CHEMICAL PROPERTIES: ARE THEY A SENSIBLE LEGAL YARDSTICK OF PATENTABILITY?

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I. INTRODUCTION

The interface of science and the law often presents difficult problems for analysis. Proper resolution of such problems requires an analytical approach which is certainly not scientific and not necessarily totally legal. The interface exists in many areas of the law, for example products liability, environmental law, and patent law, just to name a few. Our courts have been dealing with this interface in the patent law ever since the enactment of the first patent act in 1790.

With 1976 marking the 100th anniversary of the American Chemical Society, it would seem an appropriate time to focus attention upon the important issue of patentability of chemical compounds and chemical formulations. Compounds are patentable because they fall within the statutorily enumerated classification of patentable subject matter referred to as "compositions of matter."[1] Like all other inventions, chemical inventions must meet the requirements of usefulness,[2] novelty,[3] and non-obviousness.[4]

When a new chemical compound or formulation has been synthesized and has new unexpected desirable properties, almost all would agree that "something" is patentable. The question is, what? It is a question of vital importance to science and industry, especially the multi-billion dollar chemical and drug industries.

A simple example will serve to draw the issue into focus. Assume a chemist has invented compound "Z". "Z" has the unique property of stimulating hair growth. Compound "X" is a known compound structurally close to the chemical formula for compound "Z". "X" will not stimulate hair growth. The inventor of compound "Z" may be entitled: (1) to a patent claiming as his invention compound "Z"[5]; or alternatively, (2) to use a patent[6] on a method of

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1. 35 U.S.C. § 101 (1970) provides in pertinent part: "Whoever invents or discovers any new and useful . . . composition of matter . . . may obtain a patent therefor, subject to the conditions and requirements of this title." *See* Schering Corp. v. Gilbert, 153 F.2d 428 (2d Cir. 1946).
2. 35 U.S.C. § 101 (1970).
3. 35 U.S.C. § 102 (1970).
4. 35 U.S.C. § 103 (1970).
5. A typical example of a claim covering a compound per se as opposed to a use for a compound or a composition having a compound as a part of the composition is claim 6 of United States Patent No. 3,941,818 which says simply, "Zinc methionine acid sulfate."
6. The term "use patent" means a method of using a compound or composition

stimulating hair growth by treating a bald skin area with compound "Z".

The difference in the two claims is significant. The compound claim would entitle the inventor to prevent others from making "Z" for any use.[7] The method or "use claim" would entitle the inventor only to prevent the use of "Z" as a treating agent for hair growth. The direct infringers[8] of the compound claim are competing manufacturers. The direct infringers of the use claim are the multitude of patients who rub their skin with compound "Z."

Some say that since the prior art, compound "X", makes "Z" structurally obvious to a chemist, the inventor of "Z" should be confined to a use patent limited to his newly discovered method of stimulating hair growth. Others say that the inventor of "Z" was the first to bring this compound into existence and he should be entitled to a patent on the compound per se, since the compound exhibits a non-obvious, not predictable, property.

The 1952 Patent Act codified the test of obviousness applied to all novel inventions.[9] Under the test as applied by the United States Patent Office under the dictates of the Court of Customs and Patent Appeals, the single most important factor in determining patentability of a new compound or composition are the properties of that compound or composition. There are those who vociferously oppose this view. To this opposition group, allowing a patent on a compound because of the properties of that compound provides the inventor a "windfall protection" broader than his contribution to the scientific arts. This arises because the owner of a patent on a compound can stop infringing creation of the compound, or composition, without limitation to the specific use upon which the patentability was predicated.[10] To such opposition critics, structural obviousness of a compound, or formulation obviousness of a new composition, should be the sole determining factor. Properties which are inherent in the compound or formulation should be ignored. If a chemist would find it a predictable thing to create the compound or formulation, the inquiry should end. It is a provocative view. Nonetheless, it is a view which certain district courts in the Second and Third Circuits are seemingly adopting.

It is the contention of this Article that the courts using chemical properties

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to accomplish a specific result. For example, "a method of treating acne with zinc methionine acid sulfate." This claim is a use claim as opposed to claim 6 of note 5, *supra*.

7. This arises because 35 U.S.C. section 271(a) (1970) provides in pertinent part: ". . . whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." Here, since the patented invention is the compound "Z" per se, whoever makes the compound for whatever reason infringes.

8. Direct infringers are those whose infringing activity falls within the scope of the prohibited activities of 35 U.S.C. section 271(a) (1970). *See* Aro Manufacturing Co. v. Convertible Top Replacement Co., 365 U.S. 336 (1961) and 377 U.S. 476 (1964).

9. 35 U.S.C. section 103 (1970) provides in pertinent part: "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."

10. *See* note 7 *supra*.

as the determinative legal yardstick for measuring patentability are correct. The so-called "windfall protection" is more academic than real when the inseparability doctrine of *In re Papesch*[11] is considered as only a part of the inter-related role played by chemical properties in legal analysis of obviousness under 35 U.S.C. section 103, utility under 35 U.S.C. section 101, and the new use doctrine of 35 U.S.C. section 100(b).

II. Legal Obviousness and New Chemical Compounds

A. *The Inseparability Doctrine*

In re Papesch[12] has become the cornerstone of chemical patent practice, not so much because it set forth new law, but because it is the most articulate presentation of the inseparability doctrine. In *Papesch*, Judge Rich, writing for a unanimous court, set forth the Court of Customs and Patent Appeals' view on patentability of chemical compounds.

The invention was a new trialkyl compound. It had anti-inflammatory activity. The claims were to the new compound per se. In the prior art there was a homolog having three methyl[13] groups whereas the invention had three ethyl[14] groups. Unquestionably, it made the formula structurally obvious to a chemist. However, the prior art compound had no anti-inflammatory activity. This unexpected property was proven during prosecution of the Patent Application by an affidavit.

The Patent Examiner and the Patent Office Board of Appeals ignored the anti-inflammatory activity of the compounds. The Examiner said the invention was unpatentable as a new compound: "The obvious compound is not made less obvious by its properties . . . ."[15] The Patent Office Board of Appeals affirmed indicating that from the viewpoint of a chemist the compounds would without a shadow of a doubt be obvious structurally. Under such circumstances, the Board of Appeals refused to consider as persuasive of the patentability issue the unexpected properties proved by the affidavit.

The Court of Customs and Patent Appeals reversed, setting forth the often quoted and famous "inseparability doctrine:"[16]

> From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing. The graphic formulae, the chemical nomenclature, the systems of classification and

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11. 315 F.2d 381 (C.C.P.A. 1963).
12. 315 F.2d 381 (C.C.P.A. 1963).
13. "Methyl" means a CH_3 group. For example, methyl alcohol has the formula CH_3OH.
14. "Ethyl" means a C_2H_5 group. It differs from a methyl group by an additional CH_2 grouping. For example, ethyl alcohol has the formula CH_3CH_2-OH.
15. *In re* Papesch, 315 F.2d 381, 384 (C.C.P.A. 1963).
16. The doctrine is not commonly referred to as the inseparability doctrine, but the term was used in an excellent *Harvard Law Review* note on the subject under discussion. *See* Note, *Standards of Obviousness and the Patentability of Chemical Compounds*, 87 Harv. L. Rev. 607 (1974) [hereinafter cited as Harv. Note].

> study such as the concepts of homology, isomerism, etc., are mere symbols by which compounds can be identified, classified and compared. *But a formula is not a compound and while it may serve in a claim to identify what is being patented, as the metes and bounds of a deed identify a plot of land, the thing that is patented is not the formula but the compound identified by it.* And the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter. There is no basis in law for ignoring any property in making such a comparison. An assumed similarity based on the comparison of formulae must give way to evidence that the assumption is erroneous.[17]

The legal reasoning upon which the decision was based was primarily the fact that 35 U.S.C. section 103 requires consideration of the subject matter "as a whole" in determining obviousness. Therefore, according to the court, there is no basis in law for ignoring any evidence which may tend to have probative value on the issue of obviousness or non-obviousness of a chemical invention, or for that matter, any other invention.

B. *Deutsche Gold-Und-Silber*

Five years after *Papesch*, the Court of Appeals for the District of Columbia Circuit, in *Commissioner of Patents v. Deutsche Gold-Und-Silber-Scheideanstalt Vormals Roessler*,[18] adopted wholeheartedly the inseparability doctrine of *Papesch*. *Papesch* and *Deutsche* are together the most articulate presentation of the inseparability doctrine.

In *Deutsche*, the claim was on an ammonia derivative compound per se. The basic question was "whether under 35 U.S.C. § 103 (1964) structural obviousness alone is an absolute bar to the grant of a patent."[19] The compound had an unexpected vermicide property. Speaking for the court, then Judge Burger, now Chief Justice Burger, expressly followed *Papesch*. He said:

> [T]his Court and the Court of Customs and Patent Appeals for some years now have been of the view that patentability is not determined on the basis of structural obviousness alone. Obvious molecular modification coupled with a showing of novel properties or superiority of known properties can establish patentability.[20]

In rationalizing its decision, the court pointed to at least three factors. First, the court said it would be rare to find a completely new compound whose molecular arrangements could not be predicted. This the court feared would destroy the incentive aspects of the patent system for those who discover valuable properties for new compounds which could be regarded as structurally obvious. Secondly, the court reasoned that in light of *Graham v. John Deere*

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17. *In re* Papesch, 315 F.2d 381, 391 (C.C.P.A. 1963) (emphasis added).
18. 397 F.2d 656 (D.C. Cir. 1968).
19. Commissioner of Patents v. Deutsche Gold-Und-Silber-Scheideanstalt Vormals Roessler, 397 F.2d 656, 659 (D.C. Cir. 1968) [hereinafter cited as Deutsche].
20. *Id.* at 661.

Co.,[21] all relevant factors should be considered in determining obviousness, *i.e.*, the statute specifically required consideration of the subject matter "as a whole." Finally, the court pointed to the long standing practice of proof of unexpected properties as evidence of non-obviousness and to 35 U.S.C. section 101 and its requirement for utility, stating that the patent statutes as a whole would seem to favor the *Papesch* standard.

C. *View of Other Circuits*

Papesch and *Duetsche* generated extensive legal commentary, both pro and con.[22] However, the inseparability doctrine of the *Papesch* and *Duetsche* cases has been specifically approved only by the Fifth Circuit in *Eli Lilly & Co. v. Generix Drug Sales, Inc.*[23]

In *Eli Lilly*, the compound being claimed was Darvon, an excellent pain reliever. It had an unexpected absence of side effects and caused no narcotic addiction. The opinion so overwhelmingly endorses the inseparability doctrine that part of it is worth quoting:

> In the field of drug patents today therapeutic value, not chemical composition, is the substance of all incentive to invent. Except where the state of the medical art and the state of the chemical art have been advanced and coordinated to the point that it is possible for the mind to conceive or predict with some minimal reliability a correlation between chemical analogues, homologues, or isomers and their therapeutic value, reason compels us to agree that novelty, usefulness and non-obviousness inhere in the true discovery that a chemical compound exhibits a new needed medicinal capability, even though it be closely related in structure to a known or patented drug. When such a fresh, efficacious, undisclosed use is identified, its inventor deserves the full ambit of statutory protection. A limitation to "use" or process patentability, based solely on the existence of prior chemical formulations, would not accord with the basic constitutional power being exercised by the Congress to promote science and the useful arts. Such a niggardly patent reward for costly and painstaking research would discourage both the inspiration-perspiration process of the laboratory and the incentive to publicly disclose products of value to mankind.[24]

With regard to the argument that the patentee of a new compound receives windfall patent protection, the court responded:

> Contrary to expressed opinions that the patent laws must be amended or that drug patenting must be largely limited to "use" or process

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21. 383 U.S. 1 (1966).

22. *See, e.g.*, Anon, *Patentability of Chemical Compounds—In re Steminski*, 50 TEX. L. REV. 566 (1972), *reprinted at* 4 PAT. L. REV. 75 (1972); Berlowitz, *Patentability of Structurally Obvious Compounds*, 51 J. PAT. OFF. SOC'Y 56 (1969); Eggert, *Uses, New Uses and Chemical Patents—A Proposal*, 1968 WIS. L. REV. 901, *reprinted in* 51 J. PAT. OFF. SOC'Y 768 (1969) [hereinafter cited as Eggert]; Western, *Is 35 U.S.C. 103 Applicable to Chemical Compounds?*, 8 IDEA 443 (1964); Wyman, *Chemical Compounds and 35 U.S.C. 103*, 50 J. PAT. OFF. SOC'Y 586 (1968); HARV. Note, *supra* note 16.

23. 460 F.2d 1096 (5th Cir. 1972).

24. Eli Lilly & Co. v. Generix Drug Sales, Inc., 460 F.2d 1096, 1103 (5th Cir. 1972).

> claims, . . . we view 35 U.S.C. §§ 101-103 as presently providing sufficient authority to permit courts to adjudicate whether or not chemical invention has occurred. The hazard that a compound patent will preempt an after-discovered therapeutic value of a drug during its statutory term exists whether the drug is chemically novel or not. Nevertheless, this possibility must not make us timid in assaying for novelty, usefulness and non-obviousness on the evidence developed in each case, unbound by a stultifying *per se* rule of chemical similarity, albeit requiring a close eye to be kept on the state of the art in the area where and when the alleged invention took place.[25]

To date no other circuit court of appeals has adopted the inseparability doctrine. Signposts on the horizon would seem to indicate that the view of inseparability adopted by the Court of Customs and Patent Appeals, the Court of Appeals for the District of Columbia, and the Fifth Circuit, may not be as readily received by the other circuit courts of appeals, and more specifically the Second and Third Circuits.

The District Court for the Eastern District of Pennsylvania specifically disagreed with the inseparability doctrine in *Monsanto Co. v. Rohm & Haas Co.*:[26]

> Moreover, even if this were only a case of structural obviousness, we would be disposed to hold that this in and of itself should preclude issuance of a patent. It is basic to the grant of a patent that the scope of a patent should not exceed the scope of invention. If what makes a structurally obvious chemical substance patentable is the new and unobvious properties or uses discovered by the first person to compound the substance, the discoverer should have protection on what he discovered, *i.e.*, the new properties of the substance, but should not be entitled to a 17-year monopoly on the substance itself. To say that a person who has discovered a new use for a structurally obvious compound, which compound would not have been entitled to any patent protection absent the new use, should receive a patent on the compound itself is to extend the patent monopoly far beyond the reason for its existence. We think that the purposes of the patent law will be adequately served if patents on compounds which are structurally obvious from the prior art are limited to method patents directed to the new and useful characteristic or property which is the essence of the discovery or invention.[27]

Simply put, the district court said that the patentee should be confined to a use patent limited to the method of using the compound to obtain the beneficial result of the newly discovered property. Such use patents are of significantly less value since the direct infringers are users, not competing manufacturers. Thus, for example, if a patent covers a new drug as a method of treating a specific disease, the patients or the doctors are the direct infringers. Obviously, there is no adequate remedy by pursuing each of these individuals. How-

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25. *Id.* at 1103-04.
26. 312 F. Supp. 778 (E.D. Pa. 1970), *aff'd on other grounds*, 456 F.2d 592 (3d Cir.), *cert. denied*, 407 U.S. 934 (1972).
27. Monsanto Co. v. Rohm & Haas Co., 312 F. Supp. 778, 790-91 (E.D. Pa. 1970).

ever, if the patent covers the compound itself, the infringer is the competing pharmaceutical manufacturer. The real source of the infringing competition can be reached by a simple route involving a cause of action for direct infringement.

The *Monsanto* district court decision of invalidity, namely, fraudulent misrepresentation to the patent office by the patentee, was affirmed by the Third Circuit Court of Appeals on other grounds. Since the district court's comments were really not necessary even to its own decision, its commentary is dictum.

The *Monsanto* view was again adopted via dictum by the District Court for the Eastern District of New York in *Carter-Wallace Inc. v. Davis-Edwards Pharmacal Corp.*[28] In *Carter-Wallace*, the district court applied the *Papesch-Deutsche* inseparability doctrine and held the patent invalid. However, the court specifically disapproved of the doctrine. According to the district court, chemical or structural obviousness should make a compound unpatentable per se, notwithstanding any unexpected property. The court said:

> The inescapable fact is that if a composition does not occur in nature and has not yet been synthesized, it nevertheless is in the public domain if it can be called into existence on bare request [presumably chemists' requests] by known methods. It is as veritably in the public domain as any extant product.
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> . . . It may be that few claims on new chemical compositions will issue if what is readily synthesized by known methods is denied patentability as a new composition of matter because it is obvious in the art of chemical synthesis even though it evinces unanticipated "properties" or utilities so that it was—antecedentally—an unobvious choice for screening and testing in a search for such "properties" or utilities; . . . .[29]

The *Carter-Wallace* decision was affirmed on appeal with the court noting Judge Dooling's criticism of the *Papesch-Deutsche* inseparability doctrine.[30] However, in the view of the Second Circuit, the court did not have to resolve that question in the case before it.

The Second Circuit was again presented with an opportunity to affirm or reject the inseparability doctrine in *General Tire & Rubber Co. v. Jefferson Chemical Co.*[31] The court specifically noted the "two polar views:"[32] one in favor of the inseparability doctrine in *Papesch* and *Deutsche*, and the other against that doctrine in *Monsanto* and *Carter-Wallace*. Although the Second Circuit again sidestepped the issues, the court did say, "[a]ssuming without deciding that some variation of *Papesch* and *Deutsche Gold-Und-Silber-Schei-*

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28. 341 F. Supp. 1303 (E.D.N.Y.), *aff'd sub nom.* Carter-Wallace, Inc. v. Otte, 474 F.2d 529 (2d Cir. 1972), *cert. denied*, 412 U.S. 929 (1973).
29. Carter-Wallace, Inc. v. Davis-Edwards Pharmacal Corp., 341 F. Supp. 1303, 1337, 1338, 1340 (E.D.N.Y. 1972).
30. Carter-Wallace, Inc. v. Otte, 474 F.2d 529, 540 (2d Cir. 1972).
31. 497 F.2d 1283 (2d Cir. 1974).
32. General Tire & Rubber Co. v. Jefferson Chem. Co., 497 F.2d 1283, 1288 (2d Cir. 1974).

deanstalt represents the correct view,"[33] and thereafter pointed out that even assuming the inseparability doctrine for purposes of argument, it would not approve it, or more accurately assume it, to the full extent that the Court of Customs and Patent Appeals has adopted the doctrine.[34] The Second Circuit characterized the Court of Customs and Patent Appeals' view as regarding "the demonstration of significant unexpected properties as almost conclusive proof of non-obviousness."[35] It would appear that the Second Circuit will not adopt the inseparability doctrine in its entirety.

D. *The Court of Customs and Patent Appeals Response*

Since 1963, the Court of Customs and Patent Appeals has itself expanded upon its own statement of the inseparability doctrine. Thus, in *In re Huellmantel*,[36] it specifically extended the rule of *Papesch* from compounds to compositions comprising mixtures of compounds. In *In re Lohr*,[37] the court made it clear that the doctrine only applied to new properties, not where properties exhibited by the closely structurally related prior art compounds were shown to be only slightly better. In *In re Steminski*,[38] the court indicated that a patent applicant did not have to prove his new property was not also exhibited by the most closely related prior art structures where the prior art itself was silent as to its properties. And, importantly, in *In re Ruschig*,[39] the court drew a distinction between the importance of properties with regard to 35 U.S.C. section 102 (novelty) rejections and section 103 (non-obviousness) rejections. *Ruschig* is also important in that it contains the Court of Customs and Patent Appeals' response to those who argue against properties as a measure of patentability because of the "windfall protection" to the patentee:

> Our view, in brief, is that the basic principle of the patent system is to *protect* inventions which meet the statutory requirements. Valuable inventions should be given protection of value in the real world of business and the courts. We do not share the board's theoretical fear that allowing the compound claims on appeal will "dominate activity" with respect to the use of the claimed compounds for purposes such as those disclosed in the French patent, or any purposes other than the treatment of diabetes, to put it as broadly as possible. For one thing, the claims here will give no domination whatever over the compounds disclosed in the references. For another, balancing the alternatives of providing adequate protection to appellants' limited group of anti-diabetic agents against the mere possibility that someone might wish to use some of them for some such purpose as making a textile dye, we favor the former.[40]

33. *Id.*
34. *Id.* at n.13.
35. *Id.*
36. 324 F.2d 998 (C.C.P.A. 1963).
37. 317 F.2d 388 (C.C.P.A. 1963).
38. 444 F.2d 581 (C.C.P.A. 1971).
39. 343 F.2d 965 (C.C.P.A. 1965).
40. *In re* Ruschig, 343 F.2d 965, 979 (C.C.P.A. 1965).

The view expressed in the dictum of *Carter-Wallace* did not go unnoticed by the Court of Customs and Patent Appeals. Its response came in *In re Murch*:[41]

> We are aware of *Carter-Wallace, Inc. v. Davis-Edwards Pharmacal Corp.*, . . . in which Judge Dooling expressed the view that a compound is effectively placed in the public domain when there is ample motivation to make it regardless of the properties it may possess. Under his approach, newly appreciated or enhanced properties may give rise to valid patent property in the methods of using the compound which flow from the discovered properties but could have no impact on the patentability of the compound per se. With due respect to his conclusions reached after careful and exhaustive analysis of many cases involving this issue, we reaffirm the position taken in *Papesch*. To give meaning to the language of 35 U.S.C. § 103 which speaks to the subject matter "as a whole," we feel weight must be given the properties of a compound or composition of matter [citing *Eli Lilly*].[42]

Summarizing for a moment, the Court of Customs and Patent Appeals and the Court of Appeals for the District of Columbia have wholeheartedly adopted the inseparability doctrine. Only the Fifth Circuit Court of Appeals has followed their approach. The Second Circuit has indicated that it *may* not adopt wholeheartedly the inseparability doctrine. Both the Second Circuit and the Third Circuit have been presented with cases wherein the district court specifically disapproved the inseparability doctrine and in both instances they have chosen to avoid a specific decision. None of the other circuit courts of appeals have decided this issue, and no other reported district court cases have been found.

III. 35 U.S.C. SECTION 101: UTILITY

The emphasis upon properties in determining patentability of chemical compounds is not unique to the obviousness issue of 35 U.S.C. section 103. 35 U.S.C. section 101 (1970) states: "Whoever invents or discovers any new and *useful* process, machine, manufacture, or *composition of matter*, . . . [emphasis supplied] may obtain a patent therefor . . . ." This requirement has come to be known as the "utility requirement." Thus, if an invention has no use, it is not patentable. Utility has come to have a special meaning for chemical compounds. By court decisions, legal utility requires a close examination of the properties of a compound.

A. *Legal "Utility" Prior to Brenner v. Manson*[43]

Prior to *Brenner v. Manson*, the trend with regard to meeting the utility requirement of the statute for chemical compounds was a liberal one. Thus,

41. 464 F.2d 1051 (C.C.P.A. 1972).
42. *In re* Murch, 464 F.2d 1051, 1056 (C.C.P.A. 1972) (citations omitted).
43. 383 U.S. 519 (1966).

a mere allegation that a compound was a useful "synthesis intermediate" was sufficient to meet the statutory utility requirement. It seemed as if we were rapidly approaching the point where a compound would be held to be inherently useful as a tool for the synthesis chemist, like a brick is to a bricklayer. In *In re Nelson*,[44] the patent application contained the following assertion of utility for the newly synthesized compounds: "These new compounds are valuable synthesis intermediates in the preparation of steroids . . . ."[45] The Patent Office Board of Appeals held that the application did not contain a legally sufficient allegation of utility. The Court of Customs and Patent Appeals responded with the view that all intermediates are products having utility, thus meeting the utility requirement of 35 U.S.C. section 101. It was a very liberal decision but it has now been overruled.[46]

B. *Brenner v. Manson*

The Supreme Court quickly brought the Court of Customs and Patent Appeals in line. The view that non-particularized allegations of utility were sufficient to meet the legal requirement of utility under 35 U.S.C. section 101 was quickly dispelled.

In *Brenner v. Manson*, the invention was the process of making certain steroid compounds. The class of compounds made by the process had no certain utility. They were being screened for possible tumor inhibiting effects in mice. The Patent Office Board of Appeals held that there was an insufficient showing of utility for the process since the compounds produced by it had no known certain utility. The Court of Customs and Patent Appeals reversed.

The Supreme Court reviewed the utility requirement of 35 U.S.C. section 101 and noted the liberal trend in recent decisions of the Court of Customs and Patent Appeals.[47] It reversed the Court of Customs and Patent Appeals, holding that a process is not inherently useful merely because it works to produce the intended product. The rationale of the Court is summarized in the following cryptic comment:

> This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. "[A] patent system must be related to the world of commerce rather than to the realm of philosophy . . . ."[48]

So it was that the Court held that non-particularized allegations of utility were insufficient to meet the statutory requirement of a legal utility.

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44. 280 F.2d 172 (C.C.P.A. 1960).
45. *In re* Nelson, 280 F.2d 172, 176 (C.C.P.A. 1960).
46. *In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).
47. Brenner v. Manson, 383 U.S. 519, 530 (1966).
48. *Id.* at 535-36.

The Court of Customs and Patent Appeals has since expanded somewhat on the holding of *Brenner v. Manson.* In *In re Joly*,[49] the court held an allegation that a claimed chemical compound which alleged utility as a mere intermediate for building other compounds, is not a legally sufficient utility to meet the statutory requirement. *In re Kirk*[50] was a similar case decided by the Court of Customs and Patent Appeals as a companion to the *Joly* case. Again, the claims related to compounds and again the assertion of utility was an intermediate in the preparation of biologically active compounds. This was held to be a legally insufficient utility. The court specifically overruled *In re Nelson,* feeling compelled to do so in view of *Brenner v. Manson.*[51] It said: "There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized and clearly rejected by the Supreme Court. . . ."[52]

C. *Utility after Brenner v. Manson*

After *Brenner v. Manson* and the Court of Customs and Patent Appeals' decisions in *Kirk* and *Joly*, it became apparent that the properties of a new chemical compound were the paramount consideration for patentability. If the property was a non-predictable one based upon the structure of the most closely related compounds, under the inseparability doctrine of *Papesch*, prima facie obviousness of section 103 could be overcome.[53] Additionally, if the properties of the compound were such that it had a meaningful practical use, an allegation of that use would be sufficient to satisfy the legal utility requirement of section 101. If, on the other hand, a new compound was developed which only was vaguely or not specifically shown to be useful, it would not meet the requirement of a particularized utility needed to satisfy the test of *Brenner v. Manson.* Thus, if the properties of the compound were so vaguely identified that one could not allege a legally sufficient utility, no matter how unexpected those vaguely identified properties might be, one could not obtain a patent.

A delicate balance had finally been struck by the courts. Properties of compounds were the primary criteria by which non-obviousness would be determined. However, in order to satisfy the utility requirement of the law, such properties would have to be sufficiently known and employed to provide a certain, particularized utility. Thus, to obtain a patent, a use had to be a specific use, and the properties of the compound had to be not predictable from the most closely related structures.

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49. 376 F.2d 906 (C.C.P.A. 1967).
50. 376 F.2d 936 (C.C.P.A. 1967).
51. *In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967).
52. *Id.* at 945.
53. Establishment of unexpected results may be done by evidence presented as a part of the patent specification and by additional supportive affidavit evidence. 37 C.F.R. § 1.132 (1976).

The courts were not about to allow an inventor to monopolize a new compound unless he had truly made a practical contribution to the arts. If all he had done was simply synthesize the compound, that alone would be insufficient. A patent on a new chemical compound would only be awarded to the person who had (1) in fact synthesized a new compound, (2) synthesized a compound that had a non-predictable property based upon the most closely related structures and (3) employed the new property to provide a particularized, practical utility. So it is that the requirements of 35 U.S.C. section 101 and 35 U.S.C. section 103 have been intertwined to allow compound per se patents to be issued only when a definite contribution to the useful arts has been made. Seemingly, it is this rationale that Chief Justice Burger referred to in *Deutsche Gold-Und-Silber* when he pointed out that the emphasis upon properties for patentability of compounds seemed to be in general favor with the import of the patent statutes.[54]

The question remains of how to deal with a person who has discovered a new property of an old compound. Certainly the person who discovers that a known compound has the unexpected therapeutic property of effective cancer treatment has made a valuable contribution. Fortunately, he has a remedy provided in 35 U.S.C. section 100(b).

IV. New Use Doctrine

A. *Historical Perspective*

It has now become axiomatic that a new use of a known compound, no matter how valuable, does not make the compound per se patentable. This was first enunciated in *Morton v. New York Eye Infirmary*.[55] In the *Morton* case, the inventor had discovered that ether was an effective anesthetic during surgery. The patent was held invalid primarily on the basis that the properties of ether were already known and all the inventor had done was apply those properties to surgery. To use the modern day terminology, this was not a truly "new use,"[56] but rather an obvious "double use,"[57] or perhaps an "analogous use."[58]

The legal doctrine was crystallized in *In re Thuau*.[59] In *Thuau*, the inventor found that metacresolsulfonic acid condensed through an aldehyde had therapeutic value in the treatment of cervicitis. The exact composition was known and had previously been used for leather tanning. The only thing new was the therapeutic use. The patent claimed the composition. The Court of

54. Deutsche, *supra* note 19, at 663.
55. 17 F. Cas. 878 (No. 9,865) (C.C.S.D.N.Y. 1862).
56. *See* note 6 *supra*, for an explanation of "use patents."
57. "Double use" refers to use of the already known property for substantially the same purpose.
58. "Analogous use" refers to use of the known property in a closely related environment.
59. 135 F.2d 344 (C.C.P.A. 1943).

Customs and Patent Appeals correctly held that the composition was not patentable since it was not in fact new.

35 U.S.C. section 100(b) states a recognition that an inventor, like Thuau, can obtain patent coverage if the invention is properly claimed: "The term 'process' . . . includes a new use of a known process, machine, manufacture, composition of matter, or material."[60] The general concensus is that section 100(b) codified the preexisting law that new uses were patentable as a process.[61] However, in fact, there certainly has been a liberalization of granting use patents in process terms since the 1952 Patent Act. Thus, for example, in the chemical area, the only serious question is whether the use is really a new use or an inherent use of known properties of the compound, or an analogous use, the latter two not being patentable.[62]

B. *Actual Practice When New Uses Are Discovered*

When the inventor approaches his attorney with an invention which seems at first blush to be a new use of a known compound, such is more often than not, not really the case. A first and important question is whether the so-called new use requires a particular degree of purity, crystalline phase, optical isomer, admixture with diluent, critical percentage amounts for operability, or other such differences. In other words, one must carefully examine whether in fact that which is old is being used without any essential changes which might create a newly patentable composition. If any of the physical or chemical attributes of the old compound have not heretofore been known and are essential to the new use, a product claim can often be properly defined as a new composition.

In most instances, the patent lawyer will seek for his client both method claims and composition claims. *In re Wiggins*[63] is an excellent example of a situation wherein what at first blush appeared to be a new use of an old compound gave rise to a patentable composition. In *Wiggins*, certain admittedly old compounds were found to exhibit analgesic and pain relief properties. The prior known use was to protect mice from the hazard of x-ray. The patent application contained method claims in accord with 35 U.S.C. section 100(b) and also contained composition claims to a specified dosage level in combination with a pharmaceutical diluent.[64] The Examiner allowed the method claims but refused to allow the composition claims to the dosage unit. The Board of

60. 35 U.S.C. § 100(b) (1970).

61. *See, e.g.*, Gottshalk, *The Term 'Process' Includes a New Use*, 40 J. PAT. OFF. SOC'Y 451 (1958).

62. For a general discussion of the new use doctrine, *see* Eggert, *supra* note 22.

63. 397 F.2d 356 (C.C.P.A. 1968).

64. Application of Wiggins, 397 F.2d 356, 357 (C.C.P.A. 1968). Claim 13 read: "13. A pharmaceutical preparation in dosage unit form adapted for administration to obtain an analgesic effect, comprising, per dosage unit, an analgesically-effective nontoxic amount within the range from about 10 to about 1000 milligrams of at least one compound selected from the group consisting of 1:3-benzoxazine - 2:4-dione and pharmacologically acceptable alkali metal salts thereof, and a pharmaceutical diluent." *Id.* at 357.

Appeals affirmed on the basis that what in fact was discovered was a new use of a known composition and new use method claims had already been allowed in accord with section 100(b). The Court of Customs and Patent Appeals reversed. Relying upon the differences between the prior art and the appealed composition claims, the court noted that there was no disclosure in the prior art of the dosage levels of the claims. In short, while the compound employed in the composition was old, the *amount* employed was new and the result of the use of the new composition was not suggested by the prior art. Application of the new use doctrine was not appropriate.

It is important to remember that the holder of a patent on a known compound utilized either in a new composition or in a process defined as a new use in accord with section 100(b) does not have the legal lever that a holder of a patent on a new compound per se has. The patent holder on a compound per se can stop anybody from making that compound, for whatever reason. The new use patent holder cannot stop anyone from making the compound upon which the new use method or composition patentability was predicated. The subsequent inventor of a new use cannot practice his invention without a license from the holder of the dominant patent, if one exists, on the compound per se. The legal trump card is with the owner of the patent on the new compound.

On the other hand, if the new use is so important that it dominates the prior known use making the real economic value of the compound lie with the new use, a license from the patent holder on the compound per se would seem economically desirable for both parties. The discoverer of the new use will reap his profit dependent entirely upon the demand for the use he discovered. He holds the economic lever. The demand for the compound exists solely because of the discovery of its important use. So it is that the so-called windfall patent protection to the owner of a patent on a compound per se often results in a licensing situation. Again a balance has been achieved.

V. The Consequences of a Per Se Rule of Structural Obviousness

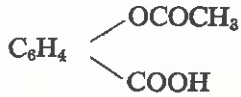
A per se rule equating structural obviousness and legal obviousness would have serious consequences on the issuance of patents on chemical compounds. Rarely is a chemical compound developed that is not structurally obvious. Consider, for example, the effect of a per se obviousness rule for chemical structures when applied to aspirin, calcium carbide, and polypropylene, each of which is one of the major chemical advances of the last 100 years.

A. *Aspirin—Felix Hoffman, United States Patent No. 644,077, February 27, 1900*

Aspirin is one of the greatest wonder drugs of all time. It is used to relieve pain of all types; it is an effective anti-inflammatory agent for rheumatoid arthritis; and it has virtually no side effects.

The aspirin patent was litigated and held valid;[65] yet, the invention was only a slight modification of the prior art, a modification which, although small, gave the world aspirin. The prior art gave the world nothing.

The patent claim was to acetyl salicyclic acid having the formula:



The compound was further characterized as being in the shape of white glittering needles when crystalized from dry chloroform, as easily soluble in benzene, alcohol, and glacial acetic acid, difficultly soluble in cold water, and having the capability to react in hot water by splitting into acetic acid and salicylic acid, its two major components. Finally, it had a melting point of about 135°C.[66]

The prior art was general knowledge relating to salicylic acid and an article by Kraut. It was known that salicylic acid itself caused desirable physiological effects. It was also known that salicylic acid per se was injurious to a patient's stomach. The Kraut article predicted the *exact* chemical formula. He prepared his product by reacting acetyl chloride and salicylic acid, whereas the patented aspirin product was prepared by reacting acetic anhydride and salicylic acid. The two products reacted differently in boiling water and with ferric chloride solution. They solidified at different temperatures, and a sharp melting point could not be obtained for the product of the Kraut reference. Importantly, although Kraut predicted the exact formula for aspirin, his product was not pure aspirin since his product did not provide the therapeutic effect that the patented aspirin did. Because the structure of aspirin was exactly predicted by the prior art, a per se rule would necessarily preclude patentability of aspirin, even though the prior art did not exhibit the unexpected properties of aspirin. The court simply rejected such a rule: "The fact that the formulae are identical cuts little figure. A chemical formula is simply symbolic expression of the composition or constitution of a substance; . . ."[67]

The inseparability doctrine although not applied by name was in fact used. The court pointed to the different properties of the prior art and the properties of aspirin.

B. *Crystalline Calcium Carbide—Thomas L. Willson, United States Patent No. 541,138, June 18, 1895*

The Willson patent claimed crystalline calcium carbide as its product. Crystalline calcium carbide, in pure form, was extremely valuable since it reacts

65. Kuehmsted v. Farbenfabriken of Elberfed Co., 179 F. 701 (7th Cir. 1910).
66. *Id.* at 762.
67. *Id.* at 703.

with water to form acetylene gas,[68] which during the last part of this century was utilized as a light source.[69] The prior art was a series of articles by the famed chemist Woehler, which showed that calcium carbide in a non-crystalline, amorphous form, was known. Thus, the exact chemical structure as the patented product was known, the only difference being a new crystalline form. The patent was litigated and held valid.[70]

Testimony showed that the patented calcium carbide product was commercially successful, whereas the amorphous form of the prior art was worthless commercially, was unfit for use in gas generators, and would deteriorate rapidly when exposed to air. Again, since chemically the exact compound was known, the only difference being that the prior art was non-crystalline whereas the patented product was crystalline, it would seem that a per se rule of structural obviousness would have negated patentability. The court emphasized the properties of crystalline calcium carbide in holding the patent valid:

> [P]atentable novelty in a case like the present may be founded upon superior efficiency; upon superior durability, including the ability to retain a permanent form when exposed to the atmosphere; upon a lesser tendency to breakage and loss; upon purity, and, in connection with other things, upon comparative cheapness. So, as supplementing other considerations, commercial success may properly be compared with mere laboratory experiments.[71]

Again, properties were emphasized and again a per se rule would have denied patentability to a major chemical advance which was instrumental in the beginning of Union Carbide, one of our nation's largest chemical companies.

C. *Polypropylene—Guillo Natta, United States Patent No. 3,112,300, November 26, 1963*

Stereoregulated polypropylene has become one of the most useful plastic polymers ever developed. It has so many uses it might be said it is to the plastics industry what lumber is to the building industry. It has enormous potential for applications as fibers, films, plastics, and rubbers. In 1963, the Nobel prize for chemistry was awarded equally between Natta and Ziegler for their discoveries relating to chemistry and technology of high polymers.[72]

In the prior art, polyethylene was known before the synthesis of isotactic polypropylene and in fact, certain crude forms of polypropylene had been synthesized. No one, it appears, however, had earlier made isotactic polypropylene.[73]

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68. The chemical reaction is: $CaC_2 + H_20 \longrightarrow C_2H_2 + CaO$.

69. In the early part of the century calcium carbide-acetylene generators were used for bicycle and automobile headlights and the reaction shown here was a primary source of acetylene for welding and cutting.

70. Union Carbide Co. v. American Carbide Co., 181 F. 104 (2d Cir. 1910).

71. *Id.* at 106-07.

72. For a discussion of the contributions of both Ziegler and Natta to polymer chemistry, see CHEM. & ENGINEERING NEWS, Apr. 6, 1976, at 187-88 [hereinafter cited as C & E NEWS].

73. This point was, of course, hotly contested in the litigation but was never fully adjudicated.

Again, the per se rule of structural obviousness would seem to preclude patentability. The very product in crude form had been prepared and the next lower homologue, namely polyethylene, was known. Structural obviousness of polypropylene per se was present. Yet if the inseparability doctrine is applied, isotactic polypropylene would seem patentable—it has different properties than polyethylene and crude, non-stereoregulated polypropylene.

The polypropylene patent, or more accurately, patents[74] have not been adjudicated to the point of a holding on the issue of validity. They have, however, been the subject of much litigation,[75] litigation which has for the most part been settled out of court. However, the important factor for our purposes here is that this major chemical advance for which the inventor received a Nobel prize in chemistry would seem to be not patentable under a strict per se rule of structural obviousness, a result which one must at least seriously question.

VI. Conclusion—A Per Se Rule Is Not Justified

The narrative could go on. Other great chemical inventions of the past century could be examined, for example, Takamine's adrenalin commercialized by Parke-Davis & Co.;[76] Carothers' nylon commercialized by duPont;[77] Plunkett's Teflon commercialized by duPont;[78] Colton's steroid synthesis which became the basis for D. Searle & Co.'s oral contraceptive;[79] Baekeland's Bakelite phenolic resins;[80] and Midgley's development of tetraethylead as an antiknock additive for gasoline,[81] just to name a few. The real point is, however, that a per se rule is not justified. The rule is not realistically related to the practical world of chemistry and chemical inventions. Therefore, it should be of little probative value on the legal issue of patentability of chemical inventions. It certainly should not be the single determinative factor.

A box of tinker toys can be used to build an infinite amount of different mechanical structures, each of which in and of itself is not particularly startling in hindsight. However, the uses to which those structures may be put offer an almost limitless possibility for beneficial results, results which ought to find meaningful protection in the patent system, if that system is to mean anything. These tinker toys can be thought of as the building blocks of new and useful chemical inventions.

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74. There are several patents relating to polypropylene in various stereoregulated forms of which the cited patent is but one example. *See* Natta, United States Patent No. 3,112,301; and Natta, United States Patent No. 3,715,344.

75. The Natta 3,112,300 patent has been involved in suits by its assignee, Montecatini, against Dart, Chevron, Exxon, Amoco, Eastman Kodak, Diamond Shamrock and Phillips. These cases were consolidated for discovery in the Delaware District Court at Wilmington, Delaware.

76. *See* Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (C.C.S.D.N.Y. 1911), *rev'd in part*, 196 F. 496 (2d Cir. 1912).

77. *See* C & E News, *supra* note 72, at 183 for a historical discussion of the development of nylon by Dr. Wallace Carothers.

78. C & E News, *supra* note 72, at 182 (discusses the accidental synthesis of teflon).

79. *Id.* at 161 (tells of the landmark development of oral contraceptives).

80. *See id.* at 178.

81. *See id.* at 118.

Adoption of any per se rule should be looked at with initial skepticism. In the antitrust laws, two rules for antitrust violations exist. The first is a per se rule for conduct which has been shown to be so offensive and non-competitive, it is illegal per se.[82] In all other situations, a rule of reason prevails.[83] In the patent law, on the issue of patentability of chemical compounds, the inseparability doctrine is the rule of reason. It is the rule which should prevail.

The very fact that a per se rule of structural obviousness might have a tendency to preclude patentability of such major chemical advances as aspirin, crystalline calcium carbide, isotactic polypropylene, adrenalin and others, should indicate that the rule has little correlation with the progress of science and the useful arts. Surely it must seem just a little incongruous that a man could receive a Nobel prize for chemistry on one hand and yet on the other hand have his novel invention declared an obvious modification of prior art structures!

Consider for a moment the practical ramifications of a per se rule of structural obviousness upon litigation of chemical patents. It would take no great imagination to foresee the possibility of a defendant introducing surveys and polls showing that the invention of the patent in suit was structurally obvious to a large percentage of the chemists working in the relevant technology. Of course, each of those answering the poll would have the wonderful benefit of hindsight, having known of the invention prior to being asked the question. The chemical patents which issued would be rare indeed and importantly, each of those which did issue would preclude a whole host of as yet never made compounds from the possibility of patentability, compounds which might exhibit properties which could solve many of the problems of mankind.

It is respectfully submitted that a per se rule would be so harsh that the courts would of necessity have to begin carving out exceptions. Ultimately, those exceptions would in all probability put us close to the present position of the doctrine of inseparability. Moreover, the doctrine of inseparability has progressed to the point where courts have provided a delicate balance between the requirements of section 103, the utility requirements of section 101, and the new use patent issue of section 100(b). This balance has worked well and it should not be discarded lightly.

One hundred and eighty-two years ago the French beheaded Lavoisier, one of our great chemical geniuses, for his sympathy with revolutionaries. In the words of Joseph LaGrange, the famous mathemetician, "It required only a moment to sever the head, and perhaps a century will not be sufficient to produce another like it." The guillotine should not be applied to patents on chemical compounds. If it ever is, it may take more than a century to recover.

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82. United States v. Topco Associates, Inc., 405 U.S. 596 (1972); United States v. Arnold, Schwinn & Co., 388 U.S. 365 (1967).

83. United States v. Addyston Pipe & Steel Co., 85 F. 271 (6th Cir. 1898).