

PATENTS 101

(Without particular emphasis on, but with some reference
to biological materials)

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Preface

There are patent laws and rules and procedures – **BUT** – application of those laws and rules and procedures to specific technologies, and particularly to new technologies that aren't well understood by judges and law makers, is unpredictable and irregular. This creates both obstacles and opportunities. Our job is to find or create the opportunities and take advantage of them.

Why Patents?

Short answer: because there is huge commercial value in patents at this particular time in history – and because everyone else is doing it. Information, no matter how unique or interesting and intrinsically valuable, has little **commercial** value in the world today unless it has proprietary rights attached to it. Protecting information as a trade secret, although it has served Coca-Cola® well indeed, is not a reasonable option for most commercial technologies. Patents are one of the playing cards in today's global economy. An array of different patents, with a range of patent claims in particular technologies, is a prerequisite in today's global marketplace.

What They Do and What They Don't Do

Patents do **not** grant any affirmative rights. In other words, if you have an issued patent claim, you do not necessarily have the right to do what the claim states. What a patent does grant is the right to exclude another party from making, using, selling or offering for sale the claimed invention. Pioneering type patents have broad claims directed to platform technologies or compositions. Narrower patent claims may be granted for improvements to those platform technologies or compositions. In order to make use of those narrower claims to improvements, a license from the holder of the broad claim is required. Claims may be "patentable over" – i.e. novel and nonobvious in view of – broader claims, and therefore patentable. They can't be used, however, without a license from the holder of the broader claim.

Bear in mind that patents are national or regional in scope. Thus, a U.S. patent is enforceable in the U.S.; a New Zealand patent is enforceable in New Zealand, etc. If a company operates in a geographical area that is outside of patent protection, by conducting research and development activities in New Zealand for example, the R and D activities avoid infringing many patents that are dominant in the U.S. or other areas of the world. **BUT**, before a company can sell products or rights to products or technologies that will be used in other countries (such as the U.S., Europe or Japan) where patent rights exist, any patent issues will need to be resolved, perhaps with the acquisition of licenses.

What may be patented?

What may be patented varies somewhat from nation to nation. In the U.S., just about “everything under the Sun” is patentable subject matter. Generally speaking, this means processes and methods of all types, and compositions of matter, including polynucleotides, polypeptides and microorganisms, as well as plants and non-human animals. For compositions of matter that are “products of nature” like polynucleotides, polypeptides, newly identified microorganisms, etc., the trick is that **isolated** and/or **purified** forms of those compositions of matter (genes, antigens, etc.) do not exist in nature and therefore may be patentable. Genetically modified host cells and plants do not exist in nature and are therefore patentable on their own. Many countries, as a matter of policy, do not grant patents on living organisms or genetically modified biological materials.

Once patentable subject matter is identified, it must meet the test of patentability: it must be novel and nonobvious in light of the “prior art,” and it must have substantial and credible utility. An invention is novel if no single prior art reference discloses that particular invention. An invention is non-obvious if no combination of prior art references discloses that invention. An editorial note: the standard of “obviousness” applied by the Patent Offices and the courts is a much lower threshold than most scientists can even imagine. Finally, the invention must have a substantial and identified, “real world” utility.

The “prior art” against which the patentability of inventions is judged is, technically, **all** information in the public domain. This includes publications of every nature, in every form, and in every language. They need not be widely circulated or well-recognized publications. It also includes other types of information in the public domain, including devices and methodologies that are publicly known. As a practical matter, the “prior art” against which your invention is judged before the Patent Office is the information the Patent Office happens to have in its library and makes available to the Examiners. This is a small fraction of the relevant prior art that exists in the universe. For this reason, many later court challenges to patents are successful.

The Elements of a Patent

The patent application, and the patent, is organized generally as follows. The “Technical Field of the Invention” provides a one paragraph or, sometimes, one sentence, description of the field of endeavor to which the invention relates. The “Background of the Invention” describes related information or technologies that exist, and generally describes the shortcomings of known approaches. The background section tells the story of what the need is that your invention fulfills.

The “Summary of the Invention” is a brief summary of the various aspects of the invention and the useful applications to which the invention may be put. The “Detailed Description of the Invention” is a more detailed description of each aspect of the invention, including precisely how the invention is most advantageously used, and presents any available scientific support for the invention. The Abstract of the Invention

is just that – an abstract describing the principle features of the invention.

The claims, which appear at the end of a patent or patent application, are what define the legal boundaries of the patent grant. The claims are what the rest of the application must support - they are what is “protected” and what the patent holder may exclude others from doing. The claims are interpreted in light of the statements made and terminology used in the rest of the patent application. No other part of the patent has particular legal significance, other than in the interpretation of the claims. The rest of the patent application is also important in terms of its prior art effect. Once the patent issues and is published, the text of the patent, in its entirety, becomes prior art and all subsequent inventors must establish novelty and non-obviousness in view of that text. For that reason, it is advantageous to describe all conceivable uses or applications of the technology, even if certain applications haven’t been demonstrated at the time the application is filed.

The Requirements of a Patent Application

There are three principle legal requirements of a patent application. First, it must provide a “written description” of the claimed invention. This has been interpreted to mean that words, rather than drawings or figures alone, must be used to fully describe the invention. Second, the patent application must “enable” someone having “ordinary skill in the art” to use or practice the claimed invention. This means that the level of disclosure must be detailed enough so that someone with some skill could, based on a reading of the patent application, make and use the claimed invention. Third, the patent application must disclose the “best mode” known to the inventors of practicing the invention. This means that if the inventors are aware of any “tricks” to making the invention work, they must be fully disclosed. The premise of the patent system is that a period of exclusivity is granted in exchange for a full public disclosure of the invention. The patent system is designed to advance the state of the art. Theoretically, with the issuance and publication of each patent, subsequent inventors rise to that level of expertise and make improvements or further inventions from that (elevated) state of technology.

The patent application is generally addressed to one having “ordinary skill in the art.” You may therefore assume some, fairly low level of knowledge with the technology. It is advisable, however, to describe the invention in very clear and simple terms and to provide enough background that someone with little technical knowledge could follow and understand the invention, at least on a simplified level. The Patent Examiners are not always knowledgeable and familiar with the field of the technology. Moreover, if the patent ever winds up in court, the judge and jury (and, in the U.S., there will likely be a jury) will likely not have any technical background whatsoever. And, that judge and that jury will be determining the meaning of your patent claims, determining whether the claims are valid, and determining whether the infringer really infringes. We would like to make it as easy as possible for all of these important interpreters of the patents to understand our invention and our patent claims.

There is no legal requirement that an invention have been “reduced to practice,” which means demonstrated to work, prior to filing a patent application. The U.S. Patent Office has tended to require a relatively high level of support for inventions relating to biological subject matter, however, and particularly for inventions relating to therapeutic methods and compositions. If therapeutic methods or compositions are claimed, it is preferable to include data demonstrating results in humans (even if anecdotal and not scientifically rigorous), or results in animal or in vitro models that are established to be predictive of humans.

One of the most important aspects of the patent application process is making sure that the inventor’s “duty to disclose” relevant prior art to the Patent Office is satisfied. This duty extends to the inventor(s) and the assignee, as well as to the representative (the patent attorney). There is no duty to conduct searches for relevant materials, or to know of relevant materials. But, to the extent you or your patent counsel know of information that is relevant to the patent claims, you are required to disclose it to the Patent Office. It is generally to the advantage of the patent applicant to err on the side of over- rather than under-disclosure. Please be sure to provide copies of relevant references both during preparation of the patent application and during the time the application is being reviewed by the Patent Office.

Patent Application Time Lines

Most of the world observes an “absolute novelty” standard of patentability, which means that a patent application must be filed **prior to** any **public** disclosure of the information. The U.S. law is a bit more lenient. Disclosures made to collaborators or partners or colleagues with whom there is a confidentiality agreement is not a public disclosure. Be careful not to make disclosures of any proprietary information to people outside your company with whom no formal confidentiality arrangement exists prior to the filing of a patent application.

Once a national patent application has been filed, the “priority date” for the information disclosed in that application is established. Patent Cooperation Treaty (PCT) International Patent Applications are filed on or before the one year anniversary of the initial filing date. If additional information concerning related inventions or additional support for the claims is available at the time of filing the PCT application, it should be included in the International Application. The PCT International application is a relatively inexpensive way to preserve rights to file patent applications in many industrialized nations, yet defer the substantial costs of filing separately in each desired nation or region for an additional 18 months. PCT patent applications, unlike U.S. patent applications, are published 18 months after the initial “priority” filing date. All information contained in the PCT international application is public domain information at that time.

National or regional phase patent applications must ultimately be filed separately in national or regional patent offices. Each national or regional patent office makes an independent determination as to the patentability of the claims. It is generally true that

patent claims for the same invention will be somewhat different in the various jurisdictions. If patent protection is desired in countries that are not members of the PCT (such as Indonesia, Malaysia, India, South Africa and most of South America), national applications must be filed in those countries prior to publication of the PCT application.

Patent Office Procedures

Bear in mind that Patent Offices the world over are government bureaucracies. When the application is filed, it is assigned to an Examining Group and a specific Examiner who has some experience (but rarely expertise) in the general field of the invention. As in any field, some Examiners are very good and some are very poor. In the U.S., Patent Examiners work on a production quota system. They don't have a lot of time to spend with each patent application. Some Examiners do a very good job. Others do a fair to poor job.

The first order of business for the Examiner in many cases is to categorize the claims into individual inventions. Thus, for example, a single application may claim: (1) a polynucleotide sequence encoding a particular polypeptide; (2) the encoded polypeptide; (3) an expression vector comprising the polynucleotide; (4) a host cell comprising the expression vector; (5) a pharmaceutical composition or a vaccine comprising the polypeptide; (6) a fusion protein comprising the polypeptide; etc. The Examiner may issue a Restriction Requirement or an Election of Species Requirement categorizing the various inventions. The applicants are then required to choose one particular set of claims for examination. The other claims may be examined later or in tandem with the claims chosen, but they are considered a separate application and undergo a separate examination.

The Examiner then performs a prior art search to identify prior art references relevant to the elected claims. In at least 95% of the cases, claims are rejected in the Examiner's first Office action. Rejections may be based in the use of indefinite claim language, the lack of enablement of the invention in the patent application, or on prior art references that, alone or in combination, disclose the claimed invention. In our response to the Examiner's action, the claims may be amended to use different language, or to include limitations not previously stated, and remarks (or arguments) are directed toward why the patent claims use appropriate language and are novel and non-obvious. Thus begins a process of negotiation with the Patent Examiner that culminates in the allowance of patent claims – or not.

The U.S. Commissioner of Patents has worked hard to make the Patent Office, and the Examiners, more accessible to its clients. Although there are still recalcitrant Examiners who are very difficult to work with, many Examiners will agree to discuss the merits of their actions and are available for phone conferences and in-person interviews. Such personal contacts with the Examiners are generally very fruitful.

When the Examiner agrees that the claims are patentable, the claims are "allowed." The patent issues and is published – in due course. The average time from filing an application to issuance of a patent may be from about two to four years. U.S. Patents

have a term of twenty (20) years from the earliest effective priority date of the application.

Infringement

Anyone who makes, uses, sells or offers for sale the “claimed invention” is guilty of patent infringement. There are some complexities in terms of process and composition of matter patents that extend the meaning of the “claimed invention.” There need not be any commercial motive for infringement – research uses are infringing. One wrinkle in U.S. patent law is that under some circumstances research performed in connection with submission of materials to the FDA is exempt from infringement.

Infringement is a legally complex determination. Literal infringement occurs if the infringer meets every requirement of the patent claim. This is not as easy a determination as it seems, because interpretation of the claim language is not always straightforward. Infringement may be found under the “Doctrine of Equivalents” if someone does substantially the same thing in substantially the same way, or if every claim element is present “equivalently” even if every literal requirement of the patent claim is not met. The scope of claims under a Doctrine of Equivalents analysis in particular cases can be highly unpredictable.

Several remedies are available to patent holders who prove infringement. Preliminary injunctive relief is available in some cases. This means that if a court makes a preliminary determination (after holding a mini-trial) that the patent is infringed and the harm to the patent holder is great, it will order the infringer to cease all infringing activities immediately. In this case, research or sales and manufacturing activities are stopped dead in their tracks during the time the trial takes place. This is relatively rare, but it is a very potent disincentive to infringers. In the usual case, if the infringer is found guilty, it is required to cease the infringing activity. The patent holder may get compensatory damages, and/or the infringer’s profits on account of the infringer’s past activities. If the infringement was “willful,” damages up to 3X the damages otherwise granted, and attorneys’ fees, may be awarded. If the infringer has obtained an opinion from competent counsel that it is not infringing, or that the patent at issue is not valid, there is generally no finding of willful infringement.

Patent Challenges

An issued patent enjoys a “presumption of validity.” This means, simply, that any challenger must show some (fairly low level of) evidence that a patent is invalid before he can “put on” a case. There are three routes for challenging patents – one within the Patent Office and two judicial routes.

Any party (generally one or several competitors) who finds one or more prior art publication that was (1) not reviewed by the Examiner during prosecution of the

application and is different from the references that were reviewed and (2) is relevant to the patentability of claim, may file a Request for Reexamination of an issued patent. If the Patent Office agrees that the prior art publication(s) raise a material new issue of patentability, the Patent Office will re-examine the patent. This is, theoretically, a valuable tool. In practice, however, the Reexamination is generally not terribly rigorous. Patent claims, sometimes in a slightly narrower form, often emerge from Reexamination.

When a patent holder sues an infringer for patent infringement, the infringer asserts many defenses. Among those is the defense that the patent is invalid and should never have been issued in the first instance. A substantial part of many patent infringement trials may be devoted to the question of whether the Patent Office did its job, or whether information that was not considered by the Patent Office would change the outcome. The alleged patent infringer generally has more resources and more incentive to conduct a highly rigorous search for prior art, and to closely examine every aspect of the patent application. It is not surprising that a good percentage of patents that are litigated are, ultimately, declared invalid. It is also not surprising that the vast majority of lawsuits filed are resolved by an agreed settlement between the parties before the trial takes place, or during trial.

The final way a patent may be challenged is a declaratory judgment action filed by someone who has been accused of patent infringement. Be **very** careful whom you accuse of infringement. It is a good practice to notify potential infringers that you have patents, and to provide copies of your issued patents to them. They are then on notice of your patents and, if they infringe or continue to infringe, they will have liability for damages and, perhaps, have liability for willful infringement. If you make a direct and aggressive infringement accusation, however, they may be entitled to file a declaratory judgment lawsuit asking the court to rule that your patent is invalid.

Conclusion

At this stage in the development of the patent law, the only certainty is that all commercial enterprises are well-advised to play the patents game. The rules are still developing, and their application is somewhat inconsistent. There are plenty of opportunities for creative approaches that are likely to pay dividends, however, both in the short and the long term.