

FEATURE ARTICLE

SOME IMPORTANT CONSIDERATIONS REGARDING CHEMICAL PATENTS

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Introduction. Achieving patent protection for a chemical invention is central to profiting from its practical application and is an essential preliminary step if one hopes that a firm will take up the invention with one as a partner and devote the substantial labor and costs necessary to developing and marketing it. In any case, the academic scientist will not profit from subsequent work developing the discovery if a suitable patent is not obtained. Whereas students are taught chemistry and their subsequent professional practice sharpens these skills, students are rarely educated in patent matters and those who become professors rarely have practical experiences suitable for learning patent law without formal study and assistance. This brief paper is intended to address this deficiency. The reader should reflect on the unfortunate circumstance that patent law is a legal specialty of considerable complexity and to some extent each patent is a case unto itself so that patent law does not lend itself readily to brief exposition any more than does organic chemistry and so the assistance of a trained and experienced patent lawyer is essential for a completely favorable outcome. Nonetheless, the chemist of ordinary experience and intelligence can readily master the principles of patent law and apply them successfully to participate in securing, defending, and enjoying patent protection. Furthermore, the chemist can utilize an introductory understanding of patent law to keep proper records which will support patent assertions and to avoid premature disclosure which would prevent patent protection. These factors are specially important as, in my experience, most academics carry out their daily activities in a spirit of openness of scientific sharing of research results that is incompatible with the proprietary nature of evidence required by law to ensure patent rights. Furthermore, student notebooks are rarely kept in the necessary manner to establish priority of scientific discovery let alone to establish legal priority of invention. It is, however, quite possible to conduct one's affairs in such manner that future patent rights are not jeopardized and yet academic enquiry is not hindered either. Fortunately, the necessary behavior modification is comparatively slight compared to what is at stake. The majority of students opt for commercial employment and profit from learning how to do these things correctly. This, however, does not happen by instinct.

The information which follows is based primarily upon United States patent law because this is the area which the author understands best. The differences in patent law in other countries are somewhat idiosyncratic but there are great similarities which we can build upon. At this time most of the major chemical firms are international in the scope of their business and require patent protection in all of the economically significant markets. Patent protection in Botswana will convey no significant rights in Europe, Asia, North America, or elsewhere. Likewise, patent protection in The United States will not give patent protection in any other country either. Choosing in which countries to apply for patent protection is important for economic as well as strategic considerations. The author hopes that the innocent academic is not daunted by these considerations and hastens to add that if one is in possession of discoveries of significant commercial merit, one can disclose this material to a firm under the protection of a secrecy agreement and the firm will usually agree to undertake the necessary patenting steps using its legal expertise provided that a partnership agreement follows and the scientific records are suitable for supporting this activity.

Background. The very first article of the Constitution of The United States (dating from 1790 when this country was first an independent entity) contains "An Act to Promote the Progress of Science and the Useful Arts" as a reflection of the importance an orderly market place has in commercial existence. In return for a full, enabling, disclosure of an invention, an inventor receives a seventeen year exclusive monopoly to the material claimed. The first date of these monopoly rights is the date of granting of the patent, often two or more years after the date of first application. Interestingly, the President (George Washington) and the Secretary of State (Thomas Jefferson) signed the first US patent which, incidentally, was for a chemical process (the making of potash). Such high officials are no longer directly involved. The Patent Office is a division of the Department of Commerce.

The advantage/incentive to the inventor is the monopoly which reduces the economic risks of bringing the invention before the public and gives the inventor the opportunity to establish a following for his/her brand that may survive the ultimate competition which takes place after the patent expires. The advantage for society is that the secret parts of inventions do not die with the inventor. The inventor has greater access to investment capital and, in due course, other inventors can profit from utilizing the thinking behind the invention and, indeed, the invention itself.

Essential characteristics of patentable matter. The essential features needed for a patent to be issuable are novelty, utility, and unobviousness. Each of these

features have been defined in a multitude of judicial decisions and are understandable in general terms although their specific meaning in specific cases is still a matter for litigation.

By novelty one means that the invention must be different from that which was known or existed before the date of your application. You may not, for example, on finding that there is no existing patent for table salt, apply for one. Table salt has existed from ancient times and is in general well understood and in common use even by untutored individuals. Table salt is said to be "in the public domain" (One digresses at this point to say that certain terms and collections of words have specific legal meaning and should be employed knowingly. "In the public domain" is such a cliché). A scientist is expected to be conversant with the chemical literature and should find all of the pertinent articles and evaluate them for anticipation of the discovery. Chemists have less access to the patent literature. This is not a trivial problem as not all of the art which is patented is subsequently published in the chemical literature. Chemical Abstracts publishes brief accounts of issued patents from every country (and a concordance so that one can identify related patents from other lands) but these are often described too briefly and cryptically to enable one to make a complete judgment. The US Patent Office keeps a complete collection of contemporary US patents and one can search these or employ an experienced searcher to identify the closest prior art. Alternatively, one can send away for a printed copy of an issued patent by paying a small fee (currently \$1.50 US). The US Patent Office maintains the strictest security regarding patent considerations until a patent is issued. Once the patent is allowed and issued, however, the entire file is available to the public upon request.

A very important consideration not generally realized by chemists is that if even the inventor himself publishes an account of the discovery before patenting, this places the matter in the public domain and precludes patenting. The invention is known to the public at the time of application and therefore is no longer novel. This is a hard lesson for academics who are used to publishing their work as soon as possible. Incidentally, a thesis or dissertation is also a publication so one may involve one's students in these problems unless one is aware of these things. The United States is an exception with respect to premature publication because it allows as much as a calendar year after public disclosure before an application must be filed with the patent office whereas every other country which this author knows about starts the clock instantaneously. Firms are very well aware of these complexities and an industrial inventor must get permission from the appropriate authority before publication is allowed. It is also a corollary of the novelty concept that the inventor must make the application for the patent. If the legal inventor is not on the patent

application, then the matter was obviously not novel! One can readily understand that a corporation cannot be an inventor. Since an idea most often occurs to an individual, one may imagine that a patent will always be taken out by a single person. This is, however, comparatively rare. Modern science is a team enterprise and in a meeting where a problem is posed and several tentative solutions are advanced, it is often difficult to decide in retrospect who advanced the key elements of the total solution. Consequently, it is common to include all those who made a significant contribution to the conceptualization of the idea. In this way all those who have a possible legal claim to having made the invention will be included. The patent has a chance of surviving a legal challenge based on the claim that the real inventor was not included so that the idea was really "in the public domain" at the time of application. One must also remember that it is the idea or concept which is the invention. The person who makes a prototype or runs the reaction successfully ("reduces it to practice") under the direction of the person or persons who conceptualized the solution is not an inventor. That person was often not present at the moment of discovery. On the other hand, a discovery which stems from a laboratory finding, most particularly when brought to the attention of the supervisor by the person making the observation, is the invention of the person who made the finding or the person who first appreciated and recorded its significance. In cases of doubt, it is better to have too many putative inventors on an application than to miss the real inventor. One may delete inventors from an application, but one cannot add them later.

If the patent examiner decides that your invention is anticipated in a significant way by a literature or patent reference, whether or not it is still in force, your application will be denied and the reasons specified. Elements of unobviousness are also usually entangled with the priority date question. The examiner will state in the rejection the grounds for believing that your invention is obvious to a person "ordinarily skilled in the art". You will have the opportunity to examine the literature cited and to rebut or change your application in order to overcome the grounds for rejection. You must do so within the time the examiner specifies or your patent will be rejected. Patent applications are almost never allowed in the first iteration. In case there is another application for the same matter, an interference will be declared and the two or more applicants will have an opportunity to resolve the conflict. It is at this stage that the date of conception and of first "reduction to practice" becomes critically important. The laboratory notebooks and disinterested corroborative witnesses are the most important supportive evidences which can be presented here. An earlier date coupled to timely subsequent experimentation recorded properly in a suitable notebook is almost impossible to overcome.

Keeping a laboratory notebook properly. The proper form for keeping a laboratory notebook is fairly straight forward to explain but is very often not complied with in academic laboratories where notebooks are usually kept in shockingly informal manner. The notebook is a form of diary and is a primary legal document of great importance. The notebook itself must be bound and have consecutively printed pages. No page should be left blank without an explanation and no page should be removed without legal permission in advance. All entries must be kept in ink and no erasures are allowed for any purpose. If one makes a mistake, it is sufficient to draw a line through the incorrect matter so that it is still legible and the cancellation can be explained at a later date if necessary. These requirements are to prevent alteration and falsification of the notebook. Each entry must be dated and each experiment must be dated and each experiment must have a title. No blank spaces should be left for subsequent entries, such as entering subsequently received analyses, etc. In such cases, late arriving data should be entered on the date of receipt or if a mass of such material is likely and will be a frequent occurrence during the whole of the time the notebook is in use, then a common practice is to put the narrative part on odd numbered pages and to make postdate entries of this type (each with its own date, of course) on the even numbered pages. These requirements are to prevent predated entries at a later time. When an experiment goes on for days, each day's work should be dated. When experiments lap over onto subsequent pages, the last entry on the page should indicate where the experiment resumes ("go to page x", for example) and the first entry on the subsequent page should indicate where the previous matter came from ("continued from page x", for example). All weights and measures are primary data and must be part of the narrative. Never put important and non-recoverable data on loose papers for entry at a "convenient" time. The notebook is a diary for your use and must be intelligible to you. It need not be written in such style that it could be published as is. Thus there is no legitimate reason to delay entry of data and observations until an experiment is complete and you have composed a polished version of the work. This would interfere with your achieving the appropriate priority date and represents post entry of data. Post entry is legally indefensible. The notebook should be written in sufficient detail that a person ordinarily skilled in the art will be able to understand what is written and to go into the laboratory and to repeat it if necessary. The person "ordinarily skilled in the art" is usefully considered to be one of your contemporaries in your laboratory who is, however, not likely to be an inventor on the project. Such a person can corroborate your assertions without fear of being accused of prejudice or self interest. You must conclude each page or each experiment with your signature and the date. Each page should then be witnessed with signature and date by at least one person familiar with you and your work and who will not be a coinventor. The person ordinarily skilled in the art

described above is an excellent notebook witness. This person may be called upon to testify in court that this is your notebook and that it was filled out on the date of witnessing. Ideally such a person should be a confidant who can also testify that he/she read and understood the entry on the date when they signed the book. In cases of disputed priority, this kind of testimony is extremely important. To provide a suitable reward for this kind of service, it is convenient to exchange notebooks with a friend and provide this service for each other. If one cannot do this exchange daily, it is very helpful if a consistent pattern is used, such as signing every Friday afternoon during tea break. If these simple procedures are followed, then you have an excellent chance of preserving your invention against legal attack.

Utility. The patent act is "an act to promote the progress of science and the useful arts". If a novel substance has no utility or practical application, it is not patentable. The invention must be shown to fill some actual or potential societal need or to be an improvement over current materials. Later in this paper when the classes of patents are taken up it will be seen that there are occasions when an impractical but demonstrative utility is sufficient to give patent protection to a new "composition of matter" (compound). Remember that the practical application or commercialization of a patent is a subsequent idea to the patent itself. It is possible to patent an agent believed by the inventor ultimately to be useful for treatment of patients with systemic fungal infections but prior to being in possession of experimental proof for this belief on the basis that the compound could, for example, be added to paint to prevent deterioration of wood by fungal action. It could well be much too expensive for this to be done actually, but this is utility sufficient for patent protection on the compound itself.

Unobviousness is a difficult term to define precisely and patents are often challenged on the basis of being obvious. If an idea would be obvious to a person "ordinarily skilled in the art" at the time of invention who was in possession of the realistically available literature and possessed a general understanding of the field of the invention at that time, then the discovery "lacks inventive merit". In other words, a person of ordinary attainments would make such a discovery and, indeed, one presumes that many people were in possession of this solution and practicing it in a practical way before the application was made. Thus, the matter was implicitly "in the public domain". Who is a person "ordinarily skilled in the art"? This mythical person is established at the beginning of trials. This person is not a Nobel laureate nor a stupid individual. For practical purposes it is useful to think of a person with the same general educational attainments and such general chemical experiences as the inventor or persons capable of addressing the problem at the time of the

invention. It is important to emphasize that all knowledge gained subsequent to the time in question is irrelevant to the patentability question and it can be challenging experience to recall precisely what a person ordinarily skilled in the art knew and did not know in, say, 1975! It is also of practical importance to instruct ones students to keep their notebooks in such a manner that a person "ordinarily skilled in the art" could successfully repeat the work. Thus the laboratory notebook is neither kept in such excruciating detail that ones mother could do the work but in also not so cryptic form that only a Nobel laureate could hope to decipher the instructions.

Another murky area for consideration in the context of unobviousness lies in the properties of homologous series. For example, suppose that we find an acetyl ester of a complex alcohol has antimicrobial properties. It is so well known to even undergraduate students of chemistry that the properties of members of an aliphatic series usually differ in degree not in kind that substitution of a propionyl ester for an acetyl ester is not of inventive merit unless the new substance has nonpredictable or unexpected and useful properties (is unobvious). Thus one often finds collective statements in patents such as "acetyl and other lower aliphatic esters" as being functionally equivalent. Inclusion of this statement takes nothing for granted and leaves no vulnerable point for someone else to exploit. It does not require specific exemplification but is generally accepted to be so.

Some things are intrinsically not patentable. Even with novelty, utility and unobviousness, some things are not patentable. In principle, physical embodiments of science such as the gaseous state are not patentable. A patent based on this would be so broad as to be meaningless and would also be unduly restrictive to the progress of science and the useful arts. A novel means of producing the gaseous state would, on the other hand, likely be patentable. Physical manipulations of existing things are also not patentable. Putting a solid in a vial, for example, would not be patentable but the vial itself could be. A patent need not be an entirely new thing but it must effect an improvement in an existing thing or a novel assembly of preexisting things which is beyond the imagination of one ordinarily skilled in the art. It must have inventive merit. Few ideas once expressed are totally without connection with anything which was previously known. In some senses everything is obvious to an expert once it is explained. Credit for invention goes to the first mind which conceives the idea. It is the closeness and obviousness in light of prior art that is involved in patenting. Phenomena of nature, such as solubility, may not be patented. A "result" may not be patented. For example, one may not patent the phenomenon of antibiosis achieved by any means whatsoever, but one can patent a novel substance which effects this result. Abstract ideas, such as purity or resonance, cannot be patented for one cannot prohibit people from thinking and one

cannot enforce such a prohibition anyhow. Assembly of existing things which continue to function as before is also unpatentable. A mixture of salt and hexane with no identified useful and nonobvious new property resulting would be an example.

The classes of chemical patents. The composition of matter patent. There are several classes of chemical patents. The most all inclusive is the composition of matter patent. In this case, one receives a patent for a given new, useful and unobvious chemical compound. It is useful to consider this as a physical possession like, for example, a pen. One owns the pen regardless of how it is made or used. If someone else finds a novel way to produce or to use a pen, the pen is still yours and they must pay you for the use of it. As a possession, you may neglect to use it, sell it, give it away, loan it, use it in new ways, improve it, make it in improved ways, etc. Interestingly, someone else making a pen for his own private purposes (not bringing it into commerce) is still infringing your patent rights and, if you should come to know of it, you can legally compel him to stop.

The process patent. A process patent is less useful. It is a novel and/or improved and unobvious means for making a composition of matter. If the composition of matter is in the public domain, a process patent is one way in which you can get patent protection in order to sell this substance. The specific claims (see below) must be written with great care. If you specify that the solvent for the process is, say, methanol, then the use of ethanol may be judged not to infringe your process. To prevent this, one often says that the reaction may be conducted in an aliphatic alcohol, preferably methanol, or some other reaction inert solvent. Another common form of expression used to broaden one's coverage is to say that a reaction inert solvent is used, such as a cyclic or non-cyclic aliphatic ether, preferably tetrahydrofuran. If your process states that reduction of a ketone to a secondary alcohol is done, it is important not to limit it to a single reducing agent but to claim all those reagents which you believe capable of effecting the transformation. A common means of expressing this is to say that the transformation is effected by use of one of the many reagents well known to those skilled in the art of which one of the alkali metal boron hydrides, such as sodium borohydride, is particularly effective. If you specify that A goes to B and B goes to C and then C goes to D, someone who carries out the sequence in different order (A to C to B to D) is not formally infringing your process. Thus you can see that constructing a definitive process patent which cannot be easily infringed is a challenging job and is best undertaken with the assistance of a patent attorney.

The use patent. A use patent is also possible. In this case, a composition of matter which is in the public domain is found to have a non-obvious and novel useful property. For example, DDT was synthesized many decades before its insecticidal properties were uncovered. At that latter time DDT as a composition of matter was in the public domain and could not be patented but its use as an insecticide could be and was. This newer use is not immediately obvious to the person ordinarily skilled in the art and is patentable. If the material involved is covered by a composition of matter patent which is still in force, then the owner of a use patent cannot practice his invention without the permission of the owner of the first patent until that patent expires.

The component parts of the patent application. The patent application usually contains five parts: the formal papers, specification, claims, filing fee and drawings.

The formal papers. The formal papers involve a petition ("please give me a patent for the following"), a power of attorney (if you have a patent lawyer representing you all subsequent correspondence will go to the attorney), any oaths or declarations (for example, that you are the inventor and to the best of your knowledge the matter which follows is, indeed, new), that you are or are not an individual or a small firm and therefore eligible for lower fee assessment, and/or an assignment (if you are working for an employer, such as the university, and a condition of your employment is making inventions, you are expected to assign your inventor's rights to your employer. Your employer may assign them back to you if he wishes. If you have formed a partnership for the purpose of pursuing your discovery with a firm, you may be obligated to assign the patent to the cooperating firm or at least to give or sell them a license to use the invention).

The specification. The specification names the invention, reviews what you believe to be the pertinent prior art, gives a detailed description of your invention with particular emphasis on its novel or inventive features as compared to prior art, and an experimental portion which contains examples illustrating its main features in sufficient detail that a person ordinarily skilled in the art can reduce it to practice without undue experimentation. You need not reduce absolutely all conceivable embodiments of the invention to practice and describe them in the experimental part, but the examples must be workable and reasonably encompassing. The question comes up from time to time whether the examples must illustrate the best methodology known to you. Generally they do not. Nonetheless they must "work" when subjected to a good faith effort by a person ordinarily skilled in the art. "Work" is taken to mean that a measurable amount of a substance must be produced by a reaction, for example. The example frequently need not produce commercial

quantities but rather shows that the idea "works". One is allowed to perfect one's own invention by subsequent experimentation without necessarily going outside the scope of one's general specifications of the invention. If one does effect an improvement by going outside of this scope, then this is a new invention.

The claims. The claims are, generally speaking, the most important part of the patent because this defines specifically and strictly what is covered by your monopoly patent and is enforceable by law. It also distinguishes the essence of what differentiates your invention from prior art. The description must be sufficiently broad as to prevent legal use by others who are simply clever but must be precise enough to be understandable. New claims cannot be added without losing the original date. One can file a continuation-in-part containing a limited amount of new information and so retain the priority date of the old matter and the new date for the added matter. One must be careful here that the new matter not be such as to alter the scope of the invention so that it is a new invention or you lose all the benefit of your earlier filing date.

The filing fee. The filing fee is the cost assessed for the patent application. This is a sliding scale such that very large firms pay more than, say individuals. These fees are altered from time to time.

The drawings. The drawings illustrate the invention in such manner that a working prototype can be constructed. Vacuum pumps, for example, would require such a drawing but chemical patents often do not. Structural formulae can be included as drawings.

Is a patent always the most desirable outcome of invention? Does one always apply for a patent when one has made an invention? No. The publication of a patent does instruct the clever in the meets and bounds of your contribution and they come into possession of your secrets. If they are clever enough and you were clumsy enough, they may be able to get your patent declared invalid in court and substitute their own version or they may figure a way to infringe your patent in a practical although legal way. The most famous nonpatented entity is Coca Cola. This beverage has been in existence for a century and its patentable exclusivity would have expired long ago if it had been patented. They would then have even more competition than the many cola drinks now provide. Thus, in cases of exceptional complexity one may decide that no one else could decipher the ingredients or the process even when in possession of the product and that it is safer for you not to get a patent. This is rarely the case with chemical inventions.

Infringement is the practice of your invention by someone without your permission. You must seek to prevent this yourself and the law will assist you but it will not do it for you. If you do not enforce your rights you may lose them for the court may decide that you have abandoned your patent rights. You are the most qualified individual to suspect or to determine that someone is practicing your invention in violation of your rights. Should this take place, your first step will be to be sure that infringement is occurring and then write to the offending party and demand that they cease and desist. This may be sufficient as they may do just that. On the other hand, a frequent response is that they are not infringing because your patent does not cover their activity or that your patent is not valid. In this case, the dispute may go to court and take years to settle.

Shop rights. A gray area is called shop rights. Since 1960 in the US, when an employee, during his regular working hours, using his employer's supplies, equipment and laboratories, conceives and perfects an invention which he subsequently patents, he must give his employer a nonexclusive right to practice the invention. If the invention is assigned to the employer, the employer owns the patent and has a perfect right to use it. Such assignment agreements should be done in advance and should be in writing. Normally this is part of the employment formalities.

Summary and conclusion. In sum, some common aspects of patent law of importance to the chemist in deciding what steps are necessary to be taken before, during and following an invention in order to secure patent protection for the discovery have been described. It is hoped thereby to increase the comfort level of academic scientists when faced with the practical necessities required when working with potentially commercially important materials.

The interested reader is encouraged to consult any of the many excellent texts on the subject for more detailed information on chemical patenting. A recent book which the author has found to be clear and concise is "Patents, Copyrights & Trademarks" by Frank H. Foster and Robert L. Shook, John Wiley & Sons, New York, 1989.

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