United States District Court,
D. Maryland.

MEDIMMUNE ONCOLOGY, INC,
Plaintiff.
v.
SUN PHARMACEUTICAL INDUSTRIES, LTD,
Defendant.

Oct. 29, 2007.

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MEMORANDUM AND ORDER RE PATENT CLAIM CONSTRUCTION

MARVIN J. GARBIS**, District Judge.**

Pursuant to the Scheduling Order, the parties have filed materials relating to what they have specified as material claim construction issues. The Court has held a hearing regarding claim construction issues (a Markman FN1 hearing) and has had the benefit of the arguments of counsel.

FN1. Markman v. Westview Instruments, Inc., 517 U.S. 370, 390, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

I. *BACKGROUND*

In this Hatch-Waxman case, Plaintiff MedImmune Oncology, Inc. ("MedImmune") sued Sun Pharmaceutical Industries, Ltd. ("Sun") FN2 for infringement of U.S. Patent No. 5,424,471, "Crystalline Amifostine Compositions and Methods For the Preparation and Use of Same" ("the ' 471 Patent"), and U.S. Patent No. 5,591,731, "Crystalline Amifostine Compositions" ("the ' 731 Patent") FN3 (collectively, "the Patents at Issue").FN4

FN2. Under 21 U.S.C. s. 355(j)(5)(B)(iii).

FN3. 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) [Document 55].

FN4. Sun filed an Abbreviated New Drug Application ("ANDA") at the Food and Drug Administration ("FDA") seeking approval to market a generic version of MedImmune's product, Ethyol(R), prior to the expiration of MedImmune's patents. In doing so, Sun was required to certify under 21 U.S.C. s. 355(j)(2)(A)(vii)(IV) that MedImmune's patents were not infringed by Sun's generic products and/or were invalid.

By the early 1990's, it was known that amifostine could be beneficial for cancer patients to alleviate the severity of the side effects associated with radiation and chemotherapy. However, it was believed to be necessary to store and ship the product at extremely low temperatures.

MedImmune asserts that the inventors of the Patents at Issue invented:

1. A process for the preparation of an amifostine crystalline composition comprising certain steps.FN5

FN5. *See* Pl.'s Mem., Ex. B [Document 96] (hereinafter referred to as " '471 Patent"), at col. 18 ("Claim 1").

2. Crystalline amifostine, prepared according to [a certain process], which is thermally-stable, sterile, and suitable for reconstitution ... into an injectable particulate-free [human] FN6 drug product ....
FN6. *See* '471 Patent, at col. 20 ("Claim 31").

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.FN7
FN7. *See* Pl.'s Mem., Ex. C [Document 96] (hereinafter referred to as " '731 Patent"), at col. 18 ("Claim 1").

In the Memorandum and Order issued January 9, 2007, this Court granted partial summary judgment to Sun, dismissing MedImmune's claim of infringement of the ' 471 Patent. DMedImmune's claim of infringement of the '731 Patent remains pending.

II. ***GENERAL PRINCIPLES OF CLAIM CONSTRUCTION***

It is a "bedrock principle" of patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004).

The construction of patent claims is a matter for the Court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 390, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

As expressed in *Phillips v. AWH Corp.:*

We have frequently stated that the words of a claim "are generally given their ordinary and customary meaning." ... We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.

* * *

Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.
415 F.3d 1303, 1312-13 (Fed.Cir.2005).

III. *DISCUSSION*

A. *The Claim Terms at Issue*

The parties seek the Court's construction of certain terms that appear in several of the Claims in the '731 Patent. Representative uses of the terms appear in Independent Claim 14 and Dependent Claims 26 and 37.

Independent Claim 14:

A DOSAGE FORM OF CRYSTALLINE AMIFOSTINE comprising THERMALLY-STABLE, STERILE CRYSTALLINE AMIFOSTINE, which is SUITABLE FOR RECONSTITUTION with a pharmaceutically acceptable vehicle INTO AN INJECTABLE PARTICULATE-FREE DRUG PRODUCT FOR PARENTERAL ADMINISTRATION TO A SUBJECT.

Dependent Claim 26:

The dosage form of Claim 14 wherein said crystalline amifostine is VACUUM DRIED.

Sub-Dependent Claim 37:

A sealed container containing a dosage form of crystalline amifostine according to Claim 26, said container having sufficient volume to allow for said reconstitution and having a SEALING MEANS for maintaining a sterile environment and for allowing entry into the container of the vehicle for reconstitution.

(Emphasis added to construed terms).

B. *Construction of Claim Terms*

1. *Dosage Form of Crystalline* AmifostineFN8

FN8. The parties jointly take the position that the term "crystalline amifostine" must have the same meaning when used in the preamble and the body of the Claim. Tr. 43-44. The Court, accepting the parties' position, is, in this segment, construing the phrase "dosage form of crystalline amifostine" and is separately construing the term "crystalline amifostine."

The term "dosage form of crystalline amifostine," while used in the preamble to Claim 14, adds a limitation.

It serves to narrow the Claim from covering all products that meet the limitations set forth after the word "comprising" to covering only those products that are a "pharmaceutical composition or pharmaceutical formulation" suitable for use as a dose of medication for a human patient. Tr. 9-18 FN9.

FN9. "Tr." reference refers to the transcript of the *Markman* hearing held July 10, 2007.

2. *Crystalline Amifostine*

The '731 Patent Claims include:

Independent Claim 14 claiming, in pertinent part:

A dosage form of crystalline amifostine

...

Dependent Claim 26 claiming:

The dosage form of Claim 14 wherein said crystalline amifostine is vacuum dried.

Sun contends that the term "crystalline amifostine" in Claim 14 should be construed to include "vacuum dried" as a limitation. MedImmune contends that the term "crystalline amifostine" in Claim 14 means amifostine in a crystal form, whether or not it is vacuum dried.

MedImmune supports its contention by reference to claim differentiation, asserting that if the term "crystalline amifostine" in Claim 14 were limited to the vacuum-dried form, Dependent Claim 26 would be superfluous. While not conclusive, the inclusion of the specific limitation "vacuum dried" in the term "crystalline amifostine" in Dependent Claim 26 "makes it likely that the patentee did not contemplate that the term [crystalline amifostine in Independent Claim 14] already contained that limitation." Phillips, 415 F.3d at 1324.

In essence, claim differentiation raises a presumption that Claim 14 does not include the limitation "vacuum dried." Amgen, 314 F.3d 1313, 1327 (2003). Of course, the presumption arising from claim differentiation is rebuttable. Sun contends that the presumption is rebutted and that the term "crystalline amifostine" in Claim 14 must be construed to mean amifostine in *vacuum-dried,* crystal-form.

In *Saunders Group, Inc. v. Comfortrac, Inc.,* the Federal Circuit stated, in a context analogous to that presented in the instant case:

Claim terms are generally given the meaning those terms would have to a person of ordinary skill in the art. Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed.Cir.2005) (en banc). It is not disputed that the ordinary meaning of the term ["crystalline amifostine"] does not require [that it be vacuum-dried]. The asserted claims can be assigned a narrower scope only if there is some indication in the patent or the prosecution history that the term [crystalline amifostine] was meant to have a more restrictive meaning as used in the patent, or a broader meaning was disclaimed during prosecution.

492 F.3d 1326, 1331 (Fed.Cir.2007). Thus, the question here presented is whether "the text of the '731 Patent and its prosecution history [do or] do not justify such a restrictive construction of the term." Id.

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

The present invention provides the first stable, *vacuum dried* pharmaceutical formulation of amifostine.

Col. 2, Lines 31-33 (emphasis added).

Also, the '731 Patent refers, in a negative fashion, to preparation processes 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 them 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] ....

* * *

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, Line 62-Col. 2, Line 35 (emphasis added).
There is no doubt that the '731 Patent refers to vacuum-dried crystalline amifostine and has, as *an* objective of the invention, the production of vacuum-dried products. The '731 Patent and the pertinent prosecution history do not, however, reflect the intention to limit the crystalline amifostine claimed in Claim 14 to vacuum-dried products. Moreover, there is no clear disavowal of coverage of crystalline amifostine that meets the limitations expressly set forth in Claim 14 but is produced by a process other than vacuum-drying.

Sun doggedly seeks to inject the '471 Patent's *process* limitations into the '731 Patent's *product* claims. However, there is a critical difference between the two patents. The '471 Patent provides process and product-by-process claims so that the product claims in the '471 Patent are subject to express process limitations. On the other hand, the '731 Patent includes product claims that do not have the "baggage" of process limitations. The ' 731 Patent claims coverage of *products* having the claimed characteristics regardless of the process used to produce them.

There is no "silver bullet" in the file wrapper. Each side may find "nuggets" supporting its position. However, there is no consistent vein, which rebuts the presumption provided by claim differentiation and otherwise permits the Court to add a limitation to the unqualified term "crystalline amifostine" used in Claim 14.

The prosecution history provides no clear indication of an intent to limit the *products* to be covered by

Claim 14 of the '731 Patent to products produced by a vacuum-drying *process*. Moreover, it does not appear that a dosage form of crystalline amifostine produced by a vacuum-drying *process* would, in terms of utilization for the intended purpose, be materially different from a dosage form of crystalline amifostine produced by a dry-filling or other *process*. The "elegant cake" of a vacuum-dried product performs essentially the same function in essentially the same way as dry-filled powder. Indeed, if a vial containing a vacuum-dried "elegant cake" is shaken sufficiently, the cake would become inelegant powder but would still perform the desired function. Tr. 129-132.

The disparagement found in the text and/or prosecution history of the '471 and '731 Patents is of then-known dry-filling and other non-vacuum drying processes. The '731 patentees asserted that a sterile powder having the desired characteristics could not be produced by then-known dry-filling or other processes. The '731 Patent was able to include allowable *product* claims on the basis that there was no *process* then-known that could produce the claimed *product*. Indeed, if a then-known process could have produced a sterile powder having the desired characteristics, the product claims of the '731 Patent would be invalid.

Finally, the Court notes that Sun seeks to find conclusive support for its position in the following from the Background of the Invention:

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. Unless otherwise specified, quantities reported herein shall be calculated on an anhydrous basis.

Col. 1, Lines 15-23. However, the foregoing does not clearly limit the scope of Claim 14 of the '731 Patent to products produced by a vacuum-drying *process*. In view of the then-perceived inadequacy of dry-filling and other known processes, the reference to pre-processed amifostine drug substance as in a "pre-vacuum-dried state," and the reference to "currently available sterile, vacuum dried formulations of amifostine drug product" as "amorphous" by no means refutes the plain language of Claim 14 or rebuts the presumption arising from claim differentiation.

When all is said and done, the bottom line is that the best way to ascertain the inventor's intent is to look at the claim language that finally and definitively states what it is that the inventor claims. Claim 14 states that what is claimed is "a dosage form of crystalline amifostine" without qualification. The Claim is construed to mean what it says, no more and no less.

3. *Thermally-stable*

Sun contends that the term "thermally-stable" is indefinite and will, in due course, assert a validity defense based upon this contention. The Court does not now resolve Sun's indefiniteness defense, but rather construes the term "thermally-stable" as used in Claim 14. In due course, the Court will address the question of whether the Claim, with the Court's construction, when read in light of the specification, reasonably apprises those skilled in the art of the scope of the invention. Personalized Media Commc'ns, L.L.C. v. ITC, 161 F.3d 696, 705 (Fed.Cir.1998).FN10

FN10. This Court does not read Bancorp Services, L.L.C. v. Hartford Life Insurance Co., 359 F.3d 1367

(Fed.Cir.2004) to hold that the mere fact that a district court issues a claim construction ruling regarding a term necessarily prevents reaching a conclusion that the term is indefinite.

The term "thermally-stable" is an inherently context-dependent term inasmuch as virtually, if not literally, every chemical product would become unstable (i.e. subject to degradation) after some period of time. Presumably, the duration of stability would be affected by the conditions of maintenance, including the temperature. Accordingly, a person of ordinary skill in the art would understand the term "thermally-stable" as used in Claim 14 to refer to a product that, if maintained within a certain range of temperatures, would remain fit for its intended use for a period of time adequate for its intended use. It is, therefore, necessary to determine the range of temperatures and the length of time referenced by the term "thermally-stable" as used in Claim 14.

In the Background of the Invention, the '731 Patent refers to the thermal instability of the currently available formulation of amifostine and the need for thermally-stable products:

This amorphous form that is produced by lyophilization is thermally unstable. As a result, this lyophilized formulation must be maintained at temperatures at about -20 (deg.) C. and shipped at temperatures at about -70 (deg.) C. to about -20 (deg.) C. to avoid degradation of the formulated product.

* * *

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.
Col. 2, Lines 11-29.
In the Summary of the Invention, the '731 Patent states:

Yet another object of the present invention concerns the preparation of a sterile pharmaceutical composition having an enhanced temperature stability in which the active ingredient ..., such as amifostine, remains stable at about 4 (deg.) C. for at least 2 years. Preferably, the ... amifostine, remains stable at about ambient temperature for at least 2 years.

Col. 4, Lines 33-40.

In the Detailed Description of the Invention, the '731 Patent states that:

Prior to the present invention, the available pharmaceutical formulation of amifostine (Ethyol(R)) was thermally unstable. Because of its instability, the Ethyol(R) formulation required the use of low temperatures during shipping and storage in order to prevent product degradation.

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 (deg.) C. to about room temperature for long periods of time without significant product degradation, thus providing a solution to a long sought need.

Col. 5, Lines 42-55.

* * *

These formulations [pursuant to this invention] provide a vacuum dried product, which has been found to be a crystalline amifostine that demonstrates improved stability over the current formulation which contains amorphous amifostine. The vials can then be stored and shipped at temperatures from about 4 (deg.) C. to about room temperature without significant product degradation.
Col. 6, Lines 45-51.
Moreover, a comparison of Independent Claim 14 and Dependent Claims 18 and 19 is pertinent:

Independent Claim 14:

A dosage form of crystalline amifostine comprising thermally-stable, sterile, crystalline amifostine ....

Dependent Claim 18:

The dosage form of Claim 14 wherein said crystalline amifostine is thermally stable at about 4 (deg.) C. for at least two years.

Dependent Claim 19:

The dosage form of Claim 14 wherein said crystalline amifostine is thermally stable at about ambient [room] FN11 temperature for at least two years.

FN11. The parties agree that "ambient temperature" means "room temperature" as used herein.

The Specification rather plainly indicates that claimed products were to be those that "can be stored and shipped at temperatures from about 4 (deg.) C. to about room temperature without significant product degradation." Col. 6, Lines 48-51. This leads to the conclusion that, in Claim 14, the thermally-stable temperature range is from about 4 (deg.) C. to about room temperature.FN12

FN12. There may be, in regard to a particular infringement or validity issue, a fact question as to the highest temperature that one skilled in the art would understand to be meant by "room-temperature" in the context in which the product is intended to be used. However, it is apparent that the range does not extend into extreme temperatures that may be endured in medical facilities in extraordinary locations or circumstances.

This conclusion is consistent with a claim differentiation analysis. As noted in Philips, 415 F.3d at 1324, the Federal Circuit in Dow Chem. Co. v. United States, 226 F.3d 1334, 1341-42 (Fed.Cir.2000) concluded "that an independent claim should be given broader scope than a dependent claim to avoid rendering the Dependent claim redundant." Thus, Claim 14 should be broader in scope than Claim 18 or Claim 19.

In reference to the temperature range aspect alone, Claim 14 as construed by the Court is not broader than Dependent Claims 18 and 19. The 4 (deg.) C. temperature in Claim 18 essentially is the same as the low end of the range in Claim 14 and the about ambient [room] temperature in Claim 19 essentially is the same as the high end of the Claim 19 range. However, construction of Independent Claim 14 so that the duration limitation therein is less restrictive than the "at least two years" limitation specified in Claims 18 and 19

would give Claim 14 broader scope than Dependent Claims 18 and 19.

With regard to the duration aspect of the term "thermally stable" in Claim 14, the '731 patent describes the product as "conveniently handled and stored at temperatures from about 4 (deg.) C. to about room temperature for long periods of time without significant product degradation." Col. 5, Lines 42-55. Thus, MedImmune seeks to have the Court construe the temporal limitation of the term as "for a long time." The Court concludes, however, that it should not accept MedImmune's position.

In the context of the '731 Patent, a claimed product would be thermally-stable only if it would remain fit (i.e., not significantly degraded for its intended use) for a period of time that a person of ordinary skill in the art would understand to be adequate for the intended use-that is, long enough for shipment and a reasonable shelf-life.

From a claim differentiation approach, Dependent Claims 18 and 19 should be construed as narrower than Claim 14. Accordingly, while the duration of thermal-stability to infringe Claims 18 and 19 must be at least two-years, the duration of thermal stability necessary to infringe Claim 14 could be less than two-years. Thus, it is possible to hypothesize a product that would infringe Independent Claim 14 because it would remain fit for a period of time (for example, one year) that would be adequate for the intended use but would not infringe Dependent Claim 18 or 19 because it would not remain fit for at least two-years.

Accordingly, the Court concludes that the term "thermally-stable" in Count 14 refers to a dosage form of crystalline amifostine that, if maintained within a range of temperatures from about 4 (deg.) C. to about room temperature FN13, would remain fit for its intended use for a period of time adequate for shipment and a reasonable shelf life.

FN13. As the term "room temperature" is understood in context by a person of ordinary skill in the art.

4. ***Sterile***

As discussed at the *Markman* hearing, the term "sterile" is construed to mean sufficiently free of microbiological contamination such that the product is suitable for parenteral administration to a human patient. Tr. 10.

5. ***Suitable for Reconstitution ... into an Injectable Particulate-Free Drug Product For*** Parenteral Administration ***to a Subject***

The parties' dispute in regard to the instant term centers on MedImmune's contention that the claim is limited to formulations that dissolve rapidly. Tr. 39-41.

It is true that the '731 Patent refers to rapid dissolution:

The vacuum dried crystalline amifostine solid compositions of the present invention *may be provided* in single dose container forms .... It is intended that these filled containers will allow rapid dissolution of the solid composition upon reconstitution with appropriate sterile diluent in situations giving an appropriate sterile solution of desired amifostine concentration for administration.

Col. 6, Line 66 to Col. 7, Line 3 (emphasis added).

However, the statement that the product *may* be provided in container forms allowing rapid dissolution does not mean that the claimed product *must* be rapidly dissolved. On the other hand, the '731 Patent indicates that the complete dissolution must take place in a manner that would be acceptable for the intended use. Hence, presumably, there could be products that would dissolve so slowly as to render them unacceptable for chemical use. Thus, it is possible that in the context of an infringement or validity issue, the speed of dissolution could be pertinent to determining the suitability of the manner of dissolution.

Accordingly, the Court concludes that the term "suitable for reconstitution" means that the solid composition is capable of complete dissolution upon reconstitution with appropriate sterile diluent(s) in a manner that is acceptable for use in a medical treatment context, yielding a solution appropriate for parenteral administration to a human patient. The phrase "injectable particulate-free drug product for parenteral administration" means a drug product that is sufficiently free of particulates for parenteral administration to a human patient.

6. ***Vacuum Dried***

MedImmune contends that the term "vacuum dried" in Dependent Claim 26 should be construed to mean dried in any process that includes some use of a vacuum. Sun, on the other hand, contends that the term "vacuum dried" in Claim 26 should be construed as limited to freeze-dried, i.e., obtained from a process involving cooling a solution of amifostine below zero degrees Celsius and then drying the resulting mixture under a high vacuum.

The '731 Patent presents examples of vacuum-drying processes that include high vacuums and freezing. It also refers to such processes as "freeze-drying." MedImmune agrees that a freeze-dried product is necessarily vacuum-dried, but contends that a vacuum-dried product is not necessarily freeze-dried. Tr. 156.

The Court recognizes that it is possible that Sun could establish at trial that a person of ordinary skill in the art would read the term "vacuum dried" in Dependent Claim 26 as referring only to freeze-dried products as described in the '731 Patent examples. Moreover, there could be a factual issue as to whether one skilled in the art would consider Sun's process to constitute a "vacuum dried" process. However, the Court does not find, on the current record, a basis to conclude as a matter of claim construction that the '731 Patent necessarily uses the term "vacuum dried" in Claim 26 to refer only to freeze-dried products.

7. ***Sealing Means***

The parties agree that the term "sealing means" refers to a sterile rubber closure or equivalent that can be used in a vial holding an injectable medication. Tr. 10-11.

IV. ***CONCLUSION***

For the foregoing reasons, the Court concludes the following with regard to the construction of the claim terms at issue:

1. The term "dosage form of crystalline amifostine" narrows the Claim to covering only crystalline amifostine products that are a pharmaceutical composition or pharmaceutical formulation suitable for use as a dose of medication for a human patient.

2. The term "crystalline amifostine" means crystalline amifostine, whether produced by a vacuum-dried or other process.

3. The term "thermally-stable" refers to a dosage form of crystalline amifostine that, if maintained within a range of temperatures from about 4 (deg.) C. to about room temperature FN14, would remain fit for its intended use for a period of time adequate for shipment and a reasonable shelf life.

FN14. As the term "room temperature" is understood in context by a person of ordinary skill in the art.

4. The term "sterile" means sufficiently free of microbiological contamination such that it is suitable for parenteral administration to a human patient.
5. The term "suitable for reconstitution" means that the solid composition is capable of complete dissolution upon reconstitution with appropriate sterile diluent(s) in a manner that is acceptable for use in a medical treatment context, yielding a solution appropriate for parenteral administration to a human patient.

6. The term "injectable particulate-free drug product for parenteral administration" means a drug product that is sufficiently free of particulates for parenteral administration to a human patient.

7. The term "vacuum dried" means dried in a process that a person of ordinary skill in the art reading the Patent would understand to yield a vacuum-dried product and is not necessarily, but may be, limited to a process including a high vacuum and/or freeze-drying process.

8. The term "sealing means" is construed to mean a sterile rubber closure or equivalent that can be used in a vial holding an injectable medication

SO ORDERED.

D.Md.,2007.
Medimmune Oncology, Inc. v. Sun Pharmaceutical Industries, Ltd.