



CHAPTER 12

Bugs and Patents

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Inventions which use a microbe are patentable under the United States Patent Law if certain criteria are met. These criteria, which have been developed over the years in several key legal decisions, have given us a meaningful body of microbiological patent law. This body of law concerns the nature of a patentable microbiological invention; the requirements for a sufficient disclosure of a microbiological invention in a patent application; and the procedure used to make a microbe available to the public in conjunction with the filing of a microbiological patent application. An understanding and the proper application of the principles of these laws are necessary for obtaining valid patent rights for microbiological inventions in the United States.

DISCUSSION

Nature of a Patentable Microbiological Invention

Not all microbiological inventions are patentable under the United States Patent Law. In order to be patentable, an invention must be new, useful, and unobvious from what is known in the prior art. This last sentence is not as simple as it may appear. A large number of legal decisions have been rendered in an effort to define the words "new," "useful," "unobvious," "known," and "prior art." Some of these decisions have been in the microbiological invention area.

A key decision by the Supreme Court of the United States in *Funk Bros. Seed Co. vs. Kalo Inoculant Co.* (1948) held that a *mixture* of bacteria was not patentable subject matter under 35 U.S.C. 101 (1952). Though the *mixture* was new, unobvious, and useful, the Court found unpatentability for at least two reasons, i.e., a lack of identification of the bacteria, and the bacteria were a "product of nature."

The "product of nature" theory has been one of the greatest barriers to obtaining full patent rights for microbiological inventions. Though the U.S. Patent system has given patent rights to such inventions as vitamin B-12, purified aspirin, purified adrenalin, and purified prostaglandins, there has been a steadfast refusal to find that new, useful, and unobvious microorganisms are patentable subject matter. This is primarily because of the "product of nature" theory which has continued to exist despite the vagueness of its scope of application. Mr. Justice Frankfurter in *Funk Bros. Seed Co. vs. Kalo Inoculant Co.* (1948) recognized the nebulous character of the "product of nature" theory in his statement: "Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.' Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent."

Though the "product of nature" theory in microbiological inventions has prevented the realization of patent rights for microbes per se, the *use* of microbes in a *process* has been the subject of many U.S. patents. Patents have been issued wherein a microbe is used in a process to make a useful product, such as an antibiotic, or perform a function, such as biological transformation of steroid molecules. The patentability of these processes is tested by the legal

requirements of novelty, unobviousness, and usefulness. Thus, a new microbe (could be a new strain of a known microbe) which is used in a process to make a useful product, or do a useful thing, is patentable in the form of a process claim. A recent decision by the Court of Customs and Patent Appeals (CCPA) in *In re Mancy* (1974) held that a new *Streptomyces* used in a process to make a known and useful antibiotic was patentable as a process claim. The U.S. Patent and Trademark Office (PTO) initially rejected the process claim reasoning that it was "obvious" in view of the prior art which disclosed the production of the same antibiotic by a different *Streptomyces*. It was the PTO position that: "It is not patentable to produce the known antibiotic from either a different strain of the same species (of microorganism) or a different species of the same genus (*Streptomyces*) unless something more is present than merely the utilization of another source from the same field of sources of these products." (In re Mancy 1974). The CCPA reversed the PTO rejection stating: "... we believe that the invention is not prima facie obvious. Without *Streptomyces bifurcus*, strain DS 23,219, knowledge of which is supplied by appellants' application and availability of which is supplied by appellants' deposit of the microorganism with the Department of Agriculture, one skilled in the art would not find it obvious to produce daunorubicin by aerobically cultivating *Streptomyces bifurcus*." (In re Mancy 1974). The application in issue in the *Mancy* case has since issued as a patent (Mancy 1975).

Finally, there are the situations where a *known* microbe is used to produce a *new* and *useful product*, or produce a *new* and *useful result* in a fermentation. These inventions are patentable in the form of process claims. In all of the above microbiological inventions, it is essential, in order to obtain patent rights, that the invention be disclosed properly in the patent application.

Disclosing a Microbiological Invention

A microbiological invention, as any invention, must be disclosed in a patent application in accordance with the requirements of the Patent Law. These requirements are designed to insure that when and if a patent issues for the invention, the public can identify the metes and bounds of the invention, and thus appreciate when the invention is being practiced. Further, the description of the invention must be sufficient to enable those skilled in the art, to which the invention pertains, to practice the invention. A disclosure of a microbiological invention using a new microorganism requires a taxonomic characterization of the pertinent microbe. This taxonomy should be conducted using the best art-recognized tests for characterizing microbes. In addition to a disclosure of the taxonomy of the pertinent microbe, it is essential that the process conditions of time, temperature, media, etc., be disclosed in the patent application.

All of the above, which includes the microbe and process conditions, *must* contain the "best mode" of practicing the invention process at the time the patent application is filed in the PTO. This is a specific statutory requirement 35 U.S.C. 112 (1952) for *all* invention disclosures. This "best mode" requirement of the law means, in the case of a microbiological patent application, that the *best* culture of the new or publicly unavailable microbe *must* be taxonomically characterized in the patent application, and it *must* be deposited in a suitable culture depository prior to the filing of the patent application.

Culture Deposit and Availability to the Public

If the best culture is already known and available to the public, then depositing and

taxonomic description are not essential to enable a person skilled in the art to practice the invention process.

The CCPA in the landmark decision, *In re Argoudelis et al.* (1970), accepted the method employed by the patent applicants in their culture deposit as being sufficient in law. The Argoudelis applicants deposited a culture of the pertinent microbe with the U.S. Department of Agriculture depository at Peoria, Illinois (NRRL), prior to the filing of a patent application in the PTO. When the patent application was filed, it contained a complete taxonomy of the pertinent microbe and the accession number for the culture deposit given by NRRL. The PTO rejected the application on the basis that the culture was not available to the public at the time the application was filed in the PTO. The CCPA reversed the PTO and held: "We do not think that 35 U.S.C. 112 (1952) requires that the microorganism be available to the general public at the time of filing the application." (*In re Argoudelis et al.* 1970). Also, the court held that: "The procedure used by appellants is sufficient to constitute a constructive reduction to practice and to entitle appellants to the benefits of a filing date since they clearly demonstrated that they had solved all technological problems involved in producing the invention. The disclosure is sufficient to permit a thorough examination by the Patent Office and to preclude the possibility that a patent could issue without any person skilled in the art being thenceforth enabled to make and use the invention." (*In re Argoudelis et al.* 1970).

The CCPA held for the patent applicants since, basically, it was abundantly clear from the record that the culture was available to (1) persons having legal access to the patent application during the pendency of the application in the PTO, and (2) the public upon the issuance of a patent disclosing the culture. Thus, the patent applicants satisfied the Patent Law fully by sufficiently disclosing and identifying their microbiological invention. The holding of the Argoudelis case was subsequently adopted by the PTO. In their Manual of Patent Examining Procedure (M.P.E.P. 1975), the PTO states that it "will accept the following as complying with the requirements of Section 112 for an adequate disclosure of the microorganism required to carry out the invention":

"(1) the applicant, no later than the effective U.S. filing date of the application, has made a deposit of a culture of the microorganism in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted, under conditions which assure (a) that access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under Rule 14 of the Rules of Practice in Patent Cases and 35 U.S.C. 122 (1952), and (b) that all restrictions on the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent;

"(2) such deposit is referred to in the body of the specification as filed and is identified by deposit number, name and address of the depository, and the taxonomic description to the extent available is included in the specification; and

"(3) the applicant or his assigns has provided assurance of permanent availability of the culture to the public through a depository meeting the requirements of (1). Such assurance may be in the form of an averment under oath or by declaration by the applicant to this effect." (M.P.E.P. 1975).

CONCLUSION

The United States Patent Law concerning microbiological inventions is advancing to give meaningful patent protection to these valuable contributions. A proper understanding and merging of legal requirements and microbiological knowledge are essential to continue this

advance. Microbiologists can contribute to the progress by continuing to standardize techniques and tests for the identification and classification of microbes. The greater the certainty in these areas of identification and classification, the better the patent lawyers' position to obtain and enforce patent rights for microbiological inventions.

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