Environmental and Experimental Botany, Vol. 21, No. 3/4, pp. 383 to 387, 1981
Printed in Great Britain

0098-8472/81/030383-05 $02.00/0
Pergamon Press Ltd.

THE LEGAL ASPECTS OF PLANT TISSUE CULTURE AND PATENTS

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BAGWILL, R. E. *The legal aspects of plant tissue culture and patents.* ENVIRONMENTAL AND EXPERIMENTAL BOTANY **21,** 383–387, 1981.—This paper covers three areas of patenting: patents in general, plant patents and a discussion of the potential hybridization of both kinds of patents in view of the Supreme Court decision involving the patentability of bacteria.[1]

SECTION 101 of the patent statutes[2] provides that:

Whoever invents or discovers any new and useful process, machine manufacture, or composition of matter, or any new and useful improvements thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Thus, anyone might patent, for example, a new process for inducing embryogenesis of an explant, a new machine like a phytotron for the regulation of external growth factors, a new machine such as a flask for containing the culture and a new growth medium which would be a composition of matter.

When you file an application for a 17-year monopoly on one or more of the above-mentioned categories of invention, you will set forth a brief abstract, a detailed description, illustrations where necessary and one or more claims which precisely spell out the novel features of the invention. The claims define the metes and bounds of your protection. Your monopoly gives you the right to exclude others from making, using and selling that which is claimed. Not only must the claimed invention be new, if it is an improvement of an old invention, that improvement must not be obvious to one having ordinary skill in the art to which the invention pertains.[3]

Sections 102 and 103 provide:

A person shall be entitled to a patent unless—
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
(c) he has abandoned the invention, or
(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of an application in the United States, or
(e) the invention was described in a patent granted on the application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2) and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or
(f) he did not himself invent the subject matter sought to be patented, or
(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

§103. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented

and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A patentable improvement often involves a difference in kind rather than degree, and unexpected results or advantages not taught by the prior art. The expression, prior art, includes prior U.S. patents, foreign patents and printed applications, periodicals, advertisements, certain graduate theses and even posters which are publicly displayed. Section 101 requires that the claimed invention be useful. I once rejected claims to methods of producing nitrogen as lacking utility, since the methods entailed the expenditure of more nitrogen than was produced. Section 112(4) requires that applicant teach one how to make and use the invention so the public can practice the invention when the 17-year monopoly period has expired.

§112. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

You must keep in mind that many worthwhile inventions have been denied patents because the inventor performed one or more of the following acts.

1. Published an enabling description of the invention more than one year before filing the application in the Patent and Trademark Office.
2. Sold or advertised the invention more than one year before filing.
3. Gave the invention to others or tested it publicly more than one year before filing.
4. Filed an application in a foreign country more than one year before filing in this country, with the issuance of the foreign patent at any time before the U.S. filing.

The Plant Patent Act came into being in 1930. Its passage was urged by nurserymen throughout the country. Its provisions are as follows.

§161. Patents for Plants

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of title.

The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

§162. Description, claim

No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible.

The claim in the specification shall be in formal terms to the plant shown and described.

§163. Grant

In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced.

§164. Assistance of Department of Agriculture.

The President may be Executive order direct the

Secretary of Agriculture, in accordance with the requests of the Commissioner, for the purpose of carrying into effect the provisions of this title with respect to plants (1) to furnish available information of the Department of Agriculture, (2) to conduct through the appropriate bureau or division of the Department research upon special problems, or (3) to detail to the Commissioner officers and employees of the Department.

The "tuber propagated" plants consist of the Irish potato and the Jerusalem artichoke. Disregarding these plants and naturally occurring species, Section 161 embraces any plant which can be asexually reproduced, even if the plant is normally reproduced by seed. Apomictic reproduction is not considered to be asexual reproduction in view of comments made in the legislative hearings.[5] The sections relating to plant patents differ from the so-called "utility" patent sections in two key respects. First, Section 112, which requires the applicant to teach one how to make and use the claimed invention, is modified to the extent that only a complete botanical description is necessary. The legislators realized that mere knowledge of the parent varieties in a cross would not enable one to achieve a specific seedling by duplicating that cross. The second difference relates to the number of claims permitted. Only one claim is permitted in a plant patent application, and that claim need only state, "a novel rose plant substantially as shown and described". If the distinguishing characteristics are visible, such as blossom or fruit color, growth habit, etc., an illustration is necessary. A plant specification must relate the manner of asexual reproduction and must include a comparison of the new variety with those varieties which are similar thereto.[6]

37 CFR 1.161. Rules applicable.

The rules relating to applications for patent for other inventions or discoveries are also applicable to applications for patents for plants except as otherwise provided.

§1.162 Applicant, oath or declaration.

The applicant for a plant patent must be the person who has invented or discovered and asexually reproduced the new and distinct variety of plant for which a patent is sought (or as provided in §§1.42, 1.43 and 1.47). The oath or declaration required of the applicant, in addition to the averments required by §1.65, must state that he has asexually reproduced the plant. Where the plant is a newly found plant the oath or declaration must also state that it was found in a cultivated area.

§1.63 Specification.

(a) The specification must contain as full and complete a disclosure as possible of the plant and the characteristics thereof that distinguish the same over related known varieties, and its antecedents, and must particularly point out where and in what manner the variety of plant has been asexually reproduced. In the case of a newly found plant, the specification must particularly point out the location and character of the area where the plant was discovered.

(b) Two copies of the specification (including the claim) must be submitted, but only one need be signed and executed; the second copy may be a legible carbon copy of the original.

§1.164 Claim.

The claim shall be in formal terms to the new and distinct variety of the specified plant as described and illustrated, and may also recite the principal distinguishing characteristics. More than one claim is not permitted.

§1.165 Drawings.

(a) Plant patent drawings are not mechanical drawings and should be artistically and competently executed. Figure numbers and reference characters need not be employed unless required by the examiner. The drawing must disclose all the distinctive characteristics of the plant capable of visual representation.

(b) The drawing may be in color and when color is a distinguishing characteristic of the new variety, the drawing must be in color. Two copies of color drawings must be submitted. Color drawings may be made either in permanent water color or oil, or in lieu thereof may be photographs made by color photography or properly colored on sensitized paper. Permanently mounted color photographs are acceptable. The paper in any case must correspond in size, weight and quality to the paper required for other drawings. See §1.84. Nonpermanently mounted copies will be correctly mounted at applicant's expense. §1.21(v).

§1.66 Specimens.

The applicant may be required to furnish specimens of the plant, or its flower or fruit, in a quantity and at a time in its stage of growth as may be designated for study and inspection. Such specimens, properly packed, must be forwarded in conformity with instructions furnished to the applicant. When it is not possible to forward such specimens, plants must be made available for official inspection where grown.

§1.67 Examinations.

(a) Applications may be submitted by the Patent and Trademark Office to the Department of Agriculture for study and report.

(b) Affidavits or declarations from qualified agricultural or horticultural experts regarding the novelty and distinctiveness of the variety of plant may be received when the need of such affidavits or declarations is indicated.

There has been very little litigation of plant patents, but one fairly recent case, Yoder Brothers, Inc. *v* California–Florida Plant Corp., may be of some interest. The suit involved the infringement of twenty-nine plant patents. The defendants countered the infringement charges with charges of patent invalidity for numerous reasons, including antitrust considerations, lack of patentable novelty, etc. One of the infringing acts was the sale of cuttings. California–Florida argued that the plant patent claim is to a whole plant, and that only the sale of whole plants could constitute patent infringement. The District Court rejected this argument and ruled in favor of Yoder Brothers, which ruling was later affirmed by the Court of Appeals.[7]

Another case is that involving Ananda M. Chakrabarty, a microbiologist working for the General Electric Company, with a genetically-engineered strain of *Pseudomonas* with a taste for crude oil. General Electric filed a patent application setting forth a description of the bacterium, the manner of producing it and a statement of utility with regard to cleaning up oil spills. The application contained three kinds of claims. There were claims to the processes of producing the bacterial strain, claims to the bacteria in combination with a straw carrier and most importantly, claims to the bacteria, *per se*. The patent examiner allowed the process and combination claims, but rejected the bacteria claims as being for (1) products of nature, and (2) living things not embraced by Section 101. General Electric asked for reconsideration of the rejection, but the examiner made a final rejection of the claims. The examiner's holding was appealed to the Patent Office Board of Appeals, which affirmed the examiner only on the second ground. An appeal was then made to the Court of Customs and Patent Appeals. The Patent Office argued that living matter was not a machine, manufacture, or composition of matter as contemplated by the framers of Section 101. They further argued that the existence of the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970[8] proved their point. Their position was that it would not have been necessary to enact either piece of legislation if Section 101 inherently embraced living matter, and that the congress must pass legislation for living matter other than plants. The Court of Customs and Patent Appeals reversed the Board of Appeals in a split decision, saying that the Patent Office interpretation of manufacture and composition of matter was too narrow, and that the existence of the Plant Patent Act was quite irrelevant with regard to the issues on appeal. The Patent Office filed a petition for *certiorari* with the Supreme Court, which constituted an appeal from the lower court decision. The Supreme Court agreed to look into the matter, and subsequently directed the lower court to reconsider its decision in light of a recent decision involving a method of calculating.[9] The lower court reheard the case and again reversed the Patent Office, adding another judge to the majority. The Patent Office went back to the Supreme Court, which court affirmed the lower court by a 5–4 margin. The majority opinion said that the Congress was not concerned with whether things to be patented were living or not, but rather, whether they were products of nature as opposed to man-made inventions. The following quote from the Supreme Court decision neatly sums things up with regard to a plasmid-laden *Pseudomonas* strain, but raises questions with regard to plant materials.

> Judged in this light, respondent's microorganism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity having a distinctive name, character, and use.

The court definition covers bacteria, but also covers plant materials ranging from single cells to whole plants. Clearly, the definition covers new animal strains as well. If Section 101 is all-inclusive, can someone obtain a plant patent under this section rather than under Section

161? Filing under the former section would enable one to protect several varieties in a single application, with separate claims for the various sister seedlings or mutants. For example, a breeder could develop a carnation strain, the varieties of which are substantially identical except for blossom color. Using the jargon of utility patent prosecution, these carnation varieties would be "species of a generic invention". However, filing under Section 101 might require adherence to the "how to make" portion of Section 112. This could be satisfied by depositing the new plant in an appropriate repository of similar plants prior to filing the patent application. Those filing applications involving the use of novel microorganisms have already been making such deposits in accordance with IN RE ARGOUDELIS *et al.*[10] The Plant Variety Protection Act requires a deposit and maintenance of viable seed of new varieties to be certified

The breeding of potatoes may increase if patent protection is secured under Section 101, bypassing the "tuber-propagated" exclusion of Section 161. The Plant Variety Protection Act excludes protection for F_1 hybrids and several vegetables. These excluded plants would appear to be covered by Section 101. Some analysts of the Chakrabarty decision believe that Section 101 covers all plants, including those which are currently protected by the Plant Variety Protection Act.

Taking Yoder and Chakrabarty together, one can envisage applications for plant organ tissue lines which produce secondary metabolites, which plant tissues never see the light of day, never to sprout roots or shoots. One can also envisage novel legumes in combination with novel nitrifying bacteria. The Patent Office has not articulated any specific policies with regard to what will or will not be considered to be patentable subject matter under Section 101.

REFERENCES

1. Diamond *v* Chakrabarty, 100 S. Ct. 2204, 206 U.S.P.Q. 193 (16 June, 1980).
2. 35 United States Code, Section 101.
3. 35 United States Code, Sections 102–103.
4. 35 United States Code, Section 112.
5. Congressional Record (House) 5 May, 1930, pp. 8391–8392.
6. 37 Code of Federal Regulations, Sections 1.161–167.
7. 537 F.2d 1347. 193 U.S.P.Q. 264 (5th Cir. 1976).
8. 7 United States Code 2321 *et seq.*
9. Parker *v* Flook, 437 U.S. 584 (1978), (198 U.S.P.Q. 193).
10. In re Argoudelis *et al.*, 168 U.S.P.Q. 99 (CCPA 1970).