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Article

***393 PATENT ELIGIBLE MEDICAL AND BIOTECHNOLOGY INVENTIONS AFTER BILSKI, PROMETHEUS, AND MYRIAD**[Joshua D. Sarnoff \[FN1\]](#)

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I.	Introduction	393
II.	Bilski	395
III.	Prometheus	400
IV.	Myriad	408
V.	Conclusion	417

I. Introduction

The United States Supreme Court recently held in *Bilski v. Kappos* that business methods may be eligible subject matter for patents. [FN1] The Court reiterated that as a matter of long-standing precedent, the patent system categorically excludes “laws of nature, physical phenomena, and abstract ideas” [FN2] (such as science, nature, and ideas), despite the broad categorical language recited in Section 101: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition*394 of matter . . . may obtain a patent therefor.” [FN3] The Court invited the U.S. Court of Appeals for the Federal Circuit to specify narrower categories or classes of abstract ideas that would provide the public with greater certainty of what can qualify as eligible and what cannot. [FN4]

The Federal Circuit is now issuing a burgeoning set of eligibility decisions regarding a wide range of practical and useful medical and biotechnology applications, such as the *Prometheus* medical treatment method case [FN5] and the *Myriad* isolated genetic sequence and diagnostics method case. [FN6] Notwithstanding the Supreme Court’s invitation, the Federal Circuit under Chief Judge Rader has signaled its desire to avoid reliance on categorical eligibility exclusions whenever possible, requiring “recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory

categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act.” [FN7] These patentability criteria are novelty, non-obviousness (inventive step), and adequacy of the disclosure in describing the invention and enabling others to use it. [FN8] Implicit in this effort to avoid eligibility exclusions is the view that Section 101 largely duplicates patentability criteria in preventing the issuance of bad patents--bad in the sense of not being really innovative [FN9]--and that there is no field of scientific, technological, or other functional endeavor for which the patent system would categorically impede rather than promote innovation. [FN10]

This article briefly explains the current and conflicting doctrinal standards for eligibility exclusions adopted by the Supreme Court in *Bilski* that the Federal Circuit and the U.S. Patent and Trademark Office (PTO) will have to apply to claims for the discovery of medical and biotechnological inventions in Part II. Part III *395 analyzes the Federal Circuit's decision in *Prometheus* and relates it to the earlier Supreme Court *Laboratory Corp.* case, [FN11] which addressed a medical diagnostic patent but did not result in an issued decision. Part IV describes the *Myriad* case and the issues that it raises. Throughout this article, the focus is on how the current doctrine determines eligible and ineligible applications of categorically excluded science, nature, and ideas. Additionally, this article discusses the difficulty in drawing lines regarding eligibility of claimed inventions, systemic benefits of employing eligibility exclusions, and the utilitarian and deontological moral concerns, e.g., social and innovation harms, raised in regard to such applications. The article concludes with a brief projection of the continuing contested future of medical and biotechnology eligibility determinations, and the recognition that patentable subject matter eligibility will remain a controversial area in the United States and around the globe.

II. *Bilski*

The Supreme Court in *Bilski* not only reaffirmed the existence of the categorical exclusions from eligibility for science, nature, and ideas, but it also reiterated the long-standing requirement to treat them as if they were already “a familiar part of the prior art,” [FN12] even when they were newly discovered by the patent claimant. This legal fiction exists because such discoveries are the “basic tools of scientific and technological work,” [FN13] and as “part of the [public domain] storehouse of knowledge of all men. . . . [They must remain] free to all men and reserved exclusively to none.” [FN14] The patent system is not supposed to reward such basic scientific or conceptual discoveries, no matter how much money, effort, creativity, and disclosure go into developing and disseminating that knowledge. [FN15] Nor does patent law exist to reward such discoveries and recoup the investments of money, effort, and creativity in making them through eligible inventions that apply the discoveries. [FN16] Rather, *396 patent claimants must invent and disclose some “other inventive concept” than a merely novel, physically limited application of the new discovery. [FN17]

As a result of the prior art status of categorically excluded science, nature, and ideas, the human creativity involved in discovering them should not contribute to assessing the nature, eligibility, or patentability of the claimed “invention” in their application. [FN18] As the Court repeated in *Bilski*, once an excluded algorithm is “assumed to be within the prior art, the application, considered as a whole, [may] contain[] no patentable invention.” [FN19] Stated differently, for an eligible and patentable invention to exist, there must be invention (human creativity) in the application of excluded discoveries and not merely creativity in identifying the discovery that makes the application possible. For this reason, the Court in *Bilski* repeated language from a recent, claimant-friendly eligibility case, *Diamond v. Diehr*, stating that “the prohibition against patenting abstract ideas ‘cannot be circumvented by limiting the[ir] use . . . to a particular technological environment’ or [by] adding ‘insignificant postsolution activity.’” [FN20]

This approach in the United States differs substantially from other approaches, such as those in Australia and under the European Patent Convention (EPC). [FN21] Australian decisional law explicitly refuses to treat new discoveries as publicly known prior art when considering the creativity of claimed inventive applications of them, although the discoveries themselves remain categorically ineligible. [FN22] Thus:

[An applicant's] claim for a patent is not validly answered by telling him that although there was ingenuity in his discovery . . . no ingenuity was involved in showing how the discovery, once it has been made, might be applied. The fallacy lies in dividing up the process that he puts forward as his invention. [FN23]

*397 In contrast, under the EPC, a “contribution” approach to eligibility similar to that used in the United States was

initially adopted, under which the creativity of categorically excluded subject matter could not contribute novelty to claimed applications. [FN24] The EPC expressly excludes from being “regarded as inventions” “discoveries, scientific theories and mathematical methods,” but only for the discoveries “as such.” [FN25] Although the EPC later abandoned the contribution approach to eligibility, the contributed knowledge of the categorically ineligible discovery remains excluded from the consideration of an inventive step (although it is not necessarily treated as prior art) when evaluating the technical contribution of the applicant. [FN26] The EPC thus currently permits claims that employ a technical means or that are a technical product for consideration as eligible inventions, even if all of the creative novelty lies in the excluded discovery. [FN27] However, it requires that any technical effect for an inventive step be reflected in a technical character found in all the features together, and thus in the application of the discovery. [FN28] Where the only creative and novel feature is non-technical (i.e., in the categorically excluded subject matter), the claim will not be patentable. [FN29] As the EPC's own Board recognized, many have criticized as “distasteful” the choice to permit discoveries to contribute to eligibility given that they do not contribute to patentability. [FN30] The U.S. “prior art” approach avoids having the creativity of new discoveries contribute to either.

The U.S. Supreme Court, however, has not been consistent in approaching eligibility and has not provided clear guidance regarding what qualifies as categorically excluded subject matter, particularly “abstract ideas” [FN31] and what applications are eligible in light of them, or in relating its practical decisions to the theoretical grounds for making them. Thus, the Court in *Bilski* held to be ineligible abstract *398 ideas various independent claims for a method of hedging risks from unexpected events that created fluctuating volumes for fixed-price-contract purchased commodities. [FN32] These claims were somewhat more specific than the underlying fundamental idea that the claims applied, i.e., hedging risks, but did not require the use of any specifically identified machines or artifacts. [FN33] In reaching its decision, the Court continued to express a concern articulated in a 1972 decision that patents may not issue if they “would wholly pre-empt the [ineligible discovery] and in practical effect would be a patent on the [discovery] itself.” [FN34] The Court also failed to explain adequately why the more specific dependent claims at issue--limiting the methods to commodities and energy markets and requiring the use of well-known techniques as inputs--added only “field of use” limits or “token post-solution components” that “did not make the concept patentable.” [FN35]

The Supreme Court also rejected the Federal Circuit's effort to create clearer rules of eligibility based on Supreme Court precedents and dicta that applications involving particular machines or accomplishing specific physical transformations are eligible. [FN36] The Supreme Court overruled the Federal Circuit's holding that the “machine-or-transformation test . . . [is] the sole test for what constitutes a[n eligible] ‘process’ (as opposed to just an important and useful clue),” [FN37] preserving the potential for expansion of the patent system to intangible and information technologies. But the Supreme Court did not apply its own clue and focused solely on the abstract idea exclusion. Nevertheless, the Court's discussion of the field of use limits and token post-solution activity in regard to the dependent claims suggests that it did not view any physical implementations of the abstract idea implied by the claim language as requiring the use of particular machines or as accomplishing sufficient physical transformations. [FN38]

In contrast, earlier Supreme Court cases have recognized, based on the prior art non-contribution approach, the need for an eligible invention to possess a sufficient kind and degree of creativity (or “sophistication” [FN39]) in the application of categorically*399 excluded science, nature, or ideas to accomplish a practical result. [FN40] This requirement generates and explains various linguistic formulas developed in other Supreme Court cases to assess the eligibility of claimed products and processes. These tests would find particular physical and scope-limited novel applications of discoveries to be ineligible unless the claimed products--derived from ineligible products of nature, i.e., physical phenomena--have “markedly different characteristics,” [FN41] or unless the claimed processes reflect non-“analogous” uses. [FN42] Merely novel but insufficiently creative applications of ineligible discoveries are not eligible inventions. [FN43] But once a sufficiently creative application has been invented, that invention (not the discovery it employs) may be patented and may thereby preempt its full scope of application. Such preemption may include all means of accomplishing a particular end, even if the inventive application is the only practical means of using the discovery to accomplish the desired result. [FN44] Thus, the horse of determining the existence of an inventive application must precede the cart of assessing the over-breadth of claim scope compared to that application.

These are the standards that establish the current, messy state of patent eligibility law in the United States. The decisions

that have been and will be issued by the Federal Circuit in applying these standards to medical and biotechnology inventions have been and likely will be similarly disharmonious. Yet further conflicts may develop if the U.S. Congress becomes involved in creating exclusions from patent eligibility, either by restricting entire areas of endeavor from the patent system or by adjusting the level of creativity found by the courts to be sufficient for eligibility of applications of ineligible discoveries (as has been proposed, e.g., for methods of reducing, avoiding, or deferring tax liability by treating them as prior art [\[FN45\]](#)). Similar conflicts would result from any future legislation to extend eligibility to areas that the courts may hold are excluded, or to levels of creativity the courts may hold are insufficient. In the latter case, constitutional concerns may arise regarding*400 whether any limits exist on Congress's power to grant patents to such "inventions," including, retrospectively, to those that have fallen into the public domain. [\[FN46\]](#)

III. Prometheus

On remand from the Supreme Court following *Bilski*, the Federal Circuit in *Prometheus* distinguished the essence of the medical treatment claims at issue as physically transformative (of humans) from the "'mere[]' data-gathering steps or 'insignificant extra-solution activity'" of clinical diagnostic claims that the Federal Circuit had earlier found to be ineligible in the *Grams* case. [\[FN47\]](#) As one commentator put it immediately after the decision, the panel's attempt to distinguish *Grams* was "less than convincing." [\[FN48\]](#) Specifically, the treatment claim addressed a multi-step method of "optimizing therapeutic efficiency for treatment of an immune-mediated gastrointestinal disorder" requiring following the steps of: (1) administering a drug containing a particular synthetic chemical (6-thioguanine, or 6TG) to a person; and (2) determining the level of 6TG in the person, where a level of 6TG at or below a specific concentration indicates a need to increase the amount of drug administered to assure efficacy, and a different level at or above a specific concentration indicates a need to decrease the amount to avoid toxicity. [\[FN49\]](#) Another claim of that patent dispenses with the requirement to administer a thiopurine drug, relying only on the determining step, and a claim of a different patent is substantially the same as the first claim, adding only a requirement to determine another metabolite's level. [\[FN50\]](#) *401 The first step necessarily requires physical activity to administer the specific drug (a composition of matter), and the second step implicitly requires some physical method (but not any specific method) of gathering data and of performing an analysis to determine the metabolite's level. But the claim as a whole does not require taking any action in response to the mental step of determining a person's level of 6TG. *Mayo* originally used the diagnostic test technology sold by *Prometheus* but later abandoned it for its own test employing different indicator levels of 6TG for evaluating thiopurine administration. [\[FN51\]](#)

The human metabolic pathway of converting synthetic thiopurine drugs into mercaptopurines and thiopurine nucleotides was well-known, as was the use of such drugs to treat autoimmune and inflammatory bowel diseases. [\[FN52\]](#) These metabolic products were known to cause serious adverse side effects including death, and thus, medical practitioners were already engaged in calculating effective doses that would minimize the risks of side effects. [\[FN53\]](#) *Prometheus* exclusively licensed the patent from its owners, who had statistically observed the blood levels of these conversion products across a range of patients and derived an association of the blood levels with regard both to effectiveness and to avoidance of toxicity. [\[FN54\]](#) The claims reflected the particular levels of the statistical associations that were observed.

The district court found that the claims were not eligible subject matter because: (1) they were merely the combination of a data-gathering step and a mental step, without requiring any actual physical treatment (implying that they were not transformative under the machine-or-transformation framework); and (2) the claims essentially recited correlations that were categorically ineligible natural phenomena (products of nature) that the applicants did not invent, and the claims wholly preempted all uses of those correlations. [\[FN55\]](#) The Federal Circuit originally reversed, *402 based on its en banc decision in *Bilski*, [\[FN56\]](#) which had imposed the machine-or-transformation framework as the conclusive test, and based on its different understanding of the claims and of the invention from that of the district court. [\[FN57\]](#) The claims were held to be eligible because "[1] the 'administering' and 'determining' steps were [physically] transformative and not merely data-gathering steps . . . and [2] as such the claims did not wholly preempt the use of the recited correlations [the specific indicators] between metabolite levels and drug efficacy or toxicity." [\[FN58\]](#)

On remand in *Prometheus* after the Supreme Court's *Bilski* decision, the Federal Circuit first held that: the Court had not disavowed the machine-or-transformation framework but had only avoided making it an exclusive test; and the machine-or-

transformation framework continued to establish the eligibility of the claims at issue. [FN59] The claims were for methods of treatment, “which are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.” [FN60] In other words, the human body itself is transformed by treatment, even if the transformations result from natural bodily processes. The district court focused on the fact that the claims did not require any subsequent action following recognition of indication levels, and thus, the claimed method could not by itself optimize therapeutic efficiency without taking the next unclaimed step of adjusting the amounts administered. In contrast, the Federal Circuit focused on the fact that the claim as a whole, based on the prior art administering step, was still a method of treatment. [FN61] Alternatively, the Federal Circuit may have found the step of physically adjusting dosages to be implicit in the claimed recognition step. Of greater significance, the Federal Circuit failed to recognize that the only novelty of the claimed invention relative to the prior art was in the step of recognizing--through unspecified but physical data gathering and presumably non-physical mental activity--the newly identified “natural” correlation between metabolite levels of synthetic drugs and medical needs, which is arguably a categorically ineligible scientific and medical discovery. If so, just like in *Bilski*, the dependent claims “as a whole, contained no patentable invention,” [FN62] even if physical data-gathering steps were employed, the information gathered was useful, and likely triggered subsequent action.

***403** On remand after *Bilski*, the Federal Circuit in *Prometheus* also reiterated that the claims were drawn to a particular application of an ineligible natural phenomenon, not to the phenomenon itself, i.e., a law of nature. [FN63] The transformations achieved by these specific steps were “central to the purpose of the claimed process.” [FN64] Specifically, the court noted that “the steps involve[d] a particular application of the natural correlations: the treatment of a specific disease by administering specific drugs and measuring specific metabolites. As such, . . . the claims [did] not preempt all uses of the natural correlations; they utilize[d] them in a series of specific steps.” [FN65] The court rejected the arguments that the claims preempted all uses and that any machine implementation or physical transformation involved in the administering and data-gathering steps were merely “insignificant post-solution activity.” Although the court agreed that the mental recognition step would not be eligible on its own, that did not preclude the method, viewed as a whole, from eligibility. [FN66] The treatment claims did “not preempt all uses of the natural correlations” as other “drugs might be administered to optimize the therapeutic efficacy of the claimed treatment.” [FN67]

The Federal Circuit's remand decision failed adequately to explain why the actual invention--the essence of the treatment claim, i.e., its “gist” or “heart” or “point of novelty” [FN68]--lay in the physically transformative administering step and not in the correlation employed by it. This was because the Federal Circuit did not recognize the need for any creative invention in the application of the new medical discovery by treating that discovery as if it were prior art. Once that discovery was treated as known, using the specific correlation in an existing process of administering drugs and testing blood levels of metabolites may have been new but certainly was not inventive. Lacking any invention, but claiming a novel combination method, the claim also could not survive patentability evaluations for obviousness so long as that correlation was treated as prior art. The claims would necessarily lack any non-obvious invention without performing some non-analogous function when combining the medical fact that had been discovered with the prior art method of ***404** treatment. [FN69] The Federal Circuit thus improperly allowed the newly discovered but ineligible correlation to contribute to assessing the “invention” for eligibility, even though the claims should be inherently obvious if the correlations are treated as prior art (even under the European approach). The court did so by focusing on the claim as a whole rather than the inventive contribution that the claim as a whole reflected, on the additional, uncreative claim limits of the otherwise-known method, and on the physical nature of the administration steps in the claim.

The Federal Circuit's decision failed to provide any convincing account of why the physical drug-administering or metabolite level-determining steps were not merely insignificant extra-solution activity for the claimed uses of the newly discovered correlation. The Supreme Court in *Bilski* found the specific antecedent data-gathering and information input steps to the hedging method claims at issue to constitute only token post-solution activity to the abstract ideas claimed, and thus, held such claims as a whole to be ineligible. [FN70] Such insignificant steps will also avoid preemption by preventing the more specific uses of newly discovered natural phenomena from excluding other unclaimed uses; claim scope concerns can be addressed through the enablement doctrine. [FN71]

The Federal Circuit's belief that the specific steps of administering the drugs avoided preemption of uses of the correla-

tions was also confused. The fact that other applications might be found for correlations that exist between other non-thiopurine drugs and the recited metabolite levels did not change the fact that the claims recited (and preempted all uses of) the specific correlations between the thiopurine drugs and metabolite levels actually discovered and claimed. Given so-called and controversial “absolute protection” that excludes all making and uses, including those that are not contemplated by inventors, [FN72] every patented claim inherently preempts all applications to which the claimed inventive principle applies. The Supreme Court long ago recognized this preemption in the seminal Alexander Graham Bell Telephone Case to be permissible even for very broad claims, so long as some inventive principle exists and is claimed in applying a scientific discovery or natural phenomenon. [FN73]

*405 The additional initial physical treatment and data-gathering steps may not necessarily change the essence of claims that apply a new discovery of a natural medical phenomenon. Justice Breyer recognized this in a non-precedential statement in the Laboratory Corp. diagnostic method case that preceded *Bilski* and was argued to the Court but dismissed without opinion [FN74]: “aside from the unpatented [prior art data-acquisition] test, [the steps] embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an unpatentable ‘natural phenomenon,’ and I can find nothing in claim 13 that adds anything more of significance.” [FN75] Justice Breyer specifically rejected the arguments that “the correlation is nonetheless patentable because claim 13 packages it in the form of a ‘process’ for detecting vitamin deficiency, with discrete testing and correlating steps,” and “that claim 13 is a patentable ‘application of a law of nature’ because, considered as a whole, it (1) ‘[e]ntails a physical transformation of matter,’ namely, the alteration of a blood sample during whatever test is used . . . and because it (2) ‘produces a “useful, concrete, and tangible result,” namely, detection of a vitamin deficiency. . . .” [FN76] These arguments are remarkably similar to the basis for the Federal Circuit’s post-*Bilski* holding. Even if the Supreme Court does not reach out in *Prometheus* to resolve whether Justice Breyer’s or the Federal Circuit’s approach is to be the master, the issues and differences of approaches will continue to present disputes and petitions for certiorari in other cases, given the large numbers of treatment and diagnostic claims that have issued and that reflect such applications of newly discovered natural medical phenomena (including those induced synthetically).

Laboratory Corp. is also significant for the public policy concerns that it raised since Justice Breyer went out of his way to discuss as a reason for seeking to have the case decided rather than dismissed—even if the Court were to resolve the case against his views—because a clear decision would then allow Congress to weigh in if it felt the need to change the law. [FN77]

To fail to do so threatens to leave the medical profession subject to the restrictions imposed by this individual patent and others of its kind. Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching patent files for similar simple*406 correlations; they may raise the cost of health care while inhibiting its effective delivery. [FN78]

Although the U.S. Patent Act contains an exception from remedies for medical practitioners and their institutions performing patented medical methods, [FN79] the potential indirect liability of the clinical laboratory in assisting the doctors posed serious First Amendment free speech and medical communication concerns. [FN80]

Various medical organizations restated many of these concerns in the *Prometheus* case arguing that non-inventive applications of basic medical discoveries “interfere with the practice of medicine, constraining the ability of physicians to make informed treatment decisions based on the latest scientific knowledge, are likely to stifle innovation, and will serve only to increase the cost and decrease the effectiveness of treatment for serious diseases.” [FN81] These organizations further argued that precluding such claims would not interfere either with the development of personalized medicine or with “incentives necessary for medical innovation.” [FN82] The existence of these harms and the sufficiency of non-patent incentives for making such medical discoveries and patentable applications of them are highly contested. [FN83] Thus, the court in *Prometheus* reasoned that invalidating claims like the one at issue “would destroy the entire field of medical treatment and diagnostic patents. Thousands, if not tens of thousands, of such patents have been granted, and they have become the essential underpinning of a vibrant and innovative industry of inestimable value to mankind.” [FN84]

Perhaps more interestingly, the medical organizations raised deontological moral arguments for invalidating patents for

such non-creative applications-- that they reflect doctor's violations of their ethical duties to share information freely. [FN85] As the medical organizations noted:

*407 Physicians have an obligation to share their knowledge and skills and to report the results of clinical and laboratory research. . . . The intentional withholding of new medical knowledge, skills, and techniques from colleagues for reasons of personal gain is detrimental to the medical profession and to society and is to be condemned. [FN86]

Such moral arguments are gaining increasing importance in political debates over the scope of patent rights, but they raise concerns that are incommensurable with the innovation policy concerns and may be even less susceptible to theoretical and empirical resolution. Furthermore, normative beliefs regarding scientific obligations to share knowledge have been changing [FN87]--in large part resulting from permitting scientists and their institutions to retain patents with government funds. [FN88] Moreover, unlike in the United States, most countries now entirely prohibit patents on medical methods of diagnosis and treatment. [FN89] The politics of these moral disputes over the proper scope of the patent system and the obligations of discoverers to freely share their useful knowledge will remain contested, [FN90] just as it is for software, [FN91] sports moves, [FN92] tax planning methods, [FN93] cloned organisms, [FN94] and the many *408 important products of biotechnological research and development, to which we now turn.

IV. Myriad

In 2009, the American Civil Liberties Union and the Public Patent Foundation (collectively the ACLU) brought suit on behalf of numerous medical organizations, doctors, scientists, and patients to challenge various specific claims that had been obtained on two genes associated with breast cancer (BRCA1 and BRCA2) and methods of diagnosing genetic mutations thereof in a person's gene sequences. [FN95] As the ACLU noted, gene patents raise civil liberties concerns by "unreasonably restraining free speech and scientific research," and by violating rights to freedom of research, thought, and expression possessed by scientific researchers, clinical geneticists and genetic counselors, and the public. [FN96]

The claims followed on the efforts of an international consortium that was in the process of sequencing the breast cancer genome. The Breast Cancer Linkage Consortium identified the chromosome on which the genome was located, and had intended to place the sequence in the public domain. [FN97] But one of the researchers, Mark Skolnick at the University of Utah, departed from the consortium and founded Myriad Genetics to commercialize the gene once it was sequenced. [FN98] Skolnick was the first to specifically locate both the BRCA1 and BRCA2 genes through his access to Mormon genealogical records. With the assistance of federal funds and research assistance, Skolnick compared these records with Utah's state public health files using computational analysis techniques, [FN99] sequenced the genes using well-known biotechnological techniques, obtained patents on the isolated sequences*409 and their diagnostic method uses, and assigned his rights to the University of Utah which licensed them exclusively to Myriad. [FN100]

After the Myriad patents were granted, they were subjected to substantial public criticism in the United States, on utilitarian grounds, for interfering with research, raising the costs of breast cancer diagnostic treatment, and preventing the use of a better, more comprehensive diagnostic test that had been developed by others and was being used in Europe. [FN101] These concerns led to a widely publicized editorial by the fiction writer Michael Crichton in the New York Times, which criticized gene patents generally on both utilitarian and deontological moral grounds and encouraged legislation to ban gene patents in the United States. [FN102] The ACLU's suit followed.

The ACLU challenged specific patent claims to genetic sequences and to methods employing them as being unconstitutional and beyond the PTO's statutory authority to grant. [FN103] The first set of claims was for isolated deoxyribonucleic acid (DNA) or isolated DNA molecules coding for BRCA1 or BRCA2 proteins, or short sequences or mutations thereof. [FN104] Although this language could, in theory, encompass pure information, the court construed these claims to apply to physical DNA. [FN105] The second set of claims was for methods of analyzing a sequence, detecting a mutation, or comparing a sequence to the normal (disclosed) sequence. [FN106] These claims did not recite any specific method for acquiring sequence information *410 and like the recognition step of the Prometheus claim, they arguably could be performed solely in the mind. [FN107]

The district court avoided reaching the constitutional issues by finding the claims to be unauthorized by the statute. [FN108] The court found that merely isolating genetic sequences, even if the resulting sequences are also minimally chemically modified, does not alter their status under the Patent Act as unpatentable “products of nature.” [FN109] Long-standing precedents distinguished ineligible products of nature from creative “human-made inventions” [FN110] based on whether the object created from the natural product was “a new and different article, having a distinctive name, character, or use.” [FN111] Merely isolating an existing substance to increase its purity while using it for its natural functions, or merely creating a synthetic analogue to the natural product, is not sufficiently creative to be an eligible invention. [FN112]

As the Supreme Court noted in *American Fruit Growers*, in order to be eligible, the new creation has to “possess[] a new or distinctive form, quality, or property. . . . There [must be a] change in the name, appearance, or general character of the [thing from which it was created].” [FN113] The Court addressed a novel, non-natural, human-made combination--borax-treated fruit--having a property, i.e., mold resistance, that was not possessed by the natural article alone, and held the claimed product to be an ineligible product of nature. [FN114] Following *American Fruit Growers*, the subsequent Commissioner of the Patent Office, who also became one of the principal drafters of the current Patent Act, acknowledged that the Patent Office had improperly granted earlier patents for biological materials and chemicals that were merely isolated or purified from naturally occurring material--such as Pasteur's isolated yeast patent and a purified adrenaline (takemine) patent.” [FN115]

*411 Similarly, the Supreme Court in *Diamond v. Chakrabarty* [FN116] upheld the eligibility of a living, synthetic organism by distinguishing its earlier holding in *Funk Brothers*, which had found ineligible a synthetic, man-made combination of bacteria that merely “serve[d] the ends nature originally provided” [FN117] The former, but not the latter, had “markedly different characteristics from any found in nature and . . . the potential for significant utility.” [FN118] Since both claimed products had significant utility, the distinction between eligible and ineligible inventions must have related to those markedly different characteristics. Further, the “markedly different characteristic” standard for products corresponded to the Court's standard for eligibility of processes, which requires new uses of existing things or processes to be non-analogous, i.e., not merely different-- and thus novel but similar. [FN119] Although the 1952 Patent Act codified a definition of “process” that included new uses of known things or processes and then included such processes in the categories of eligible subject matter, [FN120] the legislative history makes clear that Congress intended only to restore the non-analogous use standard in light of a conflicting lower court opinion. [FN121]

Returning to *Myriad*, the district court implicitly overruled the policy held by the PTO since at least 2001 that isolated or purified gene sequences are patent eligible inventions, based on an earlier grant of a patent to Louis Pasteur for isolated yeast and on a lower court opinion that isolated natural products were patent eligible. [FN122] As the PTO then stated, such sequences do “not occur in that isolated form in nature, or [are] synthetic DNA preparations . . . [and] their purified state is different from the naturally occurring compound.” [FN123] The district court unfortunately may have gone too far in seeking to justify its decisions on the isolated sequence claims on an exceptionalist view of genetic materials based on their information content. The court held:

*412 *Myriad's* focus on the chemical nature of DNA, however, fails to acknowledge the unique characteristics of DNA that differentiate it from other chemical compounds. . . . This informational quality is unique among the chemical compounds found in our bodies, and it would be erroneous to view DNA as ‘no different[]’ than other chemicals previously the subject of patents. [FN124]

Given the Supreme Court precedents discussed above, the court could have readily reached the same result of unpatentability based on the similarity of the isolated materials and the new functions that they perform as not “markedly different characteristics” and only “analogous uses.” Although the new functions, such as their use as probes and for diagnostic analysis, may have been novel and not performed by the naturally occurring materials (as in *American Fruit Growers*), the new functions would remain insufficient given their reliance on the natural materials and their inherent properties. The district court's exceptionalist approach is unlikely to survive the currently pending appeal, as the Federal Circuit may not wish to acknowledge that the many claims that have issued for isolated or purified natural chemicals and biological materials over the last 100 years have been invalid.

Remarkably, the United States Government (USG) filed a brief in the appeal admitting that for the last twenty years, the PTO has lacked authority for and improperly issued thousands of claims for isolated and purified genetic sequences. [FN125] Although the USG recognized that the claims at issue were invalid because they applied to isolated DNA, the USG also argued that if the claims had been limited to complementary DNA (cDNA)-single-stranded, extra-chromosomal gene sequences with introns, or non-coding, regions removed-they would be valid because cDNA is chemically different from isolated DNA. [FN126] The USG's distinction may not make sense, given that cDNA occurs naturally within cells, [FN127] and thus, cDNA is either merely an isolated natural DNA sequence or a synthetic reproduction of such a naturally occurring sequence. Using the USG's own "magic microscope" analogy, where if you could see the thing in the same form in nature but for extraction, isolated*413 cDNA would remain a product of nature. [FN128] Furthermore, the Supreme Court precedents noted above make clear that merely creating synthetic analogues of natural products does not generate eligible inventions. Notwithstanding the USG position that the PTO lacks legislative authority to grant patents for isolated and purified genetic sequences; the PTO has refused to stop issuing such claims while the case is pending. [FN129]

Various other approaches and distinctions that might justify eligibility have been raised in the case, but are unlikely to become the basis for an appellate court decision on the merits. For example, during oral argument some of the Federal Circuit Judges suggested a potential distinction between treating isolated natural minerals or other materials as products of nature and not treating isolated genes as such, based on the distinction of physical from chemical separation (e.g., solvent extraction from breaking of covalent chemical bonds). [FN130] The Acting Solicitor General, however, argued that such a distinction could not be justified, as it would allow patents covering natural minerals such as lithium, which also need to be chemically separated from their natural condition in order to be useful. [FN131]

Similarly, some of the amici supporting Myriad focused on the human-created, synthetic nature of the claimed isolated, extra-chromosomal sequences and the new functions such sequences can perform, e.g., gene therapy and manufacture of therapeutic proteins. [FN132] Other amici focused on the difficulty of and creative steps involved in generating the synthetic sequences. [FN133] But the difference of the new functions capable of being performed by isolated DNA from those performed in nature, and the difficulty of actually obtaining the sequences given contemporaneous public knowledge, was barely discussed during the oral argument. The only *414 significant discussion of these issues occurred in regard to whether the plaintiffs could avoid other claims of Myriad's patents, which were directed to use of isolated sequences as probes or primers, which were not challenged by the plaintiffs, if the court were to invalidate the isolated sequence claims and thus whether a decision would redress any asserted injury that the plaintiffs have suffered. [FN134] Myriad also argued in its briefs that the plaintiffs lack a sufficient threat of liability to have standing to challenge the patents, and much of the oral argument focused on the standing issue. [FN135]

The district court in Myriad also found invalid the patents for the methods because the claims did not require any physical acts and thus patented only mental steps. [FN136] The method claims were held invalid based on the machine-or-transformation approach applied by the en banc Federal Circuit in *Bilski*, [FN137] but the claims should theoretically fare no better under the Supreme Court's *Bilski* decision. Specifically, the district court rejected Myriad's argument analogizing the "analyzing" steps to the "determining" steps of the *Prometheus* claim that was upheld by the Federal Circuit (before the *Bilski* remand). The district court distinguished the *Prometheus* claims as being construed "to include the extraction and measurement of metabolite concentrations," whereas the claims at issue "are directed only to the abstract mental processes of 'comparing' or 'analyzing' gene sequences," particularly as unchallenged dependent claims recited more transformative steps. [FN138] Thus, the district court did not reach either the insignificant post-solution activity inquiry or preemption analyses, although it treated restrictions of the claims to human isolated DNA as merely further specifying the subject to be analyzed, similarly to field of use restrictions on method claims that do not supply eligibility. [FN139] During oral argument in the appeal, the method claims were addressed almost as an afterthought, and were alternatively analogized to or distinguished from the claims upheld in *Prometheus*. [FN140] They are unlikely to be upheld on appeal, particularly given their broad construction by the district court.

Returning to the theory of eligibility and contributions, the locations of the BRCA genes are clearly natural phenomena as medical facts. If those locations and sequences were treated as prior art, as is required by the existing eligibility doctrine, it would be apparent that no creativity went into isolating the genetic DNA or *415 identifying their sequences, particularly

given the advanced state of genetic technologies at the time, or into using them for comparison once the sequences were known and the molecules were isolated. Accordingly, the claims for both the isolated sequences and the methods of comparing them, which do not recite any specific steps beyond or means for performing the analysis, detection, or comparison, should not have been considered eligible inventions. It should also be apparent that such claims are necessarily obvious, just as pharmaceutical compound claims are held to be obvious if a lead compound has been identified in the art and only routine methods are needed to identify its function. [\[FN141\]](#)

Unfortunately, the decision of the district court did not provide and the forthcoming decision of the Federal Circuit is unlikely to provide meaningful analysis of the degree of creativity involved in any claimed application of the sequences, or of how the functions of the isolated DNA molecules differ from or improve upon the functions performed by naturally occurring DNA. Nor is the case likely to provide a more refined exposition of the machine-or-transformation approach to method claims, or of the centrality of various physical implementation steps to the claims. However it comes out, the case is therefore unlikely provide adequate guidance for assessing the eligibility of the many future applications of new discoveries of nature that will be claimed.

Finally, if the claims are invalidated, it is possible that legislative action will result seeking to overturn the outcome to restore eligibility. Lacking adequate judicial exposition of the theory of eligibility and responding to political pressures, Congress also would be unlikely to articulate a clear approach to eligibility. Rather, Congress is more likely to codify the eligibility of specific excluded subjects--such as isolated genetic sequences--and to leave the theory of eligibility unresolved even if many inventions restored to eligibility should also necessarily be found obvious under a prior art contribution approach.

Unlike in the United States, the attack on the Myriad gene patents in Europe proceeded even more clearly on deontological moral grounds. Various French public health organizations, national ministries, and genetics societies initiated opposition proceedings in the European Patent Office (EPO) against three of the Myriad patents, [\[FN142\]](#) leading to the revocation of one patent and the significant limitation of *416 two other patents. [\[FN143\]](#) The original application disclosed an incorrect sequence, and later corrections to the disclosure post-dated the publication of the correct sequence in accessible scientific databases so that the claims to the entire gene sequence were invalid for lack of novelty. [\[FN144\]](#) Nevertheless, the EPO upheld the patent on partial BRCA1 gene sequences used as probes or vectors. [\[FN145\]](#) It rejected arguments that the sequences were immorally obtained from cells without the consent of the donors, violated “ordre publique” given their importance to public health, and lacked “industrial application” given that the probes and vectors were primarily used for cloning or identification of mutated genes. [\[FN146\]](#)

The concept of industrial application has received an expansive interpretation, including industrial methods of production for uses that could be considered non-industrial and non-technological, even if patents for such uses are otherwise excluded from the patent system. Thus, the EPC of 1973 specifically excluded methods for diagnosis or treatment by therapy or surgery of humans or animals from being considered inventions having industrial application. [\[FN147\]](#) The Enlarged Board of Appeal called this exclusion a “legal fiction,” which “seemed actually to be based on socio-ethical and public health considerations.” [\[FN148\]](#) In contrast, the EPC of 2000 simply prohibited such patents for treatment and diagnostic methods, recognizing that such methods may be within the commercial sphere even if human bodies are not. [\[FN149\]](#)

Similarly, the 1998 European Biotechnology Directive prohibits patents that would violate “ordre publique” or morality. It also provides a non-exclusive list of things that cannot be patented, which includes processes for cloning humans and *417 commercial uses of human embryos. [\[FN150\]](#) In particular, the Directive excludes patents for genetic sequence discoveries alone, while authorizing patents for isolated genetic sequences “even if the structure of that element is identical to that of a natural element.” [\[FN151\]](#) This approach clearly differs from that in the United States, given that the Supreme Court precedents would require a markedly different function for chemical structures that are either identical or similar to the natural sequences from which they are derived. The Directive also specifies that such sequences are industrially applicable once a concrete application for them is identified, although it limits protection to the disclosed use. [\[FN152\]](#) This approach is similar to that in the United States, based on the “new and useful” language of Section 101 of the U.S. Patent Act that precludes patents on genetic sequences until a significant utility has been identified for them. [\[FN153\]](#)

V. Conclusion

Given the substantial incentives to seek patents on applications of newly discovered but categorically ineligible science, nature, and ideas at the forefront of medical and biotechnological research and development, we can continue to expect disputes over patent eligibility to arise. Such disputes will likely be hotly contested due to the long-standing historical normative commitments to protecting this public domain from piecemeal encroachment through wholesale or more limited retail patent claims to those discoveries. Furthermore, with the accelerating pace of scientific and technological discoveries, we can expect to confront these complex issues of eligibility in regard to a wide range of new and important products and processes, such as personalized medicine, computational genomics, synthetic agriculture, nanotechnology, and so on.

We therefore need to develop a greater degree of understanding of, and greater consensus regarding, the degree of creativity in the applications of such newly identified, fundamental knowledge that should support the grant of patent rights for synthetic biological, chemical, mechanical, and digital products and processes. We know that the courts have struggled with these issues, seeking to distinguish Chakrabarty's eligible synthetic bacteria from Funk Brothers' ineligible synthetic combinations, and Bilski's ineligible hedging methods from Diehr's chemical treatment *418 methods. Determining the required creativity in turn will help to determine whether we view the synthetic creations and new uses for new scientific and medical discoveries as markedly different or as non-analogous to the things and functions from which they derive. We need to chart a new and clearer relationship between newly discovered knowledge of nature and medicinal facts, as well as between new and synthetic applications of such knowledge.

Acknowledging the confusion in the existing doctrine and recognizing the prior art status (at least in American law) of categorically excluded subject matter and the importance of preserving the public domain is the first step towards reasoned development of approaches and better resolution of the conflicting issues. In our increasingly integrated world, we will also need to expand the dialog and to address the lack of harmonization in “contribution” approaches. In doing so, we will have to focus on both the utilitarian and the deontological moral concerns that are involved.

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[FN1]. See *Bilski v. Kappos*, 130 S. Ct. 3218, 3228-29 (2010) (providing reasons why § 101 does not call for complete exclusion of all business methods).

[FN2]. *Id.* at 3225; *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citing, inter alia, *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-21 (1853); *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853)).

[FN3]. 35 U.S.C. § 101 (2006).

[FN4]. See *Bilski*, 130 S. Ct. at 3229 (leaving open the possibility of some patentable business methods).

[FN5]. See *Prometheus Labs. Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1347 (Fed. Cir. 2010), petition for cert. filed, 79 U.S.L.W. 3554 (U.S. Mar. 17, 2011) (No. 10-1150) (holding that method claims reciting natural medical correlations and for calibrating dosages of drugs were patent-eligible matter).

[FN6]. See [Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office \(Myriad\)](#), 702 F. Supp. 2d 181, 181 (S.D.N.Y. 2010), appeal docketed, No. 2010-1406 (Fed. Cir. June 22, 2010) (holding that patents for isolated DNA molecules and patents for methods of analyzing gene sequences were invalid).

[FN7]. [Research Corp. Techs., Inc. v. Microsoft Corp.](#), 627 F.3d 859, 868 (Fed. Cir. 2010).

[FN8]. See 35 U.S.C. §§ 102, 103(a), 112 P 1 (2006) (addressing novelty, non-obviousness, and adequacy in describing and enabling inventions, respectively).

[FN9]. Stefania Fusco, [In re Bilski: A Conversation with Judge Randall Rader and a First Look at the BPAI's Cases](#), 20 Alb. L.J. Sci. & Tech. 123, 145 (2010); see Michael Risch, Forward to the Past, 2009-2010 Cato Sup. Ct. Rev 333, 348 (discussing the Supreme Court's grant of certiorari in Bilski).

[FN10]. See Fusco, supra note 9, at 144.

[FN11]. Lab. [Corp. of Am. Holdings v. Metabolite Labs., Inc.](#), 548 U.S. 124, 127-28 (2006) (Breyer, J., dissenting from dismissal of certiorari).

[FN12]. [Bilski v. Kappos](#), 130 S. Ct. 3218, 3230 (2010); [Parker v. Flook](#), 437 U.S. 584, 591-92 (1978) (citing [Mackay Radio & Tel. Co. v. Radio Corp. of Am.](#), 306 U.S. 86, 94 (1939); [Funk Bros. Seed Co. v. Kalo Inoculant Co.](#), 333 U.S. 127, 130 (1948)) .

[FN13]. [Flook](#), 437 U.S. at 591 (quoting [Gottschalk v. Benson](#), 409 U.S. 63, 67 (1972)).

[FN14]. [Funk Bros.](#), 333 U.S. at 130.

[FN15]. [In re Alappat](#), 33 F.3d 1526, 1553-54 (Fed. Cir. 1994) (en banc) (Archer, C.J. dissenting); see generally C.J. Hamson, Patent Rights for Scientific Discoveries 20-29 (1930) (tracing the history of the proposal to award patent rights to the discoverer of scientific principles and recognizing that the discoverer should not have any monopoly of his discovery).

[FN16]. But cf. [Ariad Pharms., Inc. v. Eli Lilly & Co.](#), 598 F.3d 1336, 1359 (Fed. Cir. 2010) (en banc) (Newman, J., additional views) (“Basic scientific principles are not the subject matter of patents, while their application is the focus of this law of commercial incentive. The role of the patent system is to encourage and enable the practical applications of scientific advances, through investment and commerce.”).

[FN17]. [Flook](#), 437 U.S. at 594.

[FN18]. See [O'Reilly v. Morse](#), 56 U.S. (15 How.) 62, 115-16 (1853) (requiring for invention more than the mere discovery of a natural process); [Morton v. New York Eye Infirmary](#), 17 F. Cas. 879, 881-82 (C.C.S.D.N.Y. 1862) (No. 9,865) (holding that not all discoveries are inventions); cf. Emir Aly Crowne Mohammed, What Is an Invention? A Review of the Literature on Patentable Subject Matter, 15 Rich. J.L. & Tech. 1, 1 (2008) (noting that some authorities question whether there must be an invention in order to get a patent); David Vaver, [Invention in Patent Law: A Review and Proposal](#), 11 Int'l J.L. & Info. Tech. 286, 289-90 (2003) (discussing TRIPS Agreement language concerning inventions).

[FN19]. [Bilski v. Kappos](#), 130 S. Ct. 3218, 3230 (2010) (quoting [Flook](#), 437 U.S. at 594) (emphasis added).

[FN20]. [Bilski](#), 130 S. Ct. at 3230 (quoting [Diamond v. Diehr](#), 450 U.S. 175, 191-92 (1981)).

[FN21]. Convention on the Grant of European Patents art. 52(3), Oct. 5, 1973, 1065 U.N.T.S. 255, 13 I.L.M. 270, available at

<http://www.european-patent-office.org/legal/epc/e/ma1.html> [hereinafter EPC].

[FN22]. See *Nat'l Research Dev. Corp. v. Comm'r of Patents* (1959), 102 CLR 252, 279 (Austl.) (requiring only one step beyond the limits of the prior art).

[FN23]. *Id.* at 252.

[FN24]. Opinion of the Enlarged Board of Appeal of 12 May 2010, Case G 003/08, P 10.6 [hereinafter EBoA Opinion].

[FN25]. EPC, *supra* note 21, arts. 52(2)(a), 52(3).

[FN26]. EBoA Opinion, *supra* note 24, P 12.2.2.

[FN27]. *Id.* PP 10.7-10.7.1.

[FN28]. *Id.* PP 12.2.1, 13.5.

[FN29]. *Id.* P 13.5.

[FN30]. See *id.* P 10.13 (rejecting a claim for lack of an inventive step rather for excluding it under Article 52(2)).

[FN31]. See *Bilski v. Kappos*, 130 S. Ct. 3218, 3236 (2010) (Stevens, J., concurring in the judgment) (concluding that the majority leaves the abstract idea criterion uncertain); cf. Brief of Eleven Law Professors and AARP as Amici Curiae in Support of Respondent at 23-24, *Bilski v. Kappos*, 130 S. Ct. 3218 (2010) (No. 08-964)(citing *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1874)) (arguing for a historical definition of an abstract idea as a property or as a result); Pamela Samuelson & Jason Schultz, “Clues” for Determining Whether Business and Service Innovations are Unpatentable Abstract Ideas, 15 *Lewis & Clark L. Rev.* 109, 112 (2011) (stating that a clue-based approach to determining subject matter patentability is still useful even though it falls short of a bright-line rule).

[FN32]. *Bilski*, 130 S. Ct. at 3231.

[FN33]. See *Bilski*, 130 S. Ct. at 3223-24 (tracing the procedural history of the claims at issue).

[FN34]. *Id.* at 3230 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972)).

[FN35]. *Id.* at 3231.

[FN36]. See, e.g., *Benson*, 409 U.S. at 70 (using transformation of an article as a clue to patentability); *Cochrane v. Deener*, 94 U.S. 780, 788 (1887) (implying that machines are patentable).

[FN37]. *Bilski*, 130 S. Ct. at 3226; see *id.* at 3227 (holding the Federal Circuit was incorrect to endorse the machine-or-transformation test as the exclusive test); *In re Bilski*, 545 F.3d 943, 954-55 (Fed. Cir. 2008) (en banc), *aff'd*, 130 S. Ct. 3218 (2010) (holding the machine-or-transformation test is the proper test for patent eligibility of process claims).

[FN38]. See *Bilski*, 130 S. Ct. at 3231 (reiterating that limiting field of use or adding post-solution components does not make an abstract idea patentable).

[FN39]. Elizabeth I. Winston, *The Technological Edge*, 6-7 (Oct. 15, 2010) (unpublished manuscript), available at

<http://ssrn.com/abstract=1692836>.

[FN40]. See, e.g., [Evans v. Eaton](#), 8 F. Cas. 846, 851 (C.C.D. Pa. 1816) (No. 4,559) (requiring a practical application and not a mere abstract principle), rev'd on other grounds, [16 U.S. 454 \(1818\)](#); accord [Boulton v. Bull](#), (1795) 126 Eng. Rep. 651, (Ct. Com. Pl.) 668 (Lord Eyre, C.J.) (requiring the embodying of abstract principles); *id.* at 663 (Buller, J.); *id.* at 660 (Rooke, J.); *id.* at 662 (Heath, J.).

[FN41]. [Diamond v. Chakrabarty](#), 447 U.S. 303, 310 (1980); see [Hartranft v. Wiegmann](#), 121 U.S. 609, 615 (1887) (holding that the cleaning and grinding of sea shells did not make the shells into a manufactured article); [Morton v. New York Eye Infirmary](#), 17 F. Cas. 879, 881-82 (C.C.S.D.N.Y. 1862) (No. 9,865) (holding that not all discoveries are inventions).

[FN42]. [Ansonia Brass & Copper Co. v. Elec. Supply Co.](#), 144 U.S. 11, 18 (1892).

[FN43]. See *id.* (“[N]othing is better settled in this court than that the application of an old process to a new and analogous purpose does not involve invention, even if the new result had not before been contemplated.”).

[FN44]. [Dolbear v. Am. Bell Tel. Co.](#), 126 U.S. 1, 534-35 (1888).

[FN45]. See Patent Reform Act of 2011, S. 23, 112th Cong. § 14(a) (2011) (stating that tax avoidance strategies are not sufficient to differentiate a claimed invention from prior art).

[FN46]. See, e.g., Brief of Amici Curiae Ten Law Professors in Support of Appellee Director of the United States Patent and Trademark Office at 6-12, [In re Bilski](#), 545 F.3d 943 (Fed. Cir. 2008) (en banc), *aff'd*, [130 S. Ct. 3218 \(2010\)](#) (No. 2007-1130) (stating that the Constitution limits patentable subject matter, and the history of exclusions reflect those constitutional limits); see also [Eldred v. Ashcroft](#), 537 U.S. 186, 203 (2002) (discussing retroactive application of patent laws); [Graham v. John Deere Co.](#), 383 U.S. 1, 6 (1966) (discussing the authority of Congress to create patent policy); [Golan v. Holder](#), 609 F.3d 1076 (10th Cir. 2010), cert. granted 131 U.S. 1600 (2011) (reviewing constitutionality of legislation restoring copyrights from the public domain).

[FN47]. [Prometheus Labs., Inc. v. Mayo Collaborative Servs.](#), 628 F.3d 1347, 1358 (Fed. Cir. 2010), petition for cert. filed, [79 U.S.L.W. 3554 \(U.S. Mar. 17, 2011\)](#) (No. 10-1150) (distinguishing [In re Grams](#), 888 F.2d 835 (Fed. Cir. 1989)).

[FN48]. Christopher M. Holman, On Remand, Federal Circuit (Once Again) Decides Prometheus v. Mayo in Favor of Patent Eligibility for Methods of Treatment and Diagnostic Tests, Holman's Biotech IP Blog, (Dec. 17, 2010, 3:22 PM), <http://holmansbiotechipblog.blogspot.com/2010/12/on-remand-federal-circuit-once-again.html>. That commentator, on behalf of a group of law professors, had filed a brief arguing that synthetic drug breakdown products and the human-made correlations they generate are not categorically ineligible natural phenomena. See Brief of Amici Curiae Interested Patent Law Professors in Support of Neither Party at 2-13, [Prometheus Labs., Inc. v. Mayo Collaborative Servs.](#), 628 F.3d 1347 (Fed. Cir. 2010), petition for cert. filed, [79 U.S.L.W. 3554 \(U.S. Mar. 17, 2011\)](#) (No. 10-1150) (No. 2008-1403) (arguing that the claims are not categorically ineligible natural phenomenon).

[FN49]. [Prometheus Labs.](#), 628 F.3d at 1350 (quoting [U.S. Patent No. 6,355,623](#) col.20 ll10-25 (filed Apr. 8, 1999)).

[FN50]. See *id.* at 1350-51 (describing [U.S. Patent No. 6,355,623](#) col.23 l.42-col.24 l.18 (filed Apr. 8, 1999) and [U.S. Patent No. 6,680,302](#) col.20 ll.24-43 (filed Dec. 27, 2001)).

[FN51]. *Id.* at 1351.

[FN52]. See Corrected Brief for Amici Curiae American College of [Medical Genetics et al. at 9](#), [Prometheus Labs., Inc. v.](#)

[Mayo Collaborative Servs., 628 F.3d 1347 \(Fed. Cir. 2010\)](#), petition for cert. filed, [79 U.S.L.W. 3554 \(U.S. Mar. 17, 2011\)](#) (No. 10-1150) (No. 2008-1403) (stating that the use of thiopurine derivatives for treatment is known and preferred over anti-inflammatory drugs) [hereinafter ACMG Brief].

[FN53]. See Brief for Appellant at 6-7, [Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347 \(Fed. Cir. 2010\)](#), petition for cert. filed, [79 U.S.L.W. 3554 \(U.S. Mar. 17, 2011\)](#) (No. 10-1150) (No. 2008-1403) (discussing the problem with metabolic drugs and calculating proper dosages) [hereinafter Prometheus Appellant Brief]; ACMG Brief, supra note 52, at 9 (stating that adverse side effects were known for decades).

[FN54]. See Prometheus Appellant Brief, supra note 53, at 6-11 (discussing the Prometheus patents); ACMG Brief, supra note 52, at 8-12 (offering medical background and concerns related to the Prometheus patents).

[FN55]. See [Prometheus Labs., 628 F.3d at 1351-52](#) (discussing the 2008 district court decision in Prometheus Labs.).

[FN56]. Id. at 1352 (discussing the 2009 Federal Circuit's reversal of Prometheus Labs.).

[FN57]. Id.

[FN58]. See id. (quoting [Prometheus Labs., Inc. v. Mayo Collaborative Servs., 581 F.3d 1336, 1349 \(Fed. Cir. 2009\)](#)).

[FN59]. Id. at 1355.

[FN60]. Id.

[FN61]. [Prometheus Labs., 628 F.3d at 1359](#).

[FN62]. [Bilski v. Kappos, 130 S. Ct. 3218, 3230 \(2010\)](#) (quoting [Parker v. Flook, 437 U.S. 584, 594 \(1978\)](#)) (emphasis added).

[FN63]. [Prometheus Labs., 628 F.3d at 1355](#).

[FN64]. Id. (quoting [In re Bilski, 545 F.3d 943, 972 \(Fed. Cir. 2008\)](#) (en banc), aff'd, [130 S. Ct. 3218 \(2010\)](#)).

[FN65]. Id.

[FN66]. Id. at 1354-55.

[FN67]. Id. at 1355.

[FN68]. Kevin E. Collins, [Semiotics 101: Taking the Printed Matter Doctrine Seriously, 85 Ind. L.J. 1379, 1381 \(2010\)](#); Mark A. Lemley, Point of Novelty, 2 (Stan. Pub. Law, Working Paper No. 1735045), available at <http://ssrn.com/abstract=1735045> (quoting [Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 875 \(Fed. Cir. 1985\)](#)).

[FN69]. See, e.g., [KSR Int'l. Co. v. Teleflex, Inc., 550 U.S. 398, 416-17 \(2007\)](#) (discussing [Sakraida v. AgPro, Inc., 425 U.S. 273 \(1976\)](#), and [Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57 \(1969\)](#)).

[FN70]. [Bilski v. Kappos, 130 S. Ct. 3218, 3231 \(2010\)](#).

[FN71]. Cf. Holman, *supra* note 48 (discussing the enablement requirement as a possible solution to address claim scope differences).

[FN72]. See [35 U.S.C. § 271\(a\)](#) (2006) (providing the basic definition of infringement); Alan W. White, Gene and Compound Per Se Claims: An Appropriate Reward?, 6 *Bio-Sci. L. Rev.* 239, 240 (2000-2001) (describing the history of per se claims).

[FN73]. See [Dolbear v. Am. Bell Tel. Co., 126 U.S. 1, 534-35 \(1888\)](#) (“The effect of [the Morse] decision was, therefore, that the use of magnetism as a motive power, without regard to the particular process with which it was connected in the patent, could not be claimed, but that its use in that connection could.”).

[FN74]. Lab. [Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 125 \(2006\)](#) (Breyer, J., dissenting from dismissal of certiorari).

[FN75]. [Id. at 137-38.](#)

[FN76]. [Id. at 135-36](#) (citations omitted).

[FN77]. See [id. at 138](#) (noting that special public interest considerations present demonstrate the need to decide this case even if the Court were to reject Justice Breyer's views on the substantive issues).

[FN78]. *Id.*

[FN79]. See [35 U.S.C. § 287\(c\)](#) (2006) (limiting liability of medical practitioners and related entities for some patented medical procedures).

[FN80]. See, e.g., [Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1365 \(Fed. Cir. 2004\)](#), cert. granted, [546 U.S. 975 \(2005\)](#), cert. dismissed, [548 U.S. 124 \(2006\)](#); Brief Amicus Curiae of AARP in Support of Petitioner at 7-8, Lab. [Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124 \(2006\)](#) (No. 04-607); Dan L. Burk, [Patenting Speech, 79 Tex. L. Rev. 99, 115-17, 136-54 \(2000\)](#).

[FN81]. ACMG Brief, *supra* note 52 at 13.

[FN82]. *Id.*; see also *id.* at 27-32 (arguing that clinical trials and historical evidence show that a lowing non-inventive patents will not stifle medical innovation).

[FN83]. See, e.g., Prometheus Appellant Brief, *supra* note 53 at 46-50 (describing innovation harms that would result from broadly holding that would invalidate medical treatment and diagnostic method patents).

[FN84]. *Id.* at 46-47.

[FN85]. See ACMG Brief, *supra* note 52 at 27 (discussing the detrimental effect on the medical profession and society of physicians' intentional withholding of new medical knowledge).

[FN86]. *Id.* at 26 (quoting Opinion E-9.08 of the American Medical Association's Code of Medical Ethics).

[FN87]. See, e.g., Rebecca S. Eisenberg, [Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research, 82 Va. L. Rev. 1663, 1665-71 \(1996\)](#) (describing changes to government patent policies and empirically assessing the effects of patents on technology transfer in the field of biomedicalresearch); Arti Kaur Rai,

[Regulating Scientific Research: Intellectual Property Rights and the Norms of Science](#), 94 Nw. U. L. Rev. 77, 78-80 (1999) (describing incomplete changes to the norm of “communality” resulting from the increased availability of patents and advocating changes to law to promote more efficient norms to stimulate creating, disclosing, and developing inventive works); but see, e.g., F. Scott Kieff, [Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science--A Response to Rai and Eisenberg](#), 95 Nw. U. L. Rev. 691,692 (2001) (responding to Rai's and Eisenberg's arguments and encouraging the use of patents in basic biological research).

[FN88]. See, e.g., Arti Kaur Rai, [Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff](#), 95 NW. U. L. REV. 707, 710-13 (2001) (discussing the impact of patent rights on transaction costs in biological research); Charles McManis & Sucheol Noh, [The Impact of the Bayh-Dole Act on Genetic Research and Development: Evaluating the Arguments and Empirical Evidence to Date 2](#) (Aug. 13, 2006) (unpublished manuscript), <http://128.252.251.212/CLIEG/documents/mcmaniscommercializinginnovationpaper.pdf> (discussing the effects of the Bayh-Dole Act, which promoted transferring technology by allowing universities, small businesses, and research institutions to retain ownership of patent rights acquired through federally funded research); see generally Arti K. Rai & Rebecca S. Eisenberg, [Bayh-Dole Reform and the Progress of Biomedicine](#), 66 L. & Contemp. Probs. 289, 291 (2003) (arguing for reform of the Bayh-Dole Act to grant the funding agencies more discretion in deciding when discoveries made through publically funded research should remain in the public domain).

[FN89]. See, e.g., EPC, *supra* note 21, art. 53(c) (prohibiting patents for methods of medical treatment).

[FN90]. See generally Shobita Parthasarathy, [Breaking the Expertise Barrier: Understanding Activist Strategies in Science and Technology Policy Domains](#), 37 Sci. & Pub. Pol'y 355, 358-63 (2010) (discussing strategies used by activists to change public discourse regarding and to challenge the patenting of breast cancer genes).

[FN91]. See, e.g., Aaron C. Chatterjee, [Europe Struggles Over Software Patents](#), IEEE Spectrum (Sept. 2004), <http://spectrum.ieee.org/at-work/innovation/europe-struggles-over-software-patents> (discussing controversy surrounding European software patentability).

[FN92]. See, e.g., Gerard N. Magliocca, [Patenting the Curve Ball: Business Methods and Industry Norms](#), 2009 B.Y.U. L. Rev. 875, 876-77 n.9 (2009).

[FN93]. See, e.g., Patent Reform Act of 2011, S. 23, 112th Cong. § 14(a) (2011) (proposed legislation that would prevent tax avoidance strategies, whether known or unknown at the time of invention, from differentiating a claimed invention from the prior art).

[FN94]. See, e.g., Ban on Human Cloning Act, H.R. 1260, 107th Cong (2001) (discussing patents in cloning).

[FN95]. BRCA: Genes and Patents, Am. C.L. Union (May 27, 2009), [http:// www.aclu.org/free-speech/brca-genes-and-patents](http://www.aclu.org/free-speech/brca-genes-and-patents).

[FN96]. *Id.*

[FN97]. See Jordan Paradise, [European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy](#), 59 Food & Drug L.J. 133, 143-44 (2004) (discussing the consortium's original intentions of openly exchanging ideas and data).

[FN98]. *Id.* at 143.

[FN99]. See Bryn Williams-Jones, History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing, 10 Health L.J. 123, 131 (2002) (discussing how Skolnick and other researchers sequenced the BRCA1 gene).

[FN100]. See, e.g., Paradise, *supra* note 97, at 143-44 (detailing Skolnick's efforts to commercially exploit the gene discovery); Williams-Jones, *supra* note 99, at 131 (stating that Skolnick filed for both composition of matter and method of use patents); see generally Brief for the Appellants at 8, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. Oct. 29, 2010); Phyllida Brown & Kurt Kleiner, Patent Row Splits Breast Cancer Researchers, *New Scientist* 1944 (Sept. 24, 1994) (discussing legal battles over Myriad's patents).

[FN101]. See, e.g., Lori B. Andrews & Jordan Paradise, [Gene Patents: The Need for Bioethics Scrutiny and Legal Change](#), 5 *Yale J. Health Pol'y L. & Ethics* 403, 407-09 (2005) (discussing the resulting harms and problems of granting gene patents); Tamar Lewin, Move to Patent Cancer Gene is Called Obstacle to Research, *N.Y. Times*, May 21, 1996, <http://www.nytimes.com/1996/05/21/us/move-to-patent-cancer-gene-is-called-obstacle-to-research.html>.

[FN102]. See Michael Crichton, Patenting Life, *N.Y. Times*, Feb. 13, 2007, at A23, available at <http://www.nytimes.com/2007/02/13/opinion/13crichton.html?ref=michaelcrichton> (calling for support for proposed legislation to halt gene patenting and noting the legislation, Genomic Research and Accessibility Act of 2007, H.R. 977, 110th Cong. (2007)).

[FN103]. See [Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office \(Myriad\)](#), 702 F. Supp. 2d 181, 184-85 (S.D.N.Y. 2010), appeal docketed, No. 2010-1406 (Fed. Cir. June 22, 2010) (challenging the claims as in violation of limits on Article I legislative power and of the First and Fourteenth Amendments because they covered products of nature, natural phenomena, abstract ideas, and thought).

[FN104]. *Id.* at 212-13.

[FN105]. *Id.*

[FN106]. *Id.* at 213.

[FN107]. See *id.* at 213-14 (discussing method claims structured for comparison of gene sequences).

[FN108]. See *id.* at 237-38 (holding the claims invalid under [§ 101](#)).

[FN109]. See *id.* at 222-32 (holding that merely isolating gene sequences does not distinguish them from unpatentable products of nature).

[FN110]. See generally [Diamond v. Chakrabarty](#), 447 U.S. 303, 306, 311, 313 (1980) (citations omitted) (discussing various cases that distinguished products of nature from human-made inventions).

[FN111]. [Hartranft v. Wiegmann](#), 121 U.S. 609, 615 (1887).

[FN112]. See, e.g., [Cochrane v. Badische Anilin & Soda Fabrik](#), 111 U.S. 293, 311 (1884) (“While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time”); [Am. Wood-Paper Co. v. Fibre Disintegrating Co.](#), 90 U.S. (23 Wall.) 566, 593-94 (1874) (holding that a purified extract of a natural substance is not a patentable invention).

[FN113]. [Am. Fruit Growers, Inc. v. Brogdex Co.](#), 283 U.S. 1, 11-13 (1931).

[FN114]. See [id. at 14](#) (holding the boric acid treated fruit claims invalid).

[FN115]. See, e.g., Pasquale J. Federico, *Louis Pasteur's Patents*, 86 *Sci.* 327 (1937) (discussing Pasteur's yeast patent). See also [Parke-Davis & Co. v. H. K. Mulford Co.](#), 189 F. 95 (S.D.N.Y. 1911), *aff'd*, 196 F. 496 (2d Cir. 1912) (holding that patents on purified materials derived from naturally occurring substances were valid).

[FN116]. [Diamond v. Chakrabarty](#), 447 U.S. 303, 310 (1980).

[FN117]. [Funk Bros. Seed Co. v. Kalo Inoculant Co.](#), 333 U.S. 127, 131 (1948).

[FN118]. [Chakrabarty](#), 447 U.S. at 310 (emphasis added).

[FN119]. See [Ansonia Brass & Copper Co. v. Elec. Supply Co.](#), 144 U.S. 11, 18 (1892) (“If an old device or process be put to a new use, which is not analogous to the old one, and ... require[s] the exercise of inventive skill to produce it, such new use will not be denied the merit of patentability.”).

[FN120]. See 35 U.S.C. §§ 100(b), 101 (2006) (providing a definition of “process”).

[FN121]. See, e.g., H.R. Rep. No. 82-1923, at 6 (1954) (explaining the replacement of the term “art” with the term “process”); Pasquale J. Federico, *Commentary on the New Patent Act*, 75 *J. Pat. & Trademark Off. Soc'y* 161, 176-78 (1993) (1954) (discussing statutory definition of the term “process”); Stefan A. Riesenfeld, *The New United States Patent Act in the Light of Comparative Law I*, 102 *U. Penn. L. Rev.* 291, 299-300 (1954) (discussing the scope of the new code's recognition of use patents).

[FN122]. [Utility Examination Guidelines](#), 66 *Fed. Reg.* 1092-02, 1093 (Jan. 5, 2001) (citing [Parke-Davis & Co. v. H. K. Mulford Co.](#), 189 F. 95 (S.D.N.Y. 1911), *aff'd*, 196 F. 496 (2d Cir. 1912)).

[FN123]. *Id.*

[FN124]. [Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office \(Myriad\)](#), 702 F. Supp. 2d 181, 228 (S.D.N.Y. 2010), appeal docketed, No. 2010-1406 (Fed. Cir. June 22, 2010) (citations omitted).

[FN125]. Brief for the United States as Amicus Curiae in Support of Neither Party at 17-18, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. Oct. 29, 2010).

[FN126]. *Id.* at 14-15.

[FN127]. E.g., [Myriad](#), 702 F. Supp. 2d at 198 (“[N]aturally occurring cDNAs, known as ‘pseudogenes,’ exist in the human genome and are structurally, functionally, and chemically identical to cDNAs made in the laboratory.”); International Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, 409 *Nature* 860, 880 (2001) (describing cellular cDNA outside of chromosomes); Nicolas Gilbert et al., *Multiple Fates of L1 Retrotransposition Intermediates in Cultured Human Cells*, 25 *Molecular and Cellular Biology* 7780 (2005) (same).

[FN128]. See Tony Dutra, *Myriad, ACLU Battle Renewed in Fed. Cir. Oral Arguments with DOJ Joining the Fray*, 81 *Pat., Trademark & Copyright J. (BNA)* No. 2010, 2-3 (Apr. 8, 2011), available at <http://ipcenter.bna.com/pic2/ip.nsf/id/BNAP-8FNK9Z?OpenDocument> (discussing the magic microscope analogy).

[FN129]. See, e.g., Turna Ray, *US DoJ Argues Against Patenting Isolated Genes, But USPTO Will Maintain Status Quo*, *Pharmacogenetics Rep.* (Nov. 3, 2010), <http://www.genomeweb.com/print/953728?page=show> (discussing the position taken

by the Department of Justice regarding patentability of genetic discoveries).

[FN130]. See Dutra, *supra* note 128, at 2 (noting the views of Judges Lourie and Bryson).

[FN131]. See Dutra, *supra* note 128, at 2 (discussing the magic microscope analogy of the Acting Solicitor General during oral argument).

[FN132]. See Brief for the Biotechnology Industry Organization and the Association of University Technology Managers as Amici Curiae Supporting Reversal at 5-12, 21-22, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. Oct. 29, 2010) (discussing how isolated DNA molecules are new man-made compositions of matter and how they have new uses and new properties).

[FN133]. See Brief of Amici Curiae Gilead Sciences, Inc., Biogenerator and Elan Pharmaceuticals, Inc. in Support of Defendants-Appellants and Urging Reversal at 3-8, 18, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. Oct. 29, 2010) (discussing the synthesis of genetic sequences).

[FN134]. See Dutra, *supra* note 128, at 2 (discussing the “redressability” argument made by the patent owner and the response from the plaintiffs).

[FN135]. See *id.* at 1-2 (discussing plaintiffs' standing).

[FN136]. Myriad, [702 F. Supp. 2d at 234-37](#).

[FN137]. [Id. at 233-37](#).

[FN138]. [Id. at 234](#) (citing [Prometheus Labs. Inc. v. Mayo Collaborative Servs.](#), 581 F. 3d 1336, 1347 (Fed. Cir. 2009), vacated, [130 S. Ct. 3543 \(2010\)](#)).

[FN139]. [Id.](#) at 235

[FN140]. See Dutra, *supra* note 128, at 3 (noting that the method claims were an afterthought).

[FN141]. See, e.g., [Daiichi Sankyo Co., Ltd. v. Matrix Labs., Ltd.](#), 619 F.3d 1346, 1352 (Fed. Cir. 2010) (discussing lead compound obviousness analysis for patents on chemical compounds); [Altana Pharma AG v. Teva Pharms. USA, Inc.](#), 566 F.3d 999, 1007 (Fed. Cir. 2009) (same).

[FN142]. See, e.g., Sharon Farnley, Pamela Morey-Nase & Diana Sternfeld, *Biotechnology - A Challenge to the Patent System*, 15 *Current Op. in Biotech.* 254, 255 (2004) (discussing the public debate in Europe over the BRCA1 patent); Paradise, *supra* note 97, at 136 (discussing challenges to Myriad's patents).

[FN143]. Jordan K. Paradise, [Lessons from the European Union: The Need for a Post-Grant Mechanism for Third-Party Challenge to U.S. Patents](#), 7 *Minn. J.L. Sci. & Tech.* 315, 320 (2005).

[FN144]. Decision of the Technical Board of Appeal, T1213/05-3.3.04, PP 8-11 (EPO) (Sept. 27, 2007) (identifying sequencing errors and disallowing disclaimers to restore novelty under Article 123(2) EPC) [hereinafter TBoA Decision]; *id.* at PP 34-35 (allowing claim priority only from the fifth priority document and requiring a finding of lack of novelty due to prior art in document D1); see generally Gert Matthijs, *The European Opposition Against the BRCA Gene Patents*, 5 *Familial Cancer* 95, 100 (2006) (discussing the revocation of European patent No. 0699754).

[FN145]. TBoA Decision, *supra* note 144, PP 43-47.

[FN146]. *Id.* (addressing ethical concerns, and interpreting EPC art. 52(2)(a) and EPC Rule 23(e)(2)); *id.* PP 60-64, 70 (addressing industrial applicability and interpreting EPC Rule 23(e)(3)); see generally Margaret Llewelyn, Schrodinger's Cat: An Observation on Modern Patent Law, in *Death of Patents* 39-45 (Peter Drahos ed., 2005) (discussing application of the Rule 53(a) morality exception, including its limited application to health and environmental risks).

[FN147]. Decision of the Enlarged Board of Appeal, Case G 0002/08, P 5.2, 5.5 (citing EPC art. 52(4) (1973)) [hereinafter EBoA Decision].

[FN148]. *Id.* P 5.3.

[FN149]. EPC art. 53(c) (2000); see EBoA Decision, *supra* note 147, P 5.6 (“[A]lthough the general principle holds good that the human body is outside the commercial sphere, that does not necessarily imply that methods for treating the human body by therapy are not as such susceptible of industrial application.”).

[FN150]. Council Directive 98/44/EC, art. 6, 1998 O.J. (L 213) 13-14 (EC).

[FN151]. *Id.* arts. 5(1)-(2); see also *id.* art. 3 (stating general criteria for patentability of biological materials).

[FN152]. See *id.* art. 5(3) (requiring disclosure of industrial applicability of a sequence); *Monsanto Tech. LLC v. Cefetra BV*, No. C-428/08, PP 45-47, 62-63, Eur. Ct. Justice (July 6, 2010); see generally Llewelyn, *supra* note 142, at 28-32 (discussing industrial applicability and use in the context of gene patents); Geertrui Van Overwalle, *Legal and Ethical Aspects of Bio-Patenting: the EU Biotechnology Directive*, in *Death of Patents* 214-25 (Peter Drahos ed. 2005).

[FN153]. [35 U.S.C. § 101 \(2006\)](#); see [In re Fisher](#), 421 F.3d 1365, 1371 (Fed. Cir. 2005) (discussing the utility requirement of [Section 101](#)).

19 Tex. Intell. Prop. L.J. 393

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