Appellant's Brief

BRIEF FOR DEFENDANT-APPELLANT, WARNER-JENKINSON COMPANY, INC.

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

Counsel for Appellant, Warner-Jenkinson Company, Inc., hereby certifies as to the following:

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

Warner-Jenkinson Company, Inc.

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

Warner-Jenkinson Company, Inc.

3. Warner-Jenkinson Company, Inc. is a wholly owned subsidiary of Universal Foods Corporation. Warner-Jenkinson Company, Inc. has no subsidiaries or affiliates that have issued shares to the public.

4. The names of all law firms as partners or associates that appeared for Warner-Jenkinson Company, Inc. are:

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Only J. Robert Chambers is expected to appear in this court.

Respectfully submitted,

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STATEMENT OF RELATED CASES

In compliance with Federal Circuit Rule 47.5, Appellant 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. Appellant 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

The trial court had jurisdiction of the original action under 28 U.S.C. § 1338. This court has jurisdiction to hear the appeal under 28 U.S.C. § 1295. The district court's judgment was entered on June 22, 1992. Timely post-trial motions under Rules 50(b) and 59 of the Federal Rules of Civil Procedure were filed in the district court. Those motions were denied by order entered on October 23, 1992, and therefore the appeal by Warner-Jenkinson Company, Inc. of November 16, 1992, was timely under Rule 4(a)(1) and (4) of the Federal Rules of Appellate Procedure.

STATEMENT CONCERNING ATTORNEY FEES

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

STATEMENT OF THE ISSUES

1. Whether, as a matter of law, there can be liability for patent infringement where the patentee conceded no literal infringement and no proof of equities favoring the patentee was introduced as a basis for triggering application of the equitable doctrine of equivalents?

2. Whether the district court erred in denying motions for judgment as a matter of law of non-infringement and in submitting the equitable doctrine of equivalents to the jury after the patentee conceded no literal infringement?

3. Whether, under the rule of law established in *Lear Siegler* and *Malta*, the district court erred, as a matter of law, in submitting to the jury the issue of infringement under the doctrine of equivalents where the patentee offered no objective evidence of the presence of each claim limitation in the accused process but rather argued only "functional equivalence" based solely on the result achieved by the accused process?

4. Whether the district court erred, as a matter of law, in failing to apply the doctrine of prosecution history estoppel to limit expansion of the patent claims to encompass Warner-Jenkinson's independently developed process, in light of amendments inserted and arguments made in the PTO to secure their allowance?

5. Whether the district court erred, as a matter of law, in failing to grant Warner-Jenkinson's renewed motion for judgment as a matter of law for non-infringement when neither the district court nor a reasonable jury could have found the properly construed claims to cover Warner-Jenkinson's process?

6. Whether the district court erred, as a matter of law, in holding the claims non-obvious based on process parameters alleged in the PTO to be "different" and "critical" to distinguish the prior art where the patentee at trial in an attempt to establish infringement under the doctrine of equivalents disavowed any such "criticality" and stated that

those parameters, in fact, were not critical and made no functional difference to the process?

7. Whether the district court erred, as a matter of law, in holding the claims in issue not invalid where the patentee admitted and other evidence showed that the allegedly "critical" claimed process parameters were provided by others, and were not invented by the named inventors?

8. Whether, as a matter of law, Warner-Jenkinson's own earlier and independently developed process is prior art and/or evidence of obviousness?

9. Whether the district court erred, as a matter of law, in holding the claims at issue not invalid where prior art patents showed ranges overlapping the claimed ranges for processing similar materials, and the patentee presented no evidence of unexpected results due to the claimed ranges?

10. Whether the district court erred, as a matter of law, in the obviousness analysis, in holding claims to a known process unobvious as applied to different starting materials?

STATEMENT OF THE CASE

I. Statement Of Facts

A. The Action And Parties

In this action, Hilton Davis Chemical Company ("Hilton Davis") contends that defendant, Warner-Jenkinson Company, Inc. ("Warner-Jenkinson") has infringed claims 1, 2, 3, 13, and 14 of U.S. Patent No. 4,560,746 ("the '746 patent") (DX502, A2171-80, Exhibit A hereto). The '746 patent is directed to a process for removal of impurities from certain dye solutions by the well-known method of ultrafiltration. Claim 1, the only independent claim, and claims 2, 3, 13, and 14 are reproduced in Exhibit B to this Brief. Claim 1 has been paragraphed and marginal notes added to facilitate its understanding in Exhibit C.

At trial, originally claims 1-6, 13, and 14 were alleged to be infringed. The case was tried to a jury on 9 days between

May 13, 1992, and June 3, 1992. During its direct case, Hilton Davis dropped its charge of infringement of claims 4, 5, and 6. (A411).* At the close of its direct case, Hilton Davis conceded no literal infringement of the remaining claims. (A668). Over Warner-Jenkinson's objection, the case went to the jury on the equitable doctrine of equivalents. On June 16, 1992, the jury returned a verdict that claims 1, 2, 3, 13, and 14 were infringed, that those claims were not invalid, that there was no willful infringement, and awarded Hilton Davis $3,564,705.00 in damages. (A2015-19).

On October 20, 1992, the district court denied from the bench Warner-Jenkinson's renewed motions for judgment as a matter of law of non-infringement and of invalidity, entered judgment in the full amount of the jury award, and entered a permanent injunction. (A001-005). The district court's oral opinion is reproduced in Exhibit G and at A006-070.

Warner-Jenkinson appeals from the October 23, 1992, amended judgment of the district court on the issues of infringement under the equitable doctrine of equivalents and patent validity. No cross-appeal on the issue of willful infringement was filed.

B. Background

Both Warner-Jenkinson and Hilton Davis manufacture, among other products, dyes approved by the Food and Drug Administration ("FDA") for use as colorants in foods, drugs, and cosmetics known generically as FD&C Red #40 and FD&C Yellow #6. According to the '746 patent, these dyes are made by diazotization reactions in the presence of hydrochloric acid to form the diazonium salt ("diazo"), which is then coupled to form the dye. (Exhibits E and F).

It is conceded that diazotization reactions to make azo dyes are more than 100 years old and the specific reactions for

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* Unless otherwise noted, citations (A) are to the Joint Appendix. A "DX" or "PX" prefix is a citation to Defendant's Exhibit or Plaintiff's Exhibit in the Exhibit Books.

making FD&C Red #40 and Yellow #6 are themselves many years old and form no part of the claimed invention. (A416-17). Claim 1 is in Jepson format showing the dye making reactions to be old. (Ex. B).

The mixtures resulting from the diazotization and coupling reactions contain impurities including unreacted starting material, by-products of the reactions, and impurities in the starting materials. (Ex. A, col. 4, l. 43 through col. 5, l. 55). The FDA has promulgated specifications published in the Code of Federal Regulations which set forth the purity levels in terms of maximum allowable amounts of impurities. They do not set forth any requirements as to how the impurities are to be removed.

For many years, both Warner-Jenkinson and Hilton Davis had been manufacturing FD&C Red #40 and Yellow #6 and purifying the dye solutions by a process known as "salting out." The salting out process involved the addition of large quantities of salt, such as sodium chloride, to the reaction solution to crystallize the dye so that it could be filtered from the remaining solution substantially free of impurities. The salting out procedure had disadvantages, however, including the expense of the salt, disposal problems of the brine produced in the final filtrate, and dye loss in the brine.

C. The Nature Of Ultrafiltration And A Brief History

Ultrafiltration (UF), which is sometimes referred to as "reverse osmosis (RO)," is a well-known process wherein a solution containing dissolved molecules, ions, and suspended particles is passed against a membrane, either natural or synthetic, under a hydrostatic pressure. The membrane is specifically designed to let molecules, ions, and particles of a smaller size pass through the membrane while the larger molecules are retained on the other side of the membrane. The material which passes through the membrane is referred to as the "permeate" or "ultrafiltrate" while the material which does not pass through the membrane is referred to as the "retentate" or "concentrate." Reverse osmosis/ultrafiltra-

tion membranes thus act as molecular sieves to segregate molecules based essentially on size. Such membranes have existed for many years, are manufactured out of a variety of materials, and can be engineered to vary the molecular size which will be permitted to pass through the membrane and that which will be retained. This is referred to in the art as the molecular weight "cut off level", i.e., molecules and ions of a size below the "cut off level" pass through the membrane and those of a size larger than the "cut off level" are retained by the membrane. For this reason, ultrafiltration membranes are often referred to as being "semipermeable." (DX548, A2584-89; DX551, A2608-32; DX552, A2634-51).

In the case of FD&C Red #40 and Yellow #6, the dye molecules have molecular weights of about 496 and 451 respectively. The organic impurities, cresidine sulfonic acid (CSA), Schaeffer's salt (SS), and sulfanilic acid (SA) have respective molecular weights of about 217, 262, and 173. The sodium and chloride ions are very much smaller and thus readily pass through the membrane with the water (molecular weight 18) into the permeate. Accordingly, if a membrane can be manufactured to have a "cut off level" of above about 300 but below about 450, the dye molecules can be retained on one side of the membrane while the salt, water, and organic impurities (CSA, SS, and SA) pass through to the permeate. (A165-67). However, triazene, another organic impurity, has a molecular weight close to the dyes and therefore does not pass through the membrane with the other impurities.

A relatively extensive discussion of membrane separation technology as it existed prior to the '746 patent is found in a July, 1978, article appearing in *Scientific American*. (DX512, A2344-2361).

D. Development Of Warner-Jenkinson's Process For Ultrafiltration of FD&C Red #40 and Yellow #6

In 1978, Warner-Jenkinson formed a joint venture with a West Coast company called Dynapol. Dynapol was formed in

the 1970's by a group of scientists to develop new and state of the art dyes for use in foods and drugs. Dynapol's idea was to depart from the traditional method of making dyes, such as azo dyes, which companies like Warner-Jenkinson and Hilton Davis had used for years, and rather to generate long polymeric backbones to which a chromophore, e.g., azo chromophore groups, would be attached to form the colorant. The idea was that with a large polymeric backbone to which the dye was attached, the size of the molecule would prevent it from passing through the walls of the human intestinal tract into the body. Rather, the new dyes would not be absorbed into the blood and tissue but would pass through the human body unabsorbed, thereby eliminating any possible health effects. Dynapol also had departed from the traditional "salting out" procedure to remove impurities from the solution and had adopted instead the use of direct ultrafiltration to purify the dye reaction solutions. (DX506, A2209-18).

Dynapol filed patent applications on a number of its developments. One such application was filed on November 18, 1976, and issued February 19, 1980, as U.S. Patent No. 4,189,380, to Booth et al. for an improvement in the ultrafiltration purification of solutions of polymeric colorants. (DX506). The Booth et al. patent describes Dynapol's application of semipermeable membranes and ultrafiltration to directly purify dye reaction solutions, without an intervening "salting out" step, to remove both organic and inorganic impurities. (Col. 2, l. 7-46). The patent is important because it subsequently became the principal reference cited by the PTO Examiner against Hilton Davis' applications.

In 1978, Warner-Jenkinson's then Manager of R&D, Dr. Lance Solter, traveled to the west coast to view the operation of Dynapol's plant. There he observed Dynapol's use of ultrafiltration to purify the polymeric dye reaction solutions. (A1008-15).

Dr. Solter returned to Warner-Jenkinson and did nothing further with ultrafiltration of Warner-Jenkinson's dyes until the summer of 1982. Dr. Solter, although highly skilled as a dye chemist, had no particular expertise in ultrafiltration purification. (A1008-11). However, he had learned of a com-

pany located in a suburb of Minneapolis, Minnesota, that specialized in fluid purification and reverse osmosis/ultrafiltration membranes and equipment. (A1011-15). That company was Osmonics, Inc. ("Osmonics"). Osmonics was founded by D. Dean Spatz in 1969 in the garage of his home shortly after he received his engineering degree at Dartmouth. (A1173-75). By the end of 1981, Osmonics had developed a significant business in ultrafiltration and reverse osmosis membranes and equipment having annual sales of over $7,000,000. (A1175, DX555, A2674-93). Osmonics and Mr. Spatz extensively advertised Osmonics' business and capabilities including the presentation and publication of a number of technical papers all directed to the many and varied applications of reverse osmosis and ultrafiltration to purification of industrial solutions. (A1176-78, A1187-88, DX548, 549, 550, 551, 552, 553, A2584-2653).

Prior to 1982, Osmonics was recommending reverse osmosis/ultrafiltration for numerous applications. (DX544, A2575-76, DX548, A2588, DX554, A2654-63). As set forth in Osmonics' 1981 corporate annual report, Osmonics was then supplying 15 different industries or markets and over 600 different customers with equipment and membranes for reverse osmosis/ultrafiltration. (DX555, A2683, A1188-89). Osmonics' entire business was built on membranes and equipment for their use. In 1981 alone, Osmonics had manufactured and sold ultrafiltration/reverse osmosis equipment containing over 1,000,000 square feet of their membranes. (DX555, A2681). These membranes, referred to by Osmonics as SEPA membranes, were made of proprietary formulations and manufacturing procedures and produced a range of molecular weight "cut off" levels from less than 200 to more than 1000. Osmonics issued prior to 1982 technical literature which described the SEPA membranes, their physical and operating characteristics, and their applications. (DX544, A2575-76).

On July 9, 1982, prior to any activity on the part of Hilton Davis, Dr. Solter instructed his engineering manager to contact Osmonics and have Osmonics process two dye coupling solutions manufactured by Warner-Jenkinson, those being

FD&C Red #40 and D&C Yellow #10, by ultrafiltration to remove salt and low molecular weight impurities such as excess Schaeffer's salt. (A1014-16, DX534, A2437). He instructed the production department to adjust the pH to 5.0 for the purpose of decomposing the triazene impurity (A1017, DX534). The use of a pH of 5.0 to decompose triazene had been a normal part of Warner-Jenkinson's process extending back prior to August, 1982. (A1018, 1068, 1153).

The unpurified Red #40 and Yellow #10 solutions were delivered to Osmonics for an application test to be run on August 17, 18, and 19, 1982. (A1018, 1165). Osmonics had a standard screening procedure dating back to 1971 for demonstrating the application of its membranes and equipment to potential customers. Osmonics would invite the customer to Minneapolis to witness the running of an application test, select three of its membranes having different molecular weight cut off levels, select the pressure and specify the pH, run the solutions through, and monitor the results. The purpose of the selection of three membranes was to give the customer a range to demonstrate Osmonics' membrane capability. (A1181-82, DX555, A2682).

Warner-Jenkinson's application test was conducted by an Osmonics engineer, Gerard Gach. (A1210-11). Prior to the application test, Warner-Jenkinson provided Mr. Gach with some basic information on FD&C Red #40 and the impurities in the reaction solution. (A1212-18, DX558, A2703). This information lead him to the conclusion, *before the tests were run*, that the molecular size difference between the desired product, the Red #40 dye molecules, and the impurities were such that purification of FD&C Red #40 was certainly technically feasible. (A1218).

Osmonics selected all of the process parameters including which membranes to use, the hydrostatic pressures to be applied, the pH of the solution, and all other test parameters. (A1213-1214, 1218, 1022-23). Osmonics performed the Warner-Jenkinson application tests at hydrostatic pressures of 400 and 600 psi and at a pH of 5.9. (A1224, DX539, A2439-2456, DX558, A2695). Also, during the tests, Mr.

Gach took Osmonics' standard SEPA membrane and chemically altered it by a process known as hydrolysis to enhance its ability to pass the salts while retaining the Red dye #40. (A1219-1225). On November 17, 1982, Osmonics issued to Warner-Jenkinson a formal written report setting forth Osmonics' conclusions and recommendations for further action. (DX539, A2439-56). The significant conclusion reported by Osmonics was that the test showed a "substantial reduction in Red #40 dye solution impurities can be accomplished with minimal loss of [Red #40 dye] by using [Osmonics'] SEPA RO/UF membranes to diafilter the contaminated solution." (A2444, A1226-28).

After the formal report was received by Warner-Jenkinson in November, 1982, Warner-Jenkinson determined that it would apply ultrafiltration to all of its synthetic dyes, including Red #40, Blue #1, Green #3, Red #3, Yellow #5, Yellow #6, and Yellow #10. Between 1982 and 1985, Warner-Jenkinson did extensive work on the development and improvement of its dye chemistry of all its synthetic dyes to make those solutions even cleaner and more concentrated so that they would be better dyes for ultrafiltration. By October, 1985, Warner-Jenkinson had demonstrated use of ultrafiltration for its Red #40, Blue #1, Green #3, and Red #3 dyes, and Dr. Solter began negotiations with Osmonics for the leasing of Osmonics ultrafiltration equipment. (A1023-34, 1043-48). The Osmonics equipment was installed in February, 1986, and Warner-Jenkinson began ultrafiltration of Red #40, Yellow #10, Yellow #6, Blue #1, Red #3, and Green #3 with the Osmonics equipment. (A1049). Simultaneously, Warner-Jenkinson was investigating other equipment so that it could select the best equipment available for its needs. (A1065). Pasilac (also known as Niro), another equipment and membrane vendor active in the reverse osmosis/ultrafiltration field, was ultrafiltering Warner-Jenkinson's Red #40 and Yellow #10 on their equipment. (A1047-49, 1052). Warner-Jenkinson also visited another ultrafiltration vendor by the name of Carre in South Carolina in July, 1986, regarding their technology. (A1050-51). In July 1986, Warner-Jenkinson ordered a larger ultrafiltration unit from Osmonics. (A1051).

It is undisputed that prior to September, 1986, Warner-Jenkinson had successfully ultrafiltered its dyes on Osmonics equipment, Pasilac equipment, and Carre equipment with no knowledge of the '746 patent or of any Hilton Davis use of ultrafiltration. (A1049-54). By September, 1986, Warner-Jenkinson was producing full 5,000 pound commercial batches of Red #40 on Osmonics equipment, as well as Blue #1 and Green #3 in full commercial batch sizes using Osmonics equipment. (A1052-53). To this day, Warner-Jenkinson has continued to manufacture all of its synthetic dyes using ultrafiltration.

Although the Hilton Davis patent issued on December 24, 1985, Hilton Davis did not bring the patent to Warner-Jenkinson's attention until December, 1989. (A984-985). Warner-Jenkinson had, however, learned of the patent when one of its technical persons found a reference to it in the literature in mid-October, 1986. (A1053). The patent was sent to outside patent counsel for Warner-Jenkinson in St. Louis, who reviewed the patent, the file history of prosecution, and the prior art, and concluded that Warner-Jenkinson's process did not infringe. In this connection, counsel relied on the process limitations set forth in the claims in concluding that there was no infringement either literally or under the doctrine of equivalents. Counsel likewise concluded that the patent was invalid in view of the prior publication of Osmonics' own literature. (A929-953, DX599, A2830-34).

E. Ultrafiltration Of The Hilton Davis Dyes By Osmonics

Prior to May of 1982, Hilton Davis was manufacturing FD&C food dyes, including Red #40, by the salting out technique. In May of 1982, Dr. Wayne Cook was hired by Hilton Davis and assigned the project of reducing manufacturing costs of its FD&C Red #40. (A130). Dr. Cook, although a Ph.D. chemist, had no prior experience with ultrafiltration or reverse osmosis. Neither he nor others at Hilton Davis had any real knowledge of ultrafiltration. (A178-79, 414-21, 425, 429). In a conversation with a long-

time Hilton Davis employee, Dr. Rebhahn, he suggested to Dr. Cook the use of dialysis for purification. Dr. Rebhahn directed Dr. Cook to an old piece of membrane equipment in a closet down the hall at Hilton Davis (A414-16). That was Dr. Rebhahn's sole inventive contribution. (A432-33).

Dr. Cook went down the hall, looked in the closet, and found the piece of equipment. It had a nameplate on it of Osmonics, Inc. Dr. Cook telephoned Osmonics in July, 1982, *after* Warner-Jenkinson's contact with Osmonics (A1014), and discussed with them purifying the Red #40 dye using Osmonics' membranes and reverse osmosis/ultrafiltration equipment. Osmonics responded that they believed Red #40 could be ultrafiltered on Osmonics' equipment to remove the impurities. (A426-27, A1180-1181, DX565, A2768). Osmonics told Dr. Cook that *it already knew of situations* where salt had been removed from dye solutions, and that they believed that it was technically feasible to purify the Red #40 dye by ultrafiltration. (A179, 1180-83, 1485-87). Osmonics also told Dr. Cook that their membranes could be used with solutions having a pH in the range of 2 to 8. (A422-425). Osmonics' published literature recommended pH ranges of 2 to 8 years prior to 1982. (DX544, A2575-76, A1184-85).

Hilton Davis, just as Warner-Jenkinson had done, arranged for the shipment of a drum of Red #40 to Osmonics for Osmonics to ultrafilter in a standard Osmonics application test. The test took place August 24-26, 1982, i.e., the week *following* the test that Osmonics had performed for Warner-Jenkinson on Warner-Jenkinson's Red #40 dye. (A182-83, 1182, 1228-29).

The scenario for the Hilton Davis test the following week was very similar to what happened with Warner-Jenkinson. However, between the time Mr. Gach completed the Warner-Jenkinson test and the following week when the Hilton Davis tests were begun, he again hydrolyzed Osmonics' standard SEPA membrane, which he had preselected for the Hilton Davis test, to enhance the membranes' ability to purify the solutions just as he had done for Warner-Jenkinson. That is, having already demonstrated the

technical feasibility of ultrafiltration through Warner-Jenkinson, he began to work on the economic feasibility by modifying the membranes to allow a quicker reduction in the impurities while still retaining the Red #40 dye product. (A1229-31).

Mr. Gach was obviously very confident that he could remove salts and low molecular weight organics from the Red #40 dye by ultrafiltration. Mr. Gach selected the three Osmonics membranes for the application test, and selected the pressures, which ranged from 200 to 400 psi. Hilton Davis' solution had pH of about 8, which was in the range Osmonics had told Dr. Cook was acceptable for its membranes before he even arrived. (A421-24, 451-52, 1231-38, 1479-80).

Mr. Gach's report of the August tests for Hilton Davis was issued by Osmonics on October 1, 1982, (DX567, A2773-89) and included Mr. Gach's conclusion which read: "A substantial reduction in impurities can be accomplished with minimal loss of product by diafiltering the Red Dye #40 using [Osmonics'] SEPA-50 (HCA) membrane." (A2778, A1238-47).

When Dr. Cook returned from Osmonics on August 27, 1982, he immediately wrote up an invention record and submitted it to the patent department. (DX576, A2790). In this invention record, he stated significantly, "Recent advances in membranes for reverse osmosis such as those sold by Osmonics, Inc., are capable of effecting the desired purification with little or no loss of product dye." Dr. Cook testified: "That meant that membranes we looked at at Osmonics had the correct pore size distribution to produce the separation that we needed to obtain separation primarily between organics and the dye." (A193).

A second application test was performed by Osmonics for Hilton Davis on October 27-29, 1982, to focus in on a membrane which Osmonics felt would *optimize* the process of removing salt and low molecular weight organics from the dye, while retaining the dye. Prior to this test, Mr. Gach further hydrolyzed the Osmonics' SEPA membranes to achieve an additional amount of salt pasage through the membrane

and thus a faster purification. In the test, Osmonics selected this Osmonics' SEPA 30 (HCA) membrane and selected an operating pressure of 400 psig. The pH was 8.1. (A1247-55; PX 5, A2871-81).

Mr. Gach concluded that: "The efficiency of reducing impurities in the dye can be *maximized* by using the [Osmonics] *30 (HCA)* membrane to diafilter the solution." (Emphasis added). (PX 5, A2874). Mr. Gach testified that the key factor which allowed these results was using the Osmonics' 30 (HCA) membrane to purify the solution. (A1256). Hilton Davis' Dr. Cook agreed that the 30 (HCA) membrane produced the best results. (A1257-59, 1462-63).

At this point, only these two tests had been performed on Hilton Davis' Red #40 dye. Both had been performed by Osmonics, with Osmonics selecting the membranes and the process conditions. Both were performed *after* the Warner-Jenkinson test. Hilton Davis had no equipment by which it could perform any ultrafiltration itself. (A1464-65, A431-32). A third test was then run by Osmonics on Hilton Davis' Yellow #6 dye. Again, the membranes and process conditions were selected by Osmonics. (A1463).

Dr. Cook's testimony as to *Osmonics'* selection of all of the process parameters is reproduced in Exhibit H because of its pertinence.

No other ultrafiltration of Hilton Davis dyes occurred prior to the March 28, 1983, filing date of the first patent application. The process conditions of 200-400 psig selected by Osmonics remained constant from the very first test in August, 1982, at Osmonics through to commercialization in January, 1985 (A1476-77). Hilton Davis recited in both of its patent applications these pressures of 200-400 psig. The Osmonics' 30 (HCA) membrane, which Osmonics had prepared for the October, 1982, application test and which Dr. Cook acknowledged was "the best" (A1464, 1468, 1470, 1471), was used by Hilton Davis thereafter including in Hilton Davis' first full-scale commercial installation in January, 1985, involving a substantial purchase of membranes. (A1468). Likewise, Osmonics had recommended to

Hilton Davis a pH range of 2-8 *before* the first test in August, 1982. (A422-25, 452, 1474).

F. The Patent In Suit And Its Prosecution In The U.S. Patent And Trademark Office ("PTO")

1. The 481,038 Application (" '038 Application") Filed March 28, 1983 (DX500, A2020)

The '038 application contained 13 claims. Claim 1, the only independent claim, as originally filed is reproduced in Exhibit I to this Brief.

In an Office Action dated October 2, 1984 (DX500, A2099-2101), the PTO Examiner rejected the claims under 35 U.S.C. § 103 as being unpatentable over Booth et al., U.S. Patent No. 4,189,380, dated February 19, 1980. (DX506, A2209). This was the patent owned by Warner-Jenkinson's joint venture partner, Dynapol. The Examiner stated that the Booth et al. reference

> discloses the purification of azo dyes by ultrafiltration in high purity and yield. It would be obvious to purify azo dyestuffs by the method of the reference in the absence of any unobvious results. (DX500, A2100-01).

The Booth et al. patent applied by the Examiner disclosed the *direct* ultrafiltration purification of aqueous synthetic dye solutions wherein both low molecular weight organic and inorganic impurities (e.g., Schaeffer's salt and sodium chloride) were removed in an ultrafiltrate leaving a purified dye (98%) in the retentate. (Col. 7, l. 14-24). No response was filed to the Office Action.

2. The 677,118 Application (" '118 Application") Filed November 30, 1984 (DX501, A2111)

The specification of the CIP '118 application was amended in two places to state that in the practice of the invention, the dye reaction mixture could be *directly* subjected to ultrafiltra-

tion without isolation of the product; or, *alternatively*, the products could be isolated in crude form from the reaction mixtures, either by *salting out* or by spray drying, and the crude product then *redissolved* in water and the resulting solution subjected to ultrafiltration. (DX501, page 3, line 33, through page 4, line 3, A2115-16, page 11, lines 8-11, A2123).

The specification was further amended to change the membrane pore diameter from 11 Angstroms to 5 to 15 Angstroms. (DX501, p. 9-10, A2121-22). The range of pH was changed from "7.0 to 9.0" to "6.0 to 9.0", but not below 6.0 (DX501, p. 12, A2124), and still substantially within Osmonics' recommended range of 2 to 8. (A422-25, 451-52, DX544, A2575-76).

Claim 1 has been reproduced in Exhibit D in the Addendum. The bracketed material was deleted from the parent claim 1 and the boldfaced material was added on filing of the CIP. The boldfaced and highlighted material was added by amendment in response to rejections of all claims by the PTO.

In an Official Action dated February 14, 1985, the PTO Examiner again rejected all claims under 35 U.S.C. § 103, as being unpatentable over Booth et al. "in the absence of any obvious [*sic* unobvious] results." (DX501, A2145-47).

Hilton Davis' patent agent, William G. Webb, then held a personal interview with the PTO Examiner on May 9, 1985. The Examiner Interview Summary Record states that Mr. Webb pointed out "4 major differences" between the ultrafiltration process disclosed by Booth et al. and the claimed process. The "4 major differences" were set out by Mr. Webb in his Record of Interview filed in the PTO on May 20, 1985. (DX501, A2164-66). One of the alleged "4 major differences" was a pH of 6 to 9. (A2165). However, that limitation was not in the claims as originally filed.

The Examiner Interview Summary Record states: "The Examiner stated that if claim 1 were amended to contain the pH range of 6 to 9, the rejection on prior art would be overcome." (DX501, A2149). This was reiterated in Mr. Webb's Record of Interview. (DX501, A2165).

On May 20, 1985, Mr. Webb also filed a more lengthy Responsive Amendment wherein he amended claim 1 to call for "a pH from approximately 6.0 to 9.0." (DX501, A2150-56). In this amendment, he also argued the purported four "major differences" between the Booth et al. patent and the patent claims sought in the '118 application.

> [T]he 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. Nevertheless, in order to further highlight the process parameters of the instant process, *and in accordance with the understanding reached at the interview*, the pH range of 6.0 to 9.0 has been inserted in Claim 1 at line 38. Support for this amendment is found in the specification at page 12, lines 31-37. (Emphasis added). (DX501, A2153).

The Hilton Davis patent agent recognized that Booth et al. disclosed the fundamental concept of the ultrafiltration purification of colorants used in foodstuffs (A2153) but went on to state to the PTO Examiner that the patentability of the instant process rested "on the novelty and unobviousness of the *process conditions*." (Emphasis original) (A2154). The PTO Examiner thereupon allowed the 17 claims, as amended, found in the '746 patent.

At no time did Hilton Davis submit evidence to the PTO Examiner that the claimed process achieved any unobvious or unexpected result. Rather, Hilton Davis' representative argued to the PTO the four "major differences" between the Hilton Davis process and Booth et al., i.e., the process conditions. Since the asserted "critical parameter" of pH of 6 to 9 was not present in claim 1, the Examiner *required* that it be inserted by amendment to overcome the prior art rejection. Hilton Davis did so, "in accordance with the *understanding* reached at the interview . . . ." (A2153, emphasis added).

II. Proceedings In The District Court

At trial, Dr. Cook, one of the named inventors, testified on behalf of Hilton Davis as an "expert" on ultrafiltration and membranes as did a university professor, Dr. Kinman. Dr. Cook disclaimed any expertise in untrafiltration other than his involvement at Hilton Davis. (A414). He has never measured any ultrafiltration membrane. (A478-79, 451). Neither had expertise with respect to the manufacture of membranes. (A126-29, 422, 520-22). Contrary to the position taken by Hilton Davis' patent agent, Mr. Webb, in the PTO, Dr. Cook stated that neither the pH nor the pressure were critical process parameters. Dr. Cook testified that "the pH has minimal effect on dye purification." (A232). He stated, "[t]he pressure has to be sufficiently high to overcome the osmotic pressure of this solution [and] make the process economically attractive." (A228). Rather, Dr. Cook testified the key to success of ultrafiltration of the Red #40 and Yellow #6 dye reaction solutions was "to find somewhere this membrane." (A159-60). If the proper membrane were available, the desired purification will be achieved. (A165-66). Dr. Cook agreed that Osmonics selected all of the membranes (A423-24, 451-52, 509-10) including that which was the best, the 30 (HC).[1] (A1464, 1468, 1470-71). Hilton Davis adopted its position at trial in an attempt to prove its infringement case by "equivalents" since Warner-Jenkinson's pH and pressure were both outside of the claimed ranges. However, in doing so, Hilton Davis disavowed the very argument it had made to obtain issuance of the claims in the first place.

Warner-Jenkinson properly moved for judgment as a matter of law of non-infringement and patent invalidity at the close of the plaintiff's case and at the close of all the evidence. In denying Warner-Jenkinson's post-trial motions for judgment as a matter of law, the court rendered only an oral opinion from the bench. As to infringement, the court stated only that the doctrine of equivalents did apply. (Ex. G, p. 51).

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[1] Dr. Cook agreed that 30 (HC) was a shorthand form of 30 (HCA). (A1454).

With regard to validity, the court stated that the claims were unobvious because Hilton Davis' "special process of pore size, pressure, and pH was dissimilar to the Booth, was nonobvious. . . ." (Ex. G. p. 43). Thus, the court read into the claims what it had read out when it determined infringement.

The court entered a permanent injunction prohibiting operation at a pH below 9.01 but refused to limit the lower end to 6.0 and extended it down to 2.0. (Ex. G, p. 22-24). The court thus expanded the claimed range of "6.0 to 9.0" to "2.0 to 9.0." The court permitted Warner-Jenkinson's continued operation at an inlet pressure above 500 psig but not between 400 and 500 psig thus expanding the claimed range of "200 to 400 psig" to "200 to 500 psig." (Ex. G, p. 50).

SUMMARY OF ARGUMENT

I. Non-Infringement Under The Doctrine Of Equivalents

A. The equitable doctrine of equivalents was established by the courts to prevent an "unscrupulous copyist" from making minor and insubstantial changes to its device or process for purposes of skirting the words of a patent claim thereby essentially "stealing" the patented invention. *London* v. *Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538, 20 U.S.P.Q.2d 1456, 1458 (Fed. Cir. 1991). The doctrine was created by the courts to find infringement where the only distinction between the infringing device or process and the patent claims was a matter of mere formalism of words. That is, the doctrine was designed to do equity. *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 339 U.S. 605, 608, 70 S. Ct. 854, 856, 94 L.Ed. 1097, 85 U.S.P.Q. 328 (1950). But the doctrine is not simply a fallback position every time literal infringement cannot be proven. It is an equitable remedy available only upon a suitable showing of the equities. To demonstrate that the equities favor application of the doctrine, the patentee must put forth proof of the equities, and the trial court must

find the type of conduct which triggers its application. *London* v. *Carson Pirie Scott & Co.*, *supra*; *Charles Greiner & Co.* v. *Mari-Med Mfg., Inc.*, 962 F.2d 1031, 1035-36, 22 U.S.P.Q.2d 1526, 1529 (Fed. Cir. 1992). As an equitable remedy, the doctrine is an issue of law for the court, not the jury.

B. Here, no equitable basis exists for application of the doctrine. Warner-Jenkinson's processes were developed in cooperation with knowledgeable and experienced vendors in the field including Osmonics, Pasilac (Niro) and Carre. There was no copying or piracy. Warner-Jenkinson had no knowledge of either the '746 patent or any Hilton Davis ultrafiltration process when it developed its processes. In fact, it is undisputed that Warner-Jenkinson had the basic concept of ultrafiltration of Red #40 before Hilton Davis and even went to Osmonics one week before Hilton Davis. Warner-Jenkinson was in commercial production of Red #40 using ultrafiltration before it even knew of Hilton Davis' patent. It has never known how Hilton Davis practices its process. Warner-Jenkinson obtained an opinion of outside patent counsel of non-infringement. Counsel relied on the pH and pressure limitations written into the claims and argued by Hilton Davis to be critical to their allowance over the prior art.

C. Equivalency of each limitation of a claim must be proven. Each limitation of the claim is material and its presence in the alleged infringing process or device must be shown for the patentee to sustain its burden of proving infringement. *Becton Dickinson and Co.* v. *C. R. Bard, Inc.*, 922 F.2d 792, 798, 17 U.S.P.Q.2d 1097, 1101 (Fed. Cir. 1990). The doctrine "does not mean one can ignore claim limitations." *Pennwalt Corp.* v. *Durand-Wayland, Inc.*, 833 F.2d 931, 935, 4 U.S.P.Q.2d 1737, 1739 (Fed. Cir. 1987) (en banc), quoting *Perkin-Elmer Corp.* v. *Westinghouse Electric Corp.*, 822 F.2d 1528, 1532-33, 3 U.S.P.Q.2d 1321, 1324-25 (Fed. Cir. 1987). Here, Hilton Davis *wholly failed to prove* what the pore size of the proprietary membranes employed by Warner-Jenkinson was or even that it had any pore size at

all, even though the claims of the patent contain express numerical limitations on those pore sizes of 5 to 15 Angstroms. Hilton Davis merely offered conclusory statements that the same "result" was obtained, i.e., separation of dye and impurities. There was no compliance with the rule in *Lear Siegler, Inc.* v. *Sealy Mattress Co.*, 873 F.2d 1422, 10 U.S.P.Q.2d 1767 (Fed. Cir. 1989), because no evidence was presented as to the presence of the 5 to 15 Angstrom claim limitation in Warner-Jenkinson's process. Likewise, Hilton Davis wholly failed to demonstrate the actual composition of the proprietary membrane material used by Warner-Jenkinson as required by claim 2 of the patent. Thus, the case should not have gone to the jury because Hilton Davis simply failed to prove the necessary elements. *Malta* v. *Schulmerich Carillons, Inc.*, 952 F.2d 1320, 21 U.S.P.Q.2d 1161 (Fed. Cir. 1991).

D. Finally, the doctrine of equivalents will not permit a claim to be so construed to reclaim that which was given up during prosecution by either argument or amendment. *Standard Oil Co.* v. *American Cyanamid Co.*, 774 F.2d 448, 452, 227 U.S.P.Q. 293, 296 (Fed. Cir. 1985). Nor will expansion of the claim scope be permitted if it would encompass the prior art. Here, in accordance with an *agreement* with the Examiner to overcome an obviousness rejection based on Booth et al., Hilton Davis specifically amended the claims to recite a range of pH of 6.0 to 9.0, which *excludes* Warner-Jenkinson's pH of 5.0. Hilton-Davis' range of pressure from 200 to 400 psig *excludes* Warner-Jenkinson's 500 psig. Both were argued to be critical to distinguishing over the prior art, and the public has a right to rely on these representations. Neither the district court nor a reasonable jury could have found the properly construed claims to cover Warner-Jenkinson's process.

II. Patent Invalidity

A. To obtain its patent, Hilton Davis' patent agent argued to the Examiner that there were *critical* parameters of pH, pressure, and membrane pore size which distinguished

the Hilton Davis ultrafiltration process from the prior art, specifically the Booth et al. patent, then owned by Dynapol. At trial, however, Hilton Davis changed its position and argued that the pH and pressure were *not* critical as there was no functional difference in the ultrafiltration process based on pH at all or based on operating pressure as long as the pressure is above the osmotic pressure. Thus, Hilton Davis at trial disavowed the very basis on which it obtained the patent in the first place. Consequently, there is no patentable distinction between its claimed process and that disclosed by the prior art Booth et al. patent and others.

B. Hilton Davis made no patentable invention. Dr. Cook, a named inventor, knowing of Osmonics as people skilled in this art, merely went to them, explained what he wanted to accomplish, and Osmonics selected the membranes, told Dr. Cook the pH range in which they were stable, and selected the pressures at which they should be operated. (A423-27, 451-52, 509-10, 1231-38, 1487). This knowledge was generally known in the field as it had been published by Osmonics well prior to 1982. (DX544, A2575-76). Osmonics reported that ultrafiltration of these dyes was within its standard practice and that there was nothing new or unobvious about it. (A1175-1183, 1211-12, 1218, 1233, 1485-87). When told what was to be accomplished, *first* by Warner-Jenkinson and then by Hilton Davis, Osmonics was 99% certain that its membranes would achieve the result. (A1178, 1183). Hilton Davis did not make the invention. It only posed the problem to Osmonics — the same problem that had already been posed by Warner-Jenkinson. *Morgan* v. *Hirsch*, 728 F.2d 1449, 221 U.S.P.Q. 193 (Fed. Cir. 1984).

C. Warner-Jenkinson's own earlier work with Osmonics in purifying FD&C Red #40 by ultrafiltration is prior art under 35 U.S.C. § 102(g). Although Warner-Jenkinson, like Hilton Davis, kept its process parameters secret, it commercialized its process and sold the resulting product to the public. *Del Mar Eng'g. Labs.* v. *United States*, 524 F.2d 1178, 1185, 186 U.S.P.Q. 42, 47-48 (Ct. Cls. 1975); *Friction Div. Prods., Inc.* v. *E. I. DuPont de Nemours & Co.*, 658 F.

Supp. 998, 1014 (D. Del. 1987), *aff'd*, No. 89-1187 (Fed. Cir. July 24, 1989) (unpublished). Warner-Jenkinson practices what is in the prior art, i.e., what it and Osmonics *first* created. This also suggests the obviousness of the claimed process. *Newell Companies, Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 9 U.S.P.Q.2d 1417 (Fed. Cir. 1988).

D. Beyond Booth et al. and Warner-Jenkinson's own processes, there are prior art patents, such as the Ciba-Geigy British '898 patent (DX513, A2362), which disclose overlapping ranges of pressures, pore sizes, and pH for the ultrafiltration of organic dye coupling solutions, including monoazo dye coupling solutions, the same class of dyes as Red #40 and Yellow #6. Process parameters cannot provide a patentable process over the prior art disclosing overlapping ranges unless the patentee can show the presence of unexpected results from the use of those parameteres. *E.g., Gardner v. TEC Sys., Inc.*, 725 F.2d 1338, 220 U.S.P.Q. 777 (Fed. Cir. 1984). Here, Hilton Davis never attempted to prove any unexpected results, there were none, and the claims in issue are invalid over the prior art. (A1175-83, 1211-12, 1218, 1233, 1485-87).

E. The claims of the '746 patent simply recite the application of well-known ultrafiltration technology to specific dye solutions. Hilton Davis asserts it was the first to use ultrafiltration to purify FD&C Red #40 and Yellow #6. However, the selection of starting materials, even if themselves new and unobvious, which these are not, does not create an unobvious process. *In re Durden*, 763 F.2d 1406, 1410, 226 U.S.P.Q. 359, 361 (Fed. Cir. 1985); *Application of Kanter*, 399 F.2d 249, 251, 158 U.S.P.Q. 331, 332 (C.C.P.A. 1968).

ARGUMENT

I. Claims 1, 2, 3, 13, And 14 Are Not Infringed By Warner-Jenkinson

A. The Doctrine Of Equivalents Is An Equitable Doctrine Designed To Prevent Fraud Or Other Inequitable Abuse; It Has No Application To This Case

As this court has stated, ordinarily infringement means literal infringement of the limitations contained in the patent claims. When necessary to protect the rights of the patentee from *fraud or other inequitable abuse*, infringement *may be* based on the equitable doctrine of equivalents. However, the doctrine of equivalents is not an automatic second prong to every infringement charge. It is an equitable remedy available only upon a suitable showing. Thus, the patentee must put forth proof of the equities, and that proof must show that an equitable basis exists for invoking the doctrine of equivalents. See, *London* v. *Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538, 20 U.S.P.Q.2d 1456, 1458 (Fed. Cir. 1991); *Charles Greiner & Co.* v. *Mari-Med Mfg., Inc.*, 962 F.2d 1031, 1035-36, 22 U.S.P.Q.2d 1526, 1529 (Fed. Cir. 1992).

The claim-based system written into our patent laws require that claims be "particular" and "distinct" so that the public has fair notice of what the patentee and PTO have agreed constitutes the metes and bounds of the claimed invention. This court has repeatedly followed the admonition that the claims measure the invention and define the limits of patent protection. See, *Continental Paper Bag Co.* v. *Eastern Paper Bag Co.*, 210 U.S. 405, 419 (1908); *General Electric Co.* v. *Wabash App. Corp.*, 304 U.S. 364 (1938). Such notice permits the public to avoid actions which infringe the patent. 35 U.S.C. § 112; *London* v. *Carson Pirie Scott & Co.*, 946 F.2d at 1538, 20 U.S.P.Q.2d at 1458. Accordingly, this court has instructed that the doctrine of equivalents is the exception and not the rule. "[A] court may not, under the guise of applying the doctrine of equivalents, erase a plethora of meaningful structural and functional limitations of the claim on which the public is entitled to rely in avoiding infringement."

Perkin-Elmer Corp. v. Westinghouse Electric Corp., 822 F.2d 1528, 1532, 3 U.S.P.Q.2d 1321, 1324 (Fed. Cir. 1987). This court has repeatedly stated that the doctrine of equivalents must not clash with the legal significance of the claims. Careful confinement of the doctrine of equivalents to its proper equitable role thus promotes certainty and clarity in determining the scope of patent rights. *Charles Greiner & Co. v. Mari-Med Mfg., Inc.*, 962 F.2d at 1036, 22 U.S.P.Q.2d at 1530. Under our system of law, the public enjoys the basic right to notice of what conduct must be avoided. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 954, 4 U.S.P.Q.2d 1737, 1755 (Fed. Cir. 1987) (Nies, J., additional views).

In this case, when plaintiff abandoned its case of literal infringement, the doctrine of equivalents was resorted to simply as the automatic second prong of the infringement charge.

The doctrine of equivalents exists solely for the equitable purpose of "prevent[ing] an infringer from stealing the benefit of an invention." *Texas Instruments, Inc. v. Int'l Trade Comm'n*, 805 F.2d 1558, 1572, 231 U.S.P.Q. 833, 842 (Fed. Cir. 1986). As stated by the Supreme Court in *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608, 70 S. Ct. 854, 856, 94 L.Ed. 1097, 85 U.S.P.Q. 328 (1950), the doctrine *may* be applied "when the proper circumstances for its application arise." *Coleco Indus., Inc. v. Int'l Trade Comm'n*, 573 F.2d 1247, 1258, 197 U.S.P.Q. 472, 481 (C.C.P.A. 1978) (Rich, J. and Markey, C.J., concurring). The most important equitable consideration is whether or not the accused infringer designed its product or process with knowledge of the patented product or process and with the purpose of making insubstantial changes to circumvent claim language. *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 932 F.2d 1453, 1457, 18 U.S.P.Q.2d 1842, 1846 (Fed. Cir. 1991) ("It is only when the changes are so insubstantial as to result in 'a fraud on the patent' that application of the equitable doctrine of equivalents becomes desirable.").

What is the equitable basis for invoking the doctrine in this case? There is none. What is the evidence that Warner-

Jenkinson committed a 'fraud on the patent'? There is none. Warner-Jenkinson did not even know of the '746 patent until *after* it was in commercial production. (A1054, 1067-68). The evidence at trial showed that Warner-Jenkinson knew that ultrafiltration could be used to remove impurities, including organic impurities, such as Schaeffer's salt, and sodium chloride from synthetic dye solutions as early as 1978 when Dr. Solter visited Dynapol who was developing new dyes in partnership with Warner-Jenkinson. (A1015). Warner-Jenkinson developed its processes as applied to all of its dyes by relying on technology first made available to it in August, 1982, by Osmonics, an acknowledged leader in the field of ultrafiltration. Osmonics is the expert in ultrafiltration not Hilton Davis. (A1448-52). Hilton Davis had to go to Osmonics to obtain all of its knowledge of ultrafiltration and have Osmonics show Hilton Davis how ultrafiltration could be used to purify these dye solutions. (A415-25). Hilton Davis went to Osmonics in August, 1982, one week *after* Warner-Jenkinson had been there. Between 1982 and September, 1986, Warner-Jenkinson extensively revised all of its dyes and worked with other significant vendors of ultrafiltration membranes and equipment as well, including Pasilac (Niro) and Carre. (A1048-66).

Warner-Jenkinson was in full scale commercial production of FD&C Red #40 using Osmonics' ultrafiltration equipment by September, 1986, before it even knew the Hilton Davis patent existed. It is undisputed that Warner-Jenkinson took no knowledge or information from the '746 patent. (A1053-56, 1067-68). Further, it is conceded that Hilton Davis kept and still keeps the practice of its process secret. Hilton Davis even kept the fact that it was using ultrafiltration at all secret. To this date, Warner-Jenkinson does not know the process conditions that Hilton Davis actually uses because that information was kept from it under the terms of a court ordered protective order. Thus, it can hardly be said that Warner-Jenkinson was an "unscrupulous copyist," a "pirate," or that it made "insubstantial changes" to pirate or "steal" the patented process. See, *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 339 U.S. 605, 609-10, 70 S. Ct. 854, 856-57, 94 L.Ed. 1097, 85

U.S.P.Q. 328, 331 (1950). Nor can it be argued that the parameters employed by Warner-Jenkinson, which lie well outside the claimed ranges, were adopted by Warner-Jenkinson to barely avoid the literal language of the claims. See, *London*, 946 F.2d at 1538, 22 U.S.P.Q.2d at 1458. Warner-Jenkinson uses a pH of 5.0 and has done so as a standard part of its process to decompose triazene even before 1982. (A1018, 1066-68, 1153). Warner-Jenkinson uses a pressure of 500 psi, which is right in the middle of the 400 to 600 range used by Osmonics in the first test in August, 1982, because that is where Warner-Jenkinson gets its best operation. (A1053-56, 1066-67). And although Hilton Davis presented no evidence as to the pore size of the membranes used by Warner-Jenkinson, it was conceded that the membranes first used by Warner-Jenkinson were simply purchased from Osmonics, and then Warner-Jenkinson switched to proprietary membranes of another type made by another manufacturer, Desalination Systems, Inc., ("Desal") because they gave better removal of sodium sulphate.

Thus, Hilton Davis did not present *any* equities which would trigger application of the doctrine of equivalents in this case. *See, Valmont Indus., Inc.* v. *Reinke Mfg. Co.*, No. 91-1377, 1378, slip op. at 8 (Fed. Cir. Jan. 7, 1993). Warner-Jenkinson's motion for judgment of non-infringement as a matter of law should have been granted.

B. Membrane Pore Diameter Of 5 To 15 Angstroms: Hilton Davis Conceded That It Did Not Even Attempt To Determine The Pore Size Of The Membrane Used By Warner-Jenkinson To Prove That This Limitation Was Met

Hilton Davis offered no evidence of what the pore size of Warner-Jenkinson's membrane was *or that it even had pores of any size*. Hilton Davis conceded that no one testified to pore size but argued that it was a "functional equivalent." (A659). Thus, the entirety of its case rested merely on the opinions of Drs. Cook and Kinman that Warner-Jenkinson's membrane "performed" to reject Red #40 and Yellow #6 dye

and therefore was a "functional equivalent." (A476-79, 550). Dr. Cook under questioning by his counsel testified that pore diameter was the most important parameter (A225-6) but asserted that the 5-15 Angstroms limitation found in claim 1 was not a numerical limitation at all, but a "functional" one. (A357-58, 476-79). This approach simply ignores any requirement by a patentee of objective proof of the presence of express numerical limitations in the accused process. Further, Hilton Davis conceded that Warner-Jenkinson does not use either membrane referenced in the '746 patent or even an Osmonics membrane. The Desal membrane used by Warner-Jenkinson was conceded by plaintiff's "expert" to be made of a proprietary material (not cellulose acetate as described in the '746 patent). (A546-47, 1104-05). The "experts" freely admitted they did not and do not know the composition of *this* proprietary membrane or any pore size of it. (A476-79, 550, 586-87). Hilton Davis' "expert" had to guess at what the membrane was even made of. (A400-01, 587-89). Although Hilton Davis' "expert" testified regarding his opinion as to the operation of membranes in general, he had never analyzed or operated the specific Desal membrane Warner-Jenkinson used. (A589). Hence, there was no evidence presented by plaintiff that *the* Desal membrane used by Warner-Jenkinson made of a different and proprietary material than that disclosed in the '746 patent had a pore diameter in the *claimed* range of 5 to 15 Angstroms.

A patentee carries the burden to prove the presence of every limitation of a claim in the accused device or process. See, *Johnston* v. *IVAC Corp.*, 885 F.2d 1574, 1577, 12 U.S.P.Q.2d 1382, 1384 (Fed. Cir. 1989); *Becton Dickinson and Co.* v. *C. R. Bard, Inc.*, 922 F.2d 792, 798, 17 U.S.P.Q.2d 1097, 1101 (Fed. Cir. 1990). In *Morton Int'l, Inc.* v. *Cardinal Chem. Co.*, 959 F.2d 948, 950, 22 U.S.P.Q.2d 1231, 1233 (Fed. Cir. 1992), the dispute centered around the existence (or lack thereof) of "partial connectivity," a limitation of the claim, in the allegedly infringing mixture. At the trial, the patentee failed to provide "objective support for the actual existence of the claimed con-

nectivities." 959 F.2d at 951, 22 U.S.P.Q.2d at 1234. This court upheld the district court stating that the patentee's evidence was "mere speculation" showing only the "possibility of the existence of the claimed compounds," and was "not convincing enough" to prove infringement. 959 F.2d at 951, 22 U.S.P.Q.2d at 1235.

Here, Hilton Davis offered no objective evidence of what the pore size of the Desal membrane was. Rather, Hilton Davis asserted that this membrance was the "functional equivalent" based merely on the "results" achieved. But invocation of the doctrine of equivalents is not a license to turn a patent claim into merely "a result oriented catch-all." *Malta*, 952 F.2d at 1330, 21 U.S.P.Q.2d at 1169 (Michel, J., concurring). To adopt plaintiff's approach would permit the patentee in every case to ignore completely proof of numerical or other limitations in a claim, and relieve the patentee entirely of its burden of objective *proof* of infringement, a result contrary to well over a hundred years of patent law. That burden cannot be met by mere speculation or possibility. *Morton Int'l, Inc., supra; Nestier Corp. v. Menasha Corp.*, 739 F.2d 1576, 1579, 222 U.S.P.Q. 747, 750 (Fed. Cir. 1984).

Hilton Davis' approach also violates the rule in *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 21 U.S.P.Q.2d 1161 (Fed. Cir. 1991). There, citing *Lear Siegler, Inc. v. Sealy Mattress Co.*, 873 F.2d 1422, 10 U.S.P.Q.2d 1767 (Fed. Cir. 1989), this court held that "offhand and conclusory statements [that an element "functioned" like the claim limitation] are not sufficiently particularized evidence" to prove that the limitation was met. 952 F.2d at 1327, 21 U.S.P.Q.2d at 1166. It is insufficient to merely show that one device achieves the same result, here separation of dye and impurities. A case based solely on *descriptive* evidence may not go to the jury. Whether or not the patentee has complied with *Lear Siegler* is a question of law. 952 F.2d at 1329, 21 U.S.P.Q.2d at 1168. *There was no evidence of any Warner-Jenkinson membrane pore size.* Absent *any* evidence, there was not the necessary "substantial evidence" on the issue of

the doctrine of equivalents. Here, as in *Malta*, without this evidence, the jury was left to its own imagination on this technical issue. The doctrine of equivalents thus became merely a "result oriented catch-all." 952 F.2d at 1390, 21 U.S.P.Q.2d at 1166 (Nichols, J., concurring).

Finally, there was no evidence presented that Warner-Jenkinson's selection of the Desal membrane was for purposes of avoiding the claim limitations of the '746 patent. Under *Malta*, the case should not have been submitted to the jury, and thus the jury verdict cannot stand. *Id.*

C. The Doctrine Of Equivalents Is Also Limited By Prosecution History Estoppel: Properly Construed, The Claims Do Not Cover Warner-Jenkinson's Process

It is well established that the doctrine of equivalents is limited by prosecution history estoppel. Indeed, prosecution history estoppel is an important rule which prevents the doctrine from clashing with claim significance. *Charles Greiner & Co.*, 962 F.2d at 1036, 22 U.S.P.Q.2d at 1529. In *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 452, 227 U.S.P.Q. 293, 296 (Fed. Cir. 1985), this court stated that "the prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." See also, *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136-37, 62 S. Ct. 513, 518-19, 86 L.Ed. 736, 52 U.S.P.Q. 275, 279-80 (1942). The entire record of proceedings in the PTO, including representations made to the Examiner that the invention is patentable, are included in the patent's prosecution history. *Jonsson v. Stanley Works*, 903 F.2d 812, 817, 14 U.S.P.Q.2d 1863, 1868 (Fed. Cir. 1990); *Tandon Corp. v. Int'l Trade Comm'n*, 831 F.2d 1017, 1027, 4 U.S.P.Q.2d 1283, 1291 (Fed. Cir. 1987). Of course, amendments made to the claim limit a patentee's reliance on the doctrine of equivalents by preventing the patentee from contending later in an infringement action that his claim should be interpreted as if limita-

tions added by amendment were not present. *Townsend Eng'g. Co.* v. *HiTec Co.*, 829 F.2d 1086, 1090, 4 U.S.P.Q.2d 1136, 1139 (Fed. Cir. 1987) (quoting *Thomas & Betts Corp.* v. *Litton Sys., Inc.*, 720 F.2d 1572, 1579, 220 U.S.P.Q. 1, 6 (Fed. Cir. 1983)); see also, *E. I. DuPont de Nemours & Co.* v. *Phillips Petroleum Co.*, 849 F.2d 1430, 1438, 7 U.S.P.Q.2d 1129, 1135 (Fed. Cir. 1988); *Jonsson* v. *Stanley Works*, *supra*.

In this case, Hilton Davis was required to assert that *no less than five* limitations of claim 1 not literally met had to be found as an equivalent. Of these five, in addition to membrane pore size of 5-15 Angstroms for which no evidence was submitted, a pH range of 6.0 to 9.0 and a hydrostatic pressure range of 200 to 400 psig, were both asserted in the PTO to be *critical parameters*, critical to distinguishing the prior art. Warner-Jenkinson will address each additional limitation separately.

1. pH Of 6.0 To 9.0 Added To Claim 1 By Amendment

The '746 patent says only the following regarding pH:

> In carrying out the present process the reaction mixture, as produced in the diazo coupling and as fed to the ultrafiltration unit, generally has a pH of approximately 9.0. While these solutions can be subjected successfully to ultrafiltration, it is preferred to adjust the pH to approximately 6.0 to 8.0 before passage through the ultrafiltration membrane. (Col. 7, l. 55-61).

In the parent application, the preferred range of pH was stated to be "around 7.0 to 8.0." However, there was no recitation of pH in either of the parent claim 1 or CIP claim 1, the only independent claim submitted with the applications. After rejection of all the claims in the CIP, an interview was held. The Examiner Interview Summary states:

> The examiner stated that if claim 1 were amended to contain the pH range of 6 to 9, the rejection on prior art would be overcome. (DX501, A2149).

Hilton Davis then inserted the language: "at a pH from approximately 6.0 to 9.0." (A2139, 2150). The Hilton Davis patent agent stressed that the claimed pH range of 6.0 to 9.0 distinguished the claimed process from Booth et al. which was stated to maintain the pH "above 9."[2]

pH is a logarithmic scale, and a single pH unit represents a ten-fold difference in hydrogen ion concentration. (A767-70). It is conceded that Warner-Jenkinson operates at a pH of 5.0. It does so for the specific purpose of causing the decomposition of the triazene impurity. (A1018, 1068, 1093, 1103, 1161). Hilton Davis operates in Osmonics' recommended range close to neutral for the purpose of maintaining membrane life (A249, 363-64). Moreover, in the process disclosed in the '746 patent, it is physically impossible to lower the pH of the coupling solution below 6.0 without, as Dr. Cook testified, "tremendous foaming problems in the plant . . . several thousand gallons of stuff that's foaming up going all over the floor and going all over the plant. . . ." (A231-32, 1475). Warner-Jenkinson uses a different process by which it *can* lower the pH to 5.0 to destroy the triazene to a level below FDA specifications without foaming the solution out of the tank. (A1093). This is a result the '746 patent is unable to achieve. (A1103-04). The use of a pH of 5.0 to destroy triazene was standard operating procedure at Warner-Jenkinson and had been employed by it even before 1982. When Warner-Jenkinson adopted ultrafiltration, it continued its well-established procedure of adjusting the pH to 5.0 to destroy the triazene. (A1018, 1066, 1068, 1161).

The doctrine of prosecution history estoppel clearly limits an interpretation of claim 1 so as to exclude that which has been disclaimed or disavowed during prosecution in order to obtain claim allowance. *Standard Oil Co.* v. *American Cyanamid Co., supra; Dixie USA, Inc.* v. *Infab Corp.*, 927 F.2d 584, 17 U.S.P.Q.2d 1968 (Fed. Cir. 1991). Although the Booth et al. patent was distinguished on the basis that its pH was "above 9", Hilton Davis clearly argued to the PTO as a

[2] Claim 9 of Booth et al. in fact says "from 9.0. . . ." (DX506, A2209, col. 15, l. 3).

basis for patentability the claimed *range* of pH of 6.0 to 9.0 to overcome the rejection based on obviousness. The function of pH in the '746 patent according to Dr. Cook is membrane stability, i.e, not to let the acidity or basicity of the solution degrade the membrane. The function of pH in Warner-Jenkinson's process is specifically to decompose the impurity pretriazene. Thus, Hilton Davis chose a narrow range of preferred pH of 7.0 (neutral) ± 1.0 (the pH was extended an additional 1.0 above 8 to encompass the normal pH of the diazo coupling solution). (A1475). However, no claim was made to a pH below 6.0 where serious foaming would occur (A231-32, 1475), and where Warner-Jenkinson operates.

The district court ruled that a pH of 9.0 meant 9.0. The permanent injunction prohibits operation at a pH below 9.01. (A004). But the district court accorded the *lower* limit of 6.0 a range of equivalents all the way down to 2.0. (Ex. G, p. 24). There is nothing in the '746 patent or its prosecution that in any way *informs the public* seeking to avoid infringement of the '746 patent that a pH as low as 2.0 would be deemed to infringe 6.0. *Kinzenbaw* v. *Deere & Co.*, 741 F.2d 383, 389, 222 U.S.P.Q. 929, 933 (Fed. Cir. 1984); *Prodyne Enters., Inc.* v. *Julie Pomerantz, Inc.*, 743 F.2d 1581, 1583, 223 U.S.P.Q. 477, 478 (Fed. Cir. 1984); *Mannesmann Demag Corp.* v. *Engineered Metals Prods. Co.*, 793 F.2d 1279, 1285, 230 U.S.P.Q. 45, 48 (Fed. Cir. 1986); *Perkin-Elmer Corp.* v. *Westinghouse Electric Corp.*, 822 F.2d 1528, 1532, 3 U.S.P.Q.2d 1321, 1324 (Fed. Cir. 1987); *Pennwalt Corp.* v. *Durand-Wayland, Inc.*, 833 F.2d 931, 4 U.S.P.Q.2d 1737 (Fed. Cir. 1987) (en banc); *Senmed, Inc.* v. *Richard-Allen Medical Indus., Inc.*, 888 F.2d 815, 821, 12 U.S.P.Q.2d 1508, 1513 (Fed. Cir. 1989).

Indeed, in the PTO, even if Hilton Davis had wanted to claim a pH below 6.0, it could not do so, since the patentee cannot enlarge the scope of the claims beyond that supported in the specification and cannot change the disclosure in a way contrary to its substance as filed. 37 C.F.R. § 1.118 (1982). The addition of an amendment claiming a pH below 6.0 would have constituted the prohibited addition of new mat-

ter. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 227 U.S.P.Q. 177 (Fed. Cir. 1985). By stating that the amendment to the claims to include a pH of 6.0 to 9.0 found "support . . . in the specification" (DX501, A2153), Hilton Davis represented, as it must, that the amendment was without the addition of new matter. Thus, the pH of 5.0 utilized by Warner-Jenkinson falls precisely into the range that Hilton Davis is estopped to claim. One cannot interpret a claim to be broader than what is contained in the specification and claims as filed. The specification and prosecution history require the claims to be limited. *Tandon Corp. v. Int'l Trade Comm'n*, 831 F.2d 1017, 1023, 1027, 4 U.S.P.Q.2d 1283, 1288, 1291 (Fed. Cir. 1987).

2. The Claims Are Limited To A Hydrostatic Pressure Of 200 To 400 Psig

The '746 patent states at column 6, lines 18-21:

> The filtration is carried out under a hydrostatic pressure of approximately 200 to 400 p.s.i.g. applied to the upstream side of the membrane.

At column 6, lines 57-58, it is stated that the reaction mixture is "fed to an ultrafiltration unit where, under a pressure of approximately 200 to 400 p.s.i.g., supplied by a high pressure centrifugal pump, the impurities are forced through the membrane into the permeate . . . ." There is no other description in the specification or prosecution history as to the meaning of 200 to 400 psig.

Hilton Davis took the position at trial that infringement was present if there was a pressure in the range of 200 to 400 psig anywhere along any membrane length including even at the very end. Warner-Jenkinson maintained that the patent meant what it said, and that 200 to 400 psig as used in claim 1 could only mean the pressure as supplied at the high pressure pump, i.e., at the inlet to the first membrane. *Senmed, Inc. v. Richard-Allen Medical Indus., Inc.*, 888 F.2d 815, 819 n.8, 12 U.S.P.Q.2d 1508, 1512 n.8 (Fed. Cir. 1989) ("[A]n inventor may not be heard to proffer an interpretation that would

alter the undisputed public record (claim, specification, prosecution history) and treat the claim as a 'nose of wax.' ") At the high pressure pump in Warner-Jenkinson's process, the pressure is 500 psig, not 200 to 400 psig. Hilton Davis asserted that pressure had meaning only in terms of it being sufficient to overcome the osmotic pressure of the fluid being processed, which in this case was about 180 psig. (A574-75). According to Hilton Davis, after the osmotic pressure was overcome, *any* pressure at which the membrane "functioned," i.e., did not compact or collapse, was the "equivalent" of the claimed range of 200 to 400 psig. (A228-29). The court in ruling on post-trial motions held that pressures *above* 500 psig at the inlet to the first membrane, i.e., at the high pressure pump, did not constitute an infringement. (Ex. C, p. 50). Thus, the court's decision was that an inlet pressure of 500 psig was the "equivalent" of 400 psig. But how is the public to know that above 500 psig a claim limitation of 400 psig is not infringed, but below 500 it is, i.e., that 400 psig is 500 psig?

Warner-Jenkinson selected its pressure of 500 psig based on experimental work conducted for it by Osmonics, Carre, and Pasilac (Niro) dating back to August, 1982. (A1054-55, 1067). A pressure range of 200 to 400 psig was expressly recited by Hilton Davis in claim 1 of its patent as originally filed. Before the PTO, Hilton Davis *argued* that the pressure *range* of 200 to 400 psig was one of the "4 major differences" that distinguished it from the prior art Booth et al. patent pressure range of 25 to 200 psig. (The examiner failed to note that the claimed range overlaps the prior art range exactly at 200 psig and therefore no distinction over the prior art existed.) (A480-81). There is nothing in the specification of the '746 patent or in its prosecution history that would *inform the public* that the claimed upper limit of 400 psig was no limit at all and that if the public, seeking to avoid infringement, operated above 400 psig, they would nevertheless be subjected to millions of dollars in damages for infringement.

As in the case of the pH limitation, Hilton Davis could not have amended the claims of the patent to recite pressures above 400 psig without the addition of prohibited new mat-

ter. 37 C.F.R. §1.118 (1982). As in the case of the pH limitation, Hilton Davis is estopped to interpret the claims to be broader than what is contained in the specification and claims as filed. *Tandon Corp.* v. *Int'l Trade Comm'n*, *supra*. Warner-Jenkinson, as any member of the public, in determining that its process was not an infringement is entitled to rely on the express limitation of the claims that 400 psig meant what it said.

3. The Hydrochloric Acid And Chloride Limitations Also Were Not Met In Warner-Jenkinson's Process

Claim 1 of the '746 patent requires in the case of both Red #40 and Yellow #6 that the diazotization reaction be carried out "in the presence of hydrochloric acid" and that the resulting products be a "chloride." See Ex. C. As a result, the salt that is produced in the claimed process is sodium chloride.

In Warner-Jenkinson's process, sulfuric acid is employed in the diazotization reaction (A1084) and the resulting product thus is a sulphate and not a chloride. The salt which is produced is sodium sulfate not sodium chloride. (A1019). Sodium sulfate is more difficult to remove by ultrafiltration from the dye reaction solution than is sodium chloride.

Hilton Davis contended that sulfuric acid was the equivalent of hydrochloric acid in that both were "strong acids" and both were effective in accomplishing the diazotization reaction. Warner-Jenkinson's witness, Dr. Solter, however, testified that Warner-Jenkinson received improved results through the use of sulfuric acid including getting faster reactions, more concentrated solutions, and the ability to operate at higher temperatures than with hydrochloric acid. Warner-Jenkinson was using sulfuric acid in its process well prior to the existence of the Hilton Davis patent. (A1083-99).

As in the case of the other process parameters, there was no evidence that Warner-Jenkinson sought to avail itself of the benefits of the Hilton Davis patent by barely avoiding the

literal language of the claims. See, *London* v. *Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538, 20 U.S.P.Q.2d 1456, 1458 (Fed. Cir. 1991); *Lear Siegler, Inc.* v. *Sealy Mattress Co.*, 873 F.2d 1422, 1425, 10 U.S.P.Q.2d 1767, 1770 (Fed. Cir. 1989). This was part of Warner-Jenkinson's process years prior to the '746 patent.

D. The '746 Patent Exists In A Very Crowded Art

The art of ultrafiltration including ultrafiltration of dye reaction solutions was well developed prior to Hilton Davis. Hilton Davis cited eight references to the PTO. At trial, an additional 12 references were cited. As discussed more fully in the validity section of this Brief, a British patent had issued in 1972 to Ciba-Geigy (DX513, A2362), which disclosed the use of semipermeable membranes having pore sizes in the range of 2 to 100 Angstrom diameter for ultrafiltration of azo dye coupling solutions. The British '898 patent recommended pH values of 3 to 9 to avoid degradation of the membrane. The patent recommended hydrostatic pressures from 3 to 100 atmospheres and, preferably, 20 to 50 atmospheres. An atmosphere is approximately 15 psig and thus the preferred range extended from 300 to 750 psig. Hilton Davis claimed narrower ranges within the prior art ranges.[3] Any competitor, including Warner-Jenkinson, should reasonably be entitled to believe that it could operate *outside* the boundaries of the *claimed* ranges and in the broader ranges of the prior art.

E. Dependent Claims 2, 3, 13, And 14 Are Not Infringed

Claims 2, 3, 13, and 14 are all dependent on claim 1. Claim 3 is dependent on claim 2. Since claim 1 is not infringed, none of the dependent claims is infringed. *Wahpeton Canvas Co.* v. *Frontier, Inc.*, 870 F.2d 1546, 10 U.S.P.Q.2d 1201 (Fed. Cir. 1989). Moreover, claim 2 calls for a specific membrane material. Just as in the case of membrane pore

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[3]

	Pore Size	pH	Pressure
British '898	2-100A	3-9	45-1500 psig
Hilton Davis	5-15A	6-9	200-400 psig

size, no objective evidence was submitted demonstrating the composition of the specific Desal membrane used by Warner-Jenkinson, only conjecture and speculation. (A400-01, 586-89). Accordingly, the judgment of infringement of these claims also cannot stand.

F. Conclusion Of No Infringement Under The Equitable Doctrine of Equivalents

Inherent in our claim-based patent system is the principle that the protected invention is what the claims say it is, and thus the infringement can be avoided by avoiding the language of the claims. *Slimfold Mfg. Co.* v. *Kinkead Indus., Inc.*, 932 F.2d 1453, 1457, 18 U.S.P.Q.2d 1842, 1846 (Fed. Cir. 1991). This is a case where the claims mean what they say. These claims equitably cannot be applied to Warner-Jenkinson's process which was totally independently developed and in commercial operation before it even knew of the '746 patent.

Once the claims are properly construed in light of the specification and prosecution history, neither the district court nor any reasonable jury could have found that they cover Warner-Jenkinson's process. *Senmed, Inc.* v. *Richard-Allen Medical Indus., Inc.*, *supra*.

II. Claims 1, 2, 3, 13, And 14 Of The '746 Patent Are Invalid

A. The Ultimate Conclusion Of Patent Validity, Including Obviousness, Is One Of Law

The ultimate conclusion of patent validity, including the conclusion of obviousness, is one of law to be determined from the facts and is to be reviewed for correctness or error as a matter of law. *See, Panduit Corp.* v. *Dennison Mfg. Co.*, 810 F.2d 1561, 1566-68, 1 U.S.P.Q.2d 1593, 1595-97 (Fed. Cir. 1987); *Sjolund* v. *Musland*, 847 F.2d 1573, 1580, 6 U.S.P.Q.2d 2020, 2026 (Fed. Cir. 1988).

B. Hilton Davis Has Disavowed Any Patentable Distinction Between The '746 Patent Claims And Booth et al. Cited By The PTO

Hilton Davis' patent agent argued "four major differences" between Booth et al. and the Hilton Davis process, and the Examiner required the claims to be amended to recite the asserted pH difference to distinguish the prior art. The claims thus were allowed. At trial, however, in order to prove its case of infringement, Hilton Davis abandoned the significance of both pH and pressure as critical to the operation of the ultrafiltration process. (A660-61, A228, A232). Thus, the very basis on which Hilton Davis asserted patentability over the prior art in the PTO was disavowed at trial, and thus the Examiner's rejection of the claims of the '746 patent as being merely the application of a known process of purification of azo dye solutions with no unexpected or unobvious results is again applicable. Hilton Davis' position at trial is directly contrary to its position in the PTO, and neither the district court nor any reasonable jury could read claim 1 both to be valid and infringed by Warner-Jenkinson. *Lemelson* v. *General Mills, Inc.*, 968 F.2d 1202, 1208, 23 U.S.P.Q.2d 1284, 1289 (Fed. Cir. 1992).

Hilton Davis' position violates the fundamental rule that claims cannot be construed one way in order to obtain their allowance and in a contrary way against alleged infringers. *Tandon Corp.* v. *Int'l Trade Comm'n*, 831 F.2d 1017, 1021, 4 U.S.P.Q.2d 1283, 1286 (Fed. Cir. 1987).

C. If There Is A Patentable *Process*, Then It Is The Invention Of Osmonics, Not Hilton Davis

Dr. Cook stated that as of August, 1982, he knew nothing about ultrafiltration and relied entirely on Osmonics' expertise. (A178-79, 414-29, 1448-52). He stated on repeated occasions that the membrane, pressures, and pH were all recommended to him by Osmonics. (A423-24, 226, 451-52, 509-10). Osmonics selected the membranes to use, selected the pressures at which to run them, and told Hilton Davis that the pH of the solution should be in the range of 2 to 8.

(A422-25). It is well settled that one who merely suggests an idea of a result to be accomplished rather than the means of accomplishing it is not an inventor. *See, e.g., Pointer* v. *Six Wheel Corp.*, 177 F.2d 153, 83 U.S.P.Q. 43 (9th Cir. 1949), quoting *Agawan Woolen Co.* v. *Jordan*, 74 U.S. 583, 602-03, 19 L.Ed. 177 (1868); *Int'l Carrier-Call & Television Corp.* v. *RCA*, 142 F.2d 493, 61 U.S.P.Q. 392 (2d Cir. 1944).

In *Morgan* v. *Hirsch*, 728 F.2d 1449, 221 U.S.P.Q. 193 (Fed. Cir. 1984), this court similarly examined the evidence and found that "Morgan did not make the invention. He only posed the problem." Submission of successive samples which Morgan criticized until he finally got what he wanted was found not to be inventorship. Here, as in *Morgan* v. *Hirsch*, the judge and jury have confused Dr. Cook's entrepreneurship with Osmonics' inventorship.

The claims in issue are not to the broad concept of using ultrafiltration to purify FD&C Red #40 and Yellow #6 solutions. Rather, the broad concept was rejected by the PTO as obvious in view of Booth et al. Mr. Webb agreed with the PTO and responded that the claims were distinguishable from Booth et al. only on the basis of *four* allegedly critical process parameters. However, each of those process parameters came from Osmonics and not from Hilton Davis. (A1231-38, 1487). If there were a patentable *process*, Hilton Davis did not invent it, Osmonics did. 35 U.S.C. § 101.

D. Warner-Jenkinson's Own Earlier Work With Osmonics In Purifying FD&C Red #40 By Ultrafiltration Is Prior Art Under 35 U.S.C. § 102(g)

On August 17-19, 1982, Osmonics ultrafiltered Warner-Jenkinson's FD&C Red #40 dye coupling solution to remove the impurities therefrom one week *prior* to Hilton Davis. Thereafter, Warner-Jenkinson investigated ultrafiltration of all its dyes, revised their chemistry to make them even better for ultrafiltration, and ultimately commercialized all of its synthetic dyes produced by ultrafiltration, including Red #40 in September, 1986. Although Warner-Jenkinson like Hilton

Davis kept the details of its process secret, that does not disqualify it as § 102(g) prior art. Making the invention publicly known requires only that the public enjoy the benefits or the use of the prior invention not that they know the details of the process. Engaging in activities designed to bring about public or commercial use of the invention is all that is needed. *Del Mar Eng'g. Labs* v. *United States*, 524 F.2d 1178, 1185, 186 U.S.P.Q. 42, 47-48 (Ct. Cls. 1975); *Friction Div. Prods., Inc.* v. *E. I. DuPont de Nemours & Co.*, 658 F. Supp. 998, 1014 (D. Del. 1987), *aff'd*, No. 89-1187 (Fed. Cir. July 24, 1989) (unpublished). This Warner-Jenkinson clearly did. Thus, Warner-Jenkinson's work at Osmonics is § 102(g) prior art, including for purposes of § 103. *E. I. DuPont de Nemours & Co.* v. *Phillips Petroleum Co.*, 849 F.2d 1430, 7 U.S.P.Q.2d 1129 (Fed. Cir. 1988). Warner-Jenkinson thus practices what is in the prior art, i.e., what it and Osmonics first created.

E. Claims 1, 2, 3, 13, And 14 Are Invalid As Obvious

1. The District Court's Holding Was Based On An Erroneous Interpretation Of The "Claimed Subject Matter"

Claim interpretation is a question of law and review is therefore plenary. *Intervet Am., Inc.* v. *Kee-Vet Labs., Inc.*, 887 F.2d 1050, 12 U.S.P.Q.2d 1474 (Fed. Cir. 1989); *Senmed, Inc.* v. *Richard-Allen Medical Indus., Inc.*, 888 F.2d 815, 818, 12 U.S.P.Q.2d 1308, 1511 (Fed. Cir. 1989). The district court's obviousness analysis was flawed because of its erroneous construction of the claims. None of the limitations impliedly relied upon by the jury and explicitly relied upon by the district court are found in the claims. Even if the question of obviousness can be submitted to a jury, where the claim interpretation necessary to support a conclusion of patent validity cannot be supported by the record, the interpretation asserted by Hilton Davis, necessarily arrived at by the jury, and adopted by the district court, cannot stand. *Senmed*, *supra*.

Hilton Davis argued to the jury and the district court accepted Hilton Davis' argument that "plaintiff was the first to successfully achieve a commercially viable continuous process for purifying FD&C Red #40 and FD&C Yellow #6 food dyes to FDA purity levels directly from the coupling solution without an intervening salting out step." (Exhibit G, p. 46). However, those limitations, not appearing in the claims, cannot be relied upon to distinguish the prior art.

Under *Graham*, it is the obviousness of the "claimed subject matter" which must be determined. Courts cannot alter what the patentee has chosen to claim as the invention. Thus, "where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims." *E. I. DuPont de Nemours & Co.* v. *Phillips Petroleum Co.*, 849 F.2d 1430, 1433, 7 U.S.P.Q.2d 1129, 1131 (Fed. Cir. 1988); *Specialty Composites* v. *Cabot Corp.*, 845 F.2d 981, 987, 6 U.S.P.Q.2d 1601, 1605 (Fed. Cir. 1988); *Sjolund* v. *Musland*, 847 F.2d 1573, 1581, 6 U.S.P.Q.2d 2020, 2027-28 (Fed. Cir. 1988) (Jury may not read limitations from the specification into the claims.). That specific examples, particular limitations, or embodiments appear in the specification does not mean that the claims are imbued with those limitations. *Loctite Corp.* v. *Ultraseal Ltd.*, 781 F.2d 861, 867, 228 U.S.P.Q. 90, 93 (Fed. Cir. 1985).

a. The Non-Existent "FD&C" Limitation

There is nothing in claim 1 of the '746 patent which limits it to food, drug, and cosmetic ("FD&C") dyes certified by the FDA (A441-42). The dyes are recited by chemical formula and nothing more. Claim 1 recites five dyes. Only two of them are *now* certified as FD&C dyes by the FDA. Red #2 was once certified but has been banned for food use in the U.S. since 1976. (A443-46). Carmoisine is not a food dye. Dr. Cook admitted that Red #2 and Carmoisine had non-food applications, for example, in dyeing textile and paper. (A446-47). D&C Yellow #10 also within the literal terms of claim 1 is approved only for non-food applications (A447). In such applications, they would not be "FD&C dyes." Thus,

claim 1 encompasses within its literal scope dyes which are not "FD&C" dyes, and claim 1 is not so limited.

b. The Non-Existent "FDA Purity Level" Limitation

Although the *specification* describes purification of the dyes in terms of FDA purity levels, the *claims* of the patent are not limited to any purity specification, FDA or otherwise. (A447-53). The only limitation *in the claims* is that the dye solutions be purified to approximately 90% purity. Dr. Cook admitted that a dye could be 90% pure and still *not* meet FDA specifications (A453). The "FDA specifications" thus are not a limitation of the claims.

c. The Non-Existent "Directly From The Coupling Solution Without An Intervening Salting Out Step" Limitation

Hilton Davis convinced the district court that claim 1 was *limited* to a process wherein the dye reaction solution was ultrafiltered directly without in intervening salting out step (Ex. G. p. 43, 46). However, claim 1 of the '746 patent was drafted specifically to *eliminate* that as a limitation and *include as an alternative*, an intervening salting out step. *The word "directly" was removed in the CIP claim 1.* See Exhibit D. Simultaneously, the *specification* was amended *in two places* to state that the coupling solution could be either *directly* ultrafiltered *or* first *salted out* and then redissolved in water ("an aqueous solution of the reaction mixture") and the resulting aqueous solution ultrafiltered. (See Ex. A, col. 2, l. 46-53; col. 6, l. 61-63).

At trial, Hilton Davis engaged in an attempted revision of history by having Dr. Cook testify that the words used in claim 1 meant only "directly" — the very term that had been *removed* from the claim. In *Senmed, Inc.* v. *Richard-Allen Medical Indus., Inc.*, 888 F.2d 815, 819, 12 U.S.P.Q.2d 1508, 1512 (Fed. Cir. 1989), this court condemned such "semantic antics" and rejected the inventor's self-serving post

hoc opinion testimony on the legal question of whether the claim should have a different meaning. "[A]n inventor may not be heard to proffer an interpretation that would alter the undisputed public record (claim, specification, prosecution history) and treat the claim as a 'nose of wax' ", citing *White v. Dunbar*, 119 U.S. 47, 51-52, 7 S. Ct. 72, 74-75, 30 L.Ed. 303 (1886).

None of the asserted limitations, not present in the claims, can be relied upon to distinguish the "claimed subject matter" from the prior art.

2. The Claims In Issue Of The '746 Patent When Properly Interpreted Would Have Been Obvious To One Of Ordinary Skill

a. Scope And Content Of The Prior Art

(1) Booth et al. (DX506, A2209)

Booth et al. cited by the PTO discloses *directly* subjecting dye reaction mixtures to ultrafiltration to remove both organic impurities and inorganic salt. (Col. 2, l. 7-17). Booth et al. states that it is of special interest to remove organic impurities (and in many cases the inorganic impurities) as completely as possible when the finished product is to be used as a non-absorbable colorant for edibles. (Col. 2, l. 7-46). Final organic impurity levels of less than 5000 ppm [0.5%] (base colorant) are recited. (Col. 2, l. 36-37). The inorganic salts are removed to less than 1%. (Col. 7, l. 14-24). Thus, the dye reaction solutions are purified to greater than "90% purity."

In the PTO, Hilton Davis attempted to distinguish Booth et al. claiming "four major differences." The Examiner required the claims to recite all four of the alleged differences. One difference was the pH of 6.0 to 9.0 in alleged contrast to Booth et al.'s asserted pH of above 9. However, Dr. Cook testified at trial that the pH of the solution had minimal effect on the operation of the process (A232) and that the process worked perfectly well at pH's above 9 or below 9. (A481-83, 1475).

Thus, in the PTO, to obtain the patent, there was a "major difference." At trial, in an attempt to prove a case of infringement, there was no difference. (A1471-78).

The second alleged "major difference" was the pressure of approximately 200 to 400 psig in alleged contrast to Booth et al.'s 25 to 200 psig. Obviously there is no distinction because the ranges overlap at 200 psig. (A480-81). Moreover Hilton Davis' testimony was that the only function of pressure was to overcome the osmotic pressure. (A228, 574-75, 590-91). In Booth et al., the pressure obviously overcomes the osmotic pressure.

The third alleged "major difference" was that Booth et al. added salt to the feed to above 1% by weight which Booth et al. found improved the initial purification process. After removal of the other impurities, there was no salt addition and the salt content of the retentate dropped well below 1% by continued ultrafiltration just as in the '746 patent. (Col. 6, l. 66 through col. 7, l. 17). Again, there is no difference. There is nothing in the *claims* of the '746 patent which *exclude* the addition of salt.

The final alleged "major difference" was that the Booth et al. dye molecules were relatively large. This is true, but that is the only "difference," and it is easily handled by appropriate membrane selection. (DX544, A2575). The prior art shows that it is an obvious difference.

(2) Osmonics' Bulletin No. 109 (DX544, A2575)

The Osmonics' Bulletin No. 109 is conceded to be prior art. Although it was cited to the PTO, the Examiner never applied it to the claims. Osmonics' Bulletin No. 109 teaches that where it is desired to have a molecular weight cut off of 400 for organics that membranes having nominal pore sizes of 8 Angstroms (within the claimed range of 5 to 15 Angstroms) may be used. The Osmonics' bulletin teaches nominal pore sizes of 5 Angstroms for a molecular weight cutoff of 200 up to 11 Angstroms for a molecular weight cut off of 600. These

are the very same molecular sizes found in the claimed dye coupling solutions, i.e., dye molecules around 500 and impurities around 200.

Further, the Osmonics' bulletin teaches that operating pressures of 200 to 600 psig may be used with these membranes and teaches that the membrane "has high stability between pH 2 and 8 and is used at other pH's depending on economics." (A2575).

Osmonics obviously applied this prior art knowledge when it selected the membranes for the Warner-Jenkinson and Hilton Davis application tests in August, 1982. It had *no* difficulty in selecting membranes of a pore size to filter impurities from the "relatively small" Red #40 molecules. The molecule size is not an unobvious difference.

(3) British Patent 1,359,898 (DX513, A2362)

Were there any doubt, the British '898 patent issued in 1972 teaches that dye coupling solutions, including specifically azo dye coupling solutions, may be directly ultrafiltered to eliminate the use of the salting out purification process to give impurity free preparations (p. 1, l. 22 through p. 2, l. 5). The British '898 patent teaches the use of semipermeable membranes having pore sizes in the range of 2 to 100 Angstroms, pH values of 3 to 9, and preferred pressures of 300 to 750 psig to achieve purification of "up to 99%, i.e., until the ultrafiltrate is free of undesired substances." (p. 2, l. 14-56) (A678-86, 728-43).

Hilton Davis attempted to distinguish the British '898 patent on the basis that it did not teach directly ultrafiltering the coupling solution. However, as set forth above, there is no limitation in claim 1 of the '746 patent requiring direct ultrafiltration. Further, the British '898 patent teaches *both* alternatives, i.e., direct ultrafiltration of the coupling solution or with an intervening salting out step identical to what is set forth at column 2, lines 46-54, of the '746 patent. Hilton Davis' Dr. Cook agreed. (A458-76, 483).

b. The "Differences" Between The Prior Art And The Claimed Subject Matter Do No Make An Old Process Unobvious

The only true "difference" is that the prior art does not disclose the application of ultrafiltration to these specific starting materials, FD&C Red #40 and FD&C Yellow #6. However, as Dr. Cook admitted, the '898 British patent specifically discloses the purification of azo dye coupling solutions to high levels of purity, including dye molecules very close to Red #40 and Yellow #6 in size. (A473-76). Even so, the selection of a starting material to be processed, even where new (which these materials admittedly are not), does not make the *process* unobvious and patentable. Selection of the starting material, even if not obvious, is not a category of patentable invention. *Application of Kanter*, 399 F.2d 249, 251 (C.C.P.A. 1968); *Application of Larsen*, 292 F.2d 531, 535 (C.C.P.A. 1961); *Application of Albertson*, 332 F.2d 379, 382 (C.C.P.A. 1964); *In re Durden*, 763 F.2d 1406, 1410 (Fed. Cir. 1985).

The claimed ranges of numerical value overlap the prior art. *In re Malagari*, 499 F.2d 1297, 1302-03 (C.C.P.A. 1974); *In re Ornitz*, 351 F.2d 1013, 1017 (C.C.P.A. 1965). Patentability cannot be founded on the alleged differences in ranges unless the particular range is shown to be critical generally by showing that the claimed range achieves unexpected results relative to the prior art range. *Gardner v. TEC Sys., Inc.*, 725 F.2d 1338, 220 U.S.P.Q. 777 (Fed. Cir. 1984); *In re Woodruff*, 919 F.2d 1575 (Fed. Cir. 1990); *In re Aller*, 220 F.2d 454 (C.C.P.A. 1955). Even the selection of an optimum value of a variable within a prior art range is deemed within the skill of the art. *In re Boesch*, 617 F.2d 272 (C.C.P.A. 1980). Neither in the PTO nor at trial did Hilton Davis ever assert unexpected results, and there are none. (A1175-83, 1485-87, 726-27, 732, 743, 767, 878-80). When Osmonics was told what was to be accomplished, it was 99% certain that their membranes would do the job. (A1178, 1183).

c. Level Of Skill In The Art Of Ultrafiltration Purification Is The Relevant Test, Not Dye Making

Plaintiff argued that the level of skill in the art was that of a dye chemist and that dye chemists (Drs. Rebhahn and Cook) would have little or no knowledge of ultrafiltration processes (which they did not). Warner-Jenkinson testified that was the wrong "art" and that the proper inquiry was the level of skill in the *relevant* art which is that of purification by ultrafiltration. The district court erroneously accepted Hilton Davis' position. (Ex. G, p. 48). The *claims* of the Hilton Davis patent are directed to a *process for purification*. The relevant art is "defined by the nature of the problem confronting the would-be inventor." *Ryko Mfg. Co.* v. *Nu-Star, Inc.*, 950 F.2d 714, 716, 21 U.S.P.Q.2d 1053, 1055 (Fed. Cir. 1991). That is the art of purification by ultrafiltration/reverse osmosis, not dye chemistry. Indeed, Dr. Cook, the dye chemist, went to Osmonics for their expertise. (A414, 416, 421, 425, 429, 1448-52). The *only* testimony regarding the level of skill in the *relevant* art is that workers would have Masters and Ph.D. degrees in chemistry and engineering and from two to ten years or more of experience in ultrafiltration. (A780-82). Thus, the level of skill was very high. Those people, such as the employees of Osmonics, would have no difficulty in selecting a membrane of proper pore size for these size dye molecules, and adopting pH and pressure as recommended in the prior art to ultrafilter these dye solutions.

d. The Conclusion Of Obviousness

When the prior art is examined against the correct level of skill in the art and the correct legal standard is applied, it is clear that the well-known process of ultrafiltration using established and well-known processing conditions to purify certain dye solutions is all that has been claimed in the '746 patent. One need only refer to the testimony of the Osmonics employees, Messrs. Spatz and Gach, who testified that when both Warner-Jenkinson and Hilton Davis asked whether or

not the dyes could be purified by ultrafiltration, they were certain that they could. (A1178, 1183, 1212, 1233). *Cf. In re Merck & Co.*, 800 F.2d 1091, 1097, 231 U.S.P.Q. 375, 379 (Fed. Cir. 1986) ("Obviousness does not require absolute predictability.") To those skilled in the *relevant* art, the selection of the process parameters of membrane pore size, pH, and pressure would have been and was wholly obvious.

3. Claims 2, 3, 13, And 14 Were Not Separately Argued To Be Valid If Claim 1 Was Not Valid

Claims 2, 3, 13, and 14 were not separately argued to be valid if claim 1 was not valid. *Gardner* v. *TEC Sys., Inc.*, 725 F.2d 1338, 1350, 220 U.S.P.Q. 777, 786 (Fed. Cir. 1984) (en banc). Claim 2 is directed merely to the membrane material being composed of cellulose acetate or a polyamide, i.e., nylon. Both materials are disclosed as suitable semipermeable membranes in British '898. (DX513, p. 2, l. 26-30, A2363) (A735-36). Claim 3, dependent on claim 2, is directed to maintaining the concentration of the solution in the range of 5 to 25 weight percent by recycling the concentrate and adding water thereto. This is likewise disclosed in the British '898 patent. (DX513, p. 2, l. 46-53; p. 3, l. 45-59, A2363-64) (A739-41). Claims 13 and 14 add nothing to claim 1 and are not valid on the same basis that claim 1 is not valid. (A741-42).

III. Conclusion

When the decisions of this court are properly applied and the claims are properly construed as a matter of law, it is apparent that there are no equities which invoke the doctrine of equivalents, that Hilton Davis has failed to carry its burden of proof of infringement, and that Warner-Jenkinson has clearly and convincingly proved the obviousness of the claimed subject matter in light of the prior art, including Warner-Jenkinson's own earlier work at Osmonics and Hilton Davis' admissions at trial, and that even if there is an invention in the process, it came from Osmonics and not Hilton Davis.

This court is respectfully requested to enter an order reversing the decision of the district court on the issues of infringement and patent validity.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that two copies of the foregoing **BRIEF FOR DEFENDANT-APPELLANT, WARNER-JENKINSON COMPANY, INC.** has been served by hand delivery, on Plaintiff-Appellee's counsel, David E. Schmidt, FROST & JACOBS, 2500 Central Trust Center, 201 East Fifth Street, Cincinnati, Ohio, 45202, on this 1st day of February, 1993.

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Attorney for Defendant-Appellant