Patentability of Diagnostic Claims: In light of Bilski (U.S.) and Amazon (Canada)

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Both the United States and Canada have recently signaled that a less strict approach be used when assessing patentability. This more relaxed approach is tentatively good news for biotechnology stakeholders, especially those with particular interest in diagnostics.

In the United States, the Supreme Court decision in *Bilski v. Kappos*, which related to a business method patent, rejected the strict machine-or-transformation test for assessing patentability but did reiterate that laws of nature, abstract ideas, and physical phenomena are not patentable. In rejecting the strict test, the Court still maintained the machine-or-transformation test as a useful indicator of patentability but stated that it is not the sole test. The Supreme Court failed to provide further guidance on what other factors should be considered if the machine-or-transformation test is not satisfied. They also did not comment on the patentability of medical diagnostic methods. Biotechnology stakeholders await the U.S. decisions in *Classen Immunotherapies Inc. v. Biogen Idec, Prometheus Laboratories Inc. v. Mayo Collaborative Sciences*, and *Association of Molecular Pathology v. USPTO*, (Myriad) for guidance on the patentability of diagnostic methods (for further details see: What to do after Bilski?).

In Canada, the recent *Amazon.com v. The Commissioner of Patents* decision also addressed the patentability of business methods. In this decision, the Federal Court rejected the “form and substance” approach and the technological requirement for patentable subject matter relied upon by the Commissioner of Patents. The Court went arguably further than the U.S. *Bilski* decision as it endorsed a test that contemplates inventions in which a “physical effect” is not present. The focus for *Amazon* is on the practical application that the method as a whole provides, on the new and inventive method applying skill and knowledge, and on whether such method yields a commercially useful result. Such a test bodes well for diagnostic method claims since most diagnostic method claims can be drafted to provide more than a mere scientific principle or abstract theorem and in the emerging era of personalized genetics clearly offer a commercially useful result. *Amazon* was appealed by the Commissioner of Patents and The Attorney General Of Canada on November 15, 2010.

In view of the above, and until a decision that directly considers diagnostic methods has issued in each jurisdiction, we recommend that method claims be drafted in order to avoid objections that the methods amount to no more than mere inspection or mere abstract ideas, both of which would fail the test in Bilski, and likely *Amazon*. For example, physical steps, such as “determining,” “measuring” and “administering,” should be included as part of the independent diagnostic method claims. Particular methodology, such as specific primers and probes useful in conducting the methods, should be inserted into dependent claims.

Thus, we await further decisions specific to diagnostic patents in both Canada and the United States. It is hoped that the Courts will affirm the patentability of diagnostic claims to provide incentive for inventors, owners, and investors to continue to pursue biotechnology research.

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