

## INTELLECTUAL PROPERTY PRIMER

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*Intellectual property* (IP) refers to ideas, creations and inventions and the legal protection of ownership on the part of the creator. Federal legal protection for inventions dates back to the U.S. Constitution and was intended to provide incentive for the generation of novel creations by establishing sole ownership and rights to practice the invention to the creator.

IP exists in the form of *patents, trademarks, copyrights, and trade secrets*. In the biotechnology world, patents and trade secrets are the dominant forms of IP. The protection of trade secrets is the responsibility of the inventor (*e.g.*, the recipe for Coca-Cola or “the Colonel’s secret eleven herbs and spices”). Patents, on the other hand, are protected under federal law upon issuance. Technically, patents do not grant permission to the inventor to pursue the commercialization of the invention, but rather, *exclude* others from practicing the invention for the life of the patent.

Claims of invention made in biotechnology-related patents are typically associated with: (1) *composition of matter* (COM), (2) *field of use*, or (3) *method of production*. Generally, COM patents represent the strongest business asset associated with an invention, because (a) infringements are easier to monitor (“police”), and (b) holders of subsequent use or methods patents often must first gain license to the related COM patents. However, patents pertaining to COM are not always possible, particularly for naturally occurring biological molecules or commonly known natural products with historical anecdotal benefits.

Keys to the determination of patentability of an invention are the concepts of *novelty, usefulness* and *non-obviousness*. A primary task of a U.S. Patent and Trademark Office (USPTO) patent examiner is to determine that the key elements of an invention are not already commonly known, claimed by an existing patent (“prior art”) or easily deduced by anyone “reasonably skilled in the art.”

The date of the earliest patent filing for an invention is considered the *priority date*. In Europe, priority date is used to resolve disputes in the event that several inventors claim ownership to an invention. In the U.S., patent holder preference is given to the inventor claiming the earlier date of conception of the invention. Therefore, documentation of studies leading to the invention (*e.g.*, lab notebooks) is critical for filings with the USPTO. For this reason, university technology transfer offices (TTOs – see *Technology Transfer Primer*) and corporate intellectual property review committees are adamant the inventors disclose their inventions immediately so that proper documentation procedures can be invoked to substantiate the date of invention.

U.S. patents typically require significant iterative dialog with the USPTO over the course of months or years before issuance - a regular U.S. patent often takes 3-5 years to issue - at a cost of \$25,000 - \$30,000 in filing costs and legal fees. These costs may skyrocket to \$100,000 - \$200,000 for international coverage that provides protection in the most

commercially dominant markets (U.S., Europe, Japan, Canada, *etc.*). Regular U.S. patents provide protection for a period of twenty (20) years from the filing date.

In the U.S., universities and resource-constrained companies often file inexpensive preliminary patents (*provisional patents*) in advance of more detailed, rigorous (and expensive) regular U.S. or international PCT (Patent Cooperation Treaty) patents. Unlike a full patent, a provisional patent can be rapidly filed with minimal supporting data or exploration of the prior art, and provides a priority date from which a subsequent full patent may “claim the benefit.” Note that the provisional application is itself never examined by the U.S. patent office, and no patent will ever issue directly from a provisional application. Further, the provisional patent is only in effect for 12 months and is disallowed if not followed by a more thorough and substantiated full patent filing within the life of the provisional patent. In the event that the provisional expires without follow up, the inventor loses the claim to the earlier priority date and may risk losing claims of novelty for the invention.

In our world of early-stage life sciences companies, solidity of IP position may be the only true asset possessed by a company, and is often a key to seeking institutional investment, co-development partnerships, and licenses. Establishment of a solid IP estate confers *freedom to operate* (FTO) to the owner as well as constituting a significant *barrier to entry* to competitors. Companies often seek an FTO opinion from their patent counsels to provide some assurance that they are not infringing on patents held by others, although these opinions are just that; FTO is often not assured until prosecuted.

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