Standing on shaky ground: US patent-eligibility of isolated DNA and genetic diagnostics after *AMP v USPTO* – Part III

Timo Minssen

Assistant Professor LLM, MIL, Centre for Information & Innovation Law (CIIR), Copenhagen University, Denmark

David Nilsson

Jur kand LLM, Associate Bird & Bird, Stockholm, Sweden

At first reading, the Federal Circuit's decision in AMP v USPTO, summarized in Part I of this four-partite paper appears to favor the biotechnological and pharmaceutical industry. Its practical impact seems moderate because clever claim drafting helps to avoid most patent eligibility traps. Yet, the split decision also contains elusive reasoning by each of the three judges that provides excellent fodder for a potential US Supreme Court review. Although legal standing requirements may block the road to 'the nine', a potential review and the pending certiorari in Prometheus could have broad implications for the future of individualized medicine and tailored drug research.¹ Acknowledging the criticism of excessively broad upstream patent claims, and referring briefly to similar European debates, this paper discusses the recent developments from a broader innovation-policy perspective. This includes consideration of additional factors, such as higher thresholds for patentability criteria, scientific advances and post-grant mechanisms. Highlighting the mitigating effects of such factors and the dynamic qualities of biomedical innovation, the authors note that overly static eligibility doctrines entail considerable risks for technological progress. While it is essential that the Supreme Court clarifies its principles, the authors urge it not to categorically close the 'patent eligibility door' to important emerging technologies.

Keywords: *biotechnology, US, DNA, Myriad, patent-eligibility, personalized medicine, genetic diagnostics*

1. Part III could in general only consider developments that have occurred before 15 March, 2012. As it turned out, on March 20, 2012 the Supreme Court unanimously reversed the Federal Circuit's decision, finding all of *Prometheus*' claims at issue to be ineligible for patent protection, *Mayo Collaborative Services v Prometheus Laboratories, Inc.*, 566 U.S. ____ (2012), argued December 7, 2011 – decided March 20, 2012, available at: <<http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf>> (accessed March 24, 2012). Only, six days later, ie on March 26, 2012, the US Supreme Court granted *certiorari* in *Assn. For Molecular Pathology v Myriad Genetics, et al.*, and sent the case back to the Federal Circuit to reconsider it in light of *Mayo v Prometheus*, see Order List: 566 U.S., Monday, March 26, 2012, No. 11-725, available at <<http://www.supremecourt.gov/orders/courtorders/032612zor.pdf>> (accessed March 27, 2012). These groundbreaking developments will be briefly addressed in a postscript to this Part and subsequently in more detail in the forthcoming Part IV.

This is the third part of a four-partite² article discussing the US Federal Circuit decision in *AMP v USPTO*,³ also known as the ACLU⁴/Myriad 'gene patenting' case ('Myriad'). Part I⁵ commenced with a description of the legal framework and an explanation of how the decision relates to the recently invigorated US debate on patent eligibility, referring *inter alia* to the 2010 US Supreme Court decision in *Bilski v Kappos*, and the pending *certiorari* in *Prometheus v Mayo*⁶ (section 1). In the light of this background, Part I recited the complex procedural history of *AMP v USPTO* (section 2) and summarized the underpinnings of the outcome, that is, the three different opinions of the Federal Circuit judges Lourie, Moore and Bryson who comprised the panel (section 3). Part II⁷ continued the tale with a detailed analysis of the decision's practical implications (section 4), which was followed by a closer look at the procedural chances for an ultimate Supreme Court review (section 5).

As of March 15, 2012, the US Supreme Court has not decided whether to grant *certiorari* or not. Thus, it remains *inter alia* still possible that the Court may combine its pending decision in *Prometheus v Mayo* with the similar method claims related questions in *AMP v USPTO*. Another possibility would be that the Court grants a separate *certiorari* in *AMP v USPTO* in order to more specifically consider both the method and product claims in Myriad's BRCA patents.⁸ Part III now clarifies why a separate Supreme Court review in *AMP v USPTO* that would consider both method and product claims in DNA-related patenting would indeed be a necessary, and – in the view of the authors – also a much welcomed development. This part elaborates on the myriad of unsolved questions raised by both *AMP v USPTO* and a bulk of subsequent case law addressing the patent-eligibility of biological correlations and software-related 'inventions' (section 6). These subsequent decisions indicate a serious split at the Federal Circuit, with potentially broad implications not only for the patent-eligibility of software-related patent applications and so-called 'Beauregard' claims, but also for biotech claims directed to personalized medicine, biological correlations and compounds containing biological information. Part IV, which will be published in a subsequent issue, finally offers a broader discussion of the recent US patent-eligibility developments from an innovation policy perspective, including brief references to

2. This multi-partite paper was initially intended to be published in two parts. Yet, recent procedural developments and new Federal Circuit decisions have raised additional questions that have increased the complexity of the patent-eligibility debate. This resulted in a very lengthy paper exceeding the page limitations of this journal. The publishers have therefore decided to split this paper into four parts.

3. *The Association for Molecular Pathology v USPTO*, 653 F.3d 1329 (*AMP v USPTO*) (Fed. Cir. July 29, 2011).

4. ACLU = American Civil Liberties Union.

5. Cf T Minssen and D Nilsson, 'Standing on Shaky Ground – US Patent-eligibility of Isolated DNA and Genetic Diagnostics after *AMP v USPTO* – Part I', (2011) 1(3) QMJIP 223–47.

6. The patent challenger sought review of the recent CAFC decision in *Prometheus Laboratories, Inc. v Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. 2010) (Lourie, J). In June 2011, the Supreme Court granted *certiorari*, see *In Mayo Collaborative Services v Prometheus Laboratories, Inc.*, Supreme Court No. 10-1150 (2011), available at: <<http://www.supremecourt.gov/qp/10-01150qp.pdf>> (accessed 10 July, 2011). Cf the recent oral hearing in *Prometheus*, see Transcript of Oral Argument, *Mayo Collaborative Services, dba Mayo Medical Laboratories v Prometheus Laboratories, Inc.*, 2011 WL 5839566 (U.S.) (No. 10-1150, December 7, 2011).

7. Cf T Minssen and D Nilsson, 'Standing on Shaky Ground – US Patent-eligibility of Isolated DNA and Genetic Diagnostics after *AMP v USPTO* – Part II' (2012) 2(2) QMJIP 136–57.

8. See the Postscript to Part II of this paper (elaborating on recent procedural developments and the possibility of a GVR).

recent European developments (section 7). This provides the basis for summarizing conclusions (section 8).

As in the previous parts, recent developments occurring after completion of Part III up until the final editorial deadline will be addressed through pre- and postscripts.

6 A MYRIAD OF QUESTIONS REMAIN UNANSWERED

Our examination of the procedural chances for an ultimate Supreme Court review in Part II demonstrated that AMP's petition for a *writ of certiorari* in *AMP v USPTO*⁹ faces a delicate procedural hurdle with regard to the legal standing issue. At the same time, however, we also pointed out that many significant issues have not been properly addressed and that this has created a better climate for grant of review. In the following sub-sections we provide a more detailed analysis of specific questions left unanswered by *AMP v USPTO* (6.1) and describe how this has led to a serious split in subsequent Federal Circuit decisions (6.2). A combined study of these cases explains why a further Supreme Court review appears indeed necessary.

6.1 Questions left unsolved by *AMP v USPTO*

Unsurprisingly, opponents of Myriad's 'BRCA' patents have vehemently criticized the majority's § 101 ruling on legal, scientific and policy grounds.¹⁰ Inspired by Judge Lourie's structure-related 'markedly different' reasoning, and in particular by Judge Moore and Judge Bryson's broader interpretation of this criterion to also apply to uses, much criticism focused on the section 101 requirement of a 'new and useful' composition of matter. Opponents continue to argue that the 'useful' requirement implies that the function of the isolated DNA – not just its chemical structure – must be markedly different from what appears in the human body, and that the BRCA DNA claimed in *Myriad* does not meet this criteria.¹¹ Even with regard to structure, gene patent opponents challenge Lourie's opinion, referring to scientific facts and pointing out that the other two members of the Federal Circuit panel and District Court Judge Robert W. Sweet all shared the view that 'isolated' genomic genes have, in principle, the same structure as genes in the human body.¹²

9. See ACLU's petition for *certiorari* at the Supreme Court, available at: <http://www.aclu.org/files/assets/association_of_molecular_v_myriad_petition_for_writ_of_certiorari.pdf> (accessed 8 December, 2011).

10. Cf ACLU's arguments presented in their unsuccessful petition for panel rehearing at the Federal Circuit, filed on 25 August, 2011, available at: <<http://patentdocs.typepad.com/files/plaintiffs-appellees-petition-for-rehearing.pdf>> (accessed 6 September, 2011) (alleging factual and legal errors in the Court's July 29, 2011 decision on both standing and patent-eligibility. According to the plaintiffs the Court had interpreted the standing standard too narrowly, and had not sufficiently considered scientific facts and the 'products of nature' doctrine). See also the arguments presented in ACLU's petition for *certiorari* at the Supreme Court, supra n 9. A good summary of the arguments is provided by Tony Dutra, 'ACLU, PUBPAT File Certiorari Petition In Challenge to Isolated DNA Patent Eligibility', Patent, Trademark & Copyright Law Daily (12 December, 2011), available at: <<http://www.bna.com/aclu-pubpat-file-n12884906157/>> (accessed 20 December, 2011). Concerning the challenges related to procedural law, see section 5 in Part II.

11. See ACLU's petition for *certiorari* at the Supreme Court, supra n 10, at 10, 12–14.

12. Ibid, at 18.

With regard to policy arguments, opponents often do not share Judge Lourie's and Judge Moore's economic concerns. On the contrary, they point out that 'the usual rationale for granting a patent – the need to create economic incentives to advance science – did not apply in this case and does not apply to products of nature'.¹³ It is typically argued that the scientific community was well on its way to the discoveries claimed by Myriad and they 'would have been made available to the public even without the patent incentive'.¹⁴ The Federal Circuit has thus been accused of failing in its duty as keeper of the Constitution's patent clause.¹⁵ It has also been claimed that:

patents on isolated DNA, whether small segments or whole genes, also violate the First Amendment of the U.S. Constitution¹⁶ because they block scientific inquiry into the patented DNA and thus prevent advances in science and medicine that could result in better diagnosis and treatment.¹⁷

Moreover, it is frequently argued that patents on isolated DNA 'grant control over a body of knowledge and pure information'.¹⁸

In contrast, supporters of DNA-related patents emphasize that this kind of argumentation willfully conflates the patent-eligibility and patentability of annotated and isolated DNA itself, which, particularly in the 1980s and 1990s, often required considerable and non-obvious human intervention, as well as the mere information it encodes, which is not patent-eligible and can be used by all. While applauding the decision's general outcome with regard to Myriad's claims on isolated DNA, this group of commentators is more worried about the panel's reasoning leading to this result. This concerns *inter alia* the majority's distinction between isolated and purified products, which created many questions with regard to biotechnological product patents. As discussed in

13. Ibid, at 22.

14. Ibid, at 23 (it could be claimed that this finding is either based on hindsight or, if this not the case, that it rather points towards a non-obviousness problem).

15. The so-called patent/copyright law clause of the US Constitution in Article 1, Section 8, provides: 'The Congress shall have power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries'. See *ibid* and Simone Rose (Wake Forest University Law Professor and former patent attorney), 'Battle Over Gene Patents Most Likely Headed to Supreme Court', Huffington Post (21 August, 2011), available at: <http://www.huffingtonpost.com/simone-rose/gene-patents-surpreme-court_b_932509.html> (accessed 10 October, 2011), arguing that the Constitution's Patent Clause requires that the granting of exclusive rights under the patent system be balanced against providing access to basic knowledge. She then points out that '[p]atenting products of nature such as isolated genes and gene sequences prevents access to these basic research tools during the term of the patent', and '[t]his impedes rather than promotes progress and is therefore in direct violation of the IP clause'. She also asks how the Court could 'allow chemical differences to supersede biological equivalence when the specific utility of the invention, namely detecting mutations linked to breast and ovarian cancer, depends on biological identity?', and argues that '[c]hemically modifying an isolated gene [ie, breaking chemical bonds during the isolation process] does not alter its biological heart', and that '[a]ccurately detecting BRCA mutations would be impossible without this biological identity'.

16. Cf the 1st Amendment, which provides that: 'Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances'.

17. Cf ACLU's arguments, *supra* n 10, at 20.

18. Ibid, at 30.

Part II, section 4.1, particularly Judge Moore's statement that 'mere purification of a naturally occurring element is *typically* insufficient to make it patentable subject matter'¹⁹ (emphasis added) has the potential to exclude from patentability a broad array of both large molecule biologics based on, for example, DNA-, protein- and stem-cell-related technology, and traditional small molecule drugs based on chemical purification.

Realizing that it would not be wise to ban the patentability of many traditional and future blockbuster drugs, the majority panel tried to explain why some products made from purified known substances, such as aspirin and adrenalin, should nevertheless represent novel and patentable products under 35 USC § 101. In an attempt to reconcile their distinction between 'isolated' and 'purified' products, with the notion that certain patents on purified products might deserve patent protection, Judge Lourie refers to Judge Learned Hand's reasoning in *Parke-Davis & Co. v H.K. Mulford Co.*, and stresses that 'purification of adrenaline resulted in the identical molecule being "for every practical purpose a new thing commercially and therapeutically"'.²⁰ Judge Moore follows a similar pathway stating:

Judge Learned Hand held that purified adrenaline, a natural product, was patentable subject matter. Judge Hand explained that even if the claimed purified adrenaline were 'merely an extracted product without change, there is no rule that such products are not patentable.' *Parke-Davis & Co. v H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y.1911). This is because 'while it is of course possible logically to call this a purification of the principle' the resulting purified adrenaline was 'for every practical purpose a new thing commercially and therapeutically'.²¹

Without more precise guidelines, however, it seems difficult to fully comprehend this reasoning and to apply it adequately to genomic and post-genomic science. Neither can this distinction easily be rationalized with Judge Moore's general finding that purified products are typically not patent-eligible. When considering the wide variety of useful products stemming from modern biotechnology, the *Myriad* panel seems to draw a

19. *AMP v USPTO*, supra n 3, at 1360.

20. *Ibid*, at 1352. ('[I]solated DNA is not purified DNA. Purification makes pure what was the same material, but was previously impure. Although isolated DNA must be removed from its native cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body. It has not been purified by being isolated. Accordingly, this is not a situation, as in *Parke-Davis & Co. v H.K. Mulford Co.*, in which purification of adrenaline resulted in the identical molecule being "for every practical purpose a new thing commercially and therapeutically." 189 F. 95, 103 (C.C.S.D.N.Y.1911). Although ... Judge Learned Hand held ... purified "Adrenalin" to be patentable ... *Id.*')

21. *Ibid*, at 1360 (adding: 'Similarly, in a case applying the Patent Act of 1952, FN1 purified vitamin B-12, another natural product, was also held patentable subject matter within the meaning of section 101. *Merck & Co. v Olin Mathieson Chem. Corp.*, 253 F.2d 156 (4th Cir.1958). The Fourth Circuit explained that purified vitamin B-12 was "far from the premise of the [naturally occurring] principle. ... The new product, not just the method, had such advantageous characteristics as to replace the [naturally occurring] liver products. What was produced was, in no sense, an old product." *Id.* at 162–63. These purified pharmaceutical cases are both consistent with Supreme Court precedent: the purified substance was "a new thing ... therapeutically," *Parke-Davis*, 189 F. at 103, and had such "advantageous characteristics" that what was produced by purification "was, in no sense, an old product." *Merck*, 253 F.2d at 162–63. In other words, the purified natural products were held to have "markedly different characteristics," as compared to the impure products, which resulted in "the potential for significant utility." *Chakrabarty*, 447 U.S. at 310, 100 S.Ct. 2204').

rather blurred and artificial line between patent-eligible isolated material and purifications resulting in a commercially and therapeutically ‘new thing’, on the one hand, and patent-ineligible simple purifications not adding sufficiently advantageous changes, on the other. In *Myriad* the BRCA sequences were of course found to be isolated and not purified, but it is plain that this murkiness is also reflected in the unclear ‘markedly different characteristics’ notion. Although, products derived from cutting edge synthetic biotechnology will mostly pass these tests, and it seems generally difficult to ascertain where the line should be drawn between ‘markedly different characteristics’ and characteristics that are not sufficiently different. Should it be a matter of different chemical structures, greater effectiveness, higher concentration/purity, or enhanced methods for a more efficient reproduction and protein expression etc.? Or should their utility be completely different from natural functions? The situation becomes even more complicated when bearing in mind that ‘everything that happens may be deemed ‘the work of nature’, and any patentable composite exemplifies in its properties ‘the laws of nature’. Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.’²² We will return to these important reflections, which apply to many pharmaceutical inventions, in the final discussion.

In this context it is further important to note that the *Myriad* panel would probably have had a much easier time in upholding *Myriad*’s claims on the isolated DNA sequences had they applied the analytical framework as it had been developed by the legendary Judge Giles S Rich in *In re Bergy*²³ (CCPA²⁴ 1979). *In re Bergy* is arguably a very relevant ‘precedent’ to the *Myriad* dispute, since it clearly states that the isolated micro-organisms of *Bergy* – which had not been modified in the same way as the modified micro-organisms that were at issue on *Chakrabarty* – are no less patent-eligible than any other chemical compounds, including ‘countless pharmaceuticals’.²⁵ Accordingly *Myriad*’s brief to the Federal Circuit heavily relied

22. *Funk Bros.* 333 U.S. at 134–5 (Frankfurter J concurring).

23. *In re Bergy*, 596 F.2d 952 (CCPA 1979) (Rich J). (Here, the CCPA upheld a patent directed toward a purified version of an antibiotic producing strain of streptomycin, a substance that appears in nature in an unpurified state.) (‘What we deal with here in each appeal is an industrial product used in an industrial process in a useful or technological art. ... The nature and commercial uses of biologically pure cultures of microorganisms like the one defined in *Bergy*’s claim 5 and the modified microorganisms claimed by *Chakrabarty* are analogous in practical use to inanimate chemical compositions such as reactants, reagents, and catalysts used in the chemical industry. ... the law has long and unhesitatingly granted patent protection to new, useful and unobvious chemical compounds and compositions, in which category are to be found such important products of microbiological process [sic] as vitamin B-12 and adrenalin and countless other pharmaceuticals ... : We were thinking of something preexisting and merely plucked from the earth and claimed as such, a far cry from a biologically pure culture produced by great labor in a laboratory and so claimed.’)

24. The US Court of Customs and Patent Appeals (CCPA), which was abolished in 1982 by the Federal Courts Improvement Act, is the predecessor of the US Court of Appeal for the Federal Circuit.

25. WD Woessner, ‘Wegner Paper Probes *Myriad* Decisions Flaws’, available at: <<http://www.patents4life.com/2011/08/wegner-paper-probes-myriad-decisions-flaws/>> (adding: ‘Such compounds can be isolated, purified, assembled from simpler “synthons” or prepared by subdividing more complex molecules (my gloss). The distinction that the *Myriad* panel tries to draw between “isolated” and “purified” – “[DNA] has not been purified by being isolated” – is artificial, not even factual and not relevant to patent-eligibility under s. 101’); cf WD Woessner,

upon *In re Bergy*, although it was only cited in a footnote in Judge Sweet's District Court opinion.²⁶ Judge Lourie, however, refused to consider *Bergy* in his majority opinion. He does not even try to distinguish it from the present case. Instead he simply states in footnote 7: 'We note that *Bergy* is no longer binding law. *Bergy* was the companion case to *Charkarbarty* [sic], and was vacated by the Supreme Court and remanded for dismissal as moot. (*Diamond v Chakrabarty*, 444 U.S. 1028, 100 S.Ct. 700, 62 L.Ed.2d 666 (1980))'.²⁷

One commentator participating for an *amicus* party involved in this case, Harold C Wegner,²⁸ vehemently criticizes the panel's decision for not basing their decision on Myriad's product claims on *Bergy*. He contends *inter alia* that *Bergy* is still binding law, since *Bergy* and *Chakrabarty* were dealt with as companion cases by the CCPA and combined for appeal to the Supreme Court. In that regard he points out the Court granted *certiorari* to both *Bergy* and *Chakrabarty*, but in its opinion simply noted that *Bergy* had been dismissed as moot after the Court had granted *certiorari*. Notwithstanding that the Court only had *Chakrabarty* to decide, he believes that the Supreme Court in no way rejected the CCPA's earlier decision in *Bergy*. Contrary to Judge Lourie's statement in footnote 7 in *Myriad*, he therefore concludes that the second *Bergy* decision²⁹ was not vacated by the Supreme Court. Professor Wegner further argues that even if assuming, *arguendo*, that *Bergy* itself would no longer be binding law, the Federal Circuit cannot ignore that the critical analytical test developed by Judge Rich in *Bergy* had later been adopted by the Supreme Court in *Diamond v Diehr*,³⁰ and has been repeatedly recited and adopted as precedent by the Federal Circuit in several cases, such as *State Street*,³¹ *Smith Kline Beecham v Apotex*³² and *In re Comiskey*.^{33, 34}

'A "Myriad" of Questions to Resolve? Back to the Basics of 101', available at: <<http://www.patents4life.com/2010/05/a-%e2%80%9cmymraid%e2%80%9d-of-questions-to-resolve-back-to-the-basics-of-101/>> (accessed November 1, 2011).

26. WD Woessner, 'Wegner Paper Probes Myriad Decisions Flaws', supra n 25.

27. *AMP v USPTO*, supra n. 3, at 1352, FN7 (FN7 contains a mistake: *Charkarbarty* should be *Chakrabarty*).

28. Former Director of the Intellectual Property Law Program and Professor of Law, George Washington University Law School; partner; Foley & Lardner.

29. See HC Wegner, 'Myriad Turns The 1952 Patent Act On Its Head', at 7–9, available at: <<http://www.ipfrontline.com/downloads/Myriad.pdf>> (accessed November 10, 2011); cf. Woessner, 'Wegner Paper Probes Myriad Decisions Flaws', supra n 25.

30. Cf *Diamond v Diehr*, 450 U.S. 175, 189–90 (1981) (quoting *Bergy*, 596 F.2d at 961).

31. See *State Street Bank & Trust Co. v Signature Financial Group, Inc.*, 149 F.3d 1368, 1372 (Fed. Cir. 1998) (quoting extensively from *In re Bergy*, 596 F.2d 952, 960 (CCPA 1979)) ('The plain and unambiguous meaning of § 101 is that any invention falling within one of the four stated categories of statutory subject matter may be patented, provided it meets the other requirements for patentability set forth in Title 35, i.e., those found in §§ 102, 103, and 112').

32. *Smith Kline Beecham Corp. v Apotex Corp.*, 403 F.3d 1331, 1362 (Fed. Cir. 2005) (Gajarsa, J. concurring) ('*In re Bergy*, 596 F.2d 952 (CCPA 1979), rev'd [sic] sub nom *Diamond v Chakrabarty*, 447 U.S. 303 (1980)').

33. *In re Comiskey*, 554 F.3d 967, 973 (Fed. Cir. 2009) ('*State St. Bank & Trust Co. v Signature Fin. Group, Inc.*, 149 F.3d 1368, 1372 n. 2 (Fed.Cir.1998) (quoting *In re Bergy*, 596 F.2d 952, 960 (CCPA 1979))').

34. Wegner, supra n 29, at 7–9 (adding: '... so it would not matter if a Federal Circuit case saying the same thing is or is not precedential'); cf. Woessner, 'Wegner Paper Probes Myriad Decisions Flaws', supra n 25.

A somewhat related issue, indicating an arguable conflation of patentability requirements by the Federal Circuit in *Myriad*, is the following statement: ‘The Supreme Court’s decisions in Chakrabarty and Funk Brothers set out the framework for deciding the patent eligibility of isolated DNA molecules’ (footnote 6 omitted).³⁵ Like the US Supreme Court in *Bilski v Kappos*,³⁶ the majority thus infers that *Funk v Kalo*³⁷ deals with patent-eligibility under 35 USC § 101. However, it is important to note that *Funk v Kalo* was decided under the pre-1952 Patent Act, which addressed what is today obviousness under 35 USC § 103, but at that time was considered to be a question of ‘patentable invention’.³⁸ Elaborating on this issue, Harold C Wegner does not mince his words in stating:

The great achievement of the 1952 Patent Act was the creation of a split statutory scheme that separated patent-eligibility from the new patentability standard of Section 103: The panel conflated the statutory requirements, reintroducing an uncertainty to the patent law that had seemingly been obviated by the 1952 Patent Act.³⁹

Accordingly, he concludes that since the Court had accepted the notion that DNA is a chemical polymer,⁴⁰ it should have followed the *Bergy* analysis and simply reversed the district court’s judgment of invalidity under 35 USC § 101, remanding the case ‘to determine whether the patent eligible compounds – the DNA claimed by *Myriad* – represent patentable subject matter as to novelty under 35 § 102 and non-obviousness under 35 USC § 103’.⁴¹

As many patent attorneys and concerned patent-holders have done, Professor Wegner is obviously arguing for an extremely low patent-eligibility threshold, and appears not to be a friend of the ‘markedly different’ standard as applied by Judge Lourie in *Myriad*. To the extent that he strives for an re-invigoration of the *State Street* standard, it seems rather unlikely that he will convince the Federal Circuit and the

35. *AMP v USPTO*, supra n 3 at 1350. (FN 6 then confirms that the Court views *Funk v Kalo* as a patent eligibility case: ‘Other Supreme Court decisions cited by the parties and amici were decided based on lack of novelty, not patentable subject matter’).

36. *Bilski v Kappos*, 130 S.Ct. 3218 (2010).

37. *Funk Bros. Seed Co. v Kalo Inoculant Co.*, 333 U.S. 127 (1948) (Here, ‘the patentee discovered that certain strains of nitrogen-fixing bacteria associated with leguminous plants do not mutually inhibit each other. 333 U.S. at 129–30, 68 S.Ct. 440. Based on this discovery, the patentee produced (and claimed) mixed cultures of nitrogen-fixing species capable of inoculating a broader range of leguminous plants than single-species cultures. *Id.* The Court held that the bacteria’s qualities of non-inhibition were, “like the heat of the sun, electricity, or the qualities of metals,” the “work of nature,” and thus not patentable. *Id.* at 130, 68 S.Ct. 440. The Court also held that application of the newly discovered bacterial trait of non-inhibition to create a mixed bacterial culture was not a patentable advance because no species acquired a different property or use. *Id.* at 131, 68 S.Ct. 440.’).

38. Cf for a more detailed discussion Wegner supra n 29 at 11–12. Cf T Minssen and RM Schwartz, ‘US Patent Eligibility in the wake of *Bilski v Kappos*: Business as Usual in an Age of new Technologies?’ (2011) 30(1) Biotech L Rep 3–58, at 16, available at: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1682574> (accessed 10 June, 2011).

39. Wegner, supra n 29, at 1.

40. Cf the concurring opinion by Judge Moore in *AMP v USPTO*, supra n 3 at 1361 (‘DNA is a chemical polymer. In principle, a polymeric DNA sequence is no different than any other well known polymer, for example, nylon. Like any polymer, DNA is made up of repeating monomer units, connected by chemical bonds to form one larger molecule’).

41. See eg Wegner, supra n 29 at 2.

Supreme Court, which have either implicitly or explicitly rejected this most recent low-water mark⁴² of the utility and eligibility standard.⁴³

However, some of his arguments relating to the inherent risk of an overly restrictive patent-eligibility barrier, as well as the apparent conflation of the basic patentability requirements, such as utility (§ 101 and § 112), novelty (§ 102), non-obviousness (§ 103) and sufficiency (§ 112), with the eligibility inquiry under § 101, certainly raises significant issues. On a more impartial basis, this also seems to be acknowledged by the US Supreme Court, which continues⁴⁴ to be troubled by the blurred relationship between the patentability and patent-eligibility criteria. Notably, this was recently confirmed during the oral hearing in *Prometheus*. In discussing this question with the parties' representatives,⁴⁵ the Judges had great difficulties in receiving straight answers. Thus Chief Justice Roberts made the following comment to *Prometheus*' counsel:

Well, it seems to me that's your – the problem with your whole approach is that every time you're pressed on 101, your answer is to fall back to 102 or 103 or the utility part of 101. And I'm just wondering why it's beneficial to essentially eliminate 101 and say oh, we'll catch everything later on.⁴⁶

6.2 Questions left open by subsequent case law

Leaving aside these important general concerns for later discussion, we now turn to related, more specific questions concerning the patent eligibility of biomedical

42. For a detailed discussion of earlier case law cf T Minssen, 'När anses en bioteknologisk uppfinning vara komplett och praktisk användbar' (A Comparative Analysis of the US Utility and the European Industrial Application Requirement in Biotech) - Del I - USA, NIR 201-60 (2008), & Del II - Europe, NIR, 339-87 (2008) (in Swedish).

43. It is at least questionable if this low-water mark of patent eligibility for process claims as represented by *State Street*'s 'useful, concrete and tangible result' test is still the law of the land. In *Bilski v Kappos* 130 S.Ct. 3218, 3222 (2010), the majority opinion neither confirms nor explicitly rejects *State Street* – noting instead that 'nothing in today's opinion should be read as endorsing interpretations of § 101 that the Court of Appeals for the Federal Circuit has used in the past. See, e.g., *State Street*, 149 F. 3d, at 1373; *AT&T Corp.*, 172 F. 3d, at 1357'. However, the two concurring opinions in *Bilski* (2010) and the Federal Circuit in *In re Bilski* both explicitly reject the useful concrete-and-tangible-result test of *State Street*. Cumulatively, this indicates an implicit rejection or at least restriction of *State Street*, cf D Crouch, 'Bilski v Kappos and the Anti-State-Street-Majority', available at: <<http://www.patentlyo.com/patent/2010/06/bilski-v-kappos-and-the-anti-state-street-majority.html>> (accessed 10 November, 2011).

44. See eg Justice Stewart's dissent in *Parker v Flook*, 437 US 584 (1978) (noting at 600 that the Court's approach imported §§ 102 and 103's criteria of novelty and non-obviousness into § 101's subject matter inquiry. The Court's reliance on the analysis of *Funk v Kalo* did not recognize that this case was decided under former 35 USC § 31 (recodified in 1946), which combined criteria for several statutory patentability requirements, and that, notwithstanding the Court's disclaimer, much of *Funk*'s attention was directed to the requirement of invention).

45. Stephen M Shapiro, on behalf of Petitioners (Mayo); Donald B Verrilli, Jr., esq, Solicitor General, Department of Justice, for United States, as *amicus curiae*; and Richard P Bress, on behalf of Respondent (*Prometheus*).

46. See Supreme Court Chief Justice Roberts, oral hearing, *Prometheus*, Transcript of Oral Argument *Mayo Collaborative Services, dba Mayo Medical Laboratories v Prometheus Laboratories, Inc.*, 2011 WL 5839566 (U.S.) (No. 10-1150, December 7, 2011), at *54.

method claims. At present much seems to depend on the abstract mental step and MOT standard under *Bilski*, as applied in *Prometheus*, *Myriad* and *Classen*. Thus, it remains crucial to incorporate active, technology-dependent steps into method claims in order to minimize the likelihood that the invention will be characterized as merely an ‘abstract idea’. Yet, while the Federal Circuit reached unanimous decisions on *Prometheus*’ and *Myriad*’s method claims, its split decision in *Classen* demonstrates that the Court still has severe difficulties in determining where exactly to draw the line between *patent-ineligible* biotechnological methods claiming abstract ideas, insignificant post-solution activities or natural phenomena, and *patent-eligible* claims directed to specific applications involving a ‘certain’ level of human intervention.

In *Classen*⁴⁷ the Federal Circuit had to consider a claimed invention, which was based on Dr John Barthelow Classen’s thesis that the schedule of infant immunization for infectious diseases can affect the later occurrence of a variety of chronic immune-mediated disorders,⁴⁸ and that immunization should be conducted on the schedule presenting the lowest risk for developing such disorders. The resulting patents, nos. 6,638,739; 6,420,139; and 5,723,283, were assigned to Classen Immunotherapies (patentee), and contained a total of 230 broadly formulated claims. The proceedings concentrated on ‘representative claims’ selected by the patentee. The claims of the ‘139 and ‘739 patents state the method whereby information on immunization schedules and the occurrence of chronic disease is firstly ‘screened’ and ‘compared’, then secondly the lower risk schedule is ‘identified’, and thirdly the vaccine is ‘administered’ on that schedule.⁴⁹ Naturally, the patentee had interpreted its claims very broadly, and contended that the ‘139 and ‘739 patents are infringed ‘when a health care provider reads the relevant literature and selects and uses an immunization

47. *Classen Immunotherapies, Inc. v Biogen IDEC*, 659 F.3d 1057 (C.A. Fed. 2011) (cf Part II, section 4.2).

48. Such as diabetes, asthma, hay fever, cancer, multiple sclerosis and schizophrenia.

49. *Classen Immunotherapies, Inc. v Biogen IDEC*, supra n 47, at 1060–61: ‘Classen states that “The patented method of the ‘139 and ‘739 patents is exemplified by Claim 1 of the ‘739 patent”. Classen Br. 11. Claim 1 states: 1. A method of immunizing a mammalian subject which comprises: (I) screening a plurality of immunization schedules, by (a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule, and (b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s), (II) immunizing said subject according to a subject immunization schedule, according to which at least one of said infectious disease-causing organism-associated immunogens of said lower risk schedule is administered in accordance with said lower risk screened immunization schedule, which administration is associated with a lower risk of development of said chronic immune-mediated disorder(s) than when said immunogen was administered according to said higher risk screened immunization schedule.’

schedule that is of lower risk for development of a chronic immune-mediated disorder'.⁵⁰ The patentee claimed further that this comprises 'the act of reviewing the published information, whether or not any change in the immunization schedule is made upon such review'.⁵¹ The '283 patent claims the *first* step of the above method, that is reviewing and comparing published information on the effects of immunization schedules in both treated and control groups of mammals, with respect to the occurrence of immune-mediated disorders.⁵² In contrast to the '139 and '739 patents, however, the '283 patent does not include the subsequent step of selecting an immunization schedule. According to the patentee the '283 patent is infringed 'when a person reviews relevant information, whether the person is a producer of vaccines, a health care provider, or a concerned parent'.⁵³ The District Court invalidated the patentee's claims finding that they were directed to an abstract idea. In December 2008 the Federal Circuit initially affirmed the District Court's invalidation in a laconic 69-word opinion, which simply referred to its recent decision in *In re Bilski* and the MOT test to arrive at the same conclusion.⁵⁴ In the wake of *Bilski v Kappos*, the Supreme Court grant-vacate-remanded the case to the Federal Circuit, where it was consigned to the panel of the judges Rader, Newman and Moore.

The majority opinion, which was written by Judge Newman and joined by Judge Rader, found that at least the '139 and '739 patents met the patent-eligibility standard of § 101. The mere fact that the '139 and '739 patents included a mental step did not necessarily contradict patent eligibility, in the view of the majority, since 'precedent has recognized that the presence of a mental step is not of itself fatal to § 101 eligibility'.⁵⁵ Instead, the Court stressed that the '139 and '739 claims included 'the physical step of immunization on the determined schedule' and that

50. Ibid, at 1061 (citing the patentee: '[T]he '139 and '739 patents in suit are directly infringed when a physician, hospital or other health care provider reads the relevant literature and selects an immunization schedule and immunizes a patient in accordance with the schedule which appears to have minimal risk. Classen Br. 22').

51. Ibid (citing the patentee: 'Classen states that the patents are infringed by the act of reviewing the published information, whether or not any change in the immunization schedule is made upon such review. Classen Br. 41 ("maintenance of the current schedule is step (II) of the Classen method")').

52. Ibid (Claim 1 was claimed to represent the '283 patent: '1. A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group').

53. Ibid (adding that 'The three patents list over four hundred references related to immunization schedules, the occurrence of immune-mediated disorders, and various studies and reports in this field').

54. *Classen Immunotherapies, Inc. v Biogen IDEC*, 304 Fed. Appx. 866, 2008 WL 5273107 (Fed. Cir. December 19th, 2008). (The decision had less words than the claims: 'In light of our decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the District Court's grant of summary judgment that these claims are invalid under 35 USC § 101. Dr. Classen's claims are neither "tied to a particular machine or apparatus" nor do they "transform[]" a particular article into a different state or thing." *Bilski*, 545 F.3d at 954. Therefore we affirm').

55. *Classen Immunotherapies, Inc. v Biogen IDEC*, 659 F.3d 1057 (C.A. Fed. 2011), at 1065.

they were therefore directed to a patent-eligible ‘specific, tangible application’.⁵⁶ The claims in the ’283 patent, however, did not include such physical steps, which led the majority to the conclusion that they were directed to a patent-ineligible abstract idea.⁵⁷

The majority’s patent eligibility reasoning was quite brief and did not sufficiently discuss that even the ’139 and ’739 claims were – unlike the claims in *Prometheus* – broadly directed to general methods for scheduling and conducting all types of immunizations without more precise specifications. Instead, the decision is supplemented by a remarkable separate section featuring additional views on patent eligibility. Here, Judge Rader, who was joined by Judge Newman, expresses his growing frustration with the rising number of patent-eligibility challenges which – at least in his view – disregard the broad language in 35 USC § 101.⁵⁸ Proposing that ‘[t]his court should decline to accept invitations to restrict subject matter eligibility’, he emphasizes a variety of public policy reasons ‘that the statute places few, if any, limits on subject matter eligibility’.⁵⁹ Most significantly, these include legal uncertainty and the problem that ‘eligibility restrictions usually engender a healthy dose of claim-drafting ingenuity’,⁶⁰ which leads to complex language and claim constructions in order to evade exclusions. In his view ‘these 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’.⁶¹

Notwithstanding these concerns, however, Judge Moore expresses completely different views in her dissent. Albeit admitting that it is inherently difficult to draw a precise line between patentable subject matter and abstract ideas,⁶² she seems to be convinced that at least in this case all three claims are clearly directed to unpatentable abstract ideas. In that regard she repeatedly expresses her strong concerns over the wide scope of these, in her view, ‘staggeringly broad and abstract claims’.⁶³

56. Ibid, at 1066–67 (‘The claims of the ’139 and ’739 patents are directed to a method of lowering the risk of chronic immune-mediated disorder, including the physical step of immunization on the determined schedule. These claims are directed to a specific, tangible application, as in Research Corporation, and in accordance with the guidance of *Bilski v Kappos* that “[r]ather than adopting categorical rules that might have wide-ranging and unforeseen impacts,” exclusions from patent-eligibility should be applied “narrowly,” 130 S.Ct. at 3229, we conclude that the subject matter of these two patents traverses the coarse eligibility filter of § 101’).

57. Ibid, at 1067–69.

58. Ibid, at 1073–74 (‘In the last several years, this court has confronted a rising number of challenges under 35 USC § 101. The language of § 101 is very broad. Nevertheless, litigants continue to urge this court to impose limitations not present in the statute’).

59. Ibid, at 1074.

60. Ibid.

61. Ibid (followed by several (historical) examples, such as US *Beauregard* claims and European Swiss claims).

62. Ibid, at 1078 (‘While I confess the precise line to be drawn between patentable subject matter and abstract idea is quite elusive, at least for me, this case is not even close’).

63. Ibid, at 1076 (see also *ibid*, at 1079: ‘Having discovered a principle – that changing the timing of immunization may change the incidence of chronic immune mediated disorders – Classen now seeks to keep it for himself’, and at 1080: ‘In the end, Mr. Classen’s claims seek to monopolize the process of discovery itself, albeit limited to a single field. Our patent system, however, does not award a monopoly that precludes others from using the basic procedures of scientific investigation to study the same phenomenon. See *Bilski*, 130 S.Ct. at 3253 (Stevens, J., concurring) (Patents on laws of nature, natural phenomena, and abstract ideas “would stifle the very progress that Congress is authorized to promote.”)’).

Judge Moore criticizes in particular the extremely broad wording of the '283 patent. In contrast to the majority opinion, however, she arrives at the same conclusions with regard to the '139 and '739 patents, since she regards the immunization step as 'nothing more than a post-solution activity'.⁶⁴ In her view, the 'post-solution immunization does not transform the unpatentable principle – that a correlation exists between vaccination schedules and incidence of chronic immune disease – into a patentable process'.⁶⁵ Consequently, she does not 'understand the distinction that the majority draws between claim 1 of the '283 patent and claim 1 of the '739 patent',⁶⁶ and concludes that all of *Classen*'s claims are directed to unpatentable subject matter.⁶⁷

Judge Moore's dissent, and the frustration expressed in Judge Rader's and Judge Newman's additional views, demonstrate clearly diverging views, not only over the content and appropriate interpretation of the patent-eligibility requirement under § 101, but also over its effects, role and function in the patent and innovation system. This has resulted in a certain level of confusion among Federal Circuit judges and users of the patent system. That the courts continue to have serious problems in coherently applying and interpreting § 101, with regard to both *method* and *product* claims, becomes even more apparent when linking *Classen* and *Myriad* with the recent Federal Circuit decisions in *CyberSource*⁶⁸ and *Ultramercial*.⁶⁹

CyberSource was decided by a panel consisting of Judge Bryson, Judge Prost and Judge Dyk, who wrote the unanimous decision. Before turning to the facts of the case, it should be recalled that at least two of these judges, Bryson and Dyk, are well known for having expressed rather restrictive views on the patentability of isolated DNA.⁷⁰ It is important to bear that in mind when analyzing the implications of this decision. The patent claims at issue in *CyberSource* were directed, firstly, to a method for verifying the validity of a credit card transaction over the Internet,⁷¹ and, secondly, to the computer-readable medium containing the program instructions for executing that

64. Ibid, at 1079 ('The immunization step of the '739 patent, like updating the alarm limit in *Parker v Flook*, 437 U.S. 584 (1978), is nothing more than post-solution activity. As the Supreme Court explained: "The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. A competent draftsman could attach some form of post-solution activity to almost any mathematical formula; the Pythagorean theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved could be usefully applied to existing survey techniques." *Id.* at 590, 98 S.Ct. 2522').

65. Ibid, at 1079.

66. Ibid, at 1080–81.

67. Ibid, at 1081.

68. *CyberSource Corporation v Retail Decisions, Inc.*, 654 F.3d 1366 (Fed. Cir. Aug. 2011) (*CyberSource*).

69. *Ultramercial, LLC v Hulu, LLC*, 657 F.3d 1323 (Fed. Cir. Sept. 2011).

70. As it has been described in Part I and Part II, section 4, Judge Bryson clearly rejected the patentability of isolated DNA that did not have a markedly different utility than natural sequences. Judge Dyk seems to share this view as it was demonstrated in *Intervet, Inc. v Merial Limited*, 617 F.3d 1282, at 1293–95 (2010) (cf Part II, section 4.1, n 20).

71. *CyberSource*, supra n 68, at 1368, fn 1 ('Claim 3, as amended during reexamination, reads: 3. A method for verifying the validity of a credit card transaction over the Internet comprising the steps of: a) obtaining information about other transactions that have utilized an Internet address that is identified with the [ ] credit card transaction; b) constructing a map of credit card numbers based upon the other transactions and; c) utilizing the map of credit card numbers to determine if the credit card transaction is valid.).

method,⁷² such as, for example, a floppy disk. CyberSource sued Retail Decisions for patent infringement, while Retail Decisions moved for a summary judgment of invalidity. The District Court held that *CyberSource's* method claim did not meet 35 USC § 101, since it failed to satisfy the MOT test. Based on the ineligibility of the first claim, the District Court also concluded that the computer-readable medium claim was also invalid. The Federal Circuit agreed with the District Court and found that the method *CyberSource* outlined was merely 'an unpatentable mental process' of gathering and comparing data, that was neither transformative nor did it necessarily involve a machine.⁷³ The Court referred *inter alia* to the Supreme Court decision in *Benson* which had concluded that 'methods which can be performed mentally, or which are the equivalent of human mental work, are unpatentable abstract ideas'.⁷⁴ Applying the *Benson* rationale to the facts of the case, the Court emphasized that all of the claim's method steps could be performed in the human mind, or by a human using a pen and paper. A human could manually list prior Internet credit card transactions, and compare Internet addresses against prior records.⁷⁵ Moreover, the Court noted that the claim's scope was not limited to any particular fraud detection algorithm, and no algorithms were disclosed in the patent's specification. Rather, the broad scope of the claim extended to essentially any method of detecting credit card fraud based on information relating past transactions to a particular Internet address. Thus, *CyberSource's* method claim for verifying the validity of a credit card transaction over the Internet was drawn to unpatentable mental processes, and was therefore held invalid.⁷⁶

Next, the Court turned to the computer-readable medium claim, also referred to as a 'Beauregard claim'.⁷⁷ *CyberSource* argued that even if its process was unpatentable, coupling the process with a manufacture or machine renders it patent-eligible.⁷⁸

72. Ibid ('Claim 2, as amended during reexamination, reads: 2. A computer readable medium containing program instructions for detecting fraud in a credit card transaction between a consumer and a merchant over the Internet, wherein execution of the program instructions by one or more processors of a computer system causes the one or more processors to carry out the steps of: [...]'). Next the claim recites several such steps.

73. Ibid, at 1370–71.

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

75. *CyberSource Corporation v Retail Decisions, Inc.*, 654 F.3d 1366, at 1372–73.

76. Ibid, at 1373 (adding: 'Methods which can be performed entirely in the human mind are unpatentable not because there is anything wrong with claiming mental method steps as part of a process containing non-mental steps, but rather because computational methods which can be performed entirely in the human mind are the types of methods that embody the 'basic tools of scientific and technological work' that are free to all men and reserved exclusively to none. *Benson*, 409 U.S. at 67, 93 S.Ct. 253').

77. Put bluntly, this is a claim to a computer readable medium (eg, a disk, hard drive, or other data storage device) containing program instructions for a computer to perform a particular process. This claim form was named after *In re Beauregard*, 53 F.3d 1583 (Fed. Cir. 1995) (Order) (Archer, CJ) ('The Commissioner now states "that computer programs embodied in a tangible medium, such as floppy diskettes, are patentable subject matter under 35 USC § 101 and must be examined under 35 USC §§ 102 and 103"').

78. *CyberSource Corporation v Retail Decisions, Inc.*, 654 F.3d 1366, at 1374 ('*CyberSource* argues that claim 2 is patent-eligible per se because it recites a "manufacture," rather than a "process," under the statutory language of § 101. [It] contends that, by definition, a tangible, man-made article of manufacture such as a "computer readable medium containing program instructions" cannot possibly fall within any of the three patent-eligibility exceptions the Supreme Court has recognized for "laws of nature, physical phenomena, [or] abstract ideas." Appellant's Br. 47–48 (quoting *Bilski*, 130 S.Ct. at 3225)').

The Court disagreed, holding that the *Beauregard* claim was actually a process claim directed to the method itself:

Regardless of what statutory category ('process, machine, manufacture, or composition of matter,' 35 U.S.C. § 101) a claim's language is crafted to literally invoke, we look to the underlying invention for patent-eligibility purposes. Here, it is clear that the invention underlying both claims 2 and 3 is a method for detecting credit card fraud, not a manufacture for storing computer-readable information.⁷⁹ ... In the present case, *CyberSource* has not met its burden to demonstrate that claim 2 is 'truly drawn to a specific' computer readable medium, rather than to the underlying method of credit card fraud detection. ... Thus, despite its *Beauregard* claim format, under *Abele*, we treat claim 2 as a process claim for patent-eligibility purposes.⁸⁰

Highlighting the fact that the method could be carried out within the human mind, the Court further held that the computer's role in the process was 'incidental', and that the claim could therefore not fall into one of the patentable categories under the MOT test.⁸¹ Accordingly, the Court concluded that both claims 2 and 3 were invalid under § 101, since they attempted to capture unpatentable mental processes (ie abstract ideas).

It is clear that *CyberSource* adds an additional dimension to the eligibility debate. By focusing on the 'underlying invention' and treating the *Beauregard* 'manufacture' claim as an invalid process claim directed to an abstract idea, it could be argued that *CyberSource* has created an additional conflict, not only with *Bergy*,⁸² but also with settled industry expectations still relying on the Federal Circuit precedent in *Research Technologies v Microsoft*,⁸³ and the – not yet explicitly rejected – *State Street* standard.⁸⁴ In that regard it should be recalled that 'settled industry expectations' had compelled Judge Moore in her opinion in *Myriad* to uphold the claims on isolated DNA. Consequently, the decision reinvigorated the criticisms of those who believe that the

79. Ibid.

80. Ibid, at 1374–75 (citing *In re Abele*, 684 F.2d 902 (CCPA 1982)).

81. Ibid, at 1376–77 ('In contrast, it is clear in the present case that one could mentally perform the fraud detection method that underlies both claims 2 and 3 of the '154 patent, as the method consists of only the general approach of obtaining information about credit card transactions utilizing an Internet address and then using that information in some undefined manner to determine if the credit card transaction is valid').

82. Supra n 23.

83. See *Research Corp. Technologies, Inc. v Microsoft Corp.*, 627 F.3d 859, 868 (Fed. Cir. 2010) (Rader, Chief Judge) ('[T]his court will also not presume to define "abstract" beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act').

84. Cf supra n 31. See also JG McEwen and R Possett, 'The Broadening Chasm between Claim Interpretation during Litigation and Examination for Product-By-Process Claims' (2011) 3(4) *Landslide* ('Currently, at least 41,334 issued patents contain at least one *Beauregard* claim. In *Bilski v Kappos*, the Supreme Court declined to comment on the validity of those issued claims and the patentability of the thousands more that are pending at the Patent Office. [*Bilski v Kappos*, 130 S.Ct. 3218, 3227–28 (2010)]'). It should, however, be recalled that although *State Street*'s broad "useful, concrete and tangible result" test had not been explicitly rejected by the majority in *Bilski v Kappos*, it has clearly been called into question by the Federal Circuit in *In re Bilski* and the concurring opinions in *Bilski v Kappos*, cf supra n 31.

Federal Circuit has conflated the patent eligibility criterion with other criteria for patentability under the US patent statute.⁸⁵

Furthermore, it is important to note that by expanding the abstract-mental-process exception set forth in *Bilski* for the patent-eligibility determination of software claims, and in particular by invalidating the *Beauregard* claim, this decision could also affect the status of other types of method and product patents. That *CyberSource* could, for example, have a severe impact on even DNA-related product claims, can be explained as follows:

The relevance of the Court's decision in *CyberSource* to the question of the patent-eligibility of DNA is rooted in two aspects of that decision: first, that the Court is empowered to look to the 'underlying invention' untethered to the expressly recited claim language, and to the argument that DNA is nothing more than information, essentially the software that directs protein production in a cell. To develop the analogy, here the 'computer' would be a cell that produces a protein according to the instructions contained in the DNA ...⁸⁶

The question is, then, whether isolated DNA, and the information that is stored on it, actually is comparable to a software program stored on a computer-readable medium. Many concerned patent attorneys, industry stakeholders, and perhaps even some molecular biologists, would vehemently reject such a notion. However, the comparison is appealing, and has been used for many years by many scientists to explain DNA and protein-related technology to laymen.⁸⁷ While much in these discussions depends on purely scientific arguments and positions, it is important to keep these potentially broad implications in mind.

Another case decided shortly after *CyberSource* by a different panel indicates that some judges at the Federal Circuit might share the concern over such far-reaching implications. In *Ultramercial*,⁸⁸ a panel consisting of Chief Judge Rader, Judge Lourie and Judge O'Malley had to consider patent claims⁸⁹ directed to a method of distributing copyrighted products over the Internet. Interestingly, both Rader J and Lourie J have, in contrast to Bryson J and Dyk J, repeatedly argued in favor of a more permissive

85. Cf Harold C Wegner, *Cybersource Conflict with Precedent*, available at: <<http://www.ipfrontline.com/depts/article.aspx?id=25676&deptid=7>> (accessed 10 December, 2011) (emphasizing that it is not at issue 'whether the Cybersource invention is patentable as novel and nonobvious'. Notwithstanding *State Street*'s questionable validity, he also argues that the Cybersource 'Beauregard claim' is directed to a 'tangible medium' and is hence patent-eligible subject matter under the *State Street Bank* doctrine. Nor does he believe that the invention is abstract under the *Research Tech. v Microsoft* standard).

86. KE Noonan, 'CyberSource and the Tragedy of Bad Analogies: Is DNA Patent-ineligible because it is like Software?', available at: <<http://www.patentdocs.org/2011/08/cybersource-and-the-tragedy-of-bad-analogies.html>> (accessed November 10, 2011).

87. As exemplified by the Nobel Prize laureate Walter Gilbert's statement in 'Vision of the Grail', in DJ Kevles and L Hood (eds), *The Code of Codes* (Harvard University Press, Cambridge, MA 1993) 96: 'Three billion bases of sequences can be put on a single compact disk (CD), and one will be able to pull a CD out of one's pocket and say, "here is a human being; it's me!"'. It is then, however, also important to realize that scientists have to simplify when talking to laymen. For example the order of DNA sequences does not provide all the necessary information as demonstrated by epigenetic insights. See also, AW Torrance, 'Gene Concepts, Gene Talk, and Gene Patents' (2010) 11 (1) Minn. J.L. Sci. & Tech. 157, citing Andrew Brown: 'It's been a growing conviction of mine that biologists have a whole other way of talking to each other in the lab than they do to the public'.

88. *Ultramercial, LLC v Hulu, LLC*, 657 F.3d 1323 (Fed. Cir. Sept. 2011).

89. US Patent No. 7,346,545.

patent-eligibility threshold.⁹⁰ In *Ultramercial*, the claimed invention was based on the novel idea that the copyrighted product, such as a movie, could be both (1) offered for sale, and (2) delivered for free if the consumer agrees to view an advertisement and the advertiser pays for the copyrighted content. The District Court held the patent invalid as patent-ineligible under section 101. On appeal, however, the Federal Circuit reversed. Writing for the Court, Judge Rader started out by emphasizing that the statutory eligibility filter is broadly permissive, and should not be used to invalidate patents based on concerns about vagueness, indefinite disclosure, or lack of enablement.⁹¹ After having categorized the contested '545 patent as process claims, the Court tried to determine in how far the invention claimed by the '545 patent was based on an unpatentable abstract idea. In that context, the Court briefly discussed the 'machine or transformation test', but decided to focus instead on the programming complexity required to carry out the claimed elements. Considering *inter alia* the Supreme Court holdings in the subject matter of the '545 patent in light of *Diehr*, *Flook & Benson*,⁹² the Court noted that:

the mere idea that advertising can be used as a form of currency is abstract, just as the vague, unapplied concept of hedging proved patent-ineligible in *Bilski*. However, the '545 patent does not simply claim the age-old idea that advertising can serve as a currency. Instead, the '545 patent discloses a practical application of this idea.⁹³

90. Judge Lourie's permissive approach to the patent eligibility of chemicals and DNA has been explicitly discussed above. Judge Rader is also well known for similar opinions. Thus, ACLU's attorneys had filed a motion on June 28, 2010 to exclude Chief Judge Randall R Rader from any involvement in the appeal. The motion is based on Chief Judge Rader's attendance at events at which the case was discussed, and his comments at two such events. For a more detailed discussion, see Tim Peterson, 'Chief Judge Rader's Views on Patentable Subject Matter – Part I', available on the Patent Docs Blog, at: <<http://www.patentdocs.org/2010/08/chief-judge-raders-views-on-patentable-subject-matter-before-the-bilski-v-kappos-decision.html>> (accessed August 17, 2010).

91. *Ultramercial, LLC v Hulu, LLC*, supra n 88, at 1326: 'More importantly, as § 101 itself expresses, subject matter eligibility is merely a threshold check; claim patentability ultimately depends on "the conditions and requirements of this title," such as novelty, non-obviousness, and adequate disclosure. ... By directing attention to these substantive criteria for patentability, the language of § 101 makes clear that the categories of patent-eligible subject matter are no more than a "coarse eligibility filter." ... In other words, the expansive categories – process, machine, article of manufacture, and composition of matter – are certainly not substitutes for the substantive patentability requirements set forth in § 102, § 103, and § 112 and invoked expressly by § 101 itself. Moreover, title 35 does not list a single ineligible category, suggesting that any new, non-obvious, and fully disclosed technical advance is eligible for protection, subject to the following limited judicially created exceptions' (internal citations omitted).

92. *Ibid*, at 1327 ('Although abstract principles are not eligible for patent protection, an application of an abstract idea may well be deserving of patent protection. See *Diehr*, 450 U.S. at 187, 101 S.Ct. 1048 ("an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection"); *Parker v Flook*, 437 U.S. 584, 591, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978) ("While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.")). The application of an abstract idea to a 'new and useful end' is the type of invention that the Supreme Court has described as deserving of patent protection. *Gottschalk v Benson*, 409 U.S. 63, 67, 93 S.Ct. 253, 34 L.Ed.2d 273 (1972). After all, unlike the Copyright Act which divides idea from expression, the Patent Act covers and protects any new and useful technical advance, including applied ideas').

93. *Ibid*, at 1328.

Most importantly, the Court then complemented this basic finding with a more detailed explanation of the specific steps for monetizing copyrighted products as described in the claims:

Viewing the subject matter as a whole, the invention involves an extensive computer interface. This court does not define the level of programming complexity required before a computer-implemented method can be patent-eligible. Nor does this court hold that use of an Internet website to practice such a method is either necessary or sufficient in every case to satisfy § 101. This court simply finds the claims here to be patent-eligible, in part because of these factors.⁹⁴

Thus, the Court regarded the fact that many of the claimed steps involved complex computer programming as further evidence for concluding that the claimed invention constituted a patentable *application* instead of an unpatentable abstract idea. In doing so, the Court seems to infer that abstractness, as a disqualifying characteristic for patentability, should manifest itself particularly plainly in order to override broad statutory categories of eligible subject matter and statutory context that direct primary attention to further patentability criteria under the Patent Act. In addition, the Court explicitly rejected the contention that software programming is directed to abstract subject matter.⁹⁵

Probably realizing that some of its findings appear to contradict *CyberSource*, the panel in *Ultramercial* finally distinguished *CyberSource* as an example of ‘purely mental steps’, while the claims in *Ultramercial* ‘require, among other things, controlled interaction with a consumer via an Internet website’. According to the Court this is ‘something far removed from purely mental steps’.⁹⁶ The panel in *Ultramercial* thus seems to draw the patent-eligibility line somewhere between logical steps that can be carried out by the human mind or by a human using pencil and paper (patent-ineligible), and more complex methods that can only be performed by a computer (patent-eligible).

Without clearer principles, however, the line between unpatentable series of purely mental steps, mere mathematical algorithms or abstract ideas, and patentable applications of abstract ideas and algorithms, appears to be rather blurred. In particular, it remains difficult to determine what amount of human intervention and level of programming complexity would be required to render an application patentable.

94. Ibid.

95. Ibid, at 1329. (Referring to its *en banc* decision in *In re Alappat*, 33 F.3d 1526 (1994), the Court found: ‘The digital computer may be considered by some the greatest invention of the twentieth century, and both this court and the Patent Office have long acknowledged that ‘improvements thereof’ through interchangeable software or hardware enhancements deserve patent protection. Far from abstract, advances in computer technology – both hardware and software – drive innovation in every area of scientific and technical endeavor’.)

96. Ibid, at 1329–30 (‘Finally, the ’545 patent does not claim a mathematical algorithm, a series of purely mental steps, or any similarly abstract concept. It claims a particular method for collecting revenue from the distribution of media products over the Internet. In a recent case, this court discerned that an invention claimed an “unpatentable mental process.” *CyberSource Corp. v Retail Decisions, Inc.*, 654 F.3d 1366, 1370 (Fed.Cir.2011). The eligibility exclusion for purely mental steps is particularly narrow. See *Prometheus Labs.*, 628 F.3d at 1358 (noting that claims must be considered as a whole and that “the presence of mental steps [in a claim] does not detract from the patentability of [other] steps”). Unlike the claims in *CyberSource*, the claims here require, among other things, controlled interaction with a consumer via an Internet website, something far removed from purely mental steps.’).

The ‘paper and pencil’ example is not sufficiently decisive and appears to be a rather artificial distinction, as it is difficult to determine human capability.

The most recent Federal Circuit decision, in *Dealertrack v Huber*,⁹⁷ which was rendered on 20 January, 2012, illustrates this very nicely, and demonstrates that the Federal Circuit split is indeed ‘alive and well’.⁹⁸ Here, another Federal Circuit panel consisting of Judges Linn, Plager, and Dyk, found claims to a computer aided method of managing a car loan credit application through an electronic clearinghouse to be unpatentable subject matter on the basis that the claims were ‘directed to an abstract idea preemptive of a fundamental concept or idea’.⁹⁹ Despite the fact that the claims were limited to the use of a clearinghouse in the car loan application process, the Court held that ‘it nonetheless covers a broad idea’.¹⁰⁰ In contrast to *Ultramercial* the *Dealertrack*, panel also held that simply adding a ‘computer aided’ limitation is insufficient to render the claim patent eligible.¹⁰¹ The Court then attempted to distinguish *Ultramercial* on the rather vague basis that in *Ultramercial* ‘the patent claimed a practical application with concrete steps requiring an extensive computer interface’, whereas ‘the claims here recite only that the method is ‘computer aided’ without specifying any level of involvement or detail’.¹⁰² Also interesting is Judge Plager’s separate opinion (concurring in part and dissenting in part), which seemed to be very much concerned with the efficiency of judicial processes, and therefore held that the courts should not ‘foray into the jurisprudential morass of § 101 [subject matter] unless absolutely necessary’.¹⁰³

That this § 101 ‘morass’ is really profound is further confirmed by the additional questions raised by *Classen* and *CyberSource*, that is to what extent ‘tangible’ features might provide a way out of the patent-eligibility trap, and, if so, how far *Beauregard* claims should be regarded as reciting sufficiently ‘non-abstract’ tangible media that

97. See case 2009-1566, -1588 *Dealertrack Inc. v David L. Huber and Finance Express, LLC., et al.* (Federal Circuit, 20 January, 2012) (Before Linn, Plager, and Dyk, Circuit Judges. Opinion for the court filed by Circuit Judge Linn. Opinion concurring in part and dissenting in part filed by Circuit Judge Plager), available at: <<http://www.cafc.uscourts.gov/images/stories/opinions-orders/09-1566.pdf>> (accessed January 23, 2012).

98. Cf N Siebrasse, ‘Post-Bilski Split on Patentable Subject Matter’, available at: <<http://ipkitten.blogspot.com/2012/01/post-bilski-split-on-patentable-subject.html>> (accessed January 23, 2012).

99. *Dealertrack v Huber*, slip op, at 35.

100. *Ibid.*, at 37.

101. *Ibid.*, slip op, at 36.

102. *Ibid.* Cf Siebrasse, supra n 98 (adding that this distinction is ‘wholly unconvincing’ and that ‘the only real distinction is that there was no overlap in the composition of the panel. Chief Justice Rader wrote the decision in *Ultramercial*, with Judges Lourie and O’Malley concurring. He has consistently been a strong proponent of the view that the it is only abstract claims which are prohibited – see his opinion in *Bilski* 545 F3d 943 (Fed Cir 2008).’).

103. See Judge Plager’s separate opinion in *Dealertrack v Huber* (concurring in part and dissenting in part), slip op, at 2 (‘However, as a matter of efficient judicial process I object to and dissent from that part of the opinion regarding the ‘427 patent and its validity under § 101, the section of the Patent Act that describes what is patentable subject matter. I believe that this court should exercise its inherent power to control the processes of litigation, *Chambers v NASCO, Inc.*, 501 U.S. 32, 43 (1991), and insist that litigants, and trial courts, initially address patent invalidity issues in infringement suits in terms of the defenses provided in the statute: “conditions of patentability,” specifically §§ 102 and 103, and in addition §§ 112 and 251, and not foray into the jurisprudential morass of § 101 unless absolutely necessary’).

would render claims on computer programs (or DNA) patentable as ‘manufactures’ instead of ‘processes’.¹⁰⁴

All this clearly indicates that many questions in terms of how to deal with patents involving informational content remain unsolved. As indicated above, this will also become a most crucial issue for the future of DNA and protein-related personalized medicine.¹⁰⁵ Under traditional case law, claims that related to either biological or electronic (software) information were not automatically regarded as patent-ineligible, as long as they did not claim information as such, and could be tied to a ‘tangible’ machine, manufacture, medium, (biological) compound and/or involved transformation. However, *CyberSource* clearly questions the foundations of this doctrine and demonstrates how patents involving either biological or electronic information are more likely to provoke patent eligibility concerns due to their potentially broad scope. This has also been realized by the US Supreme Court in *Bilski v Kappos*:

For even when patents encourage innovation and disclosure, ‘too much patent protection can impede rather than “promote the Progress of ... useful Arts.”’ ... Patents ‘can discourage research by impeding the free exchange of information,’ for example, by forcing people to ‘avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented’ methods. (internal citations omitted)¹⁰⁶

Nevertheless, *Ultramercial* appears to imply the rule that the mere practical application of an otherwise abstract invention claiming information is patentable, as long as it is complex enough and tied to a computer-readable medium or even the Internet.

104. Unsurprisingly, one of the accused infringers in *Ultramercial*, WildTangent, has now filed a petition for a rehearing *en banc*. Electronic Frontier Foundation (EFF) has recently submitted an *amici curiae* brief in support of the rehearing – arguing that an *en banc* decision is necessary in light of (1) the court’s failure to follow *Bilski*; (2) inconsistencies in application of the law apparent from the court’s decisions in *Ultramercial*, *Classen* and *CyberSource*, and (3) a growing intra-circuit division regarding patent eligibility jurisprudence. Available at: <https://www.eff.org/sites/default/files/Ultramercial_Amici_Brief_Final_iso_rehearing.pdf> (accessed November 25, 2011) (stating at 2: ‘... *Bilski v Kappos* has been cited by nearly 40 district and appellate courts since it was handed down. ... Some of those cases, unfortunately, fail to heed Justice Stevens’ warning that in “the area of patents, it is especially important that the law remain clear and stable.” ...’. Referring to *Ultramercial*, *CyberSource* and *Classen*, EFF continues: ‘This Court alone, for example, issued three rulings during the summer of 2011 that appear to contradict each other, and – when read together – imply a stringent rule not contemplated by the Supreme Court in *Bilski*, namely, that an otherwise abstract invention is patentable when tied to the internet or other computerized material’).

105. In particular when considering that *personalized medicine* is basically ‘an area of applied research devoted to developing tests that operate on biological and clinical data from a patient (e.g., protein levels, genetic mutations, medical history) to provide diagnoses, prognoses, and treatment regimens specific to the patient’, R Feldman, ‘Where do Processes of Nature End and Processes of Human Invention Begin?’, available at: <<http://www.patentlyo.com/patent/2011/12/rethinking-patent-law.html>> (accessed 13 December, 2011 (featuring an excerpt from his forthcoming book *Rethinking Patent Law* (Harvard University Press, Cambridge, MA June 19, 2012)).

106. *Bilski v Kappos*, 130 S.Ct. 3218, 3255 (2010), concurring opinion by Justice Stevens, joined by Justice Ginsburg, Justice Breyer and Justice Sotomayor (citing *Laboratory Corp. of America Holdings v Metabolite Laboratories, Inc.*, 548 U.S. 124, 126–127 (2006) (Breyer, J), dissenting from dismissal of *certiorari*).

This result is particularly significant when envisioning the future of personalized medicine.¹⁰⁷ Considering the combined potential impact of *CyberSource* and *Myriad*, one commentator, for example, questioned the practical relevance of the above discussed post-*Myriad* practical advice supporting the patentability of lab-based analysis methods by linking them to machines or transformations:

... commentators ... have offered practice tips that mostly involve interjecting machines ('sequencers') or transformations (chemical isolation or DNA sequencing) into the *Myriad* method claims to render them sufficiently non-abstract. But, in the future, diagnoses based on 'personalized medicine' are going to become more distanced from the laboratory, not more tied to it. In the future, your child's genome will probably be sequenced at birth or at least, a large number of significant genes will be sequenced and the data stored via a 'computer readable medium.' When the doctor wants to confirm a diagnosis or even the suspicion of a predilection for developing a pathology, e.g., breast cancer, the doctor will not sample the patient, but will order a computer comparison between regions of the patient's genome and various reference sequences. It may be necessary to use complex algorithms to weigh many differences between the various sequences, to reach a 'report out' that can go back to the doctor.¹⁰⁸

This example illustrates that the reasoning of the Federal Circuit in *Ultramercial* would pave the way for many future claims related to personalized medicine. The possible impact of *Ultramercial* on software solutions tied to the Internet is particularly significant, since software utilization is increasingly changing from computer-readable media (CD-ROMs, DVD-ROMs, etc.) to electronic distribution, such as Internet delivery. While tens of thousands of *Beauregard* claims directed to inventions involving computer-readable media have been granted so far, technological changes and the increasing reluctance of the USPTO (and the Federal Circuit in *CyberSource*) to accept such claims as manufactures will presumably reduce applications involving inventions to which *Beauregard* claims are typically directed. Analogies could also be made in the DNA context where the mere isolation of a biological sequence is often not considered to be inventive anymore, and where the patent focus is increasingly shifting towards inventive applications and modifications of such sequences and the information they contain (e.g. through synthetic biology).¹⁰⁹ *Ultramercial* might, however, still render many of such process-inventions patentable, that is even if they are merely tied to the Internet. The next question is then if such a result was contemplated by the Supreme Court in *Bilski*.

To sum up: while *Myriad* and *Prometheus* provide at least some useful hints for daily patent practice, many crucial issues remain unsolved. This is demonstrated by:

1. the Federal Circuit's incoherent decision on *Myriad*'s product claims directed to genomic DNA;
2. the panel's distinction between isolated and purified products contrary to present patent practice;

107. WD Woessner, 'CyberSource Corp. v Retail Decisions, Inc.' Patents 4 Life, available at: <<http://www.patents4life.com/2011/08/cybersource-corp-v-retail-decisions-inc/>> (accessed November 10, 2011).

108. *Ibid.*

109. Although it could of course be argued that it is a different issue to manipulate the structure and informational content of a DNA or protein sequence than to simply transfer complex information onto a CD-ROM.

3. the arguable ‘conflation’ of the patent eligibility assessment under 35 USC § 101 with patentability determinations under 35 USC § 102 (novelty), § 103 (non-obviousness) and § 112 (specification) in *Myriad* and *CyberSource*; and
4. the questions raised with regard to method claims by the somewhat contradictory Federal Circuit decisions in *Prometheus*, *Classen*, *CyberSource* and *Ultramercial*.

Although the Supreme Court has given the Federal Circuit little opportunity to refine its patent eligibility jurisprudence after *Bilski* by granting *certiorari* in *Prometheus*, it is plain that *Bilski*¹¹⁰ did not provide sufficiently decisive guidelines on crucial questions relating to patent-eligibility. Or, in other words: by simply referring to its old, somewhat contradictory precedent¹¹¹ as controlling, the Supreme Court in *Bilski* did not provide sufficiently clear instructions for resolving the different results in *Prometheus*, *Myriad*, *CyberSource*, *Classen* and *Ultramercial*.¹¹² That this is a central problem of the modern patentable subject matter doctrine, and has resulted in legal uncertainty, seems also to have been acknowledged by the Supreme Court Judge Breyer, who noted during the oral hearing in *Prometheus*: ‘If you look at the Court’s cases, they seem to say *Flook*, one thing, and *Diehr* another thing’.¹¹³

Obviously, further guidance by the Supreme Court is necessary to develop more coherent doctrines facilitating an effective and predictable bio-medical patent practice. It will have a great practical significance if the Supreme Court should decide to follow the Federal Circuit’s approach when it decides *Prometheus*,¹¹⁴ or at least accepts that the general rationale followed by the Federal Circuit’s majority in *Prometheus*, *Myriad*, *Classen* and *Ultramercial* – that is, if it is more consistently applied and based on clearer principles – provides an alternative basis for restricting patent-eligibility and scope on a

110. *Bilski v Kappos*, 130 S.Ct. 3218 (2010).

111. These cases are *Funk Brothers Seed Co. v Kalo Inoculant Co.*, 333 U.S. 127 (1948) (although this case was decided before the 1952 Patent Act, and it could be argued that it was primarily about obviousness); *Gottschalk v Benson*, 409 U.S. 63 (1972); *Parker v Flook*, 437 U.S. 584 (1978); *Diamond v Chakrabarty*, 447 U.S. 303, 309 (1980); *Diamond v Diehr*, 450 U.S. 175, 184 (1981).

112. Cf. Rebecca Eisenberg, ‘Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods after *Bilski*’ (2012) 3 Case W. Res. J.L. Tech. & Internet 1, available at: <<http://www.patentlyo.com/files/eisenberg.wisdomordeadhand.patentlyo.pdf>> (accessed December 7, 2012) (describing how the Supreme Court in *Bilski v Kappos* simply referred to its old precedent as controlling, and thus created uncertainty. Eisenberg points out: ‘The Supreme Court reaffirmed the authority of these decisions without explanation ..., thereby demanding formal adherence to *stare decisis* without following the discipline of common law reasoning’. She then asks the Supreme Court to use this next opportunity in *Prometheus* ‘not only to clarify the boundaries of patentable subject matter, but to explain what the doctrine of patentable subject matter is all about’). See also Minssen and Schwartz, *supra* n 38 (recognizing that *Bilski* left crucial questions unresolved and that further Supreme Court decisions will be necessary to establish more predictable principles).

113. See Supreme Court Judge Breyer, *supra* n 46 at *13.

114. See *Mayo Collaborative Services v Prometheus Laboratories, Inc.*, Supreme Court No. 10-1150 (2011), available at: <<http://www.supremecourt.gov/qp/10-01150qp.pdf>> (accessed August 10, 2011). (‘The question presented is: Whether 35 USC § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively pre-empts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve “transformations” of body chemistry’.)

more flexible case-by-case basis.¹¹⁵ Any fundamentally different rationale established by the Supreme Court, such as those sketched out in *CyberSource*, the dissenting opinion in *Classen* and in some statements in *Myriad*, would have a great impact on the future of personalized medicine and tailored drug research.¹¹⁶

The state of uncertainty created by *Bilski* has surely also contributed to the astonishing outcome concerning the product claims in *Myriad*, that is, that after nearly 30 years of established case law, which never has challenged the patentability of isolated gene sequences, the Federal Circuit could not come to a unanimous vote on this issue. Since the US Supreme Court is generally prevented from rendering judgment where there is no ‘live case or controversy’ under the Constitutional bar in Art III, § 2, cl 1, it can be expected that the pending Supreme Court review in *Prometheus* will not deliver all the answers to the specific questions raised by *Myriad*. Although *Prometheus* will hopefully provide some more clarity on the legal assessment of method claims, a further grant of *certiorari* by the Supreme Court in *Myriad* could clarify the patent-eligibility doctrine with regard to DNA and protein-related product claims, and would thus complement the pending decision in *Prometheus* very well.

However, and as discussed in more detail in Part II,¹¹⁷ it remains unclear whether the US Supreme Court will grant *certiorari* in *Myriad*, and if so, whether it would perhaps combine the case with *Prometheus* and thus consider some of the questions raised but not addressed by *Classen* and *CyberSource*. Whatever the case may be, our discussion demonstrates that it would indeed be very unfortunate if the US legal standing requirements prevent the Supreme Court from accepting the case, or if the Court for any other reasons refuses to grant a broader review.

Postscript: Incorporating events up until the last editorial deadline (March 31, 2012)

Part III could generally not consider developments that have occurred after March 15, 2012. As it turned out, on March 20, 2012 the Supreme Court rendered a, somewhat surprisingly, *unanimous* decision, holding that the claims in *Mayo Collaborative Services v Prometheus Laboratories, Inc.* (from now on referred to as ‘*Mayo*’ instead of ‘*Prometheus*’) effectively claim a law of nature and are not patent-eligible under 35 USC § 101.¹¹⁸

115. See also C Brinckerhoff, ‘Federal Circuit Issues Mixed Decision on Myriad Claims’, available at: <<http://www.pharmapatentsblog.com/2011/07/30/federal-circuit-decides-myriad-oks-isolated-dna-claims/>> (accessed December 5, 2011).

116. Cf Feldman, supra n 105 (‘... the Federal Circuit’s decision in *Prometheus* seemed to suggest that most life science inventions would satisfy the requirements of patentable subject matter, while the PTO’s application of *Prometheus* could lead to the rejection of numerous inventions in this arena. Neither extreme is necessary if one focuses on preemption of laws of nature and natural phenomena as the primary concern’).

117. Cf The Postscript to Part II, supra n 7.

118. *Mayo Collaborative Services v Prometheus Laboratories, Inc.*, 566 U.S. ____ (2012), argued December 7, 2011 – decided March 20, 2012, available at: <<http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf>> (accessed March 24, 2012). It should be recalled that the US Supreme Court had previously vacated an earlier pre-*Bilski* Federal Circuit decision (2009) in this case and remanded it back to the Federal Circuit (GVR) to consider its previous decision in light of *Bilski v Kappos* 130 S.Ct. 3218 (2010). Writing for the panel in *Prometheus Laboratories, Inc. v Mayo Collaborative Services*, 628 F. 3d 1347 (Fed. Cir. 2010) Judge Lourie continued to apply the so-called MOT test to uphold claims on ‘methods for determining the optimal dosage of thiopurine drugs used to treat gastrointestinal and non-gastrointestinal autoimmune diseases’ (628 F. 3d at 1350). The claimed methods included the steps of (a) ‘administering’ a thiopurine drug to a subject,

The decision is based upon a comprehensive assessment of the particular claims at issue in light of the Court's precedents. The Court reiterated the traditional 'laws of nature, natural phenomena, and abstract ideas exceptions' to categories of patent-eligible subject matter under 35 USC § 101, as set forth by the US Supreme Court in *inter alia* *Bilski*, *Chakrabarty*, *Flook* and *Diehr*. The Court also addressed the 'machine-or-transformation' test considered in *Bilski*, and confirms once more that it remains an 'important and useful clue' to patentability but that it does supersede the 'law of nature' exclusion. The Court underlined that a claim that is directed to a law of nature or natural correlation, with additional steps that involve well-understood, routine, conventional activity previously engaged in by researchers in the field, is not patent-eligible, regardless of whether the steps result in a transformation (an issue that would of course also be significant in the obviousness assessment). On the contrary, the Court explained that a claimed process including not only a law of nature, such as the fact that hot air promotes ignition, but also several unconventional steps, such as involving a blast furnace, might still be patent-eligible, if it confines the claims to a particular, useful application of the principle.

Turning to the facts of the case, the Supreme Court held that since the laws of nature recited by Prometheus' patent claims – that is, the correlations between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage will be ineffective or harmful – are not themselves patent-eligible, the claimed processes are likewise not patent-eligible unless they have additional features that provide practical evidence that the processes are true applications of those laws, instead of being drafting efforts designed to monopolize the correlations. The Court also found that while the additional steps recited in the claimed processes in this case cannot be considered to be natural laws as such, the patent applicant would have been required to add more in order to transform the nature of the claims.

The Court has thus clarified that in order to transform an unpatentable law of nature into a patent-eligible application of such a law, it is not sufficient to simply state the law of nature and add the phrase 'apply it'. Essentially, appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena and abstract ideas cannot render those laws, phenomena, and ideas patent-eligible.¹¹⁹

One day after the judgment, the USPTO issued a memorandum in order to provide preliminary guidance to the Patent Examining Corps.¹²⁰ Additional guidance on patent subject matter eligibility under 35 USC § 101 will be issued soon.¹²¹

and/or (b) 'determining' the drug's metabolites levels in the subject, wherein the measured metabolite levels are compared with predetermined levels to optimize drug dosage (*ibid*). In holding that the claims satisfied § 101, the Court concluded that, in addition to the 'administering' step being transformative, the 'determining' step was both transformative and central to the purpose of the claims (*ibid*, at 1357). The Court also unequivocally rejected an argument made by defendant-appellees, that the claims merely covered a process for obtaining test results and then thinking about them, holding that: 'The presence of those two steps in the claimed processes is not "merely" for the purpose of gathering data. Instead, the administering and determining steps are part of a treatment protocol, and they are transformative. [T]he administering step, therefore, is not merely data-gathering but a significant transformative element of Prometheus's claimed methods of treatment that is "sufficiently definite to confine the patent monopoly within rather definite bounds"', *ibid*, 1357.

119. See *infra* n 120.

120. See the Memorandum by AH Hirshfeld, Associate Commissioner For Patent Examination Policy (dated: March 21, 2012), available at: <http://www.uspto.gov/patents/law/exam/mayo_prelim_guidance.pdf> (accessed March 31, 2012).

121. *Ibid*.

Then, on March 26, 2012, the US Supreme Court rendered the following decision, *also referred to as a GVR*¹²²:

ASSN. FOR MOLECULAR PATHOLOGY V MYRIAD GENETICS, ET AL. The petition for a writ of certiorari is granted. The judgment is vacated, and the case is remanded to the United States Court of Appeals for the Federal Circuit for further consideration in light of *Mayo Collaborative Services v Prometheus Laboratories, Inc.*, 566 U.S. ____ (2012).¹²³

On remand to the Federal Circuit various outcomes seem possible. Since the only method claim that had been upheld by the Federal Circuit in *AMP v USPTO*, that is claim 20 of Myriad's US Patent No. 5,747,282, involves more human manipulation (of a cell) and an arguably more genuine application of a natural phenomenon (drug screening) than in *Mayo*, it appears rather unlikely that the Federal Circuit would invalidate this claim in light of *Mayo*.

The situation appears more complex with regard to the claims on the isolated DNA sequences. Obviously, the Supreme Court decision in *Mayo* was directed to method claims. However, several statements made by the Supreme Court could be interpreted to indicate that the claims directed to isolated, genomic DNA would probably have to be invalidated by the Federal Circuit, while the claims directed to cDNA would withstand the challenge.¹²⁴ On the other hand, much will depend on the Federal Circuit's interpretation of *Mayo*. After all, the Court in *Mayo* did not overturn *Diehr* and *Chakrabarty*. Bearing in mind that some judges at the Federal Circuit, such as J Lourie and J Moore were not willing to invalidate Myriad's claims on genomic DNA, they might construe the 'isolated' limitation to be sufficient to hold the claim to be a patent-eligible genuine 'application' of the phenomenon. Although not being part of the panel in *AMP v USPTO*, Chief Judge Rader also appears to follow this line of thinking, while other Judges, such as J Bryson and J Dyk, have expressed opposing views. It is evident that if the Federal Circuit would uphold Myriad's claims on genomic DNA, the case might return to the Supreme Court like a 'boomerang'.

Be that as it may, these groundbreaking developments and their potentially significant, but not necessarily devastating, impact on personalized medicine, diagnostics and biotechnology will be described and discussed in more detail in the next issues of QMJIP, as well as in Part IV of this paper. Stay tuned and follow the exciting developments in this 'year of patent-eligibility'.

122. I.e. the Supreme Court **G**rants certiorari, **V**acates the previous judgment and **R**emands it to the Federal Circuit (= GVR).

123. See Order List: 566 U.S., Monday, March 26, 2012, No. 11-725, available at <<http://www.supremecourt.gov/orders/courtorders/032612zor.pdf>> (accessed March 27, 2012).

124. As explained in Part I, the isolated DNA claims of the patents in suit in *AMP v USPTO* fall into two categories. The first category of claims is directed to isolated sequences that are identical to naturally occurring gene sequences. These include claims encompassing both the isolated full length gene sequence (eg claim 1 of '282 patent), which are thousands of nucleotides, and claims to shorter isolated DNA strands, with as few as 15 nucleotides, whose nucleotide sequence is found on the chromosome (eg claim 5 of '282 patent). The second category of claims is directed to isolated DNA sequences that are different from the naturally occurring gene sequences. These include claims to isolated cDNA molecules (eg claim 2 of the '282 patent), which differ from the natural gene sequence in that the introns are removed, and are the opposite (complementary) sequence of the naturally occurring RNA. Cf. Judge Moore supra n 3, at 1365 (adding: '[t]he ability to use isolated DNA molecules as the basis for diagnostic genetic testing is clearly an "enlargement of the range of ... utility" as compared to nature', because '[t]he same sequence, as it appears in nature as part of the chromosome, simply cannot be used in the same way').