Patentability of Diagnostic Methods in the wake of Amazon.com

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The Federal Court of Appeal (FCA) recently issued its decision in respect of Amazon.com’s (Amazon) “one-click” patent application. Although Amazon’s application pertains to a business method, this case could impact the patentability of diagnostic methods in Canada.

The Commissioner of Patents (Commissioner) initially rejected Amazon’s claims, setting out a new test for determining patentable subject matter. The test applies a “form and substance” analysis, adopted from Schlumberger, that involves parsing a claim into novel and non-novel elements and determining where the contribution over the prior art, or “invention”, lies. If the invention lies in an element deemed to be non-patentable subject matter, such as an algorithm or mental process, then the claim is rejected on that basis.

Following the Commissioner’s decision, Canadian patent examiners began rejecting diagnostic method claims if the invention was deemed to lie in the step of making a correlation between a disease indicator and a disease. It was argued that the step of correlating, or the like, is a mental step that constitutes non-patentable subject matter.

Amazon appealed to the Federal Court (FC), who overturned the Commissioner’s decision and followed the Supreme Court (SC) in Whirlpool, holding that a “purposive construction” should be applied in all cases. According to the principles of purposive construction, it is inappropriate to parse a claim into individual elements in order to evaluate patentability. The claim must be viewed as a whole. The FC found that, on a purposive construction, Amazon’s claims constitute patentable subject matter, and held that the Commissioner’s return to a “form and substance” analysis was an error of law.

The Commissioner then appealed to the FCA. Meanwhile, patent examiners continued to reject diagnostic claims on the basis of non-patentable subject matter.

The FCA also rejected the “form and substance” analysis as being incorrect in law. The FCA ruled that the question to be answered in determining patentable subject matter is whether “the subject matter defined by the claim,” and not the contribution over the prior art, falls within the definition of “invention” in the Patent Act. The FCA directed the Commissioner to reconsider the issue of patentable subject matter following a purposive construction. However, the FCA avoided setting out a definitive test for what constitutes patentable subject matter.

It should be noted that the FCA did not expressly rule out the principles from Schlumberger. In Schlumberger, the FCA determined that the only novel aspect of the claim was a mathematical algorithm and, on that basis, rejected the claims for lack of patentable subject matter. It is nonetheless arguable that the principles set by the SC in Whirlpool represent the definitive statement on patentable subject matter.

It is presently unclear how the Commissioner will apply the FCA’s decision to Amazon’s claims, and how the decision will affect diagnostic method claims in general. For now, applicants should rely on established jurisprudence on purposive claim construction to rebut non-statutory subject matter rejections in diagnostic cases.

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1 Canadian Patent Application No 2,246,933 (Hartman et al., inventors).
2 Schlumberger Canada Ltd. v Canada (Commissioner of Patents), [1982] 1 FC 845 (FCA).
4 Amazon.com, Inc v Canada (Attorney General), 2010 FC 1011, 86 CPR (4th) 321 (FCA) (Amazon.com).
5 Canada (Attorney General) v Amazon.com, Inc, 2011 FCA 328 (FCA) at para 47 (Amazon.com-FCA).
6 Ibid. at para 39.
7 Ibid.
8 Schlumberger, supra note 2.
9 Ibid. at para 5; Amazon.com-FCA, supra at para 62.
10 Amazon.com-FCA, supra note 5.