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Products of Nature: The New Criteria

*In re Bergstrom*¹ is the first patent decision to use criteria based solely on the 1952 Patent Act² to determine the patentability of products of nature and as such is a new approach not based solely upon a subjective determination.

Products of nature exist in a form unchanged by human act³ and are generally unpatentable since they are already in the public domain. Thus, that which the public already possesses cannot be excluded from it by the grant of a patent monopoly. The Supreme Court summarized the reasons for this when it stated:

[T]he heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.⁴

Prior to *Bergstrom* (1970) the criteria employed to determine the patentability of products of nature was imprecise and confusing. That is, before the 1952 Patent Act, the courts did not use specific statutory criteria⁵ to deny patent grant but rather judicially created them. Cases prior to the 1952 Act held, either impliedly⁶ or expressly⁷, that the product was unpatentable since it was a "product of nature." The 1952 Patent Act did not expressly overrule prior case law concerning products of nature. After 1952 the criteria used for determining patentability was Section 101 of the Patent Act,⁸ which states:

1. 427 F.2d 1394 (C.C.P.A. 1970).

2. 35 U.S.C. §§ 1-293 (1964).

3. See Comment, 47 MICH. L. REV. 391 (1949). In a sense all things are products of nature since nature provides the basic source materials. *Merck & Co. v. Olin Mathieson Chem. Corp.*, 353 F.2d 156 (4th Cir. 1958). The term "product of nature" could have a broad meaning encompassing both unpatentable products which are "products of nature" and products which are patentable because they are technically not "products of nature" (although referred to as "products of nature"), or a narrower meaning which is restricted solely to unpatentable products which are deemed to be "products of nature." For the purposes of this article the narrower meaning will be used.

4. *Funk Bro. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

5. Before the 1952 Patent Act a prior patent act existed, but for the purposes of this article this prior act need not be discussed since none of the cases dealing with products of nature used specific statutory sections as a criteria for patentability.

6. See, e.g., *In re Merz*, 97 F.2d 599 (C.C.P.A. 1938).

7. See, e.g., *Funk Bro. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

8. Patent Act of 1952, 35 U.S.C. § 101 (1964). See *Ex parte Siddequi*, 156 U.S.P.Q. 426 (Pat. Off. Bd. App. 1967).

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

To hold that the product was unpatentable before *Bergstrom* a court had to characterize it either as a "product of nature", or not a "new . . . composition of matter," as required by Section 101.

This article will discuss the new approach and value of the *Bergstrom* criteria in light of that used in prior cases.

The Criteria of In re Bergstrom

In *Bergstrom* the Court of Customs and Patent Appeals (CCPA) reversed the decision of the Patent Office Board of Appeals (Board of Appeals) which had affirmed the examiner's rejection of the claimed compounds⁹ in the application¹⁰ as lacking in novelty under Section 101. These compounds, which are members of a family known collectively as prostaglandins, are useful in stimulating smooth muscle and lowering blood pressure. Scientists had previously known that certain secretions and extracts obtained from human and animal male accessory genital glands possessed the pharmacodynamic effects of lowering blood pressure and stimulating smooth muscle. Although scientists thought that an independent basic compound was present, attempts to identify the active substance were unsuccessful because the basic compound could not be separated from its associated material. The patent applicants, Bergstrom and Sjoval, succeeded in isolating two distinct chemical compounds from the crude, semi-purified extracts that were already known, and these became the subject matter of their patent.¹¹ Later, they discovered that by performing an additional and different extraction step they could obtain one of the earlier compounds and two additional compounds, which were in issue in the decision.

The examiner rejected the claimed subject matter under Section 101 reasoning that the claimed compounds were naturally occurring and therefore not new within the meaning of the statute.¹² It was the examiner's position

9. The invention relates to two chemical compounds:

Claim 23. 7-[3-hydroxy-2 (3-hydroxy-1-octenyl)-5-oxocyclopentyl]-5-heptenoic acid, said acid being sufficiently pure to give a substantially ideal curve on partition chromatography using an ethylene chloride: heptane: acetic acid: water (15:15:6:4) solvent system.

Claim 53. A composition of matter consisting essentially of 7-[3-hydroxy-1, 5-octadienyl)-5-oxocyclopentyl]-5-heptenoic acid.

10. Application serial No. 203,752, filed June 20, 1962 as a continuation-in-part of serial Nos. 738,514, filed May 28, 1958 and 199,209, filed April 9, 1962.

11. Patent No. 3,069,322, issued December 18, 1962.

12. 427 F.2d 1394, 1397 (C.C.P.A. 1970).

that the compounds inherently occurred in either previously known crude extracts or nature.

The Board of Appeals agreed with the examiner that the compounds inherently occurred in the crude extracts but held that the real issue was whether the claimed pure materials were novel as compared with the less materials. The Board of Appeals further held that a claim to a purified material could not be allowed unless it exhibited properties and utilities not possessed by the unpurified material. Since the Board of Appeals did not find these new properties and utilities were present it affirmed the examiner's rejection.

The CCPA reversed both the examiner and the Board of Appeals reasoning that the answer to whether pure materials were novel as compared to less pure materials is self-evident since, by definition, pure materials necessarily differ from less pure or impure materials. The court further reasoned that, based on the record established, the claimed compounds did not exist in nature in pure form and thus this discovery was not "what has previously existed in fact in nature's storehouse, albeit unknown, or what has previously been known to exist."¹³

The court stated:

[T]he criteria for determining whether a given subject matter is 'new' within the meaning of § 101¹⁴ are no different than the criteria for determining whether that subject matter possesses the 'novelty' expressed in the title of § 102.¹⁵ The word 'new' in § 101 is defined

13. *Id.* at 1401 (emphasis added).

14. Patent Act of 1952, 35 U.S.C. § 101 (1964).

15. *Id.* § 102 (1964). Section 102 states:

Conditions for patentability; novelty and loss of right to patent.

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 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 filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States 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 the last to reduce to practice, from a time prior to conception by the other."

and is to be construed in accordance with the provisions of § 102. Thus, that which possesses statutory novelty under the provisions of § 102 is also new within the intendment of § 101. We have found no evidence of Congressional intent to define the word 'new' as used in § 101 in any different manner.¹⁶

While the court in *Bergstrom* never specifically rejected the use of Section 101 as the sole criteria for determining the patentability of products of nature, a fair reading of the decision leads to that conclusion. The court held that Section 101 is to be defined and construed in conjunction with Section 102. Section 102 defines conditions for patentability, novelty, and loss of right to a patent, and is the criteria used to determine patentable novelty.

The Prior Criteria

The cases before *Bergstrom* used "product of nature"¹⁷ or Section 101¹⁸ as the criteria for determining the patentability of products of nature. Usually it was difficult to characterize a product as a product of nature. Additional factors such as a change in purity, a new utility, a new form, or a new method of making the product clouded the determination as exhibited in the following cases.

*American Wood-Paper Co. v. The Fibre Disintegrating Co.*¹⁹ dealt with the patentability of cellulose made from wood fibers. While the cellulose produced was the same as that naturally occurring cellulose which had existed before, the method of making the cellulose was previously unknown. Because of the new method, it was more difficult to determine whether the product was also new or whether it was a product of nature and thus unpatentable. The Supreme Court held that the product was unpatentable but indicated that perhaps the *process* may be patentable. In so holding, the Court stated that "the manufacture claimed as novel is not a new composition of matter, but an extract obtained by decomposition or disintegration of material substances, it cannot be of importance from what it has been extracted."²⁰

In *Kuehsted v. Farbenfabriken of Elberfeld Co.*,²¹ a patent on aspirin was upheld because the compound had therapeutic utility, and the mass that contained the compound did not. In *Parke-Davis & Co. v. H.K. Mulford Co.*,²² a patent for adrenalin was likewise upheld because it had significant com-

16. 427 F.2d 1394, 1401 (C.C.P.A. 1970).

17. See, e.g., *Funk Bro. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

18. See, e.g., *Ex parte Siddequi*, 156 U.S.P.Q. 426 (Pat. Off. Bd. App. 1967).

19. 90 U.S. (23 Wall.) 566 (1874).

20. *Id.* at 593.

21. 179 F. 701 (7th Cir. 1910).

22. 189 F. 95 (C.C.S.R. N.Y. 1911); *affd*, 196 F. 496 (2d Cir. 1912).

mercial and therapeutic value, and the natural product had only limited therapeutic value producing harmful, if not fatal results.

In *re Merz*²³ dealt with ultramarine, which had been purified by removing non-floatable impurities, and which resulted in a brighter, more desirable pigment. Although the additional factors of purity and brightness made the determination more difficult, the court held that it was a product of nature having the same utility as the less pure, natural aquamarine and therefore unpatentable. In *Mertz*, the CCPA reasoned that a natural product does not become patentable merely because it is given a new form, which is different from a new utility. The criteria the court used to find that the compound was a product of nature was, "if the process produces an article of such purity that it differs not only in degree but in kind it may be patentable . . . [and] . . . [i]f it differs in kind, it may have a new utility in which invention may rest."²⁴

Although the courts continued to use the characterization criteria to find a product unpatentable as a product of nature, it became clear that this was not a simple determination and that the additional factors made it even more difficult. Thus, in *Union Carbide Co. v. American Carbide Co.*,²⁵ the Second Circuit stated:

In determining the question of patentable novelty, there can be no hard and fast rule. Each case must be decided upon its own facts. Mere change in form in and of itself does not disclose novelty. A new article of commerce is not necessarily a new article patentable as such. But patentable novelty in a case like the present may be founded upon superior efficiency; upon superior durability . . . upon purity, and, in connection with other things, upon comparative cheapness.²⁶

In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*²⁷ the Supreme Court was faced for the first time since the *Wood-Paper Patent* case with the issue of whether a product was unpatentable as a product of nature. *Funk Brothers*, decided prior to the 1952 Patent Act, held that a patent on a plant inoculant which was a mixed culture of bacteria was invalid and it lacked invention because it was directed toward a "product of nature." The Court recognized that the mixed culture was more convenient than the previously known cultures, an advantage that did not exist before. Other than the subjective determination that it was a "product of nature", no other criteria or

23. 97 F.2d 599 (C.C.P.A. 1938).

24. *Id.* at 601.

25. 181 F. 104 (2d Cir. 1910).

26. *Id.* at 106-07.

27. 333 U.S. 127 (1948).

factors were set forth or discussed by the Court to aid in its determination. The Court did not look at or comment on any additional factors which the prior lower court decisions had considered such as change in utility²⁸ or difference in kind.²⁹ Since *Funk Brothers*, no other case dealing with products of nature has been decided by the Supreme Court and thus the additional factors which the lower courts looked to continue to exist.

After the 1952 Patent Act, the courts continued to apply subjective criteria. In *Ex parte Siddiqui*³⁰ the Board of Appeals held that a product of nature is not novel and that its patenting is barred by the provisions of Section 101. This was not a new approach since a product still had to be characterized as a "product of nature" and, if so characterized, it was not "new" within the meaning of Section 101. The above additional factors and Section 101 continued to be the criteria of patentability.³¹

The first decision to hold that the criteria of patentability of products of nature should be something other than Section 101 or "product of nature," either alone or when other factors are considered, was *Merck & Co. v. Olin Mathieson Chemical Corp.*³² *Merck* did not set forth what specific criteria should be used. The Fourth Circuit stated:

The Patent Act of 1952 (35 U.S.C.A. § 101), as its predecessors, authorizes a patent for 'any new and useful . . . composition of matter . . .,' provided only that the conditions for patentability,³³ which are specified in succeeding sections, are met. There is nothing in the language of the Act which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useful composition of matter' and there is compliance with the specified conditions for patentability

A product of nature which is not a 'new and useful . . . machine, manufacture, or composition of matter' is not patentable, for it is not within the statutory definition of those things which may be patented. Even though it be a new and useful composition of matter it still may be unpatentable if the subject matter as a whole was obvious within the meaning of § 103 (35 U.S.C.A. 103), or if other conditions of patentability are not satisfied.³⁴

28. See *Kuehmstead v. Farbenfabriken of Elberfeld Co.*, 179 F. 701 (7th Cir. 1910); *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911); *aff'd*, 196 F. 496 (2d Cir. 1912).

29. See *In re Merz*, 97 F.2d 599 (C.C.P.A. 1938).

30. 156 U.S.P.Q. 426 (Pat. Off. Bd. App. 1967).

31. See Jacob, *Patentability of Natural Products*, 52 J. PAT. OFF. SOC'Y 473 (1970).

32. 253 F.2d 156 (4th Cir. 1958).

33. Only two sections of the Patent Laws are titled conditions for patentability, novelty and loss of right to patent, and they are set forth in Sections 101 and 103.

34. 253 F.2d 156, 161-62 (4th Cir. 1958).

The New Criteria

The criteria of *Bergstrom* is less subjective and appears more sound than the prior criteria, that is, in rejecting or allowing claims to a product, the conditions of patentability under Section 102 must be considered. The characterization problem is not present because the product does not have to be characterized as a "product of nature." A true "product of nature" would still be unpatentable but only because it would not satisfy the conditions of patentability under Section 102. In addition, *Bergstrom* stated that the use of Section 102 as the criteria follows congressional intent.³⁵

Obviousness³⁶ was not at issue in *Bergstrom* and thus the court did not consider or comment on its applicability. As a result, the criteria of *Bergstrom* does not go far enough. Even though it is novel under Section 102 a product can still be unpatentable if it is obvious under Section 103. Thus, criteria which use the conditions of patentability under Section 102 must necessarily also include the conditions of patentability under Section 103. The Supreme Court stated the desired Section 103 approach in *Graham v. John Deere Co.*,³⁷ when it stated:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or non-obviousness, these inquiries may have relevancy.³⁸

The best criteria meets both Section 102 and Section 103 conditions of patentability. If the product satisfies the conditions of patentability under Section 102, *i.e.*, it is novel, as was the case in *Bergstrom*, then the conditions of patentability under Section 103, *i.e.*, non-obviousness, must be met. Although, it did not expressly state that this was its approach, the court in *Merck*³⁹ followed it in practice.⁴⁰

35. 427 F.2d 1394, 1401 n.8 (C.C.P.A. 1970). The court cited from H.R. REP. NO. 1923 and S. REP. NO. 1979, 82d Cong., 2d Sess., accompanying H.R. 7794 (1952) which said that Section 101 sets forth the subject matter that can be patented while Section 102 covers the conditions relating to novelty and, in effect, Section 102 is an amplification and definition of "new" in Section 101.

36. Patent Act of 1952, 35 U.S.C. § 103 (1964).

37. 383 U.S. 1 (1966).

38. *Id.* at 17-18.

39. 253 F.2d 156 (4th Cir. 1958). After a discussion of Section 102 and the pertinent case law the court stated:

Nor should we overlook the presumptions arising from the fact that the

Conclusion

The criteria used in deciding the patentability of products of nature, although enlightened by *Bergstrom*, remain indefinite. None of the cases expressing criteria, such as "product of nature,"⁴¹ or the criteria set forth in Section 101,⁴² or Section 101 criteria viewed with additional factors,⁴³ has ever been expressly overruled. Furthermore, there has been no express congressional action in this area.

The *Bergstrom* criteria appear the soundest. The best criteria is an expanded *Bergstrom* criteria which would include the conditions of patentability under Section 103. This is a new approach and is less subjective than the prior one. Until Congress or the Supreme Court decides which criteria should be used, all other approaches should be abandoned.

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product of the patent filled a long felt want, went into immediate use and promptly displaced the competing liver products.

Id. at 164. This is the use of secondary considerations to give light to circumstances surrounding the origin of the subject matter sought to be patented, and as such is the approach the Supreme Court expressed in *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

40. *E.g.*, *Funk Bro. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

41. *E.g.*, *Ex parte Siddequi*, 156 U.S.P.Q. 426 (Pat. Off. Bd. App. 1967).

42. *E.g.*, *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911); *aff'd*, 196 F. 496 (2d Cir. 1962); *In re Merz*, 97 F.2d 156 (C.C.P.A. 1938); *Kuehsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701 (7th Cir. 1910).