Patent Eligible Medical and Biotechnology Inventions After Bilski, Prometheus, and Myriad

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ABSTRACT

In Bilski v. Kappos, the U.S. Supreme Court continued to require that patentable subject matter eligibility determinations under Section 101 be made by reference to three historic, categorical exclusions, for scientific principles, natural phenomena, and abstract ideas. This excluded subject matter must be treated as if already known even when newly discovered by the applicant. Unlike in other jurisdictions, the excluded subject matter thus cannot contribute creativity to the claimed inventions, either for eligibility or for patentability evaluations.

The Federal Circuit has reluctantly applied eligibility doctrine after Bilski, holding in Prometheus v. Mayo that claims to treatment methods applying the new medical discoveries are eligible inventions, even though those claims include a mental step and do not require any action following that step. In Association for Molecular Pathology v. U.S. Patent and Trademark Office (commonly known as the Myriad case, and which was filed by the American Civil Liberties Union and the Public Patent Foundation), which is pending in the Federal Circuit, the District Court found that isolated DNA molecules are not patent eligible inventions. The United States Government has now admitted that for decades it has been issuing such claims without legislative authority to do so.

This article uses the Prometheus and Myriad cases to describe the line-drawing decisions regarding patent eligibility that the courts, patent office officials, and the public now have to make in regard to medical and biotechnological inventions. It explains why the Federal Circuit’s approach will remain unsatisfying unless and until it explicitly confronts the requirement for invention in the application of the categorically excluded discoveries of science, nature, and abstract ideas that underlie the claimed applications and must be treated as if they were already known prior art. The article also describes the important deontological and utilitarian moral concerns that apply to such controversial subject matter as medical and biotechnological inventions. It concludes with a brief discussion of the need for greater clarity regarding the required degree of creativity and greater international understanding (if not harmonization) of differing contribution approaches.

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INTRODUCTION

The United States Supreme Court recently decided that business methods may be eligible subject matter for patents in *Bilski v. Kappos*. The Court reiterated, as a matter of long-standing precedent and *stare decisis*, that the patent system categorically excludes “laws of nature, physical phenomena, and abstract ideas” (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 of matter … may obtain a patent therefor.” The Court invited the U.S. Court of Appeals for the Federal Circuit (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.

A burgeoning set of eligibility decisions is now issuing from the Federal Circuit in regard to a wide range of practical and useful medical and biotechnology applications, such as the *Prometheus Laboratories Inc. v. Mayo Collaborative Services* medical treatment method case and the *Association for Molecular Pathology et al. v. U.S. Patent and Trademark Office, Myriad Genetics, et al.* (Myriad) isolated genetic sequence and diagnostic method case. 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

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4 *See Bilski*, 130 S.Ct. at 3229.
directs primary attention on the patentability criteria of the rest of the Patent Act.”

These patentability criteria are novelty, non-obviousness (inventive step), and adequacy of the disclosure in describing the invention and enabling others to use it. 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” — 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.

This article briefly explains the current (and conflicting) doctrinal standards for eligibility exclusions adopted by the Supreme Court in Bilski that the Federal Circuit (reluctantly) and the U.S. Patent and Trademark Office (PTO, perhaps more enthusiastically) will have to apply to claims for the discovery of medical and biotechnological inventions. It then briefly analyzes the Federal Circuit’s decision in the Prometheus case, and relates it to the earlier Supreme Court Laboratory Corporation of American Holdings v. Metabolite Laboratories, Inc. (LabCorp) case, which addressed a medical diagnostic patent but did not result in an issued decision. The article then describes the Myriad case and the issues that it raises. Throughout, the focus is on how the current doctrine applies to eligible and ineligible applications of categorically excluded science, nature, and ideas, which provides insights into the difficulties in drawing the required lines regarding eligibility of claimed inventions, systemic benefits of employing eligibility exclusions, and the utilitarian and deontological moral concerns (including social and innovation harms) that have been raised in regard to such applications. The article concludes with a brief

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7 Research Corp. Techs., Inc. v. Microsoft Corp., 627 F.3d 859, 868 (Fed. Cir. 2010).
8 See 35 U.S.C. §§ 102 (novelty), 103(a) (non-obviousness), 112, para. 1 (written description and enablement).
10 See Fusco, supra, at 144.
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.

1. **Bilski**

The Supreme Court in *Bilski* not only reaffirmed the existence of the categorical exclusions from eligibility for science, nature, and ideas, but also reiterated the long-standing requirement to treat them as if they were already “a familiar part of the prior art,”¹² even when they are newly discovered by the patent claimant. This legal fiction exists because such discoveries are “the ‘basic tools of scientific and technological work,’”¹³ 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.”¹⁴ The patent system is not supposed to reward such basic scientific or conceptual discoveries,¹⁵ no matter how much money, effort, creativity, and disclosure go into developing and disseminating that knowledge. 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.¹⁶ Rather, patent claimants must invent and disclose some “other inventive concept” than a merely novel, physically limited application of the new discovery.¹⁷

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¹³ *Id.* at 591 (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)).


¹⁷ *Flook*, 437 U.S. at 594.
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”\(^\text{18}\) in their application.\(^\text{19}\) 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.”\(^\text{20}\) 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 its most recent (and claimant-friendly) eligibility case, *Diamond v. Diehr*,\(^\text{21}\) 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.’”\(^\text{22}\)

This approach in the U.S. differs substantially from other approaches, such as in Australia and under the European Patent Convention (“EPC”).\(^\text{23}\) 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 (“as such”) under the


\(^\text{20}\) *Bilski*, 130 S.Ct. at 3230 (quoting *Flook*, 437 U.S. at 594) (emphasis added).


\(^\text{22}\) *Bilski*, 130 S.Ct. at 3230 (quoting *Diehr*, 450 U.S. at 191-92).

EPC, which excludes from being “regarded as inventions” “discoveries, scientific theories and mathematical methods” remain categorically ineligible. 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.

Under the European Patent Convention (“EPC”), in contrast, a “contribution” approach to eligibility similar to that of the United States’ approach was initially adopted, under which the creativity of categorically excluded subject matter could not contribute novelty to claimed applications. Although it later abandoned that 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. The EPC thus currently permits to be considered eligible inventions claims that employ a “technical means” or that are a “technical product,” even if all of the creative novelty lies in the excluded discovery. But it requires that any “technical effect” for inventive step be reflected in a “technical character” found in “all the features together” (and thus in the application of the discovery). Where the only creative and novel feature is non-technical (i.e., in the categorically excluded subject matter), the claim will not be patentable. As the EPC’s own Board recognized, many have criticized as “distasteful” the choice to permit

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24 EPC art. 52(3).
25 Id. art. 52(2)(a).
27 Id. at 252.
28 Opinion of the Enlarged Board of Appeal of 12 May 2010 in relation to a point of law referred by the President of the European Patent Office pursuant to Article 112(1)(b) of the EPC, Case G 003/08, ¶¶ 10.3, 10.4, 10.5, 10.7.1, 10.13.1, 12.2.1, 12.2.2, and 13.5.1.
discoveries to contribute to eligibility given that they do not contribute to patentability.\textsuperscript{29} 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 (particular “abstract ideas”\textsuperscript{30}) 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 ideas various independent claims for a method of hedging risks from unexpected events that create fluctuating volumes for fixed-price-contract purchased commodities. These claims were both practical and somewhat more specific than the underlying fundamental idea that the claims applied (hedging risks), but did not require the use of any specifically identified machines or artifacts.\textsuperscript{31} In reaching its decision, the Court continued to express a concern articulated in a 1972 decision that patents may not issue that “‘would wholly pre-empt the [ineligible discovery] and in practical effect would be a patent on the [discovery] itself.’”\textsuperscript{32} The Court also failed to explain adequately why the more specific dependent claims at issue – which limited the methods to commodities and energy markets and which required 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.”\textsuperscript{33}

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

\textsuperscript{29} See id., ¶ 10.13.


\textsuperscript{31} See id. at 3223-24.

\textsuperscript{32} Id. at 3230 (quoting Gottschalk v. Benson, 409 U.S. 63, 72 (1972)). See id. at 3231.

\textsuperscript{33} Id. at 3231 (citations omitted).
machines or accomplishing specific physical transformations are eligible.\textsuperscript{34} The Supreme Court overruled the Federal Circuits 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),”\textsuperscript{35} 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.\textsuperscript{36}

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”\textsuperscript{37}) \textit{in the application} of categorically excluded science, nature, or ideas to accomplish a practical result.\textsuperscript{38} 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,” \textit{i.e.}, physical phenomena) have “markedly different characteristics,”\textsuperscript{39} or unless the claimed processes (employing ineligible laws of nature or abstract ideas) reflect non-

\textsuperscript{34} See, \textit{e.g.}, \textit{Benson}, 409 U.S. at 70; \textit{Cochrane v. Deener}, 94 U.S. 780, 788 (1887).

\textsuperscript{35} \textit{Bilski}, 130 S.Ct. at 3226. \textit{See id.} at 3227; \textit{In re Bilski}, 545 F.3d 943, 954-55 (Fed. Cir. 2008) (en banc).

\textsuperscript{36} \textit{See id.}, 130 S.Ct. at 3231.


\textsuperscript{38} \textit{See, e.g.}, Evans \textit{v Eaton}, 8 F. Cas. 846, 851 (C.C.D. Pa. 1816) (No. 4,559); \textit{See also} Boulton \textit{v. Bull}, (1795) 2 H. Bl. 463, 495 (Opinion of Lord Eyre, C.J.); \textit{id. at 485} (Opinion of Buller J.); \textit{id.} at 478 (Rooke, J.), \textit{id.} at 482 (Heath, J.).

“analogous” uses.\textsuperscript{40} Merely novel but insufficiently creative applications of ineligible discoveries are not eligible inventions. But once a sufficiently creative application has been invented, \textit{that} invention (not the discovery it employs) may be patented and may thereby preempt \textit{its} full scope of application; such preemption may include all means of accomplishing a particular end, even if the \textit{inventive} application is the only practical means of using the discovery to accomplish the desired result.\textsuperscript{41} 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\textsuperscript{42}). Similar conflicts would attend future legislation to extend eligibility to areas that the courts may hold are excluded, or to levels of creativity the courts may find are insufficient. In the latter case, constitutional concerns may also arise regarding whether any limits exist on the Congress’s

\textsuperscript{40} Ansonia Brass & Copper Co. v. Elec. Supply Co., 144 U.S. 11, 18 (1892).
\textsuperscript{41} Dolbear v. American Bell Telephone Co., 126 U.S. 1, 534-35 (1888).
power to grant patents to such “inventions,” including retrospectively to those that have fallen into the public domain.43

2. Prometheus

On remand from the Supreme Court following Bilski, the Federal Circuit in the Prometheus case 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.44 As one commentator put it immediately after the decision, the panel’s attempt to distinguish Grams was “less than convincing.”45 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.46

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).\textsuperscript{47} (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 also determine another metabolite’s level.\textsuperscript{48}) 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 (even in the mind) to determine the 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 that employed different indicator levels of 6TG for evaluating thiopurine administration.\textsuperscript{49}

The human metabolic pathway of converting synthetic thiopurine drugs into mercaptopurinines and thiopurine nucleotides was well known, as was the use of such drugs to treat auto-immune and inflammatory bowel diseases. These metabolic products also 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.\textsuperscript{50} 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

\textsuperscript{47} Prometheus Labs., 2010 WL 5175124, at *2 (quoting U.S. Pat. No. 6,355,623, Claim 1).
\textsuperscript{48} See id. (describing U.S. Pat. No. 6,355,623, Claim 46, U.S. Pat. No. 6,680,302, Claim 1).
\textsuperscript{49} See id.
association of the blood levels with regard both to effectiveness and to avoidance of toxicity. 51
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, as: (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) that the claims essentially recited correlations that were categorically ineligible natural phenomena (products of nature) that the applicants did not invent, and that the claims wholly preempted all uses of those correlations. 52

The Federal Circuit originally reversed, on the basis both of its en-banc decision in Bilski, 53 which had imposed the machine-or-transformation framework as the conclusive test, and of its different understanding of the claims and the invention from that of the District Court. 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 [which must be considered as a whole, even if they included a separately ineligible mental step, and as they were limited to the particular physical steps involved] did not wholly preempt the use of the recited correlations [the specific indicators] between metabolite levels and drug efficacy or toxicity.” 54

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. The claims were for methods of treatment, “which are always transformative when one of a defined group of drugs is

51 See Prometheus Appellant Brief, supra, at 6-11; ACMG Brief, supra, at 8-12.
53 Id. at *4 (discussing Prometheus Labs., Inc. v. Mayo Collaborative Servs., 581 F.3d 1336, 1345-49 (2009)).
54 See id., 581 F.3d at 1349.
administered to the body to ameliorate the effects of an undesired condition.” In other words, the human body itself is transformed by treatment, even if the transformations result from natural bodily processes. In contrast to District Court, which apparently 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 actual optimize therapeutic efficiency without taking the next, unclaimed step of adjusting the amounts administered, the Federal Circuit apparently focused on the fact that the claim as a whole (based on the prior art administrating step) was still a method of treatment. (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 (as a whole) 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,” even if physical data-gathering steps were employed and the information gathered was useful (and likely triggered subsequent action).

On remand after Bilski, the Federal Circuit also reiterated that the claims were drawn to a particular application of an ineligible natural phenomenon, not to the phenomenon (a “law of nature”) itself, and the transformations achieved by these specific steps were “central to the purpose of the claimed process.” Specifically, the court noted that “the steps involve a particular application of the natural correlations: the treatment of a specific disease by

55 See id., 2010 WL 5175124, at *6.
56 Bilski, 130 S.Ct. at 3230 (quoting Flook, 437 U.S. at 594) (emphasis added).
57 Prometheus Labs., 2010 WL 5175124, at *7.
58 Id. (quoting Bilski, 545 F.3d at 962).
administering specific drugs and measuring specific metabolites. As such, the claims did not preempt all uses of the natural correlations; they utilized them in a series of specific steps.\textsuperscript{59} The court therefore 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.\textsuperscript{60} 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.”\textsuperscript{61}

The Federal Circuit’s remand decision failed adequately to explain why the actual invention – the essence of the treatment claim (or its “‘gist’ or ‘heart’” or “point of novelty”\textsuperscript{62}) – lay in the physically transformative administering step (or the claim as a whole) 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 (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 were treated as prior art; the claimed would necessarily lack any non-obvious invention without performing some non-analogous function when combining the medical fact

\textsuperscript{59} Id.
\textsuperscript{60} Id. at *6. See id. at *8-*10.
\textsuperscript{61} Prometheus Labs., Inc., 2010 WL 5175124, at *7.
that had been discovered with the prior art method of treatment. The Federal Circuit thus improperly allowed the newly discovered but ineligible correlation to contribute to the “invention” assessed for eligibility, for claims that also should be inherently obvious if the correlations are treated as prior art (even under the European approach). And it 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 (but uncreative) claim limits of the otherwise-known method, and on the physical nature of the administration (initial treatment) 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 had 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. Such insignificant steps will also avoid preemption, by preventing the more specific uses of newly discovered natural phenomena from excluding other unclaimed uses, and (for eligible inventions) claim scope concerns can be addressed through enablement doctrine.

The Federal Circuit’s belief that the specific steps of administering the drugs avoided preemption of uses of the correlations also was 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

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64 See Bilski, 130 S.Ct. at 3231.

65 Cf. Holman, supra, note ___.

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claimed. Given so-called and controversial “absolute protection” (excluding all making and uses, including those that are not contemplated by inventors), every patented claim inherently preempts all applications of whatever the claimed inventive principal applies to. This was long-ago recognized to be permissible, even for very broad claims, in the seminal Alexander Graham Bell Telephone Case, so long as some inventive principle exists and is claimed in applying a scientific discovery or natural phenomenon (and not the discovery being applied).

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. This was recognized by Justice Breyer in a non-precedential statement (with two of his colleagues who have now departed the Supreme Court) in the Laboratory Corporation diagnostic method case that preceded Bilski and that was argued to the Court but dismissed without opinion:

“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.”

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) ‘entails a physical transformation of matter,’ namely, the alteration of a blood sample during

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69 Id. at 137-38.
whatever test is used … and because it (2) “produces a ‘useful, concrete, and tangible result,’ ”
namely, detection of a vitamin deficiency….”70 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 approach 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).

The Laboratory Corporation case is also significant for the public policy concerns that it
raised and that 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,
as a clear decision would then allow Congress to weigh in if it felt the need to change the law.71

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 correlations; they may raise the cost of healthcare
while inhibiting its effective delivery.72

Although the U.S. Patent Act contains an exception from remedies for medical practitioners and
their institutions performing patented medical methods,73 the potential indirect liability of the

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70 Id. at 135-36 (citations omitted).
71 See id. at 138.
72 Id.
clinical laboratory in assisting the doctors posed serious First Amendment free speech and medical communication concerns.\(^{74}\)

Many of these concerns were restated by various medical organizations in the *Prometheus* case, who argued 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.”\(^{75}\) And these organizations further argued that precluding such claims will not interfere either with the development of personalized medicine nor with “incentives necessary for medical innovation.”\(^{76}\) Of course, 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.\(^{77}\) Thus, Prometheus argued 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.”\(^{78}\)

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.\(^{79}\) As the medical organizations noted:


\(^{75}\) ACMG Brief, *supra*, at 13.

\(^{76}\) Id. See id. at 27-32.

\(^{77}\) See, e.g., Prometheus Appellant Brief, *supra*, at 46-50.

\(^{78}\) Id. at 46-47.

\(^{79}\) See ACMG Brief, *supra*, at 27.
“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.”

Such moral arguments are gaining increasing importance in political debates over the scope of patent rights, but raise concerns that are incommensurable with the innovation policy concerns and may be even less susceptible to theoretical and empirical resolution. Further, normative beliefs regarding scientific obligations to share knowledge have been changing— in large part as a result of permitting scientists and their institutions to retain patents with government funds. Unlike in the United States, moreover, most countries entirely prohibit patents on medical methods of diagnosis and treatment. 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, just as it is for software, sports moves, tax planning methods, cloned

83 See, e.g., EPC, supra note __, Art. 53(c).
organisms, and the many important products of biotechnological research and development, to which we now turn.

3. **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 identified with breast cancer (BRCA1 and BRCA2) and methods of diagnosing genetic mutations thereof in a person’s gene sequences. 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.

The claims followed on the efforts of an international consortium that was in the process of sequencing the breast cancer genome, had identified the chromosome on which it was located, and had intended to place the sequence in the public domain. 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. Skolnick was the first to specifically locate both the BRCA1 and BRCA2 genes, based on his access to Mormon genealogical records, which he compared with Utah state public health records using computational analysis techniques (and federal funds and the assistance of a federal researcher at the National Institute of Health).

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Skolnick then sequenced the genes using well-known biotechnological techniques, and the University of Utah obtained patents on the isolated sequences and their diagnostic method uses. 90

After the Myriad patents were granted, they were subjected to substantial public criticism in the United States (principally on utilitarian grounds) for interfering with research, for raising the costs of breast-cancer diagnostic treatment, and for preventing the use of a better (more comprehensive) diagnostic test that had been developed by others and was being used in Europe. 91 These concerns led to a widely publicized editorial by the fiction writer Michael Crichton in the New York Times, which criticized gene patents generally and encouraged legislation to ban gene patents in the U.S. 92 The ACLU’s suit followed.

The ACLU challenged as being beyond the PTO’s statutory authority to grant and as being unconstitutional specific claims to genetic sequences and to methods employing them in the various patents. The first set of claims was for “isolated DNA” or “isolated DNA molecules” coding for \textit{BRCA1} or \textit{BRCA2} proteins, or short sequences or mutations thereof. Although this language could in theory encompass pure information, the claims were construed to apply to physical DNA. 93 The second set of claims was for methods of “analyzing a sequence,” “detecting” a mutation, or “comparing” a sequence to the normal (disclosed) sequence. These

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claims did not recite any specific method for acquiring sequence information, and (like the recognition step of the Prometheus claim) arguably could be performed solely in the mind.\(^{94}\)

The District Court avoided reaching the constitutional issues by finding the claims to be unauthorized by the statute.\(^{95}\) The court issued a broad doctrinal holding 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.”\(^{96}\) Long-standing precedents had distinguished ineligible products of nature from creative “human-made inventions”\(^{97}\) based on whether the object created from the natural product was “a new and different article, having a distinctive name, character, or use.”\(^{98}\) These precedents held that 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, was not sufficiently creative to be an eligible invention.\(^{99}\)

As the Supreme Court noted in *American Fruit Growers, Inc. v. Brogdex Co.*, in order to be eligible the new creation had 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].”\(^{100}\) The Court in *American Fruit Growers* addressed a novel, non-natural, human-made combination – borax-treated fruit – having a property (mold resistance) that was not possessed by the natural article alone; the Court held the claimed product to be an ineligible

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\(^{95}\) See Myriad, 702 F. Supp. 2d at 237-38.

\(^{96}\) See id. at 222-32.


\(^{98}\) Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887).


\(^{100}\) 283 U.S. 1, 11-12 (1931). See also id. at 12-13.
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 patents for biological and chemicals that were merely isolated or purified from naturally occurring materials (such as Pasteur’s isolated yeast patent and a purified adrenaline (takemine) patent, which was the subject of a famous opinion by Judge Learned Hand): “it may now be doubted that the subject-matter is capable of being patented.”

Similarly, the Supreme Court in the famous Diamond v. Chakrabarty case had upheld the eligibility of a living, synthetic organism by distinguished its earlier holding in Funk Brothers Seed Co. v. Kalo Inoculant Co., which had found ineligible a synthetic, man-made combination of bacteria that merely “serve[d] the ends nature originally provided.” The former, but not the latter, had “markedly different characteristics from any found in nature and … the potential for significant utility.” Since both claimed products had significant utility, the distinction between eligible and ineligible inventions must have related to those characteristics. Further, the markedly different characteristic standard for products corresponded to the Court’s standard for eligibility of processes, which required new uses of existing things or processes to be non-analogous (i.e., not merely different – and thus novel but similar). Although the U.S. Congress in 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

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101 See id. at 14.
102 See, e.g., Pasquale J. Federico, Louis Pasteur’s Patents, 86 SCIENCE 327 (1937) (citing American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1 (1931), and Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911), aff’d, 196 F. 496 (2d Cir. 1912)).
103 447 U.S. 303, 310 (1980).
104 333 U.S. 127 (1948).
105 See id. at 131.
106 See Chakrabarty, 447 U.S. at 310 (emphasis added).
the legislative history makes clear that Congress intended only to restore the non-analogous use standard in light of a conflicting lower court opinion.\textsuperscript{109}

Returning to \textit{Myriad}, 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. “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.”\textsuperscript{110} Given the Supreme Court precedents discussed above, the court could readily have 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 use as probes and for diagnostic analysis) may have been novel and not performed by the naturally occurring materials (as with \textit{American Fruit Growers}), they would remain insufficiently given their reliance on the natural materials and their inherent properties. The court’s exceptionalist approach is unlikely to survive the currently pending appeal, as the Federal Circuit may not wish to acknowledge that the myriad (pun intended) claims that have issued for isolated and/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 the PTO has, for the last twenty years, lacked authority for and improperly issued thousands

\textsuperscript{108} See 35 U.S.C. §§ 100(b), 101.
\textsuperscript{110} \textit{Association for Molecular Pathology, et al.}, 702 F. Supp. 2d at 228 (citations omitted).
of claims for isolated and purified genetic sequences.\textsuperscript{111} Although the USG recognized that the claims at issue were invalid as they applied to isolated DNA, the USG also argued that if the claims had been limited to cDNA they would be valid, because cDNA is chemically different from isolated DNA.\textsuperscript{112} The USG’s distinction may not make sense, given that cDNA occurs naturally within cells\textsuperscript{113} and thus cDNA is either merely an isolated natural DNA sequence or a synthetic reproduction of such a naturally occurring sequence. Further, the Supreme Court precedents noted above make clear that merely creating synthetic analogues of natural products does not generate eligible inventions. But notwithstanding the official position of the USG that the PTO lacks legislative authority to grant patents for isolated and purified genetic sequences, the PTO also has refused to stop issuing such claims while the case is pending.\textsuperscript{114}

The District Court in \textit{Myriad} also held invalid the patents for the methods, because the claims did not require any physical acts and thus patented only mental steps (which are excluded as abstract ideas, although the plaintiffs had also argued that such claims are patents on thought itself and violate First Amendment freedom of expression). The method claims were held invalid based on the machine-or-transformation approach\textsuperscript{115} applied by the en banc Federal Circuit in \textit{Bilski}, but should theoretically fare no better under the Supreme Court’s \textit{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

\textsuperscript{112} \textit{id.} at 14-17.
\textsuperscript{115} \textit{See Myriad}, 702 F. Supp. 2d at 233-37.
Federal Circuit (before the Bilski remand), distinguishing the Prometheus claims as having been 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.116 (The District Court thus 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.117)

Returning to the theory of eligibility and contributions, the locations of the BRCA genes are clearly natural phenomena (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 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 performing the analysis, detection, or comparison and do not specify any means for doing so) should not have been considered eligible inventions. And 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.118

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117 *See id.* at 235; *Bilski*, 130 S.Ct. at 3231.
118 *See, e.g.*, Daiichi Sankyo Co., Ltd. v. Matrix Labs., Ltd., 619 F.3d 1346, 1352-54 (Fed. Cir. 2010); Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999, 1006-09 (2009); Eisai Co. Ltd. v. Dr. Reddy’s Labs., Ltd., 533 F.3d 1353, 1359 (Fed. Cir. 2008).
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 and various national ministries and genetics societies and centers initiated opposition proceedings in the European Patent Office (EPO) against three of the Myriad patents, leading to the revocation of one and the significant limitation of two others. (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.) Nevertheless, the EPO upheld the patent on partial BRCA1 gene sequences used as probes or vectors, rejecting 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.

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 (as a “legal fiction,” although it “seemed actually to be based on socio-ethical and public health considerations”) methods for diagnosis or treatment.

121 Decision of the Technical Board of Appeal T1213/05 -3.3.04 (art. 52(2), 53(a), 54, 56, 57, 83, 84, 87 to 89, 111(1),112(1)(a), 123(2)(3) EPC) (Eur. Pat. Office Sept. 27, 2007), ¶¶ 43-57 (addressing ethical concerns, and interpreting EPC art. 52(2)(a) and EPC Rule 23(e)(2)); id. at ¶¶ 60-70 (addressing industrial applicability and interpreting EPC Rule 23(e)(3)). See generally Dr. Margaret Llewelyn, Schrodinger’s Cat: An Observation on Modern Patent Law, in DEATH OF PATENTS 39-45 (Peter Drahos ed. Lawtext Pub. Ltd. 2005) (discussing application of the Rule 53(a) morality exception, including its limited application to health and environmental risks).
by therapy or surgery of humans or animals from being considered inventions having industrial application.\(^{122}\) 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.\(^{123}\)

Similarly, the 1998 European Biotechnology Directive prohibits patents that would violate “ordre publique” or morality, and provides a non-exclusive list of things that cannot be patented, which includes processes for cloning humans and commercial uses of human embryos.\(^{124}\) 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.”\(^{125}\) 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 finds that such sequences are industrially applicable once a concrete application for them is identified, although limits protection to the disclosed use.\(^{126}\) 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.\(^{127}\)

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\(^{122}\) Nicotinic acid compositions for treating hyperlipidemia, Case G 0002/08, EPO Enlarged Board of Appeal ¶ 5.3 (2010) (citing EPC Art. 52(4) (1973). See id. ¶ 5.5.

\(^{123}\) See EPC Art. 53(c) (2000).


\(^{125}\) Directive, supra, art. 5(2). See also id. arts. 3(1) & 3(2).


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. Given 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, we can also expect those disputes to remain hot. And given 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, etc.

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 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, and 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.