ARIOSA v SEQUENOM – A PATH TO THE SUPREME COURT?

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There is no point in crying over spilled milk. The denial of an *en banc* hearing in the above case[1] is now history. Apart from looking at the small print for pointers towards a more moderate approach, the focus now shifts to the expected petition for certiorari.

Rule 10 of the Supreme Court Rules explains that grant of certiorari is discretionary, is given only for compelling reasons and is unlikely merely when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law. However, certiorari may be granted where a US court of appeals has decided an important federal question in a way that conflicts with relevant Supreme Court decisions or other court of appeal decisions or where there is an important question of federal law that has not been, but should be, settled by the Court.

It is strongly arguable that natural principle/product of nature exception to §101 eligibility in the pharmaceutical, medical and biotechnology arts is an important and at present insufficiently settled question of federal law. It will be recalled that those filing *amicus* briefs supporting *en* banc reconsideration included:

industry and professional organizations: The Intellectual Property Owners Association (IPO), The Biotechnology Industry Organization (BIO), The Pharmaceutical Research and Manufacturers of America, The Bioindustry Association (BIA), the New York Intellectual Property Law Association and the Coalition for 21st Century Medicine (Coalition);

[1] http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/14-1139.Order.11-30-2015.1.PDF

academic commentators: Adam Mossoff and other law professors (23 Professors) and a further brief from Professors Jeffrey Lefstin and Peter Menell;

research institutions: The Wisconsin Alumni Research Foundation, Amaranthus Bioscience Holdings, Population Diagnostics Inc. and Jyant Technologies; and

foreign commentators: Novartis AG (Switzerland) and Cole (UK).

The weight of concern expressed by institutions, the academic community and industry and their collective willingness to expend time and effort in explaining their concerns provides compelling evidence that an important question of federal law is at stake, and this concern has been acknowledged in the opinions of the judges deciding the *en banc* petition.

The abundance of conflicting authority identified in the petition and in the various *amicus* briefs also evidences the need for Supreme Court review. No less than 23 earlier Supreme Court authorities were argued in the Petition and by the *amici* to be conflicting: *Alice v CLS Bank, Association for Molecular Pathology v Myriad, Bilski v Kappos, Carnegie Steel v Cambria Iron*, *Dann v Johnston, Diamond v Chakrabarty, Diamond v Diehr, Dolbear v American Bell*, *Eibel Process v Minn & Ont. Paper*, *Funk Brothers v Kalo, Gottschalk v Benson, Graham v John Deere, Hartranft v Wiegmann, KSR v Teleflex, LeRoy v Tatham, Macay Radio v Radio Corporation of America, O'Reilly v Morse, Parker v Flook, Tilghman v Proctor, United States v Adams, Washburn v Beat-'Em All Barbed Wire, Webster Loom v Higgins* and *Wisconsin v Pelican.* A host of other authorities from inferior courts were also identified as conflicting, e.g. *Cameron Septic Tank v Saratoga Springs, Kuehmsted v Farbenfabriken of Elderfeld, Merck v Olin Mathieson, Park-Davis v Mulford* and *Research Corporation v Microsoft*.

Rule 14 requires a petition to begin with the questions presented for review expressed concisely in relation to the circumstances of the case.

It is arguable that the key question is defined most concisely and aptly at page 5 of the brief of Lefstin and Menell and is whether *Mayo* requires a new discovery to be applied by unconventional means[2].

[2] See also the question at page 1 of the Petition, proviso 2, Cole's question 1 at page 2 and the IPO brief questioning the threshold for "sufficiently more than just patent-ineligible subject matter".

An affirmative answer to that question, as held in the panel opinion and the concurring opinions accompanying the *en banc* decision, cannot be reconciled with existing authority as explained in the 23 Professors brief and by Cole. Indeed, as argued in an earlier article[3] such an approach was considered and rejected by the UK Court of Appeal and contradicts what is said elsewhere in the *Mayo* opinion which it is submitted should be considered and applied as a whole:

> "In effect the *Mayo* rule corresponds to the "contribution approach" suggested at first instance in the UK in *Merrill Lynch's Application* [1988] R.P.C. 1 which was to consider whether the inventive contribution resided only in excluded matter. That approach also has its difficulties and it was rejected by the UK Court of Appeal in *Genentech's patent* [1989] R.P.C. 147 where it was observed that: "Such a conclusion, when applied to a discovery, would seem to mean that the application of the discovery is only patentable if the application is itself novel and not obvious, altogether apart from the novelty of the discovery. That would have a very drastic effect on the patenting of new drugs and medicinal or microbiological processes."
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> The Supreme Court acknowledges that the rule ought not to be interpreted to cover newly discovered first or subsequent medical indications for a known substance (slip opinion at page 18): "Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws."
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> It is, however, less than clear by what logic new drugs escape the rule in *Mayo* but the Prometheus test is caught by that rule. For example, nitroglycerin was first synthesized in 1847 and was used as an explosive. In 1878 it was introduced as a treatment for angina by Dr William Murrell. Suppose Dr Murrell had claimed a pharmaceutical composition for the treatment of angina or other heart conditions comprising nitroglycerin and a pharmaceutically acceptable carrier or diluent. The anti-angina activity of nitroglycerin could be regarded as a mere phenomenon of nature "though just discovered", the reference to treatment of cardiac disorder could be a mere limitation to a particular technological environment and formulation into tablets or other forms for convenient administration to the

[3] Paul Cole, *Prometheus v Mayo – a European view*, [2012] CIPA Journal, 270-273

> patient could be regarded as an insignificant post-solution activity since the incorporation of active ingredients into tablets or other dosage forms was well known long before 1878. The pharmaceutical composition claim which is in standard form for a first medical indication would block research into further formulations and further medical indications for nitroglycerin. Indeed, blocking further development was an objection raised in the 1790's to James Watt's patent for a steam engine. It might be said that the hypothetical Murrell claim confines the reach of what has been discovered to the particular application of pharmaceuticals but it might equally be said that the Prometheus claim confines the reach of what has discovered to the particular application of a blood test for metabolites of drugs of a particular family. If there is a distinction, arguably it is no more than pragmatism."

It is clear on the face of the *Mayo* opinion that the appropriate reaction of the lower courts to the *Mayo* two-part test should have been flexibility and refinement, not literalism and over-extension. Justice Breyer himself warned in *Mayo* that "too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon or apply laws of nature, natural phenomena or abstract ideas" and that "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." A flexible rather than a rigid approach was recommended by the Supreme Court in *KSR*, and in *Bilski* the majority opinion, over a careful and considered dissent by Justice Stevens, rejected new categorical exclusion (23 Professors).

Judges Lourie and Moore, concurring in denial of *en banc* rehearing in the present case, concluded that there was no principled basis to distinguish the present case from *Mayo* as regards the requirement for post-solution activity even though: "it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps…" The concurring opinion of Judge Dyk also expressed concern about an unduly restrictive eligibility test and the need for further guidance from the Supreme Court as to the *Mayo* two-step framework, noting that: "In my view, *Mayo* did not fully take into account the fact that an inventive concept can come not just from creative, unconventional application of a natural law, but also from the creativity and novelty of the discovery of the law itself", pointing to possible inconsistency between *Mayo* and *Myriad*. Judge Newman in her dissenting opinion pointed out that the new diagnostic method was novel, unforeseen,

of profound public benefit, and represented a significant breakthrough in the medical field warranting standard legal analysis in accordance with *O'Reilly v Morse*. Judge Linn, in his panel opinion, expressed regret that as a possibly unintended consequence of the broad language in *Mayo* a meritorious invention had been excluded from the protection that it deserved and should have been entitled to retain.

Novartis questioned whether claimed subject matter can contain an inventive step for the purpose of §103 but lack an inventive concept under §101 pointing in particular to *Diamond v Diehr*, and similarly Cole questioned how relevant to the natural phenomenon exclusion of §101 is a new and beneficial result never obtained before and evidencing inventive step under §103, citing opinions from *Webster Loom v Higgins* to *KSR*. Again this is a precedent-setting issue of exceptional importance, and the present case provides a paradigm example. The equivalent European patent survived opposition challenge for lack of inventive step, see EPO appeal decision T 0146/07 *Prenatal diagnosis/ISIS* and the existence of inventive step was implicitly recognised both in the panel opinion and in *the en banc* concurring opinions. It is submitted that this provides a second important question of federal law that deserves the attention of the Court.

The panel opinion has been said to be internationally discordant rather than harmonious. The BIA brief emphasized conflict with equivalent standards in other jurisdictions and frustration of long-term harmonization efforts, and Cole raised the same issue in the context of Article 27 of the TRIPS agreement. Whether a treaty that the US sponsored should be an at least persuasive authority in US national jurisprudence is arguably a third question of exceptional importance notwithstanding the recent Australian decision in the BRCA1 case.

As to whether the present case provides an appropriate vehicle for considering the three questions raised above, it is difficult to see how there could easily be a better one. The invention was made at Oxford University which is one of the leading research universities of the world and it has received great academic acknowledgement. The claimed subject matter has been held to be ineligible, but on the materials before the court there is little question that it is inventive. A majority of the written opinions in the Federal Circuit either call for reconsideration of the most relevant Supreme Court authority or have concluded that it is inapplicable, citing other authority. The field of arguably conflicting decisions, as explained above, is very wide. Furthermore, the findings in the joint opinion of Lourie and Moore point strongly towards the claimed subject matter being a new and useful process

covered by the clear wording of §101, and it is difficult to see how the test in *Mayo* applied the breadth attributed to it by the Federal Circuit avoids reading limitations and conditions into patent law that the legislature has not expressed, contrary to principles of statutory construction recapitulated by Justice Rehnquist in *Diamond v Diehr*.

It is to be hoped that a petition for certiorari will be both filed and granted, that the Court will be assisted by advocates with a depth of experience in and knowledge of patent law as opposed, for example, to the distant field of civil rights as in *Myriad*, that *amici* will provide knowledgeable and constructive viewpoints, that the oral argument will demonstrate a grasp of the relevant law and the underlying facts by both the Justices and the advocates, and that the outcome will be a fairer and more workable approach that will help restore international respect for the US jurisprudence in this field.

December 2015

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