In The Press:
IP Watch Reports on US, EU Diverge On Medical Diagnostic Patents

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A recent article in the journal Nature Biotechnology finds that since a key United States Supreme Court decision, the European Union and United States have diverged in their patent filings for medical diagnostics.

The article, authored by Brian Amos and Alan Miller, attorneys with Amster, Rothstein & Ebenstein, LLP, in New York, tracks the status of 31 international patent applications which claimed diagnostic or prognostic methods filed in 2013 in the US and EU. While 30 of the applications filed in the European Patent Office have either matured into patents or are still pending, 29 of the same applications in the United States have been either abandoned after receiving what the authors refer to as a “Mayo” rejection, or are still pending after receiving this rejection.

This term refers to the decision in “*Mayo Collaborative Services v. Prometheus Laboratories, Inc*.” of 2012. In the case, Prometheus Laboratories had patented a diagnostic kit which was able to determine the correct dosage level for some medications used to treat autoimmune diseases. As different patients metabolised the medicines differently, the diagnostic test could determine metabolite levels in the individual patient’s blood so that a physician could either raise or lower dosage based upon patient needs.

Mayo Collaborative Services then created their own diagnostic test, and Prometheus sued for patent infringement. The US Supreme Court determined that the patent was invalid, stating that the connection of metabolites produced by patients and potential changes to medicinal dosage was a “natural law”, and therefore unpatentable. The method of determining dosage was also determined to be routine and conventional, used by scientists in the field prior to the patent.

Amos and Miller argue that the disjunction between the US and European requirements for diagnostic patent eligibility hinder global patent harmonisation. While the EU does place limits on diagnostic patents, it does not prohibit them outright. Amos and Miller explain that a rejection on the same grounds of Mayo in the EU would amount to a rejection based upon lack of ‘industrial applicability’. While 30 of the patents studied had objections in the EU based upon questions of novelty, inventiveness or clarity, none had objections which corresponded to a US Mayo rejection.

The authors acknowledge that it is not possible to completely attribute the abandonment of a patent to the receipt of a Mayo objection, but argue that the case does appear to have special importance in the fate of US diagnostic patents. They point out that prior to the decision, the US permitted more diagnostic patents than the European Patent Office in a sampling of 20 applications.

The authors recommend that innovators file patents in Europe for diagnostic methods in order to protect their intellectual property. They also point to the US Supreme Court’s refusal to hear a case on a similar matter as indication that the US Congress may need to be involved to change the law.

Clarifying to *Intellectual Property Watch* their position on potential congressional involvement, Amos and Miller said they felt the decision and subsequent law were unnecessary. “[I]n our view,” they said, “judge-made law has only served to create a complete muddle regarding what constitutes patent-eligible subject matter. Our hope is that Congress will step in and clarify this situation since the federal courts have so far seemed unable or unwilling to do so.”

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