IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan)	:	
Patent Litigation	:	No. 20-md-2930-LPS

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MEMORANDUM OPINION

July 8, 2021
Wilmington, Delaware

STARK, U.S. District Judge:

In this multi-district litigation, Novartis Pharmaceuticals Corporation ("Novartis" or "Plaintiff") sued multiple generic drug manufacturers ("Defendants"), specifically: Alembic Pharmaceuticals Limited, Alembic Pharmaceuticals, Inc., Alkem Laboratories Ltd., Aurobindo Pharma USA Inc., Aurobindo Pharma Ltd., Biocon Pharma Limited, Biocon Limited, Biocon Pharma, Inc., Cadila Healthcare Ltd., Crystal Pharmaceutical (Suzhou) Co., Ltd., Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Hetero USA Inc., Hetero Labs Limited, Hetero Labs Limited Unit III, Laurus Labs Limited, Laurus Generics Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., Lupin Pharmaceuticals, Inc., Macleods Pharmaceuticals Ltd., Macleods Pharma USA, Inc., MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, MSN Life Sciences Private Limited, Mylan Pharmaceuticals Inc., Nanjing Noratech Pharmaceutical Co., Limited, Novugen Pharma (Malaysia) Sdn. Bhd., Teva Pharmaceuticals USA, Inc., Torrent Pharma Inc., Torrent Pharmaceuticals Ltd., and Zydus Pharmaceuticals (USA) Inc. Novartis asserts that one or more of these Defendants would, if permitted to market their proposed generic drug products, infringe claims of one or more of the following U.S. Patents: 8,101,659 (the "'659 patent"); 8,796,331 (the "'331 patent"); 8,877,938 (the "'938 patent"); and 9,388,134 (the "'134 patent").

As Novartis explains, the asserted patents fall into two families and "cover two distinct inventions. Novartis initially developed the novel combination of valsartan and sacubitril, and methods of administering that combination to treat hypertension and heart failure, and filed a priority patent application to its invention on January 17, 2002. Novartis's '659 and '331 Patents . . . claim priority to that 2002 application." (D.I. 253 at 7)[1] These two patents share

[1] Citations to the docket index refer to Case No. 20-md-2930.

"substantively the same specification." (*Id.* at 4 n.4) "Several years later, Novartis developed a novel compound comprising non-covalently bound valsartan and sacubitril salts, and methods of administering that compound to treat hypertension and heart failure," which are covered by the '938 and '134 patents. (*Id.* at 7) The '938 and '134 patents also share a specification. (*Id.* at 42 n.24)

The parties submitted a joint claim construction brief (D.I. 253), technology tutorials (D.I. 240, 241), and extensive appendices, including expert reports (D.I. 254, 255). The Court held a claim construction hearing on June 8, 2021. (D.I. 275) ("Tr.")

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321 (2015) (citing *Markman v. Westview Instruments, Inc.* ("*Markman II*"), 517 U.S. 370, 388-91 (1996)). "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." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. The Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art [POSA] in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent "specification is always highly relevant to the claim construction

analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment" because "claim terms are normally used consistently throughout the patent." *Id.*

It is likewise true that "[d]ifferences among claims can also be a useful guide." *Id.* at 1314. "For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15. This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[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." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir.

1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the [U.S. Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

Sometimes, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 574 U.S. at 331. "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman II*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the ordinary and customary meaning of a term because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic

evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs SpA*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks omitted).

II. CONSTRUCTION OF DISPUTED TERMS

A. "wherein said (i) . . . and said (ii) . . . are administered in combination" / "administering . . . the combination of: (i) . . . ; (ii) . . . ; and wherein said components (i) and (ii) are administered in one unit dose form or in two separate unit dose forms"[2]

Novartis wherein said (i) . . . and said (ii) . . . , are administered in combination / administering . . . the combination of: (i) . . . ; (ii) . . . ; and wherein said components (i) and (ii) are administered in one unit dose form or in two separate unit dose forms
Defendants wherein said (i) . . . and said (ii) . . . are administered in concert as two separate components / administering . . . the combination of (i) . . . ; (ii) . . . ; and wherein said components (i) and (ii) are administered in concert in either one unit-dose form or in two separate unit-dose forms, as two separate components
Court wherein said (i) . . . and said (ii) . . . , are administered in combination / administering . . . the combination of: (i) . . . ; (ii) . . . ; and wherein said components (i) and (ii) are administered in one unit dose form or in two separate unit dose forms

"The sole dispute between the parties regarding the 'combination' terms is whether these terms, and thus the '659 and '331 Patent claims, are limited to the active agents valsartan and

[2] These terms appear in claim 1 of the '659 patent and claim 1 of the '331 patent.

sacubitril 'as two separate components' as Defendants propose, or not so limited as Novartis proposes." (D.I. 253 at 5) The Court concludes that they are not.

The intrinsic record is silent on whether sacubitril and valsartan must be separate (and not complexed). As Novartis points out, "[n]othing in the specification of the '659 and '331 Patents limits the claims." (D.I. 253 at 10) Indeed, the specification "discloses combinations of physically separate valsartan and sacubitril and does not disclose the later-invented ***compound*** of valsartan and sacubitril (wherein valsartan and sacubitril salts are associated with non-covalent bonds)." (*Id.*) As Novartis also points out, the patentee did not define or disclaim the "combination" of those two ingredients. (*Id.* at 10-11) In the Court's view, the absence of any indication in the written description that the patentee limited its invention solely to separate compounds means, in context, that a person of ordinary skill in the art ("POSA") would not read the claims as so limited.

That the patent is not limited to separate compounds is bolstered by a patent term extension granted on the '659 and '331 patents. (*See generally* D.I. 255 Exs. 11, 16) In seeking and obtaining the patent term extension, Novartis represented to the Patent Office that the '659 and '331 patents cover Entresto, a drug consisting solely of non-separate, complexed valsartan and sacubitril. (*See id.*) The parties devote much of their briefing to argument about whether this evidence is intrinsic or extrinsic (*see, e.g.*, D.I. 253 at 22-23, 33-34), an issue on which there is little helpful authority. *See, e.g.*, *Abbott Labs. v. Dey, L.P.*, 110 F. Supp. 2d 667, 673 (N.D. Ill. 2000) (determining that application for patent term extension was "extrinsic" and "should not be considered"). Here, the patent term extension evidence, whether viewed as intrinsic or extrinsic, does not contradict an unambiguous construction otherwise apparent from the indisputably intrinsic evidence. The Court believes that a POSA would give this evidence some weight in

understanding how the patentee is using the claim term in the context of the patent and would find it to support Plaintiff's construction.[3] *See generally Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730-31 (2002) ("A patent holder should know what he owns, and the public should know what he does not.").

Defendants further contend that Plaintiff's construction will render the claims invalid. (*See* D.I. 253 at 20-21, 39-40) Novartis admits that its two patents "do not disclose or suggest" a one-unit-dose-form embodiment. (*See id.* at 39) This seems to be an admission by Novartis that, at the very least, there will be a non-frivolous issue of written description and/or lack of enablement as this case proceeds on Novartis's preferred construction. *See generally Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC*, 824 F.3d 999, 1004 (Fed. Cir. 2016). At this point, the Court has no basis to believe that the construction it is adopting is necessarily consigning the asserted claims to a judgment of invalidity. Since this construction is otherwise supported, the Court will adopt it. *See, e.g.*, *Phillips*, 415 F.3d at 1327 ("While we have acknowledged the maxim that claims should be construed to preserve their validity, we have not applied that principle broadly, and we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction.").

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[3] The Court recognizes that "[t]he determination as to whether a patent is eligible for an extension will normally be made solely from the representations contained in the application for patent term extension." Manual of Patent Examining Procedure ("MPEP") § 2755 (9th ed. Rev. 10.2019 June 2020); *see also* 37 C.F.R. § 1.750; *Abbott*, 110 F. Supp. 2d at 673 ("[T]he granting of the extension appears to have had nothing to do with determining what the claims of the patent mean . . . ."). While this may mean, as Defendants contend, that Novartis' representations to the PTO in seeking the patent term extension were "litigation-inspired" (*see* D.I. 253 at 14), all statements made by a patentee to the PTO are subject to a "duty of candor and good faith," 37 C.F.R. § 1.765, and the patentee may always be asked by the PTO for further information, *see id.* § 1.750; *see also* MPEP § 2755; Tr. at 60-61 (discussing possibility that patent could be rendered unenforceable due to inequitable conduct). Again, understanding all of this, the Court believes that a POSA would nonetheless give consideration to the patent term extension evidence and, correspondingly, the Court has as well.

B. "trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl) propionate-(S)-3′-methyl-2′-(pentanoyl{2″-(tetrazol-5-ylate)biphenyl-4′-ylmethyl}amino) butyrate] hemipentahydrate in crystalline form" / "trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl) propionate-(S)-3′-methyl-2′-(pentanoyl{2″-(tetrazol-5-ylate)biphenyl-4′- ylmethyl}amino) butyrate] hemipentahydrate"[4]

Novartis substantially pure trisodium [sacubitril-valsartan] hemipentahydrate in crystalline form / trisodium [sacubitril-valsartan] hemipentahydrate
Defendants a substantially pure crystalline supramolecular complex having formula units of trisodium [sacubitril-valsartan] hemipentahydrate, wherein each formula unit in a unit cell of the crystalline complex has 2.5 water molecules and 3 sodium ions / a substantially pure crystalline supramolecular complex having formula units of trisodium [sacubitril-valsartan] hemipentahydrate, wherein each formula unit in a unit cell of the crystalline complex has 2.5 water molecules and 3 sodium ions
Court substantially pure trisodium [sacubitril-valsartan] hemipentahydrate in crystalline form / trisodium [sacubitril-valsartan] hemipentahydrate (claims 1-4); substantially pure trisodium [sacubitril-valsartan] hemipentahydrate in crystalline form (claims 5-15)

There are three issues for the Court to decide with respect to the "trisodium [sacubitril-valsartan] hemipentahydrate" and "in crystalline form" limitations:

(1) Is "trisodium [sacubitril-valsartan] hemipentahydrate" by itself limited to crystalline form?;

(2) Are the claim terms "trisodium [sacubitril-valsartan] hemipentahydrate" and "crystalline form" limited to "a . . . supramolecular complex having formula units . . . , wherein each formula unit in a unit cell . . . has 2.5 water molecules and 3 sodium ions"?; and

[4] These terms appear in claim 1 of the '938 patent and claims 1, 4-11, and 13-15 of the '134 patent. In the briefing, the chemical name "trisodium [3-((1S,3R)-1- biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl)propionate-(S)-3′-methyl-2′- (pentanoyl{2″-(tetrazol-5-ylate)biphenyl-4′-ylmethyl}amino)butyrate] hemipentahydrate" is more conveniently referred to as "trisodium [sacubitril-valsartan] hemipentahydrate." (D.I. 253 at 43) The Court adopts the same convention.

> (3) Are the '134 Patent claims limited to "substantially pure" trisodium [sacubitrilvalsartan] hemipentahydrate?

(D.I. 253 at 44 (internal citations omitted); *see also id.* at 57-58)

On the first issue, the Court agrees with Novartis that only certain claims (all of the claims of the '938 patent and dependent claims 5-15 of the '134 patent) are limited to crystalline embodiments. While claim 1 of the '938 patent explicitly requires trisodium [sacubitril-valsartan] hemipentahydrate in crystalline form, claim 1 of the '134 patent does not; instead, only dependent claims 5-15 of the '134 patent are limited to crystalline forms. The specification of the '134 patent teaches that the compound of the claims "can be in the crystalline, partially crystalline, amorphous, or polymorphous form, preferably in the crystalline form" ('134 patent at 15:63-67), all of which suggests that the claimed compound is not always and necessarily in crystalline form. Moreover, the Examiner never required Novartis to specifically elect the crystalline form during prosecution of the '134 patent. (*See* D.I. 255 Ex. 38)

Defendants are correct that, during prosecution of the '938 patent, the Examiner issued a restriction requirement, in response to which Novartis elected trisodium [sacubitril-valsartan] in crystalline form with hydrates. (D.I. 255 Ex. 20 at 11) In doing so, Novartis gave up the opportunity to prosecute other, non-crystalline forms claimed in the application that resulted in the '938 patent. The restriction requirement was accepted and understood: the Examiner made an amendment to replace solid forms with "crystalline" forms and noted that the Karpinski declaration was persuasive as to the "undue technical hurdles" to "prepare the ***claimed crystalline compound***." (D.I. 255 Ex. 28 at 3 (emphasis added); *see also id.* Ex. 20 at 11 (restriction response election)) Post-allowance, Novartis stated that "initial experiments to prepare ***the claimed crystalline*** trisodium hemipentahydrate involved screening" wherein "much

work was required to prepare the ***claimed crystalline*** trisodium hemipentahydrate." (D.I. 255 Ex. 29 at 1) (emphasis added)

This same restriction requirement and election to prosecute only crystalline claims is not part of the prosecution of the '134 patent. While the specification of the '134 patent states that the patent relates to "trisodium [sacubitril-valsartan], ***a crystalline solid***" ('134 patent at 17:41-48) (emphasis added), this is not a definition of trisodium [sacubitril-valsartan]. Nor is it, in the Court's view (and the view of a POSA, looking at the claim term in the context of the patent), a disclaimer.

On the second issue, the Court agrees with Novartis that the claims are not limited to embodiments in which the trisodium [sacubitril-valsartan] exists as a crystalline, "supramolecular complex." The Examiner recognized that the complex could exist in crystalline, solid, amorphous, and other forms. (*See* D.I. 253 at 63-65; D.I. 255 Ex. 20 at 11; D.I. 255 Ex. 38) (requiring restriction between these forms) The specification states expressly that trisodium [sacubitril-valsartan] hemipentahydrate "***may*** be considered a sodium supramolecular complex" ('134 patent at 19:10-15) (emphasis added) and ***preferably*** "has a network of non-covalent bonds" (*id.* at 7:7-9), but these are not requirements. (*See also id.* at 6:50-51) ("In a preferred embodiment, the dual-acting compound is a complex, in particular a supramolecular complex.")

On the third issue, however, the Court agrees with Defendants that all of the crystalline claims of both the '938 and '134 patents do contain the substantial purity limitation. The parties agree that the '938 patent requires a substantially pure, crystalline compound. (D.I. 253 at 57) A child patent (such as the '134 patent) that uses the same claim language as the parent patent (such as the '938 patent) imports the same disclaimed meaning as the parent patent. *See Elkay*

Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999). Moreover, the '134 patent, as a divisional, incorporates the reasons for allowance of the '938 patent, which is explicitly confirmed in an office action in the '134 patent's prosecution history. (D.I. 206-3 Ex. 34 at 25 ¶ 9) ("Incorporation by reference is made to the reasons for allowance in the parent application . . . .") Even though Novartis never expressly agreed with the Examiner's reasoning and never otherwise disclaimed non-substantially pure forms (*see* D.I. 253 at 57, 90-91), for the reasons just given the disclaimer carries over to the crystalline claims of the '134 patent (i.e., claims 5-15). The other claims of the '134 patent, not being limited to the crystalline form, do not carry the substantially pure limitation. *See Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1182 (Fed. Cir. 2006) ("[T]he doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language."); *Broadridge Fin. Sols., Inc. v. Inveshare, Inc.*, 2012 WL 1245723, at *4 (D. Del. Apr. 11, 2012) ("[E]ven if the [parent] patent disclaimer relates to the same subject matter at issue in the [child] patent claims, it may not necessarily affect the [child patent's] claim construction if the claim language is materially different.")

III. CONCLUSION

The Court will construe the disputed terms as explained above. The Court will also adopt the parties' agreed-upon constructions. An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	: :	No. 20-md-2930-LPS

ORDER

At Wilmington this **8th** day of **July, 2021**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the following claim terms of U.S. Patent Nos. 8,101,659 (the "'659 patent"); 8,796,331 (the "'331 patent"); 8,877,938 (the "'938 patent"); and 9,388,134 (the "'134 patent") are construed as follows:

Claim Term	Claims	Court's Construction
"amounts effective to treat hypertension or heart failure"	'659 patent, claim 2	"amounts of each component sufficient in combination to treat hypertension or heart failure"
"therapeutically effective amount"	'331 patent, claim 1; '134 patent, claim 1	"amount sufficient to treat heart failure or hypertension"
"effective amount"	'938 patent, claim 11	"amount sufficient to have a therapeutic effect"
"wherein said (i) . . . and said (ii) . . . are administered in combination" / "administering . . . the combination of: (i) . . . ; (ii) . . . ; and wherein said components (i) and (ii) are administered in one unit dose form or in two separate unit dose forms"	'659 patent, claim 1; '331 patent, claim 1	"wherein said (i) . . . and said (ii) . . . , are administered in combination / administering . . . the combination of: (i) . . . ; (ii) . . . ; and wherein said components (i) and (ii) are administered in one unit dose form or in two separate unit dose forms"

"trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl) propionate-(S)-3′-methyl-2′-(pentanoyl{2″-(tetrazol-5-ylate)biphenyl-4′-ylmethyl}amino) butyrate] hemipentahydrate in crystalline form"	'938 patent, claim 1	"substantially pure trisodium [sacubitril-valsartan] hemipentahydrate in crystalline form"
"trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl) propionate-(S)-3′-methyl-2′-(pentanoyl{2″-(tetrazol-5-ylate)biphenyl-4′-ylmethyl}amino) butyrate] hemipentahydrate"	'134 patent, claims 1, 4	"trisodium [sacubitril-valsartan] hemipentahydrate"
"trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl) propionate-(S)-3′-methyl-2′-(pentanoyl{2″-(tetrazol-5-ylate)biphenyl-4′-ylmethyl}amino) butyrate] hemipentahydrate"	'134 patent, claims 5-11, 13-15	"substantially pure trisodium [sacubitril-valsartan] hemipentahydrate in crystalline form"

UNITED STATES DISTRICT JUDGE