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WHAT CONSTITUTES A "NEW USE" OF A KNOWN COMPOSITION AND SHOULD A PATENTEE'S PURPORTED OBJECTIVE MAKE ANY DIFFERENCE?

David A. Kelly†

ABSTRACT

This Article examines the long-standing patent principle that new uses directed to a result or property of a known composition are not patentable. The Article demonstrates that this principle is closely related to another well-known patent principle, namely that an alleged infringer's intent when performing a claimed method is irrelevant for purposes of determining infringement. To demonstrate the relationship between these two principles, the Article examines the recent Federal Circuit case of *Jansen v. Rexall Sundown*, which distinguished a claim directed to a method of using a composition over an allegedly infringing new use of the composition by construing the claimed method as limited to achieving a particular objective. The Article suggests that *Jansen* placed too much emphasis on the alleged infringer's intent when performing the claimed method, and that the decision stands as a dangerous precedent that a method of using an old composition may be patentable simply by reciting a new property of the composition or a different purpose for using it.

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INTRODUCTION

Patents are an important means of protecting key scientific discoveries. Patentees are encouraged to disclose to the public their discoveries and, in turn, are awarded a limited monopoly in order to recoup the expenses associated with discovery and to turn a profit. There are, however, important checks on a patentee's ability to obtain such a monopoly. One such check is the requirement that all patentable inventions be novel. In the biotechnological context, courts have long applied this novelty requirement to preclude the patenting of so-called "new" uses of a known composition, where the "new" use is merely the recognition of an inherent property of that composition. Where one use already exists for a known composition, any "new" use of the composition is deemed to be anticipated by the old use, provided the composition is used in precisely the same manner as it always has been. A hypothetical illustrates this point.

Suppose that after years of research, Inventor 1 discovers that compound X, a compound well known in the art, is useful for treating arthritis. Inventor 1 subsequently obtains a patent claiming a method of using the compound to treat arthritis. The claim recites, "A method of treating arthritis, comprising intravenously administering between 1 and 100 milligrams of compound X to a patient in need thereof." Now suppose that Inventor 2, using compound X to treat arthritis, discovers that the compound is also useful for treating near-sightedness. May Inventor 2 obtain a patent claiming, "A method of treating near-sightedness, comprising intravenously administering between 1 and 100 milligrams of compound X to a patient in need thereof"? According to the general rule that new uses directed to a result or property of a known composition are not patentable, the answer should be no.

A recent Federal Circuit case, however, has suggested that a claim directed to a method of using an old composition for one purpose might be patentably distinct over a claim directed to the same method for an unrelated purpose. This Article begins by surveying the cases applying the long-standing principle that a claim directed to a new use of a known composition, where the "new" use is merely the recognition of an inherent property of that composition, is unpatentable over a reference disclosing the same composition used the same way. The Article then reviews the principle articulated by the Federal Circuit in *Hilton Davis Chemical Co. v. Warner-*

Jenkinson Co.,[1] and endorsed by the Supreme Court, that an alleged infringer's intent when performing a claimed method is irrelevant for purposes of determining infringement. The Article proposes that these two principles are not only consistent, they are actually two sides of the same coin.

To demonstrate the relationship between these two principles, the Article examines the recent Federal Circuit case of *Jansen v. Rexall Sundown*,[2] which distinguished a method of use claim over an allegedly infringing use by construing the claimed method as limited to achieving a particular objective. The Article argues that this decision was wrongly reasoned on several grounds, not the least of which is that it ignored the principle that a patentable new use of a known composition requires more than the recognition of a result or property of that composition. In so doing, the court read into the claimed method a dubious intent limitation to distinguish it from the allegedly infringing use. Consequently, the court's strained claim construction also runs afoul of *Warner-Jenkinson*.

Unless and until the Federal Circuit clarifies the law in this area, *Jansen* stands as a dangerous precedent that a method of using an old composition may be patentable simply by reciting a new property of the composition or a different purpose for using it. As such, the case stands in direct contradiction to *Warner-Jenkinson*, which eschews reading intent into claims.

I. NEW USES DIRECTED TO A RESULT OR PROPERTY OF A KNOWN COMPOSITION ARE INHERENTLY ANTICIPATED

The discovery of a new use for an old composition based on unknown properties of the composition might be patentable to the discoverer as a process of use.[3] However, when the claim recites using an old composition and the "use" is directed to a result or property of that composition, then the claim is inherently anticipated.[4] Cases from the Federal Circuit, its predecessor court, the Court of

1. 62 F.3d 1512, 35 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 1995), *rev'd on other grounds*, 520 U.S. 17, 41 U.S.P.Q.2d (BNA) 1865 (1997).

2. 342 F.3d 1329, 68 U.S.P.Q.2d (BNA) 1154 (Fed. Cir. 2003).

3. *See, e.g.*, *In re* Hack, 245 F.2d 246, 248, 114 U.S.P.Q. (BNA) 161, 163 (C.C.P.A. 1957); *see also* UNITED STATES DEPARTMENT OF COMMERCE, UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2112 (2003) [hereinafter M.P.E.P.].

4. A claim is inherently anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See, e.g.*, M.P.E.P. § 2131.01.

Customs and Patent Appeals ("CCPA"), and the Board of Patent Appeals and Interferences affirming this basic principle of patent law are particularly instructive in this regard.

A. Court of Customs and Patent Appeals Cases

In *In re Tomlinson*,[5] the patentee sought to patent a method of inhibiting light degradation of polypropylene by mixing it with one of a genus of compounds, including nickel dithiocarbamate. A prior art reference taught mixing polypropylene with nickel dithiocarbamate to lower heat degradation but made no mention of the degradative effects caused by light. The CCPA held that the patentee's claim read on the obvious process of mixing polypropylene with the nickel dithiocarbamate.[6] The court found that the preamble of the claim, "[a] process of inhibiting degradation of polypropylene caused by exposure to light," did not patentably distinguish the claim from the prior art because "[t]hat language, in effect, states the *result* of admixing the two materials."[7] The court continued, "While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a *property in the old composition*."[8]

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5. 363 F.2d 928, 150 U.S.P.Q. (BNA) 623 (C.C.P.A. 1966).

6. *Id.* at 934, 150 U.S.P.Q. at 628.

7. *Id.*

8. *Id.* (emphasis added). In *In re* Zierden, 411 F.2d 1325, 162 U.S.P.Q. (BNA) 102 (C.C.P.A. 1969), decided just three years after *Tomlinson*, the CCPA reached a different conclusion than *Tomlinson* on seemingly analogous facts. In *Zierden*, the claim at issue was directed to using a composition for "removing and preventing alluvium deposits in water systems." *Id.* at 1326, 162 U.S.P.Q. at 103. The Board found the patent anticipated and/or obvious in view of a patent disclosing the use of the same composition to prevent scale formation in "industrial waters" and secondary references disclosing that all industrial water systems contain alluvium deposits. Reversing the Board, the CCPA construed the term "water systems" as "water systems containing alluvium," and held that the claim was valid because the prior art did not disclose water systems containing alluvium. *Id.* Although *Zierden* took pains to distinguish *Tomlinson*, the only true distinction between the cases is how the courts chose to interpret the claims. *Zierden*'s construction of the claim term "water systems" to mean "water systems containing alluvium" is troubling. There is typically a heavy presumption that the words of patent claims should be given their ordinary meaning. In this case, the ordinary meaning of "water systems" would encompass *any* system of water, not just those which happen to contain alluvium. In effect, the court redrafted Zierden's claim in order to distinguish the art. This is precisely what *Tomlinson* refused to do. *Tomlinson* could equally well have read the claim term "polypropylene" as meaning "polypropylene exposed to light," and held that the prior art did not disclose such a compound. *Tomlinson*, however, rightly declined to engage in judicial draftsmanship when the ordinary meaning of the claim term was so clear.

In *In re Best*,[9] a claim was directed to a method of preparing a hydrolytically-stable zeolitic aluminosilicate, which included "cooling the steamed zeolite . . . at a rate sufficiently rapid that the cooled zeolite exhibits an X-ray powder diffraction pattern."[10] The Board of Patent Appeals and Interferences ("Board") sustained the Examiner's 35 U.S.C. §§ 102 and 103 rejection of the claim based on an issued U.S. patent to Hansford which expressly disclosed all the method limitations except for the cooling step. The Board concluded that the cooling step, though not expressly disclosed by Hansford, was nonetheless inherent in Hansford's method. On appeal, the CCPA affirmed the Board's decision, holding that any sample of Hansford's zeolite would necessarily be cooled to facilitate subsequent handling.[11] In so holding, the court stated, "[I]t is elementary that the mere recitation of a *newly discovered function or property*, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art."[12]

In *In re May*,[13] claims were directed to a method of effecting nonaddictive analgesia (pain reduction) in animals by administering to an animal an effective dosage of certain compounds. The Board found that the claims were anticipated by a prior art reference, May, which disclosed the same compounds for effecting analgesia, but which was silent as to addiction. On appeal, appellants argued that May did not anticipate the claim because it was directed to effecting analgesia generally, whereas the claim was directed to effecting nonaddictive analgesia. Relying on 35 U.S.C. § 100(b), which states that "[t]he term 'process'. . . includes a new use of a known . . . composition of matter," appellants argued that they had discovered a new use for a known compound.[14] The CCPA disagreed with appellants and affirmed the Board's holding. The court held that, "[w]hile the applicants have discovered a *hitherto unknown property*, to wit, nonaddictiveness, of the species disclosed by May, *such discovery does not constitute a new use*."[15]

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9. 562 F.2d 1252, 195 U.S.P.Q. (BNA) 430 (C.C.P.A. 1977).

10. *Id.* at 1253, 195 U.S.P.Q. at 431.

11. *Id.* at 1254, 195 U.S.P.Q. at 432–33.

12. *Id.*, 195 U.S.P.Q. at 433 (citing *In re* Swinehart, 439 F.2d 110, 169 U.S.P.Q. (BNA) 226 (C.C.P.A. 1971)) (emphasis added).

13. 574 F.2d 1082, 197 U.S.P.Q. (BNA) 601 (C.C.P.A. 1978).

14. 35 U.S.C. § 100(b) (1999).

15. 574 F.2d at 1090, 197 U.S.P.Q. at 607 (emphasis added).

B. Federal Circuit Case Law

The Federal Circuit has consistently reiterated the holdings of the CCPA. In *Mehl/Biophile International Corp. v. Milgraum*,[16] the court found claims directed to a method for removing hair using a laser anticipated by a reference that inherently taught removing hair using a laser. The patent in dispute, U.S. Patent No. 5,059,192, claimed a method for destroying the papilla, germ cells from which hairs grow, using a Q-switched ruby laser, thereby preventing hair regrowth. The district court found that the patent was anticipated by an instruction manual for a Spectrum RD-1200 laser. The manual taught the use of a Q-switched ruby laser to remove tattoos. A second reference (the "Polla article"), which the district court did not rely on, documented the tissue damage induced by Q-switched ruby laser pulses in black, brown, and albino control guinea pigs.

The Federal Circuit affirmed the district court's holding of anticipation, but disagreed with the court's rationale. The court held that the RD-1200 manual could not anticipate the '192 patent because it did not teach all of the limitations of the claimed invention.[17] Claim 1 of the patent required a step of "aligning a laser light applicator substantially vertically over a hair follicle opening."[18] The court found that the manual did not discuss hair follicles and thus did not teach alignment substantially vertically over a follicle opening.[19] Nor did the manual inherently teach this limitation of the claimed invention because "the natural result flowing from the operation as taught would result in the performance of the questioned function."[20]

Instead, the court found that the claims were anticipated by the Polla article. The court noted that Polla was replete with references to the irradiation of hair follicles and, unlike the RD-1200 manual,

16. 192 F.3d 1362, 52 U.S.P.Q.2d (BNA) 1303 (Fed. Cir. 1999).

17. *Id.* at 1365, 52 U.S.P.Q.2d at 1306.

18. *Id.* at 1364, 52 U.S.P.Q.2d at 1306.

19. *Id.* at 1365, 52 U.S.P.Q.2d at 1306.

20. *Id.* In its holding, the court cited an earlier Federal Circuit case, *In re King*, 801 F.2d 1324, 1326, 231 U.S.P.Q. (BNA) 136, 138 (Fed. Cir. 1986). In *King*, claims were directed to a method of enhancing color effects produced by ambient light through a process of absorption and reflection of the light off a coated substrate. The Board found the claims anticipated by a reference disclosing the coated substrate to produce architectural colors, but not the absorption and reflection mechanisms of the claimed process. The Federal Circuit affirmed the Board's finding that the prior art device inherently performed the function disclosed in King's method claims when that device was used in normal and usual operation. *Id.* at 1327, 231 U.S.P.Q. at 136. The court held, "[u]nder the principles of inherency, if a structure in the prior art necessarily functions in accordance with the limitations of a process or method claim of an application, the claim is anticipated." *Id.* at 1326, 231 U.S.P.Q. at 136.

inherently disclosed an "aligning" step.[21] The record showed "that holding the collimated laser in contact with the skin would align it perpendicular to the skin surface and therefore substantially vertically over follicle openings."[22] Thus, viewed as a whole, the Polla disclosure showed that the "'natural result flowing from the operation as taught would result in' alignment of the laser light over the hair follicle, as claimed."[23] This was true even though Polla did not concern itself with human skin *nor mention the goal of hair removal*.[24]

In *Eli Lilly & Co. v. Barr Laboratories, Inc.*,[25] the Federal Circuit, for the second time, found no patentable distinction between a claim directed to a method of blocking serotonin uptake by use of fluoxetine hydrochloride and a claim directed to a method of treating anxiety in humans with fluoxetine hydrochloride. In that case, Lilly charged Barr with infringing its U.S. Patent No. 4,626,549 by Barr's filing of an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration seeking approval to market a generic version of Lilly's profitable drug, Prozac. The '549 patent claimed a method of blocking the uptake of serotonin by brain neurons in animals by administering the compound fluoxetine hydrochloride, the active ingredient in Prozac. The district court granted Lilly's motions for summary judgment that the patents-in-suit were not invalid for double patenting.

On appeal, a Federal Circuit panel reversed the district court, specifically finding that the '549 patent was invalid.[26] Lilly petitioned for rehearing, and the Federal Circuit, acting *en banc*, vacated the panel's decision and reassigned the opinion to the panel for revision of the double-patenting section.[27] In its second opinion, the panel again held that the '549 patent claim was invalid, but this time in view of claim 1 of U.S. Patent No. 4,590,213.[28] Claim 1 of the '213 patent was directed to "[a] method for treating anxiety in a human subject in need of such treatment which comprises the administration to such human [of] an effective amount of fluoxetine or norfluoxetine or

21. *Mehl/Biophile Int'l Corp.*, 192 F.3d at 1365–66, 52 U.S.P.Q.2d at 1306.

22. *Id.* at 1366, 52 U.S.P.Q.2d at 1306.

23. *Id.* (quoting *In re* Oelrich, 666 F.2d 578, 581, 212 U.S.P.Q. (BNA) 323, 326 (C.C.P.A. 1981)).

24. *Id.* at 1366, 52 U.S.P.Q.2d at 1306–07.

25. 251 F.3d 955, 58 U.S.P.Q.2d (BNA) 1869 (Fed. Cir. 2001).

26. *Id.* at 958–59, 58 U.S.P.Q.2d at 1870.

27. *Id.* at 958, 58 U.S.P.Q.2d at 1870.

28. *Id.* at 972, 58 U.S.P.Q.2d at 1879–80.

pharmaceutically acceptable salts thereof."[29] The panel noted that the only difference between claim 1 of the '213 patent and claim 7 of the '549 patent was that the former addressed a method of treating anxiety in humans with fluoxetine hydrochloride while the latter claimed a method of using fluoxetine hydrochloride to block serotonin uptake in animals.[30]

The panel next addressed whether the difference between the claims at issue rendered the claims patentably distinct. It stated, "In this case, it is clear from all of the evidence proffered by Barr that the natural result flowing from administration of fluoxetine hydrochloride is inhibition of serotonin uptake."[31] Thus, the panel concluded that "the limitation of claim 7 of the '549 patent directed to blocking serotonin uptake by use of fluoxetine hydrochloride is *an inherent characteristic of the administration of fluoxetine hydrochloride for any purpose, including the treatment of anxiety*."[32] Accordingly, the panel found no patentable distinction between the claims of the '213 patent and the '549 patent and held claim 7 of the '549 patent invalid for double patenting.[33]

That same year, in *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*,[34] the Federal Circuit found a claim directed to a method of treating cancer comprising certain steps anticipated by a reference disclosing the same steps, but which had not observed any anticancer effects. Bristol held patents covering a three-hour administration of the antitumor drug paclitaxel. One of the patents claimed, "[a] method for treating a patient suffering from a taxol-sensitive tumor comprising (i) premedicating said patient with a medicament that reduces or eliminates hypersensitivity reactions, and

29. *Id.* at 962, 58 U.S.P.Q.2d at 1873.

30. *Id.* at 971, 58 U.S.P.Q.2d at 1879.

31. *Id.* at 970, 58 U.S.P.Q.2d at 1880.

32. *Id.* (emphasis added).

33. *Id.* at 972, 58 U.S.P.Q.2d at 1880. Lilly again petitioned for rehearing, and this time the Federal Circuit acting *en banc* declined to rehear the case. Judge Newman, dissenting from the refusal to reconsider, decried the panel's decision as reaching the anomalous conclusion that the earlier filed '549 patent was invalid for double-patenting over the '213 patent that was filed nine years later. She also criticized the panel's holding that "'the natural result of fluoxetine hydrochloride is the inhibition of serotonin uptake,' and . . . that a discovery of a new and unobvious biological property is unpatentable because it is inherent in the chemical compound." *Id.* at 976. Noting that every biological property is a natural and inherent result of the chemical structure from which it arises, Judge Newman added, "To negate the patentability of a discovery of biological activity because it is 'the natural result' of the chemical compound can have powerful consequences for the patentability of biological inventions." *Id.*

34. 246 F.3d 1368, 58 U.S.P.Q.2d (BNA) 1508 (Fed. Cir. 2001).

(ii) parenterally administering to said patient about 135–175 mg/m^2 taxol over about three hours."[35]

Ben Venue filed an ANDA, seeking approval to market paclitaxel prior to the expiration of the two patents, and Bristol sued. Following a claim construction hearing, the district court found the claims anticipated over an article by Kris in which Kris treated patients with three-hour infusions of paclitaxel within the claimed dosage ranges, but observed no antitumor response. The district court held that the claims were inherently anticipated "because reducing toxicity and tumor regression were necessary consequences of practicing the method steps of Kris."[36]

On appeal, the Federal Circuit affirmed the district court. Addressing Bristol's argument that new uses of old processes are patentable, the court noted that "the claimed process here is not directed to a new use; *it is the same use, and it consists of the same steps as described by Kris*."[37] The court concluded, "[a]lthough Kris did not observe any anticancer effects . . . the claims only require the administration of specific amounts of paclitaxel and not the achievement of a particular result."[38] Finding that Kris had administered three-hour infusions of 135 mg/m^2 paclitaxel to three patients and 160 mg/m^2 to four patients, the court concluded that "Kris therefore performed all of the claimed steps at dosage levels that anticipate those in the claims."[39]

In *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*,[40] the Federal Circuit cited *Bristol-Myers* for the proposition that steps of a claimed method are performed the same way regardless of whether, as stated in the preamble, a reduction in hematologic toxicity occurs. In *Catalina*, the court held that phrases in apparatus claims stating a different intended result are not limiting and, therefore do not distinguish the prior art. Although this holding was limited to apparatus claims, the court noted in dictum that the principle applies equally well to method claims reciting the same steps of an old method for a different purpose.[41] The court proposed the following hypothetical:

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35. *Id.* at 1371, 58 U.S.P.Q.2d at 1510.

36. *Id.* at 1373, 58 U.S.P.Q.2d at 1511–12.

37. *Id.* at 1376, 58 U.S.P.Q.2d at 1514 (citing *In re* May, 574 F.2d 1082, 1090, 197 U.S.P.Q. (BNA) 601, 607 (C.C.P.A. 1978)) (emphasis added).

38. *Id.* at 1378, 58 U.S.P.Q.2d at 1515.

39. *Id.*

40. 289 F.3d 801, 809, 62 U.S.P.Q.2d (BNA) 1781, 1785 (Fed. Cir. 2002).

41. *Id.* at 810, 62 U.S.P.Q.2d at 1786.

> Inventor A invents a shoe polish for shining shoes (which, for the sake of example, is novel, useful, and nonobvious). Inventor A receives a patent having composition claims for shoe polish. Indeed, the preamble of these hypothetical claims recites "a composition for polishing shoes".... Suppose Inventor B discovers that the polish also repels water when rubbed onto shoes. *Inventor B could not likely claim a method of using the polish to repel water on shoes because repelling water is inherent in the normal use of the polish to shine shoes.*... In other words, Inventor B has not invented a "new" use by rubbing polish on shoes to repel water. Upon discovering, however, that the polish composition grows hair when rubbed on bare human skin, Inventor B can likely obtain method claims directed to the new use of the composition to grow hair.[42]

A few months after *Catalina*, the Federal Circuit in *In re Cruciferous Sprout Litigation*[43] found claims directed to methods of preparing sprouts with certain properties anticipated by the sprouts themselves. One patent claimed a method of preparing a food product with many sprouts and rich in glucosinolates by harvesting the sprouts prior to the two-leaf stage. Another patent claimed a method of increasing the chemoprotective amount of Phase 2 enzymes in a mammal by creating a food product from sprouts and administering it to the mammal. The patent holders sued several broccoli farmers for infringement. The district court found that the claim was anticipated by prior art references disclosing growing and eating sprouts. The district court concluded, "a plant (broccoli sprouts), long well known in nature and cultivated and eaten by humans for decades, [cannot] be patented merely on the basis of a recent realization that the plant has always had some heretofore unknown but naturally occurring beneficial feature."[44]

The Federal Circuit affirmed. The court began by noting that the plaintiffs did "not claim to have invented a new kind of sprout, or a new way of growing or harvesting sprouts," but rather had simply recognized that some sprouts are high in glucosinolates and high in Phase 2 enzyme-inducing activity while others are not.[45] The court pointed out, however, that the glucosinolates content and Phase 2 enzyme-inducing potential of sprouts "*necessarily have existed as long as the sprouts themselves*," and are inherent characteristics of the

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42. *Id.* at 809–10, 62 U.S.P.Q.2d at 1786 (emphasis added).
43. 301 F.3d 1343, 64 U.S.P.Q.2d (BNA) 1202 (Fed. Cir. 2002).
44. *Id.* at 1346, 64 U.S.P.Q.2d at 1204 (internal quotations omitted).
45. *Id.* at 1350, 64 U.S.P.Q.2d at 1207.

sprout.[46] The court also found it significant that numerous prior art references identified those same sprouts as suitable for eating.[47] The court emphasized that it was "unnecessary for purposes of anticipation for the persons sprouting these particular cultivars to have realized that they were sprouting something rich in glucosinolates and high in Phase 2 enzyme-inducing potential."[48] The court concluded that "Brassica has done nothing more than recognize properties inherent in certain prior art sprouts. . . . While Brassica *may have recognized something quite interesting, . . . it simply has not invented anything new.*"[49]

C. *Other Notable Cases*

In *Ex parte Novitski*,[50] claims were directed to "[a] method for protecting a plant from plant pathogenic nematodes which comprises

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46. *Id.* (emphasis added). Furthermore, it was of no consequence that those of ordinary skill heretofore had not recognized the claimed inherent characteristics of the sprouts. The court cited an early Federal Circuit case which it found "particularly instructive in this regard." *Id.* In *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 U.S.P.Q. (BNA) 773 (Fed. Cir. 1985), the claim at issue was directed to a titanium base alloy characterized by good corrosion resistance in hot brine environments. The prior art disclosed a titanium base alloy having the recited components of the claim, but did not disclose that such an alloy was "characterized by good corrosion resistance in hot brine environments." *Id.* at 782, 227 U.S.P.Q. at 777–78. The Federal Circuit nevertheless held that the claim was anticipated because it was immaterial what inherent properties of the alloys the applicants discovered. *In re* Cruciferous, 301 F.3d at 1350, 164 U.S.P.Q.2d at 1207 (citing *Titanium Metals Corp.*, 778 F.2d at 782, 227 U.S.P.Q. at 777–78). The *Titanium* court noted, "Congress has not seen fit to permit the patenting of an old alloy, known to others through a printed publication, by one who has discovered its corrosion resistance or other useful properties." *Titanium Metals Corp.*, 778 F.2d at 782, 227 U.S.P.Q. at 777–78.

47. *In re Cruciferous*, 301 F.3d at 1351, 64 U.S.P.Q.2d at 1208.

48. *Id.* In the recent case of *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 67 U.S.P.Q.2d 1664 (Fed. Cir. 2003), the Federal Circuit ruled that recognition by a person of ordinary skill in the art is not required to show anticipation by inherency. The patent at issue, U.S. Patent No. 4,659,716, covered a metabolite of the antihistamine loratadine called desloratadine ("DCL"). DCL is a non-drowsy antihistamine that forms in the patient's body upon ingestion of loratadine. A prior art patent, U.S. Patent No. 4,282,233, also issued to Schering, disclosed loratadine. The district court found that the '233 patent inherently anticipated the compound claims of the '716 patent because people who ingested loratadine necessarily produced DCL, and therefore DCL was not a new result or product. Even though the '233 patent did not expressly disclose DCL, the district court found that DCL was formed as a metabolite by carrying out the process disclosed in the '233 patent. On appeal, the Federal Circuit affirmed. After finding that the metabolite was formed under normal conditions in readily detectable quantities, the court applied the longstanding patent principle that if something would be an infringement after grant, it is an anticipation if it occurs before grant and held that the prior production of the metabolite in patients taking loratadine was an anticipation of the claim to the metabolite. *Id.*

49. *In re Cruciferous*, 301 F.3d at 1350–51, 64 U.S.P.Q.2d at 1208 (emphasis added).

50. 26 U.S.P.Q.2d (BNA) 1389, 1390 (Bd. Pat. App. & Interf. 1993).

the step of inoculating said plant with a nematode-inhibiting strain of [*Pseudomonas*] *cepacia* which strain colonizes said plant." The examiner rejected the claim as obvious in view of three references. On appeal, the Board refused to sustain the obviousness rejection, instead rejecting the claims on the alternative ground that they were anticipated by one of the cited references, an issued U.S. patent to Dart.[51] Dart disclosed a method for protecting plants from fungal disease by inoculating the plant with *P. cepacia* type Wisconsin 526 bacteria. Dart, however, did not expressly disclose that *P. cepacia* type Wisconsin 526 bacteria possesses nematode-inhibiting activity, nor did it expressly disclose a method for protecting a plant from plant pathogenic nematodes. Nevertheless, the Board concluded that nematode inhibition was an inherent property of the bacteria and that "Dart's step of inoculating with *Pseudomonas cepacia* type Wisconsin 526 inherently and necessarily constitutes a method for protecting a plant from plant pathogenic nematodes."[52] The Board continued:

> [W]e find the conclusion inescapable that *Pseudomonas cepacia* type Wisconsin 526 may be accurately classified and described as "nematode-inhibiting". *A fortiori*, we find the conclusion inescapable that Dart's method of inoculating a plant with *Pseudomonas cepacia* type Wisconsin 526 constitutes a method of inoculating with a nematode-inhibiting strain of *Pseudomonas cepacia* as recited in independent claim 1 on appeal. Therefore, we find that Dart's method constitutes a method for protecting a plant from plant pathogenic nematodes as recited in claim 1 on appeal. We fully 'appreciate that Dart does not disclose appellants' claimed method *in haec verba*. Nevertheless, Dart's disclosure fully meets the terms of the claimed method because *Pseudomonas cepacia* type Wisconsin 526 inherently possesses nematode-inhibiting activity.[53]

In *Integra Life Sciences I, Ltd. v. Merck KgaA*,[54] claims were directed to a method of inhibiting animal cell proliferation comprising contacting the cell with certain RGD peptides. A prior art reference disclosed using the same peptides to interfere with the attachment of rat kidney cells to certain substrates. Finding the claims anticipated

51. *Id.*
52. *Id.*
53. *Id.* at 1391.
54. 50 U.S.P.Q.2d (BNA) 1846 (S.D. Cal. 1999).

by the prior art reference,[55] the district court noted that the experiments conducted by plaintiffs which led to the application for the '621 patent seemed to only have inquired into the results of using the RGD peptides, but failed to alter the general method of using the peptides as disclosed in the *Nature* article.[56]

The court observed that the entire basis of the '621 patent appears to have been founded only upon "plaintiffs' *extended* laboratory observations of the *exact same* Arg-Gly-Asp chemical reactions on a variety of cells and substances."[57] The court held:

> Regardless of the duration of plaintiffs' subsequent experiments, the court finds that the manipulative steps described in the '621 Patent are substantially similar, if not identical to, the steps disclosed in the *Nature* article such that plaintiffs subsequent "discovery" that the *same peptides* specifically *inhibited* animal *cell proliferation* was already inherent in the *Nature* paper and the *Nature* paper thus anticipates the '621 Patent.[58]

In finding the claim anticipated, the court cited to the Board's holding in *Novitski*, noting that in that case, "the Board determined that the *result* of the method Novitski sought to patent (namatode [*sic*] inhibition) was already inherent in the steps described in a previous patent granted to Dart."[59] The court noted that in *Novitski*, had Dart taken the manipulative steps described in his patent (inoculating plants with a particular bacteria), and then attempted to measure for the results described by Novitski (nematode inhibition), he would have uncovered it.[60] "Similarly here, if the authors of the *Nature* publication had taken the additional steps necessary to measure and locate the effects of certain RGD peptides on cell proliferation in a variety of cellular contexts, they would have uncovered it."[61]

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55. The relevant portion of *Integra Life Sciences* was affirmed by the Federal Circuit on appeal. *See* Integra Life Sciences I, Ltd. v. Merck KgaA, 331 F.3d 860, 66 U.S.P.Q.2d (BNA) 1865 (2003) (*cert.* filed March 2004).

56. *Integra Life Sciences*, 50 U.S.P.Q.2d at 1850 (emphasis added).

57. *Id* (emphasis added).

58. *Id.* at 1851 (emphasis added).

59. *Id.* at 1851 (emphasis added).

60. *Id.*

61. *Id.*

II. INTENT IS NOT AN ELEMENT OF INFRINGEMENT

In *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*,[62] the Federal Circuit, acting *en banc*, held that for purposes of infringement it is irrelevant whether an alleged infringer intends to infringe a claimed method or not. In that case, the PTO had rejected Hilton Davis' claim to a process for purifying commercial dyes over a prior art reference which disclosed a similar process at pH level above nine. In response, Hilton Davis amended the claims to include a pH range of six to nine, and the PTO granted the patent. Hilton Davis then sued Warner-Jenkinson, which employed a similar process at pH levels below six, asserting that under the doctrine of equivalents, the claim should be read broadly enough to encompass operation below the claimed pH limit. Indeed, while the upper value of the claimed range, pH of nine, was clearly needed to distinguish the prior art, there appeared to be no reason from the record for limiting the lower value of the range to a pH of six. The district court agreed with Hilton Davis and found that Warner-Jenkinson infringed the patent.[63]

The Federal Circuit affirmed, holding that the claims were infringed under the doctrine of equivalents.[64] Relying on earlier precedent, the court held:

> *Intent is not an element of infringement.* . . . This question [of infringement] is one *irrespective of motive. The defendant may have infringed without intending*, or even knowing it; but he is not, on that account, the less an infringer. His motives and knowledge may affect the question of damages, to swell or reduce them; but the immediate question is the simple one, has he infringed?[65]

In particular, the court cited to *Intel Corp. v. United States International Trade Commission*, which just a few years earlier had held that "there is no intent element to *direct* infringement."[66]

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62. 62 F.3d 1512, 35 U.S.P.Q.2d (BNA) 1641 (Fed. Cir. 1995), *rev'd on other grounds*, 520 U.S. 17, 41 U.S.P.Q.2d (BNA) 1865 (1997).

63. *Id.* at 1516, 35 U.S.P.Q.2d at 1643.

64. *Id.* at 1525, 35 U.S.P.Q.2d at 1646. The doctrine of equivalents is an equitable doctrine in patent law designed to prevent infringers from escaping liability simply by making insubstantial changes. The Supreme Court has expressed the doctrine this way: "If two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form, or shape." Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950) (citation omitted).

65. *Hilton Davis*, 62 F.3d at 1519, 35 U.S.P.Q.2d at 1646 (emphasis added) (quoting Parker v. Hulme, 18 F. Cas. 1138, 1143 (C.C.E.D. Pa. 1849) (No. 10,740).

66. 946 F.2d 821, 832, 20 U.S.P.Q. (BNA) 1161, 1171 (Fed. Cir. 2000) (emphasis in original).

On appeal to the Supreme Court, *Warner-Jenkinson* was reversed on other grounds.[67] Nevertheless, the Supreme Court upheld the Federal Circuit's determination that intent plays no role in an infringement analysis, holding "[a]pplication of the doctrine of equivalents, therefore, is akin to determining literal infringement, and *neither requires proof of intent*."[68] Indeed, just two years later, in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*,[69] the Supreme Court reaffirmed this basic principle: "Actions predicated on direct patent infringement, however, *do not require any showing of intent to infringe*; instead, knowledge and intent are considered only with respect to damages."[70]

The Federal Circuit recently reiterated the holdings in *Warner-Jenkinson* and *Florida Prepaid*. In *Dow Chemical Co. v. Mee Industries, Inc.*,[71] the court held that the motive of an accused infringer is irrelevant to the determination of infringement. In *Dow*, the patentee claimed a method for augmenting the net output of a gas turbine comprising a number of steps including adding increasing amounts of water to the compressor. The purpose of this method, as set forth in the body of the claim, was "to avoid destructive thermal stresses within the gas turbine which are related to the providing of increased amounts of liquid water to the working fluid."[72] The alleged infringer carried out the same steps, but did not do so for the claimed purpose of avoiding thermal stresses. The Federal Circuit noted that the issue was not whether the accused intended to avoid thermal stresses in employing the claimed method, but rather whether he did avoid such stresses.[73] Citing to *Warner-Jenkinson*, the court held that even if the accused carried out the process "for an entirely different reason, that would not avoid infringement, as the motive of the accused infringer when performing a claimed method is *simply not relevant*."[74]

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67. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 41 U.S.P.Q.2d (BNA) 1865 (1997).

68. *Id.* at 35, 41 U.S.P.Q.2d at 1873 (emphasis added).

69. 527 U.S. 627, 51 U.S.P.Q.2d (BNA) 1081 (1999).

70. *Id.* at 645, 51 U.S.P.Q.2d at 1089 (emphasis added); *see also* 5 DONALD S. CHISUM, PATENTS § 16.02[2], p. 16–31 (rev. ed. 1998). Professor Chisum noted, "It is, of course, elementary, that an infringement may be entirely inadvertent and unintentional and without knowledge of the patent." *Id.* (citation omitted).

71. 341 F.3d 1370, 1379, 68 U.S.P.Q.2d (BNA) 1176 (Fed. Cir. 2003).

72. *Id.* at 1375, 68 U.S.P.Q.2d at 1180.

73. *Id.* at 1380, 68 U.S.P.Q.2d at 1184.

74. *Id.* (emphasis added).

III. THESE TWO PRINCIPLES ARE TWO SIDES OF THE SAME COIN

The principle espoused in *Warner-Jenkinson*, *Florida Prepaid* and *Dow*, that the motive of an accused infringer when performing a claimed method is irrelevant, is wholly consistent with the principle discussed in section I, that a claim directed to a method of using an old composition to achieve a result or property inherent in that composition is unpatentable. Indeed, as we shall see, these two principles are really one and the same.

Let us return to the hypothetical described in the Introduction. The claim at issue is directed to a method of using a known composition (compound X). The method recites the exact same steps as a prior art method of using compound X to treat arthritis, but the preamble states that it is a "method of treating near-sightedness." This claim may be viewed in one of two ways. It may be viewed as anticipated under the general rule that a claimed use of an old composition to achieve a result or property inherently possessed by that compound is unpatentable. This is similar to the conclusion reached by numerous courts, *e.g.*, *Cruciferous*, *Eli Lilly*, *Bristol-Myers Squibb*, *May*, *Tomlinson*, and *Novitski*. In this regard, Inventor 2 has indeed discovered a heretofore unrecognized and interesting property of compound X (effectiveness at treating near-sightedness). Nevertheless, this property, while *newly discovered* by Inventor 2, is not a *new property* of the compound.

Alternatively, the hypothetical claim may be viewed as anticipated under the *Warner-Jenkinson* rule. Recall that *Warner-Jenkinson* prohibits taking intent into account when determining whether a claim has been infringed. Since infringement and anticipation analyses are the same,[75] the rule of disregarding intent when determining whether a claim is infringed should apply with equal force when determining whether a claim is anticipated. Accordingly, merely stating a different objective or purpose (treating near-sightedness) should not render the hypothetical claim patentably distinct over the prior art method, which uses the *same composition* in the *same way* but for a *different purpose* (treating arthritis).[76] Thus,

75. *See, e.g.*, Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 67 U.S.P.Q.2d (BNA) 1664 (Fed. Cir. 2003) ("[T]hat which would literally infringe if later in time anticipates if earlier." (citations omitted)); *see also* Peters v. Active Mfg. Co., 129 U.S. 530, 537 (1889).

76. After all, if merely stating a different objective were all that was required for patentability, every known method using a composition for a previously unclaimed purpose would potentially be patentable.

the claimed method would be anticipated by the prior art method, which performs all of the same steps.

It is important to bear in mind that, prior to Inventor 2's discovery that compound X treats near-sightedness, near-sighted individuals taking compound X to treat their arthritis were necessarily also treating their nearsightedness, regardless of whether they *intended* to do so or not. Thus, if Inventor 2 were issued a claim covering the use of compound X to treat near-sightedness, it would effectively remove from the public domain that which had already existed. Moreover, the granting of such a claim has anomalous consequences. For instance, an arthritic patient taking compound X intending to treat his arthritis would not be an infringer, but an arthritic patient taking compound X intending to treat his near-sightedness (or both his arthritis and his near-sightedness) would be an infringer. In this scenario, the issue of infringement would turn on what each patient was *intending* or *thinking* at the moment they took compound X.

It is readily apparent that the two views of the hypothetical method are two sides of the same coin. Consistent with *Warner-Jenkinson*'s rule against taking intent into consideration when interpreting claims is the rule that, to patent a method of using compound X to treat near-sightedness, Inventor 2 would have to recite a *new or different use* of compound X. Merely stating a different purpose (i.e., to treat near-sightedness) is really no different than reciting a previously unrecognized result (i.e., treatment of near-sightedness), and neither is enough for patentability. Rather, Inventor 2 must insert a limitation in the claim which requires some *manipulative* step be performed which was not disclosed in the prior art.[77] For instance, Inventor 2 could patent a "method of treating near-sightedness, comprising rinsing the eyes of a near-sighted patient with a solution comprising 100 mg of compound X." In this case, the use of compound X is not anticipated by Inventor 1's patent—or, alternatively stated, does not infringe Inventor 1's patent—because it recites a limitation (applying a 100 mg solution to the eyes of a near-sighted patient) not disclosed expressly *or inherently* by Inventor 1.

77. *See, e.g.*, Integra Life Sciences I, Ltd. v. Merck KgaA, 50 U.S.P.Q.2d (BNA) 1846, 1850–51 (S.D. Cal. 1999) ("Regardless of the duration of plaintiffs' subsequent experiments, the court finds that *the manipulative steps* described in the '621 Patent are substantially similar, if not identical to, the steps disclosed in the *Nature* article such that plaintiffs' subsequent "discovery" that the *same peptides* specifically *inhibited* animal *cell proliferation* was already inherent in the *Nature* paper and the *Nature* paper thus anticipates the '621 Patent." (emphasis added)).

The next section analyzes a recent Federal Circuit case which held that an alleged infringer's intent is determinative on the issue of patentability of a claimed method of using a known composition. The section points out the flaws in the court's analysis, and how the decision contradicts Federal Circuit precedent discussed above. In particular, the section highlights the anomalous consequences that result from taking intent into account when determining whether an alleged infringer has infringed a method of use claim.

IV. *JANSEN V. REXALL SUNDOWN*

A. Facts of the Case

In *Jansen v. Rexall Sundown, Inc.*,[78] Jansen was the sole inventor and owner of U.S. Patent No. 4,945,083, directed to methods of "'treating or preventing macrocytic-megaloblastic anemia' [MMA] by administering a combination of folic acid and vitamin B_{12} 'to a human in need thereof.'"[79] According to the patent, deficiencies of either folic acid or vitamin B_{12} can cause MMA, and an objective of Jansen's invention was to administer both supplements together to avoid the masking problem.[80] During prosecution of the patent, Jansen was forced to limit his claims to a specific type of anemia, MMA, rather than anemia in general, and had to add to the claim the phrase "to a human in need thereof."[81]

Rexall marketed a non-prescription dietary supplement that contained folic acid and vitamin B_{12} within the claimed ranges, but which was labeled and advertised "for maintenance of proper blood homocysteine levels," but not for prevention or treatment of MMA.[82] Arguing that all people are "humans in need of treatment or prevention of MMA," Jansen sued Rexall for indirect infringement based on alleged direct infringement by Rexall's customers.[83] The district court rejected Jansen's argument, and construed the phrase "treating or preventing [MMA]" to require that the human subject of the claimed method take the compound with *the intent of treating or preventing MMA*.[84] The district court found no evidence of such

78. 342 F.3d 1329, 1330, 68 U.S.P.Q.2d (BNA) 1154, 1155 (Fed. Cir. 2003).
79. *Id.* at 1330, 68 U.S.P.Q.2d at 1155.
80. *Id.*
81. *Id.* at 1331, 68 U.S.P.Q.2d at 1156.
82. *Id.*
83. *Id.*
84. *Id.* (emphasis added).

intent or purpose on the part of Rexall's customers, and granted summary judgment to Rexall.

On appeal, Jansen argued that the district court improperly added to the claims an intent element, which is contrary to the law, the ordinary meaning of the claims, and the prosecution history of the patent.[85] Jansen also argued that the phrase "a human in need thereof" encompasses a person who does not know his or her serum levels of folic acid and vitamin B_{12} are adequate.[86] Rexall responded that, to the extent the district court's claim construction added an intent element to the claims, it was required to do so by the particular language of the claims themselves.[87] Rexall also argued that the claims should be interpreted to require that the target group (humans in need thereof) practice the method for the stated purpose (treating or preventing MMA), especially since the both limitations were added for patentability.[88] According to Rexall, a "human in need thereof" is someone either suffering from MMA or at a recognized risk, such as by medical diagnosis, of developing that condition.[89]

B. Federal Circuit Opinion

The court began its claim construction analysis by citing to an earlier case, *Rapoport v. Dement*,[90] which involved an interference count reciting a "method for treatment of sleep apneas comprising administration of a therapeutically effective [amount of buspirone] to a patient in need of such treatment."[91] Rapoport had argued that, as to Dement, the count was anticipated by a reference Rapoport had authored, directed to treating anxiety in patients suffering from sleep apnea with 10 mg of buspirone three times a day. The Federal Circuit upheld the Board's granting of priority to Dement. The court interpreted the count's preamble, "A method for treatment of sleep apneas," as limited to treating the underlying sleep apnea disorder, and not to symptoms of that disorder such as anxiety.[92] The court stated, "There is no disclosure in the [reference] of tests in which

85. *Id.* at 1332, 68 U.S.P.Q.2d at 1157.
86. *Id.*
87. *Id.*
88. *Id.*
89. *Id.*
90. 254 F.3d 1053, 59 U.S.P.Q.2d (BNA) 1215 (Fed. Cir. 2001).
91. *Id.* at 1055, 59 U.S.P.Q.2d at 1217.
92. *Id.* at 1060, 59 U.S.P.Q.2d at 1220.

buspirone is administered to patients suffering from sleep apnea *with the intent to cure the underlying condition.*"[93]

Citing *Rapoport*, the court in *Jansen* noted that the claim preamble sets forth the objective of the method, and the claim's recitation of a human "in need" gives life and meaning to the preamble's statement of purpose.[94] "The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a *statement of the intentional purpose for which the method must be performed.*"[95] The court continued:

> Finally, that "need" must be recognized and appreciated, for otherwise the added phrases do not carry the meaning that the circumstances of their addition suggest that they carry. In other words, administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megaloblastic anemia is not practicing the claimed method, because Jansen limited his claims to treatment or prevention of that particular condition in those who need such treatment or prevention. Thus, the '083 patent claims are properly interpreted to mean that the combination of folic acid and vitamin B_{12} must be administered to *a human with a recognized need* to treat or prevent macrocytic-megaloblastic anemia.[96]

The court demurred deciding whether it would reach the same conclusion if either of the "treating or preventing" phrase or the "to a human in need thereof" phrase was not a part of the claim.[97] The court also noted that its claim construction was supported by the prosecution history, which revealed that both phrases were added to the claim in order to gain allowance.[98]

Despite the court's favorable claim construction, it nevertheless held that Jansen's evidence of direct infringement was too speculative to support an indirect infringement claim against Rexall since Rexall's customers were not shown to have taken the product "*knowingly* to treat or prevent" the anemia in question.[99] The court

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93. *Id.* at 1061, 59 U.S.P.Q.2d at 1221 (emphasis added). The court observed, for example, that the reference mentioned the possibility of administering buspirone to patents suffering from sleep apnea only "for the purpose of treating anxiety in such patients, not for the purpose of treating the sleep apnea disorder itself." *Id.*

94. *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1158.

95. *Id.* (emphasis added).

96. *Id.* at 1334, 68 U.S.P.Q.2d at 1158 (emphasis added).

97. *Id.*

98. *Id.*

99. *Id.*, 68 U.S.P.Q.2d at 1158–59 (emphasis added).

concluded, "[u]se of an over-the-counter product like Rexall's is quite different from the use of a product pursuant to a prescription from a medical doctor. In the latter case, a prescription is evidence of a diagnosis and a *knowing need to use the product for the stated purpose.*"[100]

C. *Flaws in Jansen's Analysis*

In *Jansen*, the Federal Circuit departed from the general rule that a claim directed to using an old composition to achieve a result or property inherent in that composition is unpatentable. The court distinguished a claimed method of using a composition over an allegedly infringing use by lending patentable weight to the stated *objective* of the claimed method in order to distinguish the claim from the allegedly infringing use. The court's strained claim construction and subsequent analysis are flawed for several reasons.

1. Court Disregarded Precedent That Intent Is Irrelevant

Jansen stands for the proposition that, where a claimed method states a specific objective (e.g., treating or preventing a disease with compound X), *intending to meet that objective* (e.g., taking compound X intending to treat or prevent the disease) is a prerequisite to a finding of anticipation or infringement. This conclusion, purportedly adopted from *Rapoport*,[101] is directly at odds with both Federal Circuit and Supreme Court precedent discussed above, which holds that an alleged infringer's intent when performing a claimed method is irrelevant to the question of infringement.[102]

2. Court Placed Too Much Emphasis on Holding in *Rapoport*

Jansen's holding that a statement of purpose sufficiently distinguishes a claimed method over an allegedly infringing use of the same method for an unrelated purpose is without precedent. Holding that the preamble was a statement of intentional purpose for which the method must be performed, the court cited to *Rapoport*. It should be

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100. *Id.* at 1334–35, 68 U.S.P.Q.2d at 1159 (emphasis added).

101. *See* Rapoport v. Dement, 254 F.3d 1053, 1060–61, 59 U.S.P.Q.2d (BNA) 1215, 1221 (Fed. Cir. 2001). Even if *Rapoport*, properly interpreted, stands for the proposition that a prior art reference anticipates a method claim only if it is directed to the same *purpose*, that court cited *no authority* for such a proposition.

102. *See, e.g.*, Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1519, 35 U.S.P.Q.2d (BNA) 1641, 1646 (Fed. Cir. 1995), *rev'd on other grounds*, 520 U.S. 17, 41 U.S.P.Q.2d (BNA) 1865 (1997).

noted, however, that the facts of *Rapoport* were quite distinct from those of *Jansen*. In *Rapoport*, the court upheld the Board's interpretation of the preamble "treatment of sleep apneas" as limited to reducing the frequency and severity of apnea during sleep.[103] The court noted that there was nothing in the alleged anticipatory reference of administering busipirone to patients suffering from sleep apnea "with the intent to cure the underlying condition."[104]

If the *Rapoport* court had ended its anticipation analysis there, the case might have been cited for the correct proposition. However, the *Rapoport* court did not base its holding of non-anticipation solely on the fact that the count recited a different objective (treating sleep apnea) than that disclosed by the prior art reference (treating anxiety in patients with sleep apnea). Rather, the court pointed to the fact that the reference had only *proposed* treating anxiety in patients with sleep apnea, and that in fact there was nothing in the reference which suggested that busipirone had ever actually been administered to patients with sleep apnea.[105] The court added that the reference did not teach administering busipirone at bedtime, which was an implicit limitation of the count (treating *sleep* apnea), nor did it teach administering an *effective amount* of busipirone to treat sleep apnea.[106] Finally, the court emphasized that the issue of anticipation is a question of fact, and that decisions of the Board on factual matters are to be upheld if there is substantial evidence in the record to support the Board's findings.[107]

Thus, Rapoport had been able to establish only that conditions identical to those claimed were *possible* in view of the prior art. This did not give rise to the level of certainty necessary for inherency. This was very different from the facts in *Jansen*, in which it was undisputed that, although they may not have recognized it at the time, individuals had necessarily been treated for MMA with the prior art method.

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103. *Rapoport*, 254 F.3d at 1060, 59 U.S.P.Q.2d at 1220.

104. *Id.* at 1061, 59 U.S.P.Q.2d at 1221.

105. *Id* (emphasis added).

106. *Id.* at 1061–62 (emphasis added).

107. *Id.* at 1063, 59 U.S.P.Q.2d at 1222 ("Most importantly, however . . . the issue of anticipation—whether by inherency or otherwise—is a question of fact, and we uphold the decisions of the Board on factual matters if there is substantial evidence in the record to support the Board's findings.").

3. Different Panel Reached Opposite Conclusion on Analogous Facts

Another disturbing aspect of *Jansen* is that just three days earlier a different panel of the Federal Circuit in *Dow Chemical Co. v. Mee Industries, Inc.*,[108] held that the motive of an accused infringer is irrelevant. As was the case in *Jansen*, the accused in *Dow* carried out the same steps as the claimed method, but did not do so for the claimed purpose of avoiding thermal stresses. Properly citing to *Warner-Jenkinson* as controlling precedent, *Dow* held that even if the accused carried out the process "for an entirely different reason, that would not avoid infringement, as the motive of the accused infringer when performing a claimed method is *simply not relevant.*"[109]

Referring back to *Jansen*, one could state by analogy that the issue was not whether the purchaser of the vitamin formulation intended to prevent MMA, but rather whether he *did prevent* MMA by carrying out the claimed process. It is difficult to see how *Jansen* can be reconciled with *Dow* or with *Warner-Jenkinson*.

V. *JANSEN* HIGHLIGHTS THE NEXUS BETWEEN THE TWO PRINCIPLES

The discovery of a new result or property of a known composition, while not devoid of patentable protection, should only be protected through careful drafting and consideration of what did and did not previously exist, and how something that previously existed was previously used.[110] For instance, a discoverer of a previously unrecognized property in compound X could obtain protection for a method of using the compound by inserting into the claim a limitation directed to administering the compound in a manner, to a location, or in an amount previously undisclosed by the prior art. Such a claim would constitute a new "use" of compound X.

Referring back to *Jansen*, recall that the court found a claimed method of using a vitamin B_{12} preparation to treat or prevent MMA was not infringed by Rexall, which manufactured and marketed the same vitamin preparation for "maintenance of proper blood homocysteine levels."[111] According to the patent maxim that "that

108. 341 F.3d 1370, 68 U.S.P.Q.2d (BNA) 1176 (Fed. Cir. 2003).

109. *Id.* at 1380, 68 U.S.P.Q.2d at 1184 (emphasis added).

110. *See also* Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1374–78, 67 U.S.P.Q.2d (BNA) 1664, 1667–69 (Fed. Cir. 2003).

111. Jansen v. Rexall Sundown, Inc., 342 F.3d 1329, 1331, 68 U.S.P.Q.2d (BNA) 1154, 1156 (Fed. Cir. 2003).

which infringes, if later, anticipates if earlier,"[112] presumably the court's analysis would have been the same had the procedural posture been one of anticipation, rather than infringement. In other words, had Rexall attempted to patent a "method of maintaining proper blood homocysteine levels" by administering the vitamin B_{12} preparation, the court would have held such a claim patentably distinguished over Jansen's claimed method of treating MMA because the claim's recitation of maintaining proper blood homocysteine levels is "a statement of intentional purpose for which the method must be performed."[113]

The conclusion reached by *Jansen* leads to the anomalous result that an individual taking the claimed vitamin B_{12} preparation intending to maintain proper blood homocysteine levels would not be an infringer, but an individual taking the same preparation in the same way intending to treat his or her MMA would be an infringer.[114] Indeed, the court rested its decision of non-infringement on the fact that Jansen's evidence was too speculative because Rexall's customers were not shown to have taken the vitamin B_{12} preparation "*knowingly* to treat or prevent" MMA.[115] The court drew a dubious distinction between products purchased over-the-counter versus products purchased with a prescription. According to the court, an individual performing the claimed method with a product obtained pursuant to a prescription would be an infringer because the prescription is indicative of a knowing need to use the product for the claimed purpose. On the other hand, an individual performing the claimed method with a product obtained over-the-counter would not be an infringer because there is no proof of the purpose for which the individual is using the product.

Following the reasoning of *Jansen*, the issue of infringement turns on what each individual is intending or thinking the moment they used the vitamin B_{12} preparation. Thus, in order to prove infringement, Jansen would presumably have had to produce proof

112. *See* Peters v. Active Mfg. Co., 129 U.S. 530, 537 (1889); *see, e.g.*, *Schering Corp.*, 339 F.3d at 1379.

113. *See Jansen*, 342 F.3d at 1331–33, 68 U.S.P.Q.2d at 1158.

114. *See* Robert M. Schulman, *A Review of Significant 2003 Federal Circuit Decisions Affecting Chemical, Pharmaceutical, and Biotech Inventions*, 16 No. 3 J. PROPRIETARY RTS. 1, 1 (2004) (criticizing *Jansen* for leading to a "situation where two individuals taking the same accused vitamins at the same place at the same time do not both infringe the method if one of those individuals has 'a recognized need' for treatment or prevention of MMA whereas the second is taking the vitamins for another reason.").

115. *Jansen*, 342 F.3d at 1334, 68 U.S.P.Q.2d at 1158–59 (emphasis added).

that the individual was *thinking* about treating MMA the moment he or she performed the claimed method. As discussed above, this holding squarely contradicts *Warner-Jenkinson*, which wisely avoided any inquiry into an alleged infringer's state of mind when performing a claimed method.

It should be noted that the *Jansen* panel could have reached the same outcome without running afoul of Federal Circuit precedent. Instead of construing the phrase "in need thereof" as imposing an intent requirement, the panel could have construed the phrase more broadly. For instance, every human is potentially a person "in need" of treatment or prevention of MMA. Thus, the claim could have been construed as encompassing the administration of the vitamin preparation to all individuals. The court acknowledges this: "In this case, the 'treating or preventing [MMA]' phrase and the 'to a human in need thereof' phrase were added to gain allowance of the claims after almost twenty years of repeatedly unsuccessful attempts to gain allowance of claims without those phrases."[116]

Had the panel correctly construed the claim as encompassing the administration of the vitamin preparation to all individuals (and not just those with a recognized need of treatment or prevention of MMA), it would have reached the same ultimate conclusion of non-infringement without having to contradict years of CCPA and Federal Circuit precedent. Thus, the real problem in *Jansen* was that the Patent Office ("PTO") lent patentable weight to a meaningless intent limitation to distinguish prior art. Instead of righting the PTO's wrong, the panel compounded the error by engaging in a dubious intent-driven infringement analysis to distinguish the *intended* use of the claimed method from the alleged infringing use.

Indeed, applying the rationale discussed above, to have obtained a patentable method of use in view of the prior art, Jansen should have been required to add a limitation to the claim which required some *additional manipulative step*. For instance, Jansen could have patented a method of treating MMA comprising administering the vitamin B_{12} preparation at a different concentration or via a different delivery route (e.g., intravenously or topically) than that disclosed by the prior art. This claim would have distinguished the prior art and would ostensibly have covered any individual using the vitamin B_{12} preparation in the claimed manner, *regardless of the individual's intent* when using it. Such a result is consistent with the patent principles discussed herein and provides the appropriate level of

116. *Id.* at 1333, 68 U.S.P.Q.2d at 1158.

patent protection commensurate in scope with the patentee's invention.

CONCLUSION

Language in a method of use claim that simply recites a result or property of a known composition ought not distinguish that claim from a prior art reference disclosing the very same use of that composition with a different result. The claim should be viewed as inherently anticipated by the reference, notwithstanding that the reference did not recognize all the imaginable results of using the composition. Similarly, the claim should not be construed as requiring the user to intend to achieve the previously unrecognized result in order to distinguish the claim over the art or an allegedly infringing use. Such strained claim construction invariably runs afoul of the general prohibition against taking into account the motive of an accused infringer (or alleged anticipatory reference) when performing a claimed method. To the extent that *Jansen v. Rexall Sundown* is contrary to the general principles discussed in this Article, the Federal Circuit ought to distinguish and/or overrule it.