF, *supra* note 111, at 292.

[155] *Id.* at 113.

[156] However, in some instances, even the lure of abnormal profits will not produce a viable non-infringing direct competitor. See the debate over the competition or lack of competition facing xerography in Edmund W. Kitch, *Patents: Monopolies or Property Rights?*, 8 RES. L. & ECON. 31, 41-47 (1986), and F. M. Scherer, *Comment on Edmund Kitch*, 8 RES. L. & ECON. 51, 51-57 (1986). This may mean that the initial patent claims were too broad or it might mean that inventor Chester Carlson's work was so innovative that Xerox acquired such a strong first-mover advantage that it managed to stay ahead of the competition. Distinguishing betweens these two possibilities is not trivial.

[157] *See* CARLTON & PERLOFF, *supra* note 111, at 291.

[158] *See* Stephen M. Maurer & Suzanne Scotchmer, *The Independent-Invention Defense in Intellectual Property*, 69 ECONOMICA 535, 545 (2002); *see also* SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 109 (2004).

[159] This outcome assumes that competitors will have similar fixed costs as the initial inventor. Importantly, competitors cannot substantially free-ride on the work of the initial inventor. If they do, the second-arriving competitors will have substantially lower costs and will out-price the initial inventor. This is the exact scenario that the patent system is designed to avoid. Thus, there is a difficult administrative challenge for patent law. Patent law would like to allow "honest" competition where second-arriving competitors design around without free-riding too much from the initial inventor. At the same time patent law must stop slavish imitators that are intent on directly copying and free-riding. Distinguishing between these two scenarios is not trivial. Some view the patent system as not only rewarding the patentee for the fixed costs associated with a particular successful invention, but it also rewards the patentee for all of the failed inventions also. In other words, some argue that patent law must grant high profits because so much research and development ends in failure. This has been likened to oil drilling and the costs and risks associated with "dry holes." *See* SCOTCHMER, *supra* note 158, at 116; *see also* F.M.

By driving price toward average cost, competition reduces the invention's profitability. But, somewhat counterintuitively, the competition does not necessarily change a rational inventor's decision to initially invest in creating the invention. By keeping price above average cost, design around competition reduces profit but it keeps profit non-negative if the design around competitors have similar fixed costs as the initial inventor.[160] Thus, inventors and their investors will invest in the same projects whether there is competition or there is no competition.[161]

However, there are instances where this will not occur. If an initial inventor adopts a particularly costly route to some invention, then they will have large fixed costs. It is quite plausible for a second-arriving inventor, without free-riding on the first inventor's work, to create a competing invention by a less expensive route. In such a case, design around competition may lead to negative profits (losses) for the first inventor because the second inventor has a lower average cost. This is not a failing of the system; it is a reasonable result. The market rewards the lowest-cost route that satisfies consumer demand. Inventors must carefully choose the most cost-effective route to their invention.

Scherer, *The Innovation Lottery*, *in* DREYFUSS ET AL., EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY 3 (2001). But despite this, the comparative analysis used here still holds. If second-arriving competitors also have to drill their dry holes, then they will likely also have similarly high fixed costs and they cannot unduly undercut the initial competitor. It is here that patent law must make non-trivial decisions. It must decide which costs will be protected and what costs will be unprotected and therefore free for the taking. For example, imagine that aspirin was discovered after the testing of 99 failed compounds. It is likely that the discoverer of acetaminophen (Tylenol) also needed to search through his own dry holes before striking oil. In this example patent protection for the compound aspirin would force the second researcher to also navigate the risks of dry holes. Thus, there is little worry that only the initial researcher must face the dry holes. But note that this does not mean that the second-arriving researcher cannot glean some information from the first. The first researcher established that indeed there is a strong market demand for headache relieving compounds. Already knowing that the market demand exists reduces the risks and therefore costs of the second researcher but it is unlikely that patents should be broad enough to prevent that type of free-riding. Where patent law should draw the line is not trivial in many cases.

[160] *See* CARLTON & PERLOFF, *supra* note 111, at 291 n.6 (discussing how having integer number of entrants maintains non-negative profits for all entrants).

[161] Assuming investors will invest in all projects that are expected to deliver non-negative economic profits.

2. Dynamic Costs

The second social cost is the dynamic cost caused by impeding the work of improvers. Generally, the first patentee has the potential to use the injunctive power of the courts to stop any infringement.[162] Anyone attempting to improve upon an invention would have to deal with that patentee. Absent a research use exemption, the initial patent holder could stop potential improvers.[163] Such behavior could impede progress by making subsequent improvements more difficult, more expensive, or outright impossible.[164]

Multiple competing solutions help to reduce this cost. Competitive entry tends to reduce the probability of such situations because it encourages multiple solutions to any technical problem. If one initial inventor is refusing to deal, then there are others to whom an improver can turn for substitute technology. Rather than having a single rights holder and the inherent holdout problem, a potential improver needs permission from only one of the multiple patentees. Furthermore, improvers could also avoid dealing with other patent holders altogether by designing around any potential roadblocks on their own. The multiplicity of parties helps to avoid refusals to deal. Furthermore, the availability of choice opens doors to a larger number of potential improvements. In sum, when there are multiple solutions, improvers have multiple inventions from which to start their improvements.[165]

[162] *See* 35 U.S.C. § 283 (2000). Although historically there was a general presumption that a permanent injunction would issue to protect a valid and infringed patent, the recent Supreme Court case *Ebay v. Mercexchange*, 126 S. Ct. 1837 (2006), returned patent law to a consideration of the traditional four factor test for a permanent injunction. *Id.* at 1839. It is yet to be seen whether *Ebay* will change, as an empirical matter, the prevalence of injunctions.

[163] *See* Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 460 (2004).

[164] With the power of an injunction the original patent holder can simply not allow any improvements. *See* 35 U.S.C. § 283.

[165] *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 843 (1990) ("Without extensively reducing the pioneer's incentives, the law should attempt at the margin to favor a competitive environment for improvements . . . ."); Rai, *supra* note 18, at 823 (arguing that "because multiple independent research paths are important for promoting creative development of early-stage research, competition must also play a role").

3. Rent Seeking

The third social cost is the cost associated with rent seeking.[166] This cost is often discussed in two parts. First, some have been concerned with the costs associated with duplicative research efforts seeking to solve the same problem.[167] Second, others have been concerned with the overall allocational distortions caused by the abnormal profits offered by the patent system.[168] The patent system as applied to traditional inventions reduces these costs through competition.

Before discussing the details of rent seeking in the patent system, it is worth noting that some have criticized patent critics' seeming preoccupation with rent seeking.[169] Professor Kenneth Dam, for example, argues that "it would be good to note that 'rent seeking' is to some extent another term for 'competition.'"[170] According to Professor Mark Lemley, "the costs of patent races are substantially overstated. At a minimum, the costs of duplication of effort must be weighed against the likelihood that we get better results through competition than by granting one person the right to invent in a particular field."[171] Recently, Professor John Duffy expressed a related view. Duffy looks past the various attempts that have been made to either prove or disprove that the patent system induces racing.[172] Duffy does not fault

[166] *See* Lemley, *supra* note 127, at 132 n.8.

[167] *See* Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 308 (1992).

[168] Plant, *supra* note 146, at 40.

[169] Dam, *supra* note 128, at 264 (noting that "rent seeking can be exaggerated as a problem"); *see also* Robert P. Merges, *Rent Control in the Patent District: Observations on the Grady-Alexander Thesis*, 78 VA. L. REV. 359, 381 (1992) ("[T]he rent dissipation approach itself may overestimate the 'wastefulness' of competition in the follow-on market for improvements to a basic invention.").

[170] Dam, *supra* note 128, at 263 ("By analogy, we do not normally consider the opening of a new gasoline station or grocery store near an existing one to be an example of waste, or at least not one with which public policy should be concerned, even though we believe that only one can survive and we know that some economic rent of location may accrue to the survivor. Rather, we consider the competition induced by the new entrant to lead to a better outcome than would accrue through legal protection of the existing firm.").

[171] Lemley, *supra* note 127, at 132 n.8.

[172] For example, Duffy examines both the initial arguments by Barzel that painted the patent race as common pool problem like a fishery, and the subsequent famous response from Kitch that painted the patent system as akin to mining prospects that arguably would reduce waste due to racing. *See* Duffy, *supra* note 134, at 443; *see also* Edmund Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 271-75 (1977).

the patent system for exhibiting rent-seeking behavior.[173] He asks not "*whether* rents will be dissipated, but *how* they will be dissipated."[174] To express this notion in humorous bumper sticker slang: rent seeking happens. The important question then is, in drawing people and resources into the inventive process, has the patent system expended those resources efficiently? Duffy, like Dam, argues that the patent system attempts to channel the racing into a beneficial form of competition.[175] Along similar lines, this Article emphasizes that competition channels the patent race into a socially beneficial form.

Viewed in this light, the rent-seeking concerns expressed about the patent system begin to recede but have not disappeared — they still need to be addressed. One of two types of rent seeking addresses the concern over wasteful, duplicative research.[176] This concern is founded on the incorrect view that the patent system must be a "winner take all" race. In short, many have viewed the race to a patent as the race to one single goal similar to the search for a single chest of buried treasure. For example, Professor Arnold Plant worried about the duplicative efforts of the various patentees seeking a patent. He worried that "[t]he grant of a monopoly renders almost nugatory the labours of all the rest. . . . [T]he lottery of the patent system awards but one prize. . . ."[177]

After considering the importance and ubiquity of designing around in patent law, it is clear that patent law avoids some of the duplicative waste associated with patent racing because there is not one winner, but many. It is not really a winner take all race.[178] "[P]atent races need not produce any social waste at all in cases . . . in which there are

[173] Duffy, *supra* note 134, at 443

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

[175] *See id.* Duffy argues that the prospect features of the patent system do not necessarily reduce expenditure of resources in races to capture the patent. *Id.* Instead, because the races lead to having the patents expire sooner, those races do benefit the public. *Id.* at 444. This Article agrees that the patent system channels racing behavior, but instead of focusing on Duffy's analog to Professor Harold Demsetz's natural monopoly auction, this Article argues that additional resources drawn into the patent system after the initial invention are a form of traditional competition that benefits the public by reducing both the dead weight losses, the dynamic costs of improvements, and long-term rent seeking.

[176] *See* Grady & Alexander, *supra* note 167, at 308.

[177] Plant, *supra* note 146, at 46. For a modern take on the patent system as a lottery, see Scherer, *supra* note 159, at 3.

[178] *See* Lemley, *supra* note 127, at 1063 n.127 ("At a minimum, the costs of duplication of effort must be weighed against the likelihood that we get better results through competition than we would granting one person the right to invent in a particular field.").

. . . more than one winner."[179] Generally, it is incorrect to view a race to invent as identical to a race to find buried treasure because all successful, design around patentees share the prize. By encouraging multiple different solutions, the patent system avoids some of the waste from duplication. Though the ultimate problem to be solved may be held in common, competitors are free to spread out along their own particular routes in search of their particular solution.[180] Therefore, wasteful rent seeking is reduced for two reasons. First, the existence of multiple solutions lowers the incidence of redundant duplicative research. In other words, competitors are more spread out. Second, as the patent system leaves room for competition, many second-arriving entrants still are able to get a share of the prize, thus benefiting the public. Consumers benefit from having a variety of inventions to choose from. Additionally, consumers benefit because competition drives down prices, which expands output.

The second type of rent seeking cost is concerned with the overall distortion of the economy produced by the monopoly lure of patents. Some have worried that supporters of the patent system have "failed to ask themselves, however, . . . what [inventors seeking patents] would otherwise be doing if the patent system were not diverting their attention by the offer of monopolistic profits to the task of inventing."[181] This Article argues that even this concern is generally mollified by the competition created by multiple solutions. If there is competition between inventions, even if there is the lure of short-term

[179] LANDES & POSNER, *supra* note 148, at 301.

[180] Furthermore, this spreading out of competitors allows researchers to actively tailor their research activity to use their competitive advantages and avoid their competitors. This may also be thought of as a natural balance between risk and reward. A researcher can choose an obvious route that will likely be packed with other competitors; or the researcher can strike out alone into riskier, less well-known areas.

Chester Carlson, the inventor of the Xerox machine, provides an example of such active avoidance of competitors and the attendant balance between risk and reward. Carlson described his motivations for choosing photoconductive technology rather than photographic technology for making copies as follows: "[A] lot of big companies were deeply involved in research using chemical or photographic processes and — 'Who was I to compete against Eastman Kodak?'" *See* Duffy, *supra* note 134, at 463. Using his private information about his comparative advantages, Carlson avoided a direct, likely duplicative race with Kodak and instead chose a riskier but less obvious route. It can be argued that the market awarded him accordingly for his risk taking.

The multiplicity of research programs that address a single specific problem need not be viewed as wasteful. *See* Merges, *supra* note 169, at 877 ("Given the way humans and organizations think and behave, we believe we are much better off with considerable rivalry in invention than with too little.").

[181] Plant, *supra* note 146, at 40.

abnormal profits, long-term abnormal profits are unavailable[182] and thus there is no long-term allocational distortion. Competition will drive the price of an invention down to the average cost.[183] Average cost, by definition, is where the inventor recoups her actual costs; the inventor earns normal profit.

When viewed in the short term, abnormal profits are available, but this does not mean that any socially unwanted distortion has been created by the patent system. Initially a first inventor may indeed enjoy abnormally high profits as the inventor enjoys her first mover advantage. But, as is the case in other portions of the economy, these initial, transient abnormal profits signal others to enter.[184] Thus, others will invent and enter the market with their non-infringing substitute inventions. During this time, resources will be directed towards competing inventions in that market but this is not necessarily inefficient compared to the option of having just a monopolist. As competitors enter, price will be driven down and approach average cost. As the price reaches average cost, continued allocation of resources to that inventive problem will slow, if not cease.[185] Viewed in this light, the flow of resources into inventive activities looks similar to the dynamic flow of resources in other sectors of the economy.[186]

Thus, rather than viewing the transient abnormal profits as wasteful, this Article argues that they serve an important socially beneficial purpose. They are used as informational signals to redirect resources to some new technological area so that a diversity of solutions may be produced, so that society may benefit from that diversity.[187] The

[182] *See* WILLIAM J. BAUMOL & ALAN S. BLINDER, ECONOMICS 629 (4th ed. 1988).

[183] *See* F.M. SCHERER & DAVID ROSS, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 22 (3d ed. 1990) ("[I]f positive economic profits are earned, new firms will squeeze into the industry, shifting the typical firm's demand curve to the left until, in long-run equilibrium, it is tangent to the firm's long-run unit cost function.").

[184] *Id.*

[185] *See* Yoo, *supra* note 111, at 221-22 (describing similar scenario in copyright). "The presence of any supracompetitive profits will attract entry by competitors until all such profits have been dissipated. At that point, the revenue captured by each entrant should be just sufficient to offset the author's cost of production. By bringing revenues in line with the cost of production, entry largely alleviates concerns about overstimulation of creative activity or sustained supracompetitive profits generally raised in the patent literature." *Id.*

[186] *See* BAUMOL & BLINDER, *supra* note 182, at 612-29.

[187] In addition to being an information signal, the transient abnormal profits made by the initial inventor arguably are commensurate with the risk incurred by the initial investor in developing a new invention and probing the demand in an untested market.

patent system minimizes any inefficient allocation of resources because abnormal profits will generally only be available in the short term. These transient abnormal profits are important signals that allow for a temporary allocation of resources to that market that then leads to all the benefits afforded by a multitude of solutions.

This analysis acknowledges that competitive entry leads to higher aggregate costs in terms of research and development. Clearly, as each entrant engages in her own research, she expends societal resources in the form of her fixed costs. In other words, there is no doubt that on the cost side of the equation, competition invests more in fixed costs than would a single patent holder. But, as opposed to the winner take all view, patent law, through competition, gains from these additional investments. The increased investment through competition leads to lower prices, higher output, increased product choices, lower dynamic costs, and fewer allocational distortions as compared to a single monopolistic inventor.[188]

In sum, competition serves to reduce the three costs of the patent system: monopoly dead weight loss, rent seeking, and dynamic costs. The above discussion is not a global conclusion about the patent system; it does not conclude that the traditional patent system is an optimum, minimized-cost system for encouraging innovation. In fact, there may be many instances where the equilibrium number of design around entrants may be suboptimal. There may be cases where society is worse off compared to some ideal world because too many researchers have invested in fixed costs to enter the market. But this discussion is not about the ideal patent system.[189] Instead, the above discussion conducts a modest comparison, concluding that a patent system that allows and encourages competitive entry is an improvement over a patent system without any competition.[190] In short, compared to a patent system without competition, a patent

[188] For the economic analysis of this competition with free entry and fixed costs, see CARLTON & PERLOFF, *supra* note 111, at 289-301. For a similar analysis in the copyright context, see generally Yoo, *supra* note 111, at 220-26 (describing benefits of free entry in copyright).

[189] *See* Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J.L. & ECON. 1, 1 (1969) (criticizing "nirvana" approach to institutional design and instead advocating for "a comparative institution approach in which the relevant choice is between alternative real institutional arrangements" (emphasis omitted)). Certainly important questions about how many entrants to allow, and how the entrants should be spaced, are all important questions about how to improve the overall patent system. However, they are beyond the narrow purpose of this Article.

[190] Allowing competitive entry into a technological market is likely not even a second-best solution. *See* CARLTON & PERLOFF, *supra* note 111, 296-97.

system that allows competition encourages at least the same set of inventive activities at a lower cost.[191]

C. Broad Gene Patents: No Competitive Efficiencies

Having discussed benefits of competition as applied to patents covering traditional inventions, this Article turns to gene discoveries. Gene discoveries are, in large part, created by intentional copying. A researcher who sets out to purify and isolate the gene that codes for a particular protein is attempting to get the gene responsible for that protein. For example, in *In re Bell*, the Federal Circuit made clear that "Bell does not claim all of the 10 nucleic acids that might potentially code for [the protein of interest]. Neither does Bell claim all nucleic acids coding for a protein having the biological activity of [the protein]. Rather, Bell claims only the human nucleic acid sequences coding for [the protein]." [192]

In these research efforts, as in the case for mapping, there is little room for creativity. Correct solutions are highly constrained. Just as surveyors intend to copy geographic information, gene researchers intend to copy a gene. All successful gene hunters are going to produce similar answers.

Thus, gene discoveries inhabit a very different environment than traditional inventions. Traditional inventions can be afforded broad patent claims while still allowing for competition. In the case of gene discoveries, the solution set is much narrower. Consequently, although the patent system currently grants gene discoveries the same broad claim scope as a traditional invention, patent law has left no room for competition. The first gene researcher to isolate and purify a gene blocks any second-arriving researcher from independently trying to purify and isolate the gene. Effectively, the first researcher's patent claim will block any competing products.[193] This stifling of competition is the heart of the unnecessary social costs associated with broad patent claims to gene patents. Patent law has yet to justify this added expense.

First, considering the social cost of monopoly dead weight loss, the patent system performs worse as applied to gene discoveries than

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[191] Furthermore, because designing around lowers the costs associated with improvements and because it leads to the benefits of product differentiation, it is fair to argue that design around competition encourages more inventive activities than a system without competition.

[192] *See In re* Bell, 991 F.2d 781, 784 (Fed. Cir. 1993).

[193] *See supra* Part II.B.

traditional inventions. With broad gene patent claims, there can be no competition.[194] Once the first discoverer patents her result, there can be no subsequent competitive entry from a second-arriving researcher, even from one that independently re-discovers the gene.[195] As a result, there will be no reduction of dead weight loss from competing solutions. This is analogous to allowing the first person to survey Long Island to block any other surveyors from surveying it themselves.[196] Similarly, in contrast to patents claiming traditional inventions, broad gene discovery patents are likely to incur dead weight losses even in the long term because, due to the lack of competition, prices are not driven down to average cost.

Second, patents broadly claiming a gene discovery incur higher dynamic costs. Absent a robust experimental use exception, all improvers will have to deal with the single patent holder and her attendant power of injunction.[197] Especially in the case of a gene discovery, the impact on future innovation may be quite dramatic. Returning to the mapping analogy, someone might be able to get from New York to Boston without a map, and therefore, the prospect of a holdout would not completely stop all progress. However, it is apparent that, absent the map, getting to Boston would entail a highly inefficient process of trial and error.[198] Similarly, researchers might be able to cure a genetic disease without access to the implicated gene, but absent that access, progress will be far less efficient. In the gene discovery context, there is a real cost associated with potential holdout behavior from the single patent holder.

Furthermore, improvers have only the one solution from which to choose. Imagine there is an error in the first patented gene sequence. Depending on the breadth of the claim, it may be difficult for a second-arriving researcher to even work toward detecting, much less correcting, the mistake.[199] Thus, there are higher dynamic costs

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[194] *See* Carvalho, *supra* note 136, at 733; Demaine & Fellmeth, *supra* note 69, at 418; Lee, *supra* note 1, at 84; Melissa E. Horn, Note, *DNA Patenting and Access to Healthcare: Achieving the Balance Among Competing Interests*, 50 CLEV. ST. L. REV. 253, 266-67 (2003).

[195] This is different from the way in which copyright deals with maps. Traditionally, a first surveyor could get a copyright on his map, but that copyright could not block subsequent surveyors from independently undertaking their own survey.

[196] *See supra* Part I.C (discussing map copyrights).

[197] Heller & Eisenberg, *supra* note 16, at 700.

[198] *See supra* Part I.C.

[199] *See, e.g.*, Paul Jacobs & Peter G. Gosselin, *Errors Found in Patent for AIDS Gene, Scientists Say*, L.A. TIMES, Mar. 21, 2001, at A1 ("Scientists have uncovered what they

associated with patents broadly claiming gene discoveries than with traditional inventions.

Third, broad patent claims create a true winner take all race between entrants. As opposed to traditional inventions, broad patents claiming gene discoveries are exactly the type of overly broad exclusive rights that lead to wasteful racing. In this case, all duplicative research is wasted as only the winner (i.e., the first to patent) can legally recoup any of the costs.

In addition, patents that broadly claim gene discoveries can lead to distortional inefficiencies. As there can be no competitive entry, the patentee can set the price above average cost for the patent's entire duration. As a result, the winner of the race has a definite potential to consistently earn long-term abnormal profits. Inventors will flock to this area in hopes of landing that prize. Absent the moderating effects of competition present with traditional inventions, the patenting of gene discoveries may result in a wasteful gold rush.[200]

In summary, there are three major social costs associated with the patent system.[201] Although the costs do not vanish with traditional inventions, the patent system tends to reduce these costs by encouraging competition.[202] But the patent system as currently applied to gene discoveries cannot take advantage of those efficiencies. Current gene patents are too broad because there can be no competition between competing solutions to the problem of gene discovery.[203] Based on these policy and doctrinal arguments, there really is no choice for policymakers. The assumption that the patent system can and should treat gene discoveries identically to traditional inventions needs reevaluation.[204]

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believe are glaring errors in a patent issued last month to Human Genome Sciences Inc. for a human gene that plays a crucial role in AIDS . . . . The company's description of the chemical makeup of the gene contains at least four significant mistakes . . . .").

[200] For a discussion of gene patents as a gold rush, see Matthew Erramouspe, Comment, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. REV. 961, 962 (1995).

[201] *See supra* Part II.B.

[202] *See supra* Part II.B.

[203] Carvalho, *supra* note 136, at 702.

[204] The economic cost comparisons of patenting inventions versus discoveries does not conclude that inventions can be encouraged by private property while basic discoveries must be encouraged by non-private means like academic research. All this Article concludes is that broadly claiming gene discoveries is more costly than claims for traditional inventions. Thus, to justify broad patent claims to gene discoveries, a case must be made that even as a worse bargain for society, it is somehow still worth pursuing. That case has not been made. Part III shows that there are narrower ways

III. PROPOSAL: NOT FREE TO COPY THE COPY BUT FREE TO COPY THE ORIGINAL

The above discussion establishes that broad gene patents run contrary to both the doctrinal requirement of originality and the policy goals of allowing competition within the patent system. The troubles arise not from the existence of gene patents per se, but instead from the breadth of their claims. The obvious question is whether claims for gene patents could be narrowed such that they satisfy both the doctrinal and policy aims of originality. As the discussion thus far has revolved around a comparison between gene discovery and mapping, it may seem obvious to attempt to replicate by analogy the scope of protection traditionally afforded to maps.[205] At first glance, trying to make patent protection more "copyright-like" may seem like an impossible task.[206] The challenge is to draft claims directed at gene discoveries that satisfy the requirement of originality and allow for competition while still protecting the discoverer against piracy. The following outlines a proposal to achieve those goals.

In devising a new, narrower claim, we first look to the originality requirement for guidance. The requirement restricts the patent grant to that which the patentee invented or created. Turning to copyright, a cartographer does create intellectual property despite the fact that most of a cartographer's job is just copying: he creates his version of the map.[207] The copyright in a map is a claim to a cartographer's own map but little else. Analogous to the mapping example, gene discoverers cannot say that they created the gene sequences. But they can say that they created their specific copy of it. Originality demands

to claim gene discoveries so that competition is restored while still providing the initial inventor with the patent protection.

[205] *See supra* Part I.C.

[206] Others have suggested making patent law more copyright-like. Before the Senate, Judge Learned Hand suggested some of the benefits of a copyright-like patent scheme. *See American Patent System: Hearing before the Subcomm. on Patents, Trademarks, and Copyrights of the S. Comm. on the Judiciary*, 84th Cong. 117-18 (1956); *see also* BENJAMIN KAPLAN, AN UNHURRIED VIEW OF COPYRIGHT 45 (Columbia Univ. Press 1967) ("With [Judge Frank's relatively low] originality concept [of simple independent recreation from *Alfred Bell v. Catalda*] correctly installed as central, copyright appeared as relatively easy to achieve but as correspondingly modest in its pretensions to monopoly. This apparent modesty of the system attracts sympathy, and we find Judge Hand later suggesting to an incredulous patent bar that they make over patent on the model of copyright."). As is clear, this Article does not suggest making all of patent law look like copyright. Rather, in the area of gene discoveries, a narrower, "copyright-like" claim scope is required by patent law itself.

[207] *See supra* Part I.C.

that gene researchers limit their claims to copies of their particular version of the isolated and purified gene sequence.

Currently gene discoveries are claimed as "a purified and isolated gene sequence encoding for the protein X."[208] This prevents others from pirating the work of the inventor and it prevents any competition from wholly independent discovery. In other words, a person infringes this claim by making, using, or selling the purified and isolated gene sequence regardless of how the gene sequence was made or obtained.[209] In analogy to maps, this Article proposes that claims to gene discoveries be narrowed so that they claim only copies of the patentee's version of the gene sequence that codes for protein X.[210] With this narrower claim, the researcher could still exclude others from making, using, and selling copies of his version of the gene sequence. If someone physically copied the initial researcher's sequence, then the resulting molecule would be a "copy" of the patented molecule. Therefore, making, using, or selling that molecule would be an act of infringement. In other words, this proposed narrower claim scope still protects against direct copying and piracy. However, as opposed to the current broad claims, if a second-arriving researcher independently created her own version of the gene sequence without using the initial inventor's version, then the resulting second-arriving sequence would not infringe — it is not a copy of the initial version.

This proposal has a number of advantages. As it limits claim scope to that which the inventor has invented, the proposed claim is consistent with the originality requirement while allowing the patentee some protection. The proposed claim is broad enough to protect against blatant piracy of the invention, thus serving the patent system's primary purpose, yet narrow enough to allow for competitive entry from independent, later-arriving discoverers. The proposed claim achieves the same result as broad claims while allowing for all the cost savings of competition.

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[208] *Accord* U.S. Patent No. 4,703,008 col.2 ll.1-3 (filed Nov. 30, 1984) (claiming "[a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin").

[209] *See* 35 U.S.C. § 271 (2000).

[210] Here the term "copies" uses the definition of a copy from copyright. *See* 17 U.S.C. § 101 (2000) (including as a copy "the material object . . . in which the work is first fixed"). Thus, copies of the patentee's version of the gene sequence as this Article proposes should similarly cover the actual molecule first created by the inventor along with copies made from it.

A. Stating the Problem as One of Claim Construction

From a pragmatic point of view, this proposal is designed to allow patent law to make a fundamental course correction. How should patent law implement such a proposal? If the above arguments about originality find favor in the courts or in Congress, then there immediately appears an important stumbling block: what to do with future and existing claims to gene discoveries? As to future claims, the answer is clear — patent law should prohibit broad claims covering gene discoveries. This could result from judicial or legislative decisions. But as to existing claims, how can they be fixed? Legislative invalidation of existing patents is highly problematic (and politically improbable) from a takings perspective.[211]

What other options are available? One rather draconian option is for a court to simply invalidate these overly broad claims to gene discoveries. But a gene discoverer is entitled to some claim scope; outright invalidation is a harsh result. The patent system could turn to the administrative remedies of reissue and reexamination to narrow the claims.[212]

Another option that seems to provide the "softest" possible landing for gene patents would be to state the problem as one of claim interpretation. The proposal, as a matter of syntax, requires only a minor reinterpretation of existing claims. However, as a substantive matter, it makes a dramatic change. For example, claim 2 of Amgen's U.S. Patent No. 4,703,008 reads: "[A] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin."[213] Arguably, this is ambiguous. Does it mean "any purified and isolated DNA sequence" or does it mean "the specific DNA sequence purified and isolated by the inventor?" The Federal Circuit has recognized a canon of claim interpretation that seeks to preserve a claim's validity.[214] Because of the originality requirement,

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[211] *See* Adam Mosoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689, 689 (2007).

[212] *See* 35 U.S.C. §§ 251-252, 302-305 (2000).

[213] '008 Patent col. 2 ll.1-3.

[214] *Cf.* Athletic Alternatives, Inc. v. Prince Mfg. Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996) (holding that where claims can be interpreted in more than one way, they should be interpreted to maintain their validity); *see also* Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999) (citing Klein v. Russell, 86 U.S. (19 Wall.) 433 (1873); Turrill v. Mich. S. & N. Ind. R.R., 68 U.S. (1 Wall.) 491 (1863)) (describing "the familiar axiom that 'claims should be so construed, if possible, as to sustain their validity.'"). *But see* Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999) ("We have also admonished against judicial rewriting of claims to preserve validity. Therefore, if the only claim construction that is consistent with the claim's language

the broader interpretation of these claims is argued here to be invalid.[215] Thus, applying this canon, a court could reasonably reinterpret the claim narrowly to mean "the purified and isolated copy of the DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin created by the patentee." By way of claim construction, patent law could change course in regards to gene patenting while simultaneously avoiding a massive takings problem and an overly draconian result of outright invalidation.

B. Defining Who Infringes

Because of the narrow scope of the proposed claim, only a copyist, but not an independent researcher, would infringe. It would not be an act of infringement to make, use, or sell a gene sequence if a researcher independently created it.[216] However, there are important evidentiary difficulties that immediately arise. Literal infringement of this proposed claim could occur in two ways.

First, if someone makes a physical copy of the patentee's version through techniques of DNA replication, then this is infringement. Infringement requires physically possessing the initial researcher's sample of the gene sequence or a cloned copy of it. To prove infringement, the patentee would have to show that the allegedly infringing sequence was a direct clone of the patentee's copy.

Second, it is possible that an infringing copy of the patentee's version could be made from the sequence information disclosed in the patent.[217] This is a form of information-based reverse engineering.

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and the written description renders the claim invalid, then the axiom does not apply and the claim is simply invalid.").

[215] *See infra* Part I.B.

[216] Recent scholarship has renewed discussion of an independent invention defense in patent law. *See* Mark A. Lemley, *Should Patent Infringement Require Proof of Copying?*, 105 MICH. L. REV. 1525, 1526-27 (2007); Samson Vermont, *The Angel is in the Big Picture: A Response to Lemley*, 105 MICH L. REV. 1537, 1538 (2007); Vermont, *supra* note 34, at 479-80. This recent discussion has evaluated the benefits of making an explicit independent inventor defense. Contrary to conventional wisdom, s*ee* Lemley, *supra*, at 1525, this Article's proposal shows that patent law can inherently incorporate an independent invention defense by crafting claim language. Thus, the proposal merits further review not just for its application to gene patents, but also as a general method for incorporating the independent inventor defenses directly into a patent claim.

[217] Without taking a normative stance, as a technical patent law consideration it is worth considering, *if a patentee plans only to claim her version of a gene sequence*, whether such a patent application requires full text disclosure of the sequence at all. Assume that the researcher properly deposits a physical copy of her version of the gene sequence with the Patent and Trademark Office. Does she need to disclose in

Starting from the sequence information disclosed by the initial patent, an infringer could reconstruct a copy of the patentee's version. Though not physically a clone, this would still be literal infringement as the resulting product would be a "copy" of the first patentee's gene sequence.

Lastly, even if literal infringement is not found, the courts could turn to the doctrine of equivalents to prevent piracy of the patentee's work. The Supreme Court has described "the benefits of the doctrine of equivalents" to include "prevention of copying and piracy."[218] Thus, the proposed claim protects the inventor from direct copying of her work both through literal infringement and the doctrine of equivalents.

Therefore, if the second researcher simply uses the sequence information provided in the patent application to make a direct copy, this is infringement because the resulting product is still considered a copy. In contrast, if the second researcher independently finds and creates her own copy of the gene sequence, and then only uses the initial patentee's information to check the accuracy of her result, then the gene sequence created by the second researcher would likely not be considered a copy of the initial version and thus not infringing.

But how much of the initial researcher's work could a non-infringing second-arriving researcher use? The more information the second researcher can use, the easier it will be for the second researcher to enter into the market. If too much information is used, then the second-arriving researcher can undercut the first researcher, consequently impacting the initial incentive to undertake the work.

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writing the actual sequence in the patent application? Although it seems counterintuitive, the answer seems to be that she need not disclose.

By depositing, she has enabled others to make and use the claimed invention (i.e., get a physical copy of the deposited molecule). *See* 35 U.S.C. § 112 (2000). Similarly, proof of deposit should be adequate evidence to prove to a person of skill in the art that the inventor was in possession of the claimed invention, thus satisfying the written description requirement. *See id.* Outside of being somewhat antithetical to the disclosure goals of the patent system, little precludes disclosure by deposit for narrowly claimed gene discoveries. This provides little solace to existing patentees who may now be limited to these narrow claims, yet who also have already provided the full sequence information. Note that the amount disclosed has an important impact on the potential patent position of second and later arriving researchers. *See supra* text accompanying notes 208-11.

[218] Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 34 (1997). Note that the Court in *Warner-Jenkinson* explicitly states that this "does not mean that its application is limited only to cases where those particular benefits are obtained." *Id.*

Interestingly, cases involving map copyrights have already confronted this very issue. The question is, how much of an existing map can a second-arriving surveyor use without infringing on the copyright of the first surveyor? The English case of *Kelly v. Morris*, addressed this very question.[219] The court held that a second-arriving surveyor must "go through the whole process of triangulation just as if he had never seen any former map."[220] Furthermore, the court held that "the only use that he can legitimately make of a previous publication is to verify his own calculations and results when obtained."[221]

In the United States, the Second Circuit expressed similar sentiments in *General Drafting Co. v. Andrews*.[222] The court found a second-arriving mapmaker liable for infringement, but "would have allowed [the] defendant to use [the] plaintiff's map for 'comparison or checking.'"[223] Thus, although the question of infringement by second-arriving researchers may be difficult, copyright has been dealing with an almost identical scenario for centuries. Patent law can begin to explore this admittedly difficult area by using these copyright cases as a starting point in defining exactly what constitutes a copy of the initial version of a gene sequence.[224]

Thus far, this Article has ignored administrative costs.[225] This proposal may create substantial administrative costs, because it is clear that competitors, even when acting wholly independently, will create gene sequences that are nearly identical.[226] As an evidentiary matter, it

[219] Kelly v. Morris, (1866) 1 L.R.Eq. 697, 697-700 (U.K.).

[220] *Id.* at 702; *see also* Wolf, *supra* note 88, at 229.

[221] *Kelly*, 1 L.R.Eq. at 702.

[222] Gen. Drafting Co. v. Andrews, 37 F.2d 54, 55-57 (2d Cir. 1930).

[223] Wolf, *supra* note 88, at 234.

[224] Such difficult line drawing has always been a part of intellectual property law. In discussing the limits of copyright protection, Judge Learned Hand held that "[n]obody has ever been able to fix that boundary, and nobody ever can." Nichols v. Universal Pictures Corp., 45 F.2d 119, 121 (2d Cir. 1930). Later Judge Hand commented that "[o]bviously, no principle can be stated as to when an imitator has gone beyond copying the 'idea,' and has borrowed its 'expression.' Decisions must therefore inevitably be ad hoc." Peter Pan Fabrics, Inc. v. Martin Weiner Corp., 274 F.2d 487, 489 (2d Cir. 1960); *see also* Mannion v. Coors Brewing Co., 377 F. Supp. 2d 444, 457 (S.D.N.Y. 2005) ("[T]he sort of difficulty Judge Hand identified in *Nichols* . . . is essentially one of line-drawing, and, as Judge Hand taught, is common to most cases in most areas of the law."); Wiley, *supra* note 122, at 126.

[225] *See* Norman Siebrassie, *A Property Rights Theory of the Limits of Copyright*, 51 U. TOR. L.J. 1, 22-33 (2001) (describing similar situations in copyright where it can be difficult to distinguish between copies and independent works).

[226] *See supra* notes 47-54 and accompanying text.

may be hard to discern between infringing gene sequences created by copying versus non-infringing sequences created independently. Again, copyright has already addressed these same concerns. In the famous copyright case of *Emerson v. Davies*, Justice Story noted that "it is plain that both maps must, the more accurate they are, approach nearer in design and execution to each other." [227] Despite this difficulty and its attendant administrative costs, maps have always been protected.

On the other hand, this proposal lowers administrative costs in other ways. With broad patents, researchers need to constantly keep abreast of the high volume of patents that emerge from the PTO. They must determine which actions infringe and which do not. This can be very difficult and costly. Under this proposal, the rules are much simpler: (1) if you use your own, independently created work then you are safe; (2) if you rely on the work of others without authorization, then you need to be more careful; (3) if you use too much, then you are infringing. These rules are relatively cheap for the public to self-enforce. Without any costly searching I know when I can operate freely and when I need to be more careful. Thus, even though this proposal may have higher administrative costs during judicial enforcement, this proposal also may have lower administrative costs with respect to the public's responsibility to not infringe patents.

In order to lower the costs of judicial enforcement, one avenue worth exploring is the potential for technical watermarks or other indicia of copying.[228] In other low authorship works such as factual listings, authors have been able to detect copying by the clever use of false listings. In fact in *Feist*, four of Rural's fake entries were found in Feist's directory, thus evidencing the copying that had occurred.[229] Could similar watermarks or other indicia be used in the biotechnology arena? In the present discussion of low inventorship, the addition of some conscious, intentional change in a gene sequence has an added benefit: the resulting sequence with its intentional changes would be more original than the raw sequence that was as faithful as possible to the original.

However, any intentional change could have disastrous consequences for human safety and overall utility. Professor Douglas

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[227] Emerson v. Davies, 8 F. Cas. 615, 619 (C.C.D. Mass. 1845) (No. 4436).

[228] *See generally* Dan L. Burk, *DNA Rules: Legal and Conceptual Implications of Biological "Lock-Out" Systems*, 92 CAL. L. REV. 1553 (2004) (describing biological lockout mechanisms). This Article does not suggest the use of lockout mechanisms but instead recommends technological watermarks to detect copying.

[229] Feist Publ'ns v. Rural Tel. Serv. Co., 499 U.S. 340, 344 (1991).

Lichtman voiced similar concerns over the applicability of fake entries in copyright: "The false entries in *Feist* did no harm because no consumer was ever going to look up a nonexistent neighbor. The same [result] might not be true for false entries on a map or in a research database. Thus, the use of fictional information is only plausible for certain types of work."[230] This caution applies equally to biotechnology resources.

There are other options. "Evidentiary issues are typically quite manageable in [low authorship work] because fact-intensive research generates a rich paper trail."[231] Similarly, gene research has its laboratory notebooks and other components of a research trail. These could be used to prove or disprove the copying of an initial gene researcher's work. Thus, though it is certainly worth exploring the magnitude of these administrative costs, they should not themselves rule against this proposal absent a more thorough accounting.[232]

C. Changing Patent Strategy: Forcing More Claims Downstream

Currently, researchers and research institutions continue to invest enormous amounts of money in gene discovery and its applications.[233] The biotechnology industry has come to expect that strong patent protection is available. In part the availability of broad patent protection for genes forms the basis for these investments. If gene discovery claims are construed narrowly as proposed, will the investment stop? Does that mean that biotechnology will stop funding such research?

This proposal does not invalidate these patents and it attempts to leave some real protection in place.[234] Nonetheless, there are likely many others that might feel that such narrow claims are not enough to protect their substantial and risky investments. There are important reasons to believe that the patent system as a whole can still provide adequate protection even if "composition of matter claims" to naturally occurring gene sequences are substantially narrowed.

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[230] Douglas Lichtman, *Copyright as a Rule of Evidence*, 52 DUKE L.J. 683, 711 n.126 (2003).

[231] *Id.* at 712.

[232] For a recent discussion of such administrative costs, see *id.* at 715. "[In copyright law] there are strong arguments to be made in favor of at least some narrow form of protection [for facts]. After all, the same freerider problem that (from an economic perspective) justifies copyright protection for creative work seems to justify protection for factual work as well." *Id.*

[233] For a discussion of this proposal and FDA exclusivity, see *infra* Part III.E.

[234] *See supra* Part III.B.

By arguing that the composition of matter claim to a gene sequence should be construed narrowly, this proposal is not removing all available substantive patent protection in this area. Rather, the proposal shifts how that protection is achieved. Whereas currently a single composition of matter claim can be used to control all subsequent downstream uses,[235] the proposal forces patentees, if they need more protection, to claim downstream uses separately. In other words, when a biotechnology company discovers a gene and narrowly claims it as proposed, they may argue that they have little incentive to commercialize a therapy or drug based on the gene because their patent protection is too narrow.

But the composition of matter claim has never been the only avenue of protection; the patent system offers other forms of protection. For example, if, after discovering and narrowly claiming a gene, a biotechnology company invents some new drug or a therapy based on the gene, they can then try to patent that new drug or new therapy. In other words, where gene discoverers are unsatisfied with protection offered for composition of matter claims for the genes, they should simply patent downstream uses.

As a policy matter, broad monolithic composition of matter claims should not be used to wall off all downstream uses because the broad claims block competition. Absent competition, the cost of these broad patents is too high.[236] This proposal does not remove substantive protection; it merely tailors how it will be achieved. The proposal shifts emphasis away from broad composition of matter claims covering the gene sequences to individual uses of gene sequences or methods of treating diseases based on gene sequences. In so doing, the patent system will be encouraging claims that are more amenable to competition.[237]

D. Are Second-Arriving Gene Sequences Novel?

To better understand the potential results of this proposal, one may explore the nature of the competition that will evolve between the initial gene researcher and subsequent researchers. Often for traditional inventions, each inventor seeking to solve some technical problem can receive patent protection for her own particular solution. In this way, the various competitors are on equal legal footing.

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[235] *See* 35 U.S.C. § 271(a) (2000).

[236] *See supra* Part II.C.

[237] Other claims might be indirectly impacted by rejections based on § 103 via § 102(f). *See* OddzOn Prods. v. Just Toys, Inc., 122 F.3d 1396, 1400 (Fed. Cir. 1997).

Likewise in copyright, each cartographer can copyright his independently created map.

Thus, in the market for maps there is legal equality between independent competitors. The competition that this proposal would create would not necessarily be as equal. As explained, the first person to purify and isolate a gene sequence could receive a patent claim on the sequence, albeit a narrow claim. The claims have been explicitly tailored to allow for non-infringing independent discovery by others, but will those subsequent researchers be able to patent their sequences? Can they compete with the initial researcher on an equal legal footing? Or will patent law's requirements of novelty and nonobviousness deny patent protection to these second-arriving researchers?

At first glance it may seem that a second-arriving gene sequence will not be patentable. Especially if the first researcher discloses the gene sequence in written form,[238] the second-arriving sequence will likely be anticipated by the initial gene sequence because the second gene sequences will be identical. Similarly, it may seem clear that, aside from anticipation, the second gene sequence would be obvious in light of the first gene sequence. Thus, it appears that the only way subsequent researchers can patent their versions of a gene sequence is if their version is somehow different from the first. In that case novelty and obviousness would not likely bar the patentability of the second sequence. This may be the most reasonable result:[239] patents will only issue for a later arriving gene sequence if the later discovered sequence is sufficiently different from the initial sequence. Interestingly, recent scientific results suggest that gene sequences may

[238] *See supra* note 217 (discussing whether § 112 requires disclosing gene sequence explicitly if inventor deposits copy of isolated gene).

[239] In this view researchers who independently create identical gene sequences to patented sequences will not infringe but will not be able to patent their sequence. From an economic perspective some have argued that such inequality is necessary to promote competition. *See* Vermont, *supra* note 34, at 485 ("[I]nventors must believe ex ante that there is a fair chance that convergence on the same invention will give rise to a Cournot duopoly that maintains prices above the competitive level. As discussed later, a Cournot duopoly cannot persist without some inequality between the reinventor and the patentee. Thus, awarding them equal patent rights would undermine their ex ante prospect of Cournot duopoly.").

show more variation than previously thought,[240] and thus each differing version of the gene could be patentable.

But before moving on, it is worth pushing a bit on this result. The world of low inventorship is rather unexplored in patent law. For that reason, our intuition may not be quite attuned to it. Unexpected results might emerge. For low originality inventions, does patent law more closely mimic copyright? In other words, could a second-arriving gene researcher patent her version of the gene sequence even if her gene sequence is identical to the first?[241]

Arguably, patent law could support such second-arriving patents on nearly identical gene sequences. This Article is premised on the assumption that gene discoverers cannot "invent" a gene sequence. Instead they can only invent their particular version of the gene sequence. Because this Article is premised on the idea that so very little has been invented by the initial gene researcher, then by implication very little is anticipated by that invention. The novelty provision blocks patent claims under 35 U.S.C. § 102(a) and (b) when the invention was known, used, patented, or described previously. Arguably, a second-arriving researcher's version of the gene sequence would not be anticipated by the initial gene sequence because the second researcher's invention was not known, used, or patented previously.

Another way of seeing this argument is via the oft-used aphorism: "[T]hat which infringes, if later, would anticipate, if earlier."[242] Because the gene discoverer invents very little, the patent claims are necessarily narrow. Following the proposal, it is clear that two independently created gene sequences would not infringe each other's patent claims. Accordingly, this long-held aphorism suggests that these patent claims should not anticipate each other also. Thus, the patenting of the initial gene sequence may not anticipate a patent claim to the second-arriving researcher who independently creates his version of the gene sequence even if the two sequences are very

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[240] Jon Cohen, *Venter's Genome Sheds New Light on Human Variation*, 317 SCI. 1311, 1311 (2007) ("For the first time, researchers have published the DNA sequence from both sets of chromosomes from a single person: none other than pioneering genome researcher J. Craig Venter. The new sequence suggests that there is substantially more variation between humans than previously recognized.").

[241] This may be especially important if the above economic discussion determines that it is better to allow later arriving researchers to narrowly patent their versions of the sequences.

[242] Knapp v. Morss, 150 U.S. 221, 228 (1893); *see also* Lewmar Marine v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987).

similar.[243] Though it may bend our normal intuitions about patent law, an argument could be made that a claim to a wholly independently created sequence would not be anticipated or obvious by an identical initial sequence. More research and hopefully some real cases are needed to determine how patent law doctrine can or should flex to accommodate originality and low inventorship works.

E. FDA Approval and Narrowed Patent Claims

Any proposal to modify the strength of patents pertaining to drug-related products should consider the issue of FDA approval. This Part considers how the proposed narrowing of claims covering gene discoveries could impact the economics of such drug approvals. Demonstrating drug efficacy and safety are huge, vital expenses that drug developers must be able to recoup if the drug industry is going to exist. At the same time, especially after a patent expires, there are large benefits from competition by generic drug companies.

Currently, there are two alternate avenues that developers of gene-related products can use to seek FDA approval.[244] First, gene-related products may be classified as "drugs,"[245] seeking approval under the traditional Federal Food, Drug, and Cosmetic Act ("FDCA").[246] Second, gene-related products may be classified as "biological products,"[247] seeking approval under the process outlined in the

[243] A similar argument could be made as to obviousness. At first glance, the initial gene sequence seems to render the second-arriving sequence obvious. But again consider more carefully what inventions does the initial gene sequence render obvious? By using the first researcher's sequence, it is clear that a person of skill in the art could purify and isolate a copy of the gene sequence. But because they are by assumption using the first researcher's sequence information, the resulting molecule would be a copy of the first researcher's sequence. Thus, the initial gene sequence only renders obvious a sequence derived from it. The initial sequence would render obvious any claims to "copies of the initial researcher's gene sequence." However, this is exactly what is not claimed by the second-arriving researcher. Under the proposal, the second-arriving researcher's claim would specifically exclude that subject matter. The second-arriving researcher would claim only "copies of my specific version of the gene sequence."

[244] *See generally* David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies*, 60 FOOD & DRUG L.J. 143, 145, 151-53 (2005); Gregory N. Mandel, *The Generic Biologics Debate: Industry's Unintended Admission that Biotech Patents Fail Enablement*, 11 VA. J.L. & TECH. 8 (2006) (reviewing approval process for biologics).

[245] 21 U.S.C. § 321(g)(1) (2000).

[246] *Id.* § 301 (2000).

[247] 42 U.S.C. § 262 (2000).

Public Health Services Act ("PHSA").[248] In either case, the relevant question is whether subsequent applicants can use the initial applicant's safety data as a substitute for their own subsequent safety trials.

In 1984, Congress addressed this issue for drugs approved under the FDCA by enacting the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act").[249] By definition, a generic drugmaker intends on copying the drug made by the original drugmaker. The Hatch-Waxman Act allows the generic drugmaker to use the original FDA trials proving safety to establish that their identical (bioequivalent) generic drug will also be safe. The FDA will only approve the generic drug for sale (and thereby allow the use of the original safety trials) if the generic drug does not infringe any relevant patents held by the original drug maker. Either the original drug maker never patented the compounds, or the patents have expired, or they are invalid. If proper patent protection exists, these provisions require that generic drug makers to wait until after the relevant patents expire before they can market their generic drug. In this way the original drug maker can hope to have the exclusive market position to recoup both the drug development costs but also (and often more importantly) the FDA testing and approval costs.[250]

The proposal outlined in this Article could disturb this framework envisioned by Congress. As generally set out by the Hatch-Waxman Act, a second-arriving drug competitor could not substantially free-ride on the FDA approvals of the original researcher as long as the original drug developer had a valid, unexpired patent claim covering the drug.[251] According to the proposed narrowing of gene discovery claims, a second-arriving researcher could independently create their version of the drug. Because it was independently created, the second-arriving drug would not infringe. As they do not infringe, a competitor might be able to file and receive Abbreviated New Drug Application ("ANDA") approval by way of a paragraph (IV)

[248] *Id.* § 262(a)(2)(A).

[249] Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, & 35 U.S.C.).

[250] The FDA approval process for a typical drug costs between $100 to $880 million. *See* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003) (estimating average out-of-pocket cost of approval to be $802 million); Margaret Z. Johns, *Informed Consent: Requiring Doctors to Disclose Off-Label Prescriptions and Conflicts of Interest*, 58 HASTINGS L.J. 967, 973 (2007).

[251] *See* 35 U.S.C. § 271(e)(2) (2000).

certification that they do not infringe the patent.[252] In this way, a second-arriving competitor would not be free-riding on the research and development costs of the compound itself but would free-ride on the FDA approval costs invested by the initial drug developer. As these costs are often very significant, this free-riding would likely impact the incentives to undertake the difficult road of drug development and approval.[253]

Under the proposal, the initial drug developer is not without some alternative protection. Even if gene discoveries are claimed narrowly, inventors can still more broadly claim methods of using the gene discoveries. These broad downstream claims may pick up some of the slack created by narrowing claims to gene patents.[254] Furthermore, the FDA grants some market exclusivity outside of the patent system. There is a five-year market exclusivity given to new "active ingredients."[255] But of course this five-year exclusivity is a lot less than the twenty-year exclusivity obtainable through a patent claim. Thus, this proposal to narrow claims to gene discoveries could unsettle the current balance between the patent system and the FDA approval process.

Lastly, if these alternatives are inadequate, a more invasive solution would be to modify the existing scheme for FDA data exclusivity. The proposed narrowing of claims introduces difficulties because a second-arriving drug developer could reach the market with lower fixed costs than the initial developer because they are free-riding on the FDA approvals of the initial developer. The key is the inequality of fixed costs. This is what allows one to undercut the other.[256] One way to equalize the fixed costs associated with FDA approvals is to use the cost sharing approach taken by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").[257] FIFRA provides that:

> [T]he Administrator may, without the permission of the original data submitter, consider any such item of data in

[252] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000).

[253] *See* Lemley, *supra* note 216, at 1531 n.26 ("It is when the regulatory cost structure is asymmetric, as it is under current law, that some form of exclusivity becomes important. If patent law did not provide that exclusivity to pharmaceutical developers, FDA market exclusivity would have to pick up the slack."); *see also* Vermont, *supra* note 216, at 1539 ("[T]he FDA already deals with [FDA approval free-riding] by granting five years of market exclusivity. . . .").

[254] *See supra* Part III.C.

[255] *See* 21 U.S.C. § 355(c)(3)(E)(ii)(Supp. III 2003).

[256] *See* Lemley, *supra* note 216, at 1530-31.

[257] Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 (2000).

> support of an application by any other person . . . if the applicant has made an offer to compensate the original data submitter. . . . The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such an agreement, binding arbitration. . . .[258]

This would allow each competitor entering into the market to share in the overall costs of FDA approval.[259] If the initial as well as the subsequent competitors rely on the same FDA approval data it makes sense to have these competitors all share in the expense. In so doing, this scheme tends to force all the competitors to have similar fixed costs. Thus, no one competitor can free-ride and undercut the others.

For the approval of biological products under the PHSA, currently there is no explicit statutory authority for the FDA to use previous safety testing for the approval of a subsequent similar or identical biological product.[260] In other words, there is no Hatch-Waxman analog in the PHSA scheme. There is some debate as to whether such an explicit statutory analog is necessary. Some argue that the FDA already has authority to approve subsequent biological products based on similarity to already-approved biological products.[261] In either case, Congress is already moving toward creating such an explicit scheme.[262] Nonetheless, as the exact nature of the approval process for generic biologics is developed, policymakers should also consider the exact same concerns outlined above in the context of approvals of subsequent biological products under the PHSA.

CONCLUSION

This proposal presents an opportunity for patent law to reconsider the broad claims currently granted to gene discoveries. It provides an opportunity for patent law to begin discussing what constitutes inventorship and originality. A change is called for based both on patent law doctrine and patent law policy.

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[258] *Id.* § 136a(1)(F)(iii).

[259] For a similar proposal, see Judit Rius Sanjuan et al., *A Cost Sharing Model to Protect Investments in Pharmaceutical Test Data*, CPTECH POLICY BRIEF NO. 1, at 5 (May 18, 2006), http://www.cptech.org/publications/policybrief-no1-cost-sharing.pdf.

[260] *See* Mandel, *supra* note 244, at 25.

[261] *Id.* at 27.

[262] *See* Access to Life-Saving Medicine Act of 2007, H.R. 1038, 110th Cong. § 3 (2007). Greg Mandel describes this act as "amend[ing] the PHSA to create an expedited approval pathway for generic biologics." Mandel, *supra* note 244, at 47.

This Article concludes that gene patents are unjustifiably broad. Doctrinally, broad claims to gene discoveries conflict with the constitutionally mandated requirements of inventorship and originality. Furthermore, as a policy matter, broad gene patent claims conflict with the goals of encouraging competition within the patent system.

To realign gene patents with the rest of patent law, this Article begins a new dialogue by proposing specific, narrowing claim language for gene discovery patents. A gene discoverer does not invent the gene sequence; they only invent their version of it. As a result they can claim at most only copies made from their own copy of the gene sequence. These narrower claims are consistent with the doctrinal requirements of originality. They strike a bargain that is more in line with the bargain made for traditional inventions. The proposal demonstrates that patent law can provide real patent protection for gene discoveries without necessarily preventing others from independently sequencing the genes themselves.

Though this Article focused specifically on gene discoveries, relatively broad patents have been granted on other biological materials such as cell lines, especially human embryonic stem cell lines, and antibodies. Variants on the analysis employed here may provide important insight into the proper scope of claims in those areas.