WITHIN SUBJECT MATTER ELIGIBILITY—A DISEASE AND A CURE

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ABSTRACT

Ever since the Supreme Court pronounced in Diamond v. Chakrabarty *that "Congress intended statutory [patentable] subject matter to 'include anything under the sun that is made by man,'"*[1] *the thrust of subject matter eligibility has been broadly to include all subject matters that are not "laws of nature, physical phenomena, and abstract ideas."*[2] *In essence, subject matter is eligible for protection under the patent laws if it is man-made and is ineligible if it is a part of nature. Such a definition of subject matter eligibility is, unfortunately, unhelpful in the biomedical context. A basic discovery involving a new pathological pathway, for example, represents an advancement of both basic knowledge about nature as well as basic know-how in diagnosing and treating human diseases. A successful isolation of a gene, protein, or cell represents a triumph both for our understanding of nature as well as our ability to diagnose and treat human diseases. This Article argues that subject matter eligibility should neither be a mere prohibition against the patenting of nature and abstract ideas, a mere pseudorequirement to enforce other patentability requirements, nor a mere exercise in the statutory interpretation of 35 U.S.C. § 101, but a unique constitutional requirement to ensure that the patenting of eligible subject matter promotes the useful arts. To take into account the cost side of patenting, eligibility may be defined in part as a*

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1. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).

2. *Id.*

prohibition of the patenting of "basic tools of scientific and technological work."[3] *To ensure that knowledge that can be provided freely to the public is not unwittingly removed from the public, eligibility may be defined in part by distinguishing "inventions" from "discoveries," as viewed from a person skilled in the art. To accentuate the role patents play in a nation's larger Industrial Policy,*[4] *eligibility may be limited to "industrial applications" and "technology" that are the purview of Industrial Policy. This Article emphasizes the importance of viewing the patent regime not just as a property system, but as part of a larger regulatory regime for promoting innovations.*

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3. Gottschalk v. Benson, 409 U.S. 63, 67 (1972). *Accord* Diamond v. Diehr, 450 U.S. 175, 216 n.41 (1981); Parker v. Flook, 437 U.S. 584, 591–92 (1978).

4. The term "Industrial Policy" is meant to include broadly all government policies directed toward national economic development. *See, e.g.*, *infra* note 237 (defining "Industrial Policy"); *infra* note 240 (discussing the role of intellectual property in advancing a nation's economic developments); *infra* note 267 (describing how early patent grants in England were issued as privileges to induce the development of new technologies).

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I. INTRODUCTION

The unprecedented growth in biomedical patents in recent decades has been both a source of pride as well as alarm for the biomedical industry.[5] In the biomedical field, eligible subject matter now includes stem cells, genetically modified plants and nonhuman mammals, genetic sequences, and extracted biomaterials.[6] Would-be patentees routinely patent genes,[7] stem cells,[8] and medical diagnostic and treatment techniques.[9] Outside of the biomedical field, the scope of subject matter has also been ballooning: "inventions" involving economics, law, television producing, and scriptwriting are now routinely patented.[10]

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5. *Compare* DAVID W. BEIER, BIOTECHNOLOGY INDUS. ORG., TESTIMONY ON COMPETITION AND INTELLECTUAL PROPERTY LAW AND POLICY IN THE KNOWLEDGE-BASED ECONOMY BEFORE THE FEDERAL TRADE COMMISSION AND THE DEPARTMENT OF JUSTICE 4 (2002) (quoting ECONOMIC REPORT OF THE PRESIDENT 133 (2002)), *available at* http://www.ftc.gov/opp/intellect/020226 davidwbeier.pdf (discussing how strong patents have fueled the growth of the biotechnology industry in the United States over the last few decades by, for example, making it easier to raise capital), *with* Aaron S. Kesselheim & Michelle M. Mello, *Medical-Process Patents—Monopolizing the Delivery of Health Care*, 355 NEW ENG. J. MED. 2036, 2036 (2006) ("[Certain biotechnology] patent[s] compromise[] patients' access to new procedures."), *and* Jordan Paradise, Lori Andrews & Timothy Holbrook, *Patents on Human Genes: An Analysis of Scope and Claims*, 307 SCIENCE 1566, 1566 (2005) (discussing how the growth in biotechnology patents may be threatening innovation).

6. *E.g.*, J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 143–45 (2001) (explaining that patent law protects plant varieties); *Ex parte* Allen, No. 86-1790, 1987 WL 123816, at *2 (B.P.A.I. Apr. 3, 1987) (holding that man-made life forms, specifically polyploid oysters, are patentable subject matter); Utility Examination Guidelines, 66 Fed. Reg. 1092, 1092–93, 1094–95, 1096 (Jan. 5, 2001) (explaining that genes, genetic sequences, DNA sequences, and plant varieties are patentable as long as the patentee can articulate a credible utility for the genes); Donald J. Quigg, *Animals—Patentability*, 1077 Off. Gaz. Pat. & Trademark Office 24 (1987) (explaining that the U.S. Patent and Trademark Office will consider patent applications for man-made animals).

7. *See, e.g.*, Stefan Lovgren, *One-Fifth of Human Genes Have Been Patented, Study Reveals*, NAT'L GEOGRAPHIC NEWS (Oct. 13, 2005), http://news.nationalgeographic.com/news/2005/10/1013_051013_gene_patent.html.

8. *See* Karl Bergman & Gregory D. Graff, *The Global Stem Cell Patent Landscape: Implications for Efficient Technology Transfer and Commercial Development*, 25 NATURE BIOTECHNOLOGY 419, 420 fig.1, 422 (2007).

9. *See, e.g.*, Jasemine Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy Is Public Policy?*, 34 GEO. WASH. INT'L L. REV. 223, 231–32 (2002); Christopher M. Holman, *Patent Border Wars: Defining the Boundary Between Scientific Discoveries and Patentable Inventions*, 25 TRENDS BIOTECHNOLOGY 539, 541–42 (2007).

10. *See, e.g.*, GREGORY AHARONIAN & RICHARD STIM, PATENTING ART AND ENTERTAINMENT: NEW STRATEGIES FOR PROTECTING CREATIVE IDEAS 3 (2004) (a process to exercise a cat); Andrew F.

The U.S. Supreme Court announced some three decades ago, perhaps incorrectly,[11] that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[12] This started a revolution during which many came to believe that proprietarization of knowledge is necessary for a society to innovate.[13] In so many ways, the patent system in the United States—with broad implications for much of the rest of the world[14]—has become a property regime on steroids.

Today, much of the initial enthusiasm for biotechnological patents appears to be cooling.[15] Concerns that the patent system may not provide

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Knight, *A Patently Novel Plot: Fiction, Information, and Patents in the 21st Century*, 47 IDEA 203, 204–06 (2006) (a movie plot); Floyd Norris, *You Can't Use That Tax Idea. It's Patented*, N.Y. TIMES, Oct. 20, 2006, at C1 (a tax method); *Patent Nonsense: An End to Frivolous Patents May Finally Be in Sight*, ECONOMIST (Feb. 5, 2010), http://www.economist.com/sciencetechnology/displayStory.cfm?story_id=15479680 (an arguably obvious business process); *infra* note 236 (listing a parade of horribles in patents).

11. Some argue that the oft-quoted phrase has been mischaracterized. Bilski v. Kappos, 130 S. Ct. 3218, 3248–49 (2010) (Stevens, J., concurring); Brief Amici Curiae of Professors Peter S. Menell and Michael J. Meurer in Support of Respondent at 19–22, *Bilski*, 130 S. Ct. 3218 (No. 08-964) [hereinafter Menell & Meurer], *available at* http://www.abanet.org/publiced/preview/briefs/pdfs/09-10/08-964_RespondentAmCu2 Profs.pdf.

12. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)); *id.* at 308 ("[I]ngenuity should receive a liberal encouragement." (quoting Letter from Thomas Jefferson to Oliver Evans (May 2, 1807), *in* 5 WRITINGS OF THOMAS JEFFERSON 76 (H.A. Washington ed., Philadelphia, J.B. Lippincott & Co. 1869))).

13. *See* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1666 (1996) ("Only in exceptional circumstances does [public policy] acknowledge that there may be an affirmative case for putting a discovery in the public domain for the greater good.").

14. *See* Marci A. Hamilton, *The TRIPS Agreement: Imperialistic, Outdated, and Overprotective*, 29 VAND. J. TRANSNAT'L L. 613, 614 (1996) (arguing that the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") represents "one of the most effective vehicles of Western imperialism in history"); Holman, *supra* note 9, at 539 (noting that the Indian ban on patents on "substances capable of use as medicine, drug or food . . . was terminated to comply with international treaty obligations").

15. *See, e.g.*, ADELPHI CHARTER ON CREATIVITY, INNOVATION AND INTELLECTUAL PROPERTY (2006), http://sitoc.biz/adelphicharter/pdfs/adelphi_charter2.pdf (acknowledging that while "[h]umanity's capacity to generate new ideas and knowledge is its greatest asset" and that "[c]reativity and investment should be recognised and rewarded," "[t]he expansion in the law's breadth, scope and term over the last 30 years has resulted in an intellectual property regime which is radically out of line with modern technological, economic and social trends[,] . . . threaten[ing] the chain of creativity and innovation on which we and future generations depend"); DEAN BAKER, CTR. FOR ECON. POLICY & RESEARCH, STAGNATION IN THE DRUG DEVELOPMENT PROCESS: ARE PATENTS THE PROBLEM? 3 (2007), *available at* http://www.cepr.net/documents/publications/healthcare_stagnation_2007_03.pdf (arguing how perverse incentives created by patent monopolies in the pharmaceutical industry have already stifled research of new drugs); Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REVS. 803, 803 (2002) ("Although gene patents have been granted worldwide for several years, the wisdom of this action is now being questioned."); Rebecca S. Eisenberg, *Biotech Patents: Looking Backward While Moving Forward*, 24 NATURE BIOTECHNOLOGY 317, 318 (2006) (noting that whereas most of the amicus curiae briefs to the 1980 *Chakrabarty* case

enough incentives for the development of new technologies have been replaced with concerns that patent rights may be impeding the development of new technologies.[16]

As technology advances beyond what any of the original architects of the patent regime could have imagined,[17] getting a consensus on what the scope of subject matter eligibility should be has become only more contentious. In the *Bilski v. Kappos* appeal to the Supreme Court alone, for example, over seventy amicus briefs were filed,[18] with some arguing that the scope of subject matter ought to be limited to specific technical arts,[19] others arguing that subject matter ought to include everything under the sun invented and discovered by man,[20] others offering other visions on the

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were in support of broad patent eligibility for biotechnological innovations, the amicus curiae briefs to the more recent Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc., 548 U.S. 926 (2006), case are much more "sharply divided"); James P. Evans, *Putting Patients Before Patents*, 12 GENETICS MED. (SUPP.) S3, S3 (2010), *available at* http://journals.lww.com/geneticsinmedicine/toc/2010/04001 ("It is an auspicious time for these studies to be published. The issue of gene patents is at the heart of several pending legal battles[,] . . . [and w]e are poised on the brink of exciting times in medicine . . . [that will offer unprecedented insights into] the fundamental basis of disease, provide promising novel drug targets, and usher in a new age of individualized medicine. But . . . there is a concern that fragmented ownership of the genome will interfere with [this future].").

16. *See* Aaron S. Kesselheim & Jerry Avorn, *University-Based Science and Biotechnology Products: Defining the Boundaries of Intellectual Property*, 293 JAMA 850, 850 (2005) ("Excessive proliferation of intellectual property hurdles can hinder cooperation or make collaborative efforts insurmountably expensive."); Kesselheim & Mello, *supra* note 5, at 2036 ("Medical-process patents threaten to complicate medical practice, increase costs, and restrict access to therapeutic and diagnostic procedures. The American Medical Association (AMA) has declared that this type of patent compromises patients' access to new procedures. Owing to such concerns, nearly 80 countries refuse to grant patents on medical procedures."); David B. Resnik, *Are DNA Patents Bad for Medicine?*, 65 HEALTH POL'Y 181, 182 (2003) ("A growing number of critics are concerned that DNA patents will have a negative impact on medical practice and research.").

17. *See, e.g.*, Bilski v. Kappos, 130 S. Ct. 3218, 3227 (2010) (noting that the "machine-or-transformation test," developed during the "Industrial Age," may be an anachronism); *Chakrabarty*, 447 U.S. at 314 ("[G]enetic technology was unforeseen when Congress enacted [35 U.S.C.] § 101."); *In re* Bergy, 596 F.2d 952, 974 (C.C.P.A. 1979) ("[T]he Founding Fathers and the Congresses of the past century could not have forseen [modern technology] . . . ."), *vacated as moot in part sub nom.* Diamond v. Chakrabarty, 444 U.S. 1028 (1980), *and aff'd in part*, *Chakrabarty*, 447 U.S. 303.

18. *Bilski v. Kappos*, SCOTUSBLOG, http://www.scotusblog.com/case-files/cases/bilski-v-kappos (last visited Dec. 20, 2010).

19. *See, e.g.*, Menell & Meurer, *supra* note 11, at 5–7 (arguing that the term "useful Arts" in the Intellectual Property Clause ("IP Clause") meant technology and not business practices at the time of ratification); Brief for Amicus Curiae Computer & Communications Industry Association in Support of Respondent at 42, *Bilski*, 130 S. Ct. 3218 (No. 08-964), *available at* http://www.abanet.org/publiced/preview/briefs/ pdfs/09-10/08-964_RespondentAmCuCCIA.pdf.

20. *See, e.g.*, Brief Amici Curiae of 20 Law and Business Professors in Support of Neither Party at 4, *Bilski*, 130 S. Ct. 3218 (No. 08-964), *available at* http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/08-964_NeutralAmCu20LawandBusProfs.pdf (contending that patentable subject matter should be defined based on distinguishing between applied and abstract ideas); Brief of Amicus Curiae Boston Patent Law Association in Support of Petitioners at 3, *Bilski*, 130 S. Ct. 3218 (No. 08-964),

limits of subject matter eligibility,[21] and still others arguing that subject matter eligibility is a red herring that serves no purpose beyond what other patentability requirements already offer.[22]

Part of the blame for the present crisis goes to the paucity of clear authority delineating the scope of subject matter eligibility.[23] Eligibility is defined almost exclusively in terms of the judicial prohibition against the patenting of nature and abstract ideas.[24] In today's supercharged patent culture, almost everything that is "new and useful"[25]—save a natural law, natural phenomenon, or abstract idea—has become eligible for patenting.[26] But, while the Court is probably right to refuse to limit the scope of eligible subject matter to the type existing in eighteenth-century, preindustrial

available at http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/08-964_PetitionerAmCuBPLA.pdf (arguing that a broad interpretation of subject matter eligibility fosters a robust culture of innovation).

21. *See, e.g.*, Brief Amicus Curiae of International Business Machines Corporation in Support of Neither Party at 7, *Bilski*, 130 S. Ct. 3218 (No. 08-964), *available at* http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/08-964_NeutralAmCuIBM.pdf (arguing that the guiding inquiry in determining subject matter eligibility should be whether a process "provides a technological contribution"); Brief of On Time Systems, Inc. as Amicus Curiae in Support of Neither Party at 17, *Bilski*, 130 S. Ct. 3218 (No. 08-964), *available at* http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/08-964_NeutralAmCuOnTimeSystems.pdf (arguing that because "a large portion of the world's industrial product is now comprised of intangible assets . . . , [and] modern society considers . . . non-physical objects to be just as 'real' as their concrete counterparts," abstract ideas should not be made ineligible for patenting merely because they involve manipulating intangible, "non-concrete entities").

22. *See* Brief of Amicus Curia Conejo Valley Bar Association in Support of Neither Party at 2, *Bilski*, 130 S. Ct. 3218 (No. 08-964), *available at* http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/08-964_NeutralAmCuConejoValleyBA.pdf (arguing that subject matter eligibility is a patentability requirement that provides no benefit beyond that which is already provided by 35 U.S.C. §§ 102, 103, and 112). *But see* Brief of Accenture and Pitney Bowes Inc. as Amici Curiae in Support of Petitioners at 20–21, *Bilski*, 130 S. Ct. 3218 (No. 08-964), *available at* http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/08-964_PetitionerAmCuAccentureandPitneyBowes.pdf (arguing that subject matter eligibility serves an important purpose that is separate and distinct from those served by §§ 102, 103, and 112).

23. It may seem surprising that an issue as important as subject matter eligibility in the context of biomedical innovations is not more developed. One explanation is that in an industry as dependent on patents as biotechnology, litigation among similarly minded stakeholders (for example, pharmaceutical companies, biotech companies, and universities) typically results in battles over specific patent rights but not battles to reduce the total number of rights available. *See* Andrews, *supra* note 15, at 805–06.

24. *See, e.g.*, *Bilski*, 130 S. Ct. at 3225 ("The Court's precedents provide three specific exceptions to § 101's broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.'" (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980))); Diamond v. Diehr, 450 U.S. 175, 185 (1981); *Chakrabarty*, 447 U.S. at 309; Parker v. Flook, 437 U.S. 584, 589 (1978); Gottschalk v. Benson, 409 U.S. 63, 67 (1972); O'Reilly v. Morse, 56 U.S. (15 How.) 62, 112–13 (1853); *In re* Bergy, 596 F.2d 952, 965 (C.C.P.A. 1979), *vacated as moot in part sub nom.* Diamond v. Chakrabarty, 444 U.S. 1028 (1980), *and aff'd in part, Chakrabarty*, 447 U.S. 303.

25. 35 U.S.C. § 101 (2006).

26. *See Bilski*, 130 S. Ct. at 3229–30 (tracing the history of subject matter eligibility).

America,[27] it is true neither that all innovations require patent incentives to develop[28] nor that all patenting necessarily leads to the socially optimal level of innovation and investment in research and development.[29] In fact, it still remains unclear whether patents as a whole provide a net social

27. *See id.* at 3228 ("[T]o 'freeze process patents to old technologies, leaving no room for the revelations of the new, onrushing technology[,] . . . is not our purpose.'" (alteration in original) (quoting *Gottschalk*, 409 U.S. at 71)); *id.* at 3227 (noting that the scope of subject matter eligibility should not stay constant because "times change. Technology and other innovations progress in unexpected ways"); *Chakrabarty*, 447 U.S. at 315–16 ("[A] statute is not to be confined to the 'particular application[s] . . . contemplated by the legislators.' . . . This is especially true in the field of patent law. . . . Congress employed broad general language in drafting § 101 precisely because [truly breakthrough] inventions are often unforeseeable." (first alteration and first ellipsis in original) (citations omitted) (quoting Barr v. United States, 324 U.S. 83, 90 (1945))); *id.* at 315 ("*Flook* did not announce a new principle that inventions in areas not contemplated by Congress when the patent laws were enacted are unpatentable *per se*."). *But see Flook*, 437 U.S. at 596 ("[W]e must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress."); Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 531 (1972) ("[W]e should not expand patent rights . . . [without] a clear and certain signal from Congress . . . .").

28. *See* F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 447 (2d ed. 1980) (describing situations in which innovations can be profitable even without patent protections); Zvi Griliches, Ariel Pakes & Bronwyn H. Hall, *The Value of Patents as Indicators of Inventive Activity*, *in* ECONOMIC POLICY AND TECHNOLOGICAL PERFORMANCE 97, 120 (Partha Dasgupta & Paul Stoneman eds., 1987) ("While the aggregate value of patent rights appears to be quite high, it is estimated to be only of the order of 10 to 15 percent of total national expenditures on [research and development]. Hence [the ability to patent] is unlikely to be the major factor in determining the overall level of [spending on research and development]."); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1618 (2003) ("[C]ompanies have ample incentives to [innovate] even without patent protection, because the competitive marketplace rewards companies that use more efficient business methods . . . [and because] first mover advantages and branding can provide rewards to the innovator.").

29. *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126–27 (2006) (Breyer, J., dissenting) ("[S]ometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection." (quoting U.S. CONST. art. I, § 8, cl. 8)); WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 361 (2003) (explaining "excessive investment by those seeking patent protection"); *id.* at 18 (discussing the economic inefficiencies of research and development races caused by the patent regime); SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 46–47 (2004) (discussing economic inefficiencies caused by the patent regime); Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R&D*, 2 PLOS BIOLOGY 147, 150 (2004) (describing how the patent regime has incentivized investments in research and development with "diminishing returns"); Frederic M. Scherer, *The Economics of Human Gene Patents*, 77 ACAD. MED. 1348, 1360 (2002) (discussing how it is possible to overincentivize research and development activities); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120–21 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2001) (discussing how patent thickets may extract extraordinary costs, disincentivizing rather than incentivizing innovation over the long term); Andrew W. Torrance & Bill Tomlinson, *Patents and the Regress of Useful Arts*, 10 COLUM. SCI. & TECH. L. REV. 130, 134–35 (2009) (concluding based on computer simulations and game theory that patents do not necessarily foster innovation).

benefit or harm.[30] It is time to reevaluate the patent regime and determine whether it needs an overhaul[31] and whether subject matter eligibility should be strengthened and reinvigorated as part of that overhaul to ensure patents truly promote the advancement of the useful arts.[32]

The Supreme Court's broad proclamation that "Congress intended statutory subject matter to 'include anything under the sun that is made by man'" has come to underscore both the broadness of eligibility as well as the key condition that eligible subject matter must be "made by man."[33] In a previous article, I argued that defining eligibility in terms of whether it is natural or man-made leads to only legalistic and semantics-based constructions of eligibility that do little to promote the progress of the useful arts.[34] I argued that the delineation between nature and man-made with respect to biological products depends on an arbitrary level of granularity by which these products are viewed.[35]

In this Article, I expand that framework to argue that the delineation between nature and man-made subject matter, with respect to diagnostic

30. *See* Jonathan M. Barnett, *Property as Process: How Innovation Markets Select Innovation Regimes*, 119 YALE L.J. 384, 386 (2009) (commenting that fifty years after Fritz Machlup famously reported that "[i]f we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it," our state of understanding regarding the economic value of patents remains similarly ambivalent (quoting SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE S. COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 80 (Comm. Print 1958) (prepared by Fritz Machlup))); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998) (warning that owners of different patents can block each other from conducting socially important research).

31. *See, e.g.*, eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 396 (2006) (Kennedy, J., concurring) ("In cases now arising trial courts should bear in mind that in many instances the nature of the patent being enforced and the economic function of the patent holder present considerations quite unlike earlier cases."); *supra* note 15 and accompanying text.

32. *See* U.S. CONST. art I, § 8, cl. 8; Burk & Lemley, *supra* note 28, at 1642–43 (identifying the prohibition against the patenting of nature and abstract ideas as a "policy lever" for injecting policy norms into the patent system).

33. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).

34. *See generally* Allen K. Yu, *Why It Might Be Time to Eliminate Genomic Patents, Together with the Natural Extracts Doctrine Supporting Such Patents*, 47 IDEA 659 (2007). *See also* Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land:* Bilski*'s Superficial Textualism and the Missed Opportunity to Ground Patent Law Interpretation and Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. (forthcoming June 2011) (manuscript at 11–12), *available at* http://ssrn.com/abstract=1722422 ("In its effort to shoehorn analysis of patentable subject matter into a textualist mold, the [Supreme] Court [has] collapsed the rich historical development of patentable subject matter doctrine into three amorphous, static, and ill-defined exceptions.").

35. Yu, *supra* note 34, at 695–97.

and therapeutic techniques, is just as difficult. Much of biomedical know-how today is based on discoveries about basic workings of the human body.[36] The discovery of how a virus invades, spreads through, and attacks the human body constitutes both basic knowledge about basic natural human biology as well as basic know-how dictating how diseases and conditions are diagnosed and treated. The extraction of products (for example, genes, stem cells, and proteins) from the human body constitutes the procurement of both fundamental elements of the human body as well as the procurement of basic building blocks that enable new ways of studying, diagnosing, and treating human diseases.[37] Failure to appreciate the interrelated nature of basic knowledge and applied know-how in the biomedical field—arbitrarily defining one as natural and the other as man-made—has resulted in a blind definition of subject matter eligibility based more on semantics than reality.

This Article is organized into four parts. After this introduction, Part II reviews some high-profile controversies over subject matter eligibility, touching on important technologies in the biomedical field. Part III discusses the current state of the law on subject matter eligibility and argues that the subject matter eligibility requirement should articulate the constitutional mandate that patent law must reflect informed, enlightened policy. Part IV proposes various doctrinal reforms that can transform today's rigid, inflexible doctrine-laden regime into a more dynamic, policy-driven regime. Part V concludes.

II. ELIGIBLE SUBJECT MATTERS IN THE BIOMEDICAL FIELD

Section 101 of the Patent Act stipulates that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent."[38] The statute, however, provides much less constraint than it may first appear. Under the current broad interpretation of § 101, a "process" can mean any series of steps providing a human benefit;[39] a

36. *See* Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 379 (2002).

37. *See, e.g.*, LINDA K. BEVINGTON ET AL., BASIC QUESTIONS ON GENETICS, STEM CELL RESEARCH, AND CLONING: ARE THESE TECHNOLOGIES OKAY TO USE? 11–13, 15–17, 47–53, 81–90 (2004).

38. 35 U.S.C. § 101 (2006).

39. *See, e.g.*, Diamond v. Diehr, 450 U.S. 175, 183 (1981) ("A process is . . . an act, or a series of acts . . . . If new and useful, it is just as patentable as is a piece of machinery." (quoting Cochran v. Deener, 94 U.S. 780, 787 (1877))); *id.* at 182 (equating the term "process" in § 101 broadly with the term "art" "as that term was used in the 1793 Act"); 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS

"manufacture" or "composition of matter" can include any materials that offer some "new and useful" properties;[40] and a machine can be any useful device—including general-purpose computers.[41]

Reading eligibility so broadly—based ultimately on constructive distinctions between natural and man-made or abstract and applied[42]—unfortunately confuses more than enlightens.[43] This part discusses some of the disputes involving real-life technologies and shows why—because the human body is both a product of nature as well as an object of human intervention[44]—the distinction between the natural and the man-made is so difficult.

FOR USEFUL INVENTIONS 230 (1890) (defining an "art" as the term was used in the nineteenth century as a "process," specifying that "certain things should be done with certain substances[, and] in a certain order" (quoting *Cochran*, 94 U.S. at 788)).

40. *See* Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980); *infra* notes 113, 185–86 and accompanying text.

41. While the category "machine" has not yet been as controversial as others, *see* ROBERT A. CHOATE, CASES AND MATERIALS ON PATENT LAW 515 (1973) (discussing the conventional wisdom that "[t]here is seldom controversy . . . as to whether a subject of a patent is or is not a machine"), it may become so as a result of the controversy over software patents involving questions such as whether an otherwise ineligible algorithm (process) may become eligible when tied to a "general purpose computer," Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CALIF. L. REV. 1, 10 (2001); *id.* at 10–11 (discussing this new controversy). This continues to be an unsettled area of law even after *Bilski*. *See, e.g.*, Research Corp. Techs., Inc. v. Microsoft Corp., No. 2010-1037, 2010 U.S. App. LEXIS 24984, at *7, *19 (Fed. Cir. Dec. 8, 2010) (holding that claims to a method for halftoning gray scale images are not per se abstract for subject matter eligibility purposes even if they do not recite to any machine parts); *Ex parte* MacKenzie, No. 2009-007332, at 5–7 (B.P.A.I. Dec. 20, 2010) (holding claims to a method for performing a signature operation on a message to be abstract and ineligible for patenting despite references to "components," "device," and "special purpose computer"); *Ex parte* Venkata, No. 2009-007302, at 2–3, 7–8 (B.P.A.I. Dec. 6, 2010) (holding claims to a "service discovery system" to be abstract and ineligible for patenting despite references to multiple "agents" and a "system" because, according to the patent specification, the entire "system" can be implemented solely in software); *Ex parte* Kelkar, No. 2009-004635, at 2, 5 (B.P.A.I. Sept. 24, 2010) (holding claims to a method for comparing gene profiles to be abstract and ineligibile for patenting despite reciting physical elements of "a recordable medium," "carrier wave storage," and "computer").

42. *See infra* notes 157–66, 188–92, and accompanying text.

43. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3235–36 (Stevens, J., concurring) (criticizing the majority for not providing sufficient guidance on distinguishing between an eligible and noneligible process); Parker v. Flook, 437 U.S. 584, 589 (1978) ("The line between a patentable 'process' and an unpatentable 'principle' is not always clear. Both are 'conception[s] of the mind, seen only by [their] effects when being executed or performed.'" (quoting Tilghman v. Proctor, 102 U.S. 707, 728 (1881))). *Cf.* Nichols v. Universal Pictures Corp., 45 F.2d 119, 122 (2d Cir. 1930) ("[T]he line [between copyrighted material and noncopyrightable ideas], whereever [sic] it is drawn, will seem arbitrary . . . .").

44. *Cf.* JÜRGEN HABERMAS, THE FUTURE OF HUMAN NATURE 53–54 (2003) (discussing this duality in terms of the moral dilemmas associated with eugenics).

A. PATENTING OF MEDICAL DIAGNOSTIC TECHNIQUES

Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc. is a case involving the patenting of medical diagnostic processes.[45] The dispute arose out of U.S. Patent No. 4,940,658 ("the '658 patent"), titled "Assay for sulfhydryl amino acids and methods for detecting and distinguishing cobalamin and folic acid deficency [sic]."[46] The '658 patent discloses techniques for correlating high levels of homocysteine in body fluids to deficiencies of two important vitamins—folate (folic acid or vitamin B9) and cobalamin (vitamin B12).[47] Of particular concern is claim 13, which recites "[a] method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate."[48]

In the appeal to the U.S. Supreme Court, petitioner LabCorp challenged the validity of the patent on the ground that it did not constitute patentable subject matter under 35 U.S.C. § 101.[49] LabCorp argued that the correlation between homocysteine and vitamin deficiency is a measurable scientific fact in the human body and that the patentee had conceded the point when the patentee conceded during prosecution that "[t]he heart of these claims is the concept that total homocysteine is elevated in patients with cobalamin and folic acid deficiency."[50] "[Since] it is the 'established rule' that . . . a scientific fact 'cannot be the subject of a patent,'" LabCorp

45. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 125 (2006) (Breyer, J., dissenting).

46. U.S. Patent No. 4,940,658, at [54] (filed Nov. 20, 1986).

47. *LabCorp*, 548 U.S. at 128. The Federal Circuit had earlier affirmed the lower court's broad construction that by "correlating" the claim merely requires a general "association of homocysteine levels with vitamin deficiencies"—nothing more. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d. 1354, 1362 (Fed. Cir. 2004).

48. '658 Patent col. 41 ll. 58–65.

49. In the lower courts, LabCorp had raised several theories of patent invalidity. *Metabolite Labs.*, 370 F.3d at 1365–66. It was not until the appeal to the Supreme Court that LabCorp explicitly challenged the patent based on subject matter eligibility, however. Brief for Respondents at 11, *LabCorp.*, 548 U.S. 124 (No. 04-607). *But see LabCorp*, 548 U.S. at 132 (Breyer, J., dissenting) ("LabCorp did not refer in the lower courts to § 101 of the Patent Act . . . . LabCorp [nevertheless] argued the essence of its present claim below.").

50. Reply Brief for Petitioner at 16–17, *LabCorp*, 548 U.S. 124 (No. 04-607) (noting that the patentees had represented to the U.S. Patent and Trademark Office ("USPTO") "that the scientific correlation was the heart of their invention, and that because they were the first to detect vitamin deficiencies through a total homocysteine test, they were entitled to a claim of equivalent scope, not limited to any particular process steps or methods" (internal quotation marks omitted)).

contended that the claims must be invalid.[51]

Metabolite countered that its claims recited a patentable man-made application of a natural phenomenon, not the natural phenomenon per se.[52] It contended that while "[t]he correlation between total homocysteine and deficiencies in cobalamin and folate . . . could be considered, standing alone, a 'natural phenomenon' . . . [and] an observable aspect of biochemistry,"[53] claim 13 of the patent recited a procedure that actually transformed the natural matter.[54] Metabolite argued that because the patent included such a concrete step, it did not preclude "all substantial practical applications of the correlation" and hence represented eligible subject matter.[55]

The Supreme Court at first granted certiorari to hear the case[56] but later dismissed the certiorari as improvidently granted.[57] Justice Breyer, in dissent with Justices Stevens and Souter, noted that the claim as recited appeared to be a patent on a naturally occurring correlation.[58] The claim would encompass any use of the correlation as long as a measurement of homocysteine was taken, regardless of how the measurement was taken.[59] The inclusion of the assay step—a man-made step added to what is otherwise a description of a natural correlation—is reminiscent of the type of "post-solution activity" that the Court has pronounced to be insufficient to transform a natural phenomenon into a man-made invention.[60] If there

51. Brief for Petitioner at 21, *LabCorp.*, 548 U.S. 124 (No. 04-607) (quoting Parker v. Flook, 437 U.S. 584 (1978)).

52. *See* Brief for Respondents, *supra* note 49, at 31–33 (emphasizing that the respondents' processes were "useful" and "concrete" along the lines of State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998)). Justice Breyer later viewed the so-called "useful, concrete, and tangible result" test unfavorably, *see LabCorp*, 548 U.S. at 136–37 (Breyer, J., dissenting), and the Federal Circuit, perhaps taking a hint from the Supreme Court, ultimately overturned the test, *In re* Bilski, 545 F.3d 943, 959–60 (Fed. Cir. 2008), *aff'd*, 130 S. Ct. 3218 (2010).

53. Brief for Respondents, *supra* note 49, at 31.

54. *Id.* at 34–35.

55. *Id.* at 40 (quoting Brief for the United States as Amicus Curiae at 27, *LabCorp*, 548 U.S. 124 (No. 04-607)).

56. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 546 U.S. 975, 975 (2005).

57. *LabCorp*, 548 U.S. at 125 (majority opinion) (per curiam) ("The writ of certiorari is dismissed as improvidently granted.").

58. *Id*. at 137–38 (Breyer, J., dissenting).

59. *See id*. at 136–38.

60. Diamond v. Diehr, 450 U.S. 175, 215 n.39 (1981) (Stevens, J., dissenting) ("The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. A competent draftsman could attach some form of post-solution activity to almost any mathematical formula . . . . The concept of patentable subject matter under § 101 is not like a nose of wax which may be turned and twisted in any direction . . . . " (quoting Parker v. Flook, 437 U.S. 584, 590 (1978)) (internal quotation marks

ever existed a claim so broad as to preclude all practical applications of a natural phenomenon, claim 13 looks to be one.[61]

In many ways, neither LabCorp's characterization of the invention as a natural phenomenon nor Metabolite's characterization of it as a man-made creation is strictly incorrect. This is because so much of biomedical knowledge represents intrinsically natural knowledge as well as man-made know-how. On the one hand, claim 13 is an application of natural law. The subject matter of the claims requires intervention by human beings (that is, doctors or a machine made by man)[62] whereby measurement of homocysteine would have to be explicitly made and information about the natural correlation would have to be explicitly used. The subject matter involves the use of a natural law for a human benefit—the leveraging of a natural phenomenon in a diagnostic context—which may suffice to elevate the use to be a man-made creation eligible for patenting.

On the other hand, claim 13 merely recites basic knowledge about nature. Consider the well-known physics relation $F = m \cdot a$ (force = mass multiplied by acceleration).[63] The equation $F = m \cdot a$ is a description of a natural phenomenon. Like the correlation between homocysteine and vitamin deficiency, it is a natural law. Calculating the force needed to accelerate an object—in accordance with $F = m \cdot a$—constitutes a mere exercise of one's knowledge about the natural law $F = m \cdot a$, and the mere exercising of knowledge should not automatically make that knowledge "man-made" for patentability purposes.[64] The answer does not change when the form of the natural law is changed into a process reciting a series of steps such as the following: (1) measuring a mass m of the object,

omitted)). *See also LabCorp*, 548 U.S. at 137–38 (Breyer, J., dissenting) (arguing that rewriting natural laws in the form of "instructions" or "process," even if involving a "series of steps," is not sufficient to transform a natural law into eligible subject matter).

61. *See LabCorp*, 548 U.S. at 137–38 (Breyer, J., dissenting); Reply Brief for Petitioner, *supra* note 50, at 13–14.

62. *See LabCorp*, 548 U.S. at 130–31.

63. ANTONIO C. LASAGA, KINETIC THEORY IN THE EARTH SCIENCES 232 (1998).

64. To be more blunt, there is no innovation in plugging in values to variables in a formula to make use of the formula. *See Flook*, 437 U.S. at 595 ("[I]f a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory." (quoting *In re* Richman, 563 F.2d 1026, 1030 (C.C.P.A. 1977))); *In re* Sarkar, 588 F.2d 1330, 1335 (C.C.P.A. 1978) ("No mathematical equation can be used, as a practical matter, without establishing and substituting values for the variables expressed therein. . . . If the steps of gathering and substituting values were alone sufficient, every mathematical equation, formula, or algorithm having any practical use would be per se subject to patenting as a 'process' under § 101. Consideration of whether the substitution of specific values is enough to convert the disembodied ideas present in the formula into an embodiment of those ideas, or into an application of the formula, is foreclosed by the current state of the law.").

(2) determining a desired acceleration a for the object, and (3) multiplying m and a to obtain the force needed to accelerate the object. Such a series of steps merely reflects the natural law $F = m \cdot a$ written in one specific form,[65] not an "invention" founded on $F = m \cdot a$. Merely changing the form in which natural laws are expressed does not change a "natural law" into a "man-made application."[66]

Traditionally, distinguishing between knowledge about nature and man-made know-how has not been difficult because the two types of knowledge represented distinct domains of expertise. Knowledge about nature involves insights about nature gained through observation while man-made knowledge involves know-how created by man to facilitate man's interaction with the natural world.[67] If one looks at a concrete system like a car, a person of skill in the art would have little difficulty delineating which aspects of the car constitute basic phenomena (for example, combustion, electrical conduction, friction, resonance, and so on) and which constitute technical know-how (for example, engines, fuel injection controls, sensors, feedback controls, braking systems, antiskidding controls, noise reduction designs, and so on).

But looking to the human body, one does not have such a good sense. Unlike a car, the human body is itself a product of nature. While man has taken an interest in studying, diagnosing, and treating diseases and conditions afflicting the human body, man has not really created any new processes for use within the human body nor altered the human body in any substantive sense.[68] Almost all medical interventions involve restoring or

65. In general, natural laws can be written in many forms. The relation $F = m \cdot a$ can also be written in the form of conservation of momentum $p = m \cdot v$, for example. *E.g.*, LASAGA, *supra* note 63, at 232. *See also* RUSSELL K. HOBBIE & BRADLEY J. ROTH, INTERMEDIATE PHYSICS FOR MEDICINE & BIOLOGY 83–84 (4th ed. 2007) (discussing, as another example, how continuity equations in general can be written in both integral and differential forms). As yet another example, canonical forms of quantum mechanics can be reformulated completely in terms of Feymann's path integrals. *See, e.g.*, FLOYD WILLIAMS, TOPICS IN QUANTUM MECHANICS 280–90 (2003); R.P. Feynman, *Space-Time Approach to Non-Relativistic Quantum Mechanics*, 20 REV. MOD. PHYSICS 367, 367 (1948).

66. *See LabCorp.*, 548 U.S. at 137–38 (Breyer, J., dissenting).

67. *See infra* notes 221–23 and accompanying text.

68. Some may argue that substantial modifications have already been made to the human body through artificial devices such as pacemakers. In a way, that would be correct. And if pacemaker inventors stick to patenting the "inventive part" of a pacemaker—technologies used to generate timing rhythms, specific controlling software, specific types of conductors, and so on—all will be well. If inventors go on to patent a general method to control heartbeats by use of electrical signals, however, that is when problems arise. Inventors who merely leveraged a natural phenomenon (cardiac conduction) for human benefit now want the credit of inventing the natural phenomenon itself! Unfortunately, this is what often takes place in the biomedical field—as I have tried to argue. Perhaps in the future, we will come up with a truly novel way of regulating heartbeats, using ultrasound waves or

mimicking nature, not replacing or improving nature. Perhaps in the future, man will leave his mark in the biological realm.[69] But for now, man is still at a stage in which medical know-how consists mostly of seeking basic scientific insights into how the human body works and then exercising that basic knowledge to diagnose and treat diseases.

But herein lies the problem. The thrust of much diagnostics research lies in looking to nature for better understandings about how different diseases and conditions manifest themselves and then making direct use of that knowledge to better track and diagnose those diseases and conditions, not inventing wholesale new processes and products for use with the human body. If the human body as a whole—including all the biological processes that take place within the human body—can be viewed as a basic, albeit complex, set of natural phenomena, and if mere insights into these processes will enable diagnosis and treatment of many diseases, does merely exercising basic knowledge for diagnostic or therapeutic purposes constitute a statement (or restatement) of natural law—or an application of basic knowledge rising to the level of an invention? If, in general, the human body as a whole can be considered a product of nature, should knowledge gained about the human body—in fields as diverse as pathology, immunology, oncology, ophthalmology, anatomy, endocrinology, cardiology, and pharmacology relating to both healthy and diseased states—be considered "natural" or "man-made"?

Without a deeper policy insight into the purpose of patenting, and without a solid understanding of basic science and technology, one cannot answer such questions without resorting to ungrounded legalistic and semantics-based arguments. While the Supreme Court ultimately did not decide the *LabCorp* case, one can be sure that controversial issues surrounding subject matter eligibility such as those raised in *LabCorp* will not go away.[70]

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electric signals with special wave characteristics not found in nature. But until then, we must recognize that mere imitation or leveraging of nature for human benefit does not equate to inventing nature.

69. *See, e.g.*, Drew Endy, *Foundations for Engineering Biology*, 438 NATURE 449, 450 (2005) (discussing how to address the obstacles to biological engineering); Alla Katsnelson, *Researchers Start Up Cell with Synthetic Genome*, NATURE (May 20, 2010), http://www.nature.com/news/2010/100519/full/news.2010.253.html (describing how scientists successfully created an entirely new species of bacterium out of a synthetic new genome); *infra* note 216.

70. *See LabCorp*, 548 U.S. at 138 (Breyer, J., dissenting) (arguing that the Court's taking of the case "would help diminish legal uncertainty in the area[,] . . . permit those in the medical profession better to understand the nature of their legal obligations[,] . . . help Congress determine whether legislation is needed[,] . . . [and] contribute to the important ongoing debate . . . as to whether the patent system, as currently administered and enforced, adequately reflects the 'careful balance' that 'the federal patent laws . . . embod[y]'" (last alteration and last ellipsis in original) (quoting Bonito Boats,

B. PATENTING OF MEDICAL THERAPEUTIC TECHNIQUES

Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co. is a case involving the patenting of medical therapeutic techniques.[71] The patent in dispute was U.S. Patent No. 6,410,516 ("the '516 patent"), titled "Nuclear factors associated with transcriptional regulation";[72] Ariad claimed that Eli Lilly's sales and marketing of Evista and Xigris infringed on its patent.[73]

The '516 patent concerns the use of transcription factor[74] Nuclear Factor Kappa B ("NF-κB") to control various biological activities associated with diseases.[75] NF-κB exists in most animal cell types and is involved in cellular responses associated with a wide diversity of stimuli (including stress, cytokines, free radicals, ultraviolet irradiation, oxidized LDL, and bacterial or viral antigen).[76] NF-κB is known to regulate the production of proteins, including those involved in immune and inflammatory responses, developmental processes, cellular growth, and cell

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Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989))); Eisenberg, *supra* note 15, at 318; Roger D. Klein & Maurice J. Mahoney, LabCorp v. Metabolite Laboratories*: The Supreme Court Listens, but Declines to Speak*, 36 J.L. MED. & ETHICS 141, 148 (2008).

71. *See* Ariad Pharm., Inc. v. Eli Lilly & Co., 529 F. Supp. 2d 106, 114 (D. Mass. 2007), *rev'd in part, aff'd in part*, 560 F.3d 1366 (Fed. Cir. 2009), *aff'd*, 598 F.3d 1226 (Fed. Cir. 2010) (en banc).

72. U.S. Patent No. 6,410,516 (filed June 5, 1995).

73. *Ariad Pharm.*, 529 F. Supp. 2d at 112. Since the decision, the patent has been reexamined. The patentee filed a Notice of Appeal with the Board of Patent Appeals and Interferences on May 21, 2009. *Patent Application Information Retrieval for U.S. Patent Application 90/007,503*, U.S. PAT. & TRADEMARK OFF., http://portal.uspto.gov/external/portal/pair (search "Application Number" for "90/007,503"; then follow "Image File Wrapper" hyperlink) (last visited Jan. 18, 2011) (indicating that the Appeal Brief was filed with the USPTO on May 21, 2009). The appeals for the reexamination proceedings for U.S. Patent Application 90/007,503, filed on April 4, 2005, and U.S. Patent Application 90/007,828, filed on December 2, 2005, were merged. *Id.*; *Patent Application Information Retrieval for U.S. Patent Application 90/007,828*, U.S. PAT. & TRADEMARK OFF., http://portal.uspto.gov/external/portal/pair (search "Application Number" for "90/007,828"; then follow "Image File Wrapper" hyperlink) (last visited Jan. 18, 2011) (same).

74. Transcription factors are a class of proteins involved in the expression of genes. *Ariad Pharm.*, 529 F. Supp. 2d at 112.

75. *Id.*

76. *See, e.g.*, Paul Brennan & Luke A.J. O'Neill, *Effects of Oxidants and Antioxidants on Nuclear Factor κB Activation in Three Different Cell Lines: Evidence Against a Universal Hypothesis Involving Oxygen Radicals*, 1260 BIOCHIMICA ET BIOPHYSICA ACTA 167, 167–68 (1995); Nagatoshi Ide & Benjamin H.S. Lau, *Garlic Compounds Minimize Intracellular Oxidative Stress and Inhibit Nuclear Factor-κB Activation*, 131 J. NUTRITION (SUPP.) 1020S, 1020S–21S (2001); Dayuan Li, Tom Saldeen & Jawahar L. Mehta, *γ-Tocopherol Decreases Ox-LDL-Mediated Activation of Nuclear Factor-κB and Apoptosis in Human Coronary Artery Endothelial Cells*, 259 BIOCHEMICAL & BIOPHYSICAL RES. COMM. 157, 158, 160 (1999); Neil D. Perkins, *Integrating Cell-Signalling Pathways with NF-κB and IKK Function*, 8 NATURE REVS. MOLECULAR CELL BIOLOGY 49, 49–50, 56–57 (2007); Ranjan Sen & David Baltimore, *Multiple Nuclear Factors Interact with the Immunoglobulin Enhancer Sequences*, 46 CELL 705, 712–13 (1986).

death (apoptosis).[77] In cells, NF-κB normally couples with Inhibitor Kappa B ("IκB"), forming an inactive multiprotein complex.[78] When cells are subjected to specific external stimuli, such as stress, NF-κB frees from IκB, setting off a chain reaction that in turn affects how various genes are expressed.[79] Abnormal NF-κB activities have been associated with a number of disease conditions, including cancer, arthritis, chronic inflammation, asthma, neurodegenerative diseases, heart disease, AIDS, sepsis, and atherosclerosis.[80]

The inventors of the '516 patent applied for a patent reciting a method for controlling the expression of various genes through control of NF-κB activity. Claims 1 and 95 of the '516 patent recite, for example:

> 1. A method for inhibiting expression, in a eukaryotic cell, of a gene whose transcription is regulated by NF-κKB, the method comprising reducing NF-κKB activity in the cell such that expression of said gene is inhibited.[81]
>
> 95. [A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-κB-mediated intracellular signaling, the method comprising reducing NF-κB activity in the cells such that expression of said genes is reduced], carried out on human cells.[82]

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77. *See, e.g.*, James C. Cusack et al., *Enhanced Chemosensitivity to CPT-11 with Proteasome Inhibitor PS-341: Implications for Systemic Nuclear Factor-κB Inhibition*, 61 CANCER RES. 3535, 3535 (2001); Rainer de Martin et al., *The Transcription Factor NF-κB and the Regulation of Vascular Cell Function*, 20 ARTERIOSCLEROSIS, THROMBOSIS & VASCULAR BIOLOGY 1, 1–2 (2000).

78. *See Ariad Pharm.*, 529 F. Supp. 2d at 112; Perkins, *supra* note 76, at 49.

79. *See generally* T.D. Gilmore, *Introduction to NF-κB: Players, Pathways, Perspectives*, 25 ONCOGENE 6680 (2006) (providing an overview of the current state of knowledge of the NF-κB regulatory pathway, including a review of the structures of various molecules and the schemes of various signaling pathways involved).

80. *See, e.g.*, *id.* at 6681 (apoptosis and cancer); Edward Abraham, *Nuclear Factor-κB and Its Role in Sepsis-Associated Organ Failure*, 187 J. INFECTIOUS DISEASES (SUPP. 2) S364, S364 (2003) (sepsis); John Hiscott, Hakju Kwon & Pierre Génin, *Hostile Takeovers: Viral Appropriation of the NF-κB Pathway*, 107 J. CLINICAL INVESTIGATION 143, 144–45 (2001) (AIDS); Lindsey Jackson & B. Mark Evers, *Chronic Inflammation and Pathogenesis of GI and Pancreatic Cancers*, *in* THE LINK BETWEEN INFLAMMATION AND CANCER: WOUNDS THAT DO NOT HEAL 39, 61 (Angus G. Dalgleish & Burkhard Haefner eds., 2006) (cancer); Mark P. Mattson & Simonetta Camandola, *NF-κB in Neuronal Plasticity and Neurodegenerative Disorders*, 107 J. CLINICAL INVESTIGATION 247, 250 (2001) (neurodegenerative diseases); A. Pahl & I. Szelenyi, *Asthma Therapy in the New Millennium*, 51 INFLAMMATION RES. 273, 278 (2002) (chronic inflammation and asthma); J.A. Roman-Blas & S.A. Jimenez, *NF-kB as a Potential Therapeutic Target in Osteoarthritis and Rheumatoid Arthritis*, 14 OSTEOARTHRITIS & CARTILAGE 839, 839 (2006) (arthritis); Jeffery S. Ross et al., *Atherosclerosis: A Cancer of the Blood Vessels?*, 116 AM. J. CLINICAL PATHOLOGY (SUPP. 1) S97, S101–02 (2001) (atherosclerosis); Guro Valen, Zhong-qun Yan & Göran K. Hansson, *Nuclear Factor Kappa-B and the Heart*, 38 J. AM. C. CARDIOLOGY 307, 309–11 (2001) (heart disease).

81. U.S. Patent No. 6,410,516 col. 82 ll. 13–16 (filed June 5, 1995).

82. *Id.* col. 86 l. 12 (claim 95 depends from claim 9).

In response to a jury finding that Eli Lilly had infringed four dependent claims,[83] Eli Lilly argued that Ariad's claims represented unpatentable subject matter since the regulation of NF-κB associated genes was a phenomenon that existed in nature.[84] Eli Lilly cited scientific references detailing the role the NF-κB-IκB autoregulatory loop (the "Autoregulatory Loop") played in regulating the expression of various NF-κB associated genes.[85]

Ariad countered by arguing that its claims covered man-made constructs, not natural phenomena. The biochemical processes underlying the regulation of NF-κB were not well known at the time the '516 patent was filed.[86] Even today, the detailed mechanisms of the Autoregulatory Loop are not completely understood.[87] What Ariad contributed was a useful model of how the human body worked, a model that could then be leveraged to treat real-life diseases and conditions.[88] The fact that later-obtained knowledge about nature corroborated and confirmed many aspects of Ariad's model should be a cause for celebration, not invalidation.

Part of the conflict here stems again from confusion over the basic scope of knowledge about nature. The thrust of much therapeutics research lies in learning how diseases progress in human bodies, comparing how biological processes work in diseased and healthy bodies, and then leveraging naturally occurring products and processes to control and treat these diseases and conditions. Knowledge about the Autoregulatory Loop represents an understanding of a basic phenomenon that occurs naturally in the human body. That same knowledge, however, also represents knowledge about biochemical mechanisms that doctors can directly leverage to diagnose and treat human diseases from chronic inflammation to cancer.[89] The issue here is not per se about the obviousness of medical know-how, but the intrinsic scope of natural laws. Properly understood, discoveries of the Autoregulatory Loop (and effects thereof) represent both basic insights into nature as well as know-how dictating how human

83. The claims were 80, 95, 144, and 145. *Ariad Pharm.*, 529 F. Supp. 2d at 114–15.

84. *Id.* at 116.

85. *Id.* at 117–19.

86. *Id.* at 118.

87. *See id.* at 116 ("[Ariad argues that] the Autoregulatory Loop is only a theory and has not been proven to exist in human cells *in vivo*. . . . I find that Lilly has failed to show that the proposed model of the Autoregulatory Loop actually exists in nature and thus that a natural phenomenon is encompassed by the '516 patent's claims.").

88. *See id.* (noting that what Ariad created is only a model).

89. *See supra* notes 75–80 and accompanying text (discussing how various disease mechanisms are affected by the NF-κB activities and that this fact directly informs, even defines, how diseases can be treated).

diseases are to be diagnosed and treated.

While it is true that all diagnostic or therapeutic methods—as here—necessarily include a human component (for example, observation or action by a doctor), a human component per se is often stipulated by the form in which a law is expressed—and hence should not per se be the basis for elevating all diagnostic or therapeutic processes or techniques to be "man-made."[90] The mere exercising of knowledge about nature, even if for a laudatory human goal,[91] should not automatically make the idea a "man-made application."[92]

Ariad's method comprises controlling biological activities using the same processes and for the same ends as occur naturally in healthy human bodies. No new biochemical pathways are created, no artificial elements are introduced, and no unpredictable effects are produced beyond what already happens in nature.[93] The process is more akin to determining the force needed to accelerate an object by plugging values of *m* and *a* into the formula $F = m \cdot a$ than it is to inventing new processes, new products, new effects, and new results that enable objects to be moved.

For some, allowing Ariad's claims to be invalidated on the basis of subject matter eligibility also raises the uncomfortable notion of allowing future-acquired knowledge to invalidate past claims.[94] If one is to take seriously the notion that subject matter eligibility is to be delimited based on what is natural and what is man-made, ignorance about what exists in nature at one time should not be grounds for redefining the boundary of subject matter eligibility. What is natural is natural; what is man-made is man-made—regardless of when the true character of nature is revealed.

The Federal Circuit ultimately did not reach the substance of the subject matter dispute upon appeal in the *Ariad* case; it instead held that the claims were invalid for failing to satisfy the written description requirement.[95] The lower court did reach the issue but held that Eli Lilly

90. *See supra* notes 60, 64 and accompanying text.

91. This really proves only the usefulness of the knowledge.

92. *See, e.g.*, *supra* note 64 (demonstrating that mere substitution of values into an equation does not make an application eligible for patenting).

93. *Cf.* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948) (finding that a soil bacterial mixture was ineligible for patenting because "[t]he combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility").

94. *See supra* notes 86–87 and accompanying text.

95. *See* Ariad Pharm. Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1380 (Fed. Cir. 2009), *aff'd*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc). The Federal Circuit in an en banc decision later held that 35 U.S.C. § 112, first paragraph, contains a written description requirement separate from an enablement requirement and set forth in part some of the scope and purpose of the requirement. *See Ariad Pharm.*,

failed to carry its burden to prove invalidity by "clear and convincing evidence."[96]

In another case involving the patenting of biochemical pathways in the context of medical therapeutic techniques, the Federal Circuit held certain specific "methods for calibrating the proper dosage of thiopurine drugs"[97] to be eligible subject matter.[98] The lower court had held U.S. Patents 6,355,623 ("the '623 patent")[99] and 6,680,302 ("the '302 patent")[100] to be invalid under 35 U.S.C. § 101.[101] But the Federal Circuit reversed, holding the claims to be valid under its newly announced machine-or-transformation test.[102]

Claim 1 of the '623 patent is representative of the claims in dispute[103] and recites the following:

> A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
>
> (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
>
> wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
>
> wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.[104]

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598 F.3d at 1349.

96. Ariad Pharm., Inc. v. Eli Lilly & Co., 529 F. Supp. 2d 106, 120 (D. Mass. 2007), *rev'd in part*, *aff'd in part*, 560 F.3d 1366, *aff'd*, 598 F.3d 1226.

97. Prometheus Labs., Inc. v. Mayo Collaborative Servs. (*Prometheus I*), 581 F.3d 1336, 1339 (Fed. Cir. 2009), *vacated*, 130 S. Ct. 3543 (2010).

98. *Id.* at 1345–46; Prometheus Labs., Inc. v. Mayo Collaborative Servs. (*Prometheus II*), No. 2008-1403, 2010 U.S. App. LEXIS 25956, at *21 (Fed. Cir. Dec. 17, 2010) (affirming *Prometheus I*, vacated and remanded by the Supreme Court following *Bilski*, in light of *Bilski*).

99. U.S. Patent No. 6,355,623 (filed Apr. 8, 1999).

100. U.S. Patent No. 6,680,302 (filed Dec. 27, 2001).

101. Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04cv1200 JAH (RBB), 2008 U.S. Dist. LEXIS 25062, at *46 (S.D. Cal. Mar. 28, 2008).

102. *Prometheus I*, 581 F.3d at 1342–43, 1350; *Prometheus II*, 2010 U.S. App. LEXIS 25956, at *14–16 (affirming that the machine-or-transformation test, while not the exclusive or dispositive test of subject matter eligibility, is applicable to the *Prometheus* case).

103. *Prometheus I*, 581 F.3d at 1340; *Prometheus II*, 2010 U.S. App. LEXIS 25956, at *5.

104. '623 Patent col. 20 ll. 10–25. Claims 46 and 53 forego the "administering" step, but according to the *Prometheus II* court, the "determining" step is sufficient to render the claim sufficiently transformative to constitute eligible subject matter. *See Prometheus II*, 2010 U.S. App.

According to the Federal Circuit, when a drug is administered "the human body necessarily undergoes a transformation."[105] The method includes "administering" and "determining" steps that render the treatment protocol "transformative," and hence it constitutes eligible subject matter.[106]

Unfortunately, tests such as the machine-or-transformation test do not fundamentally constitute a new analysis distinct from the nature-versus-man-made or abstract-versus-applied analysis.[107] Most natural biological processes already involve concrete, physical "transformations," with biological systems taking on characteristics of complex "machines."[108] Consider the "treatment protocol" in the '623 patent that leverages knowledge about the naturally occurring relationship between 6-thioguanine and immune-mediated gastrointestinal disorders to dictate the amount of a drug that should be taken. On the one hand, the recited method constitutes merely the natural correlation restated in "feedback form"[109] in a clinical setting.[110] On the other hand, the treatment protocol constitutes

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LEXIS 25956, at *18–19.

105. *Prometheus I*, 581 F.3d at 1346; *Prometheus II*, 2010 U.S. App. LEXIS 25956, at *15–16.

106. *Prometheus I*, 581 F.3d at 1345–47; *Prometheus II*, 2010 U.S. App. LEXIS 25956, at *16–19.

107. *In re* Bilski, 545 F.3d 943, 1013 (Fed. Cir. 2008) ("[A]ll of the transformation and machine linkage explanations simply restated the [judicial prohibition against the patenting of nature and abstract ideas]."), *aff'd*, 130 S. Ct. 3218 (2010). Note that the machine-or-transformation test has been weakened by the Supreme Court in *Bilski*, in which the Court noted that "the machine-or-transformation test is a useful and important clue, an investigative tool," but not "the sole test" "for determining whether some claimed inventions are processes under § 101." *Bilski*, 130 S. Ct. at 3227.

108. *See, e.g.*, COMM. ON BIOMOLECULAR MATERIALS & PROCESSES ET AL., INSPIRED BY BIOLOGY: FROM MOLECULES TO MATERIALS TO MACHINES 107–14 (2008) (exploring how natural molecular machineries can be leveraged to enable new forms of material processing and manufacturing in the future); Marenglen Biba et al., *A Hybrid Symbolic-Statistical Approach to Modeling Metabolic Networks*, *in* KNOWLEDGE-BASED INTELLIGENT INFORMATION AND ENGINEERING SYSTEMS: KES 2007–WIRN 2007, at 132, 132 (Bruno Apolloni, Robert J. Howlett & Lakhmi Jain eds., 2007) (discussing complex biological systems in the context of a new approach to model metabolic networks).

109. An example of $F = m \cdot a$ written in algorithmic form was discussed earlier. *See supra* notes 64–65 and accompanying text. An example of $F = m \cdot a$ written in feedback form would look something like this:

> A method to apply the correct amount of force needed to accelerate an object, comprising:
>
> (1) Determining an acceleration needed for an object;
>
> (2) Measuring the mass of the object;
>
> (3) Calculating and applying an initial force to an object in accordance with the relationship $F = m \cdot a$;
>
> (4) Measuring an acceleration for the object; and
>
> (5) Iteratively decreasing the force when the acceleration exceeds the acceleration expected and increasing the force when the acceleration falls below the acceleration expected.

110. *See Bilski*, 130 S. Ct. at 3231 ("*Flook* established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable."); Diamond v. Diehr, 450 U.S. 175, 191–92 (1981) ("A mathematical formula (or scientific principle or phenomenon of nature) . . . is not accorded the protection of our patent laws, . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment."

valuable and insightful know-how useful for treating immune-mediated gastrointestinal disorders, know-how that prescribes concrete steps for physicians to treat gastrointestinal disorders.[111]

C. PATENTING OF PURIFIED BIOLOGICAL EXTRACTS—GENES

The practice of patenting genes has existed for some time and has also generated a lot of controversy.[112] Currently, U.S. law treats genes predominately as chemical molecules and allows their patenting based on the well-established doctrine that purified forms of naturally occurring compounds may be eligible for patenting if the purified forms have been changed and provide novel properties so as to become effectively a new material.[113] Just as compounds extracted from the human body have long been deemed eligible for patenting (even if no new compounds—for example, molecules—have been produced),[114] genetic materials that have

(citations omitted)).

111. Utility alone, however, does not define subject matter eligibility. *See infra* note 195.

112. *See, e.g.*, John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part II)*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 371, 394–95 (2003) (arguing that once genes are viewed correctly as information and not mere chemical products, they should not be patentable); R. Stephen Crespi, *Patents on Genes: Clarifying the Issues*, 18 NATURE BIOTECHOLOGY 683, 683 (2000) (summarizing arguments against the patenting of genes on the grounds that "(1) Genes exist in nature and therefore, as our natural heritage, they should not be 'owned' by any individual or group. (2) Genes are discoveries and not inventions. (3) Because of their existence in nature, genes cannot be 'new.' (4) Gene isolation and cloning is now such a well-established technique that it is no longer inventive to do it"); Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 741–44 (2004) (arguing that the patenting of genes is based on outdated applications of the natural products doctrine); Paradise, Andrews & Holbrook, *supra* note 5, at 1567 (reporting on the growing domestic and international opposition to gene patents); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 298–99 (2003) (discussing how the practice of patenting genes can impede fundamental research); Phyllida Brown & Kurt Kleiner, *Patent Row Splits Breast Cancer Researchers*, NEW SCIENTIST, Sept. 24, 1994, at 44 (reporting on a debate regarding the patenting of genes); Joseph Stiglitz & John Sulston, *The Case Against Gene Patents*, WALL ST. J., Apr. 16, 2010, at A19 (voicing concern over the patenting of genes, economics Nobel laureate Joseph Stiglitz and medicine Nobel laureate John Sulston support a lower court decision finding two gene patents invalid).

113. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (describing an "isolated and purified DNA molecule" as a "chemical compound[]" and therefore patentable "subject to satisfying the other criteria for patentability"); *id.* at 1092–96 (noting that extracted genes are eligible for patenting if they demonstrate some credible utility).

114. *See* Amgen, Inc. v. Chugai Pharm. Co., 706 F. Supp. 94, 103–04 (D. Mass. 1989) (validating a patent that claims all purified EPO (a protein involved in the production of red blood cells), however derived); Scripps Clinic & Research Found. v. Genentech, Inc., 666 F. Supp. 1379, 1389 n.6 (N.D. Cal. 1987) ("There is no dispute over the patentabilility of Factor VIII:C preparation[] [(a protein that plays an essential part in blood clotting)] . . . [a]lthough Factor VIII:C molecules occur in nature . . . [since] a purified and concentrated preparation of Factor VIII:C . . . constitutes a new form or combination not existing in nature."); Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911)

been extracted from the human body may also be considered novel material eligible for patenting.[115] While the U.S. Patent and Trademark Office ("USPTO") has accepted gene patenting for some time, the European Patent Office has until recently refused to issue patents that recite human genes, but the moratorium was lifted in 1999 when the European Commission directed the European Patent Office to harmonize E.U. biotechnology patent law with that of the United States.[116]

Opponents of gene patents generally attack the patenting of genes on two grounds. The first involves arguing that the processes for gene isolation and sequencing constitute routine processing steps necessary for making genes accessible to biotechnological techniques.[117] Natural

(holding adrenaline purified and isolated from the human body to be patentable because "even if [the adrenaline] were merely an extracted product without change, . . . it became for every practical purpose a new thing commercially and therapeutically"), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912); European Patent Office, Japanese Patent Office & U.S. Patent & Trademark Office, *Comparative Study of Patent Practices in the Field of Biotechnology Related Mainly to Microbiological Inventions*, 7 BIOTECHNOLOGY L. REP. 159, 163 (1988) ("[P]urified natural products are not regarded . . . as products of nature or discoveries because they do not, in fact, exist in nature in a purified form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds. . . . Microorganisms isolated from nature would qualify for patenting, if the characteristic property or quality of the isolate is not expressed by the natural product, such as a biologically pure culture of the microorganism . . . ."). Note, however, that while the European Patent Office ("EPO") generally recognizes the patenting of purified products, the European Union has taken the position that patenting of isolated but unmodified stem cells is not allowed on moral grounds since it "may be considered . . . a form of commercialisation of the human body." *Opinion of the European Group on Ethics in Science and New Technologies on the Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, at 15, Op. No. 16 (May 7, 2002), *available at* http://ec.europa.eu/european_group_ethics/docs/avis16_en.pdf. *See also* RUSSELL KOROBKIN, STEM CELL CENTURY: LAW AND POLICY FOR A BREAKTHROUGH TECHNOLOGY 105 (2007) (noting that some U.S. holders of stem cell patents have been unsuccessful in obtaining European patents); *infra* note 133.

115. *See, e.g.*, Utility Examination Guidelines, 66 Fed. Reg. at 1093 ("An isolated and purified DNA molecule . . . does not occur in that isolated form in nature . . . . Patenting compositions or compounds isolated from nature follows well-established principles . . . ."); *id.* at 1092–97 cmts. 1, 4, 7–8, 10, 16 & 19. *Cf. Ex parte* D, No. 92-1168, 1993 WL 236533, at *2 (B.P.A.I. Jan. 29, 1993) (disallowing a patent for a DNA sequence because the claims "contain no indication that the DNA sequence is either isolated or purified. Therefore, it appears that the DNA sequence to which these claims are directed does not distinguish from the naturally occurring substance").

116. *E.g.*, Council Directive 98/44, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, art. 5, 1998 O.J. (L 213) 18 (EC); Alison Abbott & Ulrike Hellerer, *Politicians Seek to Block Human-Gene Patents in Europe*, 404 NATURE 802, 802 (2000).

117. *See* Richard F. Harris, *Patenting Genes: Is It Necessary and Is It Evil?*, 10 CURRENT BIOLOGY R174, R175 (2000) (lamenting how "intellectual property can now be manufactured by the bushel barrel. Mostly what it requires is some DNA sequencers, a cadre of PhDs and a computer algorithm that can spot homologies between novel stretches of DNA and sequences of known function. Presto, a gene patent is born"); Brian A. Jackson, *Innovation and Intellectual Property: The Case of Genomic Patenting*, 22 J. POL'Y ANALYSIS & MGMT. 5, 15–16 (2003) (questioning "whether the simple

products that are routinely isolated and purified to make them amenable to be measured, studied, and manipulated by modern biotechnological processes should not be considered a novel human "manufacture" or "composition of matter" eligible for patenting.[118]

A second line of attack involves viewing genes fundamentally as information, not chemicals.[119] Genes are sought after for the information contained within, not for their chemical properties per se.[120] As information, it is difficult to see how extracted genes can be considered so transformed as to become a new product altogether.[121] Genes that have been isolated and sequenced are valued precisely for the faithful copies of naturally occurring information contained within—information that directs life processes and that confers the keys to understanding and manipulating,

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act of disclosing a sequence is of sufficient value to merit the societal reward of monopoly rights . . . [and whether,] since research groups are willing to perform these tasks and disclose their results without the reward of patent rights, society should pay [a] premium to other firms or individuals to do so"); *Who Owns Your Genes?: Not All the Questions Raised by Genomics Are Scientific Ones*, ECONOMIST: SURV. HUM. GENOME, July 1, 2000, at 14 (quoting James Watson, one of the discoverers of the helical nature structure of DNA, to characterize today's mass-structural sequencing effort as "monkey work"—processes that according to some are "so trivial that the discoverers don't deserve patent protection").

118. *See, e.g.*, Demaine & Fellmeth, *supra* note 36, at 392 (conceding that the discovery of genes is "more complicated than turning over a rock to find a new substance," and asking "[a]t what point . . . a naturally occurring substance become[s] purified or otherwise altered to the point of newness"); Kane, *supra* note 112, at 765 (arguing that patenting of extracted gene products constitutes "effective occlusion [of the unpatentable] through the patenting of products or methods which are the only means of accessing the unpatentable").

119. Larry L. Deaven, *DNA Libraries: Recombinant Clones for Mapping and Sequencing*, *in* THE HUMAN GENOME PROJECT: DECIPHERING THE BLUEPRINT OF HEREDITY 218, 220 (Necia Grant Cooper ed., 1994) [hereinafter HUMAN GENOME PROJECT] (describing DNA as a "library" containing information); Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 786 (2000) ("DNA sequences are not simply molecules, they are also information."); *id.* at 794 ("Patent claims to information—even useful information—represent a fundamental departure from the traditional patent bargain."); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 836 (1999) ("Although DNA is, obviously enough, a chemical compound, it is more fundamentally a carrier of *information*.").

120. *See* Andrews, *supra* note 15, at 803 ("The useful properties of a gene's sequence . . . are not ones that scientists have invented, but instead, are natural, inherent properties of the genes themselves."); *id.* ("[H]uman nucleotide sequences should not be patentable . . . [simply] because such scientific information should be available to all."); Kane, *supra* note 112, at 752 (asserting that "apart from any questions related to patent law," "the genetic code should be characterized as a law of nature, based on its essential attributes, its historical treatment in scientific literature and public discourse, and its centrality in modern molecular biology"); *id.* at 712–13 ("The complexity of the DNA molecule requires a theory of the gene that incorporates its duality as chemical and template to properly evaluate its eligibility for patent protection.").

121. *See* Nuno Pires de Carvalho, *The Problem of Gene Patents*, 3 WASH. U. GLOB. STUD. L. REV. 701, 723 (2004) ("[I]solated, purified and synthesized [human] genes . . . maintain identical or very similar characteristics to those found in nature . . . [and] realize exactly the same function that genes inserted in their natural environment perform.").

at the most fundamental level, naturally occurring biological processes.[122] In fact, were genetic information to be altered by the extraction process, extracted genes would no longer be useful.[123]

What makes gene patents especially troubling is that, unlike traditional purified chemical products, isolated genes do not represent end products by themselves. In the traditional pharmaceutical context, the chemicals being patented—the isolated pharmaceutical compounds—represent for the most part end products.[124] Even if the scope of patents in the pharmacological field were incorrectly assessed, and product patents routinely issued for what are essentially process innovations,[125] the downside risks of such patenting would be limited since the effects on

122. After all, the sequencing of genes involves the faithful identification of the nucleotide sequences of genes. This is also why the resulting sequences have been referred to as an "atlas" or a "blueprint" for understanding human biology at the most basic level. James W. Fickett, *Computation and the Genome Project—A Shotgun Wedding*, *in* THE HUMAN GENOME PROJECT, *supra* note 119, at 250, 252. *See also* Andrews, *supra* note 15, at 804–05 (discussing the important role sequenced genes play in the basic understanding of diseases and conditions of the human body).

123. *See* Andrews, *supra* note 15, at 804–05. Some may argue that the process of splicing out introns to produce only the coding portion of the genome, that is, exons, should render sequenced materials a new "manufacture" under patent law. Splicing per se, however, is hardly a unique or artificial process. In normal processes occurring in the human body, subsections of genomes such as "exons" are routinely processed—such as in the production of RNAs. *E.g.*, COMM. ON MAPPING & SEQUENCING THE HUMAN GENOME ET AL., MAPPING AND SEQUENCING THE HUMAN GENOME 16 (1988); MICHAEL KENT, ADVANCED BIOLOGY 403 (2000); MARY JANE WEST-EBERHARD, DEVELOPMENTAL PLASTICITY AND EVOLUTION 48–49 & fig.3.9 (2003). *See also* WEST-EBERHARD, *supra* at 320–23 (surveying theories on the important roles that naturally occurring exons and introns play in facilitating evolution). Even if the separating of exons from introns were to be considered "artificial," it is so only when viewed at a specific level of granularity; viewing genes at the level of exons and introns, the excising of exons and introns would not produce new entities just as the separation of nickels and dimes from a pile of coins would not create new coins. *See* Brief for Amicus Curiae Affymetrix, Inc. in Support of Appellee, *In re* Fisher, 421 F.3d 1365 (Fed. Cir. 2005) (No. 04-1465), 24 BIOTECHNOLOGY L. REP. 514, 521–22 (2005) (noting in an amicus brief filed by Affymetrix—a world-leading gene chip producer—that "isolated, purified and synthesized" cDNA molecules—basic ingredients underlying modern biotechnological technologies—are products of nature, even when noncoding genetic regions have been excised, since extracted DNA materials do not differ from the naturally occurring materials in any biologically substantial way).

124. *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 882–83 (1990) ("A new chemical product is in most cases a discrete entity, or it may encompass a particular class of products, like penicillin. But particular chemical product innovations seldom are the keystones to the development of large numbers of other chemicals. Although there are recognizable families of chemical products, the invention of one chemical species seldom gives more than general guidance in the development of other species. This is primarily a function of the complex and unpredictable relationship between chemical structure and function, most clearly evident in the pharmaceutical industry.").

125. *Id.* at 914 (discussing situations in which patents should issue for "a *process*, or at most a 'product-by-process,' rather than for a product"); Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 735–36 (1990) (noting that product patents are generally favored over process patents wherever available because product patents are easier to enforce than process patents).

follow-on or concurrent innovations would be confined.[126]

This unfortunately is not the case in the genetic context. The patenting of DNA is about control over information. Those who own gene patents control the gateways to developing and practicing tomorrow's most promising diagnostic techniques and medical cures. When genes are incorrectly deemed to be eligible for patenting, the effects can chill a broad spectrum of follow-on activities.[127] In 2010, for the first time, a U.S. court, following up on the observation that genes should be assesed as information and not mere chemicals, held extracted genes to be ineligible subject matter.[128] It will be interesting to see how the Federal Circuit, and perhaps later the Supreme Court, responds.

The controversies over the patenting of genes arise from the same efforts to try to make the difficult—and often arbitrary—delineation between the natural and man-made in the biomedical field. Viewed from a high enough level of granularity—looking at DNA materials from the perspective of a layman—extracted genetic material may indeed be seen as "artificial," since a purified batch of extracted DNA material does confer properties that an unpurified, natural batch of DNA materials does not.[129] But viewed at a lower level of granularity, extracted DNA begins to look less different. Extracted DNA molecules process the same molecular

126. *See* Merges & Nelson, *supra* note 124, at 880–82 (discussing the relatively mild costs of patents with overly broad scopes in the "discrete invention model" of traditional pharmaceutical industries but warning that such patents can gravely disincentivize innovation in industries that do not practice the discrete invention model).

127. Time will tell whether these effects will be amplified or reduced as diagnostic technology moves from tests involving single genes (such as BRCA1 and BRCA2 for breast and ovarian cancers) to tests involving multiple genes or even entire genomes. *See* John R. ten Bosch & Wayne W. Grody, *Keeping Up With the Next Generation: Massively Parallel Sequencing in Clinical Diagnostics*, 10 J. MOLECULAR DIAGNOSTICS 484, 484 (2008) (discussing the technical issues and practical considerations that must be addressed before the trend toward multiple-gene and genome-based diagnostic applications "becomes accepted medical practice"); Evans, *supra* note 15, at S3 ("When rights to the human genome are fragmented to the point that thousands of genes are 'owned' by myriad parties (pun intended), how will we hack our way through the resultant thicket to facilitate the application of multiplex genotyping, multiplex sequencing, and whole genome sequencing?"). *But see* Merges & Nelson, *supra* note 124, at 912 (noting that in an industry in which the intellectual property on which real-world application is developed is sufficiently fragmented, there is an incentive to cross-license, which could "reduce[] the potential blocking effect of a broad patent").

128. *See* Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010) ("DNA represents the physical embodiment of biological information . . . . It is concluded that DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes.").

129. DNA materials in their natural forms are not amenable to being sequenced or otherwise being used in modern biotechnological applications, unlike purified DNA materials. *See, e.g.*, Kapil Mehta et al., *Recombinant Proteins and Genomics in Cancer Therapy*, *in* PRINCIPLES OF CANCER BIOTHERAPY 53, 53–54 (Robert K. Oldham & Robert O. Dillman eds., 5th ed. 2009).

structures and information as natural forms of DNA.[130] A sequence of nucleotides—a segment of information content—in extracted DNA can always be mapped one-to-one to a sequence of nucleotides—another segment of information content—in DNA occurring naturally in the human body. The fact that isolated genetic materials are often stored in complementary forms does not per se make the extracted forms artificial.[131]

D. PATENTING OF PURIFIED BIOLOGICAL EXTRACTS—STEM CELLS

The patenting of stem cells has also been controversial, with many concerned that the patenting of stem cells and related products will impede future advancements of critical technologies.[132] The controversy surrounding patents over embryonic stem cells issued to Wisconsin Alumni Research Foundation ("WARF") illustrates some of the issues.[133]

Between 1998 and 2006, three patents—all titled "Primate embryonic stem cells"—were issued to WARF.[134] Patentee James A. Thomson broadly claimed "preparations" and "purified preparations" of various embryonic stem cells. One of these claims recited

> [a] purified preparation of pluripotent human embryonic stem cells

130. For example, a naturally occurring DNA molecule with a sequence ACTG-TGAC must still have the sequence ACTG-TGAC when extracted and sequenced. Faithful reproduction of DNA sequences is essential to any extraction and sequencing technique. *See, e.g.*, THE HUMAN GENOME PROJECT, *supra* note 119, at 71, 204–06, 218, 220, 252 (characterizing the human genome project as an effort to obtain a copy—a "library," "blueprint," "map," or "atlas"—of all "instructions" that power human biological processes); J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCIENCE 1304, 1306 (2001) ("[A] correctly and accurately assembled genome sequence with faithful order and orientation of contigs is essential for an accurate analysis of the human genetic code . . . .").

131. First, the transformations of DNA molecules from one form to a complementary form routinely occur in nature. *See* KENT, *supra* note 123, at 402–05 (describing the transcription and translation processes that involve, among others things, a step for copying DNAs into complementary forms of DNAs and RNAs); *id.* at 74–75, 390–95 (describing DNA replication involving duplication of complementary strands of DNAs). Second, irrespective of whether the transformations occur in nature, the genetic information is not altered. The resultant products (isolated genes in complementary form) all correspond one-to-one with genes residing in the human body and are all converted back into the original complementarity when actually used. *See id.* at 406–07 (describing genetic engineering techniques involving reverse transcription and DNA synthesis processes).

132. *See* KOROBKIN, *supra* note 114, at 102–04 (arguing that transaction costs associated with licensing stem cells will chill future development of the critical technology); Bergman & Graff, *supra* note 8, at 422 (arguing against patenting of stem cells because workarounds will be especially difficult in the area).

133. The EPO "prohibit[ed] the patenting of human stem cell cultures whose preparation necessarily involves the destruction of human embryos." *No European Patent for WARF/Thomson Stem Cell Application*, IPBIO NETWORK (Nov. 27, 2008), http://ipbio.org/Warf.htm.

134. U.S. Patent No. 5,843,780 (filed Jan. 18, 1996) (issued Dec. 1, 1998); U.S. Patent No. 6,200,806 (filed Jun. 26, 1998) (issued Mar. 13, 2001); U.S. Patent No. 7,029,913 (filed Oct. 18, 2001) (issued Apr. 18, 2006).

> which (i) will proliferate in an in vitro culture for over one year, (ii) maintains a karyotype in which the chromosomes are euploid and not altered through prolonged culture, (iii) maintains the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) is inhibited from differentiation when cultured on a fibroblast feeder layer.[135]

It is important to realize that Thomson did not just attempt to claim the novel processes he relied on to purify and prepare stem cells, but the actual stem cells themselves (specifically the "purified preparation" of stem cells).[136]

As another example, consider a claim by Andrea G. Bodnar and others issued to Geron Corporation in 2004, reciting "[a] cellular composition comprising undifferentiated human embryonic stem cells proliferating on an extracellular matrix, wherein the composition is free of feeder cells."[137] Similar to Thomson's claim, the claim broadly recites the biological products—herein a "cellular composition" of "undifferentiated human embryonic stem cells . . . free of feeder cells"—isolated from the human body, irrespective of the methods used for obtaining the cells.

One of the key legal questions raised by patents such as the WARF and Geron patents is whether the rule that allows the first to purify a product also to receive product rights, traditionally applied to drugs and certain chemical compounds,[138] should also apply to stem cells. Should Thomson and Bodnar, being the first to succeed in isolating specific samples of stem cells, deserve rights not only to just the techniques used for isolating those cells, but also to the cells isolated, even all cells—including those yet to be isolated—sharing similar characteristics as those isolated?

The issues raised are similar to those raised by the patenting of genes. When does the extraction, purification, and preparation of naturally

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135. '806 Patent col. 21 ll. 12–20.

136. *Id.*; Peter Yun-hyoung Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine to Constrain Patents on Biotechnology Research Tools*, 19 HARV. J.L. & TECH. 79, 90 (2005).

137. U.S. Patent No. 6,800,480 col. 23 ll. 50–52. (filed Oct. 23, 1998) (issued Oct. 5, 2004). Interestingly, claim 1 recites "[a] cellular composition comprising undifferentiated primate primordial stem (pPS) cells proliferating on an extracellular matrix, wherein the composition is free of feeder cells." *Id.* col. 21 ll. 53–56.

138. *See supra* notes 113–14 and accompanying text. *Cf.* Merges & Nelson, *supra* note 124, at 851 ("[I]t is stretching the concept of inventing greatly to say that the patentee [who purifies products that exist in nature] really invented the products. The true invention seems to be a way of producing those products in a desirable form.").

occurring products render the resulting products different enough to be considered man-made? On the one hand, viewed from a high enough level of granularity, that is, at a bulk-sample level, the "cellular compositions" and "purified preparations" can be characterized as a novel, man-made "composition of matter."[139] Purified batches of stem cells (that is, "purified preparations" or "cell compositions") confer properties that natural unpurified batches of stem cells do not. One can grow and harvest a purified batch of stem cells for extended time outside the human body and later induce those cells to specialize into specific types of tissue in the human body, when one cannot do the same with natural unpurified samples of stem cells, for example.[140] Consequently, just as purified adrenaline,[141] purified yeast (free from organic germs of disease),[142] and purified Streptomyces vellosus (enabling antibiotic lincomycin to be collected in sizable quantities for the first time)[143] can be viewed as a new "composition of matter" or "articles of manufacture," so too can Thomson's "purified preparation,"[144] various purified types of prostaglandins,[145] or Bodnar's "cellular composition."[146]

On the other hand, when viewed at a low enough level of granularity, little if anything has been created. Thomson and Bodnar did not so much

139. No U.S. court has yet ruled on whether human embryonic stem cells are patentable, although biological materials that have been isolated from nature seem in general to be eligible for patents. *See, e.g.*, Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1347 (Fed. Cir. 1998) (holding U.S. Patent No. 4,714,680, covering "[a] suspension of human cells comprising pluripotent lympho-hemapoietic stem cells *substantially free of mature* lymphoid and myeloid *cells*" to be infringed, implying that the patent must be valid (quoting U.S. Patent No. 4,714,680 col. 20 ll. 56–58 (filed Feb. 6, 1984))); *id.* at 1356; Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1203–04 (Fed. Cir. 1991) (holding claims "covering purified and isolated DNA sequences encoding erythropoietin" in U.S. Patent No. 4,703,008 to be valid); *id.* at 1219; *In re* Bergy, 563 F.2d 1031, 1032, 1035, 1038 (C.C.P.A. 1977) (holding a purified culture of Streptomyces vellosus to be patentable), *vacated as moot in part sub nom.* Diamond v. Chakrabarty, 444 U.S. 1028, *and aff'd in part sub nom.* Diamond v. Chakrabarty, 447 U.S. 303 (1980); PharmaStem Therapeutics, Inc. v. ViaCell, Inc., No. 02-148 GMS, 2004 U.S. Dist. LEXIS 18638, at *2–3, *11–13 (D. Del. Sept. 15, 2004) (holding that claims of purified fetal and neonatal stem cells in U.S. Patent No. 5,004,681 and U.S. Patent No. 5,192,553 are valid), *aff'd in part, rev'd in part*, 491 F.3d 1342 (Fed. Cir. 2007).

140. *See* TED PETERS, THE STEM CELL DEBATE 4 (2007) ("What is so valuable to medical researchers is that pluripotent stem cells have the capacity of integrating into a tissue and becoming a stem cell for that tissue."); R.L. Gardner, *Present Perspectives and Future Challenges*, *in* ESSENTIALS OF STEM CELL BIOLOGY 1, 2 (Robert Lanza et al. eds., 2006) (noting that the "widely adopted convention is to describe [embryonic stem] cells as pluripotent").

141. Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 97 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912).

142. U.S. Patent No. 141,072 (filed May 9, 1873).

143. *Bergy*, 563 F.2d at 1032, 1035, 1038.

144. U.S. Patent No. 6,200,806 col. 21 l. 2 (filed Jun. 26, 1998).

145. *See In re* Bergstrom, 427 F.2d 1394, 1395, 1400–01 (C.C.P.A. 1970).

146. U.S. Patent No. 6,800,480 col. 23 l. 50 (filed Oct. 23, 1998).

create a new composition of matter as they did isolate products that already existed in nature. They did not manufacture a new cell, a new type of cell, or change the internal workings of any of the cells.[147] Coming up with a new way of isolating and coaxing specific types of stem cells to grow undifferentiated outside of the human body is not equivalent to inventing a new product altogether.[148] If someone invented a process for purifying gold, that person did not so much invent gold as create a method for purifying gold. If someone mixed naturally existing bacteria to enrich soil, that person did not so much invent a new type of soil as (perhaps) invent a new method for enriching soil.[149] Characterizing Thomson's or Bodnar's stem cells as man-made products represents a misconstrual of their contributions to the art.

While one might argue that "stem cell preparations" and "stem cells" represent different subject matters for patenting, the stakes here, similar to that of genes, may be too high to let artificial semantics dictate the terms of the debate. Stem cells—or stem cell preparations—not only hold the promise to curing many otherwise debilitating diseases and conditions, but also hold the promise of developing more effective drugs.[150] The patenting of stem cell preparations, like that of genes, may represent an "effective

147. An argument might be made that so-called induced pluripotent stem cells are man-made and not natural. While the process of inducing adult cells to regain pluripotent properties may be a unique human invention, the cells produced—especially if they are not substantively different from naturally occurring stem cells—may not be. Induced pluripotent stem cells are stem cells created by artificial means from normal adult cells. *E.g.*, Emily Singer, *Engineered Stem Cells: Mimicking Human Disease in a Dish*, TECH. REV., May/June 2010, at 52, *available at* http://www.technologyreview.com/energy/25082.

148. *See* Sina A. Muscati, *"Some More Human Than Others": Assessing the Scope of Patentability Related to Human Embryonic Stem Cell Research*, 44 JURIMETRICS J. 201, 220–21 (2004) (arguing against the patenting of unmodified stem cells because the cells are not inventive and the claims are overbroad). It is not surprising that inventors will generally try to obtain product patents for process inventions whenever possible. Product patents are generally preferred over process patents simply because product claims are generally easier to enforce than process claims. *See, e.g.*, Eisenberg, *supra* note 125, at 735–36; Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 10 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), *available at* http://www.nber.org/papers/w7552.pdf.

149. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948) (holding that a mixture of soil and various forms of bacteria was ineligible subject matter because "[t]he combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility").

150. *See, e.g.*, Singer, *supra* note 147, at 52 ("Much of the excitement over [induced pluripotent stem] cells, and stem cells in general, arises from the possibility that they could replace damaged or diseased tissue. But Thomson thinks their most important contribution will be to provide an unprecedented window on human development and disease. . . . This could allow researchers to watch the disease as it unfolds and trace the molecular processes that have gone awry. In the nearer term, [induced pluripotent stem] cells may revolutionize toxicity testing for drugs.").

occlusion [of the unpatentable] through the patenting of products or methods which are the only means of accessing the unpatentable."[151]

III. SUBJECT MATTER ELIGIBILITY, SEEDS OF A DISEASE AND A CURE

The problems discussed above stem in large part from confusion over the scope of subject matter eligibility. As demonstrated, defining eligible subject matter in terms of a prohibition against nature and abstract ideas results in a capricious delineation based in the semantics of nature versus man-made and abstract versus applied. A correlation between homocysteine and vitamin deficiency is an ineligible natural phenomenon, but correlating vitamin deficiency to homocysteine levels in a diagnostic context is potentially a man-made process. The control of biological activities through NF-κB activity is an ineligible natural phenomenon, but controlling the same biological activities, leveraging exactly the same mechanisms to the same effects in a therapeutic context, is potentially a man-made process. Genetic materials found naturally in cells represent ineligible natural products, but the same genetic materials, once extracted—even if containing faithful copies of genetic information found in naturally occurring cells—represent potentially man-made products. Stem cells found in the human body are ineligible products of nature, but the same cells, once extracted and placed in a Petri dish to grow, become potentially man-made products—even if no cells have been modified and no new types of cells have been created.

Subject matter eligibility is not just about prohibiting the patenting of nature and abstract ideas. As Justice Frankfurter in *Funk Bros. Seed Co. v. Kalo Inoculant Co.* rightly observed, "It only confuses the issue . . . to introduce such terms as 'the work of nature' and the 'laws of nature.' . . . Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.'"[152] Even without considering semantics-based arguments over what is natural and what is man-made, it is confusing enough to assess when a subject matter represents a bona-fide application of a general principle and when it is a mere restatement of a general principle with the potential to block entire fields.[153] Without policy underpinning, it is difficult to draw the boundary between what is nature versus what is man-

151. *See* Kane, *supra* note 112, at 765.
152. *Funk Bros.*, 333 U.S. at 134–35 (Frankfurter, J., concurring).
153. *See supra* note 43.

made. One could easily fall into the trap on one extreme of rejecting all human know-how as unpatentable subject matter on the ground that all human activities, no matter how clever, must conform to natural laws and therefore constitute mere consequences of nature,[154] and on the other extreme of holding any useful (newly discovered) knowledge—including fundamental knowledge such as $F = m \cdot a$—to be a creation of human ingenuity eligible for patenting.

In Section A of this part, I review the Supreme Court's jurisprudence on subject matter eligibility in search of current limits to subject matter eligibility and conclude that there are few limits, rhetoric aside, beyond the requirement that subject matters need to be "new and useful." In Section B, I argue that subject matter eligibility constitutes an independent, substantive patentability requirement that touches upon the very existential reasons for having the patent system. As such, subject matter eligibility must not be construed to be a mere rule against the patenting of nature and abstract ideas, a proxy rule to enforce other patentability requirements, or a mere framework for statutory interpretation of the terms "process, machine, manufacture, or composition of matter."[155] What is required is not more legalistic and semantics-based posturing, but a framework for articulating and injecting informed policy into the patent regime, as required by the U.S. Constitution.

A. IN SEARCH OF THE LIMITS TO SUBJECT MATTER ELIGIBILITY

The current trend in eligibility jurisprudence is to read the scope of subject matter eligibility broadly. Nearly everything that is "new and useful"[156] appears to be eligible for patenting.[157] The only subject matter

154. Sophisticated engineering objects such as airplanes, nuclear power plants, and automobiles, when divided into small enough components, can all be explained away as mere consequences of natural laws (that is, fluid dynamics, combustion, nuclear physics, electricity, and so on). Depending on the level of granularity at which things are evaluated, all man-made materials can be seen as mere reshuffling of more basic natural elements. *E.g.*, Yu, *supra* note 34, at 696.

155. 35 U.S.C. § 101 (2006).

156. Note that notions of novelty and utility also broadly encompass notions of nonobviousness (inventiveness) and enablement, with each actually providing secondary support for the other. For example, implicit in the pronouncement that something is nonobvious (inventive) is the presumption that some long-felt but unsolved needs or some previous failure of others has been overcome to produce new and useful breakthroughs. *See* Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 17 (1966) (noting that "secondary considerations" of "nonobviousness" include "commercial success, long felt but unsolved needs, [and the] failure of others").

157. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) (commenting on the broad range of eligible subject matter); Diamond v. Chakrabarty, 447 U.S. 303, 308–09 (1980) (same); Parker v. Flook, 437 U.S. 584, 589 & n.9 (1978) (same).

that is not eligible appears to be "laws of nature, physical phenomena, and abstract ideas,"[158] although even that appears to be based on underlying notions of utility and novelty.[159]

According to the Supreme Court, to be eligible for patenting, subject matter must recite *applications*—ideas that provide some new practical and useful results,[160] some "new and useful" ends beyond what nature already provides.[161] Examples of applications that are eligible for patenting include a process for curing rubber that makes use of Arrhneius' equation to make the process more efficient, even though Arrhneius' equation itself is not patentable;[162] a process for enabling telephonic communication through

158. *Chakrabarty*, 447 U.S. at 309. Thus, newly discovered minerals and plants found in nature are not eligible for patenting. *Id.* Neither is a "novel and useful mathematical formula," *Flook*, 437 U.S. at 585, including, for example, Albert Einstein's celebrated equation $E = m \cdot c^2$, Isaac Newton's law of gravity, electromagnetism, or steam power, *Chakrabarty*, 447 U.S. at 309; O'Reilly v. Morse, 56 U.S. (15 How.) 62, 112–13 (1854). *See also* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (noting that "[t]he qualities of . . . bacteria, . . . the heat of the sun, electricity, [and] the qualities of metals" are "the work of nature"). Other examples of prohibited subject matter include the Pythagorean theorem ($a^2 = b^2 + c^2$), *In re* Bergy, 596 F.2d 952, 965 (C.C.P.A. 1979), *vacated as moot in part sub nom.* Diamond v. Chakrabarty, 444 U.S. 1028 (1980), *and aff'd in part*, *Chakrabarty*, 447 U.S. 303; earth's gravity acceleration constant ($a = 32\ ft/sec^2$), *In re* Meyer, 688 F.2d 789, 794–95 (C.C.P.A. 1982); the formula used to compute a circle's circumference ($C = 2 \cdot \pi \cdot r$), *Flook*, 437 U.S. at 595; Arrhenius' equation, Diamond v. Diehr, 450 U.S. 175, 188 (1981); and the multiplication tables, *Flook*, 437 U.S. at 598 (Stewart, J., dissenting).

159. *See, e.g.*, *Bilski*, 130 S. Ct at 3225 ("While [the judicial] exceptions [that prevent the patenting of laws of nature] are not required by the statutory text, they are consistent with the notion that a patentable process must be 'new and useful.'"); *Flook*, 437 U.S. at 593 n.15 ("The underlying notion . . . that a scientific principle, such as that expressed in respondent's algorithm, [is not patentable is because it] reveals a relationship that has always existed.").

160. *Diehr*, 450 U.S. at 182 n.7 ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . . ." (quoting Cornig v. Burden, 56 U.S. (15 How.) 252, 268 (1854))); *id.* at 188 (noting that "a novel and useful structure created with the aid of knowledge of scientific truth" is eligible for patenting (quoting Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939))); *id.* at 187 ("[A]n *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."); Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1852) ("A patent will be good, though the subject of the patent consists in the discovery of a great, general, and most comprehensive principle in science or law of nature, if that principle is by the specification applied to any special purpose, so as thereby to effectuate a practical result and benefit not previously attained." (internal quotation marks omitted)).

161. *See, e.g.*, *Bilski*, 130 S. Ct. at 3230 ("[W]hile an abstract idea, law of nature, or mathematical formula [may] not be patented, 'an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.'" (quoting *Diehr*, 450 U.S. at 187)); *Diehr*, 450 U.S. at 188 n.11 (noting that patent protection requires "the application of the law of nature to a new and useful end" (quoting *Funk Bros.*, 333 U.S. at 130)); Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end." (quoting *Funk Bros.*, 333 U.S. at 130)).

162. *Diehr*, 450 U.S. at 188.

electric currents involving "putting a continuous current in a closed circuit into a certain specified condition, suited to the transmission of vocal and other sounds, and using it in that condition for that purpose," even though electric current by itself is not patentable;[163] "a new and useful improvement in the process of tanning, dyeing, [and so on], irrespective of any particular form of machinery or mechanical device," even though the biological process of tanning and the chemical process of dyeing by themselves are not patentable;[164] and a process of "manufacturing fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure,"[165] even though the biochemical principle "that the elements of neutral fat require to be severally united with an atomic equivalent of water in order to separate from each other and become free" is not patentable.[166]

In distinguishing eligible applications from ineligible natural principles,[167] the courts have resorted to constructively defining "novelty." Contrast for example the cases of *Funk Bros.* and *In re Bergy*. The invention in *Funk Bros.* concerned a unique mixture of bacteria that, when applied to certain leguminous plants, enabled the plants to fix nitrogen directly from air.[168] The invention in *Bergy* concerned a purified culture of Streptomyces vellosus that enabled researchers to produce antibiotic lincomycin in sizable quantities.[169] On the one hand, by viewing Funk Bros.'s invention at the level of each individual bacterium, the Court was able to find ineligible subject matter because "[t]he combination of species produce[d] no new bacteria, [and] no change in the [disclosed] species of bacteria . . . . Each species ha[d] the same effect it always had. The bacteria perform[ed] in their natural way."[170] On the other hand, by viewing Malcolm E. Bergy's invention at a higher level of granularity (at the level of a batch of bacteria, instead of each bacterium), the court found in a

163. Dolbear v. Am. Bell Tel. Co. (The Telephone Cases), 126 U.S. 1, 534 (1888).

164. Corning v. Burden, 56 U.S. (15 How.) 252, 267–68 (1854).

165. Tilghman v. Proctor, 102 U.S. 707, 721 (1881) (quoting U.S. Patent No. 11,766 col. 4 ll. 55–57 (issued Oct. 3, 1854)).

166. *Id.* at 729.

167. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3230 (2010) ("[W]hile an abstract idea, law of nature, or mathematical formula [may] not be patented, 'an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.'" (quoting *Diehr*, 450 U.S. at 177)); Parker v. Flook, 437 U.S. 584, 594 ("Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented.").

168. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 128, 130 (1948).

169. *In re* Bergy, 563 F.2d 1031, 1032 (C.C.P.A. 1977), *aff'd on remand*, 596 F.2d 952 (C.C.P.A. 1979), *vacated as moot in part sub nom.* Diamond v. Chakrabarty, 444 U.S. 1028 (1980), *and aff'd in part sub nom.* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

170. *Funk Bros.*, 333 U.S. at 131.

"biologically pure culture of . . . Streptomyces vellosus"[171] a new manufacture or composition of matter even though no bacterium was created and no bacterium functioned in unexpected ways.[172] Without firm policy grounding on what subject matter eligibility is about, any of several materials may be deemed arbitrarily new (man-made) or old (natural) for eligibility purposes, depending on the unarticulated level of granularity at which the materials are assessed.[173]

The Court's ad hoc definition of novelty has also been made possible by defining novelty sometimes with respect to knowledge per se and at other times with respect to the underlying subject matter. The patentability of purified extracts[174] and alloys[175] represent examples in which it appears to be knowledge, not the underlying subject matter, that is the concern of novelty. This makes sense: to the extent patenting is about the protection of knowledge and ideas—that is, the incentivizing of nonrivalrous and nonexcludable public goods[176]—novelty should refer to knowledge per se. Under this standard, however, would not all new knowledge—including new knowledge over laws of nature, natural phenomena, and abstract ideas—be eligible for patenting so long as the knowledge is newly acquired? The prohibition against the patenting of nature suggests that it is not knowledge per se that must be novel.[177] But as argued throughout this

171. *Bergy*, 563 F.2d at 1032.

172. *Id.* at 1035.

173. Consider *Diamond v. Chakrabarty*, in which the Court held a genetically modified bacterium capable of breaking down crude oil to constitute eligible subject matter. *Chakrabarty*, 447 U.S. at 305, 309–10. Had the Court delved deeper, however, and viewed the invention at a lower level of granularity, say at the genetic level, the Court might have found that nothing new had been created, only a mere reshuffling of naturally occurring elements (à la *Funk Bros.*). The Court's critical conclusion that a new type of bacterium is created with the mere addition of a few foreign plasmids does not appear to be based on scientific consensus. *See* Fredrick M. Cohan, *What Are Bacterial Species?*, 56 ANN. REV. MICROBIOLOGY 457, 457 (2002) ("Bacterial systematics has not yet reached a consensus for defining the fundamental unit of biological diversity, the species."); Case T 315/03, President & Fellows of Harvard Coll. v. British Union for the Abolition of Vivisection, [2005] O.J. E.P.O. 246, 247 (2004) (ruling a genetically engineered oncomouse—a transgenetic organism—not to be a new "animal variety" under article 53(b) of the European Patent Convention).

174. A purified extract is considered novel if it offers a previously unknown set of properties or a previously unknown or inaccessible combination of elements. *See supra* note 114 and accompanying text. It does not appear to matter whether the purified elements ever actually did exist in nature.

175. An alloy is considered novel if it offers a previously unknown set of properties or a previously unknown or inaccessible combination of elements. *See, e.g.*, Becket v. Coe, 98 F.2d 332, 336 (D.C. Cir. 1937), *rev'd in part on other grounds*, 38 U.S.P.Q. 26 (D.C. Cir. 1938) (en banc). It does not appear to matter whether the combination of elements ever actually existed in nature.

176. *See infra* note 200 and accompanying text.

177. *See, e.g.*, Parker v. Flook, 437 U.S. 584, 593 n.15 (1978) (noting that scientific truths are not eligible for patenting because they reveal "*relationship[s] that ha[ve] always existed*" (emphasis added)).

Article, because the underlying subject matter of most biomedical knowledge is not per se new,[178] novelty cannot always refer to the underlying subject matter.[179]

Similar ambiguity exists with respect to mathematical knowledge. On the one hand, mathematical relations as mathematical constructs regardless of the underlying subject matter would appear to be ineligible for patenting.[180] On the other hand, mathematical constructs may be ineligible only to the extent they describe a law of nature, physical phenomenon, or abstract idea.[181] To the extent a mathematical construct represents a man-made language or framework for exploring patterns, making rigorous deduction from axioms and definitions, and formulating and evaluating conjectures, mathematical relations may be deemed eligible for patenting.[182]

Since eligibility is also defined in terms of utility,[183] it is not surprising that utility,[184] like novelty, has been defined ad hoc. For example, based on whether purified materials offer sufficiently useful properties, products extracted from nature may be construed as new—and hence eligible—or as nature—and hence ineligible. The Court has held, any "product of human *ingenuity* 'having a *distinctive name*, *character*[, and] *use*'" can constitute an eligible "manufacture or composition of

178. Few, if any, of the products and processes found in the human body since the dawn of time are actually "new."

179. *See supra* notes 68–69 and accompanying text (discussing what might constitute truly novel biological inventions).

180. Diamond v. Diehr, 450 U.S. 175, 191–92 (1981); *Flook*, 437 U.S. at 585 (pronouncing that *Gottschalk v. Benson* stands for the proposition that "the discovery of a novel and useful mathematical formula may not be patented").

181. *See* Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("[W]hile a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be." (quoting Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939))); AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352, 1356 (Fed. Cir. 1999) ("Because § 101 includes processes as a category of patentable subject matter, the judicially-defined proscription against patenting of a 'mathematical algorithm,' to the extent such a proscription still exists, is narrowly limited to mathematical algorithms in the abstract."), *abrogated in part by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *aff'd*, 130 S. Ct. 3218 (2010).

182. While mathematical constructs are often created to describe nature, mathematics and scientific principles are not coterminous. Not all mathematical constructs are about nature and many real-life phenomena (for example, stock markets, biological systems, consciousness, chaotic systems) may never be completely described by mathematics as understood by the human mind. *See infra* note 222.

183. *See supra* notes 156–57 and accompanying text.

184. For a review of the utility doctrine, see generally Michael Risch, *Reinventing Usefulness*, 2010 BYU L. REV. 1195.

matter" under § 101.[185] As Judge Learned Hand famously pronounced in *Parke-Davis & Co. v. H.K. Mulford Co.*, products extracted from nature, "even . . . without change," can become eligible for patenting if the extracted products confer sufficient new benefits to become "for every practical purpose a *new thing commercially and therapeutically*."[186]

In *Brenner v. Manson*, the Court discussed the important role specific utility can play in defining subject matter eligibility:

> The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. 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.
>
> . . . .
>
> This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something 'useful,' or that we are blind to the prospect that what now seems without 'use' may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. "[A] patent system must be related to the world of commerce rather than to the realm of philosophy. . . ."[187]

The notion of specific utility has unsurprisingly also played a central role in defining abstractness for eligibility purposes.[188] To the extent abstract ideas represent incompletely formed ideas—unproven conceptions, unverified hypotheses, or vaguely formed ideas—such knowledge represents at best well-laid plans or wishes for further innovation, and at worst misconceptions or false conjectures about reality, neither of which constitutes the type of useful subject matter contemplated under § 101.[189]

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185. Diamond v. Chakrabarty, 447 U.S. 303, 309–10 (1980) (alteration in original) (emphasis added) (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887)).

186. *See* Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911) (emphasis added), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912). Louis Pasteur was thus allowed in 1873 to patent his famous yeasts even though he did not create any new species of organisms because his purified yeasts were something new and useful. *See* U.S. Patent No. 141,072 col. 5 ll. 13–14 (filed May 9, 1873) (claiming, among other things, "[y]east, free from organic germs of disease, as an article of manufacture").

187. Brenner v. Manson, 383 U.S. 519, 534–36 (1966) (alteration in original) (quoting *In re* Ruschig, 343 F.2d 965, 970 (C.C.P.A. 1965)).

188. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3229 (2010) (noting that "the unpatentability of abstract ideas" provides a "useful" "limiting principle" on the scope of subject matter eligibility).

189. *See id.* The notion of utility under § 101 is closely related to that of enablement and reduction

To the extent abstract ideas represent scientific and other verified truths, such ideas can become truly useful only after they have been sufficiently reduced to practice or enabled to provide specific benefits.[190] When the Court invalidated Samuel Morse's famously broad claim over "the use of the motive power of the electric or galvanic current, . . . however developed, for marking or printing intelligible characters, signs, or letters, at any distances,"[191] it was on the ground that the claimed subject matter was not sufficiently enabled and reduced to practice.[192]

Utility has also proved to be an especially useful lever for adopting the scope of eligibility to the needs of the time. For example, while applications involving nonconcrete, intangible innovations—not generally considered useful in an agrarian and industrial age—may have been considered ineligible in an agrarian and industrial age, many innovations involving intangible products and processes may be deemed useful in an information and biotechnological age and hence become eligible for patenting in an information and biotechnological age.[193]

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to practice under § 112. *See* EMI Grp. N. Am., Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1348 (Fed. Cir. 2001) ("A claimed invention having an inoperable or impossible claim limitation may lack utility under 35 U.S.C. § 101 and certainly lacks an enabling disclosure under 35 U.S.C. § 112."); *In re* Cortright, 165 F.3d 1353, 1356 (Fed. Cir. 1999) ("[T]he how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention." (quoting *In re* Ziegler, 992 F.2d 1197, 1200 (Fed. Cir. 1993))); Fujikawa v. Wattanasin, 93 F.3d 1559, 1563 (Fed. Cir. 1996) ("[A]ctual reduction to practice, which constitutes in law the final phase of invention, cannot be established absent a showing of practical utility."); *In re* Fouche, 439 F.2d 1237, 1243 (C.C.P.A. 1971) ("It appears that the examiner and the board doubted that compositions having heterocyclic moieties would be useful at all for therapeutic purposes. While this position could have led to a rejection under § 101, it also leads to a rejection under the how-to-use provision of § 112, since if such compositions are in fact useless, appellant's specification cannot have taught how to use them.").

190. *See* Gottschalk v. Benson, 409 U.S. 63, 67–71 (1972) (reviewing the Court's patent jurisprudence).

191. O'Reilly v. Morse, 56 U.S. (15 How.) 62, 112 (1854) (quoting U.S. Patent No. RE117 col. 6 ll. 44–48 (issued June 13, 1848)).

192. *See id.* at 112–13 ("It is impossible to misunderstand the extent of this claim. He claims the exclusive right to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing intelligible characters, signs, or letters at a distance. . . . In fine he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent. The court is of opinion that the claim is too broad, and not warranted by law.").

193. *See Bilski*, 130 S. Ct. at 3227 ("The machine-or-transformation test may well provide a sufficient basis for evaluating processes similar to those in the Industrial Age—for example, inventions grounded in a physical or other tangible form. But there are reasons to doubt whether the test should be the sole criterion for determining the patentability of inventions in the Information Age."); *Morse*, 56 U.S. (15. How.) at 69, 75–76, 86, 112 (validating patents drawn to "a system of signs" to be used in conjunction with telegraph technology); State St. Bank & Trust Co. v. Signature Fin. Grp., 149 F.3d 1368, 1373 (Fed. Cir. 1998) (holding that "the transformation of data, representing discrete dollar

B. SUBJECT MATTER ELIGIBILITY AS A CONSTITUTIONAL MANDATE

Often framed in terms of constructive notions of novelty and utility, subject matter eligibility has traditionally been assessed within the framework of § 101 and the judicially constructed prohibition against the patenting of "laws of nature, physical phenomena, and abstract ideas."[194] But subject matter eligibility is more than just a substantive patentability requirement,[195] it is fundamentally a constitutional requirement touching upon the very existential reasons for having a patent system.[196]

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amounts, by a machine through a series of mathematical calculations into a final share price" is eligible subject matter), *abrogated in part by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *aff'd*, 130 S. Ct. 3218; Arrhythmia Research Tech. Inc. v. Corazonix Corp., 958 F.2d 1053, 1054–55, 1061 (Fed. Cir. 1992) (holding the transformation of electrocardiograph signals involving a patient's heartbeat by a machine through a series of mathematical procedures to be eligible subject matter); *In re* Breslow, 616 F.2d 516, 517–18, 522 (C.C.P.A. 1980) (holding "transitory" and "unstable" compounds to constitute potentially eligible subject matter); Kelvin W. Willoughby, *How Much Does Technology Really Matter in Patent Law? A Comparative Analysis of Doctrines of Appropriate Patentable Subject Matter in American and European Patent Law*, 18 FED. CIR. B.J. 63, 121 (2009) (contending that "physicality" is not a good indication of eligibility).

194. *See, e.g.*, *Bilski*, 130 S. Ct. at 3225 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

195. *Id.* (noting that "[t]he § 101 patent-eligibility inquiry is . . . a threshold test" separate and independent of the novelty requirement under § 102, the nonobviousness requirement under § 103, and the full and particular disclosure requirement under § 112); Diamond v. Diehr, 450 U.S. 175, 190–91 (1981) (treating § 101 as an independent patentability requirement); *In re* Comiskey, 499 F.3d 1365, 1373 n.7 (Fed. Cir. 2007) ("The § 101 issue is an antecedent question to the [other patentability requirements]."), *aff'd in part, vacated in part* 554 F.3d 967 (Fed. Cir. 2009) (en banc); ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT 27 (2d ed. 1991) (contending that subject matter eligibility is a "precondition" to patentability, evaluated before all other patentability requirements). *But see* Kristen Osenga, *Ants, Elephant Guns, and Statutory Subject Matter*, 39 ARIZ. ST. L.J. 1087, 1115–16 (2007) (discussing how subject matter eligibility has been used as a framework for enforcing other patentability requirements).

196. *See* U.S. CONST. art. I, § 8, cl. 8; 35 U.S.C. § 101 (2006); *Diehr*, 450 U.S. at 192 ("[W]hen a claim . . . considered as a whole[] is performing a function which the patent laws were designed to protect (for example, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101."); Parker v. Flook, 437 U.S. 584, 593 (1978) ("The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes [contemplated under § 101], but rather on the more fundamental understanding that they are not the kind of 'discoveries' that the statute was enacted to protect."); *In re* Bergy, 596 F.2d 952, 960 (C.C.P.A. 1979), *vacated as moot in part sub nom.* Diamond v. Chakrabarty, 444 U.S. 1028 (1980), *and aff'd in part*, *Chakrabarty*, 447 U.S. 303 ("Section 101 *states* three requirements: novelty, utility, and statutory subject matter. The understanding that these three requirements are *separate and distinct* is long-standing and has been universally accepted."); Schering Corp. v. Gilbert, 153 F.2d 428, 435 (2d Cir. 1946) (Frank, J., dissenting) ("If the statutory provision authorizing the issuance of a patent for a 'composition of matter' were interpreted to validate [patent claims to scientific principles], then that statutory provision might well be unconstitutional, since it would authorize the creation of monopolies which 'would discourage arts and manufactures.'"); 1 PETER D. ROSENBERG, PATENT LAW FUNDAMENTALS § 6.00, at 6-3 (2d ed. 2001) ("Statutory subject matter is a substantive criterion of patentability separate and distinct from novelty, utility, and nonobviousness.").

The U.S. Constitution grants Congress the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[197] That power mandates Congress to assign exclusive rights to discoveries, but only where the securing for limited times of exclusive rights will promote the progress of useful arts, and not where all discoveries or all useful arts can be propertized however Congress sees fit.[198] That the Intellectual Property Clause ("IP Clause") provides Congress qualified power—not unbridled power—to assign patent rights sets an important, if unappreciated, limit to subject matter eligibility.[199]

According to the classic theory of patents, patents are needed because inventions are nonrivalrous and nonexcludable.[200] Inventions take resources to develop but are easily copied, conferring benefits to imitators at the expense of the pioneer.[201] Patents represent a "carefully crafted bargain" between the public and the inventors.[202] The never-ending goal of the patent system is to strive for a proper balance between protecting inventions and maintaining sufficient space in the technological landscape to allow for healthy competition for inventors to innovate.[203]

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197. U.S. CONST. art. I, § 8, cl. 8. The term "Science" in the Constitution actually refers to copyrightable subject matter. It is the phrase "useful Arts" that corresponds to the modern notion of "technologies" and "industries." *See* JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 29–30 (2d ed. 2006) (discussing the Constitution's so-called IP clause). Notions of "inventions" and "discoveries" were also not distinguished at the time of the writing of the U.S. Constitution. *See infra* note 218 and accompanying text.

198. *See* U.S. CONST. art. I, § 8, cl. 8. Given the broad construction of § 101 under *Chakrabarty*, 447 U.S. at 309, the historic construction of "process" broadly to mean "art," *see* Kevin W. O'Connor, *Patenting Animals and Other Living Things*, 65 S. CAL. L. REV. 597, 599–600 (1991); *supra* note 39, and the use of the term "useful Arts" in both the Constitution, U.S. CONST. art. I, § 8, cl. 8, and the first Patent Act, Act of Apr. 10, 1790, ch. 7, 1 Stat. 109, 110, some may construe the scope of subject matter eligibility broadly to include all "useful Arts" when the true scope is probably narrower—in other words, incorporating not all "useful Arts" per se, but merely "discoveries" that promote the advancement of the "useful Arts."

199. *See* Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 5–6 (1966) ("[The patent power represents a] qualified authority . . . [and] is limited to the promotion of advances in the 'useful arts.' . . . The Congress . . . may [not] . . . enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby.").

200. For a formal articulation of public goods (goods that are nonrivalrous and nonexcludable), see generally Paul A. Samuelson, *The Pure Theory of Public Expenditure*, 36 REV. ECON. & STAT. 387 (1954).

201. *See, e.g.*, LANDES & POSNER, *supra* note 28, at 294.

202. Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time."). *See also* Brenner v. Manson, 383 U.S. 519, 536 (1966) (concluding that a patent "is not a reward for the search, but compensation for its successful conclusion").

203. *See* Bilski v. Kappos, 130 S. Ct. 3228, 3228 (2010) (acknowledging the "great challenge in

IV. TOWARD A NEW STANDARD OF SUBJECT MATTER ELIGIBILITY

While Congress ideally should take the lead in setting policy and ensuring the law reflects those policies,[204] the courts also have an important role to play to ensure that the law and policy crafted by Congress abides by the Constitution.[205] Given the unlikely political resolution of subject matter eligibility[206] caused in part by the divergence in paradigms of innovation followed by different industries,[207] a doctrinal-based approach may be especially apt today.[208]

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striking the balance between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles"); *id.* at 3229 (noting that the patent regime is built on "the tension, ever present in patent law, between stimulating innovation by protecting inventors and impeding progress by granting patents when not justified by the statutory design"); Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 343 (1971) ("A patent by its very nature is affected with a public interest. . . . [and] is an exception to the general rule against monopolies and to the right to access to a free and open market." (quoting Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945))); *Graham*, 383 U.S. at 10–11 ("[T]he underlying policy of the patent system that 'the things which are worth to the public the embarrassment of an exclusive patent,' . . . must outweigh the restrictive effect of the limited patent monopoly."); *supra* note 32 and accompanying text.

204. *See* Diamond v. Chakrabarty, 447 U.S. 303, 317–18 (1980) (noting Congress's institutional competence in the patent arena); Gottschalk v. Benson, 409 U.S. 63, 73 (1972) (same).

205. *See supra* notes 197–98 and accompanying text. *Cf., e.g.*, Brown v. Bd. of Educ., 347 U.S. 483, 495 (1954) (striking down state segregation laws as unconstitutional under the Equal Protection Clause).

206. Expecting Congress to act decisively may be unrealistic. *See* Diamond v. Diehr, 450 U.S. 175, 217 (1981) (Stevens, J., dissenting) ("[One's perspective on subject matter eligibility] may be affected by institutional bias. In each . . . case[], the spokesmen for the organized patent bar have uniformly favored patentability and industry representatives have taken positions properly motivated by their economic self-interest."); Matthew Sag & Kurt Rohde, *Patent Reform and Differential Impact*, 8 MINN. J.L. SCI. & TECH. 1, 3 (2007) (noting that Congress has failed to pass substantive patent reform); John Farmer, *Supreme Court Increases Uncertainty over Patents*, RICHMOND-TIMES DISPATCH (July 26, 2010), http://www2.timesdispatch.com/business/2010/jul/26/farm26-ar-349996 ("Congress seems incapable of acting . . . [because p]owerful interests oppose one another.").

207. *See, e.g.*, FTC, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 3, at 1 (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf (noting that "issues of fixed cost recovery, alternative appropriability mechanisms, and relationships between initial and follow-on innovation" vary industry by industry); Burk & Lemley, *supra* note 28, at 1589 ("Recent evidence has demonstrated that [the] complex relationship [between patents and innovation] is . . . industry-specific . . . ."); Dan L. Burk & Mark Lemley, *Don't Tailor Make Patent Act*, NAT'L L.J., May 11, 2009, at 18, 18 (discussing the difficulty associated with tailoring patent law on an industry-by-industry basis); Debbie Strickland, *Patent Reform Battle Pits Biotech Against High-Tech*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (Mar. 6 2009), http://www.genengnews.com/analysis-and-insight/b-patent-reform-battle-pits-biotech-against-high-b-b-tech-b/50688785 ("Although both [biotech and high tech companies] are in the business of innovation, the way they build products is very different. Hence, they are at odds over intellectual property (IP) rules.").

208. *See* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW COURTS CAN SOLVE

A. BASIC TOOLS OF SCIENTIFIC AND TECHNOLOGICAL WORK

One approach to better articulating the policies under the patent quid pro quo is to update the Court's prohibition against the patenting of nature and abstract ideas. Nature and abstract ideas have been traditionally ineligible for patenting because they were deemed to represent ideas that are too fundamental, too basic, and too important to be proprietarized.[209] But while the prohibition against the patenting of nature and abstract ideas may have once effectively prevented truly "costly" patents from issuing, the same prohibition—diluted by today's artificial constructions of what it means to be "new and useful"—has actually come to justify the issuance of potentially costly patents.[210]

To more explicitly take into account the cost side of patenting[211]—the notion that certain subject matters represent such basic and important knowledge to human progress as to constitute "part of the storehouse of knowledge of all men[,] . . . free to all men and reserved exclusively to none"[212]—the Court should redefine its vague and relatively weak judicial prohibition against the patenting of nature and abstract ideas in terms of a stronger, more explicit prohibition against the patenting of "basic tools of scientific and technological work."[213] Regardless of whether a subject matter represents natural or applied knowledge, any knowledge that constitutes a basic tool of scientific and technological work—the patenting of which will more likely impede than promote the progress of

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IT 108 (2009) (arguing for a judiciary-led approach to patent reform in light of the incongruent ways different industries view and use patents).

209. *See* Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1853) ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."); *supra* note 24.

210. *See supra* Part III.A.

211. The law is already biased toward taking into account the benefits provided by patents, echoed by the patentability requirements of novelty, utility, nonobviousness, and enablement, which all focus on the benefits of patenting. *See* 35 U.S.C. §§ 102, 103, 112 (2006).

212. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948). *See also* Gottschalk v. Benson, 409 U.S. 63, 72 (1972) (holding that any subject matter that "wholly pre-empt[s] . . . and in practical effect [constitutes] a patent on" a natural and general principle, such as a mathematical formula, constitutes ineligible subject matter). *Cf.* STEPHEN HAWKING, ON THE SHOULDERS OF GIANTS, at ix (2002) (describing science as a series of "incremental advances" whereby if revolutionaries like Nicolaus Copernicus, Newton, and Einstein "have seen farther, it is by standing on the shoulders of giants" (emphasis omitted)); RALPH KEYES, THE QUOTE VERIFIER: WHO SAID WHAT, WHERE, AND WHEN 196–97 (2006) (noting that the original quote should probably be attributed to Bernard of Chartres).

213. *Benson*, 409 U.S. at 67 ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.").

innovation—should be deemed ineligible for patenting. To make this prohibition more administrable, courts may require the determination of whether something is a basic tool of scientific and technological work to be based on the perspective of a "person having ordinary skill in the art" ("PHOSITA").[214] A host of factors may be considered in the analysis I propose, including, for example, the nature of the invention, the nature and scope of anticipated follow-up innovation, and a PHOSITA-based anticipation regarding whether patenting would—on the whole—impede or spur follow-up developments.

Under a PHOSITA-driven, basic tool of scientific and technological work standard, whether medical diagnostic techniques, such as LabCorp's technique for detecting vitamin deficiency, are eligible for patenting will depend on whether a PHOSITA would see the technique as a basic tool of scientific and technological work. If, on the one hand, a PHOSITA finds knowledge of such a relationship to represent a basic tool of scientific and technological work, then such knowledge should not be patentable. If, on the other hand, a PHOSITA does not find knowledge of such a relationship to represent a basic tool of scientific and technological work, such subject matter could ultimately be patentable if it also satisfies the other patentability requirements of novelty, utility, nonobviousness, and disclosure. In LabCorp's case, a PHOSITA would probably not find a technique that tests for homocysteine to detect for specific types of vitamin deficiencies to constitute a basic tool of scientific and technological work; the technique involves the exercising of a specific fact about nature, the patenting of which would likely not wholly preempt entire fields.

Whether a therapeutic technique such as Ariad's method for reducing NF-κB mediated biological activities would be eligible for patenting would also depend on whether a PHOSITA would recognize such techniques as basic tools of scientific and technological work. In Ariad's specific case, however, it is difficult to fathom a PHOSITA who would consider knowledge over control of NF-κB activities to constitute anything but a basic tool of scientific and technological work. Even when not completely understood, knowledge about the regulatory pathway provides critical insight through which many human diseases may be diagnosed, controlled, and even treated. As such, Araid's methods over NF-κB would probably

214. The PHOSITA standard has been associated with the evaluation of various patentability requirements including, for example, obviousness and enablement. *See, e.g.*, KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 417 (2007) (obviousness); *In re* Wands, 858 F.2d 731, 735, 737 (Fed. Cir. 1988) (enablement); Envtl. Designs, Ltd. v. Union Oil Co. of Can., 713 F.2d 693, 695, 697 (Fed. Cir. 1983) (obviousness).

not be deemed eligible for patenting.

In general, genes and stem cells would probably not be deemed eligible for patenting under this standard. Gene materials encode the information responsible for directing all biological processes in the human body. Stem cells represent pluripotent cells from which all human cells can be derived. Thus, it would be difficult to fathom any PHOSITA who would consider either to constitute anything but a basic tool of scientific and technological work.

Specific knowledge framed in specific diagnostic and therapeutic contexts, however, may be eligible. For example, while the use of one or two products to detect for diseases known to be caused by those products should probably not be eligible for patenting,[215] the use of a set of natural products not readily known to cause the disease to diagnose or treat the disease[216]—within predefined ranges of reliability (for example, a fixed range of false positives and false negatives, efficacy, or toxicity)—may not necessarily be deemed to be basic tools of scientific and technological work that wholly preempt future innovation—even if they ultimately reflect basic knowledge about nature.

I make no pretense that an assessment whether something is a basic tool of scientific and technological work is easier (or more determinative) than an assessment whether something is a law of nature, physical phenomenon, or abstract idea. The main advantage of this requirement is that instead of focusing on legally construed notions of what is nature and what is man-made, this requirement focuses on articulating the costs of patents. If a PHOSITA can corroborate some subject matter to be a basic tool of scientific and technological work, perhaps such subject matter should be made per se ineligible, for the benefit of society—to ensure that patenting promotes, rather than hinders, the progress of the useful arts.

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215. This would include tests for breast cancer involving BRCA1 and BRCA2 genes. *See, e.g.*, *supra* note 127.

216. *Cf.* U.S. Patent No. 6,770,279 col. 39 ll. 42–48, col. 40 ll. 41–42 (filed Jun. 8, 1998) (claiming "a method of treating rheumatoid arthritis . . . comprising administering to the individual cyclosporin in combination with an anti-tumor necrosis factor alpha antibody or antigen-binding fragment . . . in therapeutically effective amounts" where the administration of each chemical alone was known previously to be ineffective in treating rheumatoid arthritis). Given the reality that the human body involves complex processes, whether these diagnostic or therapeutic processes involve creations of new, artificial biochemical processes in the human body of previously known chemicals may not be readily apparent. It may also be worth exploring whether copyright—which has been used to protect databases ("creative" agglomerations of facts) even if the underlying facts are not protectable and software (man-made computer codes and procedures) even if the underlying algorithms are not protectable—might be a better platform to protect the "creative" part of medical know-how—the "art" rather than the "science" part of the medical know-how.

B. DISCOVERIES VERSUS INVENTIONS

Another approach to invigorating subject matter eligibility is to incorporate some of the natural intuitions many in the scientific and technological field have,[217] distinguishing between discovery and invention.[218] The European Patent Convention distinguishes eligible "inventions which are susceptible of industrial application, which are new and which involve an inventive step,"[219] and ineligible "discoveries, scientific theories and mathematical methods."[220] One may refer to discoveries as knowledge about nature[221] and inventions as clever tools, contraptions, and processes created by the efforts of man to better observe and manipulate nature.[222] In other words, discoveries are the traditional

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217. *See, e.g.*, FRITZ MACHLUP, THE PRODUCTION AND DISTRIBUTION OF KNOWLEDGE IN THE UNITED STATES 162 (1962) (discussing the complex relationship between discoveries and inventions); JEREMY RIFKIN, THE BIOTECH CENTURY: HARNESSING THE GENE AND REMAKING THE WORLD 45 (1998) ("At the very heart of the issue of patentability . . . of . . . engineered genes, cells, tissues, organs, and whole organisms [is whether these] are truly human *inventions* or merely *discoveries* of nature . . . ." (emphasis added)); MATTHEW RIMMER, INTELLECTUAL PROPERTY AND BIOTECHNOLOGY: BIOLOGICAL INVENTIONS 140 (2008) (quoting John Sulston, former director of the Sanger Centre and 2002 winner of the Nobel Prize in Medicine or Physiology, as saying, "The genome sequence is a discovery, not an invention" (quoting JOHN SULSTON & GEORGINA FERRY, THE COMMON THREAD: A STORY OF SCIENCE, POLITICS, ETHICS AND THE HUMAN GENOME 266–67 (2002))); Demaine & Fellmeth, *supra* note 36, at 374–77; *id.* at 375 (distinguishing inventions from discoveries on the basis of an "inventive step" (quoting Convention on the Grant of European Patents art. 52(1), Oct. 5, 1973, 1065 U.N.T.S. 255)).

218. Note that the law does not formally distinguish between notions of discoveries and inventions. *See* U.S. CONST. art. I, § 8, cl. 8 (authorizing the protection of both inventions and discoveries); 35 U.S.C. § 101 (2006) (protecting both inventions and discoveries); ALBERT H. WALKER, TEXT-BOOK OF THE PATENT LAWS OF THE UNITED STATES OF AMERICA § 2, at 2–3 (2d ed. 1889) (noting that in the Constitution, "discovery" and "invention" are synonymous). This does not mean, however, that notions of discoveries and inventions as discussed in this section have no relevance to the discussion of subject matter eligibility. Whatever definition of discovery and invention one ultimately adopts, it is important to note that the Constitution does not call for an assignment of right to all discoveries, only the assignment of right where the assignment will promote the development of the useful arts. *See supra* notes 198–203 and accompanying text.

219. Convention on the Grant of European Patents, *supra* note 217, art. 52(1).

220. *Id.* art. 52(2)(a).

221. *See* Carlotta Piscopo & Mauro Birattari, *Invention vs. Discovery (a Critical Discussion)*, *in* 2534 LECTURE NOTES IN COMPUTER SCIENCE 457, 458–59 (Steffen Lange, Ken Saton & Carl H. Smith eds., 2002), *available at* http://www.springerlink.com/content/978-3-540-00188-1/#section=182224&page=2&locus=71 (describing discovery as knowledge about nature extracted from objective observations of nature).

222. *See, e.g.*, 20 GREAT BRITAIN PATENT OFFICE, REPORTS OF PATENT, DESIGN, TRADE MARK, AND OTHER CASES 126 (John Cutler ed., 1903), *available at* http://books.google.com/books?id=QyIzAAAAIAAJ ("Of course the difference between discovery and invention is very familiar. Discovery adds to the amount of human knowledge, but it does so only by lifting the veil and disclosing something which before had been unseen or dimly seen. Invention also adds to human knowledge, but not merely by disclosing something. Invention necessarily involves also the suggestion of an act to be

domain of science while inventions are the traditional domain of engineering.[223]

The perspectives of scientists and engineers matter because inventions have been made since time immemorial, before the creation of a patent system. It is important to see how people directly involved in the innovation process view and are motivated by the various incentives that exist for inventions[224] today, including academic-based incentives,[225] business-based incentives,[226] and government-backed incentives,[227] among others. If scientists and engineers are already willing to create and disclose inventions to the public without patent incentives, then the award of patent incentives is not only unnecessary, but may also unconstitutionally remove otherwise public knowledge from the public domain.[228]

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done and it must be an act which results in a new product, or a new result, or a new process, or a new combination for producing an old product or an old result."). The two types of knowledge may not necessarily be that easily distinguished, however. Basic knowledge about nature often intrinsically involves inventive aspects. For example, scientific theories are often expressed through inventive mathematic creations manufactured by the human mind (for example, Newtonian physics through calculus, relativity through Riemannian geometry, or quantum mechanics through Feymann's conception of path integrals). *See, e.g.*, MORRIS KLINE, MATHEMATICS: THE LOSS OF CERTAINTY 6 (1980) (quoting Hermann Weyl, "one of the greatest mathematicians of [the twentieth] century," to have said, "'[m]athematizing' may well be a creative activity of man, like language or music, of primary originality, whose historical decisions defy complete objective rationalization").

223. *See* G. GORE, THE ART OF SCIENTIFIC DISCOVERY OR THE GENERAL CONDITIONS AND METHODS OF RESEARCH IN PHYSICS AND CHEMISTRY 3 (London, Longmans, Green & Co. 1878) ("[D]iscovery . . . consists in finding new truths of nature, whilst [invention] consists in applying those truths to some desired purpose."). Famed cosmetologist Stephen Hawking has pointed out that any human description of reality is bound to be based on "models," and as such constitutes more an inventive product of human creation than reality per se. *See, e.g.*, STEPHEN HAWKING & LEONARD MLODINOW, THE GRAND DESIGN 45–51 (2010).

224. *See* PLATO, THE REPUBLIC 72 (Benjamin Jowett trans., Forgotten Books 2008) (1871) ("[N]ecessity, who is the mother of invention.").

225. *See generally* ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 281–414 (Norman W. Storer ed., 1973) (discussing the role of rewards in the pursuit of scientific knowledge).

226. *See, e.g.*, JAMES M. HULBERT, NOEL CAPON & NIGEL F. PIERCY, TOTAL INTEGRATED MARKETING: BREAKING THE BOUNDS OF THE FUNCTION 205–08 (2005) (discussing secrecy, first mover advantage, branding, and other strategies); ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 46–48 (2004) (same).

227. *See generally* Stephen M. Maurer & Suzanne Scotchmer, *Procuring Knowledge*, 15 INTELL. PROP. & ENTREPRENEURSHIP 1 (2004), *available at* http://socrates.berkeley.edu/~scotch/prizes.pdf (providing an overview of incentives to promote technological progress); Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AM. ECON. REV. 691 (1983) (discussing the use of patents, prizes, and contracts in promoting innovation). *See also* RICHARD E. JUST, DARRELL L. HUETH & ANDREW SCHMITZ, THE WELFARE ECONOMICS OF PUBLIC POLICY: A PRACTICAL APPROACH TO PROJECT AND POLICY EVALUATION 557 (2004) (discussing circumstances in which trade secrets may be more preferable than patents).

228. Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 5–6 (1966) ("The Congress in the

Under a PHOSITA-driven, discovery-versus-invention standard, a diagnostic technique such as LabCorp's method for detecting vitamin deficiency would probably be deemed ineligible subject matter on the ground that it is more of a discovery (for example, basic knowledge) than an invention (for example, clever contrivance). The correlation between homocysteine and vitamin deficiency represents a basic phenomenon in the human body. The phenomenon is the type of subject matter that a scientist traditionally would have been willing to pin his or her life's work on to discover without patent incentives. LabCorp's straightforward leveraging of such basic knowledge to provide for a human benefit thus constitutes ineligible subject matter.

Processes such as Ariad's method for controlling KB-mediated activities would probably also be deemed ineligible for patenting under this standard. From the perspective of a PHOSITA, deciphering how NF-κB activities control NF-κB-regulated activities in nature constitutes more of a discovery than an invention. Ariad's method provides no new biochemical pathways, introduces no artificial elements, and produces no new effects in the human body in addition to what is discovered in nature. Researching NF-κB activities represents an activity scientists traditionally would have been willing to participate in without patent incentives. Ariad's patent constitutes little more than an attempt to monopolize basic knowledge about the human body in a therapeutic context.

Extracted gene fragments and purified stem cells should probably also be characterized as ineligible discoveries rather than as patentable inventions. Gene fragments and stem cells are both isolated with fundamental properties unchanged from those existing in nature. Extracted gene materials faithfully preserve genetic information as found in nature.[229] Isolated stem cells faithfully preserve the pluripotent properties of stem cells as found in nature.[230] From the perspective of a PHOSITA, such isolated products represent discoveries that scientists have traditionally been willing to contribute to the world without patent incentives.

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exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. . . . Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.").

229. *See supra* note 130 and accompanying text.

230. *See generally* James F. Batty, Jr., Laura K. Cole & Charles A. Goldthwaite, Jr., *Alternative Methods for Preparing Pluripotent Stem Cells*, *in* REGENERATIVE MED. 77 (Dep't of Health & Human Servs. ed., 2006), *available at* http://stemcells.nih.gov/staticresources/info/scireport/PDFs/Regenerative_Medicine_2006.pdf (describing a key challenge of stem cell research to be the ability to maintain in extracted stem cells long-term genetic stability—that is, its naturally-occurring pluripotent properties).

C. TECHNOLOGICAL INNOVATION

Another approach to invigorating the subject matter eligibility requirement is to incorporate the natural intuitions many have in the field that only "technological" inventions should be eligible for patenting.[231] The requirement is somewhat analogous to the "industrial application" restriction for subject matter eligibility under the European Patent Convention.[232] Both the U.S. Constitution and the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") limit eligible subject matter to technological innovations.[233] While technological innovation may be difficult to define,[234] there does seem to be a movement toward worldwide consensus that patent eligibility is limited to the technological arts[235] and no shortage of parade of horribles associated with the patenting of nontechnological subject matter.[236]

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231. *See In re* Bilski, 545 F.3d 943, 1009–10 (Fed. Cir. 2008) (Mayer, J., dissenting) (arguing for a "technological standard for patentability" limiting subject matter eligibility to the "technological arts"), *aff'd*, 130 S. Ct. 3218 (2010); Willoughby, *supra* note 193, at 135–36 (noting that there is a definite trend toward a consensus around the world—outside the United States—that eligible subject matter should be limited to the technological art); *id.* at 63 ("[F]or most informed people it is common sense that the subject matter of patents is technology.").

232. Convention on the Grant of European Patents, *supra* note 217, art. 52(1). Article 52 of the European Patent Convention generally provides that patents "shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step." *Id.* The article explicitly prohibits "discoveries, scientific theories and mathematical methods," "aesthetic creations," "schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers," "presentations of information," and "[m]ethods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body" from being patented. *Id.* art. 52(2)(a)–(d), 52(4).

233. Some commentators have noted that the term "useful Art" used in the IP Clause maps most closely to notions of technology and applied science today. Karl B. Lutz, *Patents and Science: A Clarification of the Patent Clause of the U.S. Constitution*, 32 J. PAT. OFF. SOC'Y 83, 87 (1950). *See also* Robert I. Coulter, *The Field of the Statutory Useful Arts Part II*, 34 J. PAT. OFF. SOC'Y 487, 496 (1952). *But cf. supra* note 198 and accompanying text (discussing the scope of eligible subject matter under the IP Clause). TRIPS requires that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

234. *See, e.g.*, *Bilksi*, 545 F.3d at 960 (declining to adopt a "technological arts test" on the ground "the terms 'technological arts' and 'technology' are both ambiguous and ever-changing"); U.S. PATENT & TRADEMARK OFFICE, INTERIM GUIDELINES FOR EXAMINATION OF PATENT APPLICATIONS FOR PATENT SUBJECT MATTER ELIGIBILITY 42–45 (2005), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf (noting the difficulty of defining "technological arts").

235. Willoughby, *supra* note 193, at 135.

236. *See, e.g.*, U.S. Patent No. 7,255,277, at [57] (filed Apr. 6, 2006) (for a method of limiting "the embarrassment of rejection" in the context of dating by using color-coded bracelets to signal dating status); U.S. Patent No. 6,368,227 (filed Nov. 17, 2000) (for a method of swinging on a child's swing);

The constitutional basis for limiting eligible subject matter to the technological arts (even if such terms are not stated in the Constitution) is the implicit recognition that technological arts represent a particularly suitable subject matter to assign rights for development. The successes of Industrial Policy[237] in East Asian nations—most recently in China—have attracted renewed interest in the use of centrally controlled Industrial Policy to promote nations' economic and technological developments.[238] And despite the rhetorical ambiguity the United States has shown toward Industrial Policy, the industrial and technological developments of this nation are derived in no small part from explicit government policies aimed at developing technologies and industries.[239] One approach to defining subject matter eligibility is in terms of patents that help to carry out a government's Industrial Policy to promote industrial and technological progress.[240]

U.S. Patent No. 6,329,919 (filed Aug. 14, 2000) (for a system of reserving toilets); U.S. Patent No. 6,119,099 (filed Aug. 26, 1997) (for a method of enticing customers to order additional food at a fast food restaurant); U.S. Patent No. 5,851,117 (filed Apr. 23, 1997) (for a method of training janitors to dust and vacuum); U.S. Patent No. 6,049,811 (filed Nov. 26, 1996) (for a method of obtaining a patent); U.S. Patent No. 6,014,643 (filed Aug. 26, 1996) (for a method of trading securities); U.S. Patent No. 5,862,223 (filed July 24, 1996) (for a method of selling expert advice); U.S. Patent No. 5,616,089 (filed Mar. 29, 1996) (for a method of gripping a golf putter).

237. *See, e.g.*, OTIS L. GRAHAM, JR., LOSING TIME: THE INDUSTRIAL POLICY DEBATE 3 (1992) ("Industrial Policy denotes a nation's declared, official, total effort to influence sectoral development and, thus, national industrial portfolio.").

238. *See, e.g.*, *The Global Revival of Industrial Policy: Picking Winners, Saving Losers*, ECONOMIST, Aug. 7, 2010, at 68, *available at* http://www.economist.com/node/16741043 [hereinafter *The Global Revival of Industrial Policy*] (reviewing and evaluating the industrial policies of nations around the world). In tackling big problems like climate change, countries have even begun coordinating their industry policies. *See, e.g.*, Darius Dixon, *Amid Trade Tensions, U.S. Creates More Clean Tech Research Partnerships with China*, N.Y. TIMES, Sept. 14, 2010, http://www.nytimes.com/cwire/2010/09/14/14climatewire-amid-trade-tensions-us-creates-more-clean-te-79928.html.

239. *See The Global Revival of Industrial Policy*, *supra* note 238, at 59, 77 (discussing, for example, the United States' 2009 stimulus plan to encourage innovation in the renewable energy sector).

240. Just as copyright can be seen as a set of laws that help to prop up a specific set of business models deemed important to a nation, *see* David Nelson, Note, *Free the Music: Rethinking the Role of Copyright in an Age of Digital Distribution*, 78 S. CAL. L. REV. 559, 560 (2005) ("[C]opyright laws no longer benefit artists or the public, but instead merely protect the recording industry's crumbling distribution model."), so too can patents be seen as a set of laws supporting a specific set of business models and practices deemed to be important under a nation's Industrial Policy. The USPTO has recently begun to position the patent system as a vehicle for improving the economy by "accelerating the pace of [economic] growth and job creation." ARTI RAI, STUART GRAHAM & MARK DOMS, PATENT REFORM: UNLEASHING INNOVATION, PROMOTING ECONOMIC GROWTH & PRODUCING HIGH-PAYING JOBS 1 (2010), *available at* http://2001-2009.commerce.gov/s/groups/public/@doc/@os/@opa/documents/content/prod01_009147.pdf. But caution should always be exercised in extending government-sanctioned monopoly to promote business opportunities. *Cf.* Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 146–47 (2004)

One conservative definition of "technology" encompasses all "inventive" creations produced by human efforts that can be employed for a practical, useful end.[241] While such a definition would include elements of the traditional patentability requirements of novelty, nonobviousness, and utility, it would be augmented with considerations from an Industrial Policy perspective.[242] Courts may add additional flexibility and inject some normative perspectives to define technology as understood by a PHOSITA.

Under a conservative doctrinal technological analysis, diagnostic techniques such as LabCorp's method for detecting vitamin deficiency would probably be deemed ineligible subject matter. LabCorp's method broadly recites a method for diagnosing vitamin deficiency. None of these steps, however, individually or in combination, involves any inventive technology or industrial application. The method recites neither new technology for measuring homocysteine, nor technology for correlating homocysteine to vitamin deficiency, nor technology for determining whether a patient is afflicted with vitamin deficiency. Reciting no technological details, the method merely restates knowledge about nature useful in a diagnostic context and as such would not constitute eligible subject matter.

Processes such as Ariad's method for controlling KB-mediated activities would probably also be deemed to be ineligible subject matter under this standard. The method discloses neither technology for controlling NF-κB activity nor technology for affecting the way NF-κB activities naturally control the expression of NF-κB-regulated genes. Reciting nothing new apart from what occurs in nature, the method merely restates knowledge about nature useful in a therapeutic context. Neither new biochemical pathways, nor artificial compounds, nor any new effects are disclosed. The method disclosed to control NF-κB-regulated activities is based on mere exercising of knowledge regarding processes that exist in

(questioning whether "Rights of Publicity"—created to help individuals to cultivate commercially their image, likeness, and other aspects of individual identities—is necessarily a good thing, and whether market forces could be better relied on to create—democratically—publicity).

241. *See, e.g.*, Willoughby, *supra* note 193, at 90 (discussing the EPO's position that "the subject matter of a patent must contain a technical teaching addressed towards solving a technical problem using particular technical means" (emphasis omitted)).

242. Notions of "technicity," Willoughby, *supra* note 193, "industrial application," Convention on the Grant of European Patents, *supra* note 217, art. 52(1), and "commercial utility," Risch, *supra* note 184, can also be incorporated. As Mark A. Lemley has warned, however, in a market-oriented, competition-based economy, any award of monopoly must be justified by the identification of a real public goods problem, not mere identification of businesses or business models that would presumptively do more social good in a monopolistic than a competitive environment. *See* Lemley, *supra* note 240, at 148–49.

nature.

Extracted gene fragments and isolated stem cells per se would probably also be deemed to lack technology. While the processes of isolating or reproducing genes or stem cells may involve innovative technology, the products extracted are all "natural," not "technological." Neither extracted gene materials that faithfully preserve genetic information as found in nature[243] nor isolated stem cells that faithfully preserve the pluripotent properties of stem cells found in nature[244] represent the creation of new technology per se.

A more drastic notion of technology may be defined as whatever art is deemed important for development under a set of industrial policies.[245] Patents may be seen as special permits (specific privileges) given by the government to the private sector to promote development in specific sectors of industry or technology.[246] The use of genes, based on insights gained from man-made models of the human body, to diagnose within a specified range of accuracy conditions whose cause is not well known may be considered an area the government would like to promote under an Industrial Policy specifically to promote gene-based industries or technologies. Similarly, the use of one or more compounds to treat within a specified range of efficacy conditions in which those mechanisms are only vaguely understood may also be promoted as a technology under a government's explicit Industrial Policy. Stem cell preparations developed using specific processes and artificial tissues developed using specific stem cell preparations and processes may both be considered a technology under a nation's Industrial Policy. The programming of cells to carry out novel biochemical processes with artificial genomes[247] may be deemed a

243. *See supra* note 130 and accompanying text.

244. *See supra* note 230 and accompanying text.

245. The social cost of such patents can be considered to be an explicit "tax" on the users of the technologies that the government decided to promote, presumptively as a result of market failures.

246. Specific markets and technological arenas may be auctioned off the way the electromagnetic spectrum is auctioned off for development and commercialization. *Auctions*, FCC, http://wireless.fcc.gov/auctions (last visited Jan. 6, 2011). *See generally* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977) (framing patent rights as privileges enabling pioneers to "prospect for" developments in a nascent field).

247. *See, e.g.*, Daniel Gibson et al., *Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome*, 329 SCIENCE 52 (2010), *available at* http://www.sciencemag.org/cgi/content/full/329/5987/52 (reporting on novel gene creations); Nicholas Wade, *Researchers Say They Created a 'Synthetic Cell,'* N.Y. TIMES, May 21, 2010, at A17, *available at* http://www.nytimes.com/2010/05/21/science/21cell.html (same).

technology, regardless of whether a new "variety" of cell[248] is actually created.

D. COMBINATION AND CLUES

The above approaches illustrate some of the approaches that can be employed to articulate and inject policy norms into the subject matter eligibility requirement. Each focuses on a particular angle of policy (for example, to ensure that "basic tools of scientific and technological work" are not propertized, that knowledge that can be freely provided is not unwittingly propertized, and that the scope of patent eligibility is consistent and aligned with the scope of a nation's Industrial Policy). The approaches may also be implemented in combination. As an example, eligible subject matter may be defined to include inventions and technologies, but not discoveries or basic tools of scientific and technological work, where the meanings of "inventions," "discoveries," "technologies" and "basic tools of scientific and technological work" are understood from the perspective of a PHOSITA.[249]

Subject matter eligibility—like obviousness[250]—may also be defined in terms of "clues" instead of bright line rules. The assessments of whether a subject matter represents a basic tool of scientific and technological work, a technology, or an invention provide clues to whether the subject matter is eligible or ineligible, just as the assessments of whether a subject matter involves a "machine or transformation"[251] or a "useful, concrete and tangible result"[252] provide clues.[253] Whether an invention constitutes eligible subject matter involves looking to these (and perhaps other) clues, taking into account the larger policy goal that patents must promote the development of the useful arts.

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248. *Cf. supra* note 173 and accompanying text (discussing whether a modification to a genome supports the creation of a new species or variety of organism).

249. Defining and applying PHOSITA for eligibility purposes will most likely involve both questions of law and questions of fact. PHOSITA-based assessments in the context of claim construction and obviousness involve both questions of law and questions of fact. *See, e.g.*, KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 427 (2007); Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc); *id.* at 1330 (Mayer, J., dissenting).

250. *See KSR Int'l*, 550 U.S. at 415 (discussing a flexible, holistic, multifactorial framework for evaluating obviousness).

251. *See supra* note 107.

252. *See supra* note 52.

253. The lack of a more rigorous test does not argue that the tests per se are inadequate. As Einstein has been attributed to have said, "Everything should be made as simple as possible, but not simpler." ENCARTA BOOK OF QUOTATIONS 306 (Bill Swainson ed., 2000).

E. ADMINISTRATIVE INITIATIVE

Besides strengthening judicial doctrines, another approach to injecting policy into the patent regime involves augmenting the role administrative agencies play in the patent regime. In one approach, Congress tasks a specialized agency with rulemaking power to determine and assess the proper scope of subject matter eligibility. Under such a regime, it would be explicitly understood that the scope of subject matter eligibility may rise and ebb. Just as the Federal Reserve rates may change in response to changing circumstances of the economy, for example, so too may the scope of subject matter eligibility change in response to changing circumstances of the technological landscapes.[254]

Any of several administrative agencies may be co-opted to determine the scope of subject matter eligibility. The administrative agency may be a new institution or a part of existing institutions, such as the Federal Trade Commission ("FTC") or the USPTO.[255] Whatever the form, the organization would need to develop a unique set of expertise well versed not only in technology, but also in the economics of innovation. Expertise would be drawn from thought leaders from not only the scientific and engineering communities, but also the business, investment, legal, and economics communities, among others.[256] As technology advances and as the structure of the economy changes, these experts would help to define the proper scope of subject matter eligibility in a way that best incentivizes innovation.

A strong version of a policy-driven administrative intellectual property regime would call on the administrative agency to define subject matter eligibility, including to invalidate issued (and otherwise perfectly good) patents on the ground that they impede rather than foster innovation, not dissimilar to the way administrative agencies enforce market competitiveness. The agency may co-opt critical IP assets for the common

254. Certain fields may need additional patent incentives while others may be swamped with too many. *See* Burk & Lemley, *supra* note 28, at 1588–89 (describing the differences in the patent need of different industries). The scope of subject matter eligibility ("level of propertization") may also be broadened or narrowed in part based on structural, competitive factors found in the industry. *See, e.g.*, Barnett, *supra* note 30, at 409; *id.* at 405–13 (discussing how market forces—under the right market conditions, given sufficient time—can be relied on continually to adjust the strength of intellectual property to reach an optimal level of "propertization").

255. If it is the USPTO, the agency would need to be given regulatory powers, which it does not yet have. *See* Tafas v. Doll, 559 F.3d 1345, 1352, 1354 (Fed. Cir. 2009).

256. For an overview of the economics of innovation, see generally WILLIAM J. BAUMOL, THE FREE MARKET INNOVATION MACHINE: ANALYZING THE GROWTH MIRACLE OF CAPITALISM (2002).

good, compel licenses,[257] render specific patents unenforceable (to facilitate the creation of technical standards),[258] and set reasonable compensation where necessary.[259]

F. AN OVERRELIANCE ON GOVERNMENT TO PROMOTE INNOVATION?

One concern that undoubtedly arises from the above discussion relates to potentially excessive reliance on the government—through courts, administrative agencies, or other government actions—to take a more active role in shaping innovation policies.[260] One of the advantages of a property-based system for incentivizing innovation is that it relies minimally on government action for the promotion of innovation. On the whole, society can be agnostic about the direction and worth of innovation and rely on a property-based system like the patent regime to facilitate the creation, pricing, and distribution of innovation in a way that ultimately optimizes resources deployed for innovation.

In my opinion, however, it is a mischaracterization to say that a property-based system represents minimal government interference. In fact, a property-driven system such as the patent system is a very intrusive mode for incentivizing innovation, with social costs associated with monopolization spread through every spectrum of society. Government is everywhere standing behind a property-based system. The argument made here is neutral with respect to an activist or nonactivist government to drive innovation, but does stress that the patent system "by its very nature is affected with a public interest. . . . [It] is an exception to the general rule against monopolies and to the right to access to a free and open market."[261] If a patent regime is implemented, the government—whether through the

257. *Cf.* eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 396–97 (2006) (Kennedy, J., concurring) (noting that while equity-based injunctive relief should be available in patent cases, "[w]hen the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest").

258. For a general discussion on the conflicts between technical standardization and patents, see generally Gary Lea & Peter Hall, *Standards and Intellectual Property Rights: An Economic and Legal Perspective*, 16 INFO. ECON. & POL'Y 67 (2004).

259. For a short discussion of takings, see Part IV.G, *infra*.

260. For a take on the role government can and cannot play in incentivizing innovation, see generally, for example, JOSH LERNER, BOULEVARD OF BROKEN DREAMS: WHY PUBLIC EFFORTS TO BOOST ENTREPRENEURSHIP AND VENTURE CAPITAL HAVE FAILED—AND WHAT TO DO ABOUT IT (2009).

261. *See* Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 343 (1971) (alteration in original) (quoting Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945)).

legislative, executive, or judicial branch—has a positive duty to ensure that the system yields a net social surplus.[262]

G. DUE PROCESS AND REGULATORY TAKINGS CONCERNS

A concern that generally arises from a more policy-directed patent regime, especially given the ingrained notion of intellectual property as "property" in this country, relates to due process and takings concerns arising from the Fifth Amendment.[263] If intellectual property is both a property as well as a policy construct to promote progress, to what extent can intellectual property be regulated for the good of the public?

The case law is unclear on whether the Fifth Amendment applies to intellectual property.[264] Historically, the Fifth Amendment guarantees a set of rights stemming from English common law tracing all the way back to the Magna Carta in 1215.[265] At the writing of the Constitution, however,

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262. *See* KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 427 (2007) (noting that patents must "promote" not "stifle" "the progress of useful arts").

263. For an overview of some of the economic issues that arise from regulatory taking of patents, see generally Richard V. Adkisson, *Intellectual Property and Eminent Domain: If Ever the Twain Shall Meet*, 36 J. ECON. ISSUES 41 (2002). Some, however, have argued that the doctrine of regulatory takings does not arise from the Fifth Amendment. *See* John F. Hart, *Colonial Land Use Law and Its Significance for Modern Takings Doctrine*, 109 HARV. L. REV. 1252, 1258 (1996) ("[T]he Framers did not address regulation in the Takings Clause because they did not regard regulation as a form of taking."); John F. Hart, *Land Use Law in the Early Republic and the Original Meaning of the Takings Clause*, 94 NW. U. L. REV. 1099, 1100 (2000) ("[T]he Takings Clause of the Bill of Rights was originally intended and understood to protect landowners' ability to use land however they wished, free from government interference."); Michael B. Rappaport, *Originalism and Regulatory Takings: Why the Fifth Amendment May Not Protect Against Regulatory Takings, but the Fourteenth Amendment May*, 45 SAN DIEGO L. REV. 729, 730–31 (2008); William Michael Treanor, *The Original Understanding of the Takings Clause and the Political Process*, 95 COLUM. L. REV. 782, 782 (1995) ("The original understanding of the Takings Clause of the Fifth Amendment was clear on two points. The clause required compensation when the federal government physically took private property, but not when government regulations limited the ways in which property could be used."); *id.* at 783 ("Many of the framers believed that government could—and in the interests of society often should—limit individuals' free use of their property; balancing societal needs against individual property rights was left in large part to the political process."). If the regulatory takings doctrine arises only from the Fourteenth Amendment, not the Fifth, regulatory takings would probably not apply to patents since the patent regime is a product of the federal government, not states.

264. *Compare* Zoltek Corp. v. United States, 442 F.3d 1345, 1352–53 (Fed. Cir. 2006) (explaining why, based on the court's reading of Supreme Court precedent, patent rights do not represent property interests under the Fifth Amendment's taking clause), *with* Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689, 689 (2007) (arguing that nineteenth-century Supreme Court jurisprudence held that intellectual property was "property" subject to the protection of the Fifth Amendment).

265. The concept of grand juries and due process both trace their origins to the Magna Carta. *Due Process of Law Act 1354* (Cth) (Austl.); 1 EDWARDO COKE, THE SECOND PART OF THE INSTITUTES OF THE LAWS OF ENGLAND 50–51 (William S. Hein Co. 1986) (1662) (noting that due process is in general

patents were not considered among those traditionally protected "rights."[266] Patents constituted more a tool of "policy" to promote good[267] than a basic "right" to check against pervasive government encroachment.[268]

As a mere policy construct, the scope of the patent regime should be allowed to increase and decrease in accordance with the needs of society with little or no consideration of private losses.[269] Consider the Federal Reserve's policies to affect the money supply in response to changing needs of the economy. While its actions can cause unsettling effects on individual property interests,[270] few would seriously accuse the Federal

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a concept borrowed from the Magna Carta and English common law); WILLIAM SHARPE MCKECHNIE, MAGNA CARTA: A COMMENTARY ON THE GREAT CHARTER OF KING JOHN 375 (2d rev. ed. 1914) (quoting King John as promising that "[n]o freeman shall be taken or . . . imprisoned or disseised or exiled or in any way destroyed, nor will we go upon him nor send upon him, except by the lawful judgment of his peers or . . . by the law of the land"); FAITH THOMPSON, MAGNA CARTA: ITS ROLE IN THE MAKING OF THE ENGLISH CONSTITUTION 1300–1629, at 86–97 (2d prtg. 1950) (recounting several statutory reconfirmations of the Due Process of Law Act).

266. *See* Edward C. Walterscheid, *The Nature of the Intellectual Property Clause: A Study in Historical Perspective (Part 1)*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 763 (2001) ("[T]he patent custom known to the Framers involved privileges rather than property rights as such.").

267. Patents and copyrights arose from different traditions, with copyright already endowed with a legal framework at the time of the writing of the Constitution when patents were but a privilege, and that

> by using the term 'securing' as the operative verb [in the Constitution] in each instance, the Framers failed to recognize, or ignored, the fact that they were creating an interpretational contretemps . . . which is argued even to this day. . . . [D]id the Framers intend merely to give Congress power to create a property right, be it designated a patent or a copyright, or did they obligate Congress to protect a property right already existing in inventors and authors?

Id. at 778–79. *See also supra* notes 197–203 and accompanying text. Interestingly, when King Edward III of England first issued patent grants in 1331, they were issued not as general property rights for English subjects, but as special "privileges" to entice foreigners to introduce new technologies to England, where these grants—not being property per se—"regularly included a revocation clause, entitling the sovereign to revoke the grant any time he found it to be inconvenient or prejudicial to the realm." PAUL GOLDSTEIN, INTELLECTUAL PROPERTY: THE TOUGH NEW REALITIES THAT COULD MAKE OR BREAK YOUR BUSINESS 42 (2007) (internal quotation marks omitted).

268. *See* RAMON M. LEMOS, RIGHTS, GOODS, AND DEMOCRACY 99 (1986) ("[T]he right to property, along with the rights to life and liberty, is one of three fundamental natural rights."); Roscoe Pound, *Do We Need a Philosophy of Law?*, 5 COLUM. L. REV. 339, 346 (1905) ("Men have changed their views as to the relative importance of the individual and of society; but the common law has not. . . . We no longer hold that society exists entirely for the sake of the individual. . . . The common law, however, is concerned, not with social righteousness, but with individual rights.").

269. *Cf.* Andrus v. Allard, 444 U.S. 51, 65 (1979) ("[G]overnment regulation—by definition—involves the adjustment of rights for the public good. Often this adjustment curtails some potential for the use or economic exploitation of private property. To require compensation in all such circumstances would effectively compel the government to regulate by *purchase*. 'Government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law.'" (quoting Pa. Coal Co. v. Mahon, 260 U.S. 393, 413 (1922))).

270. Changes in interest rates, for example, can affect the rate of return on various property holdings, including the value and return of bonds, money market funds, stocks, an so on. Public policy designed for the good of society may nevertheless reward and ruin individual private investors or

Reserve of violating property rights in adjusting interest rates. Consider similarly the Food and Drug Administration's ("FDA's") adoption of food and drug safety rules in response to needs of public safety.[271] While FDA actions can cause substantive changes to settled investment expectations in the food and drug industry,[272] few would seriously accuse the FDA of violating property rights while regulating the food and drug industry. Consider also the FTC's broad powers to regulate the economy,[273] including broad powers to clamp down on "unfair or deceptive acts or practices" in the marketplace.[274] While FTC actions can cause substantive changes in previously settled expectations in the various commercial markets,[275] few would seriously accuse FTC policy and actions of violating property rights in ensuring competitiveness in the market.

The very essence of property, especially when promulgated in the name of social welfare, should not include the right of private individuals to hold up society for private gain. Consider *United States v. Causby*, in which a farmer brought suit against the U.S. government under the theory of trespass for allowing airplanes to fly over the farmer's property.[276] The farmer argued (among other things) that his land extended infinitely high into the air and infinitely low into the ground.[277] The Court rejected this theory by noting that this

> doctrine has no place in the modern world. . . . Common sense revolts at the idea. To recognize such private claims to the airspace would clog these [air] highways, seriously interfere with their control and development in the public interest, and transfer into private ownership that to which only the public has a just claim.[278]

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transfer wealth from one class to another, as the case may be. *See, e.g.*, Joseph E. Stiglitz, *Obama's Ersatz Capitalism*, N.Y. TIMES, Apr. 1, 2009, at A31, *available at* http://www.nytimes.com/2009/04/01/opinion/01stiglitz.html (describing a policy that helps banks and investors at the expense of taxpayers).

271. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2006).

272. For example, changes in FDA rules and regulation can have dramatic effects on the profitability of various research and development investments. *See, e.g.*, Stephanie Saul, *Drug Safety Critic Hurls His Darts from the Inside*, N.Y. TIMES, July 22, 2007, at A1, *available at* http://www.nytimes.com/2007/07/22/business/22nissen.html (reporting how an FDA probe on an already-approved drug can dramatically decrease the sales of the drug).

273. Federal Trade Commission Act, 15 U.S.C. §§ 41–58 (2006).

274. *Id.* § 45(a)(1).

275. For example, shareholders of companies designated by the FTC to be targets of inquiry for antitrust concerns may find the values of their shares fall as a result. *See* Alisatir Barr, *Visa, MasterCard, Amex Drop on Antitrust Concern*, MARKET WATCH (Oct. 4, 2010, 12:10 PM), http://www.marketwatch.com/story/visa-mastercard-amex-drop-on-anti-trust-concern-2010-10-04.

276. United States v. Causby, 328 U.S. 256, 258–59 (1946).

277. *Id.* at 260–61.

278. *Id.* at 261.

Similarly, common sense should also revolt at persisting doctrines that rigidly define subject matter eligibility and enforce patent rights to the point of impeding innovation. Rights that clog up the knowledge superhighway, impeding the ability of society to innovate, should have no place in the modern world.

Even if intellectual property were a protected property under the Fifth Amendment, the Fifth Amendment would allow much leeway in the government's assessment of both when takings occurred as well as how much compensation to provide when property has been taken.[279] To the extent regulation results in losses by potential patentees from not being able to file patents they had initially contemplated filing, the leeway would be especially great, as any loss would be speculative and nebulous at best.[280] As for issued patents, the law would probably also allow for much leeway, requiring patentees to be compensated only in instances in which regulation interferes with uses of the patent to such an extent as to be tantamount to the government's taking exclusive possession of the patent.[281] The law may require compensation, for example, where changes in regulation invalidate

279. Under current law, the government has wide discretion generally in regulating and restricting the use of private property without compensation. *See* Lingle v. Chevron U.S.A. Inc., 544 U.S. 528, 538 (2005) (holding that there is no "set formula" for valuing regulatory takings claims (quoting Penn Cent. Transp. Co. v. New York City, 438 U.S. 104, 124 (1978))); Palazzolo v. Rhode Island, 533 U.S. 606, 617 (2001) ("Since [Pennsylvania Coal Co. v. Mahon, 260 U.S. 393 (1922)], we have given some, but not too specific, guidance to courts confronted with deciding whether a particular government action goes too far and effects a regulatory taking. First, we have observed, with certain qualifications . . . that a regulation which 'denies all economically beneficial or productive use of land' will require compensation under the Takings Clause. . . . Where a regulation places limitations on land that fall short of eliminating all economically beneficial use, a taking nonetheless may have occurred, depending on a complex [set] of factors including the regulation's economic effect on the landowner, the extent to which the regulation interferes with reasonable investment-backed expectations, and the character of the government action." (quoting Lucas v. S.C. Coastal Council, 505 U.S. 1003, 1015 (1992))); *Penn Cent.*, 438 U.S. at 105 (syllabus) ("In a wide variety of contexts the government may execute laws or programs that adversely affect recognized economic values without its action constituting a 'taking,' and in instances such as zoning laws . . . this Court has upheld land-use regulations that destroyed or adversely affected real property interests."); WILLIAM A. FISCHEL, REGULATORY TAKINGS: LAW, ECONOMICS, AND POLITICS 325–68 (1995) (proving a law and economics approach to regulatory takings doctrine); ROBERT MELTZ, DWIGHT H. MERRIAM & RICHARD M. FRANK, THE TAKINGS ISSUE: CONSTITUTIONAL LIMITS ON LAND USE CONTROL AND ENVIRONMENTAL REGULATION 473–510 (1999) (providing a thorough background on regulatory takings law); Christopher Serkin, *The Meaning of Value: Assessing Just Compensation for Regulatory Takings*, 99 NW. U. L. REV. 677, 678–79 (2005) (discussing the nebulous fair market value standard).

280. *Cf. Causby*, 328 U.S. at 261 ("It is the owner's loss, not the taker's gain, which is the measure of the value of the property taken.").

281. According to one approach, the scope of damage may be limited to impediments of a patentee to practice specific embodiments without compensation, not windfall uses. *Cf.* JAFFE & LERNER, *supra* note 226, at 57 (discussing how enforcements of windfall patents—"Rembrandts in the [a]ttic"—can disrupt the innovation process).

a judgment involving a patent previously held to be valid.[282] Short of that, the government would have wide discretion in regulating patents, including compelling patentees to license or sell patents (such as for the development of open standards), setting reasonable royalty rates for licenses, making patents against specific uses (such as for research) unenforceable,[283] and proactively weeding out low-quality patents.[284]

V. CONCLUSION

It has been some three decades since the Supreme Court famously pronounced, "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[285] Practically anything new and useful that is not a law of nature, natural phenomenon, or abstract idea has become eligible for patenting.

As this Article argues, however, defining eligibility based on distinctions between what is natural and what is man-made is difficult if not impossible in the biomedical field. Knowledge about how a biochemical process works represents both basic knowledge of how nature works as well as basic know-how dictating how human diseases and conditions should be diagnosed and treated. Products isolated from the human body such as genes, cells, and proteins thus represent both basic building blocks of nature as well as basic elements defining new research, diagnostic, and therapeutic techniques.

This Article touches on several approaches by which the scope of the patent regime can be better articulated and defined. To highlight the cost side of patenting, eligibility may be defined in part to prohibit the patenting of "basic tools of scientific and technological work."[286] To ensure knowledge that can be provided freely to the public is not unwittingly

282. Just as a farmer may obtain compensation to the extent overhead flights interfere with all uses and enjoyment the farmer has in the land, not the windfall rent from allowing planes to fly over his land, it may be that a patentee may have only a right to obtain compensation if regulations interfere with all uses and enjoyment the patentee has in the patent, not the windfall profits from follow-on inventions.

283. *Cf.* 35 U.S.C. § 287(c) (2006) (rendering medical method patents unenforceable against medical providers).

284. *See* United States v. Glaxo Grp. Ltd., 410 U.S. 52, 69 (1973) ("[It is in the public interest to invalidate] specious patents. . . . For when a patent is invalid, 'the public parts with the monopoly grant for no return, the public has been imposed upon and the patent clause subverted.'" (citations omitted) (quoting United States v. Singer Mfg. Co., 374 U.S. 174, 197 (1963) (White, J., concurring))); Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc., 249 F.3d 1341, 1353 (Fed. Cir. 2001) (discussing the important "public interest in invalidating invalid patents").

285. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).

286. Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

removed from the public by patents, eligibility may be defined in part by distinguishing inventions from discoveries, as viewed from a PHOSITA. To accentuate the role patents play in a nation's larger Industrial Policy, eligibility may be defined in the context of a nation's broader economic policy to promote industrial and technological developments. The Article also argues for a more administrative-driven approach to defining subject matter eligibility, which involves mandating administrative agencies to adjust the scope of subject matter eligibility to promote the useful arts in light of a changing technological and economic landscape.

As the welfare of a society becomes increasingly dependent on the society's ability to innovate, it has become increasingly important to ensure that the patent regime promotes, and does not impede, innovation. Subject matter eligibility is neither just a mere prohibition against the patenting of nature and abstract ideas, a pseudorequirement to enforce other patentability requirements, nor an exercise in statutory interpretation of § 101. It is time to transform today's rigid, inflexible doctrine-laden regime to a more forward-looking, dynamic policy-driven regime. Within subject matter eligibility lies the disease—and the cure—to many of our patent ills.