IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MEDIMMUNE ONCOLOGY, INC.	*	
Plaintiff	*	
vs.	*	CIVIL ACTION NO. MJG-04-2612
SUN PHARMACEUTICAL INDUSTRIES, LTD.	*	
Defendant	*	

* * * * * * * * *

MEMORANDUM AND ORDER

The Court has before it Sun's Motion for Summary Judgment of Non-Infringement [Paper 85] and the materials submitted relating thereto. The Court has held a hearing and had the benefit of the arguments of counsel.

I. PROCEDURAL POSTURE

The patents at issue herein relate to sterile crystalline amifostine trihydrate, a substance in the drug Ethyol®, used by cancer patients to alleviate the severity of the side effects associated with radiation and chemotherapy.

In this Hatch-Waxman[1] case, Plaintiff MedImmune Oncology, Inc. ("MedImmune") has sued Sun Pharmaceutical Industries, Ltd. ("Sun")[2] for infringement of U.S. Patent No. 5,424,471 "Crystalline Amifostine Compositions and Methods of the Preparation and Use of the Same," ("the '471 Patent") and U.S. Patent No. 5,591,731, "Crystalline Amifostine Compositions" ("the '731 Patent").[3] On November 14, 2005 the Court issued a Scheduling Order regarding procedures through a claim construction hearing to be held in March of 2007. By Order of September 12, 2006, the Court permitted Sun to pursue the instant motion addressing, on an expedited basis, two claim construction issues asserted to be "silver bullets" that could conclude the case without the need for further proceedings.

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[1] Sun filed an Abbreviated New Drug Application ("ANDA") at the Food and Drug Administration ("FDA") seeking approval to market a generic version of Ethyol® prior to the expiration of MedImmune's patents. In doing so, Sun was required to certify under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that MedImmune's patents were not infringed by Sun's generic products and/or were invalid or unenforceable.

[2] Under 21 U.S.C. § 355(j)(5)(B)(iii)

[3] Count three of the Complaint alleging infringement of MedImmune's U.S. Patent No. 5,994,409 was dismissed with prejudice by joint stipulation. See MedImmune Oncology, Inc. v. Sun Pharm. Indus., Ltd., No. MJG-04-2612 (D. Md. filed Mar. 23, 2006)[Paper 55].

II. BACKGROUND

By the early 1990's, many of the beneficial properties of amifostine were known, but there were problems faced in trying to obtain a stable injectable product. In general terms, it seemed to be necessary to store and ship the product at extremely low temperatures. To meet the perceived need, MedImmune invented (or, more precisely, claimed to have invented):

1. A process for the preparation of a amifostine crystalline composition comprising certain steps.[4]

2. Crystalline amifostine which is prepared according to [a certain process] which is thermally-stable, sterile, and suitable for reconstitution . . . into an injectable particulate-free [human][5] drug product . . .

3. A dosage form of crystalline amifostine comprising thermally-stable, sterile, crystalline amifostine [with claimed characteristics], which is suitable for reconstitution . . . into an injectable particulate-free [human] drug product.[6]

The claims at issue are:

1. Certain product-by-process claims of the '471 Patent, and

2. Certain product claims of the '731 Patent.

Compl. at ¶¶ 10, 11.

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[4] See Pl.'s Mem., Ex. B [Paper 96] (hereinafter referred to as "'471 Patent") at col. 18 (Claim 1).

[5] See '471 Patent at col. 20 (Claim 31).

[6] See Pl.'s Mem., Ex. C [Paper 96] (hereinafter referred to as "'731 Patent"), at col. 18 (Claim 1).

Sun produces amifostine by a dry filling process that, as MedImmune concedes, does not infringe any of the process claims in the '471 Patent.

Sun seeks to have the Court grant it summary judgment because, according to Sun:

1. Sun's accused product does not meet the process limitations in the asserted product-by-process claims of the '471 Patent, and

2. Sun's accused product is not "vacuum dried" and the asserted product claims of the '731 Patent must be construed to include the limitation that the product be "vacuum dried" and

In regard to the '471 Patent, MedImmune seeks to have the Court construe the claims at issue to eliminate a limitation that is expressly set forth in the claims. In regard to the '731 Patent, Sun seeks to have the Court construe the claims at issue to add a limitation that is not expressly set forth in claims.

Sun contends that the Court can, and should, grant it summary judgment at the present stage even though it will not have the a presentation of all claim construction issues. Certainly, there are potential efficiencies inherent in such an approach. If Sun is correct, the parties can conclude the case without the need for full scale pretrial proceedings regarding issues that need not be reached. On the other hand, the Court

must be particularly cautious when making a claim construction decision based upon a less than complete contextual setting.

As discussed herein, the Court finds that, even at the present state, it can conclude that Sun is entitled to summary judgment of non-infringement with regard to the '471 Patent. However, it is not now appropriate to grant summary judgment at with regard to the '731 Patent.

III. DISCUSSION

A. The '471 Patent

The '471 Patent discloses an allegedly novel method for preparing "the first stable, vacuum dried pharmaceutical formulation of amifostine which can be conveniently handled and stored at temperatures from about 4°C to about room temperature for long periods of time without significant product degradation." '471 Patent at col. 5, ln. 51-55.

The '471 Patent includes non-infringed process Claims 1 (from which Claims 2-20 depend) and 21 (from which Claims 22-30 depend). The '471 Patent also includes product-by-process Claims 31-33 that provide:

> Crystalline amifostine which is prepared according to the process of [certain process claims] and which is thermally-stable, sterile, and suitable for reconstitution with a pharmaceutically acceptable vehicle into an

> injectable particulate-free drug product for parenteral[7] administration to a human patient.

'471 Patent at col. 20 (Claims 31-33).

Sun contends that inasmuch as the accused product was not produced according to any of the claimed processes, Sun cannot infringe the product-by-process claims. MedImmune contends that the Court must construe the claims to eliminate the process limitations therein.

There is an inconsistency between two Federal Circuit decisions regarding the including of process limitations in product-by-process claims.

In 1991, a panel of the Federal Circuit stated in Scripps Clinic & Research Foundation v. Genentech, Inc.:

> In determining patentability, we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims.

927 F.2d 1565, 1583 (Fed. Cir. 1991).

However, the next year, a panel stated in Atlantic Thermoplastics Co., Inc. v. Faytex Corp.:

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[7] Other than orally.

The entire history of product-by-process claims suggests a ready explanation for the apparent difference of view about treatment of those claims during ex parte administrative proceedings and during litigation. . . . Thus, accommodating the demands of the administrative process and recognizing the capabilities of the trial courts, this court treats claims differently for patentability as opposed to validity and infringement. The PTO's treatment of product-by-process claims as a product claim for patentability is consistent with policies giving claims their broadest reasonable interpretation. The same rule, however, does not apply in validity and infringement litigation. In any event, claims mean the same for infringement and validity.

Moreover, accepting Atlantic's invitation to ignore the process limitations in the '204 Patent's product-by-process claims would require this court to disregard several other mainstay patent doctrines. This court has repeatedly stated that infringement requires the presence of every claim limitation or its equivalent. . . . Thus, ignoring the claim limits of a product-by-process claim would clash directly with basic patent principles enunciated by the Supreme Court and this court.

In addition, Atlantic's invitation to disregard the claim limitations also would require this court to determine infringement by comparing an accused product with an embodiment of the claims, not the claims themselves. This court has repeatedly emphasized that infringement analysis compares the accused product with the patent claims, not an embodiment of the claims. . . . Thus, Atlantic's invitation would require this court to directly ignore basic patent principles.

> In light of Supreme Court case law and the history of product-by-process claims, this court acknowledges that infringement analysis proceeds with reference to the patent claims. Thus, process terms in product-by-process claims serve as limitations in determining infringement.

970 F.2d 834, 846 (Fed. Cir. 1991) (internal citations omitted).

The parties have not presented authority indicating that the Federal Circuit has, in the fifteen years since 1991, expressly addressed the inconsistency between Atlantic Thermoplastics and Scripps. Nor does there appear to be a "rule" that would require this Court to follow Scripps in lieu of the far more persuasive decision in Atlantic Thermoplastics. The Court, therefore, does not find itself required by Federal Circuit precedent to ignore process limitations in a product-by-process claim regardless of the language and context of the claims at issue.

A sensible place to start with claim construction is with the words of the claim. The instant claims present no ambiguity - the claims are limited to certain products "prepared according to the process of" specified claims. Therefore, unless there is some reason to disregard the plain language of the claims, they must be construed to include process limitations.

Construction consistent with the plain language of the claims is strongly supported by the presumption arising from

claim differentiation. Amgen, Inc. V. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1327 (Fed. Cir. 2003).

The product-by-process claims here at issue provides in pertinent part:

> 31. Crystalline amifostine which is prepared according to the process of any of claims 1,2,4,5,7,8,9,10, 21 or 30 . . . .
>
> 32. Crystalline amifostine which is prepared according to the process of claim 13 . . . .
>
> 33. Crystalline amifostine which is prepared according to the process of claim 18 . . . .

'471 Patent at col. 20.

The only variation among Claims 31, 32 and 33 lies in the specific process claims that are identified in the process limitations. If the limitation references to specified process claims were read out of the claims, the three claims would be identical. There would be no reason for the Patentee to present, and for the Patent Office to approve, three identical claims.

The Court concludes that the product-by-process claims at issue herein cannot reasonably be construed to eliminate the process limitations. Thus, the Court construes Claims 31, 32 and 33 of the '471 Patent to include, as a limitation, the process claim(s) specified herein.

In a patent case, as in any other type of case, a motion for summary judgment shall be granted if "there is no genuine issue

of material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); e.g. Jamesbury Corp. v. Litton Indus. Prods., Inc., 839 F.2d 1544, 1548 (Fed. Cir. 1988), cert. denied, 488 U.S. 828 (1988).

MedImmune agrees that the accused products do not infringe any of the process claims in the '471 Patent. Accordingly, there is no factual issue presented as to infringement. Sun does not infringe any of the product-by-process claims in the '471 Patent as construed herein.

Accordingly, Sun is entitled to summary judgment establishing non-infringement of the '471 Patent.

B. The '731 Patent

MedImmune contends that Sun infringes certain claims of the '731 Patent, including Claim 1[8] stating that what is claimed is:

> A dosage form of crystalline amifostine comprising thermally-stable, sterile, crystalline amifostine trihydrate, exhibiting [a certain crystal structure] suitable for reconstitution with a pharmaceutically acceptable vehicle into an injectable particulate-free drug product for parenteral administration to a subject.

'731 Patent at col. 18.

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[8] Inasmuch as summary judgment is denied with regard to Claim 1, it is not necessary to discuss any other claim herein.

For purposes of the instant motion, the Court assumes that the expressed limitations in the claim are found in the accused products. Sun asserts, however, that Claim 1 must be construed to include a limitation that the crystalline amifostine trihydrate be "vacuum dried." If Claim 1 is so construed, then there could be no infringement because, according to Sun, the accused products are not "vacuum dried."

C. Is "Vacuum Dried" a Limitation?

The answer to the question of whether to construe the claim at issue to include the limitation that the crystalline amifostine be "vacuum dried" is not obvious.

The words of a claim "are generally given their ordinary and customary meaning." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d, 1576, 1582 (Fed. Cir. 1996). Claim 1 does not include "vacuum dried" as a limitation. While not absolutely conclusive, the absence of a limitation in a claim is an indication, at least, that the Patentee did not wish to include it.

The next appropriate step in the instant case is to consider the context of Claim 1 vis-a-vis other claims, that is, to use

claim differentiation. Claim 12[9] of the '731 Patent depends from Claim 1. Claim 12 states:

> 12. The dosage form of claim 1 wherein said crystalline amifostine trihydrate is vacuum dried.

'731 Patent at col. 19.

While not conclusive, the inclusion of the specific limitation "vacuum dried" on the term "crystalline amifostine" in dependent Claim 12 "makes it likely that the Patentee did not contemplate that the term ["crystalline amifostine" in independent Claim 1] already contained that limitation." Phillips v. AWH Corp., 415 F.3d 1303, 1324 (Fed. Cir. 2005). In essence, claim differentiation analysis raises a presumption that Claim 1 does not include the limitation "vacuum dried." Amgen, 314 F.3d at 1327.

Of course, the presumption arising from claim differentiation is rebuttable. In the instant case there is support for Sun's contention in the '731 Patent itself.

For example, the '731 Patent Abstract states:

> The present invention relates to a sterile, stable vacuum dried crystalline amifostine composition.

'731 Patent at 1 (emphasis added).

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[9] Claims 2 - 20 all depend on Claim 1.

In the Background of the Invention section, the '731 Patent states:

> As used herein, the term "amifostine drug substance" refers to its pre-vacuum dried or pre-vacuum dried state which is available on an "as is" basis in a trihydrate form. Currently available sterile, vacuum dried formulations of amifostine drug product will be referred to as "amorphous amifostine", whereas the form covered by the present invention will be referred to as "crystalline amifostine" in order to distinguish between the two forms.

Id. at Col. 1, ln. 48-54 (emphasis added).

It further states:

> The present invention provides the first stable, vacuum dried pharmaceutical formulation of amifostine which can be conveniently handled and stored at temperatures from about 4°C. to about room temperature for long periods of time without significant product degradation, thus providing a solution to a long sought need. The formulation will allow amifostine drug product to be shipped to and stored in hospitals around the world which do not have freezer storage capabilities required for the currently available formulation.

Id. at Col. 5, ln. 46-54 (emphasis added).

Also, the '731 Patent refers, in a negative fashion, to preparation methods that do not include vacuum drying. In the Detailed Description of the Invention, the '731 Patent states:

> The present manner of manufacturing and packaging amifostine comprises [filling vials with an amifostine water solution and drying to get a powder product].
>
> . . . This avoids substantial practical problems related to the packaging of bulk, solid amifostine using the so-called "dry filling" or "powder filling" method.
>
> . . . However [the present method results in an unstable product]. . .
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> * * *
>
> Hence, there is a need to develop a dosage form which has sufficient stability to provide a long shelf life at room temperature or under less stringent refrigeration, which is not uncommon for many drug products.
>
> The present invention describes new and novel procedures which produce solid compositions containing vacuum dried amifostine. . . .

Id. at col. 1, ln. 62 - col. 2, ln. 35 (emphasis added).

Since both sides present reasonable arguments as to the putative inclusion of a "vacuum dried" limitation, the Court finds it inappropriate to make a conclusive claim construction at the present stage of the case. Resolution of debatable claim construction issues, particularly those that could result in adding an unexpressed limitation, is best done in the context of the entire patent, including all claims and limitations.

Of course, it can be possible to reach a definite conclusion as to an isolated issue, when the answer is patently clear, for

example, as discussed herein with regard to the '471 Patent. However, resolution of the question whether to impute a "vacuum dried" limitation into the '731 Patent claims at issue requires consideration of positions taken in patent prosecutions, distinctions from prior art, etc. These matters are best addressed in the context of a complete record that includes the presentation of all asserted claim construction issues.

Moreover, as discussed below, even if the claims at issue were construed to include the limitation "vacuum dried," Sun would not now be entitled to summary judgment on the present state of the record.

In sum, on the present record, and without prejudice to reconsideration at a later stage of the case, the Court will not now hold that the rebuttable presumption arising from claim differentiation analysis is overcome so as to add the unexpressed limitation that the crystalline amifostine be "vacuum dried" to the product claims at issue.

D. Is Sun's Product "Vacuum Dried"?

Even if the Claims at issue were construed to include a limitation that the crystalline amifostine be "vacuum dried," Sun would not be entitled to summary judgment on the current state of the record.

The standard for summary judgment in the Federal Circuit is, as in the other Circuits, whether there is a genuine issue of material fact. In brief, the question is whether, giving the non-movant (MedImmune) the benefit of viewing the evidence (and all reasonable inferences based thereon) in its favor could a reasonable fact finder find that the accused products were "vacuum dried"? Amgen, 314 F.3d at 1327.

For Sun to prevail on the question of infringement,[10] the limitation "vacuum dried" would have to be restricted to freeze dried in a process utilizing a high vacuum. Sun contends that its process "dries under a low vacuum and as part of a warming spinning process" [Hr'g Tr., Oct. 24, 2006 at 61] and, therefore, does not "vacuum dry." MedImmune contends that because Sun uses a vacuum in the course of its drying process, a person of ordinary skill in the art would consider its product to be "vacuum dried."

Upon the present record, it appears that a reasonable jury could, but would not necessarily have to, find that Sun is correct. Indeed, MedImmune has submitted evidence that, if accepted by a jury, would prove that to one reasonably skilled in the art, "freeze drying and vacuum drying are not the same thing.

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[10] Assuming, for purposes of the instant motion, that all other limitations are met.

Gerald Brenner, Ph.D. Declaration at ¶ 12. Moreover, MedImmune has submitted evidence that, if accepted by the fact finder, would establish that "Sun's product is vacuum dried." Id. at ¶ 14.

On the present record, the Court concludes that there are genuine issues of material fact that would prevent a grant of summary judgment even if the product claims at issue were construed to include a "vacuum dried" limitation as Sun contends.

IV. CONCLUSION

For the foregoing reasons:

1. Sun's Motion for Summary Judgment of Non-Infringement [Paper 85] is GRANTED IN PART.

2. Plaintiff's claims of infringement of U.S. Patent No. 5,424,471 ARE DISMISSED.

3. Plaintiff's claims of infringement of U.S. Patent No. 5,591,731 remain pending.

4. The case shall proceed pursuant to existing scheduling.

SO ORDERED, on Tuesday, January 9, 2007.

/ s /
Marvin J. Garbis
United States District Judge