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The Technological Edge

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THE TECHNOLOGICAL EDGE

*Elizabeth I. Winston**

To grant a patent to natural phenomena hinders innovation, taking back from the public that which the public has a right to possess. To deny a patent to man's manufacture undercuts the fundamental bargain of the patent system. All inventions, at their core, may be deemed natural, rendering it difficult to distinguish between man's manufacture and natural phenomena. Determining whether the innovative aspect of the product is a technological one, rather than a natural one, can clarify whether the patent grant promotes the progress of science and the useful arts. The higher the level of skill in the art required to innovate, the less likely it is that the invention is already in the public domain. The technological edge provides the distinction between man's manufacture and nature's handiwork.

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I. "COULD YOU PATENT THE SUN?"¹

Protecting the bargain inherent in the patent system is central to the determination of patentable subject matter. If an applicant invents something novel, non-obvious, and useful and provides a written description that enables others to practice the invention, then the applicant is rewarded with the right to exclude others from making, using, selling, or offering to sell for a limited time the invention.² The Patent Act provides an incentive to invest in innovation leading to new inventions³ and "reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'"⁴

The courts have defined several exceptions to patentable subject matter, including "laws of nature, natural phenomena, and abstract ideas."⁵ Natural phenomena are not patentable⁶ because such protection "would withdraw access to information already in the public domain."⁷ No incentive to innovate is necessary when the innovation exists already: such incentive is needed only for those "inventions which would not be disclosed or devised but for the inducement of a patent."⁸ Such inventions are those "made by man," not merely those discovered in nature.⁹

1. JANE S. SMITH, PATENTING THE SUN: POLIO AND THE SALK VACCINE (1990) (Jonas Salk responding to a question about patenting the polio vaccine in a television interview with Edward R. Murrow.)

2. 35 U.S.C. §§ 101-103, § 112, § 271.

3. See, e.g., JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 11 (2008) (an incentive, it has been argued, that is failing).

4. *Bilski v. Kappos*, 130 S. Ct. 3218, 3252 (2010) (Stevens, J., concurring) (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989)).

5. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

6. *O'Reilly v. Morse*, 56 U.S. 62, 114-18 (1853) (noting the discovery of a principle in natural philosophy or physical science is not patentable).

7. Alan L. Durham, "Useful Arts" in the Information Age, 1999 BYU L. REV. 1419, 1427 (1999).

8. See *Bilski*, 130 S. Ct. at 3252 (Stevens, J., concurring) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966)).

9. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 1979-82, at 5 (1952)); H.R. REP. NO. 1923-82, at 6 (1952) ("This same language was employed by P. J. Federico, a principal draftsman of the 1952 recodification, in his testimony regarding that legislation: '[U]nder section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man. . . .'" *Hearings on H.R. 3760 Before Subcommittee No. 3 of the House Committee on the Judiciary*, 82d Cong., 37 (1951); *Chakrabarty*, 447 U.S. at 309 n.6.

What is nature's handiwork as opposed to man's manufacture? "Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.'"¹⁰ The term itself is "vague and malleable . . . infected with . . . ambiguity and equivocation."¹¹ The Supreme Court has held that phenomena of nature are not patentable and that the relevant distinction is "between products of nature, whether living or not, and human made inventions."¹² To carry this distinction to its extreme could render "all inventions unpatentable because all inventions can be reduced to underlying principles of nature."¹³

Distinguishing between man's manufacture and natural phenomena requires analysis of the innovative aspect of the invention. The more sophisticated the manipulation is, the more likely the patent bargain is upheld through the grant of a patent. Man manipulates nature in patentable ways. Such manufactures uphold the patent bargain, promote innovation, and have been deemed worthy of patent protection, regardless of their natural origins. The distinction can be informed by asking what the educational background of the inventor and those working in their field is, what technology the invention requires, and what types of problems are encountered in the art. The greater the sophistication, the less likely the invention is already in the public domain.

Could you patent the sun?¹⁴ No, to do so would be to betray the patent bargain. However, patent protection should be extended to man's manufacture, and patenting such is in the interest of the common good. The technological edge distinguishes between man's manufacture and nature's handiwork.

II. TOO MUCH PATENT PROTECTION?

"[A] patent cannot be taken out solely for an abstract philosophical principle—for instance, for any law of nature."¹⁵ "[T]he reason for the exclusion is that sometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the

10. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132 (1948).

11. *Id.* at 134-35.

12. *Chakrabarty*, 447 U.S. at 306.

13. *Diamond v. Diehr*, 450 U.S. 175, 189 n.12 (1981).

14. Stephan Kinsella, *Mises Economics Blog: Patent and Penicillin*, LUDWIG VON MISES INSTITUTE (June 22, 2006), <http://blog.mises.org/5216/patent-and-penicillin/>.

15. *Le Roy v. Tatham*, 63 U.S. 132, 137 (1859).

constitutional objective of patent and copyright protection.”¹⁶ Providing patent protection for inventions already in the public domain impedes progress by preventing the public from practicing that which they formerly had the right to do so. When does the balance weigh in favor of granting patent protection to an innovation both natural and technological in substance?

In 1948, the Supreme Court invalidated a patent for “the discovery of a natural phenomenon, or of a quality or attribute of a well-known article and application of that quality in a successful combination which is of value to mankind.”¹⁷ In *Funk v. Kalo*,¹⁸ the inventor received a patent for “a mixture of six bacteria for use in fixing nitrogen in legumes.”¹⁹ Prior to the filing of this patent, scientists had spent many years isolating:

[I]ndividual strains of bacteria of the several cross-inoculation groups and [testing] the strains by a scientific test procedure that is known to all bacteriologists in this field, to determine the effectiveness of the various strains of the bacteria so that they could discard the weak strains and retain the strong strains from which a bacterial culture of value could be produced for use in the manufacture of satisfactory inoculants.²⁰

The inoculants, or bacteria, do not co-exist in a mixed environment in nature.²¹ Scientific research was necessary to isolate the individual inoculants, even though they are naturally occurring.²² Agroecological advances allowed the patentee to discover that strains of inoculants could be mixed without inhibiting the abilities of the inoculants to fix nitrogen to different plants.²³ This was contrary to popular belief and required extensive testing, research and skill to maximize the fixation

16. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126-27 (2006) (Breyer, Stevens & Souter, JJ., dissenting from dismissal of writ of certiorari).

17. Brief for Petitioner, *Funk v. Kalo*, 333 U.S. 127 (1948) (No. 280), 1947 WL 44426 at *5.

18. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948).

19. Edmund J. Sease, *From Microbes, to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms*, 38 *DRAKE L. REV.* 551, 556 (1989).

20. Brief for Petitioner, *supra* note 17, at *5.

21. In *Funk v. Kalo*, the Supreme Court only addressed product claims, not method claims. The product was found to be a phenomena of nature—the method of mixing the inoculants was not addressed. *Funk*, 333 U.S. at 130 (“We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable. We have here only product claims.”).

22. Brief for Petitioner, *supra* note 17, at *5 (“[S]cientists were not long in discovering that in the various species of bacteria of the several cross-inoculation groups there existed many individual strains of bacteria and that they vary greatly in their natural ability to fix nitrogen in the plants for which they are specific.”).

23. *Id.* at *5.

rates.²⁴ It is not denied that this discovery represented a tremendous commercial advance, but despite that, the patent was held invalid. The mixture of inoculants was held to be a natural phenomenon, even though it did not exist in nature, because “however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants.”²⁵ Holding that “[t]he qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men,” the Supreme Court found that no incentive was needed for this invention.²⁶ Such “manifestations of laws of nature [are] free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes.”²⁷ The patent bargain failed here, and the disclosure to the public was not worthy of the right to exclude others because patent protection here could impede progress.

Shortly after *Funk*²⁸ was decided, Dr. Jonas Salk invented the polio vaccine but did not patent it. When asked why, he responded, “Could you patent the sun?”²⁹ He did not argue that it was a natural phenomenon, nor did he address the question of whether the vaccine was a discovery or a technological advance.³⁰ The more interesting question to ask Dr. Salk would have been whether the vaccine ought to have been patentable. As the recipient of a subsequent vaccine patent, his answer

24. *Id.* at *9 (quoting U.S. Patent No. 2,200,532) (“The reason for the alleged invention is, according to Bond, that prior to him “It has heretofore been considered impracticable to prepare a composite culture inoculant containing organisms which will cause nodulation on more than one of the cross-inoculation groups. This has not been done because it was generally believed that one species produced an inhibitory effect on another species within the same culture whereby symbiotic nitrogen fixation by the plant and the organism was inhibited or even prevented.”).

25. *Funk*, 333 U.S. at 131.

26. *Id.* at 131.

27. *Id.*

28. *Id.* at 132.

29. SMITH, *supra* note 1.

30. *Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts and Intellectual Property of the H. Comm. on the Judiciary*, 106th Cong. 121 (2000) (statement of Todd Dickinson, Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office), available at <http://www.uspto.gov/web/offices/ac/ahrpa/opa/bulletin/genomicpat.pdf> (“Thank you very much for inviting me to testify today on the patenting of genes and other genomic inventions. As you know, patents in this cutting-edge area of biotechnology are a topic of considerable interest and debate in many circles. While some of this debate is unfortunately fueled by misinformation, legitimate questions have been raised about just what genomic discoveries, if any, should be patentable and whether genomic patents will inhibit researchers’ access to the data, materials, and methods needed to develop new tools for the diagnosis and treatment of disease.”).

may have been different.³¹ What is a vaccine? It's not a natural phenomenon, but a man-made manipulation of nature. "A vaccine contains a small amount of . . . a protein from the virus, or a weakened or inactive virus."³² A virus that is found in nature and through technology is isolated and transmitted to otherwise healthy recipients.³³ Dr. Salk was celebrated for not patenting his polio vaccine, yet no one questioned whether the vaccine ought to be patentable. The vaccine as administered is not a natural phenomenon, and it should not be patentable. Technology isolates and purifies the vaccine, resulting in a technological innovation, not a natural one.³⁴

In 2001, the Supreme Court found a seed³⁵ constituted patent-eligible subject matter.³⁶ This seed was the product of research in a lab, and produced hybrid corn when planted.³⁷ Representing an important commercial advance, the seed was not found to be a natural phenomenon, but was held to be patentable subject matter—implicitly

31. U.S. Patent No. 5,256,767 (filed Oct. 26, 1993).

32. Interview with Judith Tan, News Correspondent, Straits Times, in Sing. (Sept. 19, 2009), available at <http://160.96.186.100/lib/pdf/2009/Sept/ST1926.pdf>; see also *Vaccines: What is a Vaccine?*, NAT'L INST. OF ALLERGY AND INFECTIOUS DISEASES, <http://www.niaid.nih.gov/topics/vaccines/understanding/Pages/whatVaccine.aspx> (last visited Sept. 14, 2011) ("Traditional vaccines contain either parts of microbes or whole microbes that have been killed or weakened so that they don't cause disease. When your immune system confronts these harmless versions of the germs, it quickly clears them from your body. In other words, vaccines trick your immune system to teach your body important lessons about how to defeat its opponents.")

33. Interview with Judith Tan, *supra* note 32 ("The antigen, while not harming the person, stimulates the body's immune system to recognize and remember the virus, so it will produce antibodies to destroy the actual virus if it strikes.")

34. See U.S. Patent No. 2,787,577 (issued April 2, 1957) (indeed, Eli Lilly applied for a patent on a smallpox vaccine in 1953).

35. J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 127 (2001) ("The United States Patent and Trademark Office (PTO) has issued some 1,800 utility patents for plants, plant parts, and seeds pursuant to 35 U.S.C. § 101. Seventeen of these patents are held by respondent Pioneer Hi-Bred International, Inc. (Pioneer). Pioneer's patents cover the manufacture, use, sale, and offer for sale of the company's inbred and hybrid corn seed products. A patent for an inbred corn line protects both the seeds and plants of the inbred line and the hybrids produced by crossing the protected inbred line with another corn line. See, e.g., U.S. Patent No. 5,506,367, col. 3, App. 42. A hybrid plant patent protects the plant, its seeds, variants, mutants, and trivial modifications of the hybrid. See U.S. Patent No. 5,491,295, cols. 2-3, *id.*, at 29-30.")

36. *Id.* at 145 ("For these reasons, we hold that newly developed plant breeds fall within the terms of [35 U.S.C.] § 101.")

37. Pioneer Hi-Bred Int'l Intern. v. Holden Found. Seeds, Inc., 35 F.3d 1226, 1228 n.2 (8th Cir. 1994) ("Hybrid' corn seed is produced by planting two inbred parents together and allowing pollen from one inbred (used as the male parent) to fertilize silks on the other inbred (used as the female parent). In corn, inbred lines are lines developed by self-pollination and selection until the line is relatively homozygous. Inbred lines may be 'public' if developed and released by a public university, or 'private' if developed by a private entity.")

suggesting that the seed must be the product of man.³⁸ The “relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.”³⁹

Over one hundred years after the Supreme Court first held that natural phenomena are not patentable, companies continue to obtain protection for “products capable of being ‘reproduced by nature unaided by man,’”⁴⁰ as clear a definition as we have for natural phenomena. If a farmer plants the patented seed, it will grow and produce more seeds, at least some of which will be identical to the planted seed—a product reproduced by nature, unaided by man. The hybrid corn seed is such a product, and the bacteria mixture is not, yet the first is patentable, and the latter is not.

III. THE TECHNOLOGICAL EDGE

Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten. One way in which patent law seeks to sail between these opposing and risky shoals is through rules that bring certain types of invention and discovery within the scope of patentability while excluding others.⁴¹

To maintain this balance and to draw a line between products of nature and man-made manipulations of patentable subject matter require analysis of the degree of sophistication required to produce the end product. The combination of inoculants was not found patentable in *Funk*, for “[e]ven though it may have been the product of skill, it certainly was not the product of invention. There is no way in which we could call it such unless we borrowed invention from the discovery of the natural principle itself.”⁴² One hundred years earlier, in defining

38. *J.E.M.*, 534 U.S. at 144 (citing *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)) (“[t]he plain meaning of § 101 ... clearly includes plants within its subject matter.”).

39. *Id.* (quoting *Chakrabarty*, 447 U.S. at 313).

40. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1363 (Fed. Cir. 2005) (Gajarsa, J., concurring) (“The principle unifying these statements about patentability made in 1930, 1980, and 2001, is that products capable of being “reproduced by nature unaided by man,” ... are not patentable subject matter under section 101.”).

41. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (2006) (Breyer, Stevens & Souter, JJ., dissenting from dismissal of writ of certiorari).

42. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948) (“The application of this newly-discovered natural principle to the problem of packaging of inoculants may well have been an important commercial advance. But once nature’s secret of the non-inhibitive quality of certain strains of the species of *Rhizobium* was discovered, the state of the art made the production

what was patentable, the Supreme Court held that where “the improvement is the work of the skillful mechanic, not that of the inventor,” then the improvement is not patentable.⁴³ Replace the concepts of skill with discovery, and invention with technology, and we start to see a test for determining whether a product is patentable. If the innovative aspect is technological, rather than a discovery of a natural phenomenon, then rewarding the patentee provides incentives to innovate, adds to the “storehouse of knowledge of all men,”⁴⁴ upholds the patent bargain, and does not lead to overprotection.

As early as 1853, the Supreme Court raised the idea of a technological edge in patentability:

Undoubtedly, the principle that hot air will promote the ignition of fuel better than cold, was embodied in this machine. But the patent was not supported because this principle was embodied in it [H]is patent was supported, because he had invented a mechanical apparatus, by which a current of hot air, instead of cold, could be thrown in. And this new method was protected by his patent. The interposition of a heated receptacle, in any form, was the novelty he invented.⁴⁵

The novelty was not the principle, but the technology surrounding the principle: “a scientific truth . . . is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”⁴⁶

In 1943, streptomycin was first discovered.⁴⁷ In 1948, it was the subject of United States Patent No. 2,449,866, which contains 13 claims,

of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention. There is no way in which we could call it such unless we borrowed invention from the discovery of the natural principle itself. That is to say, there is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed. All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough.”)

43. *Hotchkiss v. Greenwood*, 52 U.S. 248, 267 (1850) (“Now if the foregoing view of the improvement claimed in this patent be correct, it is quite apparent that there was no error in the submission of the questions presented at the trial to the jury, for unless more ingenuity and skill in applying the old method of fastening the shank and the knob were required in the application of it to the clay or porcelain knob than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. In other words, the improvement is the work of the skillful mechanic, not that of the inventor.”).

44. *Funk*, 333 U.S. at 130.

45. *O'Reilly v. Morse*, 56 U.S. 62, 115-16 (1853).

46. *Mackay Radio & Tel. Co. v. Radio of Am.*, 306 U.S. 86, 94 (1939).

47. See Albert Schatz, *The True Story of the Discovery of Streptomycin*, IV ACTINOMYCETES 2, at 27-39 (Aug. 1993), available at <http://www.albertschatzphd.com/?cat=articles&subcat=>

the last claim of which simply reads “Streptomycin.”⁴⁸ The first antibiotic found effective for the treatment of tuberculosis, streptomycin was the subject of the 1952 Nobel Prize in Physiology or Medicine.⁴⁹ Streptomycin was “a milestone in the history of drugs to treat tuberculosis and other infections,”⁵⁰ proving invaluable “as a remedy against infectious diseases in humans.”⁵¹ This discovery was the result of scientific research and was not a fortuitous event. It required the isolation of various strains of bacteria, an incredible knowledge of soil engineering, teamwork, and numerous tests to understand what the properties of this antibiotic were. Despite this, streptomycin exists in nature—in the barnyard dirt of chicken houses and in the mycelial bacteria *Actinomycetes*.⁵² The director of the lab where streptomycin

streptomycin&itemnum=001 (“I isolated two strains of *Streptomyces griseus* from two separate sources. Both strains produced streptomycin. And streptomycin was effective against both gram-negative bacteria and the tubercle bacillus. I called one strain of *S.griseus* 18-16 because it was the 16th actinomycete I isolated from a heavily manured field soil. That was the 18th soil from which I obtained actinomycetes to test for antibiotic activity (Schatz, 1945). I isolated another strain of *S.griseus* from a petri dish which my fellow graduate student Doris Jones, now Doris Ralston, had streaked with a swab from a healthy chicken’s throat On October 19, 1943, I realized I had found a new antibiotic, and decided to call it streptomycin.”).

48. U.S. Patent No. 2,449,866 (filed Feb. 9, 1945).

49. Schatz, *supra* note 47 (“also produced in that basement laboratory the streptomycin which Doris Jones et al. used in the first *in vivo* tests at Rutgers (Jones et al., 1944), and which Feldman used for the first toxicity tests and the first animal experiment with the tubercle bacillus at the Mayo Clinic.”); A. Wallgren, Award Ceremony Speech for the Nobel Peace Prize in Physiology or Medicine (1952), available at http://nobelprize.org/nobel_prizes/medicine/laureates/1952/press.html# (“Professor Selman Waksman. The Caroline Medical Institute has awarded you this year’s Nobel Prize for Physiology or Medicine, for your ingenious, systematic and successful studies of the soil microbes that have led to the discovery of streptomycin, the first antibiotic remedy against tuberculosis.”).

50. Schatz, *supra* note 47.

51. A. Wallgren, *supra* note 49.

52. Terry Sharrer, *The Discovery of Streptomycin*, 21 THE SCIENTIST 8, 96 (2007), available at <http://classic.the-scientist.com/article/display/53395/>; See also Veronique Mistiaen, *Time and the Great Healer*, THE GUARDIAN, Nov. 2, 2002, available at <http://www.guardian.co.uk/education/2002/nov/02/research.highereducation> (“After just three and a half months, and against all the odds, Schatz’s hard work paid off. He isolated not one but two highly active strains of actinomycetes (subsequently renamed *Streptomyces griseus*), which stopped the growth of several virulent bacteria known to resist penicillin, including the dreaded tubercle bacillus. One strain had come from heavily manured field soil; the other from a swab from the throat of a healthy chicken, which Ralston had passed him through the basement window after she had finished working with it. “On October 19 1943, at about 2pm, I realised I had a new antibiotic,” says Schatz. “I named it streptomycin. I sealed the test tube by heating the open end and twisting the soft, hot glass. I first gave it to my mother, but it is now at the Smithsonian Institution. I felt elated, and very tired, but I had no idea whether the new antibiotic would be effective in treating people.”).

was first isolated is referred to as the “father of antibiotics,”⁵³ and streptomycin is an antibiotic still used today.

The grant of a patent to streptomycin did not withdraw access to information in the public domain because the naturally occurring phenomenon was not accessible without considerable scientific research and investment. Promotion of progress was accomplished in this discovery, and the reward of the right to exclude others provided an incentive for this research—an incentive that can be seen from Merck’s early investment in the research and from the rapid grant of the Nobel Prize for a natural phenomena. The validity of this patent remained untested by the judicial system. The fact that the Patent Office has issued a patent provides only a presumption of validity and does not mean that the patent will not later be found invalid by the judicial system. If found to be a natural phenomenon, streptomycin would not be patentable. However, the innovative aspect of streptomycin is a technological one, not a natural one, leading to the conclusion that streptomycin is a man-made manipulation of nature, and therefore, eligible for protection under 35 U.S.C. § 101. The progress of the useful arts would not be impeded by the grant of such a patent.

In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the innovative aspect was discovering that different inoculants as they existed in nature did not inhibit each other’s growth.⁵⁴ This was a discovery, not a technological innovation. The mixed inoculant was the product of research, but the innovation was nothing more than a natural phenomena. It was novel to mix inoculants, but to patent such a product would be to take from the public something the public could access and had the right to.

In *J.E.M. Hi-Bred v. Pioneer*,⁵⁵ the innovative aspect was an engineered hybrid corn seed, which was the product of technological innovations in the lab and the field.⁵⁶ The innovative aspect was the agricultural biotechnology that created a novel seed different from that which nature would have created on its own in the same time period.⁵⁷ Technology aided the public by providing a means to change the heart and soul of the corn seed. A farmer could plant the seed and grow new

53. Mistiaen, *supra* note 52.

54. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948).

55. *J.E.M. Hi-Bred v. Pioneer*, 534 U.S. 124 (2001).

56. *Id.* at 127.

57. *Observations on Competition in the U.S. Seed Industry*, MONSANTO, <http://www.monsanto.com/newsviews/Pages/monsanto-submission-doj.aspx> (last visited Sept. 15, 2011) (“The U.S seed industry experienced two main periods of technology-driven change in the 20th century, first with the development of hybrid seeds in the 1920s, then with the introduction of seeds improved through modern biotechnology in the 1990s.”).

seed without the aid of a laboratory, but the research and development that bypassed time and nature gave the public something innovative and worth protecting.

The innovative aspect of mixing varieties of bacteria is natural, showing ingenuity, but not inventiveness. To modify seed, even through cross-breeding, requires inventiveness and ingenuity. To find an antibiotic growing in soil, and cultivate it so that man can use it, is worthy of both a Nobel Prize and a patent. The same can be said of the isolation, purification, and replication of human insulin.⁵⁸ The difference between these advances “reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’”⁵⁹ We differentiate based on the heart and soul of the invention, and upon a determination of how to best maintain the balance essential to the patent bargain.

IV. “[T]O PROMOTE THE PROGRESS OF SCIENCE AND THE USEFUL ARTS”

In carrying out the intent of this Constitutional directive, our Founding Fathers designed an extremely flexible patent system based on principles that have proven remarkably suitable to 210 years of unceasing technological advancement. Indeed, one of the key tenets of our patent system is that it is technology-neutral; from gearshifts to genomics, it applies the same norms to all inventions in all technologies While some are critical of this aspect of the patent system, the uniformity and facileness of the patenting standards of novelty, obviousness, and utility—coupled with the incentives patents provide to invent, invest in, and disclose new technology—have allowed millions of new inventions to be developed and commercialized. This has enhanced the quality of life for all Americans and helped fuel our country’s transformation from a small, struggling nation to the most powerful economy in the world. Equally as impressive, the patent system has done all this without the need for Congress to constantly retool the law—a powerful testament to the system’s effectiveness in simultaneously promoting the innovation and dissemination of new technologies.⁶⁰

How do we determine when an innovation is a natural one and when it is a technological one? Why is a bacteria mixture not patentable

58. U.S. Patent No. 1,469,994 (filed Jan. 12, 1923).

59. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

60. *Gene Patents*, *supra* note 30.

subject matter, but a purified virus and a hybrid seed is? If we ask whether the advance is the result of the technological arts, or simply harnessing nature, then we can more readily understand whether a patent is an appropriate award or not. The technological edge can distinguish between man's manufacture and nature's handiwork. Several factors⁶¹ are worth evaluating, based on a determination of the level of ordinary skill in the art including:

- The types of problems encountered in the art;
- The sophistication of the technology involved; and
- The educational background of those actively working in the field.

A. Educational Level of the Inventor and of Workers in the Field

The higher the educational level of the inventor and the workers in the field, the less likely it is that the public has already received the benefit of the invention—even if the invention is more of a discovery, and less of a creation. To determine the level of one of ordinary skill in the art, many factors must be examined, but among the more important of these factors is the educational level. Typically, the educational level receives short shift in briefs⁶² and is often not even an issue before the Federal Circuit⁶³ in their review of the district court's findings. As pointed out in a recent case, “[o]ther than to describe one of the inventors as ‘one of America’s best-known entrepreneurs’ who holds 200 patents in multiple fields, there is nothing in the record detailing the

61. These factors are based on the AM. INTELLECTUAL PROP. LAW ASS'N, MODEL PATENT JURY INSTRUCTION 7.3, available at http://www.aipla.org/learningcenter/library/books/other-pubs/Documents/2008_03_27_AIPLA_Model_Jury_Instructions.doc (“When determining the level of ordinary skill in the art, you should consider all the evidence submitted by the parties, including evidence of: . . . the level of education and experience of persons actively working in the field at the time of the invention, including the inventor; . . . the types of problems encountered in the art at the time of the invention; and . . . the sophistication of the technology in the art at the time of the invention, including the rapidity with which innovations were made in the art at the time of the invention.”); see also *Jacobson Bros., Inc. v. United States*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *Envtl. Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 697 (Fed. Cir. 1983); *Walker Digital, LLC v. Capital One Servs., LLC*, No. 1:10cv0212 (JFA), 2010 WL 2346642, at *2 (E.D. Va. June 8, 2010).

62. See, e.g., *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256-57 (Fed. Cir. 2007) (“In making its determination regarding the level of skill in the art, the district court noted that the parties had provided ‘little more than conclusory arguments concerning this issue in their briefs. As a result, the court looked to other decisions involving patents for a method of treating a physical condition for guidance.’”).

63. See, e.g., *Envtl. Designs*, 713 F.2d at 697 (“[T]he parties are in agreement that their respective chemical expert witnesses with extensive backgrounds in sulfur chemistry are persons of ordinary skill in the art”).

two inventors' educational level or experience at the time the patent application was filed."⁶⁴

When the educational level of the inventor is evaluated, it can be distinctly illuminating, often informing the level of education of workers in the field as well.⁶⁵ The level of sophistication of the innovation focuses on what benefit the public receives, not on whether an invention is obvious or not.

Inventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system, possess something—call it what you will—which sets them apart from the workers of *ordinary* skill, and one should not go about determining obviousness under § 103 by inquiring into what *patentees* (i.e., inventors) would have known or would likely have done, faced with the revelations of references.⁶⁶

The Federal Circuit has found a range of educational levels of inventors, corresponding to a range of technologies at issue. Distinguishing between various levels of medical practitioners in one case, the Federal Circuit wrote:

The inventors of [U.S. Pat. No. 5,401,741] were specialists in drug and ear treatments—not general practitioners or pediatricians. At the time of the invention, Inventor Sato was a university professor specializing in otorhinolaryngology; Inventor Handa was a clinical development department manager at Daiichi, where he was involved with new drug development and clinical trials; and Inventor Kitahara was a research scientist at Daiichi engaged in the research and development of antibiotics. Additionally, others working in the same field as the inventors of the '741 patent were of the same skill level.⁶⁷

Showing the relationship between the various factors involved in the determination of what the level of skill is, and correspondingly, the

64. *Walker Digital*, 2010 WL 2346642, at *5 n.1.

65. *See, e.g., Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718-19 (Fed. Cir. 1991) (“Appellee’s uncontested evidence indicated that two of the three inventors of the patented device have engineering degrees. One designer of an accused infringing product has a masters degree in electrical engineering, and another has worked in the electronics industry for 28 years. Moreover, the prior art teaches that powered system activation devices utilize sophisticated electronic devices. Based on the undisputed evidence before it and all justifiable inferences flowing therefrom, the court must have resolved the level of ordinary skill in the art as being that of an engineer with low to medium capability in the technology of powered system activation devices. This resolution of the level of ordinary skill in the pertinent art, presenting no genuine issues of material fact, is sufficient to shed light on the obviousness inquiry.”).

66. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985).

67. *Daiichi Sankyo*, 501 F.3d at 1257.

determination of whether a discovery is technological in nature, the Federal Circuit referred to the problem the invention was seeking to solve in justifying the educational level of workers in the field. The problem was:

[T]o create a topical antibiotic compound to treat ear infections (otopathy) that did not have damage to the ear as a side effect [and] [s]uch animal testing is traditionally outside the realm of a general practitioner or pediatrician [who] would not have the training or knowledge to develop the claimed compound absent some specialty training such as that possessed by the '741 patent's inventors.⁶⁸

Again, showing this relationship between the problem to be solved and the level of education, in another case, one party argued "persons of ordinary skill in the art possess hands-on experience and little formal engineering education."⁶⁹ The Federal Circuit determined that the problem to be solved "demands a technical sophistication and a level of professional skill commensurate with the hazardous nature of the work."⁷⁰ Directly commensurate with the benefit to the public, parallels can be drawn between the technical sophistication of the inventor, the educational requirements to solve the problem at hand, and the technological aspect of the invention.

Determining the level of education and experience of persons actively working in the field at the time of the invention as well as the level of skill of the inventor delineates the question of what benefit the public receives. Understanding what the educational level is underlies the question of the technological nature of the invention as distinct from the other factors, including what the prior art is. In this aspect, there must be a greater showing of evidence than typically accompanies this element in an argument over what the level of ordinary skill is.⁷¹ Again, the more specialized the knowledge required to identify, distinguish, or discover the invention, the greater the benefit the public may receive from the disclosure to the Patent Office. The more difficult the discovery, the more probable it is that the discovery is one technological in nature rather than human. The discovery resulting from the

68. *Id.*

69. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

70. *Id.*

71. *See, e.g., Ryko Mfg. Co. v. Nu-Star, Inc.*, 920 F.2d 714, 718 (Fed. Cir. 1991) ("Appellee's evidence shows that most of the personnel developing the new activation device for Ryko had attained an engineering degree at the minimum. However, appellant's expert vaguely described the level of ordinary skill in the art as being 'low to medium.'").

knowledge of the inventors retains the technological edge when the benefit to the public is one that is not otherwise obtainable.

B. Types of Problems Encountered in the Art

What was the level of art at the time of the invention? Similar to the question of the educational level above, there is a strong correlation between public benefit and the level of technology required to learn about the problems in the art. The greater the technology required to discover problems in the art, the less likely it is that such problems have already been discovered, and the greater the benefit to the public of disclosing such problems and its solutions through the patent system. As with education, the discovery is more likely to retain the technological edge when the benefit to the public is one the public could not obtain without the sophistication necessary to understand the problems inherent in the art.

In order to determine when an innovation is man's manufacture and when it is nature's handiwork, the court must look at the prior art solutions: evaluating the nature of the solutions, the time spent in determining the solutions, the incentives provided for such solutions, and the very character of the art surrounding the problem and its solutions. Prior art solutions may show that the solution to this problem is a natural one, even if the technique of reaching the solution requires "extensive time, money, and effort to carry out," if "one skilled in the art would have had a reasonable expectation of success at the time the invention was made, and merely had to verify that expectation."⁷² Analogous to the test for obviousness, when the incentive to innovate need not be presented through the patent system, then the patent bargain is not fulfilled by the innovation.⁷³ The specific contribution to science and technology must be man-made and not natural. If the solution can be predicted by nature and does not require man's involvement, as foreshadowed by prior art solutions to problems, then the identity of the invention is natural, not man-made, and the technological edge is absent. Prior art solutions can provide a lens through which this determination can be made. Allowing the expansion of patentable subject matter to

72. *Pfizer, Inc. v. Apotex, Inc.* 480 F.3d 1348, 1367 (Fed. Cir. 2007).

73. 35 U.S.C. § 103 (2004) ("A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.").

exceed what is man-made and to delve into natural phenomena violates the underlying policies of the patent system.

The innovative aspects of solving problems difficult to frame without the aid of technology have long been understood to be worthy of the grant of a patent. In 1911, in holding a patent valid for isolated and purified adrenaline, Judge Learned Hand explained that compounds isolated from nature are patentable:

[E]ven if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it [adrenaline] 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. That was a good ground for a patent.⁷⁴

Courts should reflect on what the solutions bring to the public, and how they fill the patent bargain. If the innovative aspect is man-made rather than natural, then even if there is a chance that the solution might exist before man isolated it, the benefit received far exceeds the likelihood that the patent is taking back from the public something the public is already entitled to. As courts examine such novel techniques as extracting hormones from natural sources, much of what must be contemplated rests on why this is important, the benefits the public receives, and whether the hormones would otherwise be made available. In 1970, the Court of Customs and Patent Appeals (“CCPA”), in writing on a patent “dealing with the prostaglandins PGE₂ and PGE₃, extracted from human or animal prostate glands,” held a patent valid where “a patent examiner . . . rejected the claims,” reasoning that “inasmuch as the ‘claimed compounds are naturally occurring’ they therefore are not ‘new’ within the connotation of the patent statute.”⁷⁵ The CCPA held that:

[W]hat appellants claim—pure PGE₂ and PGE₃—is not ‘naturally occurring.’ Those compounds, as far as the record establishes, do not exist in nature in pure form, and appellants have neither merely discovered, nor claimed sufficiently broadly to encompass, what has

74. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001) (quoting *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F.95, 103 (S.D.N.Y. 1911)).

75. Utility Examination Guidelines, 66 Fed. Reg. 1092 (quoting *In re Bergstrom*, 427 F.2d 1394, 1397 (C.C.P.A. 1970)).

previously existed in fact in nature's storehouse, albeit unknown, or what has previously been known to exist.⁷⁶

The technological edge comes from the isolation and purification, taking the invention from the natural world into the technological world. Hormones, DNA molecules, and other chemical compounds are not found isolated and purified in their natural state. The types of problems found in the prior art clearly show this. Isolating,⁷⁷ purifying, and replicating the chemical compounds removes chemical compounds from the natural world and renders them man-made and therefore patentable.⁷⁸

It is very important to look at the type of problems encountered in the specific art involved, not just the general field in which the problem may arise, because “[g]eneral experience in a related field may not suffice when experience and skill in specific product design are necessary to resolve patent issues.”⁷⁹ There are times when the lack of sophistication in the solution can only be determined by one of ordinary skill in the art.⁸⁰ If the problem is so simple that a solution would be apparent to one of ordinary skill in the art, then the solution may be obvious under 35 U.S.C. § 103, but, in addition, the public receives minimal benefit from the problem and the solution and nothing is added to the “storehouse of knowledge of all men.”⁸¹ There is no technological edge inherent in the solution. If the problem is readily apparent to one

76. Utility Examination Guidelines, 66 Fed. Reg. 1092 (quoting *In re Bergstrom*, 427 F.2d at 1401).

77. *See generally* *Intervet, Inc. v. Merial, Ltd.*, 617 F.3d 1282, 1293 (Fed. Cir. 2010) (DYK, concurring) (“DNA ‘isolation’ applies generally to the process of extracting DNA from a cell for purposes of genetic analysis Isolation also encompasses techniques for selective amplification or cloning of such fragments, which allows for a large number of fragments to be available for analysis and sequencing.”).

78. *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 702 F. Supp. 2d 181, 196-97 (S.D.N.Y. 2010) (“Purified or synthesized DNA may be used as tools for biotechnological applications for which native DNA cannot be used. . . . For example, unlike native DNA, purified or synthesized DNA may be used as a ‘probe,’ which is a diagnostic tool that a molecular biologist uses to target and bind to a particular segment of DNA, thus allowing the target DNA sequence to be detectable using standard laboratory machinery. Purified or synthesized DNA can also be used as a ‘primer’ to sequence a target DNA, a process used by molecular biologists to determine the order of nucleotides in a DNA molecule, or to perform polymerase chain reaction (‘PCR’) amplification, a process which utilizes target-DNA specific primers to duplicate the quantity of target DNA exponentially.”).

79. *Extreme Networks, Inc. v. Enterasys Networks, Inc.*, 395 Fed. Appx. 709, 715 (Fed. Cir. 2010).

80. *In re Levin*, No. 96-1180, 1997 WL 44797, at *4 (Fed. Cir. Feb. 3, 1997) (“One of ordinary skill in the art could discern from the teachings of the Weldon patent that a less sophisticated method of visual inspection of the color coded information as exhibited in a plurality of colors may be utilized.”).

81. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

of ordinary skill, but the solution requires expertise and skill, then the public benefits from the solution, and the patent bargain is likely to be met by protecting the solution. If neither the problem nor the solution is readily apparent without an investment of time and research, then the benefit to the public greatly increases, and the patent bargain is upheld by a grant of a patent. The more sophisticated the problems encountered in the art, the less likely it is that the public would receive the benefits associated with solving problems encountered in the art without incentives. Investment must be incentivized, and the benefit the public receives from the patent disclosure is a fair trade-off for the reward granted the patentee, when the technological edge is present.

C. *Sophistication of the Technology*

The benefit the public receives far exceeds the loss to the public of allowing the right to exclude to the patentee when the technology is such that the public would not otherwise gain access to the patented innovation. To grant a patent is to prevent the public from making, using, selling, or offering to sell an innovation for a limited time. We do not want to reward an innovator for removing something from the public domain. If the innovation is a natural phenomenon, such as the heat of the sun,⁸² it is something the public has a right to exercise and use. If the innovation is a man-made manipulation of nature, such as a virus removed from a sick patient and injected into a well patient, the reward of a patent promotes innovation.

Genes are one evolving area of patentability that clearly reflects the balancing act between a natural discovery and a man-made invention. The fact that genes may be found in nature should not render moot the question of patentability as long as the patent bargain is fulfilled.

When patents for genes are treated the same as for other chemicals, progress is promoted because the original inventor has the possibility to recoup research costs, because others are motivated to invent around the original patent, and because a new chemical is made available as a basis for future research. Other inventors who develop new and nonobvious methods of using the patented compound have the opportunity to patent those methods.⁸³

The Patent Office has said:

82. *Id.* ("The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.")

83. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

[i]f an inventor . . . discloses how to use the purified gene isolated from its natural state, the application satisfies the ‘utility’ requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.⁸⁴

The technological edge is present in such a discovery. In response to comments urging the PTO not to issue patents for genes on the ground that genes are products of nature, the PTO said:

An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.⁸⁵

The focus and what differentiates a discovery from a “genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it,” comes back to the idea that the innovative aspect of the discovery is natural, while the innovative aspect of the isolation and purification of the gene is man-made. The technological edge of the isolated and purified form of the gene compels the granting of a patent. “Patenting compositions or compounds isolated from nature follows well-established principles, and is not a new practice.”⁸⁶

U.S. Patent No. 5,837,492 claims, “An isolated DNA molecule coding for a BRCA2 polypeptide, said DNA molecule comprising a nucleic acid sequence encoding the amino acid sequence set forth in SEQ ID NO:2.”⁸⁷ In 2010, Judge Sweet of the Southern District of New York held that “purification of a product of nature, without more, cannot transform it into patentable subject matter. Rather, the purified product must possess ‘markedly different characteristics’ in order to satisfy the requirements of § 101.”⁸⁸ Under that test, isolated DNA was found unpatentable subject matter under § 101. If Judge Sweet had instead

84. *Id.*

85. *Id.*

86. *Id.* (“Louis Pasteur received U.S. Patent 141,072 in 1873, claiming ‘[y]east, free from organic germs of disease, as an article of manufacture.’”).

87. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 213 n.30 (S.D.N.Y. 2010), *overruled by Ass’n For Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011).

88. *Id.* at 227.

applied the technological edge test suggested in this article, the outcome would have been different.

“[A] purified product of nature can indeed satisfy the requirements of § 101, provided it possess characteristics markedly different than those of the non-purified product.”⁸⁹ The sophistication of the technology required to isolate and purify DNA reflects the markedly different characteristics of the claimed invention from the native DNA found in a human. “Myriad’s DNA can function as ‘molecular diagnostic tests . . . , in biotechnological processes . . . and even in medical treatment (e.g., gene therapy).”⁹⁰ Isolating and purifying DNA takes knowledge, sophisticated technology, an extraordinary skill set and elevates the common good by providing access to solutions that may exist in nature, but are innovative in their man-made aspects.⁹¹ In that regard, DNA is no different from any other “isolated naturally occurring biomolecule such as a protein, a carbohydrate, a vitamin or an organic compound such as taxol.”⁹²

It can be difficult to even understand the innovation in a particularly sophisticated area of art.⁹³

Determination of the meaning that would have been attributed to a claim term by one of ordinary skill in a sophisticated field of art on the date of filing often requires examination of extrinsic evidence—a determination of crucial facts underlying the dispute . . . [o]n some occasions, a determination will be made based, in part, on the weight

89. Alan J. Morrison, *Rethinking the Gene Patent*, 29 BIOTECHNOLOGY LAW REPORT 609, 612 (2010), available at <http://users.unimi.it/minucci/deontologia%202010-2011/articoli/brevetti/blr.2010.9911.pdf>.

90. *Id.* at 613.

91. *Ass’n for Molecular Pathology*, 702 F. Supp. at 211 (“Myriad has cited a survey published in 2009 by the BIO of 150 biotechnology member companies in the therapeutic and diagnostic healthcare industry stating that the majority of companies (61%) generally in-licensed projects that are in the pre-clinical or Phase 1 stage of development, and thus still require substantial R & D investment and commercialization risk by the licensee. A substantial majority (77%) of the respondents without approved products indicated that they expect to spend 5-15 years and over \$100 million developing a commercial product. Myriad asserts that these expenditures dwarf any initial research funding by the federal government In particular, Myriad notes that a significant amount of private investment led to its identification of the *BRCA1* and *BRCA2* sequences, with the expectation of patent protection providing an incentive to fund the research into the determination of the gene sequences.”).

92. Morrison, *supra* note 89, at 615.

93. *Ass’n for Molecular Pathology*, 702 F. Supp. at 185 (“Two complicated areas of science and law are involved: molecular biology and patent law. The task is to seek the governing principles in each and to determine the essential elements of the claimed biological compositions and processes and their relationship to the laws of nature.”).

to be given to conflicting extrinsic evidence or even to an evaluation of an expert's credibility.⁹⁴

This difficulty only reflects the inability of the public to access the innovation without the incentive of the patent. "The incentive to make discoveries and inventions is generally spurred, not inhibited, by patents. The disclosure of genetic inventions provides new opportunities for further development."⁹⁵ A discovery in a sophisticated technology is far more likely to be technological in nature than man-made, and more likely to honor the patent bargain by adding to the overall wealth of public knowledge.

The higher the level of skill in the art; the greater the level of education and experience in the field; the more challenging the problems addressed by researchers in the art; the greater the prior art patents and publications; the more intense the research efforts by all; the greater the level of difficulty of prior art solutions; and the higher the degree of sophistication; the less likely it is that we are betraying the patent bargain by granting the right to exclude to the innovator. The greater the degree of sophistication, and the more technological the innovation, the lower the risk is that the innovation is merely natural in origin, and therefore not worthy of protection.

V. CONCLUSION

In 1948, a mixture of bacteria strewn on a field was found to be a "phenomena of nature," even though the specific mixture was not found in nature, because "[t]heir qualities are the work of nature."⁹⁶ In 2001, seeds were found to be patentable subject matter, in an opinion focused on preemption—treating the question of whether seeds are natural phenomena as a nonstarter. This is not a shift of the Supreme Court's definition of natural phenomena; instead, it is a reflection of the role of the technological edge in maintaining the patent bargain with respect to the patentability of natural phenomena. "The mere discovery of a new element, or law, or principle of nature, without any valuable application of it to the arts" is not in and of itself patentable subject matter. If an innovation is not found in nature and is "not nature's handiwork, but [the inventor's] own," then the innovation is not a natural phenomenon and is patentable.⁹⁷

94. *Trading Technologies Intern., Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1363 (Fed. Cir. 2010).

95. *Utility Examination Guidelines*, 66 Fed. Reg. 1092 (Jan. 5, 2001).

96. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

97. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

Today's genetic innovations were unimaginable when the Constitution was drafted, when Thomas Jefferson authored the first patent act and when the Supreme Court first held that natural phenomena could not be patented. Yet, the importance of the biorevolution cannot be understated, and the realization that agriculture was a science can be seen from Thomas Jefferson's early seed banks, from Ellsworth's musings about the role of the patent office in seed distribution, and from Justice Douglas' dismissal of the patentability of mixed-inoculants. Unchanged by man, and untouched by the technological arts, mixed inoculants set forth a path down which hybrid corn seed and Roundup Ready Alfalfa⁹⁸ could become the subject of Supreme Court opinions.

The Supreme Court has shaped 35 U.S.C. § 101 and patentability guidelines with respect to natural phenomena. Despite the lack of legislative history regarding congressional intent, the Supreme Court has remained unwavering in its guidance as to the unpatentability of natural phenomena. If the invention is man-made, then it is patentable subject matter, thus a genetically modified seed qualifies as patentable subject matter. A new plant variety created by agroecological means, however, is one that nature might be able to create, given enough time, and enough variance in breeding. Patentable subject matter must "be in the technological arts so as to be in consonance with the Constitutional purpose to promote the progress of 'useful arts.'"⁹⁹ Furthermore, it is not sufficient to mention a technology in the patent application,¹⁰⁰ rather "the innovative aspect of the claimed method" must be the technological aspect.¹⁰¹ The seed is not a natural phenomenon because the method in which the seed was made and its innovative aspect places the invention firmly in the technological arts area, and promotes the progress of science and the useful arts.

The patent bargain is fulfilled by evaluating the technological edge of advances that walk the line between natural phenomena and man-made manipulations of nature. Courts walk the line between these two categories and can best honor the patent bargain by asking what the innovative nature of the product is and what degree of technology is required for the public to benefit. The higher the level of skill in the art,

98. *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2746 (2010).

99. *In re Bilski*, 545 F.3d 943, 1002 (Mayer, J., dissenting) ("... this court had rightly concluded that patents were designed to protect technological innovations...").

100. *See, e.g., Diamond v. Diehr*, 450 U.S. 175, 192 n.14 (1981) ("A mathematical formula does not suddenly become patentable subject matter simply by having the applicant acquiesce to limiting the reach of the patent for the formula to a particular technological use.").

101. *In re Bilski*, 545 F.3d at 1002 (Mayer, J., dissenting).

the less likely it is that the Patent Office and the judicial system is betraying the patent bargain by granting the right to exclude to an innovation merely natural in origin, and therefore already belonging to the public. The technological edge supports the patent bargain, and represents a distinct difference recognized and buttressed by the Constitution, the early patent acts and the Supreme Court.

