Patenting Computer-Implemented Inventions in the Life Sciences: Challenges and Opportunities

The use of computers in the life sciences has continued to grow and evolve. Current advances include the use of sophisticated techniques such as multi-variate analysis or machine learning methods to identify risk factors or diagnose disease. Healthcare providers are considering how 'big data' may be used to gain efficiencies and improve patient care. Computers have also migrated from the desktop to individual portable devices and the 'internet of things' promises to transform fields such as agriculture, diagnostics and drug delivery.

While computer-implemented inventions in the life sciences have great potential, commercial success is far from assured. Obtaining effective intellectual property protection can be critical.

To be patentable, a claimed invention must be new and inventive over the prior art, and must be directed to patent eligible subject matter. What is considered 'patent eligible subject matter' differs in each jurisdiction. For example, in the United States “laws of nature, physical phenomena, and abstract ideas” (“ineligible elements”) are ineligible for patent protection. Driving this exclusion is the concern that a patent may pre-empt an entire field and improperly tie up fundamental concepts from future use.

Many inventions in the life sciences incorporate ineligible elements. For example, in the Mayo decision the correlation between a biomarker (thiopurine drug metabolites) and a particular outcome (therapeutic efficacy and toxicity) was considered to be an unpatentable "natural law". In Mayo, the Supreme Court also set forth a two-part test for assessing whether inventions are patent eligible. First is a law of nature, natural phenomenon or an abstract idea claimed? If not, the invention is patent eligible. If so, are there additional elements that transform the nature of the claim into a patent-eligible application of otherwise ineligible elements?

Examples of "additional elements" that may be sufficient to transform a claim into patent eligible subject matter include the use of specific reagents or analytical techniques, or incorporating unconventional method steps or elements that are separate from the natural law itself.

For some inventions, the use of a computer may be considered an "additional element" for transforming a claim into a patent eligible subject matter. In the recent Alice decision, the Supreme Court revisited the two-step test in Mayo in the context of a software patent and held that simply implementing an abstract idea on a computer is not an additional feature sufficient to 'transform' the claimed abstract idea into a patent-eligible application. In Alice, the computer was configured to implement a business method, which was not considered to improve the operation of either the computer or any other area of technology. In contrast, a computer-implemented invention in the life sciences may well be considered to constitute an improvement in technology and qualify as patent eligible subject matter.

The best strategy for claiming a particular invention will depend on the nature of invention as well as any expected commercial activities. Applicants seeking patent protection in the United States should work with their patent agent to identify ‘additional elements’ that may be used transform the claims into patent eligible subject matter without necessarily sacrificing commercially relevant claim scope. In practice, it may also be advisable to file one or more continuation patent applications in order to obtain claims that incorporate different ‘additional elements’ in order to obtain the broadest possible protection.

Compared to the United States, Canada has not yet seen the same developments with respect to restricting the patentability of laws of nature, physical phenomena or abstract ideas. For example, diagnostic methods are generally patentable as long as they do not include administration or surgical steps and meet all the other requirements for patentability. However, the law is in a state of flux and it is possible that Canada may eventually adapt restrictions similar to those that are evolving in the United States.

References:

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