# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS
CORPORATION, NOVARTIS AG,
NOVARTIS PHARMA AG, and
NOVARTIS INTERNATIONAL
PHARMACEUTICAL LTD.,

:

Plaintiffs,

:

V •

Civil Action No. 00-784-JJF

ABBOTT LABORATORIES, INC.,

:

Defendant.

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Stuart B. Young, Esquire, Josy W. Ingersoll, Esquire, John W. Shaw, Esquire of YOUNG, CONAWAY, STARGATT & TAYLOR, Wilmington, Delaware.

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### MEMORANDUM OPINION

March 27, 2003

Wilmington, Delaware

### Farnan, District Judge.

Pending before the Court is a Renewed Motion For Judgment As A Matter Of Law And Alternative Motion For A New Trial (D.I. 434) filed by Defendant, Abbott Laboratories, Inc. By its Motion, Abbott Laboratories, Inc. requests the Court to enter judgment as a matter of law in its favor on Claim 81 of United States Patent No. 6,007,840. In the alternative, Abbott Laboratories, Inc. requests the Court to grant a new trial on the grounds that the Court erroneously excluded relevant evidence and the jury's verdict is facially inconsistent and against the clear weight of the evidence. For the reasons discussed, the Court will grant Abbott Laboratories, Inc.'s Motion For Judgment As A Matter Of Law and deny as moot its Alternative Motion For A New Trial.

#### BACKGROUND

### I. Procedural Background

This action was brought by Plaintiffs, Novartis

Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, and

Novartis International Pharmaceutical Ltd. (collectively,

"Novartis") against Defendant, Abbott Laboratories, Inc.

("Abbott") alleging infringement of Claims 1, 3, 7 and 11 of

United States Patent No. 5,342,625 (the "'625 Patent"), Claims

17-19, 25, 81-83 of United States Patent No. 6,007,840 (the "'840 Patent"), and Claims 13-15 and 19 of United States Patent No.

5,963,017 (the "'017 Patent"). After conducting a Markman hearing and construing the disputed terms of the patents, the Court held a jury trial. During trial, Novartis withdrew its

claims based on the '017 Patent. In addition, Novartis withdrew several of its claims related to the '625 and '840 Patents, leaving the jury to consider only its claim of infringement pertaining to Claim 1 of the '625 Patent and Claim 81 of the '840 Patent. After deliberating, the jury returned a verdict in favor of Abbott on Novartis' claim that Abbott infringed Claim 1 of the '625 Patent. With regard to the '840 Patent, the jury returned a verdict in favor of Novartis on its claim that Abbott infringed Claim 81 of the '840 Patent.

#### II. Factual Background

### A. The Patents Generally

Both the '625 Patent and the '840 Patent relate to pharmaceutical compositions of the drug cyclosporin, which is used to prevent organ rejection in transplant patients.

Specifically, the '625 and '840 Patents disclose cyclosporin compositions in microemulsion pre-concentrate and microemulsion form, and oral methods for the administration of these compositions. Both patents claim priority from the same patent application, i.e. the predecessor application to the '625 Patent. In addition, both patents have nearly identical specifications.

Claim 1 of the '625 Patent defines compositions comprised of cyclosporin as the active ingredient and containing a hydrophilic phase component, a lipophilic phase component and a surfactant.

In full, Claim 1 of the '625 Patent provides:

- 1. A pharmaceutical composition comprising a cyclosporin as active ingredient,
- 1) a hydrophilic phase component comprising

1.1) a pharmaceutically acceptable di- or partialether of the formula

 $R_1 - [O - (CH_2)_2]_x - OR_2$ 

wherein  $R_1$  is  $C_{1-5}$ alkyl or tetrahydrofurfuryl,  $R_2$  is hydrogen,  $C_{1-}$ alkyl or tetrahydrofurfuryl, and X is an integer from 1 to 6, or 1.2) 1, 2-propylene glycol;

- 2) a lipophilic phase component; and
- 3) a surfactant;

wherein said composition is a microemulsion preconcentrate, which upon dilution with water to a ratio of 1:1 parts by weight pre-concentrate to water or more of said water, is capable of providing an oil-in-water microemulsion having average particle size of less than about  $1,000~\text{\AA}$ .

(D.I. 412, Ex. A, '625 Patent, col. 33, 11. 15-35).

Claim 81 of the '840 Patent is narrower than Claim 1 of the '625 Patent and sets forth the weights and proportions of the various components comprising a pharmaceutical cyclosporin composition. In full, Claim 81 of the '840 Patent provides:

An oral pharmaceutical composition comprising about 5 to about 25% by weight of cyclosporin A, about 0.5 to about 90% by weight of a lipophilic component, about 0.5 to about 90% by weight of a hydrophilic surfactant, all weight percents being based on the total weight of the composition, the relative proportion of said cyclosporin A, hydrophilic component, lipophilic component and hydrophilic surfactant being such that upon dilution of said composition with adequate water, an oil-in-water microemulsion having an average particle size of less than about 1,500 Å is spontaneously formed.

- (D.I. 412, Ex. A, '840 Patent, col. 38, 11. 58-67 col. 39, 11.1-2).
  - B. The Court's Claim Construction

Both the asserted claims of the '625 and '840 Patents

require that the formulation contain a lipophilic component.

('625 Patent at col. 33-34; '840 Patent at col. 34-39).

Specifically, Claim 1 of the '625 Patent requires a "lipophilic phase component" and Claim 81 of the '840 Patent requires a "lipophilic component."

In its claim construction, the Court construed the phrase "lipophilic phase component" to require:

at least one excipient meeting the following criteria: (1) a pharmaceutically acceptable lipophilic solvent in which cyclosporin is soluble, which is (2) immiscible with both water and the hydrophilic phase component(s) (in the absence of a surfactant), and which (3) lacks the amphiphilic function characteristic of a surfactant (i.e. it must not be a surfactant).

(D.I. 341). The parties agreed and the Court recognized in its claim construction decision that the term "lipophilic component" as used in the Claim 81 of the '840 Patent has the same meaning as the term "lipophilic phase component" in Claim 1 of the '625 Patent. (D.I. 342 at 3, n.1).

In addition to this common element, both claims require the spontaneous formation of an oil-in-water microemulsion upon addition to water. Addressing the parties dispute with respect to the phrase "oil-in-water microemulsion," the Court concluded that the specification provided sufficient detail regarding the meaning of the phrase, such that additional claim construction by the Court was unnecessary. (D.I. 342 at 8-9) (citing '625 Patent, col. 5, 11. 61- col.6, 11. 18; col. 6, 11. 63-68).

### C. The Accused Product

By its Complaint, Novartis contends that Abbott's product,

Gengraf, infringes Claim 1 of the '625 Patent and Claim 81 of the '840 Patent. Gengraf is a generic cyclosporin capsule containing an ingredient known as Span 80.

#### DISCUSSION

#### I. Standard of Review

### A. Legal Standard For Judgment As A Matter Of Law

To prevail on a renewed motion for judgment as a matter of law following a jury trial, the moving party "'must show that the jury's findings, presumed or express are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings.'" Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)). In assessing the sufficiency of the evidence, the court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him." Williamson v. Consolidated Rail Corp., 926 F.2d 1344, 1348 (3d Cir.), reh'g en banc denied, 1991 U.S. App. LEXIS 16758 (3d Cir. 1991); Perkin-Elmer Corp, 732 F.2d at 893. In sum, the court must determine whether the evidence reasonably supports the jury's verdict. See Dawn Equip. Co. v. Kentucky Farms, Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998); 9A Wright & Miller, <u>Federal</u> <u>Practice & Procedure</u> § 2524 at 249-266 (3d ed. 1995) ("The

question is not whether there is literally no evidence supporting the party against whom the motion is directed, but whether there is evidence upon which the jury properly could find a verdict for that party.")

# B. <u>Legal Standard For The Grant Of A New Trial</u> In pertinent part, Federal Rule of Civil Procedure

59(a) provides:

A new trial may be granted to all or any of the parties and on all or part of the issues in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States.

Fed. R. Civ. P. 59(a). Among the most common reasons for granting a new trial are the following: (1) the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) newly discovered evidence exists that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury's verdict was facially inconsistent. Zarow-Smith v. New Jersey Transit Rail Operations, 953 F. Supp. 581, 584 (D.N.J. 1997) (citations omitted).

The decision to grant or deny a new trial is committed to the sound discretion of the district court. Allied Chemical Corp. v. Darflon, Inc., 449 U.S. 33, 36 (1980); Olefins Trading, Inc. v. Han Yang Chem Corp., 9 F.3d 282 (1993) (reviewing district court's grant or denial of new trial motion under deferential "abuse of discretion" standard). However, where the ground for a new trial is that the jury's verdict was against the

great weight of the evidence, the court should proceed cautiously, because such a ruling would necessarily substitute the court's judgment for that of the jury. Klein v. Hollings, 992 F.2d 1285, 1290 (3d Cir. 1993).

In determining whether to grant a motion for a new trial, the court need not view the evidence in the light most favorable to the verdict winner. However, a new trial should only be granted where "a miscarriage of justice would result if the verdict were to stand," the verdict "cries out to be overturned," or where the verdict "shocks our conscience." Williamson, 926 F.2d at 1352; see also Price, 40 F. Supp. 2d at 550.

# II. Whether Abbott Is Entitled To Judgment As A Matter Of Law With Regard To Claim '81 Of The '840 Patent

By its Motion For Judgment As A Matter Of Law, Abbott contends that the jury's verdict that Abbott infringes Claim 81 of the '840 Patent should be set aside because (1) Novartis' infringement claims violate the "specific exclusion principle," and (2) Novartis failed to present substantial evidence to support the jury's finding that (a) Span 80 is equivalent to the lipophilic component of the claimed invention, and (b) Gengraf is capable of forming an oil-in-water microemulsion upon dilution with water.

During trial, Novartis abandoned its claim that Abbott's Gengraf product literally infringed the asserted claims of the patents in suit, and relied on the doctrine of equivalents to

support its infringement claim. Accordingly, the Court's analysis will be limited to infringement under the doctrine of equivalents.

# A. <u>Legal Principles Applicable To The Doctrine Of</u> <u>Equivalents</u>

An accused product that does not literally infringe upon the express terms of the patent may nonetheless be found to infringe if there is equivalence between the elements of the accused product and the claimed elements of the patented invention. See generally Warner-Jenkinson, 520 U.S. 17 (1997). For there to be infringement under the doctrine of equivalents, the accused product or process must embody every element of a claim, either literally or by an equivalent. Id. at 41. Thus, the mere showing that an accused device is equivalent overall to the claimed invention is insufficient to establish infringement under the doctrine of equivalents.

The primary inquiry in applying the doctrine of equivalents is whether "the differences between the claimed invention and the accused device are . . 'insubstantial.'" <u>Dawn Equip. Co. v.</u>

<u>Kentucky Farms, Inc.</u>, 140 F.3d 1009, 1014 (Fed. Cir. 1998). The determination of whether the differences between the claimed invention and the accused device are insubstantial involves the question of whether "the element of the accused device at issue performs substantially the same function in substantially the same way, to achieve substantially the same result, as the limitation at issue in the claim." <u>Id.</u> at 1016 (describing the "function/way/result" inquiry). To this effect, the United

States Supreme Court has emphasized that the "particular linguistic framework used" is not important, so long as it addresses the "essential inquiry [of whether] the accused product or process contain[s] elements identical to or equivalent to each claimed element of the patented invention." Warner-Jenkinson, 520 U.S. at 40. The Court emphasized that "[t]he determination of equivalence should be applied as an objective inquiry on an element-by element basis." Id.

By its very definition, the doctrine of equivalents necessarily deals with subject matter that is beyond the literal scope of the claim. As such, the doctrine of equivalents, if applied too broadly, can undermine the public's reliance on the patent's claim language and create a situation in which "[c]ompetitor's will never know whether their actions infringe a granted patent." London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991). Mindful of these considerations, the Federal Circuit has cautioned that application of the doctrine of equivalents should be "the exception . . . [and] not the rule" in patent infringement actions. Id.

The question of equivalence may be decided by a jury. <u>See e.g. Intel Corp. v. I.T.C.</u>, 946 F.2d 821, 842 (Fed. Cir. 1991) (recognizing that the fact finder determines "the range of equivalents to which the claimed invention is entitled"). However, the Court is responsible for determining any legal limitations on the application of the doctrine of equivalents. <u>See Warner</u>, 520 U.S. at 39, n.8 ("Of course, the various legal

limitations on the application of the doctrine of equivalents are to be determined by the court."). Although simple to articulate, the doctrine of equivalents is conceptually difficult to apply. To reduce the risk of jury confusion over the doctrine, the patentee must present "particularized testimony and linking argument" as to why the function, way and result of each element in the accused devise is substantially the same as the elements of the claimed invention. Generalized testimony concerning the similarities between the claims and the accused device and evidence or argument subsumed in a plaintiff's case of literal infringement are insufficient to establish infringement under the doctrine of equivalents. Rather, a plaintiff must "articulate the comparison" between the claimed elements and the elements of the accused device and present "substantial evidence" comparing the claimed elements and the accused device in each of the three aspects of equivalency, i.e. the function, way, and result inquiry. See Malta v. Schulmerich Carillons, Inc., 952 F.2d 1320, 1329 (Fed. Cir. 1991); Lear Siegler v. Sealy Mattress Co. of Mich., 873 F.2d 1422, 1427 (Fed. Cir. 1989).

# B. Whether Novartis' Infringement Claim Violates The "Specific Exclusion Principle"

By its Motion, Abbott contends that it is entitled to judgment as a matter of law, because Novartis could not rely on the doctrine of equivalents theory of infringement as a matter of law. Specifically, Abbott contends that Novartis' infringement claim violates the "specific exclusion principle."

Under the specific exclusion principle, the doctrine of

equivalents may not be invoked to embrace an element of a patent that was specifically excluded, either expressly or impliedly, from the patent's claims. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., 242 F.3d 1337, 1346 (Fed. Cir. 2001). As the Federal Circuit has explained:

[B]y defining the claim in a way that clearly excluded certain subject matter, the patent implicitly disclaimed the subject matter that was excluded and thereby barred the patentee from asserting infringement under the doctrine of equivalents.

<u>Id.</u> By way of analogy, the Federal Circuit further explained:

Thus, if a patent states that the claimed device must be "non-metallic," the patentee cannot assert the patent against a metallic device on the ground that a metallic device is equivalent to a non-metallic device. The unavailability of equivalents could be explained either as the product of an impermissible vitiation of the "non-metallic" claim limitation, or as the product of a clear and binding statement to the public that metallic structures are excluded from the protection of the patent. . . [T]he foreclosure of reliance on the doctrine of equivalents in such a case depends on whether the patent clearly excludes the asserted equivalent structure, either implicitly or explicitly.

#### Id. at 1347.

Related to the specific exclusion principle is the "all elements rule." "Under the 'all elements' rule,' . . . . if a court determines that a finding of infringement under the doctrine of equivalents 'would entirely vitiate a particular claim element,' then the court should rule that there is no infringement under the doctrine of equivalents." Bell Atlantic Network Servs. Inc. v. Convad Communications Group, Inc., 262

F.3d 1258, 1279-1280 (Fed. Cir. 2001) (quoting Warner-Jenkinson, 520 U.S. at 39 n.8).

In this case, Abbott contends that, by virtue of the Court's claim construction, the phrase "lipophilic phase component" expressly excludes "surfactants." Because Span 80 is a surfactant, Abbott maintains that it cannot satisfy this claim element, and Novartis is barred from asserting infringement under the doctrine of equivalents.

In response, Novartis contends that the Court repeatedly permitted it to pursue its equivalents theory, and that Abbott's argument impermissibly collapses infringement under the doctrine of equivalents into literal infringement. According to Novartis, it could properly argue to the jury under the equivalents theory that although Span 80 is labeled as a surfactant, it does not function as a surfactant in the claimed invention. Therefore, Novartis contends that Span 80 is equivalent to the lipophilic component of the claim.

After reviewing the record in light of the applicable legal principles, the Court concludes that Abbott is entitled to judgment as a matter of law on its claim that Novartis cannot, as a matter of law, establish infringement under the doctrine of equivalents. In construing the term "lipophilic phase component," the Court expressly concluded that the "lipophilic phase component" must "lack[] the amphiphilic function characteristic of a surfactant (i.e. it must not be a surfactant)." (D.I. 342 at 6) (emphasis added). As defined by the Court, a "surfactant" encompasses both "hydrophilic surfactants and lipophilic surfactants." (D.I. 342 at 11).

Although Novartis maintains that Span 80 does not function as a surfactant in the claimed composition, it is undisputed that Span 80 is, in fact, a surfactant. Even Novartis' expert witness recognized that Span 80 bears the label of a lipophilic surfactant. (Tr. at 383:23-385:4, 404:2-8, 408:14-409:9, 424:1-4). Under the Court's claim construction, the "lipophilic phase component" cannot be a surfactant. To conclude otherwise, would vitiate the Court's claim construction of the "lipophilic phase component," and would require the jury to make the internally inconsistent finding that Span 80, a recognized surfactant, is insubstantially different from something that "must not be a surfactant."

Novartis maintains that the Court permitted it to argue its theory of equivalents to the jury. Novartis is correct that the Court permitted it to proceed to trial on an equivalents theory of infringement. However, in allowing Novartis to proceed before the jury, the Court did not preclude Abbott from arguing to the Court that the legal principles of the "all elements rule" and the "specific exclusion principle" limited the doctrine of equivalents. Indeed, the Court did not substantively address this legal issue at any time prior to trial. In ruling on

The Court granted Novartis' Motion In Limine To Preclude Abbott From Arguing To The Jury That The Court's Claim Construction Precludes Infringement Under The Doctrine Of Equivalents Or Referring To The Court's Adoption Of Abbott's Proffered Claim Construction (D.I. 365). The Court's decision regarding this motion did not preclude Abbott from raising this issue to the Court, and as the Court has previously recognized, legal principles limiting the doctrine of equivalents are correctly argued before and decided by the Court, not the jury.

Abbott's summary judgment motion, the Court stated that it would consider such arguments in the context of a motion for judgment as a matter of law. See Warner-Jenkinson, 520 U.S. at 37 (recognizing that "various legal limitations . . . on equivalents are to be determined by the court, [such as] on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict.").

Novartis directs the Court to its sidebar comments during trial to support its position that the Court considered and rejected Abbott's argument that the doctrine of equivalents was inapplicable under the "all elements rule" and "specific exclusion principle." Specifically, Novartis directs the Court to the following comments made by the Court:

They are going to get by judgment as a matter of law based on the direct testimony of this witness on a doctrine of equivalents test at this juncture.

\* \* \*

[W]ith the claim construction I have provided, if the jury believes this witness' testimony that a surfactant can be the equivalent of the missing element for literal infringement, that it functions as the equivalent, then [Novartis has] established a doctrine of equivalents case. It is a question for the jury. It is a question of fact.

(Tr. 433:24-434:1; 434:12-17).

Reviewing the Court's comments in the context of the sidebar discussion, as a whole, the Court cannot conclude that it previously considered and rejected Abbott's arguments on the legal limits of the doctrine of equivalents in this case. During trial, Abbott's counsel questioned Novartis' expert witness as to

"whether, as a legal framework, the doctrine of equivalents could apply to something which is specifically excluded from the claim." (Tr. 430:25-431:2). Novartis' counsel requested a sidebar to pose an objection to the question. During sidebar, the Court sustained the objection noting that the question called for an answer that was a legal conclusion reserved for the Court. The Court stated:

That calls for a legal conclusion. He told you what legal test he applied, and he correctly stated what the legal test is for the doctrine of equivalents, which was supplied to him by Novartis' lawyers. . . . You keep pushing the envelope, asking him for an answer which, in essence, is a legal conclusion. . [Y]ou are trying to put in the jury's mind what you think the answer is. But this witness can't give you the answer. Only I can give that answer.

(Tr. 433:5-14) (emphasis added).

To the extent that the Court issued any rulings with respect to a possible motion for judgment as a matter of law, the Court stated that Novartis would "get by judgment as a matter of law.

. . at this juncture" and "at the end of their case." (Tr. 434:1, 21) (emphasis added). The Court's statements were directed to the content of the witness' testimony in the context of the trial, and not to any legal questions involving the limits on the doctrine of equivalents that might arise in the context of post-trial applications. The Court did not consider what, if any rulings, it would make on a renewed judgment as a matter of law, and the Court did not render any legal analysis on the "all elements rule" or the "specific exclusion principle."

In arguing that the specific exclusion principle does not

preclude Novartis from making an equivalents argument, Novartis contends that application of the specific exclusion principle in this case would collapse literal infringment into the doctrine of equivalents. In support of its proposition, Novartis directs the Court to the decision of the Federal Circuit in <a href="Ethicon Endo-Surgery">Ethicon Endo-Surgery</a>, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1317 (Fed. Cir. 1998) and the decision of the Northern District of California in <a href="Aclara Biosciences">Aclara Biosciences</a>, Inc. v. Caliper Technologies <a href="Corp.">Corp.</a>, 2000 WL 1639507 (N.D. Cal. Oct. 27, 2000).

After reviewing Novartis' argument in the context of this litigation and the applicable case law, the Court is not persuaded by Novartis' argument. First, the Court is not persuaded that the application of the specific exclusion principle in this case would collapse literal infringement into the doctrine of equivalents. Under the Court's claim construction, Novartis is precluded from claiming that surfactants are the equivalent of the "lipophilic phase component." However, Novartis is not precluded from arguing that certain non-surfactants may be equivalent to the "lipophilic phase component."

Further, the Court is not persuaded that the <u>Ethicon</u> and <u>Aclara</u> decisions mandate a different conclusion. In <u>Ethicon</u>, the court recognized that "literal failure to meet a claim limitation does not necessarily amount to 'specific exclusion,'" and that the "all elements rule" could swallow the doctrine of equivalents if a negative determination of literal infringement is used to

preclude a finding of infringement under the doctrine of equivalents. 149 F.3d at 1317. However, the <a href="Ethicon">Ethicon</a> court also recognized that a limitation is specifically excluded from coverage if "its inclusion is somehow <a href="inconsistent">inconsistent</a> with the language of the claim." <a href="Id.">Id.</a> (emphasis added). In <a href="Ethicon">Ethicon</a>, the court concluded that the claims at issue did not contain a specific exclusion in either the express language of the claim or as construed by the trial court, and therefore, the specific exclusion principle was inapplicable.

Unlike the circumstances in <a href="Ethicon">Ethicon</a>, in this case, the claim construction expressly excludes surfactants from the definition of the "lipophilic phase component." Because surfactants are expressly excluded from coverage, a surfactant acting as the "lipophilic phase component" is inconsistent with the language of the claim, as construed by the Court. Accordingly, the specific exclusion principle is appropriately invoked by the Court under the legal principles recognized in <a href="Ethicon">Ethicon</a>.

In <u>Aclara</u>, the court recognized the same legal principles that the <u>Ethicon</u> court recognized. However, the <u>Aclara</u> court concluded that the "specific exclusion" cases it considered involved claims which were "much more limiting - and more obviously excluded the allegedly infringing product" than the claim before the court. Further, the <u>Aclara</u> court found its claim construction to be a "close question." Unlike <u>Aclara</u>, in this case, the Court stated that the lipophilic phase component "must not be a surfactant." Given that the Court obviously

excluded surfactants from this element of the claim, the Court finds the circumstances of this case to be distinguishable from the circumstances contemplated by the <u>Aclara</u> court, and in any event, the Court is not bound by the decision in <u>Aclara</u>.

In sum, the Court concludes that the all elements rule and its corollary, the specific exclusion principle, apply in this The Court expressly concluded that the lipophilic phase component "must not be a surfactant." Because the evidence at trial established without dispute that Span 80 is a recognized surfactant, Novartis cannot establish as a matter of law, that Span 80 is the equivalent of something which "must not be a surfactant." (Tr. at 383:23-385:4, 404:2-8, 408:14-409:9, 424:1-4). Because Novartis cannot establish that all of the claim limitations are found in the accused product, the Court concludes that Novartis cannot establish infringement under the doctrine of equivalents. Accordingly, the Court will enter a judgment of non-infringement as a matter of law in favor of Abbott on Claim 81 of the '840 Patent. Having concluded that Abbott is entitled to judgment as a matter of law, the Court declines to address the remaining arguments raised by Abbott regarding the substantiality of the evidence adduced at trial and the alleged inconsistency of the verdicts rendered by the jury in this case.

#### CONCLUSION

For the reasons discussed, the Court will grant Abbott's Renewed Motion For Judgment As A Matter Of Law on the grounds that the specific exclusion and all elements rule precludes a

finding of infringement under the doctrine of equivalents as a matter of law and deny as moot Abbott's Alternative Motion For A New Trial.

An appropriate Order will be entered.

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,

: :

Plaintiffs,

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V •

Civil Action No. 00-784-JJF

ABBOTT LABORATORIES, INC.,

:

Defendant.

#### ORDER

At Wilmington, this 27th day of March 2003, for the reasons discussed in the Memorandum Opinion issued this date;

#### IT IS HEREBY ORDERED that:

- 1. The Renewed Motion For Judgement As A Matter Of Law (D.I. 434) filed by Defendant, Abbott Laboratories, Inc. is GRANTED.
- 2. The Alternative Motion For A New Trial (D.I. 434) filed by Defendant, Abbott Laboratories, Inc. is DENIED AS MOOT.
- 2. The Judgement Order (D.I. 432) entered on the jury's verdict is vacated to the extent that it enters judgment in favor of Plaintiffs on United States Patent No. 6,007,840.
- 3. Judgement of non-infringement is entered in favor of Defendant, Abbott Laboratories, Inc. on United States Patent No. 6,007,840.

JOSEPH J. FARNAN, JR.
UNITED STATES DISTRICT JUDGE