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**From *Prometheus* to *Myriad* to *Classen*, What a Messy
Subject Matter: A Review on Recent Life Science
Method Patent Cases**

Rui Xu



From *Prometheus* to *Myriad* to *Classen*, What a Messy Subject Matter: A Review on Recent Life Science Method Patent Cases

By Rui Xu*

I. INTRODUCTION

¶1 A recent thread of Federal Circuit cases demonstrates the continuous struggle that courts have had applying § 101 of Title 35 of the United States Code, the subject matter patent-eligibility inquiry regarding life science method patent claims. These cases suggest the inclination of, if not apparent desire by, the Federal Circuit to undercut the subject matter inquiry, rendering this traditionally significant patent law area muddier than ever. While the Supreme Court has repeatedly suggested that broad categorical rules may not be advisable or even feasible for determining subject matter patent-eligibility, it has never suggested that subject matter inquiry lacks merit and should be forgone. These recent cases reflect the confusion among courts about the Supreme Court ruling in *Bilski v. Kappos*,¹ and leave unclear how patent applicants should proceed when drafting relevant claims, and which existing method claims remain viable. The fine line between abstract processes (unpatentable) and specific applications of abstract processes (patentable) still proves to be elusive. More clarification is desperately needed, especially considering the preemptive force such method patents hold over a wide range of uses of an abstract process.

¶2 This Note begins in Part II by providing a historical review of the legal framework on § 101, and examining the machine-or-transformation test generally used by the courts to examine patent-eligibility. Part III then focuses on the three most recent Federal Circuit cases in an attempt to decipher current standards of § 101 for life science method claims: *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*;² *Association for Molecular Pathology v. U.S. Patent & Trademark Office* (the “Myriad” case);³ and, *Classen Immunotherapies, Inc. v. Biogen IDEC*.⁴ By examining the claims in these three cases, both patentable and unpatentable claims, this Note then delves into an analysis of the inconsistencies among the rulings and attempts to provide some unifying interpretations. The Note then asks whether it was correct for the Court in *Prometheus* and the Federal Circuit in *Myriad* to treat changes in a biological body after treatment as equivalent to “transformation,” whether the *Classen* Court was well-advised to hold patentable for claims consisting of just a mental step and an action step, whether the *Classen* Court’s policy concerns are valid, and how significant the preemptive effects of

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¹ 130 S.Ct. 3218 (2010).

² 628 F.3d 1347 (Fed. Cir. 2010).

³ 653 F.3d 1329 (Fed. Cir. 2011), *reh'g denied* (Sept. 13, 2011), *reh'g denied* (Sept. 16, 2011).

⁴ 659 F.3d 1057 (Fed. Cir. 2011).

the broadening § 101 standard are. Finally, this Note provides some practical guidance for drafting method claims in light of these recent rulings.

II. 35 U.S.C. § 101 PATENT-ELIGIBILITY: A HISTORIC REVIEW

¶3 The subject matter patent-eligibility of method claims is often evaluated under the machine-or-transformation test, which essentially renders a method patent-eligible if it is implemented with a particular machine to carry out the process, or transforms an article from one state or thing to another. The Supreme Court has elaborated on the test in a long thread of cases, most recently in *Bilski v. Kappos*.⁵ However, the exact minimum requirements for satisfying the test remain undetermined. In *Bilski* the Supreme Court held that the machine-or-transformation test is not the only test for patent eligibility, which leaves open other possibilities to satisfy the subject matter requirement of § 101.

A. Machine-or-Transformation Test

¶4 Section 101 of Title 35 U.S.C. sets out the subject matter that can be patented: “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”⁶ In discussing § 101, the Supreme Court has stated that its four categories—process, machine, manufacture, and composition of matter—encompass “anything under the sun that is made by man.”⁷

¶5 In the 1980s, the Supreme Court upheld a series of method patent claims (also known as “process claims”),⁸ which led to a significant increase in patent applications related to new software, business methods, and medical diagnostic and therapeutic methods.⁹ Life science method patents have become particularly abundant and controversial in recent years, and their merits have been challenged in the Courts.¹⁰

¶6 The classic test of patent-eligibility of method claims is the machine-or-transformation test, which grants patent-eligibility to a process claim if it (1) is implemented with a particular machine specifically devised and adapted to carry out the process in a way that is not concededly conventional nor trivial; or else (2) transforms an article from one thing or state to another.¹¹ The test has been articulated in a long line of cases, and most recently by the Supreme Court in *Bilski v. Kappos*. In *Bilski*, the Court held the definition of process in § 100(b) to be sufficient,¹² which defines process as a

⁵ 130 S. Ct. at 3220-21.

⁶ 35 U.S.C. § 101 (2006). For an overview of § 101 patent-eligibility, see Efthimios Parasidis, *A Uniform Framework for Patent-eligibility*, 85 TUL. L. REV. 323 (2010).

⁷ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

⁸ “Process” usually refers to a manufacturing process, while a “method” usually refers to a way of using a product to accomplish a given result.

⁹ Margaret Kubick, *An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States*, 9 NW. J. TECH. & INTELL. PROP. 280 (2010).

¹⁰ *Id.*

¹¹ See *Bilski v. Kappos*, 130 S. Ct. 3218, 3224 (2010); Stefania Fusco, “*Is In re Bilski a Deja Vu?*”, STAN. TECH. L. REV. 1 (2009).

¹² 130 S. Ct. at 3231.

"process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."¹³

^{¶7} *Bilski* and its predecessors, such as *Gottschalk v. Benson*,¹⁴ leave unexplained what features of a "particular machine" and what forms and amounts of transformation are sufficient to grant patent-eligibility.¹⁵ The Court in *Bilski* suggested that the machine prong of the machine-or-transformation test remains uncertain. The name "machine" might also be a narrow misnomer, as natural-principle processes can also be physically implemented not only with a machine, but also with an article of manufacture or composition of matter.¹⁶ While a process tied to a "particular machine" might be patent-eligible, *Parker v. Flook* suggests that "inventive application of [natural] principle" may be patented too while "some inventive concept in its application" is essential.¹⁷

^{¶8} On the transformation prong, with regard to the article to be transformed, the *Bilski* Court seemed to agree with the Federal Circuit's opinion in *In re Schrader* that "the article" does not necessarily need to be a physical object, but could be a non-physical entity (e.g. electronic signal as in *In re Schrader*) representative of certain physical actions.¹⁸ However, "legal obligations, organizational relationships, and business risks" are not considered patentable "articles" but just "abstract constructs."¹⁹ As to the necessary degree of transformation, the Supreme Court had held that insignificant extra-solution activity, such as data gathering or outputting, will not transform an unpatentable principle into a patentable process.²⁰ While a "substantial" physical or chemical change of properties material to the objectives of the method might be enough, the clear line to be drawn remains unclear.

B. Machine-or-Transformation Test Not the Sole Test

^{¶9} The Supreme Court, however, has held in *Gottschalk v. Benson* and *Bilski v. Kappos* that the machine-or-transformation test is not the sole test for the patent-eligibility of processes, but rather serves "a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101."²¹ The Court declined to adopt a categorical rule other than the well-established exceptions for

¹³ *Id.* at 3221; 35 U.S.C. § 100(b) (2006).

¹⁴ *Gottschalk v. Benson*, 409 U.S. 63 (1972).

¹⁵ *See Fusco*, *supra* note 11.

¹⁶ *See, e.g., Armour Pharmaceutical Co. v. Richardson Merrell, Inc.*, 396 F.2d 70, 74 (3d Cir. 1968) (natural principle was not implemented with a machine but by coating an enzyme with an enteric coating—either a composition of matter or an article of manufacture, or both).

¹⁷ 437 U.S. 584, 594 (1978).

¹⁸ *See In re Schrader*, 22 F.3d 290 (Fed. Cir. 1994).

¹⁹ *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008) *aff'd* but criticized *sub nom. Bilski v. Kappos*, 130 S. Ct. 3218, 177 L. Ed. 2d 792 (U.S. 2010).

²⁰ *See Diamond v. Diehr*, 450 U.S. 175, 191-192 (1981) ("insignificant postsolution activity will not transform an unpatentable principle into a patentable process."); *see also Parker*, 437 U.S. at 590 ("The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance.").

²¹ *Bilski v. Kappos*, 130 S. Ct. 3218, 3227 (2010); *see also Gottschalk v. Benson*, 409 U.S. 63, 71 (1972) ("It is argued that a process patent must either be tied to a particular machine or apparatus or must operate to change articles or materials to a 'different state or thing.' We do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents.").

laws of nature, physical phenomena, and abstract ideas,²² and also held that “an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”²³ Nonetheless, a scientific principle cannot be made patentable by limiting its use to a particular technological environment or by adding insignificant post-solution activity.²⁴

¶10 The *Bilski* case centers on whether a method patent claims abstract processes (unpatentable) or specific applications (patentable), and expresses particular concerns about method patents that preempt all uses of an abstract process.²⁵ Unfortunately, the Supreme Court failed to provide any further guidance for the proper application of the machine-or-transformation test in a life science context. In light of this decision, the Supreme Court first granted judicial review, vacated the decisions of the Federal Circuit, and remanded to the Federal Circuit for reconsideration both the *Prometheus* case and the *Classen* case.²⁶ After the Federal Circuit’s second ruling, the Supreme Court has granted certiorari for the *Prometheus* case.²⁷ Hopefully the Supreme Court will shed more light on this important issue, as more guidance on life science method claims is desperately needed. Until then, however, the focus remains on understanding the three most recent Federal Circuit cases.

III. RECENT LIFE SCIENCE METHOD CASES

¶11 Since 2010, the Federal Circuit has ruled on three life science cases involving method claims. They serve as the guiding authority of the current state of the courts’ standard for the § 101 subject matter inquiry. We need to first conduct a thorough analysis of the three rulings individually before we can ascertain the current rules.

A. *Prometheus Labs v. Mayo Collaborative Services* (*Fed. Cir. 2010*)

¶12 In *Prometheus*, the method claims held patent-eligible by the Federal Circuit (Claim 1 of the ‘623 patent, Claim 1 of the ‘302 patent) constitute methods for determining the optimal drug dosage to treat specific diseases, by administering specific drugs and measuring the drugs’ specific metabolites. They are applications of naturally occurring correlations between blood metabolite levels and drug efficacy. These two method claims essentially consist of abstract descriptions of: (1) *administering* a drug (to a patient suffering immune-mediated gastrointestinal disorder), (2) *determining* the level of the drug’s metabolites (in a patient’s bloodstream), and (3) such level would indicate (the “warning step”) whether adjustment in dosage may be required (to maximize therapeutic efficacy).²⁸

²² *Bilski*, 130 S. Ct. at 3225.

²³ *Id.* at 3230.

²⁴ *Diamond v. Diehr*, 450 U.S. 175, 191-92 (1981).

²⁵ *Bilski*, 130 S. Ct. at 3253.

²⁶ *See Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012) (granting certiorari, vacating judgment); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011) *vacated*, 3541 (2010) (granting certiorari, vacating judgment).

²⁷ 132 S. Ct. 1289 (granting certiorari).

²⁸ *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1350 (Fed. Cir. 2010).

¶13 The Federal Circuit, in reversing the district court’s opinion, held that the “*administering*” and “*determining*” steps were *both* transformative, “not merely data-gathering steps” nor “insignificant post-solution activity,” but were “part of treatment regimes.”²⁹ The recitation of the transformative steps, as the Court held, was sufficient to satisfy the transformation prong of machine-or-transformation test.³⁰ The Court stated that it is the chemical and physical changes in the human body that affords the process “transformation,” as it is “always transformative when a defined group of drugs is administered to a body to ameliorate the effects of an undesired condition,” since the drugs “necessarily [undergo] a transformation.”³¹ The transformation is the result of the physical administration of a drug to a subject to transform—i.e., treat—the subject, which is itself *not* a natural process.³² It seems that the Court is basing the patent-eligibility of such claims entirely on the fact that this *administering* step is not “natural processes” thus is “transformation.”

¶14 The Court also held that although the final “warning step” is a mere mental step, and thus not patent-eligible *per se*, it does not by itself negate the transformative nature of the prior steps.³³ Also, the claims do not preempt the broad use of a natural correlation, but rather recited specific treatment steps with specific drugs, which is a “particular application of the natural correlations.”³⁴

¶15 As for Claims 46 and 53 of the ‘623 patent which lack the *administering* step but contain only the *determining* step, the Court held that the *determining* step alone is transformative and determining the level of the drug’s metabolites (in the clinical samples taken from patents) is a subject that necessarily involves a transformation.³⁵ Some form of manipulation or some other modification of the substances to be measured is necessary to extract the metabolites from a bodily sample and determine their concentration, which “is clearly a transformation.”³⁶ The Court seems to be saying that as long as one exerts certain controls on or changes certain aspects of the article, one has satisfied the transformation prong.

¶16 The Court distinguished the *Prometheus* claims from the principles enunciated in the Federal Circuit Court’s 1989 case *In re Grams*. The method claim in that case was held patent-ineligible and involved (1) *performing* a clinical test on individuals and (2) based on the data from that test, *determining* if an abnormality existed and determining possible causes of any abnormality by using an algorithm.³⁷ The Court in *Prometheus* noted that the process in *Grams* was unpatentable because “it was merely an algorithm combined with a data-gathering step” (*performing* a clinical test), and thus did not convert a patent-ineligible algorithm claim to a patent-eligible method claim. The essence of the claimed process was the mathematical algorithm, rather than any transformation of the tested individuals.³⁸ “If the steps of gathering and substituting

²⁹ *Id.* at 1358.

³⁰ *Id.* at 1355.

³¹ *Id.* at 1355-1356.

³² *Id.* at 1356.

³³ *Id.* at 1358.

³⁴ *Id.* at 1355.

³⁵ *Id.* at 1357.

³⁶ *Id.*

³⁷ *In re Grams*, 888 F.2d 835, 837 (Fed. Cir. 1989); *see also Prometheus*, 628 F.3d at 1358.

³⁸ *In re Grams*, 888 F.2d at 837.

values were sufficient on their own, every mathematical equation, formula, or algorithm having any practical use would be *per se* subject to patenting as a "process" under § 101."³⁹ On the contrary, the process claims in *Prometheus* are part of treatment regimes for various diseases using certain drugs, thus not mere data gathering steps. However, as the *Prometheus* Court ruled that the *determining* step there is enough to satisfy transformation, the only difference between the two seems to be vague at best. It seems that if one determines by using an algorithm, it is data-gathering; if one determines by using some form of modification or manipulation of the objects to be measured, it is transformation.

B. AMP v. USPTO (*Fed. Cir. 2011*) (the "Myriad" case)

¶17 In the *Myriad* case, the Federal Circuit held patent-eligible Myriad's diagnostic method of screening potential cancer therapeutics by analyzing growth rates of cells with altered BRCA genes (very important breast cancer genes) in the presence or absence of the treatments (Claim 20 of the '282 patent). Nonetheless, the court held another diagnostic method claim patent-ineligible, which consisted of "analyzing" BRCA gene sequences and "comparing" those with cancer-predisposing mutations to normal or wild-type gene sequences (claim 1 of the '001 patent and claim 1 of the '999 patent).⁴⁰

¶18 In upholding the patent, the Court found that step (1) *growing* certain cells in the presence or absence of certain compounds (potential cancer therapeutic), and step (2) *determining* the rate of growth of cells in the presence and absence of the compounds serve as transformative steps, making the claim satisfy the machine-or-transformation test. The other two steps are (3) *comparing* the growth rate of the groups of cells step, and (4) a "warning step" which states that "a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic."⁴¹ The *growing* and *determining* steps largely resemble the two transformative steps in *Prometheus*, and are "inherently transformative step[s]" because they involve "the manipulation of the cells and their growth medium."⁴² Also, these steps are central to the purpose of the claimed process, which is "to assess a compound's potential as a cancer therapeutic, and growing the cells and determining their growth rate is what achieves that goal."⁴³

¶19 Regarding the rejected claims, the '001 patent constitutes a method for detecting a specific gene alteration, comprising a step of *analyzing* a sequence (of the gene or cDNA or RNA).⁴⁴ The '999 patent claim is about a method for screening a tumor sample for a specific gene alteration, comprising a step of *comparing* sequences (DNA or RNA or cDNA) from said tumor sample with a second sequence from non-tumor sample, wherein a difference in the sequence between two samples indicates an alteration in this gene in the tumor sample.⁴⁵

³⁹ *In re Grams*, 888 F.2d at 839 (citing *In re Sarkar*, 588 F.2d 1330, 1335 (C.C.P.A. 1978)).

⁴⁰ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1355-1356 (Fed. Cir. 2011), reh'g denied (Sept. 13, 2011), reh'g denied (Sept. 16, 2011).

⁴¹ *Id.* at 1335.

⁴² *Id.* at 1357.

⁴³ *Id.* at 1358.

⁴⁴ *Id.* at 1334.

⁴⁵ *Id.*

¶20 The Court invalidated both claims because the two patents did not recite affirmative steps for obtaining the sequences, and thus could be infringed “merely” by comparing or analyzing sequences.⁴⁶ The Court held that they “recite[] nothing more than the abstract mental steps necessary to compare two different nucleotide sequences,”⁴⁷ and “do not apply the step of comparing two nucleotide sequences in a process . . . [but] the step of comparing two DNA sequences is the entire process claimed.”⁴⁸ Moreover, those terms' plain meanings do not include Myriad's proposed sample-processing steps; neither comparing nor analyzing means or implies “extracting” or “sequencing” DNA or otherwise “processing” a human sample.⁴⁹

¶21 The Court distinguished these two rejected claims from the patentable claims in the *Prometheus* case, which contained affirmative steps (“*administering*” and “*determining*”) that are transformative. In contrast, Myriad's claims do not include “*determining*” the sequence of genes, by e.g., isolating the genes from a blood sample and sequencing them, or any other necessarily transformative step.⁵⁰ Rather, the comparison between the two sequences can be satisfied or infringed by “mere inspection” alone, therefore it encompasses merely an abstract idea or mental steps.⁵¹

C. Classen Immunotherapies v. Biogen IDEC (*Fed. Cir. 2011*)

¶22 In *Classen*, the challenged patents were based on Dr. Classen's discovery that “the schedule of infant immunization for infectious diseases can affect the later occurrence of chronic immune-mediated disorders . . . and that immunization should be conducted on the schedule that presents the lowest risk with respect to such disorders.”⁵² The three patents at issue generally related to methods of comparing information on immunization schedules with the occurrence of chronic disease and identifying an immunization schedule that might provide a lower risk of such disease.⁵³

¶23 The Court held that the claimed methods of immunizing a person in accordance with a lower-risk schedule (‘739 patent and ‘139 patent) to lower the risk of disease (chronic immune-mediated disorder) was eligible for patent protection.⁵⁴ These method claims consisted of: (1) screening multiple schedules by *identifying* first and second patient population immunized with certain immunogens according to first and second immunization schedules; (2) *comparing* the effectiveness of said first and second

⁴⁶ *Id.* at 1335-1356; See also Kevin E. Noonan, *Association for Molecular Pathology v. United States Patent and Trademark Office* (*Fed. Cir. 2011*), PATENT DOCS (Aug. 01, 2011), <http://www.patentdocs.org/2011/08/association-for-molecular-pathology-v-united-states-patent-and-trademark-office-fed-cir-2011.html>.

⁴⁷ *Ass'n for Molecular Pathology*, 653 F.3d at 1356.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.* at 1357.

⁵¹ *Id.*

⁵² *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011); see also Noonan, *supra* note 46; Jason Rantanen, *Classen Immunotherapies v. Biogen: The Broad, Broad Scope of Statutory Subject Matter*, PATENTLY-O (Aug. 31, 2011, 04:27 PM), <http://www.patentlyo.com/patent/2011/08/classen-immunotherapies-v-biogen-the-broad-broad-scope-of-statutory-subject-matter.html>.

⁵³ *Classen Immunotherapies, Inc.*, 659 F.3d at 1060.

⁵⁴ *Id.* at 1060-61.

schedules; and (3) *immunizing* said patients according to a schedule with lower risk.⁵⁵ While such patents involve mental steps of reviewing the relevant literature to determine the lower-risk immunization schedule, like the *Prometheus* court, the Court here ruled that the presence of a mental step as part of the claimed process was not of itself fatal to patent-eligibility.⁵⁶ The question is where the claimed methods fall on “the continuum from abstractness to specificity.”⁵⁷ Here, it is the presence of the physical step of *immunization* that converted the otherwise unpatented abstract mental step to a “specific, tangible application.”⁵⁸

¶24 In contrast, the rejected method claim (‘283 patent) constituted a method of determining whether an immunization schedule affects a disease (chronic immune-mediated disorder) in the treatment group compared to the control group, which comprises *immunizing* patients in the treatment group with immunogens according to an immunization schedule; and *comparing* the results (incidence, prevalence, frequency or severity of said disorders) in the treatment group and control group.⁵⁹ This patent claim was held an abstract idea claim unfettered to any physical steps, and did not meet the threshold of patent-eligibility because the claimed process did not utilize the information derived from the claimed method for immunization purposes.⁶⁰ The Court stated that the claims “do not include putting this knowledge to practical use, but are directed to the abstract principle that variation in immunization schedules may have consequences for certain diseases.”⁶¹ “In contrast, the claims of the ‘139 and ‘739 patents require the further act of *immunization* in accordance with a lower-risk schedule, thus moving from abstract scientific principle to specific application.”⁶² This comparison between the patents here strengthened the belief that the subsequent step of selecting an *immunization* schedule in the ‘139 claim was the bridge between an unpatentable abstract idea and a patentable process.

¶25 The rejected patent states the idea of collecting and comparing known information, which is similar to *Myriad* which held that methods that “simply collect and compare data, without applying the data in a step of the overall method, may fail to traverse the § 101 filter.”⁶³ The “immunizing” in the rejected patent refers to the gathering of published data, while the immunizing of the ‘139 and ‘739 patent claims is the physical implementation of the mental step claimed in the ‘283 patent.⁶⁴

¶26 Compared to the rejected claims in this case, the claims upheld in *Prometheus* are for a method of controlling individualized dosages of a specific drug by measuring its metabolic products in the blood of individual patients, while the *Classen* patents operate on published information to determine general immunization schedules.⁶⁵ The principles applied in *Prometheus* support the patent-eligibility of the *Classen* claims that include

⁵⁵ *Id.*

⁵⁶ *Id.* at 1065-66.

⁵⁷ *Id.* at 1069.

⁵⁸ *Id.* at 1066, 1081.

⁵⁹ *Id.* at 1061.

⁶⁰ *Id.* at 1083-184.

⁶¹ *Id.* at 1067.

⁶² *Id.* at 1067-68.

⁶³ *Id.* at 1067.

⁶⁴ Noonan, *supra* note 46.

⁶⁵ *Classen Immunotherapies, Inc.*, 659 F.3d at 1068.

such transformative steps, but are not relevant to claims that require no more than referring to known information but do not include immunization in light of that information.⁶⁶

D. Summary of the Three Cases

¶27 The table below summarizes all the patent claims in the three cases. A “full-spectrum” life science method claim could potentially contain languages covering some information gathering steps (administering drugs/performing experiments, reading data/results, and comparing the treatment group and control group), and then some warning/indication languages based on the information thus acquired, and at last some way of putting the information into practical use.

TABLE 1. SUMMARY OF PATENT CLAIMS IN RECENT CASES

Patents	Patent-eligible?	Information Gathering			Warning/ Indication Based on Info	Putting info into practical use
		Experiment-administering	Data-reading	Comparison of Treatment and control		
<i>Prometheus</i> (Claim 1 of '623, Claim 1 of '302)	Yes	Administer (a drug to body)*	Determine (level of drug in body)*		Different level suggest whether adjustment needed	
<i>Prometheus</i> (46 and 53 of the '623)	Yes		Determine (level of drug in body)*		Different level suggest whether adjustment needed	
<i>Myriad's</i> '282 patent	Yes	Grow (= administer) (cells with or without drug)*	Determine (rate of cell growth)*	Compare (rate of cell growth)	Slow rate of growth indicates good drug	
<i>Classen's</i> '739 and '139 claims	Yes	Immunize = Administer (drugs according to 1 st and 2 nd schedules)	Identify(1 st and 2 nd populations)	Compare (effectiveness of two schedules)	Implied: schedule with lower risk is good	Immunize (with schedule with lower risk)*
<i>Myriad's</i> '001 claim	No			Analyze (DNA sequence)		
<i>Myriad's</i> '999 claim	No			Compare (DNA sequences from test and control)		
<i>Classen's</i> '283 claim	No	Immunize (= administer) (in treatment group according to a immunization schedule		Compare (results in the treatment group and control group)		

* denotes steps that the Court held transformative

⁶⁶ *Id.*; Noonan, *supra* note 64.

IV. INTERPRETATIONS OF RECENT RULINGS

¶28 The *Prometheus* case and the *Myriad* case both held that the *administering* and *determining* steps are transformative. The *Classen* court, however, rejected the first two similar steps and held that only the *immunization* step grants the claim transformation, as it serves as a step “putting information gathered to practical use,” a concept lacking in the two “transformative” steps in *Prometheus* and *Myriad*. One plausible way to explain such discrepancy is to broaden the *Classen*’s principle to not only include claims that serve a practical function (*Classen*’s “putting information gathered to practical use”), but also that have the potential to serve a practical function (*Prometheus*’s and *Myriad*’s administering and determining steps). However, such interpretation would loosen the subject matter patent-eligibility standard too much. Also, the Court in *Prometheus* even held that the *determining* step *per se* is transformative, simply because the claim relates to biological changes in the body caused by the method. In the Supreme Court’s dismissal of certiorari in *LabCorp v. Metabolite Labs*, Justice Breyer’s powerful dissent suggested that he believed such biological changes are ancillary at best, and do not separate the method from “natural phenomenon” to justify finding “transformation.”

A. How to Justify the Discrepancy Between *Classen* and the Other Two Cases?

¶29 The holding in *Classen* is very different from the principles elucidated in *Prometheus* and *Myriad*. In *Classen*, the Court held that it is the final *immunization* step that by itself is distinguishing, while the prior information-gathering steps fail to constitute a “transformation.” This means that it takes a step of “putting information gathered to practical use,” such as an active treatment step based on the information acquired, to separate patentable process from mental steps.⁶⁷ If the claimed methods only culminate in information/data acquisition, and nothing more, they are unlikely to fit the requirement.⁶⁸ However, the *Prometheus* case and the *Myriad* case suggest otherwise. None of the patentable claimed methods in these two cases involved any physical application/treatment that constitutes “putting information gathered to practical use.” In the *Prometheus* case, after the *administering* and *determining* steps, the only words left are some warning/conclusion languages, which state that one can use the information thus gathered to adjust dosage accordingly to maximize efficacy. If this final step vaguely conveys some minimum “practical use” application, the ‘282 patent claim in *Myriad* falls further short, as it only indicates that a slower rate (which is the information gathered) “is indicative of a cancer therapeutic.” Moreover, the *Prometheus* and *Myriad* cases explicitly stated that the warning/indication step is not transformative, but it is the drug *administration* and/or drug level *determination* steps that are transformative, and determinative in separating abstract ideas from statutory process.

¶30 However, considering the dispositive role the *Classen* Court gave on “putting information gathered to practical use,” another unifying interpretation for all these claims

⁶⁷ See Courtenay C. Brinkerhoff & Jacqueline Wright Bonilla, *Federal Circuit Reverses Course on Classen, Finds That Many Method Claims Satisfy 35 USC § 101, Safe Harbor of 35 USC § 271(e)(1) Does Not Shelter Many Defendants*, FOLEY & LARDNER LLP (Aug. 31, 2011), <http://www.foley.com/federal-circuit-reverses-course-on-iclasseni-finds-that-many-method-claims-satisfy-35-usc--101-safe-harbor-of-35-usc--271e1-does-not-shelter-many-defendants-08-31-2011/>.

⁶⁸ *Id.*

could be that the process has to serve a practical function (*Classen*) or has the potential to serve a practical function (*Prometheus* and *Myriad*). For example, as for the upheld claims in *Prometheus*, after the drug administration and drug blood metabolite level determination steps, and based on the drug blood metabolite level, the results of different drug metabolite levels provide us with the potential practical use of adjusting the dosage needed for optimal effectiveness. On the other hand, the rejected claims in *Myriad* only serve to detect a gene alteration by analyzing gene sequences, or to screen a tumor sample for a gene alteration by comparing sequences from a tumor sample with those from a non-tumor sample, but nothing more to follow. The rejected claim in *Classen* determines whether an immunization schedule affects a disease by immunizing patients in the treatment group with an immunization schedule and then comparing the results in the treatment group with the control group. For the three rejected claims, the purpose of the claim is not for a practical use, and no reasonable follow-up practical use is possibly needed to attain the purpose of the process.

¶31 Next, it seems that the consistent rule in all three cases is that it is the data reading step following experiment performance that is the deciding factor. The determination steps held transformative in *Prometheus* and *Myriad* are comparable to the identifying steps in *Classen*'s patentable '739 and '139 claims, while missing in *Myriad*'s unpatentable '001 and '999 claims and *Classen*'s unpatentable '283 claims. As a result, however, if that is the case, not only does it partly negate the majority's reasoning in *Classen*, but it also loosens the subject matter eligibility requirement to a degree that it amounts to patenting the principle behind the experiments, as there are always ways to read data in the treatment group and the control group, so that we are essentially patenting the idea of administering such an experiment. The administering and determining steps are necessary steps for any use of the natural phenomenon, which can be the scientific discovery of natural correlations in *Prometheus*, which means that since any use of the natural phenomenon would require the administration of the drug and determination of the concentration of the metabolite, the patent preempted the entire use of the natural phenomenon."⁶⁹

B. Why Treatment and Data Reading are Transformative in *Prometheus* and *Myriad*?

¶32 The logic behind treating experiments and data reading as "transformative" in *Prometheus* and *Myriad* is evasive and puzzling. The only plausible explanation given by the *Prometheus* Court was that it is the chemical and physical changes in the human body accompanied by the experiment/drug administration that affords the process "transformation." However, many life science methods, if stated in proper languages, could involve some changes in the subject's body due to the experiment or treatment, but it does not necessarily make the method "transform" the subject from one state to another. Therefore, by equating performing experiments on subject with "transforming" the subject, the Court is opening the gate for a torrent of potential patenting abuse.

⁶⁹ Dan Hoang, *Prometheus Laboratories v. Mayo Clinic's Gift to the Biotech Industry: A Study of Patent-Eligibility of Medical Treatment and Diagnostic Methods After Bilski*, 9 NW. J. TECH. & INTELL. PROP. 457, 12 (2011).

¶33 In Justice Breyer's vigorous dissent (joined by Justices Stevens and Souter) to the Supreme Court's dismissal of certiorari in *LabCorp v. Metabolite Labs*, a case involving a method claim (used to diagnose vitamin deficiencies) that resembled *Prometheus'* application in many respects,⁷⁰ he undertook the analysis over method claims the Supreme Court had avoided. The patent had two steps: (1) "assaying" a body fluid to determine what level of homocysteine (a type of amino acid) it contained, and (2) *determining* whether the level of homocysteine was above normal.⁷¹ Justice Breyer stated that the "correlation between homocysteine and vitamin deficiency" in the claim is a "natural phenomenon," and the claim is "not a process for transforming blood or other matter," as the "transformation" simply "instructs the user to (1) obtain test results and (2) think about them."⁷² Here, aside from the unpatented test, they embody only the correlation between homocysteine and vitamin deficiency the researchers uncovered.⁷³ In Breyer's view, "to use virtually any natural phenomenon for virtually any useful purpose could well involve the use of empirical information obtained through an unpatented means that might have involved transforming matter."⁷⁴ Also, the dissent concluded that the claim effectively monopolizes the scientific correlation between the levels of homocysteine and vitamin B, and preempts the use of a natural phenomenon.⁷⁵

¶34 The *LabCorp* claim and the upheld claims in *Prometheus* and *Myriad* have striking similarities: all these claims center on *determining* a primary measurable fact/data point (the homocysteine levels in *LabCorp*, the metabolite levels in *Prometheus*, or the presence of a DNA mutation in *Myriad*), and that data point leads to a conclusion or the determination of a secondary non-measurable fact (the patient's metabolic state, the therapeutic potential of a pharmaceutical, or a patient's genetic susceptibility to cancer).⁷⁶ However, under the principle Justice Breyer laid out, the relationships between the primary and secondary facts in all these claims are actually unpatentable scientific correlations that are the results of natural biological phenomena.⁷⁷ None of these claims, in their most general form, specifically require the use of a particular test method, or device, or machine. Such absence further suggests that the claims must be evaluated for impermissibly claiming natural phenomena. Consequently, holding any knowledge of the primary fact, deliberately acquired or not, would potentially infringe the method patent if the fact is then interpreted to arrive at a correlative conclusion or secondary fact.⁷⁸

¶35 However, despite the loose and yet inconsistent standards for transformation, it is certain that a method claim reciting only mental steps, without a transformation step of some sort, is not enough. The cases suggest that for a step in the claim to be adequately

⁷⁰ *Lab. Corp. of Am. Holdings v. Metabolite Labs, Inc.*, 548 U.S. 124 (2006) (per curiam); see Stephen Pessagno, Comment, *Prometheus and Bilski: Pushing the Bounds of Patentable Subject Matter in Medical Diagnostic Techniques With the Machine-or-Transformation Test*, 36 AM. J.L. & MED. 619 (2010).

⁷¹ *Lab. Corp. of Am. Holdings*, 548 U.S. at 125.

⁷² *Id.* at 136.

⁷³ *Id.* at 137-38.

⁷⁴ *Id.* at 136.

⁷⁵ *Id.* at 135.

⁷⁶ See Eileen M. Kane, *Patenting Genes and Genetic Methods: What's at Stake?*, 6 J. BUS. & TECH. L. 1, 5 (2011).

⁷⁷ See Kane, *supra* note 77 at 24, 29.

⁷⁸ See Kane, *supra* note 77 at 29.

transformative, it should not be carried out by mere inspection, and the claim should recite some physical act or manipulation for a transformation to take place.⁷⁹ Also, by tying or directly relating a physical step to the objectives of the process, a claim is less likely to be construed as only “data gathering.”⁸⁰

C. Why Mental Step is Out While in *Classen* Mental Step Plus Act Is?

¶36 The Federal Circuit stated in *Classen* that a mental step element alone should not be dispositive. Then how can merely coupling a mental step with an act make everything patentable?⁸¹ Such an act amounts to mere post-solution activity, as Judge Moore points out in her dissent, which does not transform the unpatentable fundamental scientific principle into a patentable process.⁸² The patentable claim in *Classen* was still essentially protecting all application based on the principle that a correlation exists between vaccination schedule for infectious disease and later occurrence of chronic immune diseases of all sorts and that immunization should be conducted on the schedule that presented the lowest risk with respect to such disorders. While the idea and principle might be novel and useful, the process was a mere intuitive broad application of the idea.

¶37 Judge Moore contends in her dissent that the majority gave “no consideration of the extent of preemption by these staggeringly broad and abstract claims” in this case, which included no specificity limitation for treatment steps, immunization schedules, “drugs,” “control groups,” or specific chronic immune disorders.⁸³ She found that “it is hard to imagine broader claims . . . [or] a more conceptually abstract claim in the immunization area . . . [and] *Classen*’s claims are directed to a thought apart from any concrete realities, specific objects or actual instances. This is very much like patenting $E=mc^2$.”⁸⁴

¶38 It seems that the new rule in *Classen* provides clever drafters a range of weapons to make every method description sound patentable, as every process is simply a link in a longer process and one can just go a step further to couple the mental step with adequate act.⁸⁵ Such interpretations might have lowered the § 101 eligibility bar too low, inviting patent lawyers to bring abstract methods within the realm of patentable subject matter simply by putting more perfunctory technical detail in the claims themselves.⁸⁶

D. *Classen*’s Policy Considerations

¶39 In *Classen*, Judge Rader, joined by Judge Newman, expressed frustration with the rising number of § 101 challenges by accused infringers. He stated it is difficult to

⁷⁹ See Kristel Schorr and Jackie Wright Bonilla, *Top Twelve Practice Tips Following Myriad and Prometheus*, PERSONALIZED MEDICINE BULLETIN (Aug. 09, 2011), <http://www.personalizedmedicinebulletin.com/diagnostic-methods/top-twelve-practice-tips-following-myriad-and-prometheus>.

⁸⁰ *See id.*

⁸¹ *See Rantanen, supra* note 53.

⁸² *Classen Immunotherapies, Inc.*, 659 F.3d at 1076-77.

⁸³ *Id.*

⁸⁴ *Id.* at 1078.

⁸⁵ *See Rantanen, supra* note 53.

⁸⁶ *See* John Conley & Dan Vorhaus, *Pigs Return to Earth: Federal Circuit Reinstates Most—But Not All—of Myriad’s Patents*, GENOMICS LAW REPORT (July 31, 2011), available at <http://www.genomicslawreport.com/index.php/2011/07/31/pigs-return-to-earth-federal-circuit-reinstates-most-but-not-all-of-myriads-patents/#more-6120>.

“invent” any category of subject matter that does not fit within the four classes acknowledged by Title 35: process, machine, article of manufacture, and composition of matter. He stated that “eligibility restrictions usually engender a healthy dose of claim-drafting ingenuity” resulting in evasions of subject matter exclusions, and such evasions “add to the cost and complexity of the patent system and may cause technology research to shift to countries where protection is not so difficult or expensive.”⁸⁷ These policy concerns partly explain the loose eligibility standard the Federal Circuit applied in the recent cases, in that the Court wants to further discount the importance of careful drafting or formatting, thus giving 35 U.S.C. § 102 (novelty), § 103 (non-obviousness) and § 112 (specification) more weight in deciding on patentability issues. However, the Courts’ decisions will create a market satiated with abstractly drafted patents that are merely diagnosis, measurement, correlation, interpretation, or mentality.

¶40 The majority’s policy justifications amount to an undercutting, if not a total neglect, of the traditional importance of subject matter patentability in the patent world. Even as the Supreme Court has suggested that a broad, all-inclusive categorical rule might be unfeasible, it has never discredited the subject matter inquiry. As § 101 serves an important gate-keeping function, its regular challenges in patent disputes are expected, if not by design, and it should not be a policy reason to discredit such a legitimate statutory inquiry. It is also hard to see in what way § 101 differs from § 102, § 103, and especially § 112 to deserve such a special treatment.⁸⁸

¶41 Moreover, the Court’s standard that what separates a mental step from patentable subject matter can be just an additional physical act defeats its own policy considerations. Now clever patent drafters need only look one step forward to be reassured, by linking the idea/principle/theory with some act to make the claim patentable, which, contrarily, incentivizes costly legal design-arounds.

E. Potential Outcomes Due to Preemption

¶42 We need to note the far-reaching repercussions of the over-broadening granting of subject matter patent-eligibility in the medical world, as life science method patents have direct impacts on patient care. As Mayo Clinic contended in *Prometheus*, with biotechnology and pharmaceuticals industries being granted exclusive private ownership of scientific observation, physicians might be held liable for patent infringement simply for receiving information of the metabolite correlations, regardless of what those doctors did with the information after they received it⁸⁹—suggesting that “mere thought” would become actionable, carrying the threat of sanctions including actual and treble damages.⁹⁰ For example, a physician would infringe the *Prometheus* patent anytime the physician, having ordered and administered thiopurine drugs to a patient, measured the levels of metabolites produced in the body and considered adjusting the dosage of thiopurine.⁹¹

⁸⁷ *Classen Immunotherapies, Inc.*, 659 F.3d at 1074-76.

⁸⁸ See Rantanen, *supra* note 53.

⁸⁹ See Brief for Appellees at 22, *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010) (No. 2008-1403).

⁹⁰ Petition for Writ of Certiorari at 28, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 130 S.Ct. 3543 (2010) (mem.) (No. 09-490).

⁹¹ Kubick, *supra* note 9, at 32.

¶43 Also, the significantly broad language in *Classen*'s upheld claim would end up preempting the entire immunization field from considering any two schedules prior to immunizing any patient with any drug for any treatment. This claim expresses nothing but a broad way to apply a fundamental epidemiology principle, not only easy to apply but also intuitive in nature. Most investigations on immunization schedules relevant to chronic immune disorders would essentially infringe such patents: a doctor might compare a patient's outcome to those of other patients' and then immunize according to the least-risky schedule known to him.

¶44 The resulting increase in litigation would not only strain the physicians' financial resources, increase health care costs, but would also take time away from what they were supposed to be doing—practicing medicine,⁹² and decrease treatment effectiveness as it interferes with the doctors' ability “to make informed treatment decisions based on the latest scientific knowledge.”⁹³ Customers may encounter similar problems of access and cost, as the prices of medical care may rise as a result of the expensive licensing, and critical care may be delayed or even abandoned because a single inventor has monopolized the tools for adequate care.⁹⁴

V. STRATEGIES AND PRACTICE TIPS FOLLOWING THE RECENT CASES

¶45 These recent decisions suggest that the courts are leaning toward a more liberal interpretation of the “transformative steps” and more lenient view of patent-eligible subject matter. It is still not clear what specific recited steps are the minimum requirements for patent-eligibility. Therefore, patent applicants would be well-advised to expound on all practical applications and physical steps in the method patent application that might be used to explain that the invention is a practical application but not an abstract idea. Below are several practice tips that might better facilitate patent applicants in securing their life science method patents:

- 1) Transformative Step: Drafters of method claims should explicitly recite at least one active, physical, preferably technology-dependent “transformative” step associated with the process. Such practical use or active procedure could be adjusting the dosage, performing a procedure, administering a drug, isolating and/or purifying a sample, determining a sequence, or detecting certain features.⁹⁵ It is even better to draft claims that clearly show how physical objects are transformed from one state to another.⁹⁶

⁹² See Brief for Appellees, *supra* note 90, at 25.

⁹³ Corrected Amici Curiae Brief for the American College of Medical Genetics et al. in Support of Defendants-Appellees at 9, *Prometheus*, 581 F.3d 1336 (Fed. Cir. 2009) (No. 2008-1403).

⁹⁴ See Pessagno, *supra* note 71.

⁹⁵ See Bonilla, *supra* note 78; Kevin E. Noonan, *Bilski v. Kappos: What Effects on Biotechnology Patents?* PATENT DOCS (July 1, 2010, 11:59PM), <http://www.patentdocs.org/2010/07/bilski-v-kappos-what-effects-on-biotechnology-patents.html>; Irah H. Donner, *Classen Immunotherapies, Inc. v. Biogen IDEC: Federal Circuit Rules Immunization Method is Patent-eligible (But Identifying Lower Risk Immunization Schedule is Not)*, at 5, STROOK & STROOK & LAVAN LLP SPECIAL BULLETIN (Sep. 15, 2011), <http://www.stroock.com/sitecontent.cfm?contentID=58&itemID=1106>.

⁹⁶ David R. Heckadon, *Six Months After Bilski: Practical Claim Drafting Tips for Software and Business Method Patents*, GORDON & REES LLP (Nov. 2010), available at <http://www.gordonrees.com/publications/viewPublication.cfm?contentID=1705>.

- 2) Machines: As appropriate, patent application should couple the steps with specific equipments/machines/devices, for example, by describing in the specification the particular equipments/machines/devices that can perform the operations of the processes, and providing multiple examples and embodiments in the specification.⁹⁷ The essence is to make claims appear not too abstract but practical to minimize the likelihood that the invention will be characterized as merely an “abstract idea.”
- 3) End Result Step: It is also a good idea to “includ[e] at least one end result step that follow an analysis or comparison, e.g., adjusting a dosage or treatment protocol.”⁹⁸
- 4) Warning Language: When no practical use or procedure is reasonable or possible given the purpose of the claim, try to have at least some indication/warning language suggesting the conclusion of the process, from which some potential use is reasonably foreseeable.
- 5) Purpose Language: The *Prometheus* Court seemed to suggest that the purpose languages in the specification and preambles of the asserted patent claims, which indicated the invention’s purpose to treat the human body,⁹⁹ helped reinforce the “transformative” nature of the process. Therefore, when the process serves or has the potential to serve a practical purpose, state such a purpose in the specification and preambles.
- 6) Single Infringer: In drafting process claims, it is better to avoid a joint infringement situation wherever possible. Therefore, it is advisable to try to provide claims that are likely to be infringed by a single infringer, or recite steps that will be directed by a single entity.
- 7) Reissue Application: Existing patent holders might consider filing a reissue application if concerned about the continued validity of their patents. They can add or amend claims to recite additional features (such as what step 1-5 suggest) to support patent-eligibility.¹⁰⁰ Federal Circuit decision in *In Re Tanaka* held that a reissue application could be filed for the sole purpose of adding a dependent claim.¹⁰¹

VI. CONCLUSION

¶46

The three recent Federal Circuit life science method patent cases on § 101 subject matter eligibility largely demonstrate that courts have been grappling with this fundamental concept and illustrate the inconsistencies or even contradictions in the rulings. The necessary condition for steps in a claim to satisfy “transformation” is evasive. There is a strong need for the courts to strike a balance between encouraging

⁹⁷ See Bonilla, *supra* note 80; Mainak H. Mehta & Diallo T. Crenshaw, *Patent Prosecution and Enforcement Tips in view of In re Bilski*, SUGHRUE MION PLLC, <http://www.sughrue.com/files/Publication/eb20b3d3-3f13-44f2-bba9-014b543fd63f/Presentation/PublicationAttachment/dc91ea35-bd19-42b2-a2d2-12805e75d109/Miku%20Mehta%20-%20In%20Re%20Bilski%20Article.pdf> (last visited Nov. 6, 2011).

⁹⁸ See Bonilla, *supra* note 80.

⁹⁹ *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1356 (Fed. Cir. 2010).

¹⁰⁰ See Brinckerhoff & Bonilla, *supra* note 68.

¹⁰¹ See *In re Tanaka*, 640 F.3d 1246 (Fed. Cir. 2011).

innovations by granting patents, and being cautious to not overly broaden the standards for patent-eligibility. § 101 inquiry serves as the first gate-keeping function, and thus a unifying set of standards is in dire need.

¶47 With the new development in fields such as whole-genome sequencing and personalized medicine, life science diagnostic and therapeutic method patents that cover some fundamental scientific relationships, principles, or correlations have the potential of impermissibly preempting the utilization and application of most basic principles and knowledge. Considering the sharp contrast between the formal silence of the Supreme Court on the § 101 issue in *LabCorp v. Metabolite* and the forcible dissent from Justice Breyer which would cast serious doubt on the validity of the upheld patents in *Prometheus*, *Myriad*, and *Classen*, hopefully the Supreme Court's upcoming hearing of the *Prometheus* case will shed more light on this messy patent arena.

