PATENT PRIMER

Patentability in the United States

Sarah J. Fashena and David A. Jackson

Protecting your invention globally requires an understanding of the patent rules of many countries. In the United States, an inventor should be familiar with the statutes of the Patent Act. Patentable claims in the United States are directed to either processes or products, and to improvements to known processes and products, which must be new, useful and non-obvious in light of public knowledge.

The late US Federal Court Justice, Judge Learned Hand, referred to the "…ant-like persistence of [patent] solicitors…" (*Lyon v. Boh*, SDNY, 1924). Patent agents do advance towards the goal of claim allowance by incremental steps that resemble those of an ant. The first of these incremental steps addresses patentability. In short, what is the invention and is it patentable? The answer to the former should be a constant, the answer to the latter varies with jurisdiction.

In accordance with the US Patent Act of 1952, the categories of subject matter that qualify for patent protection are processes, machines, manufactures and compositions of matter. Process claims capture a means for achieving an end product, whereas machine, manufacture and composition — or product — claims focus on the respective end product(s). Such product and process claims, and new and useful improvements thereof, are the domain of utility patents in the United States.

An invention must also satisfy the requirements of being new, useful and non-obvious to qualify as patentable subject matter. Adjudication of whether an invention fulfils these criteria is determined in light of the prior art, which encompasses that which is in the public domain and is, therefore, not patentable.

In the United States, claims directed to a process requiring a computer, computer program or mathematical formula are patentable as long as the end product generated has been transformed "…to a different state or thing" (*Gottschalk v. Benson*, US, 1972). The computer program used, however, is not entitled to patent protection, but is copyrightable.

Confusion regarding patentable subject matter can stem from misconceptions directed to 'making the claimed invention', which in patenting idiom is referred to as 'reduction to practice'. It is not necessary to reduce an invention to practice to achieve patent protection. But the specification must provide ample guidance to enable an artisan to practice the invention and a comprehensive written description of the invention.

Plant and design patents

Patentable subject matter includes living plants (plant patents) and ornamental designs (design patents). These patent types differ from utility patents. Plant patentability is predicated on novelty, distinctiveness and non-obviousness. A plant patent can only be obtained to protect a new and distinct variety of asexually reproducing plant. That is, a variety not found in nature which has been purposefully bred. A design patent is directed to a new and original ornamental design for an article of manufacture. The requirements of a design patent are novelty, ornamentality and non-obviousness. Utility (usefulness) is expressly prohibited in design patents. The legal counterparts of plant and design patents outside the United States are the Plant Breeders' Rights Certificate and the Design Registration.

Living organisms

In 1987, the US Patent and Trademark Office determined that non-naturally occurring, non-human living organisms are patentable. Transgenic animals and plants are considered products of human ingenuity and are, therefore, patentable. In that human beings are non-statutory subject matter, they are categorically excluded from this classification. Methods for treating or diagnosing human beings are, however, considered patentable in the United States. Such 'method' claims are essentially equivalent to European-style claims directed to a 'first or second medical use' of a compound.

Gene sequences

The onset of genomics and proteomics has produced enormous databases of nucleic and amino acid sequences that have the potential to become patentable subject matter, but are non-patentable until further characterization is performed. An expressed sequence tag (EST), for example, might comprise a novel nucleic acid sequence, but in the absence of at least one recited significant function the EST remains unpatentable.

Exceptions

Judicial exceptions to patentability include naturally occurring substances, printed matter, laws of nature, business methods, methods of calculation and ideas. Naturally occurring substances are rendered patentable when produced with human intervention (for example, when isolated or purified). A previously undiscovered property of a known product is not patentable, because it constitutes the realization of a property inherent to the known product. And even though an idea is not patentable, the application of the idea might be. So the dividing line between patentable and non-patentable subject matter can be murky. Such issues can usually be clarified by objective analysis of the development of the invention and the application for which the invention is used. Precedence in the law also provides guidance relating to patentability — the development of new technologies has periodically tested the boundaries of that which is deemed patentable.

THE BALANCING ACT OF PATENTING

The claims of a patent establish the boundaries of an invention and provide the inventor with an exclusive right to practise the invention. A patent enables the inventor to exclude others from practising the disclosed invention. Incentive for disclosure is generally based on anticipated financial support from either direct commercial exploitation or through financial arrangements with potential licensees. The incentive for awarding a patent is to reward the patentee for disseminating advances in technology to the public.

In that the claims define the scope of patent protection to which a patentee is entitled, the language utilized therein is crucial. To be patentable, the claims must clearly define the invention. Such a requirement serves a dual purpose — it protects novel features of the claimed invention, and prevents an overly broad interpretation of the claimed invention that confers inappropriate rights to the patentee. In short, a determination of the scope of a patent must properly balance the interests of the patentee with those of the public. In the words of Justice Fortas, "A patent is not a hunting license." (*Brenner v. Manson*, US, 1966).

Sarah J. Fashena, Scientific Advisor;
David A. Jackson, Patent Attorney, Klauber & Jackson, Continental Plaza, 411 Hackensack Avenue, Hackensack, NJ 07601, USA.
e-mails: sjfashena@kjiplaw.com and David.Jackson@kjiplaw.com
doi:10.1038/nrd1388