United States District Court,
D. Delaware.

SEPRACOR INC,
Plaintiff.
v.
DEY, L.P. and Dey, Inc,
Defendant.
Sepracor Inc,
Plaintiff.
v.
Barr Laboratories, Inc,
Defendant.

Civil Action No. 06-113-JJF

Dec. 18, 2008.

Background: Patentee brought infringement action against competitor, alleging infringement of patents for methods of using optically pure R(-) isomer of albuterol to treat bronchial disorders while reducing side effects associated with use of raceraic mixture of albuterol. Parties sought claim construction.

Holdings: The District Court, Farnan, J., held that:
(1) term "side effects" meant effects other than the desired therapeutic effect associated with the administration of racemic albuterol;
(2) terms "chronic administration" and "chronically-administering to the individual" meant prophylactic or periodic administration;
(3) term "acute administration" meant treatment after the onset of an asthma attack;
(4) term "inducing bronchodilation or providing relief from bronchospasm" meant inducing relaxation of smooth muscle in the walls of the bronchi and bronchioles or providing relief from contraction of smooth muscle in the walls of the bronchi and bronchioles;
(5) term "preventing bronchospasm in a patient with reversible obstructive airway disease" meant preventing bronchospasm in a patient with a respiratory disorder such as asthma, chronic bronchitis, or emphysema; and
(6) term "treating bronchospasm in a patient with reversible obstructive airway disease" meant treating bronchospasm in a patient with a respiratory disorder such as asthma, chronic bronchitis, or emphysema.

Claims construed.

5,362,755, 5,547,994, 5,760,090, 5,844,002, 6,083,993. Construed.

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MEMORANDUM OPINION

FARNAN**, District Judge.**

This action was filed by Plaintiff Sepracor Inc. ("Sepracor") against Defendants Dey, L.P., Dey, Inc., and Barr Laboratories, Inc. (collectively, "Defendants") alleging infringement of United States Patent Nos. 5,362,755 ("the '755 patent"); 5,547,994 ("the '994 patent"); 5,760,090 ("the ' 090 patent"); 5,844,002 ("the '002 patent") and 6,083,993 ("the '993 patent") (collectively the "patents-in-suit"). The parties briefed their respective positions on claim construction, and the Court conducted a Markman hearing on the disputed terms. This Memorandum Opinion provides the Court's constructions of the disputed terms.

BACKGROUND

The patents-in-suit all claim priority to the single parent application that ultimately resulted in the '755 patent, and they all share the same specification. Briefly, the patents-in-suit pertain to methods of using the optically pure R(-) isomer of albuterol to treat bronchial disorders while at the same time reducing side effects associated with the use of the raceraic mixture of albuterol.

DISCUSSION

I. The Legal Principles of Claim Construction

[1] [2] [3] [4] [5] Claim construction is a question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 388-90, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). When construing the claims of a patent, a court considers the literal language of the claim, the patent specification and the prosecution history. Id. at 979. Of these sources, the specification is "always highly relevant to the claim construction analysis. Usuallyit is dispositive; it is the single best guide to the meaning of a disputed term." Phillips v. AWH Corporation, 415 F.3d 1303, 1312-17 (Fed.Cir.2005) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996)). However, "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.' " Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed.Cir.2004)(quoting Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed.Cir.2002)).

[6] A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in order to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. Phillips, 415 F.3d at 1318-19; Markman, 52 F.3d at 979-80. However, extrinsic evidence is considered less reliable and less useful in claim construction than the patent and its prosecution history. Phillips, 415 F.3d at 1318-19 (discussing "flaws" inherent in extrinsic evidence and noting that extrinsic evidence "is unlikely to result in a reliable interpretation of a patent claim scope unless considered in the context of intrinsic evidence").

[7] [8] [9] In addition to these fundamental claim construction principles, a court should also interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed.Cir.1984). If the patent inventor clearly supplies a different meaning, however, then the claim should be interpreted according to the meaning supplied by the inventor. Markman, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in patent). If possible, claims should be construed to uphold validity. In re Yamamoto, 740 F.2d 1569, 1571 (Fed.Cir.1984).

II. The Meaning of the Disputed Terms

The core dispute among the parties is the scope of the term "side effects," which is used in most of the asserted claims. The following claim from the ' 755 patent is illustrative of how this term is used in the asserted claims:

1. A method of treating asthma in an individual with albuterol, while reducing side effects associated with chronic administration of racemic albuterol, comprising chronically administering to the individual a quantity of an optically pure R(-) isomer of albuterol sufficient to result in bronchodilation while simultaneously reducing undesirable side effects, said R isomer being substantially free of its S(+) isomer.

In general, Defendants maintain that the claims should be limited to the reduction of specific "side effects" set forth in the specification, while Sepracor contends that the term should be understood more broadly.

Although the exemplary claim above refers explicitly to "asthma" treatment, not all asserted claims include an explicit "asthma" limitation. Such a claim from the '002 patent is as follows:

1. A method of inducing bronchodilation or providing relief of bronchospasm, comprising administering to an individual a quantity of optically pure R-(-) albuterol sufficient to induce said bronchodilation.

A subsidiary dispute among the parties is whether claims such as these should be limited specifically to the treatment of asthma or an asthma attack, notwithstandingthe lack of an explicit reference to "asthma."

Finally, some of the asserted claims refer to either "chronic administration" or "acute administration" of R(-) albuterol. *See, e.g.,* '090 patent claim 1; '994 patent claim 1. An additional subsidiary dispute among the parties concerns the meaning of these terms.

A. "Side Effects"

Sepracor's Construction	Dey's Construction	Barr's Construction
The side effects are those associated with chronic administration of racemic albuterol. The side effects are not limited in scope to the examples that are specifically identified in the patent specification.	Beta-adrenergic and teratogenic side effects associated with the periodic or prophylactic administration of albuterol that are caused directly by the S(+) enantiomer of albuterol.	Central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol.

1. *The Parties' Contentions*

Dey contends that the term "side effects" is limited to "beta adrenergic" and "teratogenic" side effects caused directly by the S (+) enantiomer of albuterol. In support of this position, Dey notes that the

specification explains that "it is important to have a composition which is a potent broncho-dilator and which does not exhibit the adverse side effects of many beta-adrenergic drugs." (D.I. 264 at 21 (citing '755 patent at 1:50-53).) Dey further notes that the specification explains that "certain levels of racemic albuterol can cause teratogenic effects...." (Id. at 1:63-66.) Based on these excerpts from the specification, Dey argues that the term side effects must be limited to "beta adrenergic" and "teratogenic" side effects. Dey further contends that "side effects" encompasses only effects caused "directly" by the S(+) enantiomer of albuterol. For this limitation, Dey relies on the prosecution histories, noting, for instance, that the patentee argued during prosecution of one patent that his "invention clearly distinguishes over the prior art by specifying the R(-) isomer, rather than the racemate or the S(+) isomer, to result in bronchodilation and to reduce undesirable side effects associated with beta-adrenergic drugs...." (D.I. 265, Exh. 10 at DLEV012082.)

A point of great contention is whether certain side effects, most notably airway hyperreactivity, that were allegedly discovered only after filing should be excluded from the definition of "side effects." Dey notes that during prosecution of the '755 patent, the patentees stated that "applicants did not specifically disclose airway hyperreactivity as a side effect to be avoided by the use of the pure R isomer...." (Id. at DLEV012278.) Thus, according to Dey, the patentees conceded that there was no support in the specification to include "airway hyperreactivity" in the definition of "side effects." (D.I. 264 at 23.) Dey further contends that reduction of airway hyperreactivity was unknown to the inventors at the time of filing and was, in fact, identified by other researchers. (Id.) In these circumstances, Dey argues, including airway hyperreactivity in the definition of "side effects" improperly expands the scope of Sepracor's patent beyond what the patentees were actually in possession of at the time of filing. (*See* id. at 22-23.) Thus, in its claim construction Answering Brief, Dey clarifies that its construction is intended to encompass only "side effects typically associated with beta-adrenergic drugs *as of the priority date* ...." (D.I. 279 at 3 n. 3 (emphasis added).) Whether Sepracor is attempting to improperly expand the scope of its claims to encompass side effects discovered only after filing appears to be the key dispute among the parties.

Like Dey, Barr relies on the specification for its construction of "side effects," contending that the patentees "defined" the term in the specification when stating that "[t]hese side effects include central nervous system effects, such as tremor, nervousness, shakiness, dizziness and increased appetite, and cardiac effects, such as arrythmia," and could include "teratogenic effects associated with albuterol." (D.I. 270 at 11 (quoting '755 patent at 3:25-35).) Accordingly, Barr's construction limits the term "side effects" to these specific side effects, and would categorically exclude airway hyperreactivity from the definition of "side effects." Barr argues strenuously that any broader construction would render the claims invalid as indefinite or invalid under the written description requirement. (D.I. 270 at 12-17.) With regard to indefiniteness, Barr argues that the "side effects" claim term "was the one and only distinction Sepracor made over the prior art," and, as such, requires both special focus and a construction that provides a "definite boundary" as to what "side effects" are within the scope of the claim. (D.I. 270 at 13.) With regard to written description, Barr, like Dey, contends that at the time of filing it disclosed the "side effects" it was aware of in the specification and cannot now, through a broad claim construction, claim "side effects" that were discovered post-filing. (Id. at 14-17.)

Sepracor contends that the term "side effects" should not be limited to the specific side effects mentioned in the specification. Sepracor notes that in listing "side effects" the patent prefaces such lists with phrases like "for example" or "such as," making clear that the listed side effects were not intended to be exhaustive. (D.I. 268 at 10-11.) Sepracor further contends that it would be unreasonable to limit "side effects" to those listed in the specification because certain claims of the '755 patent were allowed precisely on the basis of the term "side effects" not being limited to one of the many examples set forth in the specification. (Id. at 11.) Specifically, Sepracor notes that during prosecution of the '755 patent, Dr. Gunnar Aberg, the Vice President of Research and Development at Sepracor, submitted to the PTO a declaration and two accompanying journal articles demonstrating that airway hyperreactivity was reduced through the use of the optically pure

R(-) isomer of albuterol. (*See* D.I. 265, Exh. 10 at DLEV012149-57.) Because the journal articles appeared subsequent to filing, the patentees argued, they supported the notion that, at the time of filing, side effect reduction through the use of the optically pure R(-) isomer of albuterol was unexpected. (Id. at DLEV012125-26.) The patentees further argued that although the specification did not explicitly disclose airway hyperreactivity, it is "certainly a side effect and avoiding airway hyperreactivity could be said to reasonably flow from the disclosure of avoiding side effects." (Id. at DLEV012278.) Ultimately, the examiner allowed the claims, stating that, in his opinion, the Aberg declaration established that it would not have been expected from the prior art that R (-) albuterol did not cause airway hyperreactivity. (Id. at DLEV012293.) With the claims having been allowed for this reason, Sepracor maintains that it would be unreasonable to exclude airway hyperreactivity from their scope.

2. *The Court's Construction*

[10] The Court will first address the ostensibly core issue of whether Sepracor is attempting to improperly expand the scope of its claims to encompass "side effects," most notably airway hyperreactivity, that were allegedly discovered only after filing. None of the cases cited by the parties appear to be precisely on point. Sepracor relies on a set of cases that allegedly stand for the proposition that patent claims can in fact encompass "after-arising" technology. However, in the cases relied upon by Sepracor, a recurring theme is that at the time of filing the allegedly "after-arising" technology was in fact known in the art. FN1 Here, by contrast, there is little to suggest that at the time of filing Sepracor was aware that the use of optically pure R(-) albuterol could reduce airway hyperreactivity. Furthermore, unlike the cases cited by Sepracor, it is clear from the claim language and prosecution history that the term "side effects" is at the very essence of the invention. Indeed, during prosecution, the patentees repeatedly distinguished the prior art on the basis of the R(-) isomer reducing side effects, further explaining that "[t]he thrust of Applicant's invention is the reduction of side effects, which arise in the treatment of asthma with racemic albuterol ...." (D.I. 271, Exh. 13 at 2-3; *see generally* D.I. 270 at 3-6.) Thus, construing the term "side effects" to cover after-arising technology in this case may very well be at odds with the rationale-most often employed in doctrine of equivalents cases-for allowing patents to cover such technology. *See, e.g.,* Varco, L.P. v. Pason Sys. USA Corp., 436 F.3d 1368, 1376 (Fed.Cir.2006) ("Because this case seems to present an instance of after-arising technology (e.g., improvements on prior innovations), the district court may find it appropriate to consider infringement under the doctrine of equivalents."); Datascope Corp. v. SMEC, Inc., 776 F.2d 320, 326 (Fed.Cir.1985) ("As this court and its predecessor courts have stated, 'an embellishment' made possible by technological advances may not permit an accused device to escape 'the web of infringement.' ").

FN1. *See, e.g.,* SuperGuide Corp. v. DirecTV Enters., 358 F.3d 870, 879 (Fed.Cir.2004) ("Although analog may have been the dominant format of video data when the '578 patent application was filed, we have little doubt that those skilled in the art knew of the existence of digital video data at the time."); Marsh-McBirney, Inc. v. Montedoro-Whitney Corp., 882 F.2d 498, 504 (Fed.Cir.1989) ("At the time of the invention, acoustic probes were part of the prior art. Marsh was aware of them, and testified that he chose to use the electromagnetic probe because it best served his needs. But that is not to say that he excluded acoustic probes from his patent."); Bd. of Trs. v. Roche Molecular Sys., 528 F.Supp.2d 967, 980 (N.D.Cal.2007) ("[T]his new type of antiretroviral therapy was anticipated. Articles published in 1990 and 1991 discussed protease inhibitors, indicating they were known. It just took three or four years for their development and availability.").

Defendants, on the other hand, rely principally on Schering Corp. v. Amgen, Inc., 222 F.3d 1347 (Fed.Cir.2000). In Schering, the parties disputed the meaning of the term "IFN-(alpha)," which, at the time of filing, was understood to refer to only a single type of protein. Id. at 1353. However, at the time of litigation, scientists understood the term to refer to several families of proteins. Id. at 1353-54. Nevertheless, the Federal Circuit held that the mere use of this term "did not and could not enlarge the scope of the patent

to embrace technology arising after its filing." Id. at 1353. Unlike the cases cited by *Sepracor,* the Schering case provides no indication that the alleged after-arising protein was, at the time of filing, known or otherwise suggested in the art.

However, critical to the result in Schering was that the Federal Circuit had understood the patentee as having "expressly" limited the meaning of "IFN-(alpha)" to encompass only the single protein described in the original application. Id. Here, by contrast, there is no clear expression limiting or defining the term "side effects" to be those set forth in the original application. Indeed, post- Phillips, there remains a high bar for the court to conclude that the patentee explicitly defined a term within the specification. *See, e.g.,* Abbott Labs. v. Andrx Pharms., Inc., 473 F.3d 1196, 1210-11 (Fed.Cir.2007) (overruling a district court that concluded that the phrase "[t]he pharmaceutically acceptable polymer is a water-soluble hydrophilic polymer ..." amounted to an express definition of "pharmaceutically acceptable polymer"). Here, as Sepracor correctly notes, the specification refers to specific "side effects" not with definitional language, but with language suggesting that the enumerated side effects are merely exemplary. (*See, e.g.,* '755 patent at 1:47-50 ("side effects, such as central nervous system stimulatory effects and cardiac arrhythmia"); *id.* at 2:6-9 (referring to "undesirable side effects, for example, central nervous system stimulatory effects and cardiac disorders").) This militates against adopting either Dey's or Barr's construction, both of which essentially propose to limit the term "side effects" to those specifically set forth in the specification.

Furthermore, unlike Schering, where the disputed claim term was "IFN-(alpha)," the disputed claim term here, "side effects," is not clearly technical in nature, but is a general term amenable to facile understanding. As the Federal Circuit explained in Phillips, "[i]n some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed.Cir.2005). The Court views this case as being in that category. Accordingly, rather than limit the claims to specific side effects in the specification, the Court will construe "side effects" to be, as Sepracor contends, effects other than the desired therapeutic effect associated with the administration of racemic albuterol. (*See* D.I. 302 at 111; D.I. 283 at 3.)

With this construction, the Court has not accepted Dey's proposal that side effects be limited to those caused "directly" by the S(+) enantiomer of albuterol. The claims plainly associate the "side effects" with the administration of "racemic albuterol" and are not limited to the side effects associated with a particular enantiomer. Though certain statements in the prosecution histories can be interpreted as characterizing "side effects" to be associated with only the S(+) isomer of albuterol, other statements are clear that the claim language is referring broadly to side effects "associated with the racemic mixture or the *therapeutically inactive* isomer, i.e. the S(+) isomer, of albuterol, but *not* with the R(-) isomer." (D.I. 265, Exh. 10 at DLEV012112 (emphasis in original).) In these circumstances, the Court does not see a clear and unmistakable disavowal of claim scope necessary for a court to limit the claims. *See* Voda v. Cordis Corp., 536 F.3d 1311, 1321 (Fed.Cir.2008) ("[I]n order to disavow claim scope during prosecution a patent applicant must clearly and unambiguously express surrender of subject matter.") (citations omitted); *see also* Phillips, 415 F.3d at 1317 ("[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.").FN2

FN2. Defendants have argued that if the Court were to accept Plaintiff's proposed claim construction, the patents may be invalid on grounds such as indefiniteness and written description. Of course, Defendants may be correct and Plaintiff's patents may ultimately be found invalid on these grounds. However, in the Court's view, the facts of this case present circumstances where indefiniteness and written description are best dealt with in a context other than the Court's initial consideration of claim construction.

B. "Chronic Administration" And "Chronically Administering To The Individual"

Sepracor's Construction	Dey's Construction	Barr's Construction
To administer the drug to a human on a *recurring* basis to prevent or reduce the extent to which bronchospasms occur.	Treating periodically or prophylactically.	Treating prophylactically or periodically.

[11] Citing a medical dictionary that defines "chronic" as being "marked ... by frequent recurrence over a long time ...," Sepracor contends that its definition corresponds to the plain meaning of the term "chronic." (D.I. 283 at 12.) Sepracor further argues that the prosecution histories support their construction. Specifically, during prosecution of the '755 patent, the examiner "questioned in light of the specification" whether claims pertaining to the treatment of "chronic asthma patient" were supported. (D.I. 265, Exh. 10 at DLEV012274). In response, Sepracor submitted the declaration of Dr. T. Scott Johnson, who opined therein that "if the treatment were not chronic, cessation of administration might or might not lead to an immediate [asthma] attack, but it would certainly lead to reestablishment of the disease condition." (Id. at DLEV012281-82.) Based on this, Sepracor concludes that "chronic administration" must correspond to "recurring" administration.

Like Sepracor, Defendants also rely on the Johnson declaration for their construction. In particular, Defendants note that in the same passage of the Johnson declaration cited by Sepracor, Dr. Johnson explained specifically that the "application was referring to chronic therapy when it speaks of either prophylactic or periodic administration." (Id.) Defendants further point out that Sepracor obtained allowance of its claims specifically on the basis of the Johnson declaration. (*See* id. at DLEV012292-93.)

Given that both parties direct the Court to the Johnson declaration for support in construing "chronic administration," and given that the claims were, in fact, allowed on the basis of the Johnson declaration, the Court will look to the Johnson declaration for its construction of the "chronic administration" term. On review, the Court concludes that the section of the Johnson declaration relied upon by Defendants speaks most directly to the meaning of the term "chronic" as it is used in the context of the '755 patent. Indeed, Dr. Johnson specifically explained that the patent was "referring" to chronic therapy when discussing "either prophylactic or periodic administration." By contrast, the excerpts of the Johnson declaration relied upon by Sepracor merely lay the foundation for why "chronic administration," a term not used in the specification, may nevertheless be understood as "either prophylactic or periodic administration." Accordingly, the Court will construe "chronic administration" to mean, as Defendants contend, prophylactic or periodic administration.

C. "Acute Administration"

Sepracor's Construction	Dey's Construction	Barr's Construction
Administration to treat an acute attack of asthma.	Treatment after the onset of an asthma attack.	No construction offered.

[12] This disputed term appears only in Claim 1 of the '994 patent, which explicitly pertains to a "method of treating an acute attack of asthma." Accordingly, the dispute over this term does not actually pertain to whether it refers to treatment of an asthma attack. Rather the dispute appears to be over the timing of treatment. Dey contends that "acute administration" is limited to treatment only "after" the onset of an asthma attack, while Sepracor apparently asks for a broader definition, though Sepracor does not clearly state what that definition should be. Indeed, Sepracor states in a small table introducing its discussion of this term that it should be given its "plain meaning-administration to treat an acute attack of asthma." (D.I. 283

at 17.) But in the text that immediately follows, Sepracor states the term "refers to a one time administration as opposed to chronic administration which requires recurring use." (Id.) Sepracor offers no evidence-either intrinsic or extrinsic-in support of either of these constructions.

Dey, by contrast, notes that the body of the claim refers to "administering to an individual suffering from an acute attack of asthma a quantity of an optically pure R(-) isomer...." Referring to an individual already suffering from an acute asthma attack, Dey contends that "acute administration" must thus refer to administration after onset of the attack. (*See* D.I. 302 at 95:16-96:2.) Dey further points to the declaration of Dr. Johnson, discussed above, in support of the allowance of the claims of the '755 patent. There, Dr. Johnson explained that in the "acute" "mode" of asthma treatment, "albuterol is administered 'after onset of asthma.' " (*See* D.I. 265, Exh. 10 at DLEV012281.) In light of this evidence, and because Sepracor points to no evidence in support of its construction, the Court will construe "acute administration" to mean, as Dey contends, treatment after onset of an asthma attack.

D. "Inducing Bronchodilation Or Providing Relief Of Bronchospasm"

Sepracor's Construction	**Dey's Construction**	**Barr's Construction**
Bronchospasm means a contraction of smooth muscle in the walls of the bronchi and bronchioles, causing narrowing of the lumen, which is not limited to bronchospasms associated with asthma.	Treating asthma.	Treating asthma or an asthma attack.

[13] Defendants contend that this claim term should be limited to the treatment of asthma because the specification refers to "bronchospasm" as merely a symptom associated with asthma. (D.I. 281 at 10; D.I. 264 at 31.) For instance, Defendants note that the specification explains that "R (-) albuterol ... is active in bronchial tissue sufficient to reduce bronchial spasms associated with asthma." ('755 patent at 1:44-46.) Defendants further point to a number of statements in the prosecution histories where the applicant explained that the invention was directed to the treatment of asthma. (*See, e.g.,* D.I. 264, Exh. 20 at DLEV011571 ("The claims of the issued patents 5,844,002; 5,760,090; 5,547,994; and 5,362,755 relate to methods for treating asthma.")). With Sepracor having characterized the overall invention as pertaining to asthma, Defendants contend that Sepracor should not now be allowed to claim the treatment of other conditions. Along these lines, Barr argues that in the specification Sepracor described no condition other than asthma or an asthma attack and "cannot now claim the benefit of any other conditions." (D.I. 280 at 10.)

Sepracor draws its construction from a medical dictionary definition for the term "bronchospasm." (*See* D.I. 268 at 19.) In support of this construction, Sepracor notes first that the relevant claims specifically do not include an "asthma" limitation but instead refer to the ostensibly more general terms "inducing bronchodilation" and "bronchospasm." (Id. at 20.) With regard to the specification, Sepracor contends that asthma is described only as an exemplary bronchial disorder, and that the claims should thus not be limited to the treatment of "asthma." (*See, e.g.,* ' 755 patent at 1:46-51 ("The present invention relates to a method of treating bronchial disorders, such as asthma....").) As for the prosecution histories, Sepracor notes that during prosecution of the '002 patent the applicants specifically explained that claims of the parent application were directed to a "method of treating asthma," whereas new claims were directed to "inducing bronchodilation or providing relief of bronchospasms." (D.I. 269, Exh. 14 at SEP0729190.) Thus, notwithstanding broad statements characterizing the overall invention as pertaining to asthma treatment, Sepracor contends that the prosecution histories confirm that "bronchospasm" and "asthma" are distinct concepts. (D.I. 268 at 21.) Along these lines, Sepracor further contends that the doctrine of claim differentiation requires this claim term be construed differently from the claim term "asthma." (D.I. 268 at

19-20.)

[14] The Court will begin its analysis with the principle that "the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed.Cir.2004) (citations omitted). The Court agrees with Defendants that the specification describes "bronchospasm" as part of the physiology of asthma and the inducement of "bronchodilation" as one manner of treating asthma. But this does not lead to the conclusion that these terms are exclusively synonymous with asthma treatment, and it certainly does not rise to the level of a "manifest exclusion or restriction" of claim scope. The same can be said with regard to statements in the prosecution history explaining, for instance, that the "thrust" of the invention is the treatment of asthma or that the claims "relate to" the treatment of asthma. Indeed, far more compelling is that during prosecution the patentee specifically explained to the examiner that claims including the term "inducing bronchodilation or providing relief of bronchospasms," which issued as part of the '002 patent, were distinct from claims pertaining to a "method for treating asthma," which issued as part of the '755 patent. (D.I. 268, Exh. 14 at SEP0729190.) Based on this, the Court concludes "inducing bronchodilation or providing relief of bronchospasms" should not be construed synonymously with "treating asthma."

Having declined to accept Defendants' proposed construction, the Court is left with the question of whether it is appropriate to, as Sepracor contends, look to a dictionary definition for support in construing this term. Because this claim term is not specifically defined in the internalrecord, the Court concludes that consultation of a dictionary is appropriate. Furthermore, "[b]ecause dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." Phillips, 415 F.3d at 1318; *see also* Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 996 (Fed.Cir.2006) ("Because there is no suggestion that the intrinsic evidence defines the term 'catalyst,' one may look to technical dictionaries for assistance in determining that term's meaning to a person of ordinary skill in the art."). Here, Sepracor's dictionary definition defines "bronchospasm" as "a contraction of smooth muscle in the walls of the bronchi and bronchioles, causing narrowing of the lumen." (D.I. 268 at 19 (citing Stedman's Medical Dictionary 25th Ed. at 214).) Though Defendants contend that this definition is not supported in the specification or file history, *see* D.I. 281 at 11, they do not clearly dispute the correctness of it. On the contrary, Defendant Dey explains in its Opening Claim Construction Brief that the term "bronchodilation," which is part of the disputed claim term, refers to "relaxation of the airway smooth muscle." D.I. 264 at 31. Furthermore, the specification explains that "[a]lbuterol acts selectively on the $beta_2$-adrenergic receptors to relax smooth muscle tissue, for example, in the bronchial system." ('755 patent at 1:18-20.) Thus, construing this disputed phrase in terms of smooth muscle tissue relaxation appears to be well aligned with the specification. Accordingly, the Court will construe "inducing bronchodilation or providing relief from bronchospasm" to mean "inducing relaxation of smooth muscle in the walls of the bronchi and bronchioles or providing relief from contraction of smooth muscle in the walls of the bronchi and bronchioles."

E. "Treating Bronchospasm **In A Patient With Reversible** Obstructive Airway Disease**" And "Preventing** Bronchospasm **In A Patient With Reversible** Obstructive Airway Disease**"**

Sepracor's Construction	**Dey's Construction**	**Barr's Construction**
Reversible obstructive airway disease is a respiratory disorder such as asthma, chronic bronchitis, and emphysema.	The "treating bronchospasm ..." term refers to treating a patient after the onset of an asthma attack, and the "preventing bronchospasm" term refers to chronically treating a patient for asthma.	Reversible obstructive airway disease refers to asthma or an asthma attack.

1. *Whether These Terms Should Be Limited To Asthma Treatment*

[15] [16] As with other terms pertaining to "bronchodilation" and "bronchospasm," the core of the parties' dispute is whether "reversible obstructive airway disease" should be limited to "asthma." In support of the position that it should be so limited, Dey raises essentially the same arguments it raised for the term "inducing bronchodilation or providing relief from bronchospasm." *See supra* Part II.D. Specifically, Dey contends that during prosecution the patentees characterized the invention as a whole as pertaining to "asthma" and that the specification contains no support for the treatment of conditions other than "asthma." (D.I. 264 at 33-34.) Dey furtherpoints to extrinsic evidence that it contends demonstrates that "reversible obstructive airway disease" is synonymous with "asthma." (Id.) Barr, like Dey, also contends that this term should be limited to "asthma or an asthma attack" "[f]or substantially the same reasons" that it argued "inducing bronchodilation or providing relief of bronchospasm" referred only to asthma treatment. (D.I. 281 at 13-14.)

Sepracor's principal position on this term appears to be only that the term should not be limited to asthma treatment. Though Sepracor provides a definition from a journal article for this term, Sepracor does not urge the Court to adopt this definition as its construction. Rather, Sepracor contends that it provided the definition only to demonstrate that those of skill in the art understand "reversible obstructive airway disease" to refer to more than just "asthma." (D.I. 268 at 23 n. 14.) Sepracor further contends that the patentees clearly explained during prosecution of the "3 patent that "reversible obstructive airway disease" was distinct from "asthma." Specifically, just like the term "inducing bronchodilation or providing relief from bronchospasm," Sepracor notes that the patentees explained that unlike previous claims, which were directed to "asthma" treatment, new claims were directed to "reversible obstructive airway disease." (D.I. 269, Exh. 16 at SEP0729306.)

Again, the Court must consider whether there has been a clear intention to limit the claim scope of the claims using "words or expressions of manifest exclusion or restriction." Liebel-Flarsheim, 358 F.3d at 906. For the same reasons set forth above, the Court concludes that there has been no such intention to limit claim scope. Furthermore, the extrinsic evidence relied upon by Dey does not demonstrate that "reversible obstructive airway disease" is "synonymous" with "asthma." For instance, the 1991 Report of the National Heart, Lung and Blood Institute that Dey relies upon merely confirms that asthma is, in fact, one type of "reversible obstructive airway disease," not that it is the only kind. (*See* D.I. 264, Exh. 22 at SEP0743646.) With regard to the Physician's Desk Reference that Dey argues "indicates reversible obstructive airway disease is used interchangeably with asthma," (D.I. 275 at 34), the Court notes that Dey does not quote any specific language from this document demonstrating this to be the case. After reviewing the document, the Court does not identify any such language either. Finally, as to the journal article Dey cites, (*see* D.I. 265, Exh. 24), the Court concludes that this article actually suggests that "reversible obstructive airway disease" should not be limited to "asthma." Indeed, Table 1 of this article characterizes data for 16 patients having "reversible airway obstruction." The "Clinical Diagnosis" listed for such patients includes, in addition to various types of "asthma," "Pulmonary emphysema" and "Chronic Bronchitis," suggesting that those of skill in the art understand "reversible airway obstruction" to refer not just to "asthma." (*Id*. at 1368.)

Having concluded that this claim term will not be limited to treatment of "asthma," the Court must now consider what additional construction, if any, is required. The Court agrees with Defendants' that the term "reversible obstructive airway disease" is not defined in the specification. (*See* D.I. 281 at 13; D.I. 264 at 33-34). In these circumstances, it is not inappropriate for the Court to consider extrinsic evidence for assistance in construing this term. *See* Phillips, 415 F.3d at 1318. As explained above, the article Dey points to suggests that "reversible obstructive airway diseases" can include, at least, asthma, pulmonary bronchitis, and emphysema. Likewise the extrinsic evidence that Sepracorpoints to explicitly explains that "[r]eversible obstructive airways disease (ROAD) include asthma, chronic bronchitis, and emphysema." (D.I. 269, Exh.

15 at 154, 155.) Thus, the Court will construe "reversible obstructive airway disease" to mean, as Sepracor states in its Answering Claim Construction Brief, "a respiratory disorder such as asthma, chronic bronchitis, and emphysema." (D.I. 283 at 17.) This construction confirms that the term is not limited to "asthma" and, at the same time, illuminates the meaning of the term by setting forth the types of conditions that those of skill in the art understand to be within the scope of "reversible obstructive airway disease."

2. *Whether The "Treating Bronchospasm" Term Must Be Limited To Treatment "After An Asthma Attack"*

In addition to contending that this term should be limited to "asthma" treatment, Dey contends that this term includes a temporal component. Specifically, Dey contends that it refers only to treatment "after" onset of an asthma attack. In support of this position, Dey notes that the specification explains that "for example, R(-) albuterol is administered to an individual after onset of asthma." ('755 patent at 2:29-31.) Given the Court's determination that this claim term is not limited to "asthma" treatment, it makes little sense to, in the first instance, require that treatment take place only "after" an "asthma attack." Likewise, the Court sees nothing about the words "treating bronchospasm" that calls for the imposition of a temporal limitation. The specification excerpt Dey cites to, describing one exemplary manner of using R(-) albuterol, does not call for this either. Furthermore, unlike the term "acute administration," *see supra* Part II.C, the Court finds nothing in the claim language or file history suggesting such a limitation. Accordingly, the Court will not limit this term to post-asthma attack treatment.

3. *Whether The "Preventing* Bronchospasm*" Term Must Be Construed As "Chronic" Treatment*

With their proposed construction, Dey essentially contends that the term "preventing" should be construed to refer to "chronic" treatment. In support of this position, Dey points to the prosecution history of the parent '755 patent. In particular, Dey points to the declaration of Dr. Johnson, who opined that one passage of the application discussed both acute and chronic therapy. (D.I. 265, Exh. 10 at DLEV012881.) The application was referring to chronic therapy, Dr. Johnson explained, when it described the administration of albuterol prior to the onset of bronchospasm in an asthma attack in order to prevent its occurrence. (Id.) But these statements do not establish that a treatment designed to "prevent" bronchospasm must always be defined as "chronic" treatment. Moreover, the Court's construction of "chronic," which Dey advocated for, already encompasses the concept of preventative treatment through its use of the word "phrophylactic." As such, the Court does not understand how defining "preventing" in terms of "chronic" treatment would meaningfully advance the understanding of the claim to one of skill in the art. Accordingly, the Court will not redefine "preventing" to correspond to "chronic" treatment.

CONCLUSION

For the reasons discussed, the Court has construed the disputed terms and/or phrases of the patents-in-suit as provided herein. An Order consistent with this Memorandum Opinion will be entered setting forth the meanings of the disputed terms and/or phrases in the patents-in-suit.

ORDER

At Wilmington, this 18 day of December 2008, for the reasons discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that the following terms and/or phrases in United States Patent Nos. 5,362,755 ("the '755 patent"); 5,547,994 ("the '994 patent"); 5,760,090 ("the '090 patent"); 5,844,002 ("the '002 patent") and 6,083,993 ("the '993 patent") are assigned the following meanings:

1. The term "**side effects**" means "effects other than the desired therapeutic effect associated with the

administration of racemic albuterol."

2. The terms "**chronic administration**" and "**chronically administering to the individual**" mean "prophylactic or periodic administration."

3. The term "**acute administration**" means "treatment after the onset of an asthma attack."

4. The term "**inducing bronchodilation or providing relief of** bronchospasm" means "inducing relaxation of smooth muscle in the walls of the bronchi and bronchioles or providing relief from contraction of smooth muscle in the walls of the bronchi and bronchioles."

5. The term "**treating** bronchospasm **in a patient with reversible** obstructive airway disease" means "treating bronchospasm in a patient with a respiratory disorder such as asthma, chronic bronchitis, or emphysema."

6. The term "**preventing** bronchospasm **in a patient with reversible** obstructive airway disease" means "preventing bronchospasm in a patient with a respiratory disorder such as asthma, chronic bronchitis, or emphysema."

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