GORDON & REES LLP

REQUIREMENTS FOR PATENTABILITY OF INVENTIONS

Each country has its own patent law and sets its own standards for what can be patented in that country. There are, however, some requirements which are common to most patent systems, at least in general principle. This brochure will first describe the major requirements under U.S. law, and then will mention common variations found overseas. Keep in mind, however, that this brochure presents only a general overview, and that in many cases there are exceptions or limitations to the basic rules which may apply in individual specific cases.

WHAT CAN BE PATENTED?

The U.S. Patent Law states that "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor ..." subject to meeting the Patent Law's requirements for patentability. The Supreme Court has said that **virtually any subject matter which meets this definition** can be eligible for a patent. Thus an inventor can obtain a patent for almost any type of chemical, biological, electronic, medical, mechanical, software or other technology or method of doing business.

There are some subjects which are **not** eligible for patents. Physical, chemical or biological laws of nature and mathematical algorithms are not patentable.

UTILITY REQUIREMENT

An invention must be new and **useful**. **Useful** means that the invention must have at least one recognized, verifiable and practical end use. If the claimed end use is purely speculative, or not reasonably believable, the invention is not "useful." If the only end use is as a subject for further research, the invention is also not "useful" from a patent standpoint. The commercial value of the stated end use is not important. The end use itself does not need to be inventive; many patents are issued on alternative ways of accomplishing an old end use. The issue of utility arises most often in the fields of biotechnology, pharmaceuticals and chemistry.

NOVELTY REQUIREMENT

The basic concept of **novelty** means that to be **new** and useful an invention **cannot have been previously known to the others in the public**. An invention may be known by having been the subject of a prior patent or publication or by having been used or available

in the marketplace. Any prior knowledge is normally sufficient, regardless of how long ago that may have been or whether or not any commercialization occurred.

Evidence of prior knowledge commonly is found by reference to previous patents, trade literature, technical papers, advertisements and other publications, or to actual commercial products or processes. Such references can be identified in a patentability search made when considering whether to file a patent application.

The U.S. law grants a one-year **grace period** to inventors prior to filing a patent application. During this period an inventor can disclose and commercialize the invention without forfeiting the "novelty" aspect of the invention. Disclosures by others during this period do not affect "novelty" (although they may give rise to a question of who is actually the first inventor). Importantly, however, most foreign countries do **not** permit such a grace period, presenting a major limitation on an inventor's actions with respect to the invention prior to filing the U.S. application. (See page 4 below and also the Gordon & Rees brochure, Foreign Patent Considerations.)

NONOBVIOUSNESS REQUIREMENT

Even if an invention has not previously been known (that is, it meets the "novelty" requirement), it will still **not** be patentable if "the differences between the [invention] and the prior art are such that the subject matter as a whole **would have been obvious** at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains." The Supreme Court has ruled that a determination of what is **obvious** requires consideration of several factors: what are the scope and content of the prior art, what are the differences between the invention and the disclosures of the prior art, and what is the level of ordinary skill in the art.

Determining nonobviousness is more subjective than determining novelty. For instance, in some technologies an ordinary mechanic may be the "person of ordinary skill in the art," while in others that person may be a doctoral level researcher. How a prior art disclosure is to be interpreted or what it actually teaches are often subject to substantial disagreement among skilled people in the technical field.

The issue of nonobviousness usually constitutes the major topic of discussion between the inventor's patent attorney and **the Patent Examiner** at the U.S. Patent and Trademark Office (**USPTO**) when the Examiner is considering the patentability of the claimed invention. Commonly an Examiner contends that one or more references teaches the invention, and the attorney counters with a different interpretation which teaches away from the invention. An Examiner may argue that combining the information disclosed in two or more references make the claimed invention obvious while the attorney counters that the references disclose nonanalogous subjects and therefore should not be combined. In the majority of the cases agreement is reached on how best to define the invention to meet the nonobviousness requirement.

REQUIREMENTS ABOUT THE APPLICATION ITSELF

The Patent Law also imposes standards on the **written application itself**. The application is written to be read by a person already familiar with the technical or business field, and therefore does not have contain basic knowledge needed to understand the invention in context. The law requires that the invention, and the manner of making and using it, be described in "such full, clear, concise, and exact terms as to **enable** any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use" it. If drawings, formulas or diagrams are necessary for clear understanding of the invention, they must be included. The application must also describe the **best mode** contemplated by the inventor for carrying out the invention. Examples and data are often included in an application to aid in defining the full scope of the invention or establishing its utility. The descriptive part of patent application is called the **Specification**.

Regular applications always conclude with at least one **claim**. Claims are the numbered paragraphs at the end of an application which legally define the invention. The law requires a rather formalized format for claims. While the technical disclosure in the Specification can be used to interpret the "legalese" in the claims, **the subject matter which is legally patented is what is defined in the claims**. In many cases claims will be amended by the inventor during examination and negotiation with the Examiner, so that actual scope of the invention as defined in the issued patent's claims is often **narrower** (less comprehensive) than the scope of the invention as it was defined in the claims as originally filed by the inventor.

A U.S. patent commonly has numerous claims, each of which defines the invention in a different manner. Usually the first claim is the broadest definition of the invention, and the subsequent claims focus on narrower scope definitions or highlight specific important variants or embodiments of the invention. A **provisional** patent application does not contain claims, but is required to meet the other patentability requirements. However, a provisional patent lapses after one year, and a related regular application with claims must be filed during that year if the inventor wants to continue to seek a patent on the invention.

A patent application must be **self-contained**. While it may rely upon prior sources for background knowledge of the technical field, the invention itself must be described completely within the application. An application cannot be amended to add "new matter" to the description of the invention. (However, if subsequent research gives rise to improvements or alternative inventions, additional applications may be filed which can supplement or in some cases replace earlier applications.)
The examination period in the USPTO currently takes at least a year, and normally one and one-half to three years, because of the USPTO's large backlog of pending applications. In some fields such as biotechnology and computer software where the backlog is greatest, the examination period can be even longer.

FOREIGN PATENTABILITY REQUIREMENTS

Under foreign patent laws, many similar principles apply, although often under different names. However, there are also significant differences. For instance, most foreign countries have severe **limitations** on the extent to which an inventor can disclose the invention prior to filing his or her home country patent application, and many of the major foreign countries do not permit **any** prior disclosure (a requirement called **absolute novelty**). This means that if an U.S. inventor is to retain the option to apply for foreign patents, the U.S.'s grace period cannot be utilized. Foreign countries also commonly have more limitations on what can be patented. In some countries only inventions with industrial applications can be patented, which may exclude household, recreational, business, etc. inventions. In most countries in vivo human and veterinary medical treatment methods are **not** patentable (although in vitro methods and medical compositions may be patentable). The number of claims in foreign applications are often less, since foreign patent laws concentrate more on the central concept of the invention and less on specific details than does the U.S. law. Also, prior art is often interpreted in a more limited manner overseas, and in some countries very old references will not be considered by the Examiner. Finally, in many foreign countries the owner of the patent application (usually the inventor's employer) is considered to be the patent applicant, and the identity of the inventor may or may not be considered significant.

It is extremely important for inventors and their companies to consult with patent counsel at an early stage in an invention's research and development, to insure that no actions by the inventor or employer are inadvertently taken which would jeopardize potential patentability either in the U.S. or in foreign countries.