VIRGINIA JOURNAL OF LAW & TECHNOLOGY

SUMMER 2005

UNIVERSITY OF VIRGINIA

Structural Nonobviousness: How Inventiveness is Lost in the Discovery

VARU CHILAKAMARRI †

ABSTRACT

Courts have treated inventions and discoveries as indistinguishable for purposes of patentability. Although both inventions and discoveries can be important for the progress of science, there is an inherent difference between these two categories that should affect how courts analyze their patentability. An invention is a physical embodiment of the patentee's inventive contribution to the art, whereas a discovery is a physical manifestation of nature. This distinction is pivotal to the nonobviousness inquiry, because an examination of the physical structural of a discovery reveals little about the patentee's unique contribution to the art. Put simply, the natural properties of the discovered item cannot be used to measure the patentee's ingenuity. The fact that a molecule is or is not structurally similar to other discovered molecules says more about nature's serendipity than it does about human inventiveness.

Consequently, as long as discoveries are patentable subject matter, the courts should reevaluate the structural test and consider a nonobviousness standard for discoveries that is rationally related to the purposes that drive the nonobviousness requirement: namely, whether or not the patentee's contribution to the art is qualitatively worthy of a patent.

^{© 2005} Virginia Journal of Law & Technology Association, *at* http://www.vjolt.net. Use paragraph numbers for pinpoint citations.

[†] J.D., Georgetown University Law Center, 2004. B.S. in Environmental Science, B.A. in Political Science, The Ohio State University, 2001.

TABLE OF CONTENTS

I.	Introduction		. 2
II. The Requirements of Patentability and How They A		Requirements of Patentability and How They Apply to Discoveries	. 4
	A.	Eligible Subject Matter	. 4
	B.	The Novelty of Discoveries	. 5
	C.	The Nonobviousness of Discoveries	. 6
	D.	The Utility of Discoveries	. 8
III.	Stru	ctural Nonobviousness	10
	A.	The Purpose Behind the Nonobviousness Requirement	10
	B.	Why the Goals of the Nonobviousness Requirement are Achieved by	
		Analyzing an Invention's Structure	11
	C.	How the Courts Have Analyzed the Structure of Isolated and Purified	
		Discoveries to Determine Nonobviousness	15
	D.	Why the Goals of the Nonobviousness Inquiry Are Not Achieved by Analyzir	ıg
		the Structure of Discoveries	19
IV.	The Nonobviousness Standard Should Adapt in Response to the Inclusion of		
	Disc	coveries as Eligible Patentable Subject Matter	22
	A.	The Suggestion Test	22
	B.	Alternative Possibilities for Evaluating the Nonobviousness of Discoveries	23
V.	Con	clusion	24

I. INTRODUCTION

From its inception, the underlying purpose of the U.S. patent system has been to reward intellectual endeavors that produce inventive contributions to society.¹ Toward this end, a broad array of inventions are potentially patentable, ranging from products such as household items and scientific devices to processes such as specific business practices and even certain athletic moves.² However, some items and processes remain *prima facie* unpatentable—for example, "[t]he laws of nature, physical phenomena, and abstract ideas"—because a patent on such things would not encourage the type of intellectual endeavors that the patent system was designed to reward.³

 \mathbb{T}^2 Along these lines, naturally occurring items such as plants or minerals are generally ineligible for utility patent protection⁴ because they are viewed as belonging in the public domain—they are items belonging to everyone, but created by no one.⁵ Thus,

^{1.} See U.S. CONST. art. I, § 8, cl. 8 (granting Congress authority to issue patents).

^{2.} U.S. Patent No. 5,616,089 (issued Apr. 1, 1997) (claiming a method of putting for golf).

^{3.} Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

^{4.} *Id*.

^{5.} See id. at 309 ("Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. . . . Such discoveries are 'manifestations of . . . nature, free to all men and

there is a dichotomy between those items that are naturally occurring and therefore inherently unpatentable, and those items that are not found in nature, which are patentable. This dichotomy has inspired courts and advocates alike to further question what the term "naturally occurring" means.

¶3 The answer is not intuitive. Under current law, *portions* of items found in nature are eligible for patent protection if their claimed form is different from their natural form. For example, the compound that makes up adrenaline is patentable subject matter in its pure form—when it is isolated from surrounding molecules and separated from the living organism—because technically, it is not found in nature⁶ in that form.⁷ One result of this formalistic reading of the term "naturally occurring" is that some items "discovered" in nature may be patented when the patentee both finds them and purifies or extracts them from their natural state.

¶4 For the purposes of this article, the term "discovery" will refer to that which is found in its entirety in nature, and the term "invention" will refer to that which is created and constructed by the human mind, but is otherwise absent from nature.⁸ While there is support for the argument that the words "invention" and "discovery" have different meanings,⁹ the U.S. Constitution, which expressly provides for the patent system, does not draw a distinction between naturally occurring items and human-conceived inventions. Rather, it states that Congress shall have the power to "promote the Progress of Science and useful Arts, by securing for limited Times to . . . *Inventors* the exclusive Right to their . . . *Discoveries*."¹⁰ Congress has likewise chosen to treat inventions and discoveries as if they were synonymous.¹¹

¶ 5 The purpose of this paper is not to quarrel with the eligibility of discoveries for patent consideration. Although there is historic opposition to the technical basis behind

reserved exclusively to none.") (citations omitted). However, certain asexually-reproduced plants may be eligible for a plant patent (as opposed to a utility patent) under the Plant Patent Act, 35 U.S.C. § 161. Additionally, the Plant Variety Protection Act, 7 U.S.C. § 2402(a), provides patent-like protection in the form of a certificate for novel varieties of sexually reproduced plants. *Id.* at 310-311.

^{6.} *See id.* at 310.

^{7.} *See* Parke-Davis & Co. v. H.K. Mulford & Co., 196 F. 496, 497 (2d Cir. 1912) (approving the patent application for adrenaline reduced to its pure form).

^{8.} Compare OXFORD ENGLISH DICTIONARY (2d ed. 1989) (defining "invention" as "[t]he original contrivance or production of a new method or means of doing something, of an art, kind of instrument, etc. previously unknown; origination, introduction"), with id. (defining "discovery" as "[t]he action of uncovering or fact of becoming uncovered"). Thus, for example, a transgenic fish would be considered an invention for purposes of this paper, whereas a newly discovered species of fish would be a discovery. See generally Pyrene Mfg. Co. v. Boyce, 292 F. 480, 481 (3d Cir. 1923) ("Invention is a concept; a thing evolved from the mind. It is not a revelation of something which exists and was unknown, but is the creation of something which did not exist before, possessing the elements of novelty and utility in kind and measure different from and greater than what the art might expect from its skilled workers.").

^{9.} Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 367-69 (2002).

^{10.} U.S. CONST. art. I, § 8, cl. 8 (emphasis added).

^{11. 35} U.S.C. § 100(a) (2000) (stating that "the term 'invention' means invention or discovery").

this acceptance,¹² the view that discoveries are patentable is well entrenched. Instead, this article addresses a lingering problem that exists, given that discoveries are patentable: there remains a distinct difference between inventions and discoveries that is overlooked by the courts when they apply a uniform standard for determining whether a claimed item is obvious. The courts have continued to examine the physical structure of both inventions and discoveries—the so-called "structural test"—when determining whether an item is too obvious to be granted patent protection. This paper explores whether the current standard for testing nonobviousness truly effectuates the underlying purposes of the patent system when it is applied to discoveries.

¶6 Before analyzing whether the current nonobviousness standard is appropriate for assessing discoveries, it is necessary to first examine how the general requirements of patentability apply to discoveries. Part I of this paper will provide a brief overview of the requirements of patentability (i.e., novelty, nonobviousness, and utility), and how they apply to patents on discoveries. Part II will take a closer look at the purpose behind the nonobviousness requirement and will consider how nonobviousness operates to evaluate inventions as compared to discoveries. Part III will argue that the current structural test for nonobviousness is inappropriate when applied to discoveries. This Part will also explore various ways of evaluating the nonobviousness of discoveries, which do not rely entirely on a structural examination.

II. THE REQUIREMENTS OF PATENTABILITY AND HOW THEY APPLY TO DISCOVERIES

¶7 To obtain a U.S. patent, one must first claim subject matter that is eligible for patent protection.¹³ Next, the claimed item must be novel, nonobvious, and useful.¹⁴ Finally, the patentee must fully disclose the specifications of the invention so as to enable a person of ordinary skill in the art to be able to make and use the item.¹⁵ A patent issued by the U.S. Patent and Trademark Office ("PTO") gives its holder the right to exclude others from the unauthorized making, using, selling, offering to sell, or importing the protected invention for approximately twenty years from the filing date.¹⁶

A. Eligible Subject Matter

¶8 Over the years, courts have debated whether naturally occurring items that have been isolated or purified from their surroundings should be eligible for patent

^{12.} See Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 10 n.3 (1966) (quoting a letter from Thomas Jefferson to Isaac McPherson in which Jefferson stated: "[a] mere change of form should give no right to a patent, as a high-quartered shoe instead of a low one; a round hat instead of a three-square; or a square bucket instead of a round one").

^{13. 35} U.S.C. § 101 (2005).

^{14.} Id. §§ 101-03.

^{15.} Id. § 112.

^{16.} Id. §§ 154, 271.

protection.¹⁷ In 1873, Louis Pasteur was granted a patent on a type of yeast in its pure form because he was able to process the yeast in such a way that it was free of germs.¹⁸ However, years later in *General Electric Co. v. De Forest Radio Co.*, the Third Circuit invalidated a patent on substantially pure tungsten.¹⁹ There, the patentee had extracted, from naturally occurring tungsten compounds, a pure form of tungsten that had greater ductility and tensile strength than the more brittle tungsten compounds found in nature.²⁰ The court held that although the patentee "was the first to uncover [the pure tungsten] and bring it into view . . . he did not create pure tungsten, nor did he create its characteristics," and therefore it was unpatentable subject matter.²¹

¶9 In contrast, the Fourth Circuit in 1958 upheld a patent claiming a new process of extracting vitamin B-12 from strains of fungi, as well as the extracted vitamin itself.²² The court noted that all "of the tangible things with which man deals and for which patent protection is granted are products of nature in the sense that nature provides the basic source materials."²³ While the Fourth Circuit pointed out that all the ingredients of every invention are ultimately derived from nature, the court was silent about the fact that the patentee was attempting to obtain patent protection over an actual ingredient.

¶ 10 Despite these conflicting opinions, it is now well settled that a product of nature that is sufficiently purified and isolated from its natural surroundings is eligible subject matter for patent protection.²⁴ It is important to note, however, that even if a particular discovery is eligible subject matter, it may still lack novelty or utility, or it may be too obvious to be afforded patent protection.

B. The Novelty of Discoveries

¶11 Novelty is a narrow inquiry. To be novel, the claimed discovery must not be an exact copy of something already patented by another or already known in the art.²⁵ In

- 18. U.S. Patent No. 141,072 (issued July 22, 1873).
- 19. 28 F.2d 641 (3d Cir. 1928).
- 20. *Id.* at 642-43.
- 21. *Id*.

^{17.} Several courts simultaneously continued to deal with the patentability of artificially produced chemical compounds. *See* Union Carbide Co. v. Am. Carbide Co., 181 F. 104, 108 (2d Cir. 1910) (holding that a new form of crystalline calcium carbide was patentable, despite prior art of different forms of the compound, because "[t]o hold an important discovery which has given the world a commercially new product—a product [of] high utility . . . not entitled to protection for want of novelty, would, as it seems to us, be applying the patent statute to defeat its fundamental purposes"); Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 F. 887 (C.C.N.D. Ill. 1909) (holding that the product of a new process of purifying the chemical compound for "asperin" was patentable). For purposes of this paper, artificially created chemical compounds are considered inventions.

^{22.} See Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 164 (4th Cir. 1958).

^{23.} *Id.* at 161-62.

^{24.} *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991) (upholding patent on DNA sequence and corresponding gene even though patentee did not "invent" the gene).

^{25.} Section 102 of the Patent Act bars patentability if "(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed

Parke-Davis & Co. v. H.K. Mulford & Co., the Second Circuit upheld a patent on adrenaline that was isolated and purified from animal suprarenal glands.²⁶ Although the prior art included dried and powdered animal suprarenal glands, the court below had distinguished the patent at issue from the prior art because the patentee's compound was isolated from the animal glands.²⁷ Because no one had yet isolated adrenaline, the court considered the isolated form to be novel. Previously, in an opinion by the lower court, Judge Hand had stated:

[E]ven if it were merely an extracted product without change, there is no rule that such products are not patentable. [The patentee] was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically.²⁸

Or as another court explained over a half-century later, "[t]he existence of a compound as an ingredient of another substance does not negative novelty in a claim to the pure compound."²⁹ Consequently, in determining whether an isolated or purified discovery is novel, the courts do not compare the discovery to the unpurified, naturally occurring form from which it was derived. Instead, the court looks to see if the discovery is already known or patented by others in its new isolated or purified form.

C. The Nonobviousness of Discoveries

¶ 12 Section 103 of the Patent Act denies patentability for an invention or discovery if the claimed item would have been obvious to a person of ordinary skill in the art at the time it was made.³⁰ Unlike the requirement of novelty, which bars the patentability of an item only if its exact replica exists in the prior art, the nonobviousness requirement allows the PTO to reject an item even if it is only *similar* to the prior art. Generally, if there are two or three prior art teachings that, when put together, would suggest the claimed invention or discovery, a patent application for that discovery may receive an obviousness rejection. When determining whether an invention or discovery is obvious, the PTO and the courts can consider the scope and content of the prior art, the differences between what is claimed and what is in the prior art, and the level of skill in the prior art.³¹ Additionally, the courts may consider secondary factors, including, but not limited to: (1) the commercial success of the claimed invention; (2) a demonstrated, long-felt but unresolved need for the claimed invention; and (3) the attempt and failure by others in the

publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of the application for patent in the United States . . ." 35 U.S.C. § 102 (2005).

^{26. 196} F. 496 (2d Cir. 1912).

^{27.} See id. at 497.

^{28.} Parke-Davis & Co. v. H.K. Mulford & Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911).

^{29.} In re Bergstrom, 427 F.2d 1394, 1402 (C.C.P.A. 1970).

^{30. 35} U.S.C. § 103.

^{31.} See Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17 (1966).

art to fulfill the need for which the claimed invention was created.³² Critically, when a court evaluates whether an invention or discovery is obvious, it focuses on the end product that is claimed in the patent rather than the process by which that product is obtained. In fact, section 103 of the Patent Act states that "[p]atentability shall not be negatived by the manner in which the invention was made."³³ A *prima facie* case of obviousness is made only when the claimed compound or composition is structurally similar to some prior art reference(s).³⁴ In unpredictable arts, such as chemistry and biology, a *prima facie* showing of obviousness can be rebutted by evidence from the patentee that the claimed compound has some unexpected utility that is not found in the structurally similar prior art compounds.³⁵ A showing of unexpected utility implicitly suggests that there are, in fact, relevant structural differences that were overlooked.³⁶

¶13 Courts have maintained that they apply the same nonobviousness standard to both discoveries and inventions.³⁷ The nonobviousness inquiry for inventions focuses on whether the structures of the prior art items are similar enough to the claimed item such that it would have been obvious to one skilled in the art how to make the claimed item.³⁸ Although courts have not fully articulated the requirement for discoveries, the analysis seems to be whether the structure of the prior art item is so similar to the claimed item that it would have been obvious to obtain the item and hence make the discovery.³⁹ When evaluating the structure of an isolated or purified chemical discovery, courts have

- 34. In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990).
- 35. See In re Eli Lilly & Co., 902 F.2d 943, 943 (Fed. Cir. 1990).

36. Some commentators have criticized the courts for recognizing unexpected utility as a rebuttal to a showing of structural obviousness. *See* Demaine & Fellmeth, *supra* note 9, at 338 (arguing that the therapeutic value is an improper measure because it mistakes utility for newness). Their argument is that nonobviousness should remain a separate inquiry from utility, especially considering that once an inventor obtains a patent, he or she will have rights to all the subsequently discovered uses of the invention, regardless of whether he or she was the first to discover them. One response to this argument is that a showing of unexpected utility is an indication that the claimed compound is actually quite different, structurally, from the prior art, and that because of the nuanced nature of the chemical and biological arts, one structure may appear to be obvious when, in fact, its subtle differences make it quite unique. *See In re* Papesch, 50 C.C.P.A. 1084, 1097 (1963) (arguing that structure and properties are viewed together for nonobviousness: "[a]n assumed similarity based on a comparison of formulae must give way to evidence that the assumption is erroneous").

37. See In re Deuel, 51 F.3d at 1557-58.

38. *In re* Rouffet, 149 F.3d 1350, 1359 (Fed. Cir. 1988) (stating that the "Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious").

39. In re Deuel, 51 F.3d at 1558.

^{32.} See id. at 17-18.

^{33. 35} U.S.C. § 103; *see* Langston v. Southwestern Bell Tel. Co., No. 90-1229, 1991 U.S. App. LEXIS 21500 (Fed. Cir. Sept. 6, 1991) (invalidating a jury instruction which included a statement that "workmanship of a good mechanic, or engineer or a chemist skilled in the pertinent art is not invention," because "[t]he relevant issue is patentability, not 'invention' and § 103 makes clear that 'patentability shall not be negatived by the manner in which the invention was made"); *In re* Deuel, 51 F.3d 1552, 1557-58 (Fed. Cir. 1995) (stating that unless the patentee is actually claiming a process or method rather than a product, the nonobviousness inquiry should not focus on processes or methods).

looked both at the compound's chemical composition and at the compound's shape.⁴⁰

¶ 14 In its 2001 Utility Guidelines, the PTO reaffirmed that the obviousness inquiry is focused primarily on the structure of the claimed compound.⁴¹ The PTO clearly stated that the methodology or process of isolating or purifying a compound is irrelevant to the issue of obviousness of the compound itself.⁴² This issue will be explored in more detail below.

D. The Utility of Discoveries

¶ 15 In addition to the aforementioned requirements of patentability, a patentee must also identify at least one use of any claimed item.⁴³ The courts have recognized that the patent system is not the arena in which to establish policy regarding whether certain claimed items are immoral or deceptive.⁴⁴ Rather, the patent system requires only that a patentee identify *any* use for an invention.⁴⁵ Thus, prior to the emerging practice of patenting chemical and biological compounds, utility was a fairly lenient requirement.

¶ 16 However, this standard was somewhat altered in *Brenner v. Manson.*⁴⁶ In *Brenner*, the Supreme Court was asked to determine whether a chemical compound produced by the patentee's claimed process was useful (thereby making the process useful) merely because a structurally similar compound was known to be useful.⁴⁷ At issue was a chemical process that created a particular steroid.⁴⁸ The patentee could not show the utility of the steroid produced, but the patentee could show the utility of an adjacent homologue of the steroid.⁴⁹ The adjacent homologue had a tumor-inhibiting effect in mice and therefore had a therapeutic utility.⁵⁰ The Court determined that structural similarity to an adjacent homologue's same utility.⁵¹ Because chemistry is a less predictable art than many mechanical fields, the Court noted that:

Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps

^{40.} *Id.* at 1554 (analyzing whether a specific DNA sequence would have been predictable given that there is a finite number of combinations of nucleotides from which to choose).

^{41.} Utility Examination Guidelines, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001).

^{42.} *Cf. In re* Lalu, 747 F.2d 703, 706 (Fed. Cir. 1984) (stating that an element of obviousness is the motivation of a person of ordinary skill in the art to make it).

^{43. 35} U.S.C. § 101 (2005); Utility Examination Guidelines, 66 Fed. Reg. at 1094 (stating that "[t]he patentee is required to disclose only one utility, that is, teach others how to use the invention in at least one way").

^{44.} See Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999).

^{45.} See id.

^{46. 383} U.S. 519, 522 (1966).

^{47.} *Id*.

^{48.} *Id.* at 531.

^{49.} *Id*.

^{50.} *Id*.

^{51.} Id. at 532.

unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. . . Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.⁵²

¶ 17 The Court found that the patentee failed the utility requirement because he could not show a "sufficient likelihood" that the steroid produced by his process had the same character as its homologue.⁵³ Although *Brenner* primarily concerned a process claim, its analysis focused on, and is applicable to, the utility of chemical compounds themselves.

¶18 The PTO Utility Guidelines echo the *Brenner* Court's sentiment. The Utility Guidelines apply to all types of inventions and discoveries, and they set forth two initial ways that an applicant can satisfy the utility requirement: (1) "it becomes readily apparent that the claimed invention has a well-established utility," or (2) "the applicant has asserted that the claimed invention is useful for any particular practical purpose."⁵⁴ A well-established utility can be shown if a person of ordinary skill in the art can readily perceive the utility of the claimed invention or discovery either by inferring the utility from readily known concepts or by sufficiently analogizing the invention or discovery to similar compounds.⁵⁵ Whether the particular utility is readily apparent to the PTO, or whether the applicant affirmatively asserts a particular utility, the PTO, in keeping with *Brenner*, will consider the particular utility acceptable only if it is specific, substantial, and credible to a person of ordinary skill in the art.⁵⁶ The PTO further clarified that mere "throw away utilities" are insufficient to meet the specific and substantial utility requirement.⁵⁷ Consequently, an applicant cannot, for example, obtain a patent on a genetically-altered mouse by claiming that the mouse could be used as snake food.⁵⁸

¶ 19 The requirement that an invention or discovery's utility be "specific and substantial" is a critical barrier for many applicants seeking to patent genetic sequences. In the past, many applicants have attempted to obtain patents before they knew what a particular sequence could be used for beyond being a research tool to study itself and its corresponding amino acid and protein structures.⁵⁹

58. *Id*.

^{52.} Id. at 534-35.

^{53.} *Id.* at 532.

^{54.} Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001).

^{55.} See id.

^{56.} *Id.*

^{57.} *See* U.S. Patent and Trademark Office, Revised Interim Utility Guidelines Training Materials 7, *available at* http://www.uspto.gov/web/menu/utility.pdf (last visited February 13, 2005).

^{59.} See id. at 5-6 ("For example, a claim to a polynucleotide whose use is disclosed simply as a 'gene probe' or 'chromosome marker' would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.").

III. STRUCTURAL NONOBVIOUSNESS

A. The Purpose Behind the Nonobviousness Requirement

¶20 Section 103 of the Patent Act was enacted to codify, clarify, and amend the case law, which had developed to provide a qualitative standard for patentability.⁶⁰ The purpose of section 103 is to prevent some items from getting a patent because they are mere trivial variations over the prior art and are thus not worthy of a monopoly.⁶¹ Previously, courts had created various standards for determining whether a claimed invention exhibited qualities of inventiveness that entitled it to patent protection as envisioned by the Constitution.⁶² However, the drafters of section 103 chose not to use the word "inventiveness" because of the difficulty in defining the term; instead, they required a showing that an invention was not "obvious."⁶³

¶21 Although the term "inventiveness" is not used in the patent statute, the nonobviousness inquiry focuses upon the contribution that the inventor made to the art, including whether that contribution already existed in some form in the prior art or whether it was unique to the inventor.⁶⁴ Even though courts examine the physical invention to determine whether it would have been obvious to make, it would be an oversimplification to say that the nonobviousness inquiry is limited to whether the inventor structure is obvious. Rather, the more precise question is whether the *inventor* contributed something that was not obvious to others at the time.⁶⁵ Sometimes, the most valuable thing an inventor can contribute to a field is not merely the solution to a problem but, prior to that, the precise identification of the problem. For example, in *Eibel Process Company v. Minnesota & Ontario Paper Company*, the Supreme Court evaluated a patent for an improvement on a papermaking machine that allowed the machine to run at higher speeds, thereby increasing production by twenty to thirty percent.⁶⁶ The patentee's improvement consisted of placing the wire sieve component of the machine at an incline so that the wood pulp would flow over the sieve by gravity at a

65. That the nonobviousness inquiry itself is temporally fixed at the time the invention was made indicates that the court is looking not only at the structure of the invention, but the structure as it is linked to its inventor.

66. 261 U.S. 45, 64 (1923).

^{60.} Judge Giles S. Rich, Laying the Ghost of the 'Invention' Requirement, 1 AIPLA Q.J. 26, 29 (1972).

^{61.} The nonobviousness requirement also aids the PTO in making rejections when its limited resources prevent it from finding an exact prior art reference for a section 102 rejection. *See infra* pp. 21-22.

^{62.} See Rich, supra note 60, at 29.

^{63.} *Id.* at 34.

^{64.} See id. at 26 (stating that Section 103 allows "exclusive rights to inventors only when their inventions would not have been obvious to the ordinary workers in the field, preserving inviolate the common fund of technical knowledge which is obvious to the workers of the art. . . .[a]s a necessary corollary, the disclosure in a valid patent gives to the public knowledge it did not possess, *actually or potentially*, and thereby makes for progress") (emphasis added); *see also* Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966) (stating that as a secondary consideration for nonobviousness, "commercial success . . . might be utilized to give light to the circumstances surrounding the *origin* of the subject matter sought to be patented") (emphasis added).

maximum speed.⁶⁷ The Court stated that "[i]n administering the patent law, the court first looks into the art, to find what the real merit of the alleged discovery or invention is, and whether it has advanced the art substantially," and concluded that:

[O]ne essential part of Eibel's [invention] was that the trouble causing the defective paper product under high machine speed was in the disturbance and ripples some ten feet from the discharge, and that they were due to the unequal speeds of stock and wire . . . Had the trouble which Eibel sought to remedy been [a] well-known difficulty . . . a patent for this improvement might well have been attacked on the ground that he was seeking monopoly for a mere matter of degree. But that is not this case. On the other hand, if all knew that the source of the trouble Eibel was seeking to remedy was where he found it to be and also knew that increased speed of the stock would remedy it, doubtless it would not have been invention on his part to use the pitch of the wire to increase the speed of the stock.⁶⁸

 \P 22 Accordingly, a patentee's inventive contribution includes not merely his or her *solution* to a particular problem, but also the patentee's initial *identification* of what may have been an undefined or elusive problem. In fact, the patentee's particular defining of the problem may shape the solution, and could therefore shape the actual structure of the subsequent invention.⁶⁹

¶ 23 Thus, although courts appear to limit the nonobviousness inquiry to a structural analysis of an invention, this analysis automatically informs the courts about more than structure; it often informs the courts about the inventive contribution of the patentee. While courts do not ordinarily analyze the obviousness of an invention in such painstaking detail, these steps are implicit in any structural examination of an invention.⁷⁰ This is not to say that the inventor's contribution has to be especially important or ingenious,⁷¹ but that the structural examination of the claimed invention guides courts to a recognition of what the *inventor's* contribution was, big or small.

B. Why the Goals of the Nonobviousness Requirement are Achieved by Analyzing an Invention's Structure

¶ 24 In determining whether an invention is obvious, courts first analyze the structure and arrangement of the invention's components. This analysis includes a determination

^{67.} See id. at 52.

^{68.} *Id.* at 67-68.

^{69.} This is not to say that the inner-workings of a claimed invention are always readily apparent from the structure itself; sometimes the patent specification may be helpful or even necessary to understanding how a particular innovation functions in practice.

^{70.} See infra Part II.B.

^{71.} See Rich, supra note 60, at 36 (stating that "[t]he specific intent of that sentence [that "Patentability shall not be negatived by the manner in which the invention was made"], which courts universally accepted without question, was to overrule the *Cuno* case dictum that a 'flash of genius' was necessary").

of what the intended function of each component is, as compared to the function of similar components in prior art. This inquiry ultimately leads courts to a determination of whether those components, or a combination thereof, would have been obvious to a person of ordinary skill in the art. More importantly, as the forthcoming examples indicate,⁷² this structural analysis allows courts to understand *why* the inventor *chose* one particular structure over another.

¶25 An example of how the courts' analysis of an invention's structure is also an analysis of the inventor's contribution can be seen in *In re Conte*.⁷³ There, the court determined that the invention at issue—an insect swatter—was obvious in light of the prior art.⁷⁴ The insect swatter was comprised of an elastic band that was stretched between two ends of a gun, which could be aimed at an insect and from which the band could be released by a trigger mechanism, swatting the insect.⁷⁵ The court reviewed several references in what it determined were analogous arts, including a release mechanism for striking objects with a rubber band by Caron, a toy gun for striking insects by Kopp, and a device that shoots rubber band projectiles produced by Watkins.⁷⁶ In evaluating the structure of the inventor's insect swatter and comparing it to the prior art references, the court focused on the structural components of the invention and specifically on what function each component served.⁷⁷ The court identified structural components of the prior art and then determined what problem those components were designed to solve:

Caron's release mechanism for a device for striking any object with a rubber band is pertinent to addressing the problem of an appropriate release mechanism for a device that strikes insects with a rubber band. Watkins is also analogous art because it addresses the problem addressed in claims 7-10, viz., attaching a rubber band to a mechanical gun and discharging that rubber band in the direction of an object.⁷⁸

The court determined that it would have been obvious to a person of ordinary skill in the art to combine the teachings revealed by the structure of the three prior art references as the patentee did.⁷⁹ Thus in *In re Conte*, while the court's inquiry was clearly focused on the structure of the inventor's insect swatter as compared to prior art structures, the court looked at the structure as an indication of the particular problem the inventor was attempting to solve—i.e., finding an appropriate release mechanism for the fly swatter.

¶ 26 Due to the nature of the nonobviousness inquiry, courts do not look for prior art that is structurally identical to the claimed invention; rather, they examine the prior art for

^{72.} The examples chosen are all of mechanical devices, because the structural components of these inventions are more easily understood than other inventions.

^{73. 36} Fed. Appx. 446 (Fed. Cir. 2002).

^{74.} Id. at 450.

^{75.} Id. at 447.

^{76.} *Id.* at 451.

^{77.} *Id.* at 447-448.

^{78.} Id. at 450 (citations omitted).

^{79.} Id. at 451.

a sense of how others in the field have solved problems. If the prior art taught certain structural choices as a means of solving similar problems, then it is more likely that a person of ordinary skill in the art had all the knowledge needed to make the same invention.⁸⁰

¶27 A detailed articulation of the nonobviousness inquiry can also be found in *National Steel Car, Ltd. v. Canadian Pacific Railway, Ltd.*, where the invention at issue was a "center-beam" flat railway car used to pull lumber.⁸¹ The claimed innovation was that the inventor's railway car was a "drop-deck" car which had a portion of its floor lowered to allow more lumber to fit into the car, also lowering the center of the car's gravity which made it less likely to tip and thus safer to operate.⁸² The defendant argued that the inventor's patent (the "575 patent") was invalid because it was an obvious variation over the prior art, and in particular, over the "Wagner" and "Udstad" prior art patents.⁸³ The Wagner patent "was for a center beam railroad car. The patent covered a car with a lightweight center sill and side sills, cross-bearers supporting the floor, and a vertical center beam joined at its bottom to the center sill and extending longitudinally the length of the car between the bulkheads at each end of the car."⁸⁴ The court found that the '575 patent had something that the Wagner patent did not:

The limitations of the '575 patent that are not present in Wagner are those related to the depressed center or drop-deck. The claims of the '575 patent encompass a car with higher floor sections on the ends and a flat lower section in between. *To achieve this difference in elevation*, the '575 patent also claims a pair of 'side sill assemblies,' running along the outside edges of the floor on both sides of the railcar, that are higher next to the higher end floor sections and lower next to the lower floor section in the middle.⁸⁵

Thus, the court found that the structural difference in elevation between the '575 patent's car and Wagner's car translated into an important functional difference which made the '575 patent's car capable of holding more lumber and being more stable. However, the court then found that what motivated the structural characteristics of the '575 patent's car was not some unique idea, but rather the same idea that motivated the structure of the Udstad prior art car. The court stated:

[In Udstad's patent,] the bottom of the railroad car between the end truck assemblies is lower than the portion over the end truck assemblies because the [cargo] can fit vertically into the railroad car only if this additional space between is utilized. To achieve this lowered center portion, Udstad

^{80.} See Eibel Process Co. v. Minn. & Ont. Paper Co., 261 U.S. 45, 65-66 (1923).

^{81. 357} F.3d 1319, 1322 (Fed. Cir. 2004).

^{82.} *Id.*

^{83.} *Id.* at 1335.

^{84.} *Id*.

^{85.} Id. at 1336 (citation omitted, emphasis added).

teaches a side sill assembly that is also higher on the ends and lower in the center. 86

Although there were still structural differences between Udstad's car and the embodiment in the '575 patent, the court ultimately combined the components of Wagner's car and Udstad's car to find that, together, they "suggest[ed] depressing the bottom of the center portion of the car."⁸⁷

¶28 The court's analysis focused on the structural differences between the three inventions; however, the structural analysis revealed the motivation of each inventor. Thus, the "side sill assemblies" in and of themselves were unimportant. Rather, they became an important component because the inventor of both the '575 patent and the Udstad patent placed the assemblies in a particular position in order to achieve a difference in elevation and create a lowered center car. Because Udstad had already contributed the idea of how to create a lowered center car by placement of the side sill assemblies, the '575 patentee's contribution to the art was no longer viewed as unique. The language used by the court in *National Steel Car* is but one example of how an invention's structure alone is relevant for patent purposes only insofar as it reveals the extent of the inventor's contribution to the art.

¶ 29 One Supreme Court case, Graham v. John Deere Co. of Kansas City, was particularly important in defining the modern standard of nonobviousness.⁸⁸ The patent in question was on a spring clamp in a plow that allowed the "plow shanks to be pushed upward when they hit obstructions in the soil, and then springs the shanks back into normal position when the obstruction is passed over."⁸⁹ A plow incorporating this spring clamp would be better equipped to pass through rocky soils undamaged. In evaluating whether the spring clamp would have been obvious to a person of ordinary skill in the art, the Court looked at plows in the prior art, and found a prior art patent disclosing a spring clamp in a plow with a position that was reverse to that of the patentee's plow.⁹⁰ The patentee claimed that the particular placement of the spring clamp in his plow was different from the prior art because his positioning resulted in a greater degree of flexibility for the plow shanks.⁹¹ Assuming that there were structural differences in arrangement between the patentee's plow and the prior art, the Court determined that the invention was an obvious variation over the prior art because "the mechanical operation is identical," and "a person having ordinary skill in the prior art, given the fact that the flex in the shank could be utilized more effectively if allowed to run the entire length of the shank, would immediately see that the thing to do was what Graham did."⁹² Thus. Graham provides a concrete instance in which the Court derived from the structure of the patentee's plow the patentee's intended function. Moreover, the Court essentially stated

^{86.} *Id*.

^{87.} *Id.* at 1337.

^{88. 383} U.S. 1 (1966).

^{89.} *Id.* at 19-20.

^{90.} *Id.* at 22.

^{91.} *Id.* at 23-24.

^{92.} *Id.* at 25.

15

that the structures of the prior art examples were relevant insofar as they provided one skilled in the art with the kernel of knowledge necessary to create Graham's invention.

¶ 30 The aforementioned cases demonstrate how courts typically infer, directly from the structure of an invention, exactly how an inventor defined and solved a problem, and therefore what the inventor's inventive contribution to the art was. By analyzing why an inventor chose one particular structure over another, courts can determine whether the inventor's choice would have been obvious to a person of ordinary skill in the art. This analysis is not explicit, but is instead an implicit step which the courts can avoid verbalizing when evaluating inventions that are created by the patentee, because the structure itself is a mere embodiment of the idea for which the patentee is being rewarded.

C. How the Courts Have Analyzed the Structure of Isolated and Purified Discoveries to Determine Nonobviousness

¶31 Although this structural approach to nonobviousness functions suitably with inventions, it does not transfer well when applied to discoveries that the patentee finds or extracts. The reason for this disconnect is that the structure of a discovery does not directly disclose the patentee's inventive contribution to the art in the same way that the structure of an invention does. For inventions, the patentee's contribution lies in the identification and solution of a particular problem in the art. The patentee's unique approach and unique solution to the problem is evident from the physical embodiment that the patentee creates. In contrast, for discoveries, the patentee's unique contribution may be in finding or purifying the claimed item where it was before difficult to find or purify it.

 \P 32 With discoveries, there are two separate types of problems that may be solved: (1) the discovered item itself may have characteristics that render it useful in solving some type of problem (such as a medical problem, for example); and (2) there might have been a problem in locating and purifying the item. The patentee who claims the discovered item alone in its pristine form cannot take credit for how the item functions. For example, if the patentee is claiming a DNA sequence that encodes a valuable protein, the patentee cannot take credit for the fact that the certain sequence of nucleic acids interact so that they are read by cellular machinery to create an amino acid, forming a part of a protein. What the patentee can take credit for is having the ingenuity to find a way of isolating or purifying the sequence when those of ordinary skill in the art did not look for it, could not find it, or were unable to isolate or purify it. Or, perhaps, the patentee can take credit for using known methods but applying them to find the desired item in a way that one of ordinary skill in the art would not have done. Put simply, the natural properties of the discovered item cannot be used to measure the patentee's ingenuity. This is not to say that the natural properties may not give courts some guidance. A court could infer, for example, that if the structure and composition of the discovered item were already known, and known to be useful, then the patentee's unique contribution to the art was not the idea to search for the item. Still, the structure of the claimed discovery does not lend itself to the same type of nonobviousness analysis that is used for inventions.

¶ 33 This disconnect has become prevalent in light of improvements in technologies, as patentees have been able to claim more purified and isolated discoveries than before. Nonetheless, as the following examples indicate, courts have not altered the standard of nonobviousness for discoveries, as they continue to rely upon the structural test.

¶ 34 In *Hoffmann-La Roche, Inc. v. Promega Corporation,* the patentee claimed a particular purified thermostable enzyme.⁹³ Although the central issue of the case was whether or not the patentee had engaged in inequitable conduct, the case provides valuable insight into what factors the PTO and the courts use in determining whether a purified or isolating discovery was nonobvious in light of prior art references. The Federal Circuit noted that during prosecution, in response to an anticipation/obviousness rejection, the patentees distinguished their enzyme from another enzyme disclosed in the prior art by making the following two-part argument:

First, they asserted that the claimed enzyme was distinct from the prior art enzyme, citing differences in molecular weight, specific activity, and fidelity. Second, they contended that even if, contrary to their belief, the claimed and prior art enzymes were identical, the claimed enzyme would still be patentable because it was "far more pure" than the enzyme [created in previous] preparations.⁹⁴

The patentee relied on the perceived structural and compositional aspects of the claimed enzyme, such as its molecular weight, salt content, and purity, in order to distinguish it from compounds purified by others in the field.⁹⁵ The patentee noted, for example, that its enzyme had "an estimated molecular weight of 86,000-90,000 daltons when compared with a phosphorylase B [prior art] standard, [which was] assigned a molecular weight of 92,500 daltons."⁹⁶ The patentee also argued that the claimed enzyme had a specific activity that was ten times greater than the prior art enzyme.⁹⁷ Ultimately, the Federal Circuit remanded the case to the lower court for more specific findings on whether the prior art compounds were material in the context of an inequitable conduct claim.⁹⁸ For our purposes, what is important is that the Federal Circuit did not dispute the lower court's use of a structural analysis in determining nonobviousness. There was no discussion regarding why the physical differences between the claimed and prior art enzyme were relevant to the nonobviousness inquiry.⁹⁹

¶ 35 In Johns Hopkins University v. CellPro, Inc., the University's patent claimed "[a]

- 97. *Id.* at 1359.
- 98. *Id.* at 1372.

99. One could argue that the structural analysis in this case was more relevant to the novelty argument than to nonobviousness. However, insofar as the PTO and courts treated the anticipation/obviousness rejection as a single argument and did not delve further into whether it would have been obvious to find or purify the enzyme, the PTO and courts essentially collapsed the obviousness inquiry into the novelty inquiry and eviscerated any qualitative standard for patentability in this case.

^{93. 323} F.3d 1354, 1358 (Fed. Cir. 2003).

^{94.} *Id.* at 1359.

^{95.} *Id.* at 1359-62.

^{96.} *Id.* at 1358-59.

suspension of human cells comprising pluripotent lympho-hemapoietic stem cells substantially free of mature lymphoid and myeloid cells."100 Because the term "substantially free," was vague, the lower court limited this claim to a cell suspension of at least 90% purity.¹⁰¹ On appeal to the Federal Circuit, the accused infringer presented new evidence and argued that the University's patent on a purified stem cell suspension was obvious and therefore invalid because a prior art reference enabled the production of a stem cell suspension of 90% purity.¹⁰² The court did not determine whether the prior art reference did in fact make the patentee's claim obvious; it instead remanded the issue for further fact-finding.¹⁰³ The fact that the court remanded the issue is relevant because it indicates an acceptance of the structural analysis as the legal standard in determining obviousness: the degree of purity of a compound is a structural description of that compound. One could argue that the degree of purity of the stem cell suspension could also inform the court about the patentee's unique contribution to the art because the patentee did something more than what others had done in the prior art in order to obtain a 90% pure suspension. However, the structural inquiry is not specific enough to capture the patentee's unique contribution. The simple fact that a patentee did more work than others in the prior art does not alone meet the nonobvious requirement. Nonobviousness was designed to provide some sort of qualitative standard for determining whether the patentee's contribution is deserving of the patent monopoly. Thus, the fact that the patentee's stem cell suspension was purer than prior art suspensions could mean one of two things: it could mean that the patentee worked longer and more meticulously to refine and purify the suspension using techniques common to the art, or it could mean that the patentee used a unique process or used a known process in some unique way in It is the latter that would be worthy of patent order to purify the suspension. consideration because the latter act would be offering some kernel of knowledge to the art that was not evident before. However, an analysis of the structure of a discovery alone will never differentiate between these two possibilities.

¶ 36 In the case of In re Deuel, the Federal Circuit was directly confronted with determining whether a discovery was obvious, and the court continued the established practice of applying the structural test.¹⁰⁴ The patentee claimed isolated and purified human and bovine DNA sequences and their corresponding amino acid sequences.¹⁰⁵ These sequences ultimately encoded for proteins called "heparin-binding growth factors," which "stimulate mitogenic activity (cell division) and thus facilitate the repair or replacement of damaged or diseased tissue."¹⁰⁶ The PTO rejected Deuel's claims as obvious in light of two prior art references.¹⁰⁷ The Bohlen reference disclosed a protein group called "heparin-binding brain mitogens," which is useful in treating damaged

^{100. 152} F.3d 1342, 1347 (Fed. Cir. 1998) (emphasis omitted).

^{101.} See id. at 1349.

^{102.} Id. at 1356.

^{103.} Id. at 1357.

^{104.} In re Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995).

^{105.} Id. at 1555.

^{106.} Id. at 1554.

^{107.} Id. at 1555-56.

tissue, particularly brain tissue.¹⁰⁸ The Bohlen reference also taught at least part of the amino acid sequence which encode for these proteins, and the first nineteen amino acids of Bohlen's sequence were identical to the first nineteen of Deuel's sequence.¹⁰⁹ The Maniatis reference taught a generic method of isolating DNA sequences using a gene probe and a DNA library.¹¹⁰ The PTO found Deuel's claimed sequences to be obvious over the combined references because:

Bohlen's published N-terminal sequence would have motivated a person of ordinary skill in the art to clone such a gene because cloning the gene would allow recombinant production of HBGF, a useful protein. ... [A] person of ordinary skill in the art could have designed a gene probe based on Bohlen's disclosed N-terminal sequence, then screened a DNA library in accordance with Maniatis's gene cloning method to isolate a gene encoding an HBGF.¹¹¹

¶ 37 The defendants essentially argued that once the amino acid composition was known, there was a finite range of possible DNA sequences that could code for that particular amino acid.¹¹² The court found that the PTO applied the wrong legal standard for obviousness by evaluating the method of making the molecules.¹¹³ The court held that the proper legal standard was whether the claimed compound was structurally similar to a prior art compound, by being for example, a homolog, analog, or isomer of that compound.¹¹⁴ The court noted that:

Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.¹¹⁵

¶ 38 Under this legal standard, the court determined that the Bohlen and Maniatis references provided nothing more than a general motivation to search for some gene but

114. Id. at 1558.

115. Id.

^{108.} Id. at 1556.

^{109.} Id. at 1556 n.5.

^{110. 51} F.3d at 1556.

^{111.} Id.

^{112.} There are a total of four possible DNA nucleotides: adenine, guanine, cytosine, and thymine. A combination of three nucleotides makes up a codon and there are total of sixty-four possible codons. These codons each code for one of the twenty possible amino acids. Thus, many of the amino acids are "degenerate," meaning that more than one codon can code for a particular amino acid. *See* WILLIAM S. KLUG & MICHAEL R. CUMMINGS, CONCEPTS OF GENETICS, 350 (6th ed. 2000). This means that if one knows the amino acid composition of a particular protein, then one cannot automatically know the DNA sequence, because there will remain a finite range of possible codons which could have resulted in the amino acids.

^{113.} In re Deuel, 51 F.3d at 1557.

they did not disclose the particular gene claimed by Deuel.¹¹⁶ The court stated that in this particular case, although there was a finite set of possible DNA sequences that could code for the amino acid, because the range was so broad, much more research was needed beyond the prior art to decipher and extract the exact sequence.¹¹⁷ The court noted, however, that if the range of possibilities were smaller, then its analysis might change.¹¹⁸

¶ 39 Thus, by proceeding from only a structural standpoint, the court evaluated the claimed DNA sequence in a vacuum, without reference to what particular methods were used to obtain the sequence and whether or not those methods were themselves innovative. Once the court framed its analysis in this light, it essentially defined the problem as one of picking the correct structure among a large set of predetermined structures. However, the court did not look further to determine whether this "problem" of picking out the correct DNA sequence from a finite set was difficult in a way which made it deserving of a patent. While the problem very well may have been difficult, requiring creative research, it may also be that the solution involved standard trial-anderror type work. Thus, this analysis could reward the patent applicant with the most workers or the fastest computers, rather than the applicant who provided a creative contribution and some valuable knowledge to the art. A structural examination of a claimed sequence might be useful for comparing it with the prior art and deciding whether or not the prior art provided the "requisite motivation" to the patentee to look for the claimed sequence. But the inquiry should not end with the structure. By evaluating and comparing only the physical appearance of the claimed sequence with other sequences, it is possible that the only thing that the structural analysis accomplished in this case was to reward the patentee for the sweat of his brow.

¶40 The aforementioned cases demonstrate how courts have continued to use a structural analysis when evaluating whether a claimed discovery is obvious over the prior art. Admittedly there have been only a few instances where courts have set forth an indepth analysis of a discovery's structural obviousness; however, these cases provide a stark contrast to how courts use the nonobviousness inquiry in inventions.

D. Why the Goals of the Nonobviousness Inquiry Are Not Achieved by Analyzing the Structure of Discoveries

¶41 In the context of discoveries, a pure structural inquiry serves only one of the two purposes of the nonobviousness requirement. First, the nonobviousness requirement serves as a safety valve for the PTO, which may not always be able to find every pertinent piece of prior art.¹¹⁹ Thus, examiners have some room in which to couch a rejection, even if they cannot find an exact replica of the applicant's claimed invention. This purpose is roughly served by the structural analysis regardless of whether it is

^{116.} See *id.* at 1558-59 (stating that no particular DNA sequence "can be obvious unless there is something in the prior art to lead to the particular DNA and indicate that it should be prepared").

^{117.} Id. at 1559.

^{118.} See id.

^{119.} See John R. Thomas, Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties, 2001 U. ILL. L. REV. 305, 318 (2001).

applied to inventions or discoveries, because if the PTO can find very similar prior art references, it can reject a patent application even if it does not find the exact replica of the claimed item in the prior art. However, the other, arguably more important, purpose of the nonobviousness requirement is to provide some sort of qualitative standard of patentability. In evaluating the standard of patentability, the PTO and the courts are essentially trying to determine what the inventor contributed to the art and whether the inventor's idea, manifested as the embodiment of the invention, is worthy of a patent. Today, this standard is called "obviousness" and not "inventiveness," but these labels do not change the fact that the inquiry is focused on the inventor's abstract contribution and not merely the physical invention.¹²⁰

¶42 The previous examples of mechanical inventions—the fly swatter, the drop-deck railway car, and the plow-show how the nonobviousness inquiry is more than a superficial structural examination of an object. Although the courts in the above examples focused their nonobviousness inquiry on the inventions' structural components, this inquiry necessarily revealed the inventor's contribution to the art. When patent examiners or judges are attempting to understand the structure of an invention, they must necessarily consider the problem the inventor sought to solve and how the inventor chose to solve it by using particular structural components. For example, when the National Steel Car court considered the patented railway car, it learned that the patentee sought to create a railway car that could hold more lumber than previous designs, and it learned the inventor attempted to accomplish this by positioning the side sill assemblies so that they lowered a portion of the floor of the car.¹²¹ Likewise, when the Graham Court considered the patented plow, it learned that the patentee sought to solve the problem of plow shanks being damaged as they run through rocky soils, and that the patentee attempted to do this by adding a spring clamp that added greater flexibility to the shanks.¹²²

¹⁴³ Accordingly, a court or patent agent's examination of an invention's structure reveals not only the invention's visible physical attributes but also the inventor's act of deliberate creation. A structural examination of Graham's plow not only revealed that it was a standard plow with a spring clamp that allowed the shanks to flex, but also the more basic idea that a flexible shank rather than a rigid one could pass over obstructions in the soil undamaged. The Court then determined that this idea was already available in the prior art, based upon the structural innovations already in existence. Consequently, in the case of inventions, when one examines a claimed structure, one cannot help but understand why the inventor chose each component, why a certain size and shape was

^{120.} See generally Richard L. Robbins, Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity, 112 U. PA. L. REV. 1169, 1173-74 (1964) Noting this, the author states:

A thousand monkeys working at a thousand benches for a thousand years is impressive in monkey-hours, but one well-equipped technician would undoubtedly produce superior innovations. Therefore, the quality of research should also be examined. Research by simple repetitive routines should not be the basis for an inference that the solution was not obvious to those skilled in the art.

^{121.} Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd., 357 F.3d 1319, 1322 (Fed. Cir. 2004).

^{122.} Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 19-20 (1966).

chosen for each component, and why the inventor arranged the components in that particular manner. Even the components of an invention that may be substituted by other pieces reveal something about the nature of that invention.¹²³

¶44 On first glance, this analytic step may not seem worthy of discussion because it is inherent in the courts' structural analysis. However, as the cases examining discoveries indicate, this step appears to be absent when courts evaluate the structure of isolated and purified discoveries. When courts examined Deuel's DNA sequence, or the University's stem cell suspension, they did not discuss why the structure of each compound was the way it was—unlike with inventions, the courts in these cases did not decipher the inventive contribution from the patentee by examining the structure of a given DNA sequence or the purity of the stem cell suspension.¹²⁴ The reason is clear—the patentee did not *create* the discovery. While an examination of the structure of an invention has been sufficient to understand the creativity of the inventor, in a discovery the structure is no longer directly relevant to the inventor's contribution. This is because the inventor did not actually make the item; instead the inventor found and purified it. This is not to say that the discovery and extraction of a DNA fragment is any less important for the progress of science. However, the fact that the molecule is or is not structurally similar to other discovered molecules says more about nature's serendipity than it does about human ingenuity. If one of the major goals of the nonobviousness inquiry is to determine what inventive contribution was made to the art, then the courts have gone astray by looking solely at the structure of discoveries.

¶45 The *Deuel* court gave a single justification for why structurally similar prior art would be relevant to the obviousness of a claimed discovery: "[s]tructural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds ... and therefore chemists of ordinary skill would ordinarily contemplate making them ..."¹²⁵ In the context of isolated and purified discoveries, this means that a prior art item may suggest to persons of ordinary skill in the art to *look for* and *purify* other similar structures. However, the court stopped there. While the structure of a prior art item might be construed as the kernel of knowledge that sparked the patentee to begin a voyage to find a similarly useful discovery, the court did not delve further to determine whether, based on the structure of the prior art, it would have been obvious for the patentee to look for the discovery. The court simply concluded that the

^{123.} Because an embodiment is only an example of what the claims of a patent may cover, only the claims themselves limit the scope of the patent. Additionally, the doctrine of equivalence may allow for further flexibility in construing the claims of a patent.

^{124.} In examining discoveries, the courts never attribute the claimed compound's characteristics *to the patentee* as they do for true inventions. In describing how a patentee could rebut a showing of structural similarity of a compound, one court noted that:

[[]U]nless a verified showing is made that the claimed compounds possess unexpected or unobvious beneficial properties not possessed by the homologous (or isomeric) compound of the prior art, and which properties differ in kind from the properties of the prior art compound, *the claimed compounds do not involve invention* over the prior art compound.

Sterling Drug, Inc. v. Watson, 135 F. Supp. 173, 175 (D.D.C. 1955) (emphasis added).

^{125.} In re Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995).

DNA sequence was not obvious because the prior art did not pinpoint the exact sequence for the patentee and the patentee had to do some looking to find it. The bottom line is that the court did not consider whether the "some looking" required in this case was qualitatively a creative contribution to the art or whether it was merely an obvious but labor-intensive endeavor.¹²⁶

IV. THE NONOBVIOUSNESS STANDARD SHOULD ADAPT IN RESPONSE TO THE INCLUSION OF DISCOVERIES AS ELIGIBLE PATENTABLE SUBJECT MATTER

¶46 The reason why discoveries are problematic is because they were the exception to the rule in the first place—patent system reformers had to make a highly formalistic argument in order to justify discoveries as eligible subject matter. However, now that discoveries are patentable, it is useful to evaluate what possibilities exist to better test their obviousness.

A. The Suggestion Test

¶47 Two of the major commentators on this subject, Anita Varma and David Abraham, have argued against the structural nonobviousness standard for DNA claims.¹²⁷ These commentators argue that structural similarity does not work for DNA in particular because of the chemical and biological functions of DNA. Basically, they contend that because extremely minor structural changes in a DNA sequence can significantly affect its function in terms of what protein it encodes, a structural examination is inappropriate.¹²⁸ They further note that in the DNA context, when a showing of unexpected utility rebuts a structural similarity, courts do not have a proper standard to replace the traditional test.¹²⁹ Thus, Varma and Abraham argue that when an applicant claims "a DNA sequence for which the protein it codes is partially or fully known in the art," courts should not apply the structural test; rather, courts should apply a "suggestion

^{126.} The PTO itself has indirectly admitted that the nonobviousness inquiry for discoveries should involve more than a mere structural analysis. In its 2001 Utility Guidelines, the PTO responded to a public comment that pointed out a perceived conflict between the "well-established" utility standard and the nonobviousness standard. A "well-established" utility is shown by analogizing the patentee's item with structurally similar compounds (i.e., homology studies) that have known utilities. The commentator argued that such an analogy would necessarily negate a nonobviousness showing, because if there existed a structurally similar prior art item, it would have provided the requisite motivation for the patentee to look for and find the discovered item. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1096 (Jan. 5, 2001). The PTO rejected this argument, claiming that the nonobviousness inquiry is separate from the utility inquiry, and emphasizing that "[w]here 'the prior art teaches a specific, structurally-definable compound . . . the question becomes whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention [or find the claimed discovery].''' *Id.* at 1097 (quoting *In re* Deuel, 51 F.3d at 1558). Thus, the PTO argued that having a structurally similar prior art item is not enough to render the claimed discovery obvious, or not obvious, because there must be further analysis into whether the prior art informed the patentee as to how to find the discovery.

^{127.} Anita Varma & David Abraham, DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market, 9 HARV. J.L. & TECH. 53 (1996).

^{128.} Id. at 68-69.

^{129.} See id. at 73-80.

test" for these particular claims.¹³⁰ They describe the suggestion test as a showing that "the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art," coupled with the requirement that "the prior art must provide one of ordinary skill in the art a reasonable chance of success."¹³¹ Under the suggestion test, Varma and Abraham argue that the presence of a functional protein automatically suggests the existence of a corresponding DNA sequence, and therefore, *if* there are also known methods of isolating the DNA sequence, *then* the DNA sequence would be obvious.¹³²

¶48 Varma and Abraham are correct to propose an alternate standard to the structural test; however, their rationale is far too limited. They argue against the structural test only for DNA claims because of the way in which DNA functions. While this justification may pinpoint the unique nature of DNA, it does not address the larger problem that occurs with all discoveries: the structural test does not adequately capture the inventive contribution of the patentee. In order for the nonobviousness inquiry to properly focus on what unique teaching the patentee offers the art, the inquiry must look beyond the structure of the discovery, because the patentee has no impact on its structure.

B. Alternative Possibilities for Evaluating the Nonobviousness of Discoveries

¶49 In the context of discoveries, the patentee may have contributed a crucial methodology, or perhaps discovered a use of the compound that was previously unknown. These actions would provide future persons of ordinary skill in the art with particular knowledge that came directly from the inventor. However, it is precisely these questions that one is not permitted to ask when evaluating whether a discovered compound is obvious, because only the discovery's structure may be analyzed.¹³³ As long as discoveries remain patentable subject matter, it is disingenuous to suggest that the structure of a discoveries are a distinct category of patentable subject matter that requires a different analysis. This does not mean that the structures of prior art references as compared to a claimed discovery are completely irrelevant, only that the inquiry must not end there.

¶ 50 There are several ways in which courts could approach this disconnect. First, courts could adopt the "suggestion test" for *all* discoveries, essentially asking whether the discovery was suggested by the prior art and whether the prior art also taught the patentee how to obtain the discovered item. If these two conditions are met, then the discovery would be obvious and unpatentable. A potential problem with this approach is that to some extent, it still requires a type of structural similarity—it would require that the prior art in some way described or suggested the discovery. Thus, even if the methods used to obtain the discovery are well-known, so long as the discovery itself was never before

^{130.} Id. at 56.

^{131.} Id. at 67.

^{132.} *Id.* at 82.

^{133.} In re Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995).

described, then it would likely be nonobvious under the "suggestion" test. The result would be that a patentee who "accidentally" comes across a new and useful discovery while using common methods may be able to obtain a monopoly over the discovery. This would not be altogether disfavored, because one might view the finding of the discovery itself as the patentee's contribution, particularly because the patentee would have to replicate his or her finding of the discovery. Thus, the patentee's contribution would be the path to the discovery. Courts could qualitatively measure the patentee's contribution in such a case by relying more heavily on two specific secondary factors from the *Graham* case: the demonstrated long-felt but unresolved need to find the discovery.¹³⁴

¶ 51 Another possibility would be to grant only an altered version of product-by-process claims for discoveries. A product-by-process claim is unique in that the patent is defined and limited by the process by which a product is made, even though patentability is measured by the product itself. Such claims would specify a product defined only by several process steps.¹³⁵ In order to address the previously mentioned concerns for discovery patents, courts would need to modify the current product-by-process regime by examining only the process and not the product for patentability purposes.¹³⁶ Although a product-by-process claim sets forth one way of making a product, if courts were to construe such claims as covering the identified product regardless of how it was made,¹³⁷ then discoveries would continue to enjoy the same level of patent protection as they currently do, but courts could more rationally focus their nonobviousness inquiry on the process by which the discovery was made. Thus, for patentability purposes, the process must satisfy some standard of inventiveness; however, once that is proven, the patentee would have effectively earned the right to the resulting product, no matter how it is made. It is unclear how well the product-by-process claims would work in the discovery context, since this type of claim has traditionally been reserved for products that have been hard to describe.¹³⁸

V. CONCLUSION

¶ 52 The courts have treated inventions and discoveries as indistinguishable for the purposes of patentability. Although both inventions and discoveries can be important for the progress of science, there is an inherent difference between the two categories that should affect how courts analyze their patentability. An invention is a physical embodiment of the patentee's inventive contribution to the art, whereas a discovery is a

^{134.} See Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966).

^{135.} MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 647 (1998).

^{136.} Even for product-by-process claims, the determination of patentability is based on the product itself, although for infringement purposes, both the product and the process must be infringed. *See* Atl. Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 845 (Fed. Cir. 1992).

^{137.} *Compare* Scripps Clinic & Research Fdn. v. Genentech, Inc., 927 F.2d 1565, 1583 (Fed. Cir. 1991), *with* Atl. Thermoplastics Co., 970 F.2d at 845 (indicating that there are two lines of cases regarding the scope of product-by-process claims).

^{138.} See Irah H. Donner, Combating Obviousness Rejections Under 35 U.S.C. Section 103, 6 ALB. L.J. SCI. & TECH. 159, 229 (1996).

physical manifestation of nature, although the steps taken by the patentee to make the discovery may themselves be akin to inventions. For the purposes of the nonobviousness inquiry, a structural examination of the physical discovery, apart from the process in which it was found, reveals little about a patentee's unique contribution. Consequently, as long as discoveries are to be patentable subject matter, courts should reevaluate the structural test and consider a nonobviousness standard that is more rationally related to the purposes of nonobviousness—namely, determining whether or not the patentee's contribution to the art is qualitatively worthy of a patent. Such a shift would mean that the structural appearance of a discovery would be less important to its patentability, and as a result, the truly unique structures as well as the fairly common structures would be on a level playing field with regards to patentability. This approach would allow the PTO and courts to focus their attention on what a patentee contributed to the public in the way of knowledge, and would more thoughtfully embrace the purposes of the patent system.