Judicial Exclusions to Patent Eligibility in the U.S. – The Beginning of the End?

July 10, 2019

The United States is often the largest target market for Canadian innovators, but exceptions to patentability extended by U.S. courts in recent years have made it difficult for innovators to obtain patents for certain cutting edge inventions in the electronics and medical industries. A draft bill recently introduced by a bipartisan group of U.S. senators and representatives aims to resolve this issue, and to restore certainty in the U.S. patent system. In parallel to this, proposed United States Patent and Trademark Office (USPTO) examination guidelines that are not yet in force appear to mitigate the most problematic aspects of the current system. With more than one possibility of change on the horizon, Canadian innovators who previously saw no realistic prospect of obtaining a U.S. patent may wish to re-evaluate their commercialization strategies.

In recent years, high-profile decisions of the United States Supreme Court (USSC) have extended judicial exceptions to patent eligibility, effectively closing the door for patents in some areas of technology. Decisions such as *Bilski v. Kappos*[1], *Mayo v. Prometheus*[2], *ACLU v. Myriad Genetics*[3], and *Alice Corp. v. CSL Bank*[4] have been described as having a "chilling effect" on patenting and as "stifling" innovation.[5] Without the prospect of the proprietary position afforded by a patent, the fear has been that innovations will not be commercially developed for the U.S. market, with cutting edge industries, such as precision medicine and computing, being disproportionately effected.

Proposed Bill to Amend Subject Matter Eligibility Requirements

To address this, a bipartisan group of U.S. senators and representatives released a draft bill on May 22, 2019, to amend patent laws under Title 35 of the United States Code (35 U.S.C.). The proposed amendments aim to, "[R]estore predictability and stability to the patent eligible subject matter inquiry," and, "ensure that the patent system is available to incentivize innovation in key areas of our economy."[6] Amendments to sections 100 and 101 of 35 U.S.C. aim to simplify subject matter eligibility requirements. The press release accompanying the draft bill states:

> …this bipartisan discussion draft shows our commitment to reforms that unleash our nation's game-changing innovation, instead of stifling it. This draft proposes

crucial steps to reform our patent laws to better reflect the twenty-first century's rapidly evolving scientific and technological advancements.[7]

The proposed legislative changes include the following:

- The provisions of section 101 shall be construed in favor of eligibility.
- No implicit or other judicially created exceptions to subject matter eligibility, including "abstract ideas," "laws of nature," or "natural phenomena," shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated.
- The eligibility of a claimed invention under section 101 shall be determined without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this title.[8]

If enacted in its present form, the proposed bill would seemingly abolish the most problematic exceptions to patent eligibility in the U.S. For instance, the current approach is expressly ruled out.

Senate hearings on the draft bill ended in June, and further developments are awaited.

Proposed USPTO Subject Matter Eligibility Guidelines

In parallel, the United States Patent and Trademark Office (USPTO) released draft guidelines on subject matter eligibility, with a consultation period that ended in March. The proposed guidelines acknowledge that the growing body of legal precedent has become increasingly difficult for examiners to apply in a predictable manner.

Under the proposed guidelines, a new step is inserted into the analysis of subject matter eligibility, which requires examiners to look beyond ineligible features and to determine if the additional features integrate the former into a "practical application". This question can be satisfied, for example, if there is, "an additional element that applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition," or if, "an additional element implements a judicial exception with, or uses a judicial exception in conjunction with, a particular machine or manufacture that is integral to the claim." If this part of the test is satisfied, there is no need for an examiner to proceed on to the next step, which aligns more closely with the current test. Importantly, the proposed guidelines indicate that failure to meet the requirements of the new step should be a "rare circumstance."

Implications for Canadian Innovators

The changes in U.S. patent eligibility requirements proposed in both the draft bill and in the USPTO's revised guidelines could make patenting easier for Canadian innovators seeking U.S. protection, and thus stand to benefit the Canadian economy as a whole. Certain Canadian-made technologies would find stronger commercialization potential in the U.S. than ever before. With change in the wind, prospective patentees may wish to re-evaluate the potential for commercialization in the U.S. market, while those planning

to abandon pending U.S. applications should consider if it may be worthwhile to weather the storm a little longer.

Subject Matter Eligibility in Canada

Canadian innovators in the computer and medical diagnostic fields have, since at least 2013, faced a difficult situation for subject matter eligibility in examination before the Canadian Intellectual Property Office (CIPO). CIPO's examination guidelines are predicated on an assertion that relevant Supreme Court of Canada (SCC) jurisprudence applies only to issued patents, and not to applications undergoing examination.[9] CIPO memos have described the approach to subject matter eligibility as "intermediate" to that of Europe ("less stringent") and of the U.S ("more stringent").[10] However, the proposed U.S. changes, if adopted, would change this state of affairs and leave Canada as an outlier amongst developed nations in its treatment of subject matter eligibility for diagnostic, personalized medicine, and computer-implemented technologies. Fortunately, CIPO could harmonize the Canadian approach to patent eligibility with the proposed U.S. changes simply by following the SCC.

[1] *Bilski v. Kappos*, 561 US 593, 130 S Ct 3218 (2010).

[2] *Mayo Collaborative Services v. Prometheus Laboratories Inc*, 132 S Ct 1289 (2012).

[3] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

[4] *Alice Corporation Pty Ltd v. CLS Bank International*, 134 S Ct 2347 (2014).

[5] See articles "Supreme Court Patent Decisions Are Stifling Health Care Innovation", "Top court rules against two diagnostic patents", and "Dave Kappose Calls for Abolition of Section 101".

[6] See article "Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the *Patent Act*".

[7] *Supra*, note 1.

[8] *Supra*, note 6.

[9] See BLG article "CIPO Examination Guidelines for Medical Diagnostic Methods Turns Three".

[10] See articles "Diagnostic Methods at CIPO" and "Talking Points on Recent Article".

By

Kathleen Marsman, Graeme Boocock

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Centennial Place, East Tower
520 3rd Avenue S.W.
Calgary, AB, Canada
T2P 0R3

T 403.232.9500
F 403.266.1395

Ottawa

World Exchange Plaza
100 Queen Street
Ottawa, ON, Canada
K1P 1J9

T 613.237.5160
F 613.230.8842

Vancouver

1200 Waterfront Centre
200 Burrard Street
Vancouver, BC, Canada
V7X 1T2

T 604.687.5744
F 604.687.1415

Montréal

1000 De La Gauchetière Street West
Suite 900
Montréal, QC, Canada
H3B 5H4

T 514.954.2555
F 514.879.9015

Toronto

Bay Adelaide Centre, East Tower
22 Adelaide Street West
Toronto, ON, Canada
M5H 4E3

T 416.367.6000
F 416.367.6749