APPELLEE'S BRIEF

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CORRECTED BRIEF FOR PLAINTIFF-APPELLEE, HILTON DAVIS CHEMICAL CO.

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

93-1088

HILTON DAVIS CHEMICAL CO.,
Plaintiff-Appellee,

v.

WARNER-JENKINSON COMPANY, INC.,
Defendant-Appellant.

Appeal from a Decision of the United States District Court
for the Southern District of Ohio, Western Division
Civil Action No. C-1-91-218
Honorable Herman J. Weber, District Judge

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CERTIFICATE OF INTEREST

In compliance with Federal Circuit Rule 47.4, counsel for appellee, Hilton Davis Chemical Co., hereby certifies as to the following:

1. The full name of each party represented by me is:

Hilton Davis Chemical Co.

2. The name of the real party in interest represented by me is:

Hilton Davis Chemical Co.

3. Hilton Davis Chemical Co. is a wholly owned subsidiary of PMC, Inc. Hilton Davis Chemical Co. has no subsidiaries or affiliates that have issued shares to the public.

4. The names of all law firms whose partners or associates that appeared in the Court below or are expected to appear in this Court are:

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Only David E. Schmit is expected to appear in this Court.

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STATEMENT OF RELATED CASES

In compliance with Federal Circuit Rule 47.5, Appellee states that it knows of no other appeal in or from the same civil action which was previously before this or any other appellate court. Appellee is similarly unaware of any case pending in this or any other court which will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF JURISDICTION

To clarify Appellant's Statement of Jurisdiction, only a post-trial motion to alter or amend the judgment under Fed. R. Civ. P. 59(e) was filed. No motion for a new trial under Rule 59 was filed by Appellant.

STATEMENT CONCERNING ATTORNEY FEES

In compliance with Federal Circuit Rule 47.7, Appellee does not make any claim for attorney fees in this Brief.

STATEMENT OF THE CASE

I. Statement of Facts

A. The Nature of the Case

This action involves a patent owned by Hilton Davis. The patent covers an innovative complex chemical process for producing two specific red and yellow food dyes: FD&C Red 40 and FD&C Yellow 6. The patented process was the first to successfully purify these food dyes to the extremely high purity required for human consumption by the FDA without the use of a very costly and environmentally undesirable step known as "salting out."

By a series of acquisitions, Warner-Jenkinson became the only U.S. company besides Hilton Davis making these food dyes. Warner-Jenkinson began infringing in 1985 when it converted its old "salting out" process to the patented process. Because Warner-Jenkinson kept its process secret, Hilton Davis did not learn of it until 1990. When Warner-Jenkinson would not change its process to a non-infringing one, the present action was brought in the Southern District of Ohio.

B. The Proceedings in the Trial Court

Before trial, the Court denied Warner-Jenkinson's summary judgment motions of non-infringement and patent invalidity which raised substantially the same issues presented in post trial motions and to this Court. Warner-Jenkinson does not appeal from those decisions. The trial lasted nine days and involved nine expert and technical fact witnesses. The jury deliberated for several days, returning a verdict supported by nine special verdicts. A2015-19. The jury's damage award represented 20% of that requested by Hilton Davis. A38-9.

Briefing on Warner-Jenkinson's post trial motions consumed over 400 pages. The Trial Court denied those motions in a carefully reasoned oral opinion. A6-70. The Court also entered a narrowly drawn permanent injunction which permitted Warner-Jenkinson to continue practicing its process at a pressure above 500 p.s.i. and at a pH above 9.01. A4-5. Within weeks after the entry of the

injunction, Warner-Jenkinson was able to modify its process to be allegedly non-infringing. (Confidential Addendum hereto , filed under seal.)

C. A Brief History of Food Dye Purification

The processes for making the two synthetic FD&C (food, drug and cosmetic) dyes involved in the present action involves coupling a diazo with Schaeffer's salt. The resulting "coupling solution" contains various complex inorganic and organic impurities and water. To meet stringent FDA requirements, these impurities, as well as most of the water, must be removed. A108-9; 21 CFR §§ 74.340, 74.706.

Historically, Hilton Davis and Warner-Jenkinson purified the coupling solution by a "salting out" step in the manufacturing process. This laborious and expensive "salting out" process involved adding large quantities of rock salt to cause the dye to crystalize out of solution, filtering the crystalline dye in large filter presses to produce a semi-solid press cake, manually scraping the press cake from the filter, subjecting the press cake to a series of successively more dilute salt solution washes, redissolving the press cake in water, and finally evaporating the solution to produce the dry dye. A139-50; 3224; 3225. Besides being labor intensive, the "salting out" process had severe disadvantages including substantial dye loss during the filtering and washing stages, environmental disposal problems of the filtrate, and the expense of the salt. A144-8; 2171; A2172-6.

D. Hilton Davis' Development of the Patented Process

In 1982, Dr. Cook, the primary inventor of the patented process, was placed in charge of a project to reduce the cost and product loss for Hilton Davis' FD&C Red 40 manufacturing process. A130; 152. Although a number of process changes were considered, each retained the costly and inefficient "salting out" step. A152. In June 1982 Dr. Rebhahn, a co-inventor, suggested that "dialysis" might be used to remove some of the impurities from the coupling solution, thereby eliminating the "salting out" process altogether. A152; 169-70; 414. Drs. Cook and Rebhahn visualized that initial concept as

a membrane separation process to separate the dye from its impurities, permitting the process to go directly from the coupling solution to spray-drying. A152-3; 169-70; 2882; 2884-6.

Following that initial conception, Dr. Cook approached Osmonics, a filtration equipment manufacturer, and proposed a program for applying his approach to food color purification. A171-2; A2767-9. Subsequently, Hilton Davis hired Osmonics to test dye coupling solutions prepared and furnished by Hilton Davis. A1205; 1328; 1339-40; 1381-82. The purpose of that testing, as admitted by the Osmonics employee who did the testing (Gach), was to demonstrate the "technical feasibility" of the proposed process based on Hilton Davis' objectives to uncover any "disaster type of scenario" such as destruction of the membrane, enormous dye losses, economic infeasibility, passage of all impurities, etc. A181; 1270; 1515.

Dr. Cook, like other average workers in this field, wasn't sure the process would work, since the only way to determine whether an ultrafiltration process would work was to "try it." A554; 556. A major concern was whether the conceived process could remove the organic impurities, particularly Schaeffer's salt, because of the small difference in size between the organic impurity molecules and the dye molecules. A158-9; 1345; 1388; 2940-54.

The first Hilton Davis test occurred in August 1982. Hilton Davis furnished a representative sample of FD&C Red 40 coupling solution produced by its own chemical process for the test, and educated Osmonics on the chemistry of its dye under a secrecy agreement. A182; 507; 1200; 1205; 1327-8; 1340; 1382; 1481-2; 2893-916; 2940-54. The Osmonics employee (Gach) initially expressed surprise at the coupling solution, since Osmonics was unfamiliar with testing such highly concentrated materials. A188.

During the first test of the Hilton Davis process, the Osmonics employee's participation was to physically run the equipment and record some data. A511; 1235. The first test used several different membranes because of uncertainty how they would perform with the specific impurities present in the Hilton Davis solutions. A1208. It immediately became apparent that Osmonics lacked the experience to remove organic impurities or intermediates from dyes, or to purify dyes to the level of purity required by Hilton Davis to meet FDA

specifications, and the equipment necessary to evaluate whether the process actually achieved Hilton Davis' objectives. A179; 187; 189; 1330; 1338; 1342-3; 1445; 1498. Consequently, Dr. Cook analyzed the data and determined that the first test was unsuccessful in meeting Hilton Davis' objectives. A1330; 1332; 1343; 1347-8; 2895-9; 2990-4. Based on his analysis, Dr. Cook determined that the passage of Schaeffer's salt through the membranes would determine whether or not the process was viable. A1361. To test that hypothesis, Dr. Cook suggested three modifications to the test procedure: substitute a membrane with larger pores, which, while passing more dye, would hopefully facilitate purification; run the test longer to determine if Schaeffer's salt actually was being removed; and monitor the rate of Schaeffer's salt passage using special monitoring equipment developed by Dr. Cook. A1330; 1334; 1336-9; 1345; 1358; 1361-5; 1384; 1516, 2895-9; 2917-34; 2940-54. Dr. Cook recognized that the entire essence of a viable process was to obtain a proper tradeoff between dye loss and impurity removal, and he hoped that these modifications would facilitate faster impurity removal without unacceptable dye loss. A1335-7; 1359.

A second test using Dr. Cook's approach occurred in October 1992. Dr. Cook again set the objectives of this test, and analyzed the critical Schaeffer's salt passage to insure that the FDA purity goal had been reached. A1361-2; 1364-5; 1383; 1385; 1498; 2930-4; 3103-6. The Osmonics employee had *no* input on the critical dye passage or Schaeffer's salt variables. A1367. The data from this test was again analyzed by Dr. Cook who determined, *inter alia*, that the total dye loss of 1.9% was acceptable; the level of other dyes in the final product had increased, but was still acceptable as a tradeoff; Schaeffer's salt could be removed to FDA limits; the tradeoff between dye loss and Schaeffer's salt passage was acceptable; a membrane with very high dye rejection and salt passage would probably also afford satisfactory Schaeffer's salt passage; and a substantial cost savings was realized. A185; 428; 1256-7; 1342-3; 1347; 1367-73; 1375; 1385; 1498; 2841-81; 2900-16; 2935-9; 2955-61. Osmonics was not involved in *any* of these tradeoff decisions; rather, Dr. Cook alone decided the test was successful in meeting Hilton Davis' objectives. A185-6; 1364; 1370-2; 1375; 1385; 1390-3.

The first patent application was filed based upon the data, results and conclusions from Dr. Cook's testing and analysis. A1395-6; 1502-3; 2020-110; 2962-8. The application disclosed and claimed the use of a cellulose acetate membrane having a nominal pore diameter of 11 Angstroms, which was the membrane Dr. Cook decided produced the optimum results. A458; 502; 1397-8; 1468-9; 2020-110. To further improve the process, Hilton Davis purchased its own equipment and performed additional testing (without Osmonics) on a wide range of different dyes, membranes, pH ranges, pressure ranges, and coupling solutions, in order to determine the optimum conditions for the invented process. A1373-9; 1400; 1405-7; 1412-16; 1420-2; 1496; 2935-9; 2962-82; 2990-4; 3091-9; 3108-50. Dr. Cook's testing included a polyamide membrane (0 PA) (nominal pore diameter 7-10 Angstroms) which was found to be superior to other membranes, particularly for sodium sulfate passage, and a polyvinylfluoride membrane (20 VF) membrane which had better pH and thermal stability. A1412-9; 2983-94; 2990-4; 3101-2. Osmonics was involved in <u>none</u> of this testing. A1413.

One and a half years after this extensive testing began, Dr. Cook finally arrived at the conclusion that the claims of the pending application were too narrow, and should be expanded to include membranes having nominal pore diameters within the range 5-15 Angstroms, that the limitation of cellulose acetate should be eliminated, and that other membrane materials should be added to dependent claims. A408-9; 1415-6; 1426-7; 2883. That pore size range was selected based on Dr. Cook's technical judgment of membranes that he thought could perform the overall purification process. A1507; 1509. Osmonics was ***<u>not</u>*** involved in that decision. A1427.

In November 1984, the second (CIP) application incorporating this new information was filed. A1427-8; 1521; 2111-170. The final claim language incorporated the specific combination of process conditions found by Dr. Cook to meet his objectives, particularly the tradeoffs which he had discovered between dye loss and the amount of impurities passing the membrane to produce the most efficient process. A1520-1.

E. Prosecution of the Hilton Davis Patent Applications

The claims of the first patent application were initially rejected as unpatentable over the Booth patent, the examiner commenting that "[I]t would be obvious to purify azo dye stuffs by the method of the reference in the absence of any [un]obvious results." A2100. That rejection applied an improper legal standard. *American Hoist & Derrick Company v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 U.S.P.Q. 763, 771 (Fed.Cir. 1984) ("Our predecessor courts have considered and rejected the notion that a new result or function or synergism is a requirement of patentability"). Before a response was filed to that Office Action, and following Dr. Cook's extensive experimentation, the CIP application was filed. That application met the same initial rejection.

Later, in distinguishing the claims from the Booth patent, Hilton Davis noted four major differences:

(1) The enormous differences between the molecular weights of the dyes purified by Booth and those purified by the present process;

(2) The requirement in the Booth process to add salts to the retentate;

(3) The very high pH ranges deliberately sought in the Booth process, i.e., above 9.0 and preferably 11 to 13 by addition of basic materials to the retentate, in contrast to the relatively low pH's used in the present process (i.e., from around 6 to around 9). . . ;

(4) The low pressures used in the Booth process, i.e., 25-200 p.s.i.g., preferably 50-150 p.s.i.g. and more preferably 75-125 p.s.i.g., . . . in contrast with the higher pressures required by the present process (i.e., 200-400 p.s.i.g.).

A2151-6, 2164-6.

After that combination of distinguishing features was pointed out to the Examiner, the Hilton Davis patent issued.

F. Warner-Jenkinson's Infringement

In 1978, Warner-Jenkinson learned of the Dynapol process for purifying polymeric food dyes. The Dynapol process, which was not

successful, is described in the Booth patent. A257-8; 796; 805. However, Warner-Jenkinson did not use the Dynapol process, but rather investigated using ultrafiltration to pass the coupling solution through the membrane, collect the filtrate in a crystalliization (i.e., "salting out") tank, and complete the purification through standard filter and washing techniques. A293-5, 2996-7. However, that approach was never pursued.

Between 1979 and July 1982, Warner-Jenkinson did nothing toward adopting a FD&C dye purification process which eliminated "salting out." In August 1982, Warner-Jenkinson tested a dye solution at Osmonics. However, that dye solution contained alcohol. A1178. An alcohol wash is usually the last step in the salting out process to obtain a press cake. A1447; 2177 (col. 10, line 30.) Consequently, the first solution which Warner-Jenkinson tested at Osmonics was produced by redissolving a salted out press cake, rather than resulting directly from the coupling solution. Moreover, the August Warner-Jenkinson test was not successful in achieving the required purity levels. A297; 2439-56. Dr. Solter, Warner-Jenkinson's R&D manager, acknowledged that the process was absolutely worthless for making food dye if the required purity could not be reached, the process needed more R&D work, and that even the membrane used was a "toss-up" whether it was good enough for his objectives. A1143-4; 1268. Consequently, the Warner-Jenkinson process was neither reduced to practice nor suitable for its intended purpose since it could not produce a sufficiently pure dye.

Following the unsuccessful 1982 test, Warner-Jenkinson abandoned the process for purifying the dyes covered by the Hilton Davis patent, and concentrated on other (less commercially valuable) dyes, particularly Blue 1 and Green 3, which are not covered by the Hilton Davis patent. A1026-7; 1044; 1146.

During the period February 1983 through January 1986, no work was done on the Warner-Jenkinson process for purifying the dyes covered by the Hilton Davis Patent. A1144-5; 3243-6. Even Osmonics was puzzled why the Warner-Jenkinson process was unsuccessful. A3085. In fact, there was evidence to show that Osmonics was using information obtained from Hilton-Davis to assist Warner-Jenkinson with development of its process, in violation of a

confidentiality agreement. A3074-85. Finally, in 1986, long after Hilton Davis had successfully reduced its process to practice and the patent had issued, Warner-Jenkinson was finally able to produce commercially acceptable FD&C Red 40 and FD&C Yellow 6 dyes using a process which eliminated the "salting out" step.

SUMMARY OF THE ARGUMENT

II. Substantial Evidence Supports The Infringement Verdict

A. Infringement under the doctrine of equivalents is a question of fact for the jury. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 626, 225 U.S.P.Q. 634, 642 (Fed Cir. 1985) While the doctrine is designed to "do equity", the "equity" involved is whether the change from the literal claim language is so insubstantial as to amount to a "fraud on the patent". *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 932 F.2d 1453, 1457, 18 U.S.P.Q. 2d 1842, 1846 (Fed. Cir. 1991). Whether a change is "insubstantial" is determined by the familiar triparte test: does the accused process perform "substantially the same function in substantially the same way to produce substantially the same result". *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608, 85 U.S.P.Q. 328, 330 (1950). In the present case, substantial evidence supports the jury's infringement verdict, and by implication, its finding of equivalency. *Sun Studs, Inc. v. ATA Equipment Leasing, Inc.*, 872 F.2d 978, 987, 10 U.S.P.Q. 2d 1338, 1346 (Fed Cir. 1989).

B. There is no case law or statutory support for Warner-Jenkinson's argument that a patent owner must prove "equities" to support infringement by equivalents. Even so, there is substantial evidence of "equities" in favor of Hilton Davis. Nor is evidence necessary of piracy, stealing, fraud or copying, or that the defendant designed around , or was even aware of, the patent. There is no intent element to infringement. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 478, 181 U.S.P.Q. 673, 677, 40 L. Ed. 2d 315, 94 S. Ct. 1879 (1974); *Intel Corp. v. U.S. International Trade Comm'n*, 946 F.2d 821, 832, 20 U.S.P.Q. 2d 1161, 1171 (Fed. Cir. 1991).

C. Substantial evidence showed that each claim limitation is found in Warner-Jenkinson's infringing process. Expert testimony was properly used to demonstrate that the membrane used in the infringing process met the *Graver Tank* tests. *See, Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1574, 19 U.S.P.Q. 2d 1241, 1245 (Fed. Cir. 1991).

D. Patent coverage was not surrendered in the PTO for a process pressure greater than 400 psig and a pH less than 6. Hilton Davis argued the combination of ***four*** differences distinguished over the prior art, which did not create an estoppel for each difference separately. *Read Corporation v. Portec, Inc.*, 970 F.2d 816, 824, n.4, 23 U.S.P.Q. 2d 1426, 1433, n.4 (Fed. Cir. 1992). Nor was coverage surrendered for arguments made which were not required in response to an Examiner's rejection. The prior art was distinguished , *inter alia*, on the basis of low pressure and high pH, not the high pressure **and** low pH used in the infringing process. *Mannesmann Demag Corp. v. Engineered Metal Products Co., Inc.*, 793 F.2d 1279, 1284, 230 U.S.P.Q. 45, 48 (Fed. Cir. 1986).

III. THE PATENT WAS NOT PROVED INVALID

A. Hilton Davis has **not** abandoned the significance of the pressure and pH claim limitations, which remain important in distinguishing the patented invention from the prior art. The infringing process was shown to use the higher pressure and lower pH of the patented process rather than the lower pressure and higher pH of the prior art.

B. Inventorship is a factual determination. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624, 225 U.S.P.Q. 634, 641 (Fed. Cir. 1985); *Amax Fly Ash Corp. v. United States*, 514 F.2d 1049, 1047, 182 U.S.P.Q. 210, 215 (Ct. Cl. 1970). Warner-Jenkinson failed to show sufficient evidence to overcome the presumption of proper inventorship, or that another person should be named inventor. *Amax Fly Ash Corp.*, 514 F.2d at 1047, 182 U.S.P.Q. at 215. There was substantial evidence to prove that Drs. Cook and Rebhahn not only conceived the invention, but made ***all*** of the inventive contributions, while the Osmonics employee (Gach) was hired only to perform testing under the direction of Dr. Cook and did

not contribute ***anything*** inventive. The inventors as named in the patent are proper. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624, 225 U.S.P.Q. 634, 641 (Fed. Cir. 1985); *Consolidated Aluminum Corp. v. Foseco International Ltd.*, 10 U.S.P.Q. 2d 1143, 1172 (N.D. Ill. 1988).

C. Warner-Jenkinson's prior work is distinguishable from the patented process, and is not prior art because it was not reduced to practice and was abandoned. 35 U.S.C.§ 102(g); *Lutzker v. Plet*, 843 F.2d 1364, 1366, 6 U.S.P.Q. 2d 1370, 1371 (Fed. Cir. 1988); *Kimberly-Clark Corporation v. Johnson & Johnson*, 745 F.2d 1437, 1445, 223 U.S.P.Q. 603, 609 (Fed. Cir. 1984).

D. The conclusion of non-obviousness by the District Court and jury was correct. under the *Graham* tests. There is no requirement that a patent owner show unexpected results. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 U.S.P.Q. 763, 771 (Fed. Cir. 1984). Nor do *In Re Durden* and *Application of Kanter* establish a separate inquiry for obviousness apart from the *Graham* "subject matter as a whole" test. *In re Dillon*, 919 F.2d 688, 695, 16 U.S.P.Q. 2d 1897, 1903 (Fed. Cir. 1990).

ARGUMENT

IV. There Is Substantial Evidence To Support The Special Jury Verdict That The Cook Patent Has Been Infringed By Warner-Jenkinson

A. Infringement Is A Question Of Fact For The Jury

By Special Verdict 6 (A2107), the jury found infringement of claims 1-3, 13 and 14, a factual finding. *Wahpeton Canvas Company, Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1554, n.15, 10 U.S.P.Q. 2d 1201, 1209, n.15 (Fed. Cir. 1989).

Contrary to Warner-Jenkinson's unsupported assertion that it is for the Court and not the jury to decide, infringement under the doctrine of equivalents has, from its earliest days, been a question of fact. *See, e.g., Winnans v. Denmead*, 56 U.S. (15 Howard) 330, 343, 14 L. Ed. 717, 722 (1853); *Graver Tank & Mfg. Co. v. Linde Air*

Prods. Co., 339 U.S. 605, 609, 85 U.S.P.Q. 328, 331 (1950) ("[A] Finding of equivalence is a determination of fact"); *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 626, 225 U.S.P.Q. 634, 642 (Fed Cir. 1985) ("[b]oth infringement and equivalents are questions of fact"). Even this Court's most recent discussions of the doctrine of equivalents have stressed that it is a question of fact for the jury, and not the Court to decide. *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1325, 1345, 21 U.S.P.Q. 2d 1161, 1165, 1171 (Fed Cir. 1991) ("[T]he issues of infringement and of equivalency are issues of fact")(right to jury trial on factual issue of equivalents cannot be extinguished; Newman, J. dissenting).

As a question of fact for the jury, the only question on appeal is whether or not substantial evidence supports the jury's verdict. *Sun Studs, Inc. v. ATA Equipment Leasing, Inc.*, 872 F.2d 978, 987, 10 U.S.P.Q. 2d 1338, 1346 (Fed Cir. 1989). "On review of a jury's finding of infringement, the court must consider the evidence in the light most favorable to the party in whose favor the jury found, and must not substitute its choice for the jury's in drawing inferences or deciding between conflicting evidence." *Ibid.* In the present case, there is substantial evidence to support the jury's finding of infringement under the doctrine of equivalents, and thus its decision should not be disturbed. Moreover, a reviewing Court must accept a jury's factual findings, presumed from a favorable verdict, which are supported by substantial evidence. *Newell Companies, Inc. v. Kenney Manufacturing Company*, 864 F.2d 757, 765, 9 U.S.P.Q. 2d 1417, 1423 (Fed. Cir. 1988).

B. The Only Test To Be Applied In Determining Infringement Under The Doctrine Of Equivalents Is The Tripartite Test Of *Graver Tank*

1. A Proof Of "Equities" Is Not Necessary To Prove Infringement Under The Doctrine Of Equivalents

Warner-Jenkinson is apparently laboring under the mistaken belief that the doctrine of equivalents has somehow changed recently, and now requires a *patent owner* to prove "equities" in order to prevail. While the Supreme Court in the seminal case of *Graver Tank* stated

that "the essence of the doctrine was that one may not practice a fraud on a patent," nowhere did the Court *require* a plaintiff to prove "equities." *Graver Tank*, 339 U.S. at 608, 185 U.S.P.Q. at 330. While many courts have stated that the doctrine of equivalents is designed "to do equity," *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361, 219 U.S.P.Q. 473, 480 (Fed. Cir. 1983), the *only* test that has been employed to prove infringement by equivalents is the familiar tripartite test of *Graver Tank*: does the accused process perform "substantially the same function in substantially the same way to produce substantially the same result." 339 U.S. at 608, 85 U.S.P.Q. at 330.

While courts since *Graver Tank* have recognized the tension between preventing a fraud on the patent and insuring that the public has a reasonable indication of the scope of the claim, they have resolved this balancing by following the *Graver Tank* test. The only "equity" involved is whether or not the change from the literal language of the claim in question is so insubstantial as to amount to a "fraud on the patent." *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 932 F.2d 1453, 1457, 18 U.S.P.Q. 2d 1842, 1846 (Fed. Cir. 1991).

Thus, the first question is: "has a substantial change been made?" Only if the answer to that question is "yes" should an accused infringer escape liability. This is where the *Graver Tank* tripartite test comes into play; the differences between an accused device and a claimed device are considered to be "insubstantial" when the accused device performs substantially the same function in substantially the same way to achieve substantially the same result as the claimed device. The determination of whether an accused device meets this test is one of fact. *Ibid.* Consequently, when the change is "insubstantial," as shown by the *Graver Tank* test, an "equitable" basis for invoking the doctrine of equivalents is met.

This Court's most recent discussion of the doctrine of equivalents supports this mode of analysis:

> In applying the doctrine, the Supreme Court refused to allow an "unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied

> matter outside the claim." . . . This statement elucidates both the purpose of the doctrine and the type of conduct which triggers its application. An equivalent under the doctrine of equivalents results from an insubstantial change which, from the perspective of one of ordinary skill in the art, adds nothing of significance to the claimed invention. (Emphasis added.)

Valmont Indus, Inc. v. Reinke Mfg. Co., Inc., 25 U.S.P.Q. 2d 1451, 1454 (Fed. Cir. 1993).

In other words, while one of the purposes of the doctrine might be to prevent unscrupulous copying, the only fact which triggers its application is an "insubstantial" change from the patented invention.

While it is clear that application of the doctrine of equivalents is required when there is merely an insubstantial change, as measured by the *Graver Tank* test, it is equally clear what is not required. Infringement, whether literal or under the doctrine of equivalents, has *never* required a plaintiff to show piracy, stealing or fraud, or that the defendant copied, designed around the patent, or was even aware of the patent. Intent to infringe is not necessary; the patent law forbids even independent creation. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 478, 181 U.S.P.Q. 673, 677, 40 L. Ed. 2d 315, 94 S. Ct. 1879 (1974); *Intel Corp. v. U.S. International Trade Comm'n*, 946 F.2d 821, 832, 20 U.S.P.Q. 2d 1161, 1171 (Fed. Cir. 1991) ("there is no intent element to *direct* infringement"). Thus, infringement by equivalents, even if unknowing, is nevertheless a violation of the patentee's exclusionary right. *See, e.g., Blair v. Westinghouse Elec. Corp.*, 291 F. Supp. 664, 670, 160 U.S.P.Q. 155, 160 (D.D.C. 1968); *A. Stucki Co. v. Schwam*, 634 F. Supp. 259, 264, 229 U.S.P.Q. 903, 907 (E.D. Pa. 1986) ("neither intent to infringe or knowledge that a subsisting patent covers what one is making, using or selling is an element of a direct patent infringement action"). If this Court were to adopt Warner-Jenkinson's interpretation of the application of the doctrine of equivalents, there would rarely be a need to inquire as to the question of willful infringement, since by Warner-Jenkinson's definition only *willful* infringement would be actionable under the doctrine of equivalents. *See, Avia Group International, Inc. v. Nike, Inc.*, 22 U.S.P.Q. 2d

1475, 1477 (D. Ore. 1991) ("Because intent is irrelevant to a determination of patent infringement, there is no overlap concerning willfulness between the issue of liability and damages.").

Simply put, no court has ever said that copying is a prerequisite to a finding of infringement either literally or under the doctrine of equivalents; neither has knowledge of the existence of the patent itself being cited as a requirement.

Warner-Jenkinson also argues that because infringement "may" be found under the doctrine of equivalents, its use is limited and should only be resorted to to prevent "abuse". However, it is clear that this Court has noted that the doctrine is limited only in the sense that it does not extend "(1) to cover an accused device in the prior art, and (2) to allow the patentee to recapture through equivalence certain coverage given up during prosecution". Pennwalt Corp. v. Durand-Wayland, Inc., 833 f.2d 931, 934 n.1, 4 U.S.P.Q. 2d 1737, 1739, n.1 (Fed. Cir. 1987).

2. Regardless Of The Fact That A Proof of "Equities" Is Not Required, Equities In Hilton Davis' Favor Do Indeed Exist

Irrespective of the fact that proof of "equities" is not required to invoke the doctrine of equivalents, numerous equitable factors in Hilton Davis' favor exist in the present case. Furthermore, as this Court has stated, "[e]ach case in which infringement by equivalents is asserted turns on its facts, as Graver Tank emphasized, and requires the trier of fact [the jury in the present case] to balance the competing public policies of avoiding a 'fraud on the patent,' and the need for reasonable certainty by the public as to the scope of the patent grant." Sun Studs, Inc. v. ATA Equipment Leasing, Inc., 872 F.2d 978, 987, 10 U.S.P.Q. 2d 1338, 1346 (Fed. Cir. 1989). Thus, if there is to be any balancing of "equities," it is a determination of fact for the jury, and thus the issue is only reviewable under a substantial evidence standard. Here, the substantial evidence presented at trial clearly supports the fact that any "equities" are in Hilton Davis' favor.

The evidence clearly showed that Warner-Jenkinson was unable to achieve a workable process until after Hilton Davis had succeeded in doing so, and evidence was presented from which the jury could

have concluded that Warner-Jenkinson obtained information concerning the Hilton Davis process, through Osmonics, which enabled Warner-Jenkinson to perfect its process. A271; 1269-73. Hilton Davis and Warner-Jenkinson performed their first tests at Osmonics one week apart A1264; however the evidence showed that Hilton Davis achieved its desired objectives *before* Warner-Jenkinson. A1269-73. After Hilton Davis was successful, information from its testing suddenly appeared in an Osmonics' file concerning further testing to be performed for Warner-Jenkinson, enabling the jury to conclude that Warner-Jenkinson obtained helpful confidential and critical information concerning Hilton Davis' process. A1272-3. This, along with the fact that Warner-Jenkinson continues to utilize the same equipment and membranes as Hilton Davis A522-3; 545, clearly could have led the jury to conclude that Warner-Jenkinson copied its process from Hilton Davis.

The evidence also showed that Warner-Jenkinson was "immediately concerned" about the Hilton Davis patent because it had been working on the same process, but was simply too committed to its process to stop infringing. A897; 912-3. Warner-Jenkinson's president testified "you don't take action to practice a patent without good legal advice". A909.

The evidence further showed that Warner-Jenkinson did not obtain a written infringement opinion until one year after it became aware of the Hilton Davis patent. A922. Furthermore, Warner-Jenkinson failed to disclose all of the information necessary for its patent counsel to formulate a proper infringement opinion. A949; 971-2; 976. In fact, after Warner-Jenkinson became aware of the Hilton Davis patent, it took no steps to move further away from the claim parameters, but merely sought a perfunctory confirming opinion from its counsel. A895-900. As demonstrated from its actions after the Trial Court entered the injunction in the present case (Confidential Addendum hereto, filed under seal) , it would have been very easy for Warner-Jenkinson to avoid infringement; however no such steps were taken until the jury found infringement.

3. When The Proper *Graver Tank* Analysis Is Employed, It Is Clear That Substantial Evidence Supports The Jury's Finding Of Infringement

Hilton Davis has been unable to find a *single* case where the tripartite test of *Graver Tank* was not employed to decide issues of infringement under the doctrine of equivalents. Amazingly, however, Warner-Jenkinson never once cites the test in its brief. Rather, it relies on generalized statements carefully chosen to try to convince this Court that the long-established *Graver Tank* analysis has been significantly modified, or even abrogated, in recent years. As shown above, however, the *Graver Tank* triparte test remains the touchstone for an equivalents analysis.

To prove infringement under the doctrine of equivalents, Hilton Davis was required to show that the accused process met every limitation of at least one claim either literally or by a substantial equivalent. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 935, 4 U.S.P.Q. 2d 1737, 1739-40 (Fed. Cir. 1987) (*en banc*). Although Warner-Jenkinson has challenged the jury's factual finding as to the presence of certain claim elements in its process, substantial evidence supports the jury's verdict that these elements are present either literally or under the doctrine of equivalents. When the evidence is considered in a light most favorable to Hilton Davis, as it must on this appeal, the jury's finding of infringement must stand. *Sun Studs, Inc. v. ATA Equipment Leasing, Inc.*, 872 F.2d 978, 987, 10 U.S.P.Q. 2d 1338, 1346 (Fed. Cir. 1989); *Toth v. Yoder Company*, 749 F.2d 1190, 1194 (6th Cir. 1984).

C. There Is Substantial Evidence That The Pore Size Limitation Is Met In The Warner-Jenkinson Process

Warner-Jenkinson argues that there was no evidence of the pore size of its membrane or that the membrane even had pores. First, there was substantial evidence that the membrane had pores. A226-7; 357-8; 478-9; 550-1. Further, actual measurements are not necessary to support a finding of infringement. *Uniroyal, Inc. v. Rudkin-Wiley Corporation*, 837 F.2d, 1044, 1056, 5 U.S.P.Q. 2d 1434, 1443 (Fed. Cir. 1988). The evidence showed that the actual pore size is influenced by temperature and water properties, and

therefore cannot merely be measured under a microscope. A551-2. Thus, the pores are defined as a "nominal pore diameter." A557. The pore sizes are measured based on performance and named in terms of how much or how fast the dye or impurities are passed. A227. The membrane thus is defined functionally in the claims with pore sizes, together with other process parameters, to achieve the goals of the process. A478-9.

Based on expert testimony and claim charts, the evidence established that the Desal Series G membrane used in the infringing process was the legal equivalent of that called for by the claims. *See*. *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1574, 19 U.S.P.Q. 2d 1241, 1245 (Fed. Cir. 1991) (Expert testimony and claim charts sufficient to support infringement finding). The evidence showed that the function of the membrane is to separate impurities, salts and inorganics (starting materials and byproducts) from the dye, such as sodium chloride, sodium sulfate, and organics such as CSA and Schaeffer's salt, and that this separation must be performed just right to obtain the desired results. The membrane also functioned to remove the impurities to a level sufficient to achieve FDA certification. These functions are met in the patented and infringing processes. A111-2; 337-8; 355; 378-9; 381; 496-7.

The way in which these functions are accomplished is that impurities smaller than the nominal pore diameter, and water, pass through the membrane, while the dye is retained on the concentrate side of the membrane. Both the patented and infringing process perform these functions in substantially the same way. A113-4; 355-7; 378; 497.

The result achieved is that "substantially all impurities" are removed from the concentrate, which defines a way of measuring when the desired purity level (FDA purity) has been reached. Another result is that the final product achieves 90% purity. Finally, other results achieved are that impurities are not present in the permeate and the process results in producing principally an FD&C dye. All of these results are found in the patented and infringing processes. A337-8; 381-2; 1113.

Thus, the jury was fully justified in drawing the conclusion that the Warner-Jenkinson membrane had an *effective* pore size of 5-15 angstroms, and was the functional equivalent of the claimed membrane.

Warner-Jenkinson relies on *Morton International* is support of its position. In *Morton*, literal infringement was not proved because there was no evidence at all of the existence of a particular required material. Thus, there was "no objective support for the actual existence of the claimed "material." In the present case, it is undisputed that the Warner-Jenkinson processes use a membrane which has pores of *some* size. Nor in *Morton*, was there any attempt to prove infringement by equivalents. However, when analyzed under *Graver*, it is clear that Warner-Jenkinson's membrane is functionally equivalent to the claimed membrane. Consequently, the cases are easily distinguishable; here, there is substantial evidence to support the infringement finding.

Finally, Warner-Jenkinson argues that it did not choose the membrane to avoid the patent claims. However, as noted above, intent is not a requirement for infringement; the only test is whether the *Graver* requirements have been met.

D. Prosecution History Estoppel Does Not Limit Application Of The Doctrine Of Equivalents In This Case

Warner-Jenkinson argues that Hilton Davis is estopped to rely on the doctrine of equivalents because of arguments made to the PTO. Those arguments, however, stressed the combination of four differences (molecule size, addition of salt, pH and pressure) from the Booth patent. Consequently, at most, an estoppel would be created by all of these combined distinctions, not each individually. *See, Read Corporation v. Portec, Inc.*, 970 F.2d 816, 824, n.4, 23 U.S.P.Q. 2d 1426, 1433, n.4 (Fed. Cir. 1992):

> Every statement made by a patentee during prosecution to distinguish a prior art reference does not create a *separate* estoppel. Arguments must be viewed in context. In context, Read distinguished, for example, the Deister reference because of a wealth of differences.

* * *

> Thus, any estoppel created by Portec's argument encompasses *all* of these *combined* distinctions of Deister and not an estoppel respecting *each* of the *individual* differences, *e.g.*, that any device with non-movable wheels cannot infringe.[fn] That feature in itself was never asserted to be the basis for patentability over Deister. Thus, there is no basis for an assertion that Read is seeking to recapture anything which was surrendered to obtain the patent, the essence of the prosecution history estoppel.
>
> * * *
>
> fn. Acceptance of Portec's argument respecting estoppel for each item in a patentee's list of distinctions between the invention and a prior art reference would mean that the less material a prior art reference, the more the estoppel merely by a patentee's pointing out numerous differences. This turns an equitable doctrine into an illogical mechanical rule and would allow easily distinguishable prior art, here Deister, to emasculate the doctrine of equivalents.

1. Hilton Davis Did Not Surrender Patent Coverage For pH Less Than 6.0

In its Brief, Warner-Jenkinson confuses the issues of prosecution history estoppel and infringement under the doctrine of equivalents. As to the first issue, during prosecution, applicants differentiated the prior art Booth patent, *inter alia*, because it used a higher pH than the claimed process. The pH value of 9.0 was added to stress the difference from the higher pH of Booth, which used a pH of 9-11. Moreover, the focus here must be on "why" a particular change was made. *Sun Studs, Inc. v. ATA Equipment Leasing, Inc.*, 872 F.2d 978, 987, 10 U.S.P.Q. 2d 1338, 1345 (Fed. Cir. 1989). There was no argument, or any other express or implied intent, that a pH *less* than 6 be excluded in any way. Specifically, applicants argued that "the very high pH ranges deliberately sought by the Booth process, i.e., above 9.0 and preferably 11 to 13 by addition of basic materials to the retentate, in contrast to the relatively low pH's used in the present process (i.e., from around 6 to 9. . . .)." Thus, at most,

Hilton Davis surrendered coverage (together with the other limitations argued) for processes using a pH *greater* than 9. Further, since there was no reason to limit the lower pH range in response to an Office Action, this is a case where a patentee's amendment was not required in response to an examiner's rejection, and therefore no estoppel should be found. Mannesmann Demag Corp. v. Engineered Metal Products Co., Inc., 793 F.2d 1279, 1284, 230 U.S.P.Q. 45, 48 (Fed. Cir. 1986).[1]

Where, as here, a limitation was not necessarily the critical limitation that secured the patent, estoppel does not apply. See, Therma-True Corp. v. Peachtree Doors Inc., 24 U.S.P.Q. 2d 1493, 1503 (E.D. Mich. 1992)(0.005 inch claim limitation doesn't preclude infringement of device measuring 0.0045 inches).

The claim also specifically requires a pH from "approximately" 6.0 to 9.0. The broadening term "approximately" cannot be ignored, Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1577, 1 U.S.P.Q. 2d 1593, 1604 (Fed. Cir. 1987), offers leeway in determining if infringement is present, Seattle Box Co. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 829, 221 U.S.P.Q. 568, 576 (Fed. Cir. 1984), and creates a question of fact. W.L. Gore & Assoc., Inc. v. Garlock, Inc., 842 F.2d 1275, 1280, 6 U.S.P.Q. 2d 1277, 1282 (Fed. Cir. 1988). The use of the term "approximately" here indicates an intent *not* to limit the pH to the literal range recited.

The inapplicability of the doctrine of prosecution history estoppel to the facts of the present case is dramatically illustrated in Px. 94 (A2892), diagrammed in part in Exhibit A attached hereto. This shows that Warner-Jenkinson's process pH lies on the *opposite* end of the range where Warner-Jenkinson argues Hilton Davis surrendered patent coverage in order to differentiate from the Booth process.

The substantial evidence also showed that Warner-Jenkinson's use of pH 5 was the functional equivalent of a pH of 6-9 within the

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[1] The Trial Court clearly recognized this distinction when it limited the permanent injunction to a pH greater than 9.01. A4, 54-5.

overall process. Employing the *Graver* analysis, the "function" of the pH is to (1) insure operation at a pH which prevents damage to the membrane, (2) produce a more or less neutral product required by the FDA, and (3) be compatible with the chemistry of the process. The evidence showed that Warner-Jenkinson operates within a pH meeting these functions. As to "way," in the patented process the pH is adjusted after coupling by means of an acid to obtain the desired value, just as in the infringing process. A2178 (col. 3-6; col. 11, lines 49-52); 2793; 2798; 2812. Finally, the result of utilizing the appropriate pH is that the membrane is not destroyed and the process operates to produce certifiable dyes – these results are achieved in the infringing process. A231; 364-5; 1295; 2174, 2178, (co. 3-6; col. 11, lines 49-52).

There was further evidence that operating at a pH of 5 rather than 6 makes no functional difference to the chemistry of the process or to the actual membrane separation. A232; 365; 1472-3; 1477-8. There was also evidence from which the jury could conclude that Warner-Jenkinson actually operated its process near, if not at, pH 6, and that operation anywhere in the range 4-8 made no difference. A372-5; 552; 560; 864-6; 1557; 2439-56; 2998-3000; 3012; 3013; 3222. This evidence, which was for the jury to consider, supports a finding of *literal* infringement of this claim limitation.

Warner-Jenkinson argues that it achieves an additional function, i.e., destruction of triazine, thereby avoiding infringement. However, a feature added to a claimed invention does not necessarily avoid infringement. *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corporation*, 739 F.2d 604, 614, 222 U.S.P.Q. 654, 662 (Fed. Cir. 1984). Furthermore, the claimed and accused processes need not have identical results; the result can be substantially the same and the accused process can be an improvement. *Atlas Powder Company v. E.I. DuPont de Nemours and Co.*, 750 F.2d 1569, 1580, n.3, 224 U.S.P.Q. 409, 417, n.3 (Fed. Cir. 1984). Warner-Jenkinson cannot escape infringement by asserting its process performs an additional function.

Moreover, the substantial evidence demonstrated that the claimed pH range functions equally well to destroy triazine. Evidence from a wide variety of sources, including the FDA and Hilton Davis' own

tests, showed that triazine is destroyed by an acid pH, including pH 6. A366-9; 376; 1017; 1118-9; 1123; 1329; 1390; 2175 (col. 5, line 21); 2887-91; 2895-9; 2955-61; 3001-11. Since this was well known, the patent was not required to teach it. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986); *In re Aufhauser*, 399 F.2d 275, 283, 158 U.S.P.Q. 351, 357 (CCPA 1968). From this evidence, and the fact that Hilton Davis and Warner-Jenkinson produce certifiable dye in approximately the same time (A1548), the jury could draw the inference that operating within the claimed pH range and under the other claimed conditions effectively removes triazine to certifiable levels. It is apparent Warner-Jenkinson's "triazine" argument is an afterthought, as demonstrated by the fact that it did not appear in any of the opinion letters from Warner-Jenkinson's patent lawyer. A2820-34.

Warner-Jenkinson argues that the claims are limited to a lower limit of 6 because of "foaming problems." There is nothing in the patent to support such a limitation. The evidence showed that the patented process was successfully tested at pH values substantially below 6, down to 2.2. A1406; 1410-11; 1516-7; 3108-45. The lower pH value was a matter of convenience, not necessity. A1477. The process worked even at these low pHs, and there was no evidence that the alleged "foaming" in any way affected the process. A232; 1099. Since one of the functions of the pH was compatibility with the process chemistry, if a function was to avoid "foaming," that function was clearly accomplished in the Warner-Jenkinson process.

Finally, Warner-Jenkinson cites *Tandon Corp.* as limiting the doctrine of equivalents. In *Tandon*, the infringing device fell squarely within the range expressly surrendered during prosecution. Here, the infringing process uses a pH *opposite* the range surrendered during prosecution. Thus, *Tandon* does not preclude infringement in the present case. Warner-Jenkinson's change from pH 6 to 5 is insubstantial in the context of the overall process, and there is substantial evidence to support the implied infringement finding by the jury of this claim limitation.

2. Hilton Davis Did Not Surrender Patent Coverage For Pressures Greater Than 400 PSIG

Again, Warner-Jenkinson mixes prosecution history estoppel and the doctrine of equivalents. The pressure requirement of claim 1 was *not* added by amendment, but was present in *both* the parent and CIP applications. During prosecution, the applicants pointed out that one of the differences between the Booth patent and that claimed was "the rather low pressures used in the Booth process, i.e., 25-200 psig., preferably 50-150 psig., and more preferably 75-125 psig. . . , in contrast with the higher pressures required by the present process." A2151-6, 2164-6. Thus, Hilton Davis distinguished its invention from the prior art, *inter alia*, on the basis of *low* pressures, *not* the *higher* pressures now used by Warner-Jenkinson.

The inapplicability of prosecution history estoppel to the facts of the present case is dramatically illustrated in Px. 94 (A2892), diagrammed in part in Exhibit 2 attached hereto, which shows that Warner-Jenkinson's process pressure lies on the *opposite* end of the range where Warner-Jenkinson argues Hilton Davis surrendered patent coverage in order to differentiate from Booth.

Thus, at most, Hilton Davis surrendered patent coverage (together with the other limitations) for processes using pressures less than 200 psig.; nowhere in the prosecution history is there *any* intent demonstrated to surrender patent coverage for pressures *greater* than 400 psig. Hilton Davis is not estopped from applying the doctrine of equivalents to Warner-Jenkinson's process which used pressures greater than 400 psig. since it is not attempting to recapture something which was originally surrendered.

Further, the upper value of 400 psig. does not exist in the claim to distinguish the process from the prior art, particularly in Booth, but rather to protect the membranes available at that time. A229. Where a patentee's amendments were not required in response to an examiner's rejection or critical to the allowance of the claims, no estoppel has been found. Mannesmann Demag Corp. v. Engineered Metal Products Co., Inc., 793 F.2d 1279, 1285, 230 U.S.P.Q. 45, 48 (Fed. Cir. 1986); SRI International v. Matsushita Electric

Corporation of America, 775 F.2d 1107, 1120, n. 13, 227 U.S.P.Q. 577, 585, n. 13 (Fed. Cir. 1985).

Moreover, since there was substantial evidence to support literal infringement of this limitation, prosecution history estoppel is not applicable at all. The evidence showed that the actual pressure on some of the membranes in the Warner-Jenkinson process measured in the 200-400 psig. range. A525-30; 580; 582; 592; 1588; 3238; 3240. Thus, a major portion of the membrane was actually receiving pressures literally within the claimed range. A530; 580.

Warner-Jenkinson argues that the pressure should be measured "at the high pressure pump, i.e., at the inlet to the first membrane." This makes no sense since it is the pressure applied to the membrane itself which is important to the functioning of the process; i.e., the object is to exert a pressure greater than the osmotic pressure on the coupling solution so that water and impurities are forced through the membrane into the permeate. A164; 228-9; 361-2; 860; 1161-2; 1166. The patent specification defines the pressure as "applied to the upstream side of the membrane." A1564-6; 1570; 2175 (col. 6, lines 20-21). Expert testimony established that the "pressure" is that applied to the concentrate side of the membrane. A591; 1588. Both the patent specification and expert testimony may be used as aids to determine the meaning of terms in the claims. *Snellman v. Ricoh Company, Ltd.*, 862 F.2d 283, 287, 8 U.S.P.Q. 2d 1996, 2000 (Fed. Cir. 1988); *SRI International v. Matsushita Electric Corporation of America*, 775 F.2d 1107, 1118-20, 227 U.S.P.Q. 577, 584-6 (Fed. Cir. 1985); *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570-1, 219 U.S.P.Q. 1137, 1140 (Fed. Cir. 1983). The Trial Court also agreed with this interpretation. (A65-7.)

There was also substantial evidence to show that the pressure used in the infringing process was the functional equivalent of that claimed. The claim uses the word "approximately" which provides some leeway, as noted above. Further, higher pressures are possible today because of advances in membranes. An appropriate range of equivalents may extend to post-invention advances. *American Hospital Supply Corporation v. Travenol Laboratories, Inc.*, 745 F.2d 1, 9, 223 U.S.P.Q. 577, 583 (Fed. Cir. 1984) (Fed. Cir. 1984).

The evidence showed that the function of the pressure was to exert sufficient pressure on the reactant mixture applied to the upstream side of the membrane to overcome the osmotic pressure to drive water, organic impurities and inorganic impurities through the membrane into the permeate at an economically useful rate. This function was achieved (the "way") by overcoming the osmotic pressure with additional pressure to force the water, organic impurities and inorganic impurities through the membrane while retaining the dye. The result achieved was that water and impurities were removed to obtain a dye of a particular quality in terms of impurity level and dye concentration, which was suitable for spray drying or other means of isolation. The evidence showed that this function/way/result was achieved in the Warner-Jenkinson process. A164; 228-9; 360-2; 534-8; 544; 592; 860; 1161-2; 1166-7; 1289; 1296; 1567; 1589. Thus, the *Graver* tests for functional equivalence are met.

Warner-Jenkinson's argument that it did not select its operating pressure to avoid the Hilton Davis patent is irrelevant. Intent to infringe is not necessary; the patent law forbids even independent creation. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 478, 181 U.S.P.Q. 673, 677, 40 L. Ed. 2d 315, 94 S. Ct. 1879 (1974). However, there was evidence to show that Warner-Jenkinson *did* adopt its higher pressures *merely* to avoid the literal pressure ranges of the patent claims, and for no other reason. It was not necessary to operate at the higher pressure to achieve the process goals; rather, Warner-Jenkinson artificially increased its pressure by "pinching off" valves to attempt to get the pressure outside the literal claimed range. A532; 592; 1543-4. The jury was entitled to credit this evidence. *See, Yarway Corporation v. Eur-Control USA, Inc.*, 775 F.2d 268, 275, 227 U.S.P.Q. 352, 357 (Fed. Cir. 1985). Finally, Warner-Jenkinson's reliance on *Tandon Corp.* is misplaced for the same reasons noted above. Warner-Jenkinson's change from 400 to 500 psig. is insubstantial in the context of the overall process, and there is substantial evidence to support infringement of this claim limitation.

Howes v. Medical Components, Inc., 814 F.2d 638, 2 U.S.P.Q. 2d 1271 (Fed. Cir. 1987) is very similar to the present case. There, the

patentee amended a claim for a catheter by specifying that the catheter have a "uniform outer diameter" in order to distinguish over a patent disclosing a catheter having protuberances along its length, and also to distinguish over a catheter having a nonuniformity in the middle of its body. This Court stated that this at most precluded the patent owner from asserting equivalents of catheters having size changes along its insertion length; however, a catheter having a tapered tip could meet the limitation of a "uniform outer diameter" under the doctrine of equivalents. Thus, even though the accused device literally fell outside of the limitation that had been added to overcome prior art, it was equivalent, notwithstanding the doctrine of prosecution history estoppel since the prior art dealt with nonuniformities of diameter along the length of the catheter and not at the tip. In the present case, the prior art dealt with high pH and low pressures; the Warner-Jenkinson process, like the Hilton Davis process, uses low pH and high pressures. Thus, the doctrine of equivalents is fully applicable in the present case.

E. Warner-Jenkinson's Infringing Process Uses A Functionally Equivalent "Acid" And Produces An Identical Product

Without question, infringement under the doctrine of equivalents was an issue of fact for the jury. Nevertheless, Warner-Jenkinson would have this Court set aside the jury's implied finding that the acids employed in the two processes were equivalent, even though substantial evidence supports that finding.

In determining whether or not ingredients (e.g., acids) are equivalent, this Court has stated:

> "Where, as here, the accused product avoids literal infringement by changing one ingredient of a claimed composition, it is appropriate for a court to consider in assessing equivalence whether the changed ingredient has the same purpose, quality, and function as the claimed ingredient. If it does, the accused and claimed products should meet the *Graver Tank* tripartite test of "function, way, and result."

Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1579-80, 224 U.S.P.Q. 409, 416 (Fed. Cir. 1984).

The "purpose" of the acid, in both the patented and infringing processes, is to contribute a hydrogen ion and thereby react with sodium nitrite causing the necessary diazotization reaction to occur. A391-2; 1108; 1443. As for "quality," both are strong mineral acids. A339-40; 393; 1108; 1443. As for function, both acids react with sodium nitrite to produce nitrous acid, an intermediate which reacts with CSA to produce the required diazonium salt. A1444. The diazonium salt reacts with Schaeffer's salt to produce the desired dye (A1444), and it is uncontroverted that the dye thus produced is the same regardless of the acid employed. A347-8. "Substitution of an ingredient known to be an equivalent to that required by a claim presents a classic example for a finding of infringement under the doctrine of equivalents." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1261, 9 U.S.P.Q. 2d 1962, 1969 (Fed. Cir. 1989). There was evidence that sulfuric and hydrochloric acids were known equivalents. A340; 393; 1443-4. In the context of the processes involved in the present case, the two acids clearly are equivalent.

Warner-Jenkinson attempts to distinguish its process by arguing that, since it uses sulfuric acid, its process produces a sulfate, which it claims is more difficult to remove than the chloride produced in the patented process. Despite the fact that this is *not* an element of the claim, Hilton Davis presented expert testimony at trial that directly contradicted this assertion, showing the two inorganic salts to be equivalent within the context of the overall process. A396; 1111-3; 1299; 1458; 1549. The jury would be entirely justified in determining that Hilton Davis' witness was more credible. Furthermore, the patent clearly states that sodium sulfate is also produced in the patented process. A2171-81 (e.g. col. 4, line 68). Likewise, Warner-Jenkinson's assertion that its choice of acid provides a faster reaction was shown to be inconsequential by Hilton Davis' experts, both by testimony and by live demonstration before the jury. A1445.

Warner-Jenkinson also asserts that its use of sulfuric acid permits it to produce a more concentrated dye solution; however this is an element of claim 3 of the patent, *not* claim 1. Limitations in a dependent claim cannot be read into an independent claim.

Environmental Designs, Ltd. v. Union Oil Co. of California, 713 F.2d 693, 699, 218 U.S.P.Q. 865, 871 (Fed. Cir. 1983). Likewise, Warner-Jenkinson's assertion that its choice of acid permits it to operate at higher temperatures is without merit, as this is also not part of the claimed invention and there was no evidence that this produced any substantial functional difference between the two processes.

Finally, Warner-Jenkinson's argument that there was no evidence it was using a different acid to barely avoid the literal language of the claim is irrelevant. Intent to infringe is not necessary. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 478, 181 U.S.P.Q. 673, 677 40 L. Ed. 2d 315, 94 S. Ct. 1879 (1974). The use of an equivalent acid is no more than an insubstantial change, and there is substantial evidence to support the implied finding of infringement of this claim limitation.

F. Application Of The Doctrine Of Equivalents Is Not Limited By Prior Art

While not clear from its brief, Warner-Jenkinson apparently argues that its process cannot infringe under the doctrine of equivalents because the patent claims are limited by the prior art. In support of these contentions, Warner-Jenkinson cites two isolated pH and pressure ranges in one prior art reference (the British '898 patent) which partially overlap the Hilton Davis ranges, and then draws the logically inconsistent and legally wrong conclusion that it should be able to operate within these ranges. Warner-Jenkinson ignores the clear fact that the patented invention is more than just pressure and pH, but rather includes *many* other requirements to form the whole process. *See, Read Corp.*, 970 F.2d at 824-5, 23 U.S.P.Q. 2d at 1433.

The proper test is set forth in *Wilson Sporting Goods Co. v. David Geoffrey & Associates*, 904 F.2d 677, 684, 14 U.S.P.Q.2d 1942, 1948 (Fed. Cir. 1990): a "patentee should not be able to obtain, under the doctrine of equivalents, coverage which he could not have obtained from the PTO by literal claims." The test is *not*, as Warner-Jenkinson would have this Court believe, whether or not two particular limitations, divorced from the remainder of the claimed

invention, are found *somewhere* in the prior art, but rather whether or not the entire claim, when read to cover the infringing process, reads literally upon the prior art. If "a hypothetical patent claim, sufficient in scope to literally cover the accused product . . . [would] have been allowed by the PTO over the prior art," then the prior art does *not* bar infringement under the doctrine of equivalents.

When the proper test is employed, it becomes readily apparent that the cited prior art cannot limit application of the doctrine of equivalents in the present case. A hypothetical claim having a pressure limitation extending above 400 psig, and a pH limitation below 6 clearly, with the other limitations of the Hilton Davis claims, would be patentable over the British '898 patent. Patentability is based upon the claim as a whole, Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1578, 1 U.S.P.Q.2d 1593, 1605 (Fed. Cir. 1987), not less than the whole. As outlined in more detail in the obviousness discussion hereafter, many of the other limitations in the claim are not present in the British patent.

Warner-Jenkinson also argues that this is a crowded art. However, even if true, this does not change the fact that the breadth to be afforded an invention under the doctrine of equivalents is within the province of the jury, Sun Studs, Inc. v. ATA Equip. Leasing, Inc., 872 F.2d 978, 987-8, 10 U.S.P.Q. 2d 1338, 1346 (Fed. Cir. 1989). In the present case, there is substantial evidence to support the jury's finding of equivalence.

G. Dependent Claims 2, 3, 13 And 14 Are Infringed

Since claim 1 is infringed, it is irrelevant to a finding of liability whether the dependent claims are infringed. However, there was substantial evidence to support a finding of infringement of claim 2. There were opinions by two experts that the material used in the Warner-Jenkinson membrane was a polyamide based upon the material's chlorine sensitivity, pH range, stability, toughness and long life, as well as the demonstrated split between concentrate and permeate flows in the Warner-Jenkinson process which was typical of a polyamide membrane. A401-3; 545-6; 548-9; 587-8. That evidence was not refuted. See, Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 1574-5, 19 U.S.P.Q. 2d 1241, 1245-6

(Fed. Cir. 1991) (Expert's testimony sufficient to establish *prima facie* infringement case).

There was also substantial circumstantial evidence that the Warner-Jenkinson membrane was a polyamide. A404-7; 548-9; 1555; 2612; 3014-31.

H. Conclusion - There Is Substantial Evidence To Support The Jury's Special Verdict Of Infringement

There is substantial evidence of record to support the jury's factual finding that the Warner-Jenkinson process contains literally or the functional equivalent of each of the disputed claim limitations. Whether Warner-Jenkinson's process was "totally independently developed" is irrelevant, and there is substantial evidence to show that it was not. The infringement finding is fully supported by the evidence and should not be disturbed.

V. Warner-Jenkinson Failed To Prove The Cook Patent Invalid

A. While The Legal Conclusion Of Patent Invalidity Is One Of Law, That Conclusion Is Based On Factual Findings

While the ultimate conclusion of obviousness is one of law, that conclusion is based upon factual findings. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291, 227 U.S.P.Q. 657, 662 (Fed. Cir. 1985). The existence of factual findings and legal conclusions necessary to support the verdict reached by the jury is presumed. *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corporation*, 739 F.2d 604, 607, 222 U.S.P.Q. 654, 656 (Fed. Cir. 1984).

B. There Is A Substantial Factual Distinction Between The Cook Invention And The Booth Process

Warner-Jenkinson's argument is based on a faulty premise: Hilton Davis has not "abandoned the significance of both pH and pressure as critical to the operation of the ultrafiltration process." Hilton Davis has never, including before the PTO, said that these operating conditions were "critical." During prosecution, applicants argued that "the process disclosed by Booth et. al. is submitted to be so totally dissimilar, in all its critical parameters, to the present process

that the Booth process is in no way suggestive of the present invention." A2153. Thus, Hilton Davis argued that Booth had "critical parameters" which were ***totally dissimilar*** to the Hilton Davis process. Hilton Davis specifically noted that "the only feature the claimed process has in common with the Booth process is that both processes relate to the ultrafiltration purification of colorants used in foodstuffs." A2153. Hilton Davis distinguished the Booth process on the *combination of four differences*: the enormous difference in molecular weights of the materials to be separated, the addition of salt in the Booth process, the substantial difference in pH, and the substantial difference in pressure. *See*, *Read Corp.*, 970 F.2d at 824-5, 23 U.S.P.Q. 2d 1433.

None of the alleged "evidence" relied on by Warner-Jenkinson establishes "abandonment" of the "significance of both pH and pressure." The evidence showed that the pH and pressure remain important to the patented and infringing processes for the reasons noted above. It remains true that a pH too high will adversely affect the membrane and the final product, while a pressure too low will prevent separation of the impurities. There was substantial evidence to show that these operating conditions remain important to the overall functioning of the process, and have **never** been "disavowed." A164; 228-32; 360-1; 364-5; 535-6; 1161-2; 1166; 1295-6; 1472-5.

C. Cook And Rebhahn, Not Osmonics, Invented The Patented Process

Warner-Jenkinson asserts that if there is a patentable process, then Osmonics invented it and not Hilton Davis, citing 35 U.S.C. § 101. Apparently, Warner-Jenkinson challenges the jury's factual finding of Special Verdict 2 (A2016), but not the factual finding of Special Verdict 4 (A2017)(which relates to coinventorship). Further, nowhere, does Warner-Jenkinson state **who** at Osmonics it considers to have invented the process, even though it is axiomatic that only individuals, and not companies, can be inventors. 37 C.F.R. § 1.41.

Warner-Jenkinson also argues that neither Cook nor Rebhahn were inventors. However, at trial, Warner-Jenkinson specifically ***stipulated*** that Mr. Gach, the only Osmonics employee who

participated in the Hilton Davis project, was *not* an inventor of the patented process. A1249-51. Warner-Jenkinson is now estopped to say otherwise. Warner-Jenkinson's own patent law expert admitted at trial that Rebhahn made an "inventive contribution." A1304-5. Moreover, Warner-Jenkinson has never mentioned any individual, other than Rebhahn and Cook, who might be considered an inventor, and therefore the only conclusion can be that they are the only true inventors.

Despite this gaping inconsistency in Warner-Jenkinson's argument, it is well-settled that the named inventors in a patent are presumed valid, and claims of improper inventorship are "subject to the closest scrutiny." *Amax Fly Ash Corp. v. United States*, 514 F.2d 1041, 1047, 182 U.S.P.Q. 210, 215 (Ct. Cl. 1970); *Garrett Corp. v. United States*, 422 F.2d 874, 880, 164 U.S.P.Q. 521, 526 (Ct. Cl. 1970). In Special verdicts 2 and 4 the jury found Cook and Rebhahn to be the proper inventors. A2016; 2017. As this Court has stated, "[t]o the extent that conflicting viewpoints were presented to the jury [on the question of inventorship], that was within the province of the jury. . . . [T]here was substantial evidence on which a reasonable jury could have found that the inventors were correctly named." *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624, 225 U.S.P.Q. 634, 641 (Fed. Cir. 1985). Thus, inventorship is a factual determination. See, *also*, *Amax Fly Ash Corp.*, 514 F.2d at 1049, 182 U.S.P.Q. at 215. On appeal, this Court "must accept the factual findings, presumed from a favorable jury verdict, which are supported under the substantial evidence/reasonable jury standard." *Newell Companies, Inc. v. Kenney Mfr'ing Co.*, 864 F.2d 757, 765, 9 U.S.P.Q.2d 1417, 1423 (Fed. Cir. 1988). In the present case, substantial evidence, when considered in light of the proper legal standard, clearly supports the jury's finding of proper inventorship.

In determining the question of inventorship, the threshold question must always be who conceived the invention. *Consolidated Aluminum Corp. v. Foseco International Ltd.*, 10 U.S.P.Q.2d 1143, 1172 (N.D. Ill. 1988). Conception is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*,

802 F.2d 1367, 1376, 231 U.S.P.Q. 81, 87 (Fed. Cir. 1986). The conception must also be of the invention defined in the claims, Amax Fly Ash, 514 F.2d at 1048, 182 U.S.P.Q. at 215, and the claimed invention consists of the preamble in combination with the improvement when the claims are in the Jepson format as in the present case. Pentec, Inc. v. Graphic Controls Corp., 776 F.2d 309, 315, 227 U.S.P.Q. 766, 770 (Fed. Cir. 1985).

As discussed above, the evidence proved that Rebhahn and Cook conceived the invention: a reduced cost commercially viable continuous process for purifying to FDA certifiable quality and with low dye loss FD&C Red 40 and FD&C Yellow 6 directly from the coupling solution using membrane separation technology by separating molecules of very close molecular size, while eliminating salting out altogether. The actual specific dye synthesis process contained in the preamble clearly was not invented by anyone at Osmonics; however it clearly *was* a part of the process conceived by Rebhahn and Cook. Further, Cook and Rebhahn conceived the basic essence of the invention: proceeding directly from a specific coupling solution, containing a specific dye as well as a narrowly defined set of impurities, to spray drying of an FDA certifiable dye by utilizing a membrane separation process. It is proper in determining questions of conception to consider the gist or essence of the invention. Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1529, 1533 n.8, 3 U.S.P.Q.2d 1321, 1325 n.8 (Fed. Cir. 1987). There was no evidence presented at trial that anyone at Osmonics conceived of the patented process. Thus, the jury's implied finding that Cook and Rebhahn alone conceived the invention is supported by substantial evidence. See, also, A152-3, 168-9, 179, 182, 185-90, 209-10, 226-7, 359-60, 346, 408-9, 414, 428, 458, 502, 505-7, 511, 1204-7, 1256-7, 1270, 1304-5, 1316-8, 1326-49, 1357-85, 1390-3, 1399-1400, 1405-7, 1412-1430, 1441-2, 1445, 1459-62, 1467-9, 1491, 1496, 1498, 1507, 1509, 1516, 1521, 2841-86, 2893-2994, 3091-3106, 3108-3150.

Once the process had been conceived, Cook hired Osmonics only to evaluate the feasibility of the conceived process. A1452. Once conception has taken place, "[a]n inventor 'may use the services, ideas, and aid of others in the process of perfecting his invention

without losing his right to a patent.'" Shatterproof Glass, 758 F.2d at 624, 225 U.S.P.Q. at 641. An inventor need not himself undertake all the steps necessary to reduce the invention to practice in order to be an inventor. Idacon, Inc. v. Central Forest Products, Inc., 3 U.S.P.Q.2d 1079, 1088 (E.D. Okla. 1986). In addition, a person who merely follows the instructions of another in performing experiments is *not* an inventor. Consolidated Aluminum, 10 U.S.P.Q.2d at 1172. If the rule were otherwise, then the named inventors on many patents would become an endless litany of every laboratory technician and assistant that ever performed work on a project that ultimately resulted in a patentable invention. The patent law contemplates on "inventor" as one who makes an "inventive contribution," not one who merely follows the instructions of another as a "pair of hands."

Hilton Davis hired Osmonics to test dye coupling solutions prepared and furnished by Hilton Davis. A1205. Dr. Cook set all of the objectives and specifications for the testing, including the amount of salt that the process had to remove, the required dye purity, acceptable dye loss levels, the pH tests were to be run at, and all of the other criteria for the claimed process. A187; 505; 1204; 1207; 1327; 1341; 1367; 1381-3; 1461-2. The evidence also showed that Osmonics had never purified dyes to the level of purity required by Hilton Davis, and even lacked the capability and equipment necessary to evaluate whether or not the process actually achieved Dr. Cook's objectives. A179; 187; 189; 1330; 1342-3; 1445; 1498. The ultimate conclusion as to whether or not the process actually achieved what Rebhahn and Cook had conceived was made by Cook, and not anyone at Osmonics. A1270; 1330; 1332; 1334; 1369. Thus, the substantial evidence at trial was that Cook merely enlisted the "services, ideas and aid" of Osmonics in perfecting his and Rebhahn's invention. Shatterproof Glass, 758 F.2d at 624, 225 U.S.P.Q. at 641. The jury correctly found that *that* enlistment does not make anyone other than Cook and Rebhahn inventors of the patented process.

Finally, the failure of others to claim inventorship is evidence permitting an inference that they are not inventors. O'Reilly v. Morse, 56 U.S. (15 How.) 62, 109, 14 L. Ed. 601, 622 (1854). In

the present case, Osmonics' president testified that no claim had been made by Osmonics to inventorship, even though he also stated that it was important that Osmonics retain the right to its own technology. A1193; 1203. Here, too, industry custom would not have considered anyone from Osmonics an inventor. A1370. Thus, this evidence further supports the jury's factual conclusion that Rebhahn and Cook are the only true inventors of the Hilton Davis patent.

D. Warner-Jenkinson's Prior Work Does Not Affect The Presumed Validity Of The Cook Patent

It is irrelevant whether Warner-Jenkinson's prior work qualifies as legal prior art because it is distinguishable from the patented invention. As described above, the 1982 Warner-Jenkinson dye solution resulted from a redissolved salted-out press cake, and did not directly use the coupling solution. Also, the test was not successful. Thus, Warner-Jenkinson had no actual reduction to practice, which requires that the process be embodied in a physical form sufficient to demonstrate that it will work practically for its intended purpose. *Tomecek v. Stimpson*, 513 F.2d 614, 617-8, 185 U.S.P.Q. 235, 238-9 (CCPA 1975); *Kimberly-Clark Corporation v. Johnson & Johnson*, 745 F.2d 1437, 1445, 223 U.S.P.Q. 603, 609 (Fed. Cir. 1984). A reduction to practice is necessary to qualify as § 102(g) prior art. *Kimberly-Clark*, 745 F.2d at 1444, 223 U.S.P.Q. at 606.

Warner-Jenkinson's work also does not qualify as § 102(g) prior art because it was abandoned, suppressed or concealed. No steps were taken to make the process publicly known, such as filing a patent application or using the invention publicly. *Lutzker v. Plet*, 843 F.2d 1364, 1366, 6 U.S.P.Q. 2d 1370, 1371 (Fed. Cir. 1988), *citing Correge v. Murphy*, 705 F.2d 1326, 1330, 217 U.S.P.Q. 753, 756 (Fed. Cir. 1983). Since Warner-Jenkinson did nothing with its process for three and a half years, and in fact kept it secret, there is an inference of abandonment, suppression or concealment which must be drawn in Hilton Davis' favor. *Lutzker*, 843 F.2d at 1367, 6 U.S.P.Q. at 1371; *Toth v. Yoder Company*, 749 F.2d 1190, 1194 (6th Cir. 1984); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721

F.2d 1540, 1550, 6 U.S.P.Q. 2d 1277, 1284 (Fed. Cir. 1983) (Law favors one who publicly discloses process over one who conceals it).

E. Warner-Jenkinson Failed To Prove The Cook Invention Obvious

1. The District Court Correctly Interpreted The Scope Of The Claim

Warner-Jenkinson accuses the Trial Court and the jury of reading limitations from the specification into the claims. However, the patent specification can be used to ascertain the scope and meaning of limitations already in the claims. Specialty Composites v. Cabot Corp., 845 F.2d 981, 987, 6 U.S.P.Q. 2d 1601, 1604 (Fed. Cir. 1988); McGill, Inc. v. John Zink Co., 736 F. 2d 666, 674, 221 U.S.P.Q. 944, 949 (Fed. Cir. 1984). Each of the limitations argued by Warner-Jenkinson appears in the claim; the only issue was the meaning of those limitations, a factual inquiry resolved by the jury and the Trial Court. The extrinsic evidence properly interpreted what was meant by the claim language. Intervet America, Inc. v. Kee-Vest Laboratories, Inc., 887 F.2d 1050, 1053, 12 U.S.P.Q. 2d 1474, 1477 (Fed. Cir. 1989). Further, although claim interpretation is ultimately a question of law, in cases such as the present one involving complex scientific principles and conflicting expert testimony, an underlying factual question is created, and due deference must be given to the decision of the jury and trial judge. Tol-O-Matic v. Proma Produkt-Und Mktg., 945 F.2d 1546, 1549-52, 20 U.S.P.Q. 2d 1332, 1336 (Fed. Cir. 1991); Howes v. Medical Components, Inc., 814 F.2d 638, 643, 2 U.S.P.Q. 2d 1271, 1273 (Fed. Cir. 1987). The implied finding in Hilton Davis' favor concerning the meaning of disputed claim language is supported by substantial evidence and should not be disturbed in the present case.

a. The Claims Are Limited To High Purity Dyes

Warner-Jenkinson argues that the claims are not limited to FD&C dyes certified by the FDA. One of the key objectives of the patented process is achieving the high purity levels required for FDA certification. A221-2; 378-9; 381; 383. This objective is clearly stated in the specification. A2173-5 (col. 4, lines 19-23, col. 5, lines

62-64, col. 2, lines 31-34). This purity requirement is expressed in the claims by the two limitations: "substantially all said impurities have been removed from said concentrate" and "recovering said dye in approximately 90% purity from said concentrate." Further, in the claim, the required removal of impurities is evidenced by "their essential absence in said permeate." "Impurities" refers to organic compounds (e.g., Schaeffer's salt, PSCA) and inorganic impurities (inorganic salts). A378. The language "substantially all said impurities" refers to removing impurities necessary to meet FDA specifications. A379. All of the examples given in the patent for FD&C Red 40 and FD&C Yellow 6 are defined in terms of levels of impurity necessary to meet FDA standards, and nowhere is there any reference to an FD&C Red 40 purity level other than in terms of the FDA requirements. A221-2; 225; 379-80; A2176-7 (cols. 9, 10, 12). The language "approximately 90% purity" refers not to the impurity level, but rather to the amount of pure color, i.e., the dye itself. A382; 1301. Warner-Jenkinson's expert admitted that purity was a "key" to the process. A824.

Finally, Warner-Jenkinson admits that the chemical formulas recited in claim 1 for the dyes at issue are "FD&C Red #40" and "FD&C Yellow #6." (Addendum Exhibit C to Appellant's Brief.) The evidence is undisputed that an FD&C dye is one certified by the FDA. This evidence is clearly sufficient to support an interpretation that the claims are limited to dyes having purity levels sufficient to meet FDA certification.

b. The Cook Invention Eliminates The Prior Art "Salting-Out" Step

Warner-Jenkinson argues that the claims cover dye solutions which are directly ultrafiltered and produced from a redissolved press cake formed by salting out, pointing to elimination of the word "directly" in the CIP claims as filed.

Claim 1 as originally filed read "directly subjecting the reaction mixture resulting from said coupling to ultrafiltration." A1890; 2041. In the CIP application, that language was changed to read "subjecting an aqueous solution of the reaction mixture resulting from said coupling . . . to ultrafiltration." There is no evidence why this

change in language was made; certainly it was not made in response to avoid prior art. Thus, we "cannot speculate on the reasons for the [change]; we can only interpret the clear language of the claims as granted." Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1563, 19 U.S.P.Q. 2d 1500, 1504 (Fed. Cir. 1991). However, it is clear that the specification in numerous places stresses the need to avoid salting out and the addition of salt to the process. A2174-6 (col. 4, lines 14-18, col. 7, lines 55-57). Moreover, Booth was distinguished *inter alia*, on the basis of eliminating the steps of salting out and the addition of salt. Thus, the *addition* of salt, as speculated by Warner-Jenkinson, would make no sense in the patented process which is intended to *remove* salts. A247; 2151-6; 2164-6. Consequently, it is a reasonable inference that the word "directly" was dropped as mere surplusage, since the term is not necessary if the reaction mixture resulting from the coupling itself is being directly subjected to ultrafiltration. Obviously, with an intervening salting-out step, there would be no way for an "aqueous solution of the reaction mixture resulting from said coupling" to be subjected to ultrafiltration. Moreover, claim coverage for a process which incorporates salting out, in combination with the other limitations, was clearly surrendered during prosecution because of the arguments made to distinguish over Booth. Thus, this case falls squarely within the holding of Unique Concepts where the court rejected the argument that a claim should be read broadly to cover two disclosed embodiments, where one of those embodiments was clearly surrendered during prosecution. 939 F.2d at 1563, 19 U.S.P.Q. at 1504.

Further, there was evidence to show that in the dye industry, the "reaction mixture" means the solution where the reaction takes place, not a solution of dye after it had been salted out or redissolved. A484-5. Probably most probative, is the testimony of Warner-Jenkinson's expert who testified that the redissolving of a press cake was not included as part of Claim 1. A830.

2. Warner-Jenkinson Failed To Prove The Cook Invention Obvious

a. Warner-Jenkinson Ignores The Invention As A Whole

Warner-Jenkinson ignores the requirement that obviousness is judged of the claimed subject matter as a whole based upon the four *Graham* factual findings. *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 291, 227 U.S.P.Q. 657, 662-3 (Fed. Cir. 1985). Further, both the Trial Court and the jury found that Warner-Jenkinson had not proved the claims invalid; thus, the existence of factual findings and legal conclusion necessary to support the verdict reached by the jury is presumed. *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corporation*, 739 F.2d 604, 607, U.S.P.Q. 654, 656 (Fed. Cir. 1984). Warner-Jenkinson must show either that the jury's presumed findings are not supported by substantial evidence, or that the legal conclusions implied from the special verdict cannot be supported by those findings. *Ibid.*

b. The Scope And Content Of The Prior Art

The scope of the prior art is that reasonably pertinent to the particular problem facing the inventor. *Lindemann Maschinenfabrik GmBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1460, 221 U.S.P.Q. 481, 487 (Fed. Cir. 1984); *Stratoflex, Inc. v. Aeroquip Corporation*, 713 F.2d 1530, 1535, 218 U.S.P.Q. 871, 876 (Fed. Cir. 1983). The problem facing the Hilton Davis inventors, described above, was the development of a reduced cost commercially viable continuous process for purifying to FDA certifiable quality and with low dye loss FD&C Red 40 and FD&C Yellow 6 directly from the coupling solution using membrane separation technology by separating molecules of very close molecular size, while eliminating salting out altogether. The prior art simply did not address that specific problem.

c. The Booth Patent Is Substantially Different From The Hilton Davis Invention

As noted above, Booth was distinguished during prosecution and at trial on the basis of the ***combination*** of ***four*** primary differences. The pH and pressure factors have been discussed. It should be

noted, however, that Warner-Jenkinson mischaracterizes the testimony of Dr. Cook that pH had minimal effect on the operation of the process. The evidence, cited above, noted that while pH *per se* would not effect molecular separation, it was an important factor to preserve the stability of the membrane. Booth's high pH would have destroyed the membrane in the patented process. A248. Similarly, the patented process would not work at all with Booth's low pressures. A253.

Warner-Jenkinson argues that there is nothing in the claims which excludes the addition of salt. However, the arguments made to distinguish over Booth clearly place that limitation in the claim, as Warner-Jenkinson admits. Appellant's Brief, at 43. Moreover, the removal of impurities as expressly required in the claim is antithetical to the addition of more impurities, such as salt. Also, as noted above, the limiting language "subjecting an aqueous solution of the reaction mixture resulting from said coupling" clearly precludes, to one of ordinary skill in the art, the addition of salt through a separate salting-out process.

Finally, Warner-Jenkinson concedes that the difference in molecular size of the Booth and patented processes is a major difference. The problem was separating dyes from impurities of very close molecular size, a problem not present in Booth.[2] Consequently, differentiation was much more difficult and required significant tradeoffs, particularly with respect to the elusive Schaeffer's salt impurity.

d. The Osmonics Bulletin Is Substantially Different From The Hilton Davis Invention

This prior art was considered on at least two occasions by the examiner during prosecution, and is described in the patent specification. A2047, 2144. While this Bulletin contains broad

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[2] Booth dealt with "polymeric colors" having molecular weights of thousands to hundreds of thousands; FD&C Red 40 and FD&C Yellow 6 have molecular weights of 400-500. A245-6; 456; 1280; 2111-70.

"recommended" operating conditions for various membranes, it does not describe or suggest their use in connection with the purification of food dyes, or any similar material. A267. Nor is there any suggestion of the particular combination of membranes or parameters which could be used in an operational food dye purification process of the type claimed in the Hilton Davis patent. A1318. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Carella v. Starlight Archery & Pro Line Co., 804 F.2d 135, 140, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986). Warner-Jenkinson failed to carry its burden to show there was some suggestion in the Bulletin to combine its teachings with other prior art to produce the *specific* process claimed by Hilton Davis, particularly for the types of dyes and impurities involved. In particular, there is nothing in the Bulletin to suggest a membrane which would achieve the types of tradeoffs considered by Dr. Cook to result in the claimed process to achieve acceptable dye retention and impurity passage. In fact, the Bulletin teaches away from the Hilton Davis invention by suggesting membranes with high salt rejection (98CA, 97CA) and lower maximum pressures (50CA, 300 psig).

The lack of suggestion in the Bulletin is further shown by the unpredictability of applying particular membranes to specific materials, which includes many complex factors, and the inability of both Hilton Davis and Warner-Jenkinson to produce acceptable results using, even with Osmonics' participation, information from the Bulletin. A184; 277; 425-6; 553-8; 692; 1268; 1332; 3033-45 ("the separation between the dyes and the intermediates of similar molecular weights will be the most difficult tasks"); A285-9. The failure of others, particularly the alleged infringer, to find a feasible solution to a long-standing problem is strong evidence of non-obviousness. Intel Corp. v. International Trade Commission, 946 F. 2d 821, 835, 20 U.S.P.Q. 2d 1161, 1173 (Fed. Cir. 1991); In re Piasecki, 745 F.2d 1468, 1475, 223 U.S.P.Q. 785, 790 (Fed. Cir. 1984). Even Osmonics, a supposed "expert" in the field, was puzzled why Hilton Davis had acceptable results, but Warner-Jenkinson did not using Osmonics membranes. A3085.

e. The British Patent Is Substantially Different From The Hilton Davis Invention

The British patent is nearly identical to the South African patent considered by the PTO, both resulting from related work by Ciba-Geigy. Warner-Jenkinson's expert also admitted that the British and Booth patents were fundamentally very similar to each other. A806. Consequently, Warner-Jenkinson's burden to show invalidity was more difficult to meet. Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 447, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). The heavy burden of showing the British patent is more pertinent than the prior art considered by the PTO has not been overcome. American Hoist & Derrick Company v. Sowa & Sons, Inc., 725 F.2d 1350, 1360, 220 U.S.P.Q. 763, 770 (Fed. Cir. 1984).

It is also noteworthy that seven years later, Ciba-Geigy still had not solved the basic problem addressed by the British patent, as evidenced by the later South African work. The goal of the British process was to remove excess salt to insure that the textile dyes did not separate in storage, rather than purifying a dye to high purity levels as with the Hilton Davis invention. The processes described in the British patent began with a press cake produced by salting out (adding additional salt to the dye solution), which was then redissolved to produce a suspension which was subjected to ultrafiltration. A139-41; 827; 835-7; 841-2; 844-5; 2362-2376 (examples 1-52). This is the antithesis of the Hilton Davis patent which eliminates the salting out step, and deals with a *solution*. The British patent suggests proceeding from the coupling solution only where the dye *cannot* be salted out except with extreme difficulty to produce a press cake; neither FD&C Red 40 nor FD&C Yellow 6 is difficult to salt out. A270; 494; 2364. And, this example described "a printing paste for printing paper" of unspecified purity, not a high purity *dry* FD&C food dye. A884-5. Thus, the British process is not germane to the problem facing the Hilton Davis inventors which involved dyes easily salted out. Further, the Hilton Davis Process was not concerned with the British solubility problem, but rather purifying the dyes to specified purity levels. See, Lindemann

Maschinenfabrik GmBH v. American Hoist and Derrick Co., 730 F.2d 1452, 1460, 221 U.S.P.Q. 481, 487 (Fed. Cir. 1984).

The British patent also does not teach purifying to high levels of purity, but only of achieving a "purifying effect" of unspecified purity. There is a substantial difference between a "purifying effect" and "purity," the former referring to how much impurity is removed, the latter to the end result of purification. A271; 488-90; 492-3; 843-5; 847; 850; 1447-8.

The evidence also showed that the wide generic membrane pore size and pressure ranges would not work for separating impurities from the dye in the Hilton Davis process. A488-9.

The subsequent Koll patent teaches that the process described in the British patent "has the disadvantage that severe sedimentation of the dyestuffs occurs in the flow channels of the membrane separation equipment and blockages arise." A3088 (col. 1, lines 48-51). This showed the British process dealt only with dyes that were sparingly soluble or insoluble in water, as distinguished from the claimed "aqueous solution of the reaction mixture." Further, Koll shows the British process didn't work, since it produced a dispersion or a suspension which was turbid, settled out, and blocked the membranes. A729; 744, 830; 833; 1529-30; 1563-4; 1573; 1577; 1579-80; 1585; 1593-4. These defects in the British patent fail to suggest, but rather teach away from, the Hilton Davis invention. *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1577-8, 19 U.S.P.Q. 2d 1241, 1248 (Fed. Cir. 1991); *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 299, 227 U.S.P.Q. 657, 672 (Fed. Cir. 1985).

Basically, Warner-Jenkinson argues it would be "obvious to try" the British approach. That standard is not the test for obviousness. *Hodosh v. Block Drug Co.*, 786 F.2d 1136, 1143, n.5, 229 U.S.P.Q. 182, 187, n.5 (Fed. Cir. 1986).

f. There Is No Separate "Starting Material" Or "Numerical Value" Test For Obviousness

Warner-Jenkinson argues the claims are obvious because the starting material is old, and the claimed ranges overlap the prior art.

These arguments do not provide an independent basis for determining obviousness -- *Graham* remains the touchstone.

Further, contrary to Warner-Jenkinson's assertion, the differences between the claimed process and the prior art comprise more than just the selection of the specific starting materials. In determining questions of obviousness, the subject matter of the claim *as a whole* must be considered. 35 U.S.C. § 103. Obviousness must also be examined in light of the problem facing the inventor. *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 935, 15 U.S.P.Q. 2d 1321, 1324 (Fed. Cir. 1990). Rebhahn and Cook were looking for a process that would eliminate the costly salting-out step, and there is simply nothing in the prior art which would render their claimed process as a whole obvious.

Warner-Jenkinson has correctly stated that *mere* selection of a starting material, by itself, is not patentable invention. Its reliance on *In re Durden* and similar cases, however, is clearly misplaced. As this Court recently stated:

> Suffice it to say that we do not regard *Durden* as authority to reject as obvious every method claim reading on an old type of process, such as mixing, reacting, reducing, etc. The materials used in a claimed process *as well as the result obtained therefrom*, must be considered along with the specific nature of the process, and the fact that new or old, obvious or nonobvious, materials are used or result from the process *are only factors to be considered, rather than conclusive indicators of the obviousness or nonobviousness* of a claimed process. When any applicant properly presents and argues suitable method claims, they should be examined in light of all these relevant factors, free from any presumed controlling effect of *Durden*. *Durden* did not hold that all methods involving old process steps are obvious; the court in that case concluded that the particularly claimed process was obvious; it refused to adopt an unvarying rule that the fact that nonobvious starting materials and nonobvious products are involved ipso facto makes the process nonobvious. Such an invariant rule always leading to the opposite conclusion is also not the law.

In re Dillon, 919 F.2d 688, 695, 16 U.S.P.Q. 2d 1897, 1903 (Fed. Cir. 1990). Even *Durden* recognized that the evidence must be considered on its own facts and for the "subject matter as a whole". 763 F.2d at 1410, U.S.P.Q. at 362. Thus, the fact that old starting materials are being utilized does not, by itself, render a process obvious. All of the materials and results, as well as the nature, of the claimed invention must be considered. When that proper legal test is applied, the Hilton Davis invention is not an obvious one.

Furthermore, the fact that the claimed numerical ranges may arguably overlap those shown in the prior art, does not change the fact that it is the claimed process *as a whole* which must be considered. Focusing on the obviousness of substitutions and differences, instead of the invention as a whole is a legally improper way to determine obviousness. *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 724, 16 U.S.P.Q. 2d 1923, 1927 (Fed. Cir. 1990). The prior art discloses many different ranges, all unique to particular applications and materials. Where the prior art gives no indication of which of many possible choices are likely to be successful, an "obvious to try" situation is presented, *In re O'Farrell*, 853 F.2d 894, 903, 7 U.S.P.Q. 2d 1673, 1681 (Fed. Cir. 1988), which is an impermissible standard for determining obviousness.

Warner-Jenkinson's statement that Hilton Davis did not prove any unexpected results is equally erroneous, as such a requirement would improperly shift the burden of proof. There is simply no requirement that Hilton Davis show any new and unexpected results, nor must such even exist for the claims of the patent to be valid. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360, 220 U.S.P.Q. 763, 771 (Fed. Cir. 1984).

3. The Jury Impliedly Resolved The Factual Issue Of The Level Of Skill In Hilton Davis' Favor

The level of ordinary skill in the art is a factual question. *Ryko Manufacturing Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718, 21 U.S.P.Q. 2d 1053, 1057 (Fed. Cir. 1991). The substantial evidence showed that the "art" is the purification of food dyes to FDA certifiable quality, and that workers in that field at the time of the Hilton Davis invention typically had an advanced degree in

chemistry, a minimum of several years experience, but very little experience in ultrafiltration or similar processes. A178; 319-20; 414; 553. Moreover, even if the person of ordinary skill is defined as one involved in membrane technology work, that person would not have been familiar with the specific problems of purifying a concentrated dye solution to remove the unreacted starting materials and impurities present. A553-4. Thus, there was substantial evidence to support the level of skill advanced by Hilton Davis implied from the jury's conclusion on non-obviousness.

4. There Are Substantial Objective Indicia Of Non-Obviousness

Warner-Jenkinson ignores the substantial objective indicia of non-obviousness in this case, some of which has already been discussed. Both parties' dyes made by the patented process were significantly commercially successful, both parties had realized a substantial cost savings, and no other U.S. manufacturer produced food dyes by any other method. A113-5; 186; 622; 1002-4; 1070-1; 1151; 3223. Commercial success is a strong factor favoring non-obviousness. *AKZO N.V. v. U.S. International Trade Commission*, 808 F.2d 1471, 1481, 1 U.S.P.Q. 2d 1241, 1246 (Fed. Cir. 1986), particularly when compared to the unsuccessful prior processes e.g., Booth. *TWM Manufacturing Company, Inc. v. Dura Corporation*, 722 F.2d 1261, 1266 , 221 U.S.P.Q. 25, 28 (6th Cir. 1983).

There was a long-standing need to eliminate the salting-out process, which had not previously been solved by Dynapol, Warner-Jenkinson or anyone else. Warner-Jenkinson's expert admitted in 1985 that "few, if any, commercial applications" had been found for the generic type of process practiced by Hilton Davis and Warner-Jenkinson. Contemporaneous publications of Osmonics failed to mention any applications similar to Hilton Davis' invention. Even after Hilton Davis' invention, a major membrane manufacturer acknowledged that "no single separation device has yet proved to provide the best performance in every situation, especially because of wide variation in feed materials." A177; 293-5; 325-7; 709; 854-7; 2608-33; 2996-7; 3023-31; 3237. Solving a long-standing problem in an industry is a strong indication of non-obviousness.

See, *Standard Havens Products, Inc. v. Gencor Industries, Inc.*, 953 F.2d 1360, 1370-1, 21 U.S.P.Q. 2d 1321, 1329-30 (Fed. Cir. 1991).

The failure of Warner-Jenkinson and Hilton Davis initially to achieve a successful process is also evidence of non-obviousness. *Intel Corp. v. International Trade Commission*, 946 F.2d 821, 835, 20 U.S.P.Q. 2d 1161, 1173 (Fed. Cir. 1991). Further, there was evidence that Osmonics had supplied Hilton Davis' information to Warner-Jenkinson to make its process viable, as noted above. Copying by an alleged infringer can be an objective indication of non-obviousness. *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546, 221 U.S.P.Q. 1, 7 (Fed. Cir. 1984).

The unpredictability of membrane purification was also demonstrated by the failure to successfully process similar dyes, such as Blue 1, even though it was expected that this dye would be easier to process than FD&C Red 40 because of its larger dye molecule. Both Hilton Davis and Warner-Jenkinson were unable to successfully process this dye, demonstrating (as in the case of the British process) that not all dyes can be successfully subjected to ultrafiltration. A211-3; 297-8; 1027-8; 3046-67.

5. The Jury's and Court's Conclusion Of Non-Obviousness Is Correct

In this appeal, Warner-Jenkinson has failed to show, clearly and convincingly, that this Court should reach a conclusion on non-obviousness any different from that arrived by the District Court or the collective judgment of the eight jurors. Today, ten years later, with the aid of 20/20 hindsight, and full knowledge of the patented process, the Hilton Davis invention might seem "obvious." However, in 1982, it truly was an innovation in the food dye industry where purification was still being done by the archaic salting-out method. The fact "that the elements noted by the court lay about in the prior art available for years to all skilled workers, without, as the court found, suggesting anything like the claimed inventions, is itself evidence of non-obviousness." *Panduit Corporation v. Dennison Manufacturing Co.*, 810 F.2d 1561, 1577, 1 U.S.P.Q. 2d 1593, 1605 (Fed. Cir. 1987).

In the obviousness analysis, the focus must be on the specific problem facing the Hilton Davis inventors: development of a reduced cost commercially viable continuous process for purifying FD&C Red 40 and FD&C Yellow 6 to FDA certifiable quality with low dye loss directly from the coupling solution using membranes to separate dye and organic impurity molecules of very close molecular size, while eliminating "salting out" (the addition of salt or formation of a press cake).

Warner-Jenkinson's approach is to dissect the claims and prior art into separate pieces, and then pick and choose favorable facts, while discarding unfavorable facts. That is improper. Smithkline Diagnostics, Inc. v. Helena Laboratories Corporation, 859 F.2d 878, 886-7, 8 U.S.P.Q. 2d 1468, 1475 (Fed. Cir. 1988). The entire claimed invention must be considered in view of all of the prior art. Panduit Corporation v. Dennison Manufacturing Co., 810 F.2d 1561, 1566, 1 U.S.P.Q. 2d 1593, 1595 (Fed. Cir. 1987). The prior art focused on separating dye and impurity molecules of large size differential (Booth), adding salt or creating an intermediate press cake (Booth, British), or creating a membrane-clogging suspension rather than a true solution (British, Koll). The prior art was not concerned with the type of synergistic tradeoffs necessary to produce extremely high purity dyes without significant dye loss through the membrane (cf. British). Hilton Davis' departure from these previous approaches indicates non-obviousness. Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1546, 221 U.S.P.Q. 1, 7 (Fed. Cir. 1984). Here, the prior art skirts all around the claimed invention, but does not suggest it. However, it is immaterial that all of the process elements were old. Gillette Company v. S.C Johnson & Sons, Inc., 919 F.2d 720, 724, 16 U.S.P.Q. 2d 1923, 1927 (Fed. Cir. 1990) There is lacking a clear suggestion of a viable process *in toto*, which separates dyes in *aqueous solution* such as FD&C Red 40 and FD&C Yellow 6 from organic impurities of *very close* molecular size; eliminates adding large quantities of salt; utilizes an aqueous solution thereby avoiding large suspended particles which clog the membrane; operates within a pH range which protects the membrane while not adversely affecting dye chemistry; operates within a pressure range which overcomes the osmotic pressure of the complex dye/impurity solution; passes substantially all impurities (particularly

the difficult to remove Schaeffer's salt) through the membrane to achieve FDA impurity levels, while retaining sufficient dye on the upstream side of the membrane to make the process commercially viable; achieves drying the resulting concentrate directly from the filtered coupling solution; and achieves a 90% pure dye level in the final dried product. This combination of features is not suggested by the prior art. "Where, as here, nothing of record plainly indicates that it would have been obvious to combine previous separate process steps into one process, it is legal error to conclude that a claim to that process is invalid under 35 U.S.C. § 103." *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1546, 225 U.S.P.Q. 26, 32 (Fed. Cir. 1985). Warner-Jenkinson's focus on substitutions and differences, rather than on the invention as a whole, is legally improper. *Gillette Company v. S.C. Johnson & Sons, Inc.*, 919 F.2d 720, 724, 16 U.S.P.Q. 2d 1923, 1927 (Fed. Cir. 1990); *Stratoflex, Inc. v. Aeroquip Corporation*, 713 F.2d 1530, 1537, 218 U.S.P.Q. 871, 877 (Fed. Cir. 1983).

The objective evidence also supports the District Court's conclusion of non-obviousness: the initial failure of Hilton Davis and Warner-Jenkinson (even with the involvement of Osmonics), surprise by Osmonics (a supposed "expert"), the inability of Osmonics to suggest a viable membrane, the uncertainty and unpredictability of membrane separation, the absence of contemporaneous applications of similar process, the parties' commercial success, Warner-Jenkinson's use of Hilton Davis' information to achieve a viable process, etc.

Considering the foregoing evidence together under the *Graham* test, the District Court (and the jury) were clearly correct in concluding that Warner-Jenkinson had not met its burden of showing obviousness.

6. Warner-Jenkinson Failed To Prove The Dependent Claims Obvious

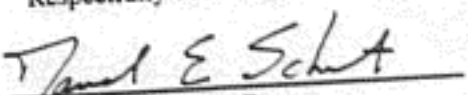
It is Warner-Jenkinson's *burden* to show *invalidity*, not Hilton Davis' burden to show *validity* of dependent claims. Warner-Jenkinson has not met its burden. The *Gardner* case, cited by Warner-Jenkinson, is not applicable. There, the claims had been

held invalid, and thus the patent owner assumed the burden of overcoming that holding. In the present appeal, the dependent claims remain valid until obviousness of their subject matter as a whole has been shown, a burden not met by Warner-Jenkinson.

VI. Conclusion

This Court is respectfully requested to affirm the judgment of the District Court.

Respectfully submitted,

By: 

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CERTIFICATE OF SERVICE

I hereby certify that two copies of the foregoing CORRECTED BRIEF FOR PLAINTIFF-APPELLEE, HILTON DAVIS CHEMICAL CO. have been served by First Class U.S. Mail, postage prepaid, on Appellant's counsel, J. Robert Chambers, WOOD, HERRON & EVANS, 2700 Carew Tower, Cincinnati, Ohio 45202, this 22nd day of March, 1993.

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