A Patent Law Primer for Clinical Chemists and Other Scientists

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There is considerable ignorance, and some prejudice, among scientists about patenting, particularly in academic circles. Recently (1), a survey was conducted among 1200 faculty members involved in the new biotechnologies (2) in 40 of the most research-intensive United States universities. The survey probed attitudes concerning industrial sponsorship of research in their institutions. Industry support was seen by most, whether or not they had such support, as creating pressures for faculty to spend excessive time on commercial activities, and shifting too much emphasis to applied research. In contrast, most of the two groups of faculty members agreed that industry support involves less red tape than government funding, and increases the rate of applications from basic research.

Although there clearly are potential drawbacks to an overemphasis on patenting and commercialization in an academic environment, particularly where basic research is sacrificed, it is undisputed that the patenting systems of the world enable the public to benefit from practical applications of biomedical research. Firstly, it is quite unlikely that industry will invest the money and time to bring an invention to the marketplace without protecting their investments by patents and licenses. Secondly, royalties from the licensing of patent rights can be an important source of research funds for the scientist and his employer. For example, the Wisconsin Alumni Research Foundation, the organization that exploits inventions developed by University of Wisconsin scientists, generated about $100 million of income during the period of 1982–1982 (3). About 85% of these earnings were plowed back into university research, the remainder going to the inventors. And this was before the era of the new biotechnologies!

It is the thesis of this article that there are many good reasons for clinical chemists and other scientists to avail themselves of the fruits of the biotechnology revolution of which they are a part. These reasons apply not only to clinical chemists and other scientists in industry, for whom patents and trade secrets are a raison d'être, but as well to clinical chemists and other scientists in universities, freestanding hospitals, and government institutions.

The Patent Systems

All of the industrial nations of the world, many of the under-developed nations, and even socialist countries such as the USSR, have patent systems. In the United States, the Patent and Trademark Office (PTO), which is a part of the Department of Commerce, has statutory responsibility for issuing patents and trademarks to applicants from any country. As of March 1984, these two PTO units (containing 28 Examiners) involved in examining biotechnology patent applications had a caseload of about 800 new and in-program applications (4). As of January 1985, this figure had reached 2200, with the same number of Examiners. As of January 1986, there were about 3100 new and in-program biotechnology patent applications, but now with 52 Examiners. Thus, in less than two years, there was a fourfold increase in the number of biotechnology patent applications, and only a slight increase in the number of Examiners. This enormous caseload is reflected in the fact that, in the United States, only about 180 patents were issued in biotechnology during the period 1978 to 1985. Yet, even that small number of U.S. patents is well in excess of the number of patents issued from the European Patent Office (EPO), the German Patent Office (GPO), and the Japanese Patent Office (JPO) (5).

With such caseloads, it is not surprising that the prosecution of a patent application is a slow process in the United States. The period from filing of an application to patent issue is typically over 18 months, even for an uncomplicated, non-controversial application (4). Lapsed times are similar in the European patent office (EPO), the West German Patent Office (GPO), and the Japanese Patent Agency (JPA), despite the fact that the number of biotechnology patents issued by these three agencies was far less than that issued by the United States during the 1978–1985 period (5).

Under the Paris Convention of 1883 for the Protection of Industrial Property, any resident or national of any member nation who files an application in his own country may, within 12 months, file a patent application in any member nation and receive as his priority date (official date of the filing) the filing date of his first filed application. In this manner, an inventor can, for example, file a United States patent application in the United States on June 1, 1986, and thereafter can publish his invention without affecting his right to apply for foreign patents (Paris Convention) on the same invention, as long as the latter is filed within a year, i.e., by June 1, 1987. This procedure obviates the problem that occurs in many countries, particularly those in western Europe, where almost any public disclosure of the invention prior to the filing of an application thereon in that country prevents the inventor from obtaining patent protection, i.e., the "absolute-novelty" countries. Japanese patent statutes provide a limited exception to the absolute-novelty bar: submission of a paper to a scientific meeting or presentation of a paper at an "official" international meeting will not create a novelty bar if the patent application is filed within six months of such disclosure.

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Inventors can enjoy the right of priority in a similar manner under the Patent Cooperation Treaty (PCT) and the European Patent Convention (EPC).

The PCT allows an inventor to file a single international application (in a special PCT office within his national patent office) designating the specific countries in which the inventor wishes to seek national patent protection. After an initial novelty search is conducted by the international searching authority, copies of the application and search report are sent to each designated country's patent office. Within 20 months of the initial filing date (or within 20 months of the first filed foreign application upon which the PCT international application is based) the inventor may file a request to have each of the national patent offices of the designated countries examine his application. Filing of this request provides the applicant with an eight-month extension within which to enter the "national phase" of the designated countries. The examination in the national phase is based upon the national patent laws of each designated country. Thus, filing under the PCT simplifies the filing of foreign applications, but at a price of increased costs. It is important to note that the PCT does not ensure an international patent, because it is only a procedural device.

Similarly, the EPC permits the filing of a single European patent application in the European Patent Office (EPO) designating various member European countries in which the examination will be based upon the substantive laws of the EPC. But in contrast to the PCT system, upon allowance, an EPO patent is granted and is registered in the designated countries. The EPC patent is then enforceable (and attackable) under the national laws of each country. But note! There is no "European Patent" per se, merely a bundle of national European rights.

Substantially all the countries in the world are members of the Paris Convention. Notable exceptions include the Republic of China and Venezuela. PCT members include Belgium, France, Austria, the Federal Republic of Germany, Great Britain, Italy, Luxembourg, The Netherlands, Sweden, Switzerland, Liechtenstein, Australia, Brazil, Denmark, South Korea, Hungary, Japan, Madagascar, Malawi, Monaco, Norway, Roumania, Sri Lanka, the USSR, and the USA. As to non-member countries, a United States inventor can still receive the right of priority based upon reciprocal national legislation or upon the Inter-American Conventions for the Protection of Inventions, Patents, Designs and Industrial Models. EPC member countries include Italy, Belgium, France, Austria, the Federal Republic of Germany, Great Britain, Luxembourg, The Netherlands, Sweden, Switzerland, Liechtenstein, Greece, and Spain.

In view of the procedural advantages provided by one of the international treaties set forth above, publication and public use or sale of an invention should be delayed until either a United States patent application, a PCT international application, or an EPC application is on file. Otherwise, the possibility of obtaining foreign patents or a regional patent under the EPC on an invention in most countries may be lost. An exception to this rule should be noted: a sale of an invention may be non-enabling and thus not novelty-defeating in the EPC.

Misconceptions about Patents

Patents give to the patent owners (patentee or licensee) the right to exclude others from making, using, or selling a patented invention for a statutorily defined period of time. A patent does not guarantee the patent owner income or commercial advantage just because his patent issues. In fact, the patentee may never obtain any benefit from his patent where, for example, a critical component of his invention is covered by a patent held by another. Further, merely because a patent office issues a patent does not mean that the patent owner will prevail in a subsequent court action in which the validity of his patent is challenged.

As a matter of law, a patent gives one the right to exclude (more practically, it gives one the right to attempt to exclude) others from practicing one's invention. That attempt may indeed be a complicated and expensive proposition, and many patent owners suffer because of that. This is an important attribute of the patent system that people who are not accustomed to, or familiar with, it might bear in mind.

A patent gives the right to exclude for a limited time and with regard to limited subject matter. In the United States, the interval is 17 years after the patent issues, but limited patent extensions have been available since 1964 for drugs and other products that are subject to extensive review by governmental regulatory agencies before being approved for public use (6). For example, data provided by the U.S. Food and Drug Administration reveals that, as of mid-1986, the agency had reviewed, for the purpose of allowing public use, seven DNA probe and recombinant DNA test kits and 168 diagnostic kits in which monoclonal antibodies are used (7). Another source (8) lists another 33 DNA probes that are in development and that will have to obtain regulatory agency approval for public use. Were the patent terms for these medical devices to be shortened by the time necessary for regulatory review, manufacturers would have been unfairly penalized. Hence, the genesis of the patent extension act (6).

It is also important to be aware that exclusive rights afforded by patents have to do with the subject matter that is described in the claims of the patent, not the rest of the subject matter, i.e., in the patent's specifications or drawings (that part of the application that closely resembles a scientific journal paper). The right to exclude runs headlong into the strong public policy against monopolies that has pervaded United States societal history since the turn of the century. As a result, we have in the United States a very delicate balance in the courts between the desire to hold valid and to give fair scope to a patent, and, on the other hand, to make available to the public that which, perhaps, it already had (e.g., a natural product). That is a fundamental tension in the system that must be kept in mind. It is dangerous to believe that one can use a patent to monopolize subject matter outside the scope of the claims. If one tries it, one may find oneself held to be guilty of "misuse"; that is, the patent may be held unenforceable.

Patents

Four terms are critical in patent law: validity, infringement, enforceability, and the public interest.

A patent has a statutory presumption of validity when it issues from a patent office. The patent must be valid to be infringed. An invalid patent cannot be infringed. Hence, a routine defense in a legal action against an alleged infringer is an allegation of patent invalidity.

A patent must be enforceable to obtain relief (injunction or damages) as a result of infringement. An unenforceable patent may lead to no relief, or it may lead to the necessity of the patent owner changing his course of action in order to enable him to gain relief under the patent.

All of these concepts must be considered in the light of the
public interest, which is to promote the "advancement of the useful arts," according to the United States Constitution. That objective is obtained by full disclosure of the invention in the patent (9).

Patent Validity

Validity has three elements: utility, novelty, and obviousness or non-obviousness.

Utility. In the United States, usefulness is the subject of Section 101 of the patent statute (10). The invention must have utility, and the statute defines this as "... any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . ." Utility has been broadly interpreted, and essentially excludes only things that are "mischievous or immoral" (11).

In 1980, the United States Supreme Court's landmark opinion in Diamond v Chakrabarty (12) decided the question of whether certain claims to a microorganism defined patentable subject matter under Section 101. The Court found that Congress, in choosing the expansive language of this section, had plainly contemplated that the patent laws would be given wide scope, and intended statutory subject matter to "include anything under the sun that is made by man" (12). On this basis, the Court held that an engineered microorganism was patentable subject matter.

In Japan, an important source of biotechnology patents, patentable subject matter is similar to that in the United States; thus, microorganisms per se; DNA, such as as foreign genes, vectors, recombinant vectors, and promoters; tissue-culture cell lines, including hybridomas; viruses; molecules such as monoclonal antibodies, antigens, haptons, and physiologically active substances; diagnostic materials and devices; plants; process of producing any of the above; use of such as pharmaceuticals and herbicides—are all patentable.

Unpatentable in Japan, but patentable in the United States, are methods that inevitably utilize the human body. For example, a method of curing a disease in man is not patentable, although drugs and apparatuses for doing so are patentable. Methods for treating animals other than humans are all patentable. Materials isolated from humans are not deemed to be the human body. Thus, for example, a gene-manipulation process utilizing a human gene is patentable.

Patentable subject matter in most EPC signatory countries is similar to that of the United States (13). Naturally occurring and engineered microorganisms, animal and human cells, and viruses; DNA/RNA polymers; naturally occurring and mutant (recombinant DNA) plasmids or other organelles; products produced by naturally occurring or engineered microorganisms; processes for using microorganisms, cell lines, and viruses; and diagnostic devices and methods—these are all patentable. Certain countries—e.g., Sweden, Spain, and Brazil—are unique in deeming non-patentable virtually any product of biological origin, natural or engineered. Plant varieties are not patentable in EPC countries, although they are in the United States.

Novelty. Timing is critical to patent statutes. There are two policies based upon timing. The first policy is "firstness". Under all patent systems there is a strong policy of awarding the patent to the person who is the first inventor. The second policy is "promptness. This is the policy that encourages an inventor to file his application in a patent office promptly. Together, these two policies provide the legal fabric that pervades the timing aspects of Section 102 of the United States patent statutes (14).

Section 102 sets forth criteria by which the novelty of claimed inventions within the defined classes of statutory subject matter may be determined. The purposes of this section are to prevent the granting of patents to applications claiming subject matter that already belongs to the public, and to encourage the prompt filing of patent applications after the invention has become known. Thus, because of the "firstness" policy, events that occur before the actual invention date of the patent application qualify as potential "prior art," and—because of the "promptness" policy—events that occur more than one year before the application date also qualify as potential "prior art."

Any claim that encompasses ("reads on") something already in the public domain ("prior art") such as machines, instruments, organisms, processes, conference abstracts, or published articles, is "anticipated" and thus unpatentable. In contrast, claims to novel "pure cultures" of isolated naturally occurring microorganisms may be allowable if the pure culture has some novel feature not exhibited by the organism as it is found in nature (15).

The technical terms in the preceding paragraphs can best be understood by reference to the events that create an invention. An invention consists of two steps. The first step is the mental step of conceiving the idea. It is good practice to have this date documented by a dated, signed, and witnessed record in a laboratory notebook. The second required step is to reduce the idea to practice, the manual aspect; this, too, must be carefully and legally documented. The law provides that, even if one does not actually take the manual step, one's idea is still protected because the filing of the patent application that fully describes the invention can be regarded as "constructive reduction to practice." In that case, the invention date would be the filing date of the application, because that is when the second step would have been completed.

Events preceding the date of filing may create presumptive prior art, and the dates of such events are the "effective dates of presumptive prior art." Unless it can be shown that the inventor's date of invention was earlier than these events, the presumption will become conclusive. There are several mechanisms available to show an earlier date of invention: (a) the United States patent statutes provide means for claiming an "earlier effective filing date" by taking advantage of earlier filing dates in the United States (Section 120) and in foreign countries (Section 119); and, (b) pursuant to Rule 131 of the PTO Rules of Practice, an applicant can claim an "earlier effective invention date" by providing evidence via an affidavit or declaration that he made the invention before the effective date of the presumptive prior art, i.e., "swearing behind the references." This boils down to showing either (a) an actual reduction to practice before the effective date of the presumptive prior art or (b) conception before that effective date coupled with diligence in development of the concept from just prior to that date to the date of his own actual or constructive reduction to practice.

Parenthetically, the "effective date" of a publication of any type is the date of actual release to the public, and not the date of submission. In the United States, the effective date of a foreign patent is its patenting date, and not the date of filing; however, the "effective date" of a United States patent is its U.S. filing date (Section 102(e) of the patent statutes).

The United States patent laws somewhat arbitrarily establish a period of one year as the maximum permissible
delay between a "promptness" event, such as a description of the invention in a printed publication anywhere or a public use or sale in the United States, and the filing of a patent application on the invention. The theory is that an inventor ought to have a year in which to perfect the invention after its initial disclosure.

In contrast to the United States, there are many countries in the world—e.g., the EPC nations (16)—in which there is an absolute bar to novelty if the subject matter is published (in almost any way, to take the conservative approach) prior to the filing date of the patent application. This means that it is prudent, once you have the invention, to rush to some patent office and file an application before you publish. You may harm yourself if you publish anywhere the subject matter of your invention and then file later. You may find that you have lost your right to file a foreign patent. The word "publish" is construed broadly, and even includes verbal disclosures (a talk with slides or a poster presentation) as long as your disclosure was "enabling", i.e., you provided sufficient information so that those of ordinary skill in the art present in the audience could repeat your invention. There are certain exceptions to this rule in most countries: where the members of the audience were surrounded by written restrictions of confidentiality, a violation of such restrictions will not constitute a "publication."

Obviousness. This is the battleground on which most validity disputes are fought in the courts.

Section 103 of the United States Patent Law (17) sets forth the criteria of unobviousness by which useful and novel inventions are determined to be patentable. Their purpose is to preclude patent protections for those inventions that are so close to the prior art that their production is within the skill of the hypothetical person of "ordinary skill in the art."

As interpreted by the United States Supreme Court (18), Section 103 requires an analysis of differences in the scope and content between the prior art and the claimed invention. If the invention as a whole, notwithstanding these differences, would have been unobvious to the ordinary worker in the pertinent field at the time the invention was made, then the claimed invention is patentable. The determination of unobviousness is a subjective one, but the statute provides procedures and standards by which the decision may be made.

Several misconceptions may be held by scientists about the unobviousness requirement. Two of these were alluded to above, and warrant some expansion of the concept. One is that the invention must not have been obvious to one with ordinary skills in the art. This means that, even if the invention might have been obvious to the most sophisticated, highly-skilled practitioner in the field, he is not the benchmark—the journeyman scientist is the standard.

Secondly, the timeframe during which one determines unobviousness is the time at which an invention was made, not at some time in the future—e.g., not at the time of a patent infringement claim some years after issue of the patent.

Thirdly, the state of the art at the time an invention is made is viewed by the courts not only from the standpoint of the technological realities, but also from the standpoint of commercial realities. Was there a problem facing the art at the time the invention was made? Was there a commercial need to solve that problem? Did others try and fail? Did they succeed? What happened after the invention? Were there technological or commercial tributes paid to the inventor with regard to his contribution to the art?

Enablment

The "specification" of a patent has to comply with statutory requirements. These are particularly strict under the United States system (19). Technically, in the patent statute, "specification" also includes the claims. In actual practice, "specification" is the term loosely applied to the descriptive material in the application, including drawings, tables, and textual material preceding the claims section.

In the United States and elsewhere, the specification must provide a description of the invention that enables a person with ordinary skill in the art to produce the invention. The inventor is required to provide the "best mode" that is contemplated for carrying out the invention. This section most resembles a scientific paper, and includes an introductory section devoted to the background literature ("relevant background art"); an abstract ("summary of the invention") plus a formal "abstract"); sections devoted to methods, results, and discussion ("description of the preferred embodiments"); and supporting data ("examples" with actual laboratory data).

The claims that are in numbered paragraphs at the end must particularly point out and distinctly claim the invention. That is so that the rest of the world will know to what it is entitled with regard to the inventor's view of the rights granted him by a government.

Claims are not to be read in a vacuum. They must be supported by information in the specification. Claims are written by lawyers, not the inventors, and are written in an arcane style and unique language that are designed to avoid ambiguities, while providing functional broad protection to the inventor. An inventor is entitled to create his own lexic, and he can use words in the claims that to the rest of us may be ambiguous or unclear. One looks to the specification to see what the inventor meant and what he was, or was not, inventing.

Patent offices have had to devise special rules with which to deal with the new biotechnologies. For example, whereas a legally sufficient description of a chemical composition may easily be made through figures and text, it is often more difficult to explain the production and use of a genetically engineered organism, bacterial plasmid, bacteriophage, or hybridoma. One way in which to satisfy Section 112 of the U.S. patent statutes (and its counterparts in other countries) is to deposit the cells, plasmids, virus, or hybridoma in an independent depository accepted by each country's patent office, such as the American Type Culture Collection (Rockville, Maryland) for United States patents. In the United States, ever since Lundak (20), such deposits can be made after the patent application is filed, but before the patent is issued. In contrast, in EPC countries, deposits must still be made at the time of filing of the application, and the depository must be completely independent of the applicant.

Co-inventors and Co-authors

Often, an invention is the product of the collaboration of several individuals, each working toward the same end. Where each has made some contribution to the inventive thought (mental step) and (or) has contributed crucial suggestions leading to the final result (reduction-to-practice step)—even if the contributions are of unequal magnitude—they are all joint inventors.

When a research project is completed, the results, which may include a patentable advance in the art, are often published in a scientific journal. This is particularly true in
not-for-profit research, and is frequently the case for industrial research and industry sponsored academic research.

Commonly, the paper will list as co-authors not only those researchers who actually directed the course of the research but also the administrative head of the laboratory and (or) department, individuals who may have provided some material component of the research (e.g., patients’ sera), and technicians and graduate students who performed experimental work under the direction of the chief scientist. In addition, co-authorship credit may be given to collaborators who contributed to some phase of the project, such as an analysis, but not to the actual patentable subject matter.

Thus, the co-authors are not necessarily joint inventors. Should, however, a patent office consider that each of the authors of an article disclosing an invention is also a joint inventor of that invention, absent a showing otherwise? Can an article written by A and B be used to establish the lack of novelty of an invention claimed by A alone, although an article written by A alone would not have that effect?

Case law in the United States (21) holds that in an instance where there is multiple authorship of a published disclosure, but fewer than all are listed as joint inventors of the subject matter disclosed, it is incumbent upon the applicant(s) to provide a satisfactory showing that he is (they are) the sole inventor(s). A declaration (affidavit) by the named inventors that the omitted co-authors have not made any inventive contribution, but are simply being rewarded for collateral contributions, should, under Katz (21), suffice to satisfy the PTO.

The conclusion to be drawn is that patent applicants and their attorney must head off inventorship/authorship problems before they appear. Before a patent application is filed, applicants should describe, in writing, the nature of the contribution of each person who worked on the project. The patent attorney should then decide whether to include or exclude them from the inventorship entity.

If at all possible, this decision should be made before any scientific article is published, and those concerned should be given a brief opportunity in which to disagree with the determination of inventorship. Their failure to disagree, or reasons for discarding their claims, should be recorded. Those who are not deemed inventors, but who are declared co-authors, should be given an opportunity to sign disclaimers. If they refuse, then perhaps the decision to designate them as co-authors should be reconsidered.

**Patents in Academic Institutions**

**Guidelines and patent policies.** In the United States, guidelines for the development of patents at colleges and universities (22) have been developed by the Council on Governmental Relations (COGR).

COGR recommends that all institutions from which patentable inventions are likely to stem should have a formal patent policy approved by the governing board, which defines the rights and obligations of the inventor, the institution, and, where applicable, a sponsor. Institutional patent policies should be published in a formal document, typically arranged as follows: Preamble, Applicability of the Policy, Establishment of Inventorship, Commitment Rights of the Parties, Income-Sharing Arrangements, and Administrative Arrangements.

There should be a designated person—called, e.g., the Patent Administrator—responsible for patent matters, to provide a focal point for patent information, to serve as a collection point for invention disclosures, and to assure their evaluation and appropriate processing. These matters should all be spelled out in a set of administrative procedures, i.e., in a patent manual, distributed to all involved parties, which also include guidelines for keeping laboratory records and making disclosures.

**Guidelines for keeping laboratory records** (23). Appropriately kept laboratory records must be suitable to support a patent application and to defend against certain charges of invalidity by an infringer or by a competing applicant in an "interference" proceeding in a patent office. These are largely a matter of common sense. A complete and accurate record of the scientist's daily research activities should be entered in a bound notebook, legibly and in ink, with each page dated and signed. Whenever possible, preface each series of pages with a generic statement of the problem and your proposed solution. Similarly, when an experiment or run is completed and it represents the reduction-to-practice of only one or more species, include a paragraph setting forth still other species and parameters of variables, stating the reasons you expect them to be effective, in order later to provide a valid basis for a generic claim. Your work should be faithfully corroborated by having your notebooks witnessed by dated signature of an associate or a co-worker (but not one who is or could be a joint inventor); notation of the witness should appear after the last line of your experiment or run, and not necessarily only at the bottom of each page. Do not destroy any samples, run sheets, recordings, or records of any kind without checking with the director of the project as to possible value. Clear all proposed publications (including abstracts and poster presentations) with the director of research, in order most fully to protect and preserve property rights in research. Record your observation of physical results even if not fully appreciated or understood at that time. Use the first or last portions of the laboratory notebook for an index. Start a new page for each new experiment and draw a continuous diagonal line in ink through unused portions of pages. Avoid erasures; instead, where necessary, cross out with a single line and initial the deletion.

**Guidelines for disclosures** (23). The first step toward obtaining a patent is to determine whether you have made a possibly patentable invention. If you have discovered or made a new and useful process, device or apparatus, article of manufacture, composition of matter (including chemical compounds, microorganisms, cell lines, and the like), plant, or related improvement, or a new use for a known material or device, then you probably have made an invention that is patentable. If you are not sure, do not hesitate to discuss it with your institutional patent office. If this office does not have sufficient expertise, they will refer you to a scientific advisory panel or, lacking that, to the institution's biotechnology patent attorneys.

When you believe that you may have a patentable invention, the next step is promptly to submit an invention record ("disclosure") to the institution's patent office. For uniformity, a "Record of Invention" form should be used. The disclosure should include the following: a title; an abstract; statement of the invention; the state of the art to which the invention pertains; a description of the prior art; a summary of the invention; the utility of the invention; a description of any form of publication of the invention; a list of all budget numbers to which expenses for the research were charged; and signatures, witnesses, and dating.

As this information is confidential, do not send the
disclosure to others, not even to your research sponsor, without approval of your institution’s patent office.

A preliminary evaluation of the disclosure should be made in-house by the professional staff (if it exists) of the institutional patent office and (or) by an institutional patent committee (there usually is one in large scientific enterprises).

If, after preliminary review, your invention qualifies for further patent action, it will be referred to an outside patent attorney for a preliminary patentability opinion. It is becoming increasingly common for patent law firms, particularly those interested in the new biotechnologies, to employ patent attorneys who are, or have been, professional scientists in these technologies. Normally, the patent attorney will confer with the inventors at this point. In many cases, but not always, the patent attorney is requested to conduct a novelty search of the appropriate patent literature. Even if the inventors are aware of the pertinent literature related to their invention, a novelty search can be of substantial value to the inventor since it often reveals a state of the patent art not apparent to the inventors from the technical literature.

If, upon review of the patentability search and opinion, it is decided to proceed with patenting your invention, your patent administrator will instruct the attorney to draft a patent application. The patent attorney will need to work closely with you in the preparation of the application, as the application has many features in common with a scientific publication. Indeed, the inventors may have already drafted a scientific paper for future submission to a journal which the attorney may use in drafting the patent application. In some instances, the patent attorney may suggest additional work so that a proper application may be drafted.

Upon completion of the application, including your detailed review of the final draft and execution of the necessary documents (a Declaration or Oath of Inventorship), the patent attorney will submit the application to the PTO in your name. Before the application is submitted, however, you will usually be asked by your institution to assign patent rights to your employer. This is done by use of a special assignment form that you will execute (sign and date), which is submitted to the PTO along with the application.

Prosecution of the patent application. In general, at least a year will elapse before the U.S. PTO takes any substantive action. This first “Office Action” generally, but not always, is a rejection by the Examiner assigned by the PTO to your case of all, or some, of the proposed claims, with reasons provided. Don’t feel rejected! Patent prosecution is essentially a negotiation with the Government. Your patent attorney generally presents the broadest possible claims in order to obtain the broadest possible protection for your invention. The Examiner usually finds some prior art which shows some aspects of your invention as it is defined in the claims (Section 102 rejection), or the Examiner may find that your claims are not justified by the detailed description of the invention in the specification (Section 112 rejection), or the Examiner may find your invention obvious over the prior art (Section 103 rejection), or to have no utility (Section 101 rejection).

At this point, your patent attorney will consult with you and prepare a detailed response to the PTO, revising claims where necessary. Even if the Examiner thereafter accepts all of your claims, in the United States about two years will usually have elapsed between your filing of the application and the issuance of the patent.

Publications

Ordinarily, academic institutions do their best not to interfere with your right to publish research results promptly through the usual academic channels (but watch the patent provisions of your agreement with your research sponsor!). In fact, publications and oral presentations can play an important role in promoting interest in inventions among potential licensees. However, as indicated above, you should be aware that a public enabling disclosure of your invention before the filing date of the United States patent application automatically destroys patent rights in nearly all foreign countries. Remember, however, that United States patent law allows you a one-year grace period after your first enabling printed publication or public use or sale of your invention, in which to file a patent application, but BEWARE!!! “Enabling”, “printed publication”, “sale,” “experimental use”, and “invention” are legal terms defined by a vast body of case law, not by ordinary usage. It bears repeating that—in addition to journal papers—abstracts, posters, Ph.D. and Master’s theses, and typewritten papers distributed freely at a conference may constitute “printed publication.” But remember, conferences whose printed rules include a confidentiality statement may not constitute a public disclosure.

Patent License Agreements

A patent owner, having the right to exclude others from practicing the patented invention, may also give permission to others to infringe. This is normally done by a contract, usually referred to as a license. Licensing restrictions imposed on federally funded inventions are described in the United States Patent Law (24). Generally, a non-profit or small business firm may, within a reasonable time after disclosure and under certain conditions, elect to retain title to an invention developed with federal funds.

The purposes of licensing inventions to industry are (a) to provide a mechanism for transferring the results of laboratory research to the public for the public benefit and (b) to generate income for the instruction for education and research. Net proceeds from licensing income may be shared between the inventor and the institution, according to the institution’s patent policy. In the University of California system, for example, the inventor and the university share equally in the net proceeds from licensing income (23).

Terms and conditions for licensing agreements generally are negotiated on a case-by-case basis. The agreement sets forth the complete understanding of the parties, and covers the following points, among others: (a) the period of the license; (b) the geographical territory of the license; (c) whether the license is exclusive, non-exclusive, limited by field of use, or limited by time; (d) an exclusive license typically requires payment of an initial consideration to the patent owner; (e) the royalty rates; (f) means for assuring diligence of development by the exclusive licensee, with revocation of the license being a penalty for non-diligence; (g) retention by the institution of rights to practice the invention royalty-free; (h) payment by the exclusive licensee of the cost of prosecuting the patent application if it has not yet been issued at the time of the licensing agreement; and (i) indemnification of the institution by the licensee, particularly for product liability.

Transfer of Technology outside the Patenting Practice

Educational institutions provide considerable public utilization of faculty’s scientific findings outside of the patent
route. Typically, this is accomplished by the publication in scientific journals of information that, although not itself patentable, is important to the advancement of a given technology.

Another means of retaining ownership of concepts and technologies outside of the patent system is by the utilization of the doctrine of trade secrets. A trade secret may consist of any formula, pattern, device, or compilation of information that is used in one's "business" and that gives one an opportunity to obtain an advantage over competitors who do not know or use it. The subject of a trade secret must, therefore, be secret, and must not be generally known to the public. The requisite element of secrecy is not lost if the trade secret information is disclosed to another (e.g., a licensee) under appropriate conditions, typically a confidential relationship in which the recipient agrees not to make the information known to others. For example, in the case of a genetically engineered organism, it is sometimes possible for the inventor to disclose to the public its existence, yet retain the organism per se as a trade secret, and license its use to industry. There is no statutory term to a trade secret, as there is in patent law. The life of a trade secret is strictly subject to events: whether or not its owner continues to protect it, whether or not it continues to have value, and whether or not others independently discover the trade secret. A patent can be infringed without copying the subject matter of the patent, that is, without deriving directly from the patent owner. In contrast, a trade secret right normally is not infringed without direct derivation, that is, without either the violation of a confidential relationship or out-and-out theft.

Trade secrets are not protected by federal law, but by state law. Thus, an action against someone who steals a trade secret is grounded, whether in a federal or a state court, by the statutes and the case law of the state in which the action is brought.

In the course of evaluating an unpublished invention, it is often worthwhile to determine if the invention has commercial merit by disclosing it to prospective licensees. In order to protect the institution's right in the invention, as well as foreign patent rights, disclosure of such unpublished information to third parties should be made only after the third party has signed a suitable secrecy agreement. By determining whether or not there is commercial interest in the invention, the institution can make a decision as to whether or not the expense of filing a patent application can be justified. In fact, it is often the case that a commercial organization will agree to underwrite patent expenses in return for the right to obtain a license to the invention, even prior to patent issue.

Summary

Patenting and commercialization by academic scientists, despite potential drawbacks, are on balance highly desirable if technology is to be transferred from the laboratory to the public use, and if the scientist and his institution are to be encouraged to participate in this transfer.

If that premise is accepted, there is much that academic institutions can do to foster utilization of their biotechnological discoveries. Such institutions should have a patent policy that is known to all and that includes a professional patent administrator and clear administrative procedures for carrying out such policy. Scientists should be trained to recognize and protect their inventions and to appropriately disclose their inventions to their patent officers. Ideally, scientists should know the rudiments of the patent statutes of their own country and should be aware of what constitutes trade secrets. Scientists should be given guidance in working with patent attorneys in the preparation and prosecution of patent applications.

Finally, given human nature, institutions should see to it that their scientists are provided with a suitable environment in which to invent, and appropriate incentives to do so.

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References and Notes
2. The "new biotechnologies" include fields such as recombinant DNA technology, monoclonal antibody-based technologies, gene sequencing and synthesis, cell and tissue culture methodologies, large-scale fermentations, enzymology, and diagnostics. Office of Technology Assessment, Commercial biotechnology: an international analysis. Washington, DC: Govt. Printing Office, 1984.
5. Vossius V. Patenting genetic engineering inventions in Europe: recombinant DNA and hybridoma patent issues in the European and German patent offices. Ibid., 118.
7. Dissealble data provided by the Division of Clinical Laboratory Devices, Office of Device Evaluation, Center for Devices and Radiological Health, pursuant to a Freedom of Information Act request.
10. 35 U.S. Code, Section 101—Inventions patentable.
11. Lowell v Lewis, 1 Mason 1A2, 15 Fed. Cases 1018, No. 8568 (Circuit Court of the District of Massachusetts, 1817). Unfortunately, the United States Supreme Court has overnarrowly construed the utility requirement to things of known, practical commercial utility [Brenner v Manson, 383 U.S. Rep. 519 (1966)]. The EPC has even more-stringent rules: the invention must have "industrial application."
14. 35 U.S. Code, Section 102—Conditions for patentability; novelty and lack of right to patent.
17. 35 U.S. Code, Section 103—Conditions for patentability; non-obvious subject matter.
25. General sources of information on patenting: