

Mayo v Prometheus: The Eternal Conundrum of Patentability vs Patent-Eligibility

Aman Kacheria†

156, Ashirwad, Sindhi Society, Chembur, Mumbai 400 071, India

Received 4 September 2014

In 2012, the US Supreme Court adjudicated a profound medical claim in *Mayo Collaborative Services v Prometheus Laboratories Inc*, which has the potential of radically altering patent law and US § 101 jurisprudence. The judgment came as a shock to the patent community; however, judgments of the lower courts therewith have echoed similar decisions to show the judgment in *Prometheus* simply cited Supreme Court jurisprudence. This paper talks about the judgment and its effects on the rulings of the Federal Circuit as well as District Courts, and its effect on medical claims. It gives an insight into patent law in the United States and where it is headed. While the Federal Circuit remains split as to how narrowly it should construe *Prometheus* so as to apply it to other cases, its forthcoming opinion *en banc* on *CLS Bank Int'l v Alice Corp Pvt Ltd* is likely to unify its interpretation. What is yet to be seen is how broadly the District Courts will interpret the judgment so as to judge similar medical claims. The process has already started, as is explained in this paper; the effects of which however are too early to be discussed.

Keywords: Patentability, intellectual property, biomedical claims, patent-eligibility

Section 101 of the US Patent Act (35 US Code) broadly defines patentable subject matter as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”. The United States patent system incentivizes investment in discoveries that will benefit society by ensuring that rightful inventors possess “the exclusive right to their respective ... discoveries” for a certain period of time.¹ Although the legislative history of the Patent Act suggests that “anything under the sun that is made by man” is patent-eligible, the courts of course have created various exceptions that will be more closely looked at in the following sections of the paper.²

However, patent laws are also crafted to prevent patents from being granted when such patents would stifle scientific and technological progress.³ Laws of nature, physical phenomena, and abstract ideas are not eligible for a patent.⁴ But an innovation is not rendered unpatentable simply because it contains one of these unpatentable concepts.⁵ “An application of law of nature or mathematical formula to a known structure or process may well be deserving of patent protection”.⁶

It is due to this hindrance that the courts have repeatedly found it difficult to interpret a general framework that needs to be followed in determining

patent-eligible matter, and are forced to consider each case on its merits. This hindrance is only aggravated as the US Supreme Court has never provided a framework for determining when additional limitations change an unpatentable idea into a patentable application.⁶

For that reason, a claimed invention must contain patentable subject matter⁷ and be novel⁸, non-obvious⁹, and fully and particularly described.¹⁰

Historically, “laws of nature, natural phenomena and abstract ideas”,¹¹ have been the sole basis for courts to reject the claims for patents under § 101. Granting of a patent by any court of law under one of these categories would have a transgressing effect on patent law as believed by them and would “impede innovation more than it would promote it” by preventing the free use of basic scientific and technological tools.¹²

This equation, however, radically changed pursuant to the judgment of the Supreme Court in *Mayo Collaborative Services v Prometheus Laboratories Inc*, which has attracted the attention of practitioners and members of the business community across multi disciplines because of its ostensible breadth, its apparent break with Supreme Court precedent, and its potential to create a widespread uncertainty as to patent validity.¹³

In March 2012, the Supreme Court held in *Mayo Collaborative Services v Prometheus Laboratories*

†Email: amankacheria94@gmail.com

Inc., that a § 101 patentability analysis is the threshold inquiry in any determination whatsoever of whether a patent is valid or not, and that a claim must contain a patenteligible concept to pass this threshold inquiry.³

The court had only recently addressed the question of patent-eligibility in *Bilski v Kappos*¹⁴, in which it reiterated the patent-ineligibility of abstract ideas. The Supreme Court judgment in *Prometheus* in turn analysed the question of patent-eligibility of inventions that invoked a natural law, and in doing so the Supreme Court appeared to import the patentability questions of novelty and obviousness into the patent eligibility inquiry, despite having held in 1981 in *Diamond v Diehr*¹⁵ that those analyses should be held separately.¹³

In this regard, *Prometheus* could be relevant to evaluating the validity of claims that implicate exceptions to eligibility other than laws of nature,¹⁶ including claims unrelated to medical treatment methods.¹³ It has been opined by the lower courts that the judgment is not being seen in the light of recent developments but simply echoes prior Supreme Court jurisprudence. The question remains open as to whether the United States Court of Appeals for the Federal Circuit will embrace or deviate from the *Prometheus* holding.³

Mayo Collaborative Services v Prometheus Laboratories Inc

The patent eligibility issue was again challenged by the Supreme Court in *Prometheus*. The patents in question were related to medical diagnostic methods. The Supreme Court considered whether a method for optimizing the dosage of a drug, constituted patentable subject matter and found that in view of the current case, it did not.¹⁷ In reversing the judgment of the Federal Circuit, not only did the Supreme Court reduce the ‘machine and transformation test’ to a mere formality but also expressed its views on the test for judging medical claims relating to patents and found that it could not be the sole basis on which a medical claim would rest.¹⁷

History of the Case

Given up for adjudication, the issues in the case were Prometheus’s patent claims directed to a method of optimizing the dosage of thiopurine drugs used to cure Crohn’s disease.¹⁷ As every person metabolizes thiopurines differently, it became increasingly difficult to find an optimum dose that would be uniform in its delivery. The claims therefore

suggested a three-step process.¹⁸ They first directed a medical practitioner to administer the thiopurine drugs to the patient.¹⁹ They then suggested that the practitioner measure the level of thioguanine metabolites in the patients’ blood. And finally, that the dosage in light of the optimum dosage as directed by Prometheus be increased or decreased¹⁹ thus: a level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicated a need to increase the amount of the dosage while a level greater than about 400 pmol per 8×10^8 red blood cells indicated a need to reduce the same.²⁰ At first the claims seemed to be unusual and unique and to show that a correlation between the level of thioguanine metabolite in the blood and the drug dosage had been discovered, but the step of adjusting the dosage was however missed.

Mayo Clinics used the Prometheus patent till 2004, pursuant to that however, announced their intention to sell a slightly different version of the test.²¹ Prometheus subsequently sued Mayo for patent infringement.¹⁹

The District Court seemed to agree with Mayo, holding Prometheus’s patent ineffective as they sought to patent the ‘laws of nature’, specially the correlation sought between metabolite levels and the efficacy and dangers of thiopurine dosages.²¹

The Federal Circuit reversed this judgment on the narrow ideology of the ‘machine and transformation test’, and upheld the patent taking into consideration only that.²² The test is satisfied for a claimed process if it is (i) attached to a machine; and (ii) it transforms a particular article to a different state.¹⁴ In this case, Prometheus involved the “transformation of the human body or blood taken from the human body”.²³

The case was then transferred to the Supreme Court, which upheld the decision of the District Court and granted *certiorari*. It then remanded the Federal Circuit in light of its judgment in *Bilski v Kappos*, indicating that the ‘machine and transformation test’ was a mere formality under § 101 and that patent claims must be seen in light of prior precedent.¹⁴ Even in the light of *Bilski* the Federal Circuit upheld the patent because it did “not encompass the laws of nature or pre-empt natural correlations”.²⁴ The Supreme Court then granted *certiorari* once again in this constant volley.²⁵

The Supreme Court’s Reasoning

The Supreme Court began its systematic disapproval of the patent under two premises that encompass patent law.²⁵ It began with its

jurisprudence on the laws of nature and natural phenomena, and implicitly abstract ideas.⁷ The argument then went on to a broad analysis of patents, which interpretation was such that it would prevent any patent from being issued at all.²⁵

It was understood that medical patents at some point would fall under laws of nature and natural phenomena, and applying the rule strictly would impede any innovation from coming forth.²⁵ These principles underlie every patent claim and the patent law system as a whole.³

To be patent-eligible under § 101, a claim based on natural laws must contain additional steps that either individually or collectively contain a patent-eligible concept.²⁶ The Court went on to investigate each step individually and assess its patent-eligibility. The correlation between the proper dosage of thiopurine and the level of thioguanine metabolites in a patients' blood stream was held to be a natural law.²⁵ The steps as scrutinized by the Court showed that the steps as described by Prometheus in their claims¹⁹ were merely directed to the physician and contained nothing innovative thereof to make them patent-eligible. Finally, looking at all the three steps together, there was nothing new added to the law of nature and the patent was found ineligible,¹² as it merely pronounced a routine to be followed.

Patentability vs Patent-Eligibility

Hotchkiss v Greenwood,²⁷ laid down the precedent almost a 100 years ago regarding the two meanings of the word 'invention' in the patent system.

Patent-eligibility being the first meaning finds its roots in the late eighteenth century American law where the term invention referred to patent-eligible subject matter.²⁸ This usage of the word 'invention' found its application in the 1952 Patents Act which remains unchanged in the 2011 amendment to the patent law.²⁹

On the other hand, patentability is the requirement that an invention be both novel and non-obvious.²⁸ While novelty has been a part of patent law from its very inception, the element of invention dates back to *Hotchkiss v Greenwood*.²⁷ Conflation ended through the Patents Act of 1952, but was however resurrected post *Mayo v Prometheus*.¹²

Conflation between Patent-Eligibility and Patentability post *Prometheus*

Mayo v Prometheus challenged patentability with patent-eligibility in violation of the 1952 Patent Act,

in the civil war between patent-eligibility under § 101 and patentability under § 101, 102. The judgment by the Supreme Court in *Prometheus* suggests that patent-eligibility should precede patentability, but the examples the Court relied on in adjudicating the case were patentability issues that fell under the purview of novelty under § 102 and that of non-obviousness under § 103.

The Court's decision hence created an indefinite loop of arguments of redundant efforts, thus propagating a completely unworkable model. In evaluating patent-eligibility under § 101, the court speaks consistently in terms of patentability determinations under § 102, 103; using the words "conventional", "obvious", "insignificant", having "unconventional steps".¹²

The Court in reviewing an English case found that it was patentable, and noted in *Mayo* that "the claimed process included not only a law of nature but also several unconventional steps".³⁰ Non patentability of the *Bilski* invention was linked to a citation in *Flook* that "established that limiting an abstract idea to one field did not make the concept patentable."²⁸

The Infinite Loop

The Court investigated the overlap between patent-eligibility and patentability in 'evaluating the significance of additional steps' for determining whether the patent in question was in fact patentable, and by extension patent-eligible.²⁹

In its justification, the Court said: "to shift the patent eligibility inquiry entirely to these later [patentability] sections risks creating significantly greater legal uncertainty". To then find an evaluation of the same outside the statute, when the Court gave no guidelines for the same created even greater legal uncertainty. Indeed, the test for *Mayo v Prometheus* if anything is the antithesis of a standard that would "create significantly greater legal uncertainty."²⁸

This therefore creates an infinite loop of arguments that would never be accepted in the evaluation of the question. How could it, when the Supreme Court answered questions regarding § 101 after a thorough evaluation of § 102, 103.

Redefining Patent Law or Echoing Common Jurisprudence?

Mayo v Prometheus shocked the patent community at large as the judgment was very close to redefining patent law altogether, and pursuant to this numerous articles have discussed the decision in less than a

year.³¹ Whether or not the judgment radically changed patent law was really the question.³² The contrary was expressed in the judgments of lower courts however.³

Assessment of Patent-Eligibility under § 101: The Effect of *Prometheus* on Case Law

The assessments of judgments of the lower courts show a shift in attitude in judging patent claims post *Mayo*. Lower Federal Courts have interpreted *Prometheus* in three ways that reaffirm prior patent-eligibility precedent that lower courts were not always following.³

Firstly, the lower courts, post *Prometheus* used the judgment as a precedent to assess patent-eligibility.³³ The courts post *Diehr*⁵ first looked at any additional steps individually and then collectively to see if they were patent-eligible. The Supreme Court in the case of *Prometheus*¹² carried out the same exercise but disregarded the existence of patent-eligible subject matter before hand. The lower courts seemed to have used this study in their judgments as *Prometheus* expressed this sentiment explicitly.³⁴

Secondly, the district courts of Columbia and North Carolina cited *Prometheus* for assessing medical claims after carefully analysing them in the light of the judgment.³⁵ All later judgments have used *Prometheus* as a benchmark.³

And lastly, barely a week after the *Prometheus* decision was announced the District Court of Columbia held that *Prometheus* reconfirmed that § 101 is the threshold inquiry for any patent case.³⁶ The Court noted the Federal Circuits resistance of the Supreme Courts previous determination of § 101 as at least a threshold inquiry.¹² The Federal Circuit in more than one instance directed litigants to express patent invalidity with respect to the patent defences in § 102, 103 and 112.³⁷ The Supreme Court previously in *Bilski* indicated that § 101 was to be held as a threshold inquiry and the act of the District Court reaffirmed this implicitly by rejecting the findings of the Federal Circuit.³

The lower courts having accepted this approach, the Federal Circuit too effectively deviated from the use of § 101 analysis as a threshold inquiry in *CLS Bank*.³⁸ Circuit Judge Linn noted that *Prometheus* established that § 101, 102, 103, and 112 were to be viewed differently in their individual capacities, as they “serve a different purpose and play different roles”.³⁹ The Federal Circuit therefore did not treat § 101 as a threshold inquiry that must be addressed first. Perhaps it was considered to be mere *dictum*.³

The opinion and attitude of the Federal Circuit regarding this is still somewhat unclear. They are currently rehearing this case *en banc* and may address the issue.⁴⁰

The Federal Circuits Smoking Weapon

As already discussed above, the Federal Circuit did not accept the arguments proposed in *Prometheus* and held an opinion different from that of the District Court as well as the Supreme Court.

The Federal Circuit, found that the *Prometheus*'s claim was patent-eligible after applying the ‘machine and transformation test’, even though under *Bilski* this was no longer a dispositive test.³ The Supreme Court however, remanded them again and found that *Prometheus* failed both prongs of the test, reducing the ‘machine and transformation test’ to a mere formality to be conducted.¹²

After this, the Federal Courts systematically first applied the ‘machine and transformation test’ and then moved onto guidelines expressed through the Supreme Court in *Prometheus*.⁴¹

In almost all cases, both the analyses came to the same conclusion regarding whether a claim is patent-eligible. Thus, the ‘machine or transformation test’ remains an independent and important, but not solely dispositive means for courts to assess patent-eligibility.³ The Federal Circuit refused to budge from its application of the ‘machine and transformation test’ subsequent to *Prometheus* and thus remains its smoking weapon in patent analysis.

The Dominoes of Case Law Muddles

The law of patent-eligibility is profound and deep. Every additional case law in the field seems to direct the wind in a different direction. It is not of consequence what the pattern is (that in turn is directing the law), but that the pattern is a change in perception with every additional claim.

What started off in the software area in *Bilski* soon spread to the pharmaceutical region post *Prometheus*.¹² It was, of course the negative effect in *Benson*⁴² and *Flook*⁴³ that created the need for the Supreme Court to keep *Chakrabarty*² open for broad interpretation of § 101 for composition in matter.²⁸

Thus, the *Prometheus* judgment had an effect on judgments of various District Courts and the Federal Circuit that had now shifted from their original approach in patent law.⁴⁴ This muddling in technology related patents might very well continue should the court grant review in the coming weeks to *WildTangent*.⁴⁵

The Supreme Court might send *WildTangent* snowballing back to the Federal Circuit for review in light of the recent developments in *Prometheus*.¹² This once again could change the court's attitude in perceiving patent law, and if the event of disagreement could be reviewed yet again. The pattern found in *Bilski*, *Flook*, *Diehr*, *Benson* and now reaffirmed in *Prometheus* echoes an old school of thought for patent law.

The judgments reiterate the trends in previous decisions used again and again to form an understanding of patent law in general. The misdirection and lack of information in patent law is often its guiding light as seen in the abovementioned cases. An all-encompassing rule of law is hard to establish while dealing with something as abstract as the laws of nature. While authors have tried to define it and create some amount of clarity on the idea,⁴⁶ it has been extremely difficult to interpret the same so as to establish a common set of guidelines to be followed. That is probably the reason why many authors expressed their dissatisfaction for the Supreme Court judgment given in *Prometheus*⁴⁷, as to how something as definitive as science can be plunged into a fog by its conception and understanding thereof in law.

Coming back to *WildTangent*, the petitioner challenged the § 101 applicability with regard to an Internet method patent.⁴⁵ The question presented is "whether, or in what circumstances, a patent's general and indeterminate references to 'over the Internet' or at 'an Internet website' are sufficient to transform an unpatentable abstract idea into a patentable process for purposes of 35 U.S.C. § 101."²⁸

Redefining Medical Method Claims

Post *Prometheus*, it is clear that the laws of nature are excluded from patent applicability. However, what is not explained is to what extent an application of a patent-eligible law of nature needs to be 'transformed' in order for it to be patentable.⁴⁸

If the *Prometheus* judgment is broadly applied in the future, it would require diagnostic method claims to include additional and more limiting steps to show a transformation has happened. The addition of these steps may make it difficult for patentees to prove infringement cases.⁴⁸ The Supreme Court has now created a void in patent law that is to be filled by the lower courts, and as mentioned earlier, the District Courts have already started this process.

Two cases in which *Prometheus* was fully analysed were *Smartgene Inc v Advanced Biological Laboratories*⁴⁹ and *Association for Molecular Pathology v Myriad Genetics Inc*.⁵⁰ The District Court in *Smartgene*⁴⁹ concluded that patents regarding "the system, method, and computer program for guiding the selection of therapeutic treatment regimes for complex disorders" were not patent-eligible.³ The Court summarized the claims in *Benson*, *Flook*, *Diehr*, *Bilski* and *Prometheus* before framing issues identical to those of *Prometheus*.⁴⁹ That is, Smartgene's claims were not patent-eligible because they merely restated abstract ideas regarding the method of diagnosis by physicians.

In the *Myriad*⁵⁰ case, the court investigated the patentability of various claims, the most relevant being diagnostic "method claims for comparing or analyzing isolated DNA sequences associated with predisposition of breast and ovarian cancers." The Federal Circuit closely compared the situation to that in *Prometheus*, and found that that the claimed steps comparing breast cancer DNA sequences from patients with control DNA sequences was similar to the administering and determining steps in *Prometheus*. Therefore this part of the claim was found to be patent-ineligible.

The two cases as discussed above clearly show that personalized medical treatment through comparison of a patient's symptoms or naturally occurring DNA sequences to a standard treatment mechanism or standard DNA sequence will not be patent-eligible.³ This clearly shows a shift in the treatment of medical claims and that the patentability of the same would be viewed favourably only if they have a physically transformed product derived from the patient to guide treatment.

Whether or not *Prometheus* has radically changed patent law is still under consideration, the trend however has been set. The judgment however, is not totally disparate as compared to similar judgments in the same category; rather it reiterates Supreme Court jurisprudence. The question now is how broadly the lower courts interpret *Prometheus* to give it an all-encompassing meaning in patent law, even as the Supreme Court has shown that § 101 is the threshold analysis in any case. Nonetheless, critics do appear to be correct in that *Prometheus* has had a strong impact on courts' view of method claims regarding personalized medical techniques and will likely continue to pose a great challenge to patentability of these types of claims.³

Conclusion

Patent law, in all essentials, is vital to maintain and sustain a progressive market, safeguarding both, the inventor as well as the exploiter. An interpretation detrimental to even one could change the scenario radically and may also harm the general interests of genuine development.

The *Prometheus* judgment has stunned the patent community and the ripples created continue to distort the interpretation of genuine patent claims and force them to take a direction less logical and less commercially viable. An interpretative law often calls for an interpretation suggested and supported by logical conclusion and popular opinion. As apparent as the above observation sounds, it is an observation less practised, seen and often lost. It is essential to realise the prospects of the same in a clearer manner and re-characterize patent law so as to suit a more viable and logical solution.

References

- 1 Article I, Section 8, clause 8, US Constitution.
- 2 *Diamond v Chakraborty*, 447 U.S. 303,309 (1980).
- 3 Belle J, *Prometheus v Mayo: Limited implications for § 101 jurisprudence*, *Washington Journal of Law, Technology & Arts*, 8 (5) (2013) 555.
- 4 *Gottschalk v Benson*, 409 U.S. 63, 67 (1972); *Mackay Radio & Tel Co v Radio Corp*, 306 U.S. 86, 94 (1939).
- 5 *Diamond v Diehr*, 450 U.S. 175, 187 (1981).
- 6 Chao B, *Moderating Mayo*, *Northwestern University Law Review*, 107 (1) (2012) 423.
- 7 35 U.S.C. § 101.
- 8 35 U.S.C. § 102.
- 9 35 U.S.C § 103.
- 10 35 U.S.C. § 112.
- 11 *Diamond v Diehr*, 450 U.S. 175, 179 (1981).
- 12 *Mayo v Prometheus*, 566 U.S. ___, 132 S. Ct. 1293 (2012).
- 13 Sheehan T P, *Mayo v Prometheus: The overlap between patent eligibility and patentability*, *NYSBA Bright Ideas*, 21 (2) (2012) 3.
- 14 *Bilski v Kappos*, 561 U.S. ___, 130 S. Ct. 3218 (2010).
- 15 *Diamond v Diehr*, 450 U.S. 175, 187 (1981).
- 16 *Bilski*, 130 S. Ct. at 3221 (quoting *Diamond v Chakraborty*, 447 U.S. 303 (1980)). The Court has not always been consistent in identifying which exception operates to render a given invention patent-ineligible. For example, in *Gottschalk v Benson*, 409 U.S. 63, 68 (1972), the Court rejected as patent ineligible a claim that recited a mathematical algorithm because it was too “abstract,” but the holding in *Benson* was subsequently characterized in *Parker v Flook*, 437 U.S. 584, 589 (1978), as applying “the established rule that a law of nature cannot be the subject of a patent.” The Court in *Flook*, in turn, held a claim to a process using an algorithm to be patent ineligible because it was drawn to a law of nature (437 U.S. at 589-90), but the Court in *Bilski* characterized *Flook* as pertaining to the exemption of abstract ideas from patent-eligibility (130 S. Ct. at 3230). Thus, the Court does not appear to consider the boundaries between these exemptions to be particularly restrictive and somewhat freely cross-applies analytical frameworks between them.
- 17 *Mayo v Prometheus*, 566 U.S. ___, 132 S. Ct. at 1295-6.
- 18 *Mayo v Prometheus*, 566 U.S. ___, 132 S. Ct. at 1296-7.
- 19 *Prometheus* brief as submitted in the Supreme Court, <http://sblog.s3.amazonaws.com/wp-content/uploads/2011/11/Mayo-Labs-respondent.pdf> (accessed 4 June 2014).
- 20 U.S. Patent no. 6,355,623 (filed 8 April 1999).
- 21 *Mayo* brief as submitted to the Supreme Court, http://www.americanbar.org/content/dam/aba/publishing/prviewbriefs/Other_Brief_Updates/10-1150_petitioner.authcheckdam.pdf (accessed 4 June 2014).
- 22 *Mayo v Prometheus*, 628 F.3d 1347, 1350 (Fed. Cir. 2010).
- 23 *Prometheus v Mayo*, 581 F.3d 1336, 1339 (Fed. Cir. 2009).
- 24 *Mayo v Prometheus*, 566 U.S. ___, 132 S. Ct. at 1355.
- 25 *Mayo v Prometheus*, 566 U.S. ___, 132 S. Ct. at 1295.
- 26 Chivvis M A, McEllhone K & Mullen J J III, *Mayo v. Prometheus: The Supreme Court finds that certain medical diagnostic claims are not patent-eligible*, Morrison/Foerster Client Alert, 20 March 2012, <http://media.mofo.com/files/Uploads/Images/120320-Mayo-v-Prometheus.pdf> (accessed 4 June 2014).
- 27 *Hotchkiss v Greenwood*, 52 U.S. (11 How.) 248 (1851).
- 28 Wegner H C, *Mayo v. Prometheus: Implications for “Compositions of matter”*, 27 April 2012, http://www.grayonclaims.com/storage/Wegner_Mayo_v_Prometheus_April27REV.pdf (accessed 10 June 2014).
- 29 Leahy Smith America Invents Act, Patent Law 112-29 (2011).
- 30 *Mayo v Prometheus*, 566 U.S. ___, 132 S. Ct. at 1300.
- 31 Malecek M & Kenneth M, *The Prometheus effect on software patents*, *Intellectual Property and Technology Law Journal*, 24 (6) (2012) 3; McNamara B, *Patent protection of computer hardware and software*, *Wake Forest Journal of Business and Intellectual Property*, 2 (2012) 137; Laakmann A, *An explicit policy lever for patent scope*, *Michigan Telecommunications and Technology Law Review*, 19 (2012) 43; Oppenheimer M S, *Patents 101: Patentable subject matter and separation of powers*, *Vanderbilt Journal of Entertainment and Technology Law*, (15) 1 (2012); Rogers E, *Patenting medical diagnostic methods: The MorT strikes back*, *Journal of Technology Law and Policy*, 17 (2012) 111; Reed N, *A new metric to determine patent eligible subject matter for medical methods*, *Michigan State University of Medicine and Law*, 16 (2) (2012) 321; Peachman S F, *The patent eligibility of diagnostic methods after Prometheus: A redefined test for transformation*, *Health Matrix*, 22 (2013) 589; Harvard Law Review Ass’n, *Diagnostic method patents and harms to follow-on innovation*, *Harvard Law Review*, 126 (2013) 1370; Chao B, *Moderating Mayo*, *Northwestern University Law Review*, 107 (1) (2012) 423; Jacob J, *Should our genes be part of the patent bargain? Maximizing access to medical diagnostic advances while ensuring research remains profitable*, *Santa Clara Computer & High Technology Law Journal*, 28 (2012) 403; Murphy S, *Who is swimming in your gene pool? Harmonizing the international pattern of gene patentability to benefit patient care and the biotechnology industry*, *University of Detroit Mercy Law Review*, 89 (2012) 397.

- 32 Sachs R R, Punishing Prometheus: The Supreme Court's blunders in Mayo v. Prometheus, PatentlyO, 26 March 2012, <http://patentlyo.com/patent/2012/03/punishing-prometheus-the-supreme-courts-blunders-in-mayo-v-prometheus.html> (accessed 10 June 2014).
- 33 *Association for Molecular Pathology v Myriad Genetics Inc*, 689 F.3d 1303; *OIP Techs Inc v Amazon.com Inc*, 2012 WP 3985118; *Classen Immunotherapies Inc v Biogen IDEC*, 2012 WL 3264941.
- 34 *Smartgene Inc v Advanced Biological Labs*, 852 F. Supp. 2d at 56–55 (D.D.C. 2012).
- 35 *OIP Techs Inc v Amazon.com Inc*, 2012 WP 3985118, *4 (N.D. Cal 2012).
- 36 *Smartgene Inc v Advanced Biological Labs*, 852 F. Supp. 2d, 42, 52-52; Belle J, Prometheus v Mayo: Limited implications for § 101 jurisprudence, *Washington Journal of Law, Technology & Arts*, 8 (5) (2013) 555.
- 37 *MySpace Inc v GraphOn Corp*, 672 F.3d 1250, 1260 (2012).
- 38 *CLS Bank Int'l v Alice Corp Pty Ltd*, 685 F.3d 1341, 1348 (Fed. Cir. 2012).
- 39 *CLS Bank Int'l v Alice Corp Pty Ltd*, 685 F.3d 1341, 1350 (Fed. Cir. 2012).
- 40 *CLS Bank Int'l v Alice Corp Pty Ltd*, 484 F. App'x 559 (Fed. Cir. 2012).
- 41 *Smartgene Inc v Advanced Biological Labs*, SA, 852 F. Supp. 2d 42 (D.D.C. 2012); *Advanced Software Design Corp v Fiserv Inc*, 625 F. Supp. 2d 815 (E.D. Mo. 2012); *Bancorp Services LLC v Sun Life Assurance Co of Can*, 687 F.3d 1266 (Fed. Cir. 2012); *Aria Diagnostics Inc v Sequenom Inc*, 2012 WL 25999340 (N.D. Cal. 2012).
- 42 *Gottshchalk v Benson*, 409 U.S. 63, 67 (1972).
- 43 *Parker v Flook*, 437 U.S. 584, 589 (1978).
- 44 *Smartgene, Inc. v Advanced Biological Labs*, SA, 852 F. Supp. 2d 42 (D.D.C. 2012); *Advanced Software Design Corp v Fiserv Inc*, 625 F. Supp. 2d 815 (E.D. Mo. 2012); *Bancorp Services LLC v Sun Life Assurance Co of Can*, 687 F.3d 1266 (Fed. Cir. 2012); *Aria Diagnostics Inc v Sequenom Inc*, 2012 WL 25999340 (N.D. Cal. 2012); *CLS Bank Int'l v Alice Corp Pty Ltd*, 685 F.3d 1341, 1348 (Fed. Cir. 2012); *Ass'n for Molecular Pathology v US Patent and Trademark Office*, 689 F.3d 1303; *Classen Immunotherapies Inc v Biogen IDEC*, 2012 WL 3264941.
- 45 *WildTangent, Inc v Ultramercial LLC*, Supreme Court No. 11-962 (2012).
- 46 Chao B, Moderating Mayo, *Northwestern University Law Review*, 107 (1) (2012) 423; Jacob J, Should our genes be part of the patent bargain? Maximizing access to medical diagnostic advances while ensuring research remains profitable, *Santa Clara Computer & High Technology Law Journal*, 28 (2012) 405.
- 47 Murphy S, Who is swimming in your gene pool? Harmonizing the international pattern of gene patentability to benefit patient care and the biotechnology industry, *University of Detroit Mercy Law Review*, 89 (2012) 397; Laakmann A, An explicit policy lever for patent scope, *Michigan Telecommunications and Technology Law Review*, 19 (2012) 43; Oppenheimer M S, Patents 101: Patentable subject matter and separation of powers, *Vanderbilt Journal of Entertainment and Technology Law*, (15) 1 (2012); Rogers E, Patenting medical diagnostic methods: The MorT strikes back, *Journal of Technology Law and Policy*, 17 (2012) 111; Reed N, A new metric to determine patent eligible subject matter for medical methods, *Michigan State University of Medicine and Law*, 16 (2) (2012) 321.
- 48 Jackman P A & Brandes L, Mayo Collaborative Services v. Prometheus Labs., Inc.: Medical diagnostic methods merely applying a law of nature are not eligible for patent protection, <http://skgf.com/media/pnc/4/media.1734.pdf>, 6 (accessed 6 June 2014).
- 49 *Smartgene Inc v Advanced Biological Laboratories*, 852 F. Supp. 2d 42, 45 (D.D.C. 2012).
- 50 *Association for Molecular Pathology v Myriad Genetics Inc*, 689 F.3d 1303, 1305 (Fed. Cir. 2012).