IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD., and LTS LOHMANN THERAPIE-SYSTEME AG, Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	Civil Action No. 11-1077-RGA (Consolidated)

TRIAL OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd., and LTS Lohmann Therapie-Systeme AG (collectively, "Novartis" or "Plaintiff") brought this suit against Watson Laboratories, Inc., Watson Pharma, Inc., Watson Pharmaceuticals, Inc. (collectively "Watson"), and Par Pharmaceutical, Inc ("Par" or "Defendant")[1] alleging infringement of U.S. Patents Nos. 6,335,031 ("the '031 patent") and 6,316,023 ("the '023 patent") (collectively, "the patents in suit"). Both patents share the same specification.[2]

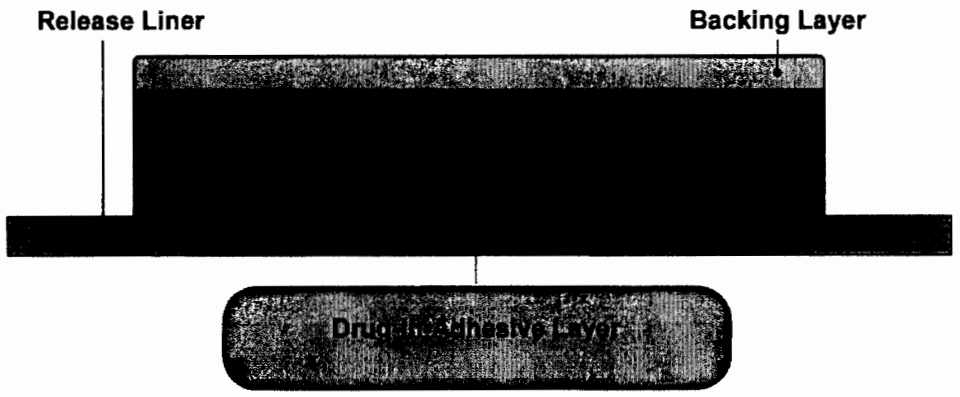
Novartis sells an Exelon® transdermal patch for the treatment of Alzheimer's disease that contains rivastigmine. (D.I. 374-1 at 4).[3] Novartis listed the '031 and '023 patents in the Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations," frequently referred to as the "Orange Book," as covering the Exelon® patches. Par's Abbreviated New Drug Application 202,339 ("ANDA") seeks approval to engage in the commercial manufacture, importation, use, or sale of a rivastigmine transdermal system, in 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24hr dosage strengths. The basic design of the drug is depicted[4] below:

[1] Both the Par and Watson defendants were scheduled for trial beginning on August 26, 2013. Par and Novartis informed the Court on the morning of the first day of trial that a settlement had been reached. Relying on this representation, the Court entered an order staying the action with respect to Par for forty-five days and dismissed Par from the trial. (D.I. 293). The settlement later fell through, and a trial for Par and Novartis took place on May 1, 2014.

[2] Unless otherwise noted, all citations to the specification refer to the '031 patent.

[3] Unless otherwise noted, all citations to the docket are to case 1:11-cv-01077-RGA.

[4] The picture is modified from trial exhibit PDX 102. It is presented here only as a general demonstrative and no part of it should be considered a factual finding by the Court.



Novartis asserts that Par's ANDA products infringe claim 7 of the '031 Patent because acetaldehyde meets claim 7's antioxidant requirement. (D.I. 403 at 5). Par counters that if acetaldehyde is found to be an antioxidant, then claim 7 fails to meet the requirements of 35 U.S.C. § 112, as the claim is both indefinite and the claim does not meet the written description requirement.

The Court held a two day bench trial on May 1 and 2, 2014. (D.I. 398, 399 (collectively referred to as Tr.)). As explained below, Novartis failed to prove that Par's ANDA products infringe by a preponderance of the evidence, and thus the Court does not reach the issue of invalidity.[5]

I. INFRINGEMENT

The one asserted claim in the '031 patent, claim 7, depends from non-asserted independent claim 1. Claim 1 of the '031 patent recites:

> A pharmaceutical composition comprising:
>
> (a) a therapeutically effective amount of (S)-N-ethyl-3-{(1-dimethylamino)ethyl}-N-methyl-phenyl-carbamate in free base or acid addition salt form (Compound A);

[5] Par's counterclaim for invalidity was based upon a finding of infringement. As there is no infringement, the Court need not reach the issue of invalidity. Par specifically stated that it would only be pursuing its invalidity arguments if there were a finding of infringement.

(b) about 0.01 to about 0.5 percent by weight of an antioxidant, based on the weight of the composition, and

(c) a diluent or carrier.

'031 patent, claim 1. In the claim language "Compound A" refers to rivastigmine, the "S" enantiomer of the racemic compound RA_7. Claim 7 narrows claim 1 by limiting it to a specific delivery method. Claim 7 reads:

> A transdermal device comprising a pharmaceutical composition as defined in claim 1, wherein the pharmaceutical composition is supported by a substrate.

Id., claim 7.

Claim 7 is a "presence" claim, and thus requires proof that Compound A and an antioxidant are present. The Court defined "antioxidant" as an "agent that reduces oxidative degradation." (D.I. 250, pp. 1-2). There is no additional requirement that the antioxidant function with respect to Compound A because that is specifically required in the function claims. (*Id.*, p. 2 ("The patents repeatedly disclose the combination of Compound A and the antioxidant without specifically requiring that the antioxidant affect Compound A. It would be improper to preclude those embodiments by limiting 'antioxidant' to require that interaction." (internal citations omitted))).

The parties agree that whether Par's ANDA product infringes raises only two issues: (1) whether an antioxidant is present and (2) whether that antioxidant will be present in Par's ANDA products in the amount claimed by the `031 patent. (D.I. 403 at 5; D.I. 410 at 6). Novartis argues both that acetaldehyde is an antioxidant and that it is present in the patch in sufficient quantities to infringe the `031 Patent. Par maintains that acetaldehyde is not an antioxidant, and

even if it were, it would not be present in the final ANDA product at sufficient levels to violate the '031 Patent.

A. Legal Standard

"Under [35 U.S.C.] § 271(e)(2)(A), a court must determine whether, if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). The application of a patent claim to an accused product is a fact-specific inquiry. *See Kustom Signals, Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326, 1332 (Fed. Cir. 2001). Literal infringement is present only when each and every element set forth in the patent claims is found in the accused product.[6] *See Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575-76 (Fed. Cir. 1995). The patent owner has the burden of proving infringement by a preponderance of the evidence. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984) (citing *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361 (Fed. Cir. 1983)). Infringement can be shown by "any method of analysis that is probative of the fact of infringement," and, in some cases, "circumstantial evidence may be sufficient." *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009).

B. Findings of Fact

1. Oxidation is the process in which one compound, the reducing agent, transfers an electron to another compound, the oxidizing agent.
2. Oxidative degradation is the process by which oxidation causes a chemical compound to degrade.
3. Acetaldehyde is a reducing agent.

[6] There are no assertions of infringement by the doctrine of equivalents.

4. Reducing agents can work as antioxidants.
5. Acetaldehyde does not form a stable radical and therefore it can also contribute to oxidative degradation.
6. A stress test is when a researcher creates an oxidizing environment that is capable of accelerating oxidative degradation.
7. Dr. Davies's stress test has not been performed prior to the present litigation.
8. Typical levels of confidence accepted in the scientific community are 0.9, 0.95 and 0.99.
9. Acetaldehyde has not been previously considered an antioxidant.
10. Plaintiff has not proven acetaldehyde is an antioxidant.

C. Conclusions of Law

1. The asserted claim does not require an antioxidant that acts upon Compound A

Three limitations of the presence claims are: Compound A, a certain weight percent of antioxidant, and a diluent or carrier. *See, e.g.*, '031 patent, claim 1. Unlike the function claims, nowhere in the presence claims is any function of the antioxidant mentioned. *Compare id.* (requiring Compound A and "about 0.01 to about 0.5 percent by weight of an antioxidant"), *with id.*, claim 11 (requiring Compound A "and an amount of antioxidant *effective to stabilize Compound A* from degradation" (emphasis added)). The Court cautioned in its claim construction opinion that it would be "improper to impute the antioxidant's stabilizing effect on Compound A, explicitly claimed in some claims [*i.e.*, the function claims], into claims that do not contain that explicit limitation [*i.e.*, the presence claims]." (D.I. 250, p. 2). Par nevertheless maintains that "antioxidant," as used in the patents in suit, "requires the presence of an agent that reduces oxidative degradation of some component in the claimed composition." (D.I. 318, pp.

12-13 ("The definition of 'antioxidant' adopted by the Court, 'an agent that reduces oxidative degradation,' plainly recognizes that the term is a functional limitation that requires a reduction of oxidative degradation in the claimed composition.")). This argument is rejected as being inconsistent with the Court's claim construction.

2. It was not proven that acetaldehyde is an antioxidant

The Plaintiff argues that acetaldehyde is an antioxidant, while the Defendant maintains that acetaldehyde is not an antioxidant.

a. The mere fact that acetaldehyde is a reducing agent does not make it an antioxidant.

The Plaintiff's first argument is that acetaldehyde is a reducing agent, and as reducing agents can act as antioxidants, acetaldehyde is an antioxidant. (D.I. 403 at 7). The parties do not contest that acetaldehyde is a reducing agent. They do disagree whether the simple fact that acetaldehyde is a reducing agent, by default, makes it an antioxidant. The Court agrees with the parties that acetaldehyde is a reducing agent. *See* JTX061 (VAN NOSTRAND'S CONCISE ENCYCLOPEDIA OF SCIENCE ("[Acetaldehyde] also is used as a reducing agent. . . .")). The Court finds, however, that the Plaintiff failed to put forth sufficient evidence to show that because acetaldehyde is a reducing agent, it must be an antioxidant.

Oxidation is the process in which one compound, the reducing agent, transfers an electron to another compound, the oxidizing agent. (Tr. 233).[7] When a compound accepts an electron, it is reduced, and when a compound gives away an electron, it is oxidized. *Id.* This process is generally referred to as the redox process. *Id.* The redox process leads to oxidative degradation, "the process by which the oxidation level of [a] chemical compound results in [the

[7] Par presents no explanation within its post-trial briefing as to how the oxidation cycle works. The Court relies upon the Defendant's expert's testimony for how a redox reaction works. There was no meaningful disagreement between the experts regarding how redox reactions work.

chemical's] degradation." *Id.* The process itself "begins with some organic compound[]," which is oxidized to become a radical. *Id* at 233, 234. The radical then reacts with a molecule of oxygen to form a peroxy radical. *Id.* at 234. When the "peroxy radical encounters another organic molecule[,] such as the substance being degraded," "[t]he peroxy radical will abstract the hydrogen and be reduced, thus forming . . . a peroxide . . . and regenerating the initial radical. . . ." *Id.* This process is cyclical, and thus can cause a chain reaction and cause organic compounds to transform into their oxidative degradation products. *Id.* This cyclical process can be broken or slowed by the presence of an antioxidant, which the Court construed as an "agent that reduces oxidative degradation." (D.I. 250 at 1). Antioxidants can be reducing agents that function by forming a radical, after being oxidized, that is more stable than the degradation pathway, and thus slows or stops the redox reaction. (Tr. at 236-37). As discussed above, reducing agents are simply substances that will reduce some other compound. *Id.* at 238. Therefore, some reducing agents form one class of antioxidants. (Tr. at 79, 238-39).

Both parties agree that acetaldehyde is a reducing agent. (D.I. 410 at 12; 417 at 6). The question then is, has the Plaintiff put forth enough evidence to show that acetaldehyde additionally is an antioxidant. While the Plaintiff's experts testified that *some* reducing agents act as antioxidants, there was no testimony as to what portion of reducing agents *are* antioxidants. Therefore, the most that can be garnered out of the Plaintiff's expert's testimony is that, as acetaldehyde is a reducing agent, it *may* be an antioxidant. This is not sufficient to show, by a preponderance of the evidence, that acetaldehyde is an antioxidant.

Par's expert, Dr. Ganem, convincingly testified that the likelihood that acetaldehyde is an antioxidant is decreased because it does not form a stable radical. (Tr. 237). Instead, as Dr. Ganem testified, acetaldehyde forms a highly reactive radical that itself can contribute to

oxidative degradation. *Id.* Furthermore, the principal review journal of the American Chemical Society, *Chemical Reviews*, reports that when acetaldehyde undergoes oxidation it can form four different chemical radicals, each of which can contribute to oxidative degradation. *Id.* at 240-42; JTX 86 at 335. Dr. Ganem further testified that all of these reactive radicals form readily at room temperature. (Tr. at 242-43). While the Plaintiff argues that these radicals would only form at minus 30°C, and thus are not relevant to this analysis, the Defendant's expert persuasively explained that this temperature was used during the experiment so as to be able to isolate the various compounds and that the various compounds would also form at room temperature. *Id.* It is noteworthy that the Plaintiff's own experts are not cited by the Plaintiff as discussing this issue. Thus the Court finds both that the Plaintiff has not demonstrated that acetaldehyde is an antioxidant, merely because it is a reducing agent, and that the Defendant demonstrated that acetaldehyde could promote oxidative degradation, thus making it an "oxidant" rather than an "antioxidant."

b. Dr. Davies' Stress Test does not show that acetaldehyde is an antioxidant.

The Plaintiff argues that Dr. Davies' stress test shows that acetaldehyde is an antioxidant, while the Defendant argues that the test is not reliable and thus provides the Court with no additional relevant evidence.[8]

A stress test involves creating an oxidizing environment that is capable of accelerating the degradation of a compound so that its degradation can be studied within a relatively short period of time. (Tr. at 88). Thus by adding or subtracting variables, such as an additional chemical or different lighting, stress tests can be used to determine a variable's effect on the

[8] The parties dispute as to whether Dr. Davies' test meets the requirements of *Daubert*. The Court assumes without deciding that the test does meet the *Daubert* standard.

reaction. *Id.* at 89. Thus, if an experiment is properly conducted, by changing a single variable, one can determine how the presence of a particular chemical alters the results of the chemical reaction.

Dr. Davies, the Plaintiff's expert, conducted such a stress test. As described by the Plaintiff, the stress test involved the following steps:

1. Preparing a single stock solution containing 0.36% rivastigmine and 1.3% of the peroxide t-butyl hydroperoxide ("TBHP") in ethyl acetate solvent to eliminate any variability that would result from multiple solutions;

2. Dividing the stock solution into two identical parts, added 0.0017% acetaldehyde (an amount similar to that reported in some batches of Par's ANDA product) to only one half of the stock solution, and used the other half as a control;

3. Dividing each of the acetaldehyde-containing and control solutions into three samples;

4. Stressing the samples at 60°C; and

5. Measuring the extent of oxidative degradation after 6, 15, and 21 hours by analyzing the samples using high performance liquid chromatography ("HPLC"), a common technique used in the pharmaceutical industry to identify and quantify different compounds of a mixture.

(D.I. 403 at 8 (internal citations omitted)).

The credibility of Dr. Davies' test is diminished by the fact that, with the exception of its use in the present case, Dr. Davies could not cite any literature or reference showing that the test had ever been used to determine whether or not a compound was an antioxidant. (Tr. at 174). Further because the experiment had not been conducted before, the potential rate of error for the test is unknown. The test's unknown error rate is further compounded by the fact that Dr. Davies did not repeat the test, or even run the test with a known antioxidant. Furthermore, Dr. Davies failed to account for numerous substances in the experiment, which may have been generated by side reactions with TBHP. *Id.* at 253. The Defendant's expert focuses on how this lack of

accounting would prevent the study from being published. *Id.* at 254. The Court is not so concerned about whether the study is appropriate for publication. A study being appropriate for publication would certainly provide a reason for the Court to provide greater weight to the study, but the inability to publish the report, without more, is inconsequential, especially without testimony as to the standards for publication, which was lacking here. Instead, the inability of Dr. Davies to account for a large portion of the compounds present in the test, when combined with the fact that this test has not been previously used, decreases the Court's confidence in the persuasiveness of Dr. Davies' test. The Court notes that the Defendant also points out other deficiencies of the test. For example, it does not properly model the conditions of the transdermal patch. As the patent claim is a presence claim, however, these shortcomings are not relevant to the present analysis. (D.I. 410 at 20).

The results of the test showed that the samples containing acetaldehyde resulted in more rivastigmine and less rivastigmine oxidative degradation products than the control samples without acetaldehyde. However, the two parties disagree as to how the results should be interpreted. The Plaintiff's expert stated that he used a one-tail t-test, while the Defendant's expert argued that a two-tail t-test was appropriate. Dr. Davies testified that a one-tail t-test was appropriate as he expected that acetaldehyde would either have no effect or would be an antioxidant. (Tr. at 129-30). The Defendant's expert, Dr. Michniak-Kohn, argued that a two-tail t-test was appropriate as acetaldehyde could have promoted or reduced the rate of the degradation cycle. Neither party put forth an expert on statistics to aid the Court in determining which test is appropriate. Instead, the parties rely on argument, unsupported by persuasive evidence, as to the appropriateness of the relevant tests. In the absence of evidence, the party with the burden of proof fails. Thus, the lack of evidence as to which statistical test to use in

determining whether the results of the stress test are significant prevents the Court from relying on the test. However, if the Court were required to determine which test to rely upon, based on the evidence presented, it seems more likely than not that the two-tail t-test is appropriate, as evidence was presented at trial that acetaldehyde could act to both speed up and slow down the redox cycle, which would support Dr. Michniak-Kohn's testimony. Further, choosing between the testimony about statistics by two non-statisticians, the Court accepts Dr. Michniak-Kohn's testimony that one-sided T-tests are rarely appropriate.

Using the two-tail t-test, the test results were inconclusive. There would be an 87 percent level of confidence that the difference between the sample with acetaldehyde and without acetaldehyde was significant. (Tr. at 401). The Plaintiff argues that this level of confidence is above the necessary threshold to show that acetaldehyde is an antioxidant. The Court disagrees. First, the Plaintiff cites *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.* 616 F.3d 1283, 1287 (Fed. Cir. 2010). *Adams* turned on claim construction. The Federal Circuit found that it was not necessary that the patentee prove that a drug was within a certain bioequivalent range to a 90 percent confidence level because that requirement had not been incorporated into a relevant claim construction. *Id. Adam*s thus is of no assistance in deciding any issue before this Court. Second, the confidence level is a determination of the likelihood that the differences between the test results are statistically significant, that is, that the differences are real. It is not the case that a confidence level of 87% means that 87% of the time acetaldehyde will be an antioxidant. Instead a confidence level of 87% means that the difference between the results in the vials with and without acetaldehyde have an 87% chance of being real. Dr. Michniak-Kohn testified that such a result indicates that the one cannot draw a reliable conclusion from Dr. Davies' data as a 95% confidence level is scientifically preferable. (Tr. at 375). Her direct testimony was

supported by the Plaintiff's cross examination of her, in which an exhibit she relied on indicated that typical confidence levels are 90, 95, and 99 percent with 95 percent being the most common. *Id.* at 398. Eighty-seven percent falls below all of these confidence levels. While the Plaintiff argues that 87% is still significant, the Plaintiff points to no evidence to support such a conclusion. (D.I. 403 at 11). Argument is not evidence. Therefore, as there was no evidence presented at trial that the parties cited in their briefing to show a confidence level of less than 90 percent is significant, the Court finds that the results of the stress test cannot be relied upon as the results were not statistically significant.

The Court finds that the Plaintiff's stress test was not persuasive because: (1) Dr. Davies failed to provide any evidence that the test had previously been used to determine whether a chemical was an antioxidant, (2) the error rate for the test is unknown, and (3) Dr. Davies failed to account for numerous unknown substances that formed as part of the test. However, even accepting the test at face value, it did not yield statistically significant results because: (1) the Plaintiff did not show that a one-tail t-test was the correct statistical tool to analyze the results, and (2) under the two-tail t-test analysis, the results were not statistically significant. Thus Plaintiff did not prove infringement.

c. Other Evidence

The Defendant presented other evidence to show that acetaldehyde is not an antioxidant.

First, Par presented evidence that acetaldehyde is not generally recognized as an antioxidant. Dr. Buckton, an expert on drug substance testing, formulation development, and stability testing of pharmaceutical products, testified that acetaldehyde is not listed as an antioxidant in the `031 patent, the Handbook of Pharmaceutical Excipients, and other pharmaceutical literature, because "acetaldehyde has never been used as and is not recognized as

an antioxidant." (Tr. at 436). Dr. Buckton's testimony was bolstered by that of Dr. Ganem who testified that in his forty years as a chemistry professor with an expertise in oxidation and reduction reactions he had never heard of acetaldehyde as an antioxidant. *Id.* at 238. Dr. Davies additionally admitted that acetaldehyde is not listed as an antioxidant by the FDA. The Court finds that while, the lack of acetaldehyde being listed as an antioxidant does not by itself prove that acetaldehyde is not an antioxidant, it does move the needle in the Defendant's direction and highlight the necessity of the Plaintiff's own testing demonstrating that acetaldehyde is an antioxidant.[9]

Second, Par performed stability testing, as described in the `031 patent, which Par argues shows that acetaldehyde is not an antioxidant. (D.I. 410 at 14). The test involved comparing batches of ANDA product that contained detectable levels of acetaldehyde with batches that did not contain detectable levels of acetaldehyde. Dr. Buckton testified that the test showed "absolutely no evidence at all that acetaldehyde can reduce oxidative degradation because the product is clearly stable without any need for it." (Tr. 449-51). The Court finds this testimony unhelpful. No evidence was presented that indicated what, if any, other compounds were either present or not present within the batches. Furthermore, the Court was presented with no testimony as to whether the results were statistically significant. In sum, the Court finds that Par's testing was completely lacking in reliability and therefore the Court places no weight on it.

Third, Par argues that the Plaintiff's testing should be discredited because it was conducted for the purpose of litigation. This argument is baseless. Parties in many cases (and particularly in ANDA cases) regularly conduct testing for the purposes of litigation. When that

[9] It occurs to me that this is a case in which claim construction has just confused the issues. The "presence" claims require an antioxidant. No person of ordinary skill in the art would consider acetaldehyde to be an antioxidant. Giving antioxidant its plain meaning, Par's ANDA product does not infringe because it does not contain what a POSITA would consider an antioxidant.

testing is conducted, it has to be evaluated on its own merits, which is what I have tried to do here. Dr. Davies is a reputable scientist. He has been subject to cross-examination, and Par presented reputable experts to counter his work. I have evaluated the evidence in dispute.

d. *Plaintiff has not shown by the preponderance of the evidence that acetaldehyde is an antioxidant.*

The Plaintiff has failed to prove by the preponderance of the evidence that acetaldehyde is an antioxidant. First, the mere fact that acetaldehyde is a reducing agent does not show that acetaldehyde is an antioxidant. Second, the experiment conducted by Dr. Davies provides no usable evidence for the Court. The design of the experiment itself was uncertain. The Plaintiff did not meet its burden of proving that the results of the experiment were significant. Therefore, the Court finds that Dr. Davies' experiment does not show that acetaldehyde is an antioxidant. Third, Par's testing provides no usable information for the Court. Fourth, Par's evidence that acetaldehyde has never been considered an antioxidant is some evidence in Par's favor. Considering all of this evidence, the Court finds that the Plaintiff has failed to provide sufficient evidence to prove that it is more likely than not that acetaldehyde is an antioxidant. Therefore, as the '031 patent requires the presence of an antioxidant and the Plaintiff identified no substance other than acetaldehyde that could be an antioxidant, the '031 patent is not infringed.

II. INVALIDITY DEFENSES

Par indicated at both the trial and in its briefing that its asserted invalidity defenses are only at play if acetaldehyde is found to be an antioxidant. (D.I. 401 at 6). As the Court did not find acetaldehyde to be an antioxidant, the Court need not, and does not, make any findings

related to the Defendant's invalidity defenses. Judgment for Plaintiff will be entered on the invalidity defenses.[10]

III. CONCLUSION

Novartis did not prove that Par's ANDA products infringe claim 7 of the '031 patent. Par should submit an agreed upon form of final judgment within two weeks.

[10] Par's position was predicated on a non-infringement finding. Should the non-infringement finding be vacated or reversed, I would not consider Par to have waived any right to argue its invalidity defenses on the record created at trial.