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# Separating sheep from goats: a European view on the patent eligibility of biomedical diagnostic methods

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As is evident from Dan Burks' excellent paper<sup>1</sup> and critique, the Supreme Court's decisions in *Mayo*, *Myriad* and *Alice* and the CAFC's in *Roslin*<sup>2</sup> focused widespread attention on the formulation of patent-eligibility exclusions for specific biological material and diagnostic methods.

The debate recently intensified with the CAFC's *Sequenom* decision and denial of a rehearing *en banc*.<sup>3</sup> The claims at issue in U.S. Patent No. 6,258,540 ('US '540 patent') are directed to methods of genetic testing by detecting and amplifying paternally inherited fetal cell-free DNA from maternal blood and plasma.<sup>4</sup> Before the development of

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<sup>1</sup> Dan L. Burk, *Dolly and Alice*, J. L. BIOSCI. 2, 606–626 (2015) DOI:10.1093/jlb/lsw042.

<sup>2</sup> See *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S., 132 S.Ct. 1289, 182 L.Ed.2d 321 (2012) ('*Mayo*'); *Association for Molecular Pathology v. Myriad Genetics, Inc.* U.S. 133 S. Ct. 2107, 186 L.Ed.2d 124 (2013) ('*Myriad*'); and *Alice Corporation Pty Ltd v. CLS Bank International U.S.*, 134 S.Ct. 2347, 189 L.Ed.2d 296 (2014) ('*Alice*'), *In re Roslin Institute 750 F.3d 133* (Fed. Cir. 2014) ('*Roslin*').

<sup>3</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* 788 F.3d 1377 (Fed Cir. 2015) ('*Sequenom*') and *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 802 F.3d 1282, 1286 (Fed Cir. 2015) ('December 12 Order') (*Per curiam* Order Denying petition for rehearing *en banc*.); petition for cert. filed, sub nom. *Sequenom, Inc., v. Ariosa Diagnostics, Inc.* 2016 WL 1105544 (U.S. Mar. 21, 2016) (No. 15–1182.).

<sup>4</sup> See claim 1 of the US '540 patent U.S. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

this non-invasive prenatal diagnostic test, patients were placed at higher risk and maternal plasma was routinely discarded as waste.

A reluctant CAFC formulaically interpreted the Supreme Court-devised bifurcated test<sup>5</sup> to identify patent ineligible subject matter and invalidated the patent for this ground-breaking method. Notably, Judge Linn wrote that this innovation deserves patent protection, but that the ‘sweeping language of the test’ established in *Mayo* requires a determination that the claims are patent ineligible.<sup>6</sup> On March 21, 2016, *Sequenom Inc.* filed for *certiorari*<sup>7</sup> and the issue may once again find itself at the Supreme Court. As framed by *Sequenom*, the question presented is:

Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?

Interestingly, in Europe the EPO upheld essentially the same claims.<sup>8</sup> European equivalents of the patents considered in *Myriad*, *Mayo*, *Alice* and *Roslin* were also treated differently than in the USA.<sup>9</sup> Hence, these cases undermine the global integration of patent standards and provide fodder for discussing patentability requirements at an international level.

Referring to these developments, our brief comment complements Burk’s paper by discussing these issues from a comparative European perspective. Section 1 provides a very brief summary of the European patent framework and case law regarding medical diagnostic methods. Leaving aside national peculiarities that would exceed the limitations of this short paper, we focus on the EPO’s patent eligibility approach vis-à-vis medical diagnostic methods similar to those in *Sequenom v. Ariosa*. Section 2 discusses our findings and the differences between the USA and European approaches from a broader innovation and patent policy perspective providing the basis for concluding remarks in Section 3.

## 1. EXCLUSIONS AND EXCEPTIONS TO PATENTABILITY IN A EUROPEAN CONTEXT

Apart from international patent treaties, such as the TRIPS agreement<sup>10</sup> and the PCT<sup>11</sup>, patent law in Europe is primarily governed by three European legal

<sup>5</sup> *Alice* 134 S. Ct. at 2355 set out this test as first identifying whether the claims were ‘directed’ to patent ineligible subject matter and, if so asking “[w]hat else is there in the claims before us?” Adding to the confusion, *Alice* describes step two as a ‘search for “an inventive concept”’ to ensure that the patent is ‘significantly more’ than a patent on the ineligible subject matter. *Id.*

<sup>6</sup> 788 F.3d at 1380 (Linn Concurring.)

<sup>7</sup> 2016 WL 1105544 (U.S. Mar. 21, 2016) \*1.U.S. S. Ct.- Case No. 15-1182.

<sup>8</sup> Case T-146/07 of Dec. 13, 2011 (Non-invasive prenatal diagnosis/ISIS INNOVATION LTD).

<sup>9</sup> Cases T-1213/05 (Breast and ovarian cancer/UNIVERSITY OF UTAH) of Sept. 27, 2007; T-666/05 (Mutation/UNIVERSITY OF UTAH) of Nov. 13, 2008; T-80/05 (Method of diagnosis/UNIVERSITY OF UTAH) of Nov. 19, 2008; T-156/08 (BRCA2/ UNIVERSITY OF UTAH) of Jan. 14, 2011; EP 849990 B1 2001 and EP847237 B1 2008 (PCT/GB96/02099 and PCT/GB96/02098) (Roslin Institute (Edinburgh)).

<sup>10</sup> Agreement on Trade Related Aspects of Intellectual Property Rights. Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on Apr. 15, 1994, (‘TRIPS’) 1869 UNTS 299. Cf Article 27 (1) TRIPS.

<sup>11</sup> Patent Cooperation Treaty, Done at Washington, June 19, 1970, in force Jan. 24, 1978, as amended, (‘PCT’) 28 UST 7645.

sources.<sup>12</sup> The European Union ('EU') promotes the internal harmonization of substantial and procedural patent law, prosecution, and litigation, most notably through the emerging European unitary patent and litigation system set out in the rules of the so-called European patent package and the draft rules of procedure. In addition, the Biotech Directive<sup>13</sup>, which was incorporated into the implementing regulations<sup>14</sup>, significantly affects the way biotech inventions at the EPO are assessed (although the EPO is not formally bound by EU law).

Article 52(1) EPC provides that European patents shall be granted for any inventions, in all fields of technology, provided, that they are new, involve an inventive step, and are susceptible of industrial application. Most importantly, patents must display a 'technical invention' as confirmed by the implementing regulations to the EPC, which emphasize that the invention must have *technical features* (Rule 43(1)), which relate to a technical field (Rule 42(1)(a)) and are concerned with a technical problem (Rule 42(1)(c)).

In contrast to the USA, case law-based patent law exclusions, patent claim ineligibility under the EPC is codified in the form of 'exclusions' and 'exceptions'. EPC Article 52(2) explicitly codifies exclusions, at least if they are claimed 'as such'. Article 52(2) excludes claims that are abstract in nature (discoveries) or non-technical in nature (scientific theories or methods for performing mental acts). These are considered 'non-inventions' 'whose common feature is a substantial lack of technical character'.<sup>15</sup> The test for whether or not a claimed invention claims excluded matter 'as such' first looks to the technical features claimed.<sup>16</sup> In Opinion G 3/08, a case having much in common with *Diamond v. Diehr*<sup>17</sup>, the EPO's Enlarged Board of Appeals reasoned that it was vital, especially in new fields of technology, to carefully examine all of the claims to determine the dividing line between excluded and permissible matters.<sup>18</sup>

<sup>12</sup> These are the Convention on the grant of European Patents Done at Munich Oct.5, 1973, in force Oct. 7, 1978, 1065 UNTS 199, as revised by the Act revising Article 63 EPC of Dec. 17, 1991 and the Act revising the EPC of Nov. 29, 2000 ('EPC'). See also OF 4/2007 Revision of the European Patent Convention (EPC 2000); The EU 'patent package' consisting of the UPCA OJ 2013 C 175/1; Regulation (EU) No. 1257/2012 OJ 2012 L 361/; and Council Regulation (EU) No. 1260/2012 OJ 2012 L 361/89; and the Preliminary set of provisions for the Rules of Procedure ('Rules') of the Unified Patent Court, 18th draft of July 1, 2015; see also Implementing Regulations to the EPC of Oct. 5, 1973 as amended ('IR').

<sup>13</sup> Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the legal protection of biotechnological inventions, OJ 1998 L 213 ('Biotech Directive' or 'Directive 98/44').

<sup>14</sup> Decision of the Administrative Council [of the EPO] of June 16, 1999 OJ EPO 1999, p. 437-440 and 573 ff.

<sup>15</sup> Opinion G 02/13 of Mar. 25, 2015 (Tomato II/Broccoli II) ('Opinion G 02/13') VII Application of the Rules of Interpretation 2. (3) (a). The case concerned a Product by Process which Burke points out is implicated in Roslin.

<sup>16</sup> Opinion G 2/88 of Dec. 11, 1989 (Friction reducing additive/MOBIL OIL III) ('Opinion G 2/88') Reasons at 8.

<sup>17</sup> *Diamond v. Diehr*, 450 U.S. 175, 188–190 (1981) ('*Diamond v. Diehr*').: In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. ... The 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.

<sup>18</sup> Opinion G-3/08 of May 12, 2010 (computer-implemented inventions, CIIs), OJ EPO 2011, 10, reasons point 13 ff., see also note 24 in the Reasons for the Decision Point 7.3.4. ('Where jurisprudence enters new legal territory, caution is required to avoid making statements that will prove untenable in the very next case to arise'.)

Accordingly, excluded matter is not hived off from permissible matter in considering the claims since ‘features which would, taken in isolation, belong to the matters excluded from patentability by Article 52(2) EPC may nonetheless contribute to the technical character of a claimed invention, and therefore cannot be discarded in the consideration of the inventive step’.<sup>19</sup> Opinion G 2/88 further demonstrates that the EPO has long recognized that when an idea or concept underlying the claimed subject matter resides in a discovery, it does not necessarily mean the claimed subject matter is a discovery as such.<sup>20</sup> Consequently, the current November 2015 EPO Guidelines distinguish a mere discovery from a practical application of that discovery as follows:

If a new property of a known material or article is found out, that is mere discovery and unpatentable because discovery as such has no technical effect and is therefore not an invention within the meaning of Art. 52(1). If, however, that property is put to practical use, then this constitutes an invention which may be patentable. [...].<sup>21</sup>

In addition to Article 52 (2) EPC, Article 53 EPC sets forth five main groups of inventions for which no patent may be granted (‘exceptions’) but ‘does not envisage a system of general exceptions to patentability that per se would allow or even necessitate a broad interpretation of any of the exclusions’.<sup>22</sup> EPC Article 53 (c) codifies the ‘exception’ of medical diagnostic methods and methods of treatment practiced on the human body.

In Opinion G 1/04 ‘Diagnostic methods’, the EPO’s Enlarged Board of Appeal held that ‘Diagnostic methods practiced on the human body’ encompass the following consecutive steps: (1) an examination phase involving the collection of data, (2) comparison of the results with standard values, (3) identifying any significant deviance, that is, a symptom, during the comparison, and (4) the attribution of the deviance to a particular clinical picture, that is, the deductive medical or veterinary decision phase.<sup>23</sup>

The Enlarged Board’s organization of the reasoning into a four-part examination<sup>24</sup> is significant in comparison with *Mayo*’s broader, less focused deductive approach.<sup>25</sup> Additional statements from the Enlarged Board in Opinion G 1/04 are also significant. First, ‘diagnosis’ with regard to the exception of diagnostic methods practiced on the human body was defined as ‘the determination of the nature of a medicinal condition intended to identify a pathology’,<sup>26</sup> and that to determine the scope of the exclusion all of the steps must be considered.<sup>27</sup> The Board also found that, for purposes of

<sup>19</sup> *Id.* at point 12.2.2 of the reasons (referring to T 0208/84 (Computer-related invention) of 15.7.1986).

<sup>20</sup> Opinion G 2/88, point 9.3.

<sup>21</sup> Cf. Guidelines for Examinations in the EPO, November 2015 version, Part G - Chapter II-3.1, 1 [http://documents.epo.org/projects/babylon/eponet.nsf/0/A62ECC3718E570B3C1257EF100351F38/\\$File/guidelines\\_for\\_examination\\_part\\_g\\_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/A62ECC3718E570B3C1257EF100351F38/$File/guidelines_for_examination_part_g_en.pdf) (accessed Mar. 19, 2016) (examples omitted); regarding biotechnological inventions see also G-II, 5, 5.3 to 5.5, and G-III, 4.

<sup>22</sup> Opinion G 02/13 note 22, VII Application of the Rules of Interpretation 2. (3) (a).

<sup>23</sup> Opinion G-1/04 of Dec. 16, 2005 (Diagnostic methods) (“Opinion G-1/04”).

<sup>24</sup> *Id.* Reasons for the Opinion point 5.

<sup>25</sup> Cf. Opinion G-1/04 Reasons for the Opinion points 5-5.3 and, cf. *Mayo* 132 S. Ct. at 1299 (‘The claim simply tells doctors to measure the current level of the relevant metabolite, use particular laws of nature, calculate the current toxicity/inefficacy limits, and reconsider the drug dosage in light of the law of nature.’)

<sup>26</sup> *Id.* Reasons for the Opinion, point 5.1.

<sup>27</sup> *Id.* point 6.

determining exemption from patentability, the diagnostic method has to comprise all the steps mentioned above in points (1)–(4). Second, ‘practiced on the human body’ is a prerequisite, referring only to technical method steps, whereas the deductive decision phase itself is a non-technical, merely intellectual exercise.<sup>28</sup> The Board added the *caveat* that claims solely directed to a deductive decision phase are excluded pursuant to Article 52(2) EPC as concerning only mental acts.<sup>29</sup> All of these steps must be examined together due to the multistep nature of medical diagnosis.<sup>30</sup> Thus, to be patent eligible such methods must encompass preceding technical steps *not* practiced on the human body. Third, the Board clarified the status of diagnostic methods where some or all steps concern *in vitro* techniques in a laboratory not directly practiced on the human body. This includes genetic diagnostic methods, such the use of DNA microarrays or DNA sequencing. The Board considered such steps to be of a purely technical nature concluding that genetic diagnostic methods claiming these technical steps are, in principle, not excluded by Article 53 (c). Significantly, the Board held that method steps of ‘obtaining results or findings’ do not provide a sufficient basis for denying patentability under Article 53(c) EPC.<sup>31</sup>

Against this background, it is particularly interesting to see how the EPO dealt with the European counterpart of Sequenom’s ‘US ’540 patent’<sup>32</sup>, ie. European patent EP 994 963 (‘EP ’963’). Sequenom’s EP ’963 was examined and granted by the EPO and covered claims that are substantially identical to US claim 1 of the ’540 patent<sup>33</sup>. EP ’963 subsequently prevailed in a third-party opposition procedure, and even withstood even an appeal to the EPO Technical Boards of Appeal.<sup>34</sup> Interestingly, these proceedings did not deal with subject-matter eligibility, which—unlike the CAFC—appears to have been tacitly acknowledged by the EPO. Instead the EPO focused on determining if the method claimed were novel and inventive.<sup>35</sup>

To sum up, while patents directed to the isolated BRCA genes, related diagnostic methods, and claims similar to the claims at issue in *Sequenom* remain highly controversial in Europe, both legislation and case law regard them as patent eligible under EPC Articles 52 and 53.<sup>36</sup> The CAFC’s exceptionally restrictive interpretation of the *Mayo* and *Myriad* mandated ‘significantly more’ criteria in *Sequenom* do not exist in that form in European patent law and practice.

<sup>28</sup> *Id.* point 5.2.

<sup>29</sup> *Id.* point 6 (referring back to point 5.2.)

<sup>30</sup> *Id.* point 6.2.2.

<sup>31</sup> *Id.* point 6.2.3.

<sup>32</sup> *Cf. supra* note 2.

<sup>33</sup> Cf. claims 1 and 4 of European patent EP 994 963: A detection method performed on a maternal serum or plasma sample from a pregnant female, which method comprises detecting the presence of a nucleic acid of foetal origin in the sample, wherein said nucleic acid is a paternally inherited sequence which is not possessed by said pregnant female. [...] 4. A method according to [claim 1], wherein said detecting comprises amplifying said nucleic acid.

<sup>34</sup> See Case No. T 0146/07 - 3.3.08 (Prenatal diagnosis/ISIS) of 13.12.2011.

<sup>35</sup> *Id.*

<sup>36</sup> Cf. Robert M. Schwartz & Timo Minssen, *Life after Myriad: The Uncertain Future of Patenting Biomedical Innovation and Personalised Medicine in an International Context*, 3 INTELL. PROP. Q. 189 (2015) (adding that European legislation and case law appears to be more restrictive with regard to the scope of protection granted to patents utilizing isolated (human) DNA sequences. But this is not addressed in the framework of the patent eligibility standard).

## 2. DISCUSSION

Differences in patent law may be expected worldwide, but divergent approaches to genetic product and process patent eligibility institutionalize deep-seated differences in the approaches of different courts to new technologies, especially in the life sciences. *Sequenom's* disjunctive eligibility test deviates from the integrated approach of *Diamond v. Diehr*,<sup>37</sup> mirrored in the integrative European approach to patent ineligible subject matter. *Diamond v. Diehr* does not necessarily conflict with the holdings of the *Mayo*, *Myriad*, *Alice* trilogy.<sup>38</sup> However, as Judge Linn's *Sequenom* concurrence demonstrates, the CAFC believed that *Mayo* impliedly modified *Diamond v. Diehr* to eliminate all 'conventional activity' from the claims analysis.<sup>39</sup> He interpreted this as requiring the excision of any post solution activity that was purely obvious or conventional.<sup>40</sup> Such an interpretation threatens to rewrite the patent laws by combining the 'new and useful' of § 101 with the 'novelty' of § 102.<sup>41</sup> While it is unlikely that the US Supreme Court will revise the gravamen of its three recent decisions regarding patentable subject matter under 35 U.S.C. § 101, it may clarify the eligibility test they establish.

Although it appears as if both the European and the US eligibility standards share the common goals of excluding 'mere' discoveries from patentability, the contradictory US and European applications of patent eligibility standards expose fundamental discrepancies in the US's analytical approach. *Sequenom's* §101 test conflicts with the holistic, harmonized European approach to excepted or excluded subject matter. Its atomistic approach to claims eligibility threatens an over 20-year-old US policy encouraging global convergence of patent standards. As applied, it may violate international treaties to which the USA is a party.<sup>42</sup> These provisions include Rules 39.1 and 67.1 of the PCT and arguably Article 27 of the TRIPS agreement which were patterned on the Supreme Court's jurisprudence.<sup>43</sup>

Aside from disrupting and conflating traditional patent law doctrines, *Sequenom's* interpretation adds to the controversy over the future role of the patent system in enhancing biomedical innovation vis-à-vis complementary forms of protection, such as regulatory exclusivities and trade secrets.<sup>44</sup> We recognize that patents may not always be the most appropriate tool to enhance innovation and access to therapies in some specific areas of medical innovation. However, we believe that future innovation requires an efficient and more open collaboration among various stakeholders including governments, public authorities, patients, and the industry. Due to the disclosure requirement and its value for technology transfer, patents play an important role in such

<sup>37</sup> See *supra* note 13.

<sup>38</sup> *Diamond v. Diehr* was approvingly quoted (450 U.S. at 188) by *Alice* 134 S. Ct. at 2355 n. 3.

<sup>39</sup> *Sequenom*, 788 F.3d 1380 (Linn concurring).

<sup>40</sup> *Id.* J. Linn was not alone, as one of the judges concurring in *Sequenom* and three judges (including Linn) concurring in the December 12 Order, believed that they were left with no discretion despite concerns over the test's detrimental effect on life science innovation., cf. J. Lourie and Moore's concurrences, *supra* note 3, 802 F.3d at 1286.

<sup>41</sup> Cf. *Diamond v. Diehr*, 450 U.S. at 188, 190 (holding that it is inappropriate, especially in the context of 'processes', to consider old and new elements in isolation because it would import 'novelty', from §102 into §101).

<sup>42</sup> See U.S. Const. Art. VI, cl. 2.

<sup>43</sup> Cf. Decision G-1/07 of Feb. 15, 2010 (Treatment by surgery-MEDI-PHYSICS) VIII The comments made by the President of the EPO, 4. International patent law and practice. (Pointing out that EPC (1973) Article S2 (4) was based on PCT Rules 39.1 and 67.1 and Article 27.3 (a) of TRIPS.)

<sup>44</sup> Cf. Arti K. Rai & Jacob S. Sherkow, *The Changing Life Science Patent Landscape*, 34 NAT. BIOTECH. 292 (2016).

collaborations<sup>45</sup>, whereas trade secret protection might result in unwanted information bottlenecks and regulatory exclusivities are not adequately available for diagnostics. Without appropriate complementary forms of protection or alternative incentives in place, and considering the broader spill-over impact of the CAFC's interpretation, we believe that these developments will not only be detrimental to innovative medical diagnostics, but also harm the development of other (medical) technologies and hence patients worldwide.<sup>46</sup> A more developed and instructive analytical framework is needed to give more useful guidance to lower courts and to ultimately achieve reasonable results and legal certainty.

Significant differences in eligibility standards strain the operation of and cooperation among, the Trilateral Offices (USPTO, EPO, and the Japanese Patent Office, JPO) *inter alia* increasing the cost and complexity of obtaining triadic patent family protection in the life sciences.<sup>47</sup> They raise costs by threatening economies of scale, create uncertainty, and risk fragmenting the global delivery system for innovative medicinal products and diagnostics. They can also disrupt the existing balance among different forms of IP protection sought by technology innovators.

We believe that a more holistic application of the Supreme Court's patent-eligibility rationale would better support investment in biopharmaceutical innovation and the development of innovative treatments and precision medicine towards market approval. Such approach would go a long way towards assuring that differences among the world's patent law systems do not create unnecessary compliance costs ultimately borne by consumers of medical care.

Both in Europe and in the USA, concerns have been raised about overly preemptive patents scope, but these are addressed at different levels. In our view, and as pointed out in Dan Burk's paper, the current approach conflates the patent eligibility test with issues that could be more sensibly addressed within a strict and coherent assessment of novelty, non-obviousness, and sufficient disclosure criteria or on the post-grant level. To transplant those issues into the patent eligibility, assessment might categorically close the patentability door to many well-defined and beneficial inventions that otherwise deserve patent protection corresponding to the inventors actual contribution to the state of the art.

If the CAFC's restrictive interpretation should prevail, however, we believe that it will be crucial to swiftly optimize the framework for regulatory exclusivities on an international level to allow for greater flexibilities and encompass further technological areas, such as biomedical diagnostics. Article 39 of the TRIPS agreement should provide sufficient leeway for such changes.

### 3. CONCLUDING REMARKS

The argumentation framework established in *Mayo*, *Myriad* and *Alice* as interpreted by *Sequenom* stands in clear contrast to current European legislation and practice. Such decisions can exert significant influence on European debates and patent practices.

<sup>45</sup> See also Dan L. Burke, *Patents as Data Aggregators in Personalized Medicine*, 21 B.U. J. SCI. & TECH. 233 (2015).

<sup>46</sup> Cf. Rachel Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. DAVIS L. REV. (2016). SSRN <http://ssrn.com/abstract=2596875> (last accessed June 1, 2015).

<sup>47</sup> Triadic patent families are a set of patents granted by the EPO, JPO, and the USPTO which share one or more priorities. OECD Patent Statistics Manual (OECD Publishing 2009) Ch. 1 Glossary.



Legal developments in patent law, while local in immediate effect, migrate within an increasingly global economy and may destabilize the objective of harmonizing an efficient world patent system. Disruption in one pathway easily spills over into others. It is important to identify potential conflicts early and rectify them before positions become path dependent and resistant to resolution. In innovative, not well-understood technologies, courts tasked with supervising patent law should give clear signals that all of the moving parts must be as carefully considered as possible. Too *static* legal interpretations in high-tech patenting might dry up the wells supplying technological progress.

*Sequenom* provides an opportunity to clarify the patent eligibility tests enunciated in the Court's recent case law. The patent claims' scope were forensically construed in a *Markman* proceeding<sup>48</sup> and have already been examined during an USPTO *inter partes* review.<sup>49</sup> In addition, the patent includes not only relatively broad independent claims, but also well-defined dependent claims directed to individual tests. While well-defined method claims may also be found in *Mayo*, it remains unclear whether the Supreme Court intended to import the policy considerations of *Mayo* into a product of nature analysis. Although *Sequenom*'s claims are clearly process claims, they still involve products of nature.

We therefore urge a clarification of the US's patent eligibility test more in line with the Supreme Court's longstanding jurisprudence, and in harmony with international and European law to accomplish a more uniform culling of unpatentable goats from patentable sheep.

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<sup>48</sup> *Ariosa Diagnostics, Inc., v. Sequenom, Inc.*, 2013 WL 5701532 (N.D. Cal. Oct. 16, 2013) (not reported in F.Supp.2d.)

<sup>49</sup> Another question is of course whether the USPTO could have better advised the applicant during those proceedings, and if the broader claims should have been granted in the first place.