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THE *EN BANC* REHEARING OF *IN RE DILLON*: POLICY CONSIDERATIONS AND IMPLICATIONS FOR PATENT PROSECUTION

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A patent on a chemical composition may be granted if it is established that the composition is useful, novel,¹ and nonobvious.² The nonobvious standard divides new and useful technological improvements which result from a genuinely creative scientific effort from those which merely employ common substitutions or variations.³

Courts have struggled over the years to determine when a chemical composition may be deemed *prima facie* obvious. The Court of Appeals for the Federal Circuit's recent decision in the *en banc* rehearing of *In re Dillon*⁴ reflects this continuing struggle. As a practical matter, the decision serves to raise the inventor's burden of satisfying the nonobviousness test.

This article examines the policy implications of the *Dillon* decision upon both chemical patent application prosecutions and the economics of the patent system. Section one discusses nonobviousness. Section two examines the evolution of the *prima facie* obvious standard for chemical compositions. Section three discusses the *Dillon* case. Section four analyzes the policy implications of the *Dillon* decision.

I. NONOBVIOUSNESS

Any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof is potentially patentable.⁵ A patentable invention must additionally satisfy the "nonobviousness" test.⁶

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1. 35 U.S.C. §§ 101-102 (1988).

2. *Id.* § 103.

3. In *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1851) the Supreme Court, in deciding that a method of making doorknobs from clay was unpatentable, interpreted the Patent Act as demanding inventiveness (today called nonobviousness). *Id.* at 267. The Court said that "unless more ingenuity and skill . . . were required . . . than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention." *Id.*

4. 919 F.2d 688 (Fed. Cir. 1990).

5. 35 U.S.C. § 101.

6. *Id.* § 103.

In 1952, Congress codified the nonobviousness requirement in title 35, section 103 of the United States Code. Section 103 provides in 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.⁷

The addition of this section served only to codify a condition upon which courts had long since insisted.⁸ Congress adopted section 103 in order to stabilize the judicially created "inventiveness" standard.⁹ In doing so, Congress made it clear that to obtain a patent, a device must be more than simply novel and useful; it must satisfy the "nonobviousness" standard.¹⁰

Thirteen years later, in *Graham v. John Deere Co.*,¹¹ the Supreme Court interpreted this standard. The Court concluded that "the section was intended merely as a codification of judicial precedents embracing the *Hotchkiss*¹² condition, with congressional directions that inquiries into the obviousness of the subject matter sought to be patented are a prerequisite to patentability."¹³ The Court stated that section 103 permits a more practical test of patentability,¹⁴ noting that patent validity is ultimately a question of law which "lends itself to several basic factual inquiries."¹⁵

7. *Id.*

8. S. REP. NO. 1979, 82d Cong., 2d Sess. 6, reprinted in 1952 U.S. CODE CONG. & ADMIN. NEWS 2394, 2399.

9. See Rich, *Why and How Section 103 Came To Be*, in NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY 1:201, 1:206 (J. Witherspoon ed. 1980) where the author explains:

Out of that decision [*Hotchkiss*] came the 'requirement for invention'—the requirement that to be patentable an invention had to involve a mysterious quality called 'invention' . . . [T]he third requirement, beyond the novelty and utility which were in the statute, and which evolved purely as case law, became . . . the 'plaything of the judiciary' and meant anything the judges chose to make it mean.

The author notes that the patent bar perceived an antagonism in the judiciary toward patents. He suggests that the discontent began with the Supreme Court's decision in *Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84 (1941). This Court, while applying the *Hotchkiss* rule in a patent case, declared something unpatentable because it lacked a "flash of creative genius." *Id.* at 90. The patent bar, irked by this highly subjective standard, pushed for the codification of the standard which, as the author points out, was named "inventiveness." S. REP. NO. 1979, 82d Cong., 2d Sess. 6, reprinted in 1952 U.S. CODE CONG. & ADMIN. NEWS 2394, 2399 ("This section should have a stabilizing effect and minimize great departures which have appeared in some cases.").

10. See Rich, *The Vague Concept of "Invention" as Replaced by Section 103 of the 1952 Patent Act*, in NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY 1:401, 1:408 (J. Witherspoon ed. 1980) ("What Section 103 itself says is that what is patented must not have been obvious to one of ordinary skill in the art involved, at the time the invention was made . . . This is not a 'standard of invention' and it is not called a 'requirement of invention.'").

11. 383 U.S. 1 (1966).

12. 52 U.S. (11 How.) 248 (1850).

13. *Graham*, 383 U.S. at 17.

14. *Id.*

15. *Id.*

Graham articulated a three-part test for determining nonobviousness: (1) determine the scope and content of the prior art; (2) ascertain the difference between the prior art and the claims at issue; and (3) resolve the level of ordinary skill in the pertinent art.¹⁶

Since the enactment of section 103, there have been numerous decisions involving the evidentiary burden required for establishing a prima facie case of obviousness. From among a milieu of conflicting rulings emerges a trend, particularly in the area of chemical patents. Courts construing early chemical patents required only a showing of structural obviousness of the novel chemical compound relative to prior art compounds to create a presumption of obviousness.¹⁷ More recent cases have required not only structural similarity, but a suggestion in the prior art that the novel composition would have the new property.¹⁸

II. EVOLUTION OF PRIMA FACIE OBVIOUSNESS IN CHEMICAL COMPOSITIONS CASES

This section examines the role of composition properties in obviousness determinations.¹⁹ Chemical compounds present a special problem for nonobviousness analysis.²⁰ Chemical bonds are formed based on well known rules. These rules provide the skilled chemist, presented with a structure on paper, with the ability to synthesize the compound.²¹ The nonobviousness analysis problem is to determine whether the inventor simply created a novel compound which has the desired properties by searching through prior disclosures and making minor structural adjustments to a known composition. This question has driven the judicial quest for a standard to distinguish the nonobvious chemical compound claim.²²

16. *Id.* The Court also stated that secondary considerations of "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." *Id.* at 17-18.

17. See *infra* notes 26-34 and accompanying text.

18. See *infra* notes 35-78 and accompanying text.

19. As used in decisions interpreting section 103, the properties of a chemical composition are its uses or utilities. A property of a novel composition is said to be unexpected if it was not previously possessed by related prior art compositions. It is said to be unexpectedly improved if the property is shared by the prior art and novel compositions and if the novel composition demonstrates an unexpectedly improved effectiveness in that shared property over the prior art composition. A novel composition is said to demonstrate actual differences from the prior art composition if it does not share the unexpected property with the prior art composition. If a property of a novel composition is actually shared with a prior art composition, a distinction is also made as to whether it was known that the prior art composition possessed the property. Thus, an unexpected property of a novel composition may be truly new and not actually possessed by prior art compounds, or it may be new only in the sense that the property was not previously known to be possessed by prior art compositions.

20. See Note, *Standards of Obviousness and the Patentability of Chemical Compounds*, 87 HARV. L. REV. 607, 607 (1974) ("Perhaps no area of patent law is more uncertain than that concerning the application of the section 103 test of 'nonobviousness' . . . to chemical compounds . . .").

21. See D. CHISUM, PATENTS § 5.04(b), at 5-312 (2d ed. 1990).

22. There are various articles on the standard for determining nonobviousness in chemical compounds. See Blodgett, *Relative Significance—A Concept in Chemical Structural Obvi-*

Prior to the enactment of section 103, an obviousness determination required a demonstration of close structural relatedness between the novel composition and the known compositions.²³ Underlying this early rule was the presumption that structurally similar chemicals have similar properties. In the early cases, a presumption of obviousness could be rebutted by a showing that the novel composition possessed a property not actually possessed by related prior art compositions.²⁴ These early cases do not generally refer to a "prima facie" case of obviousness; rather, they refer to presumptions or determinations of obviousness.²⁵

*In re Hass*²⁶ examined the patenting of homologs of prior art compounds.²⁷ The court ruled that "[n]ovel members of a homologous series of chemical compounds must possess some nonobvious or unexpected beneficial properties not possessed by a homologous compound disclosed in the prior art."²⁸

*In re Henze*²⁹ extended the ruling of *Hass*. *Henze* placed a "presumption of unpatentability" on a composition of matter claim for which the adjacent homolog was old in the art.³⁰ The court placed the burden on the applicant to rebut the presumption by showing that the claimed compound possessed unobvious or unexpected beneficial properties not actually possessed by the prior art homolog.³¹ The court considered it immaterial that the known compound was not "[r]ecognized or known to be useful for the same purpose or to possess the same properties as the claimed compound."³²

To rebut the presumption of obviousness derived from structural

ousness Cases, 63 J. PAT. OFF. SOC'Y 69 (1981) (justifying the use of the relative significance of claimed compound with similar structure in the prior art to rebut a presumption of obviousness); Marquis, *An Economic Analysis of the Patentability of Chemical Compounds*, 63 J. PAT. OFF. SOC'Y 3 (1981) (presenting an economic analysis of the effectiveness for standards of patentability in chemical compounds and using the analysis to compare the gravity of a composition claim based on a novel use against the granting of a method claim). See also Note, *supra* note 20 (assessing the standards for patentability of novel chemical compounds).

23. *In re Henze*, 181 F.2d 196, 201 (C.C.P.A. 1950) (overruled by *In re Stemniski*, 444 F.2d 581 (C.C.P.A. 1971)).

24. *Henze* at 201.

25. *Id.*

26. 141 F.2d 130 (C.C.P.A. 1944). This is the third of three companion cases. The other two are *In re Hass*, 141 F.2d 127 (C.C.P.A. 1944) and *In re Hass*, 141 F.2d 122 (C.C.P.A. 1944).

27. "A series of compounds in which each member differs from the next member by a constant amount is called a homologous series, and the members of the series are called homologs." R. MORRISON & R. BOYD, *ORGANIC CHEMISTRY* 101 (2d ed. 1966). All members of a homologous series of chemicals tend to possess the same principle characteristics. Knowledge of the properties and chemical behavior of one member of a homologous series suggests the properties and chemical behavior of another member of a series. *Hass*, 141 F.2d at 125.

28. *Hass*, 141 F.2d at 125.

29. 181 F.2d 196 (C.C.P.A. 1950) (overruled by *In re Stemniski*, 444 F.2d 581 (C.C.P.A. 1971)).

30. 181 F.2d at 201.

31. *Id.*

32. *Id.*

similarity, the *Henze* court required that the novel composition contain a novel property not actually shared by prior art compositions.³³ The court indicated that a mere improvement in a property shared with prior art compositions was not sufficient to impart nonobviousness.³⁴

*In re Papesch*³⁵ synthesized the *Hass-Henze* doctrine in light of section 103. The novel compound possessed a structure similar to compounds in the prior art. The prior art compounds, however, did not possess certain anti-inflammatory capabilities present in the novel compound.³⁶ The Patent and Trademark Office Board of Appeals and Interferences (Board) rejected the composition claim on the basis of obviousness due to structural similarities.³⁷ The Board stated that the compound was so similar to the prior art, its obviousness was beyond doubt.³⁸ The Board noted that the fact that compound possessed properties nonexistent in the prior art could be used only to resolve doubt.³⁹

The Court of Claims and Patent Appeals reversed, stating that the Board's finding that a showing of properties was necessary only to resolve doubt rested on a "fundamental error of law."⁴⁰ The court ruled that since a compound is inseparable from all of its properties, an obviousness determination requires the consideration of both similarities in properties and structures.⁴¹

The scope of the *Hass-Henze* rule was limited by several later cases. *In re Mills*⁴² limited the legal presumption of obviousness to only adjacent homologs. The court found that the prior art compositions containing alkyl sulfates of C₈-C₁₂, compounds useful as anti-caking agents in detergents, did not create a presumption of obviousness for methyl (C1) sulfates, another type of anti-caking agent.⁴³ The court ruled that the *Henze* presumption of obviousness was applicable only to immediately adjacent homologs and not more distant members of the homolo-

33. *Id.*

34. *Id.*

35. 315 F.2d 381 (C.C.P.A. 1963).

36. *Id.* at 383.

37. *Id.* at 385.

38. *Id.*

39. *Id.* at 386.

40. *Id.* at 391.

41. *Id.* at 391-92. The court said:

From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing And the patentability of the thing [compound] 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.

. . . .

The other factor of importance [in an obviousness determination] is that the prior art disclosure was not merely of a structurally similar compound but also, at least to a degree, of the same desired property relied on for patentability in the new compound. Such an 'other factor' must of course be considered because it bears on the obviousness of the compound, which is, realistically and legally, a composite of both structure and properties.

Id. (emphasis in original) (citations omitted).

42. 281 F.2d 218 (C.C.P.A. 1960).

43. *Id.* at 221.

gous series.⁴⁴

The *Hass-Henze* rule was further limited by *In re Stemniski*.⁴⁵ In *Stemniski* the claimed compounds had an antioxidant property not known to be possessed by prior art compounds. In fact, the prior art compounds had no known utility. Ruling that the claimed composition was nonobvious, the court suggested that it was immaterial whether the prior art compounds actually had antioxidant properties.⁴⁶ The court explicitly overruled *Henze*, indicating that the *Henze* rule does not apply where the applicant describes a utility for the novel composition, and the prior art does not disclose or suggest any usefulness for the prior art compounds.⁴⁷ The court suggested that the applicant was under no obligation to demonstrate that the unexpected property of the novel composition was not actually possessed by the prior art compounds.⁴⁸

The *Stemniski* limitation was extended in *In re Albrecht*.⁴⁹ In *Albrecht* the novel composition exhibited unexpected antiviral activity not possessed by the closest prior art compound. The prior art compound possessed anesthetic activity but was unsuitable for such use because it caused skin irritation. The Board found that prima facie obviousness was not rebutted by the unexpected antiviral activity.⁵⁰ It ruled that the inventor had the burden to show that the novel composition did not produce anesthetic activity.⁵¹

Reversing the Board, the court stated that the unexpected antiviral activity did rebut prima facie obviousness.⁵² The court reasoned that there was no motivation for those skilled in the art to synthesize the related novel composition because the prior art disclosed the unsuitability of the known compounds for use as anesthetics.⁵³

The *Hass-Henze* doctrine was further limited by *In re Chupp*.⁵⁴ *Chupp* involved a claim for a herbicide structurally similar to prior art herbicides. To rebut prima facie obviousness, the applicant submitted evidence showing that the novel composition produced superior herbicidal results.⁵⁵ The court stated that evidence to rebut prima facie obviousness "may include data showing that a compound is unexpectedly

44. *Id.* The court stated:

Where, as here, the invention for which a patent is sought relates to one member of an homologous series and the disclosure of the prior art is of a non-adjacent member of the series. [sic] *In re Henze* . . . is not authority for a 'legal presumption' of obviousness of the claimed invention.

Id. (citation omitted).

45. 444 F.2d 581 (C.C.P.A. 1971).

46. *See id.* at 587.

47. *Id.*

48. *See id.* at 587.

49. 514 F.2d 1389 (C.C.P.A. 1975).

50. *Id.* at 1393.

51. *Id.* at 1396.

52. *Id.*

53. *Id.*

54. 816 F.2d 643 (Fed. Cir. 1987).

55. The superior herbicidal property in *Chupp* concerned selective weed-killing properties (controlling quackgrass and yellow nutsedge without damaging corn or soybeans). *Id.* at 644.

superior in a property it shares with prior art compounds Evidence that a compound is unexpectedly superior in one of a spectrum of common properties, as here, can be enough to rebut a *prima facie* case of obviousness.”⁵⁶

By the 1980s, *prima facie* obviousness decisions began to explicitly require an analysis of similarity of properties. In *In re Grabiak*⁵⁷ the court ruled that a novel composition exhibiting “safening”⁵⁸ activity in herbicides was not *prima facie* obvious.⁵⁹ The court reasoned that there was no suggestion in the closest prior art that the structural change be made nor was there sufficient evidence indicating that the safening activity was predictable even for closely related structures.⁶⁰ The court stated that “[w]hen chemical compounds have very ‘close’ structural similarities and similar utilities, without more a *prima facie* case may be made.”⁶¹

*In re Payne*⁶² contains a similar *prima facie* analysis. The court ruled that a *prima facie* case was made because there was a close structural similarity with prior art compounds and because the pesticidal activity of the novel composition was a known property of the prior art compounds. The court stated:

An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that the compounds similar in structure will have similar properties.

.....

The similarity in chemical structures and properties between the prior art and claimed compounds is sufficiently close to support a *prima facie* case of obviousness.⁶³

56. *Id.* at 646. We note that the *Chupp* ruling is directly contrary to dicta in *Henze* indicating that a mere improvement in a shared property is not sufficient to impart nonobviousness. See *Henze*, 181 F.2d 196, 201 (C.C.P.A. 1971).

57. 769 F.2d 729 (Fed. Cir. 1985).

58. A safener protects growing crops from weed killers. *Id.* at 729.

59. *Id.* at 732.

60. *Id.* at 732-33.

61. *Id.* at 731.

62. 606 F.2d 303 (C.C.P.A. 1979).

63. *Id.* at 313-14 (citations omitted). See *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988) where the court held that the Patent Office had not established a *prima facie* case of obviousness because the combination of elements of applicant’s gas chromatograph/detector was not suggested by the prior art and because the temperature range limitation on the system claims had a different purpose than the temperature range specified in the prior art. It was immaterial that there was some overlap in the temperature ranges. *Id.* at 1074-75. See also *In re Wright*, 848 F.2d 1216 (Fed. Cir. 1988) where the court held that the Patent Office had not established a *prima facie* case because none of the cited references suggested the claimed combination of Wright’s structure (an improved carpenter’s level) as a solution to the problem of increasing pitch measurement capacity. *Id.* at 1220. The court in *Wright* said:

The determination of whether a novel structure is or is not ‘obvious’ requires cognizance of the properties of that structure and the problem which it solves, viewed in light of the teachings of the prior art.

.....

Thus the question is whether what the inventor did would have been obvious to one of ordinary skill in the art attempting to solve the problem upon which the inventor was working.

A line of post-*Henze* cases discuss balancing the significance of the unexpected property of the novel composition with the significance of the expected properties of the prior art composition.⁶⁴ *In re Nolan*⁶⁵ used a balancing test to determine whether the unexpected property of a novel device was sufficiently significant to rebut evidence of obviousness.⁶⁶ It found that the unexpected properties did not have a significance equal to or greater than that of the expected property to rebut the other evidence of obviousness.⁶⁷

A balancing approach was also applied in *In re De Montmollin*⁶⁸ and *In re Mod*.⁶⁹ *De Montmollin* involved the rejection of a claim for a water soluble dye used for dyeing wool, cotton and cellulose.⁷⁰ The prior art dyes were of a similar structure and could be used for dyeing wool.⁷¹ The appellant argued that the rejection failed to consider the unexpected use (cotton and cellulose dyeing) not mentioned in the prior art.⁷² The court stated that "a single variance in the properties of new chemical compounds will [not] necessarily tip the balance in favor of patentability where otherwise closely related chemical compounds are involved."⁷³

In re Mod involved a claim for a novel antimicrobial agent.⁷⁴ The prior art compounds were structurally related and shared the property of insecticidal activity with appellant's novel compound.⁷⁵ The prior art compounds, however, did not possess antimicrobial activity.⁷⁶ After balancing the unexpected antimicrobial activity against the shared ex-

Id. at 1219 (citations omitted).

64. See *infra* notes 68-78 and accompanying text. While the function of this balancing is not readily apparent, it is performed following the initial determination of prima facie obviousness. In at least some of these decisions, it appears that the balancing is done to determine whether the new or unexpected property is sufficiently significant to rebut the prima facie case of obviousness.

65. 553 F.2d 1261 (C.C.P.A. 1977).

66. The Nolan invention was an improvement in a gaseous discharge display/memory device having an electrical memory and the capability of producing a visual display. The improvement comprised the use of a defined ionizable gaseous medium containing neon and a small percentage of rare gas (argon, krypton and xenon). *Id.* at 1262. The device had the benefits of higher memory margin, higher luminous efficiency, and lower peak discharge current through the use of the claimed gas mixture. The court found the higher memory margin to be expected in view of the prior art, and the higher luminous efficiency and lower peak discharge current to be unexpected properties. *Id.* at 1267.

67. *Id.* at 1267.

68. 344 F.2d 976 (C.C.P.A. 1965).

69. 408 F.2d 1055 (C.C.P.A. 1969).

70. 344 F.2d at 977.

71. *Id.* at 978.

72. *Id.*

73. *Id.* at 978 (emphasis in original). The court held:

The claimed substances, as well as those in the prior art, are water soluble materials useful as dyes. Both sets of compounds have the property of being wool dyes and both result in dyeings on wool fabrics which are fast to washing and fulling. Under the circumstances and weighing the available evidence, we do not regard the additional ability to dye cotton sufficient to render the subject matter as a whole unobvious.

Id. at 978-79 (emphasis added) (footnotes omitted).

74. 408 F.2d 1055, 1055 (C.C.P.A. 1969).

75. *Id.* at 1055-56.

76. *Id.* at 1056.

pected property, the court ruled that the invention was obvious.⁷⁷ It noted that the unexpected antimicrobial activity was not sufficiently significant to find nonobviousness.⁷⁸

III. THE IN RE DILLON DECISION

There are two *In re Dillon* decisions. The first is the Federal Circuit panel decision rendered on December 29, 1989 (the Panel Decision).⁷⁹ The second is the court's *en banc* rehearing decision rendered on November 9, 1990 (the *en banc* Decision).⁸⁰

Dillon requested a patent for a novel composition comprising a hydrocarbon fuel and an effective amount of tetra-orthoesters, and a method for reducing particulate emissions by the combustion of the composition.⁸¹ Dillon's broadest composition claim was directed to a composition comprising a hydrocarbon fuel and an amount of tetra-orthoesters sufficient to reduce particulate emissions during the combustion of the hydrocarbon fuel.⁸² Her broadest method claim was directed to a method of reducing particulate emissions during the combustion of hydrocarbon fuel by combusting a mixture of the hydrocarbon fuel and an amount of tetra-orthoesters sufficient to reduce particulate emissions.⁸³

The Board rejected Dillon's patent application on obviousness grounds. In doing so, the Board cited three prior art references. The first cited reference taught a composition of tri-orthoesters mixed with hydrocarbon fuels in order to "de-water" the fuel.⁸⁴ The second cited reference taught the use of tri-orthoesters in a mixture of hydrocarbon fuels and immiscible alcohols where the tri-orthoesters serve as co-solvents to prevent phase separation between fuel and alcohol.⁸⁵ The third

77. *Id.* at 1057.

78. *Id.* The court stated:

Inasmuch as the claimed compounds and those of [the prior art] do possess a close structural relationship and it is not denied that they have a *specific, significant* property in common, viz. insecticidal activity, we do not regard the additional antimicrobial activity discovered by appellants for the claimed compounds sufficient ground to hold that the subject matter as a whole is unobvious.

Id. (emphasis in original). A similar property-balancing analysis is conducted in *Solder Removal Co. v. United States Int'l Trade Comm'n*, 582 F.2d 628 (C.C.P.A. 1978). In *Solder Removal* the court stated "[w]here the reason for the practice suggested by the prior art is much less significant than the reason derived from the inventor's solution to another problem, the results may be so unexpected as to support a conclusion of nonobviousness." *Id.* at 635.

79. 892 F.2d 1554 (Fed. Cir. 1989), *withdrawn and superseded*, 919 F.2d 688 (Fed. Cir. 1990).

80. 919 F.2d 688 (Fed. Cir. 1990). On February 12, 1990, the Commissioner of the Patent and Trademark Office filed a Petition for Rehearing *en banc*. Shortly thereafter, an opposing petition by Ms. Dillon and several amicus curiae briefs were filed with the court. On May 21, 1990, the Federal Circuit accepted *Dillon* for rehearing *en banc* and vacated the December 29, 1989 panel decision.

81. 919 F.2d at 690-91.

82. *Id.*

83. *Id.*

84. *Id.* at 691.

85. *Id.*

cited reference taught the use of tri-orthoesters and tetra-orthoesters as water scavengers in hydraulic (non-hydrocarbon) fluids.⁸⁶

Dillon appealed the Board's decision. The appellate court panel overturned the Board's decision stating that similarity of structure alone does not establish a prima facie case of obviousness: "there must be some reason, arising in the prior art, to expect that the claimed compounds or compositions will have the properties found by the applicant."⁸⁷ The *en banc* court overruled the panel decision, and affirmed the Board's rejection of Dillon's patent.⁸⁸ The court found that the prior art neither taught a fuel composition comprising tetra-orthoesters for any use nor specifically taught or suggested the use of tetra-orthoesters to reduce particulate emission in the combustion of hydrocarbon fuels.⁸⁹ The court ruled that there was no evidence of a relationship between the properties of water-scavenging and reducing particulate emissions upon combustion.⁹⁰

IV. ANALYSIS

A. *The Dillon Rules*

While the *en banc Dillon* decision does resolve a number of inconsistencies appearing in prior cases, it does so at the expense of inventors. It has the practical effect of placing a greater evidentiary burden on the inventor by making it easier for the Patent Office to establish prima facie obviousness.

The court stated that although a composition is novel and its new property is not shown or suggested by the prior art compositions, a prima facie case of obviousness for the composition is made where the examiner can show that: (1) prior art compounds possess similar structures to the novel composition, and (2) the prior art gives a reason or motivation to make the claimed novel compositions.⁹¹

According to the court, an applicant can rebut a prima facie case by showing one of the following: (A) the claimed composition possesses properties not actually possessed by prior art compositions (Option A); (B) the claimed composition possesses an unexpectedly improved property shared with prior art compounds (Option B); or (C) the prior art is so deficient that chemists have no motivation to make obvious compositional changes (Option C).⁹² The court suggests a further rebuttal option of arguing the relative importance of the claimed compositions compared with the prior art.⁹³ This option is similar to Option C.⁹⁴

86. *Id.* at 690-91.

87. 892 F.2d 1554, 1565 (Fed. Cir. 1989).

88. 919 F.2d at 698.

89. *Id.* at 691.

90. *Id.* at 694.

91. *Id.* at 692. The court notes that the reason or motivation need not be related to the new problem solved by the novel composition. *Id.* at 692-93.

92. *Id.* at 693.

93. *Id.* at 694.

94. *Id.* at 692-93. By pointing out that Dillon failed to argue the relative importance

As to the elements necessary to establish a prima facie case, the *Dillon* decision is consistent with *Hass*⁹⁵ and *Henze*,⁹⁶ but inconsistent with such later cases as *Payne*,⁹⁷ *Gabiak*,⁹⁸ *Fine*,⁹⁹ and *Wright*.¹⁰⁰ As regards the options for rebuttal of a prima facie case: Option A is consistent with *Henze*;¹⁰¹ Option B is consistent with *Chupp*;¹⁰² and Option C and related dicta regarding "relative importance" of properties are reminiscent of the property balancing cases of *De Montmollin*,¹⁰³ *Mod*,¹⁰⁴ *Nolan*,¹⁰⁵ and *Solder Removal*.¹⁰⁶

The court also overruled *Wright*¹⁰⁷ to the extent that it is contrary to the *en banc* definition of a prima facie case.¹⁰⁸ The court said that a prima facie case does not require a suggestion in, or an expectation from, the prior art indicating that the claimed composition will have the newly discovered and unexpected property.¹⁰⁹

B. Implications for Biotechnology Practice

The underlying premise of *Dillon* is that compositions having similar structures predictably have similar properties. This premise, however, often fails in the field of biotechnology.

Many patent law practitioners characterize biotechnology and chemistry inventions as having similar levels of predictability relative to mechanical inventions.¹¹⁰ Some aspects of biotechnology, however, are

of her composition compared with the prior art, the court suggests that such arguments may have been considered by the court in rebuttal of the *prima facie* obviousness. *Id.* at 695. Unfortunately, *Dillon*, operating on the assumption that *Wright* was good law, apparently did not present these arguments to the Board, although they were presented in her Brief in Opposition to Rehearing. Brief for Appellant *Dillon* in Opposition to Petition for Rehearing and Suggestion for Rehearing *En Banc* at 9, 919 F.2d 688 (Fed. Cir. 1990) (No. 88-1245). Given the overwhelming significance of the emission reduction property relative to the de-watering property, it is not inconceivable that had *Dillon* made the significance arguments, her composition claims may have been held to be nonobvious.

95. *In re Hass*, 141 F.2d 122 (C.C.P.A. 1944).

96. *In re Henze*, 181 F.2d 196 (C.C.P.A. 1950) (overruled by *In re Stemmiski*, 444 F.2d 581 (C.C.P.A. 1971)).

97. *In re Payne*, 606 F.2d 303 (C.C.P.A. 1979).

98. *In re Gabiak*, 769 F.2d 729 (Fed. Cir. 1985).

99. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

100. *In re Wright*, 848 F.2d 1216 (Fed. Cir. 1988).

101. *Henze*, 181 F.2d 196 (C.C.P.A. 1950).

102. *In re Chupp*, 816 F.2d 643 (Fed. Cir. 1987).

103. *In re De Montmollin*, 344 F.2d 976 (C.C.P.A. 1965).

104. *In re Mod*, 408 F.2d 1055 (C.C.P.A. 1969).

105. *In re Nolan*, 553 F.2d 1261 (C.C.P.A. 1977).

106. *Solder Removal Co. v. United States Int'l Trade Comm'n*, 582 F.2d 628 (C.C.P.A. 1978).

107. *In re Wright*, 848 F.2d 1216 (Fed. Cir. 1988).

108. *In re Dillon*, 919 F.2d 688, 693 (Fed. Cir. 1990).

109. *Id.* The court indicates that even a use limitation in a composition claim (such as *Dillon's* limitation that the tetra-orthoester quantity be sufficient to reduce particulate emissions) will not save a novel composition from an obviousness rejection where structural similarity to prior art compositions and any motivation to synthesize the novel composition have been established. *Id.* at 693 n.4.

110. See, e.g., R.P. Blackburn, Comments Made at American Intellectual Property Law Association's Chemical and Biotechnology Practice Course (Chicago (Sept. 14, 1990); San Francisco (Oct. 5, 1990); and Newark (Nov. 2, 1990)).

so clearly empirical that they eliminate any predictability of properties based on similarities of structure.¹¹¹ The relative unpredictability in some aspects of biotechnology is due to the fact that small variations in structure may or may not result in significant changes in biological function.¹¹²

For example, the Board has acknowledged the empirical, unpredictable nature of monoclonal antibodies.¹¹³ The effect of a single amino acid or nucleotide substitution in a sequence on the biological function of the sequence is empirical; thus, the effect on biological function cannot be known or even predicted with a reasonable amount of certainty until the substitution is performed and the sequence tested for biological function.¹¹⁴

The relative unpredictability of biological activity of molecules is directly contrary to the underlying premise of *Dillon*, i.e., that structurally similar compositions have similar properties.¹¹⁵ The following hypotheticals illustrate the inequities that can result from the application of the *Dillon* rule to biotechnology inventions.

For example, assume it was known in the art that glycoprotein "A," having a known amino acid sequence, is an integral membrane protein in murine muscle cells. Further assume that it was known that the protein functions in the transport of certain nutrients across the cell membrane by receptor-mediated endocytosis. The question becomes whether a novel glycoprotein "B" having a 90% amino acid sequence homology with "A" is deemed nonobvious if it were found to function as a viral accession site in human muscle cells. The "A" glycoprotein was previously isolated, characterized and used to manufacture monoclonal antibodies useful in the diagnosis of certain genetic disorders related to deficient nutrient uptake by muscle cells. In addition to discovering that glycoprotein "B" is a human muscle cell viral accession site, purified "B" has been found by the inventor to mitigate infection by the virus when administered to infected individuals. Purified "B" has great medical value in the abatement of viral infection of human muscle cells. Although not previously known, the inventor has also determined that "A" has a viral accession function in murine muscle cells.

111. See, e.g., Kalusa, Alvarez-Morales & Hennecke, *Oligonucleotide-directed Mutagenesis of the Rhizobium japonicum nifH Promotor*[sic], 188 FED'N OF EUR. BIOCHEM. SOC'Y 37, 41 (1985) [hereinafter *Oligonucleotide-directed Mutagenesis*].

112. B. ALBERTS, D. BRAY, J. LEWIS, M. RAFF, K. ROBERTS & J.D. WATSON, *MOLECULAR BIOLOGY OF THE CELL* 97-100 (2d ed. 1989).

113. See, e.g., *Ex parte Old*, 229 U.S.P.Q. (BNA) 196, 200 (PTO Bd. Pat. App. & Int'f 1986) where the Board states:

Although the technique underlying hybridoma technology is well recognized, nevertheless, the results obtained by its use clearly are unpredictable. Hybridoma technology is an empirical art in which the routineer is unable to foresee what particular antibodies will be produced and which specific surface antigens will be recognized by them. Only by actually carrying out the requisite steps can the nature of the monoclonal antibodies be determined and ascertained; no "expected" results can thus be said to be present.

114. See, e.g., *Oligonucleotide-directed Mutagenesis*, *supra* note 111.

115. *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990).

Applying the *Dillon* rule to this scenario, "B" is deemed prima facie obvious over "A" because it is structurally similar and there would be some motivation to isolate and sequence "B" to determine and utilize its nutrient transport function. It is not possible to rebut the prima facie case by showing that "B" contains a property not actually possessed by prior art "A" (Option A) because "A" was determined by the inventor to have the same viral accession function in murine muscle cells. It is also not possible to rebut the prima facie case by demonstrating an unexpectedly improved property (Option B). Furthermore, the prima facie case cannot be rebutted by demonstrating that there is no motivation provided in the prior art to sequence "B" (Option C). The only possible means of rebutting the prima facie case is to provide evidence showing that the unexpected property of viral accession is more significant than the expected property of nutrient transport.

The *Dillon* court did not articulate criteria by which to judge the relative significance of expected and unexpected properties. In *De Montmollin*,¹¹⁶ *Mod*,¹¹⁷ and *Nolan*,¹¹⁸ however, none of the unexpected properties were held to be sufficiently significant relative to the expected properties. While it is difficult to know at this stage of the law whether the viral accession property of "B" would be deemed more significant than the nutrient transport property of "A," it seems unlikely. The medical significance of each function seems roughly equivalent. It seems unlikely that the inventor would be able to rebut the prima facie case by showing superior significance.

This outcome is inequitable because the viral accession property of "B" is truly unpredictable from the structure of "A" or its nutrient transport or viral accession functions. Just because "A" demonstrates viral accession function does not mean that structurally related "B," having 10% amino acid substitution over "A," will also have a viral accession function.

In some situations, where an unexpectedly improved property of the novel composition can be shown, the *Dillon* rule will not have a negative impact. For example, ribulose 1,5-bisphosphate carboxylase, also known as "Rubisco," is the enzyme that catalyzes the reaction of CO₂ with 1,5-bisphosphate to form two molecules of 3-phosphoglycerate.¹¹⁹ Rubisco is located on the stromal surface of thylakoid membranes in chloroplasts. In addition to its carboxylase activity, Rubisco also catalyzes a competing oxygenase activity.¹²⁰ The oxygenase and carboxylase reactions are carried out at the same active site and compete with each other. The rate of the carboxylase reaction is four times that of the oxygenase reaction under normal atmospheric conditions at 25°C. The oxygenase reaction is considered wasteful as it produces a product,

116. *In re De Montmollin*, 344 F.2d 976, 978-79 (C.C.P.A. 1965).

117. *In re Mod*, 408 F.2d 1055, 1057 (C.C.P.A. 1969).

118. *In re Nolan*, 553 F.2d 1261, 1267 (C.C.P.A. 1977).

119. L. STRYER, *BIOCHEMISTRY* 534 (3d ed. 1988).

120. *Id.* at 535-36.

phosphoglycolate, which is not a very versatile metabolite.¹²¹ If an inventor were able to alter the amino acid sequence of Rubisco sufficiently to improve the carboxylase activity relative to the oxygenase activity, it could provide plants with improved efficiency in carbon dioxide fixation. Such a plant would have great commercial value because it would substantially improve crop yields.¹²²

Under the *Dillon* rule, the inventor could rebut the prima facie case of obviousness by demonstrating an unexpectedly improved property over prior art compositions. The property would be unexpectedly improved because the improvement in carboxylase activity could not have been reasonably predicted from the amino acid substitutions employed. While it would be "obvious to try" various substitutions, until such substitutions were performed and tested in biological systems, their effect on carboxylase activity could not be known or predicted with reasonable certainty.¹²³ Consequently, an "obvious to try" substitution is not an acceptable basis for an obviousness rejection.¹²⁴

Biotechnology is an infant industry which typically requires large expenditures in research and development in order to obtain a market-ready product. Many investors have become frustrated with the expense and time required for development of new products.¹²⁵ Because many biotechnology inventions cannot be adequately protected as trade secrets, it is incumbent upon the patent system to recognize the need for adequate protection for novel compositions having unexpected properties which might otherwise not be discovered without the benefit of the system. The vacated *Dillon* panel recognized this need:

There is merit to the classical explanation that the incentive to study new variations of known compounds and compositions, in order to search for new uses, would be diminished if such *new* compounds and compositions cannot be patented despite discovery of new and unobvious properties. The contrary view carries scant counter-balancing public benefit.¹²⁶

In the glycoprotein "A" and "B" hypothetical, the "B" amino acid sequence exhibiting viral accession activity in human muscle tissue could be easily reverse engineered. Once a pharmacological product containing effective amounts of "B" was on the market, "B" could be easily sequenced and its sequence could not be maintained as a trade secret. Thus, without adequate protection under the patent system, the inventor cannot recoup sunk costs¹²⁷ or benefit from the fruits of his inventiveness.

The net result of this failure to protect and reward may be to dis-

121. *Id.* at 536.

122. *Id.*

123. *Ex parte* Old, 229 U.S.P.Q. (BNA) 196, 200 (PTO Bd. Pat. App. & Int'l 1986).

124. *Id.*

125. Gianturco, *Biotechnology Isn't Dead*, FORBES, May 1, 1989 at 410.

126. *In re Dillon*, 892 F.2d 1554, 1569 (Fed. Cir. 1989), *withdrawn and superseded*, 919 F.2d 688 (Fed. Cir. 1990).

127. *See infra* notes 128-31 and accompanying text.

courage biotechnology innovations. This consequence will not only be a blow to many industries—such as the agricultural, medical and pharmaceutical industries—but also a loss to society since these innovations can vastly improve our quality of life.

C. *Economic Policy Implications*

The cost to society of granting a patent must be offset by the social benefit flowing from the innovation.¹²⁸ In this regard, the patent system serves as a mechanism through which competing interests are balanced. This section briefly examines the economic policy implications of the *Dillon* decision.

The *Dillon* claims involve a fuel composition which reduces air pollution from the operation of diesel-motored engines. The question arises: What incentive did Union Oil of California (Unocal)¹²⁹ have to develop this fuel composition? It would appear that in a highly competitive market, Unocal has very little incentive. Assuming that truck drivers are more interested in the price of fuel than in its features, drivers will tend to buy the lowest priced product. If Unocal (or any other producer) attempts to internalize the research and development costs of its innovation, demand will favor the lower cost non-innovative competitor's fuel.¹³⁰ Consequently, fuel producers have no incentive to develop cleaner fuels and governmental regulation of pollution emissions becomes necessary.

Ironically, it is governmental regulation which ultimately spurs much of private research and development in this area. In anticipation of regulation, fuel producers begin developing fuel compositions aimed at satisfying the expected governmental requirements. Once the regulation is promulgated, the company which first develops and patents the

128. See generally Marquis, *supra* note 22 at 58-62. The article discusses private costs and value versus social cost and value and how it relates to analyzing the patent law system:

Granted, that there results an increment in national product attributable to inventions that are generated, or whose application is accelerated, by the patent incentive. Against this, however, must be set the reduction in national product that is attributable to restriction in the use of those inventions which are patented but which would have appeared at the same time without patent incentive and would have been free for unrestricted use by anybody.

Id. at 63. See also *Graham v. John Deere Co.*, 383 U.S. 1 at 10-11 ("[T]he underlying policy of the patent system that 'the things which are worth to the public the embarrassment of an exclusive patent,' as Jefferson put it, must outweigh the restrictive effect of the limited patent monopoly.").

129. Unocal was *Dillon's* employer.

130. See Marquis, *supra* note 22 at 58-62. The article discusses why the marginal cost of the research and development is zero and, therefore, in a competitive market with no patent protection the innovator cannot recover sunk costs of development. The author states:

If the invention is used competitively—by anybody who cares to, and without restrain or payment—the quantity of goods produced will be so large that the price at which they are sold will cover no more than the marginal cost; hence, the selling price will contain nothing for the use of the invention, no return on the sunk investment.

Id. at 59.

innovative fuel composition recoups its sunk costs by licensing fees to other producers who must meet the new standards.

The *Dillon en banc* decision serves to undermine this incentive. By placing a greater evidentiary burden on the inventor, the *en banc* decision makes it more difficult to obtain composition patents. Composition patents are generally regarded as more valuable than process patents because the former allows the patentee to exclude others from selling the composition, as well as precluding others from actually making or using it.¹³¹ Faced with a lower likelihood of obtaining the more valuable composition patents, fuel producers are motivated to shift resources away from research and development and into other more profitable areas. As a result, society ultimately suffers because of the disincentive provided to private industry.

V. CONCLUSION

The authors believe that progress in the useful arts is ill-served by the *en banc Dillon* decision. The law as set forth in *Dillon* increases the evidentiary burden on the inventor without any appreciable benefit to the public. The decision impairs the capacity of the patent system to protect and reward those who develop novel compositions having unexpected properties. In this regard, applying *Dillon* to biotechnology inventions may result in incorrect obviousness determinations and discourage further innovations in the biotechnology industry.

131. U.S.C. § 154 (1988) states that "[e]very patent shall contain . . . a grant . . . of the right to exclude others from making, using or selling the invention throughout the United States"