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Solid Form Patents
Data in Claims

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PPXRD-14

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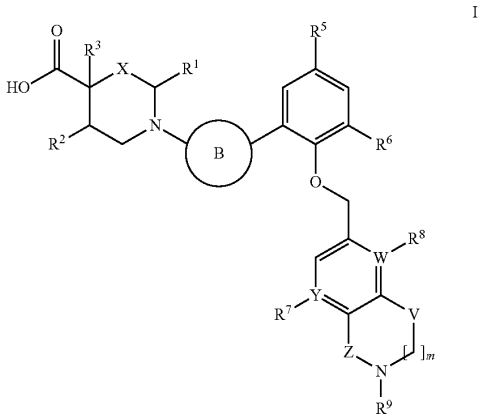
Data Claiming - How Solid Form Claims Differ from Chemical Structure Claims

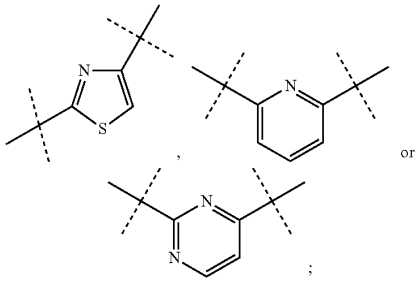
U.S. Patent No. 9,353,090

1. A compound of the formula I



I

wherein:
X is CHR^4;
R^1 is H;
R^2 and R^3 together with the carbons they are bonded to form a fused 3-membered ring; and
R^4 is H; or
R^1 is H;
R^2 and R^4 form a 2-carbon alkylidene bridge; and
R^3 is H; or
R^2 and R^3 are H; and
R_1 and R_4 together with the piperidine ring they are bonded to may form an octahydropyrano[3,2-b]pyridine ring; or
R^1 is H;
R^2 is -OMe or -OEt;
R^3 is H; and
R^4 is H; or
X is a bond;
R^1 is H, Me, or $—CH_2OMe$; and
R^2 and R^3 together with the carbons they are bonded to form a fused 3-membered ring;
Y is C or N;
W is C or N, provided that Y and W are not both N;
V is $—C(R^{11})(R^{12})—$ or $—OCH_2—$, provided that if V is $—OCH_2$, then Z is $—CH_2—$, Y and W are both C;
Z is $—CH_2—$, $—C(R^{10})_2CH_2—$ or —C(O)—;
B is



;

R^7 is H, Me, Et, -OMe, CN, F, or $—CH_2OMe$ or is not present when Y is N;
R^8 is H, Me or F or is not present when W is N;
R^9 is H or C_{4-6}cycloalkyl, optionally substituted with one to two F, or R^9 is $—(CH_2)_n$ heterocyclyl, wherein the heterocyclyl is selected from tetrahydropyranyl, tetrahydrofuranyl, oxetanyl and [1,4]-dioxanyl or $—CH(R_{10})$ heteroaryl, wherein the heteroaryl is selected from the group consisting of pyrazine, imidazole, pyridyl and isoxazolyl and wherein the heteroaryl is optionally substituted with a methyl group;
each R^{10} is independently H or Me;
R^{11} is H or Me;
R^{12} is H or Me;
m is 0 or 1, provided that if m is 0, Z is $—CH_2—$, V is $—C(R^{11})(R^{12})—$ and R^{11} and R^{12} are both H;
and
n is 0 or 1;
or a salt thereof.

Data Claiming – How Solid Form Claims Differ from Chemical Structure Claims Compare to U.S. Patent Number 9,314,525

- No good language exists to define crystalline forms to pharmaceutical scientists which is as robust and commonly accepted as organic nomenclature for covalently bound compounds
- Unit cells not a convenient way to discuss solid forms in Pharma
- So, we use data as a surrogate for nomenclature
- The quality, amount, and type of data are critical when patenting solid forms

1. Picropodophyllin polymorph C having an X-ray powder diffraction pattern exhibiting peaks at 5.5, 7.0, 8.3, 11.0, 11.6 and 11.8±0.2° 2θ.

2. Picropodophyllin polymorph C according to claim **1**, wherein the polymorph exhibits a peak at 5.4±0.2° 2θ.

3. Picropodophyllin polymorph C according to claim **2**, wherein the polymorph exhibits peaks at 5.4 and 6.9±0.2° 2θ.

4. Picropodophyllin polymorph C according to claim **2**, wherein the polymorph exhibits peaks at 5.4, 6.9, 8.2, 9.7, 10.0, 10.9, 11.5 and 11.7±0.2° 2θ.

5. Picropodophyllin polymorph C exhibiting an X-ray powder diffraction pattern as shown in FIG. **3**.

6. Picropodophyllin polymorph C exhibiting an X-ray powder diffraction pattern as shown in FIG. **4**.

7. Picropodophyllin polymorph C according to claim **6**, wherein the polymorph has an IR spectrum exhibiting a peak at 1773.8 cm^{-1}.

Claims with data limitations (Single peak used to prove infringement)

1. Form 2 ranitidine hydrochloride characterised by an infra-red spectrum as a mull in mineral oil showing the following main peaks:

3260	1075	
3190	**1045**	
3100	1021	
2560	1006	
2510	991	
2470	972	
1620	958	
1590	810	
1570	800	
1263	760	
1230	700	
1220	660	
1195	640	
1163	620	cm^{-1}
1130		

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Glaxo v. Novopharm (Fed. Cir. 1997)

"It is elementary patent law that all limitations are material. The single-peak analysis was thus insufficient because, as the district court correctly noted, in order to prove infringement Glaxo was required to establish the presence of each limitation of the asserted claims."

- Twenty-nine claims
- Nineteen end in 0.
- Several – OH stretches claimed

Pfizer v. Dr. Reddy's
Civ. No. 09-943-LPS (February 28, 2011)

Claim 1. A crystalline Form I atorvastatin hydrate having an X-ray powder diffraction containing the following 2θ value measured using CuKα radiation: 22.0°θ

Form

- Pfizer argues "form" is just a reference and that "form" is not a limitation to the claim and should not affect the scope of the claim.
- DRL argues "form" has to have some meaning and that meaning should be based on specific data in the specification.
- Court: Pfizer has better argument. "Form I" read in context with each claim so the amount of data needed depends on that claim. Moreover, Pfizer not limited to claiming the forms with an entire data set, it has freedom to define how to claim each form.

Takeda v. Handa et al. (N.D. CA, April 11, 2012)

Claim Term	Hanchen	Takeda
"about" in context of "a melting start temperature "not lower than about 131C" and "about 135C."	A variation of not more than 0.5C	Approximately

Court: The specification indicates that measurements were with DSC - "which is capable of determination to within 'a few tenths of a degree' – the temperature in the asserted claims are stated without error bars or standard deviations, suggesting that 'about' might permit a broader range of temperatures."
Thus, inappropriate to assign a specific range so "approximately" it is.

BMS v. Mylan et al. (C.A. No. 09-651, D. Ct. Del. 16 May 2012)

- U.S. Patent No. 6,673,372
- 1. Form 2 of crystalline Efavirenz which is characterized by an x-ray powder diffraction pattern substantially in accordance with that shown in FIG. 2.
- 4. The compound of claim 1, which is characterized by an x-ray powder diffraction pattern comprising four or more 2θ values selected from the group consisting of: 6.8±0.2, 9.2±0.2, 12.3±0.2, 16.2±0.2, 21.4±0.2, 22.7±0.2, 24.1±0.2, and 28.0±0.2.
- 5. The compound of claim 1 which is characterized by a differential scanning calorimetry thermogram having a peak at about 116° C. to about 119° C.

BMS v. Mylan et al. (C.A. No. 09-651, D. Ct. Del. 16 May 2012)

Claim Term	Mylan	BMS
Form 2	"a crystalline form of efavirenz characterized by the powder x-ray diffractogram and differential calorimetry thermogram depicted [for each Form in the Figures]"	"a polymorphic crystal form of [efavirenz] that can be distinguished from other forms"

- Court rejects importing data from specification into claims
- Analysis

BMS v. Mylan et al. (C.A. No. 09-651, D. Ct. Del. 16 May 2012)

1. Claims. They each define the forms with different amounts of data and some recite the entire figures, those should be limited to the entire figure. No basis for importing figures into claims that do not expressly incorporate them.

2. Specification. The specification "repeatedly describes different Form embodiments using less than the full set of XRPD and/or DSC data shown in the Figures."

3. Prosecution History. "Form" standing alone sans data were rejected for lack of enablement by the Examiner, which was withdrawn after specific data added. Such amendment would be unnecessary if "Form" incorporated the entire figures.

Celgene v. Natco et al. (C.A. No. 10-5197, D. Ct. N.J. 27 May 2014)

- Court finds that Form A means 'the lenalidomide crystal form described in the specification as Form A, having all of the characteristics assigned to Form A in the specification"
- "To ignore the specific attributes of Form A as defined in the specification would render such language meaningless and give no meaning to the term 'Form A."
- Note, a difference between this case and BMS is that in BMS, the patent was crafted so that different embodiments of efavirenz were described with different amounts of data. In Celgene, although there was some language that some peaks are characteristic, it was not as apparent as with efavirenz where the different amounts of data were characterized as different embodiments.

Eisai Co., Ltd. v. Glenmark Pharmaceuticals, Ltd. CA No. 13-1279-LPS (March 17, 2015)

"Crystal Modification A"

Eisai	Roxane	Court
"a crystal modification of the compound 1-(2,6-difluorobenzyl)-1H -1,2,3-triazole-4-carboxamide (as opposed to a method of use or a method of manufacturing), referenced as `A,' and having the characteristics specifically set forth in each respective claim or the claim from which it depends"	Defendant Roxane's Proposed Construction: "the crystal modification melting at 242° C and characterized by characteristic lines at interplanar spacings ('669 patent at 2:23-26) as determined by means of an X-ray powder pattern"	"a crystal modification of the compound 1-(2,6-difluorobenzyl)-1-1,2,3-triazole-4-carboxamide, referenced as `A,' and having the characteristics specifically set forth in each respective claim or the claim from which it depends"

- Court finds "crystal modification A" a limitation & not "term of convenience as Pfizer found above.
- It limits modification to a crystal modification, not just any modification (e.g., synthetic)
- Roxanne rejected because no reason to import more data into claim. Per Court, Applicant clearly cited specific lines or characteristics in file history, not all lines. Likewise, melting point fails as additional limitation, in part, because that value quoted incorrectly by Roxanne & was never made "definitional" for modification A.

Eisai Co., Ltd. v. Glenmark Pharmaceuticals, Ltd. CA No. 13-1279-LPS (March 17, 2015)

"Characterized by… determined by means of an x-ray powder pattern"

Eisa	Roxane	Hetero	Court
"identifiable by reference to an X-ray powder pattern that includes characteristic lines at interplanar spacings (d values) of 10.5 Å, 5.14 Å, 4.84 Å, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å"	"having the exact interplanar spacings (d values) and relative intensities for the specified pattern of lines at 10.5 A, 5.14 A, 4.84 A, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å, as determined by means of an X-ray powder pattern"	"with selected lines at interplanar spacings (d values) of 10.5 Å, 5.14 Å, 4.84 Å, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å ± measurement error, determined by means of an X-ray powder pattern"	"identifiable by reference to an X-ray powder pattern that includes characteristic lines at interplanar spacings (d values) of 10.5 Å, 5.14 Å, 4.84 Å, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å"

- Issues:
  - (1) Does "characterized" account for experimental error? (yes)
    - Claims and specification silent on error
    - Both experts agreed XRPD "universally known at the pertinent time to be subject to measurement error"
    - "It follows that a person of ordinary skill's understanding of the term XRPD would include the expected error associated with the measurement being used."

Eisai Co., Ltd. v. Glenmark Pharmaceuticals, Ltd. CA No. 13-1279-LPS (March 17, 2015)

"Characterized by… determined by means of an x-ray powder pattern"

Issues:

- (2) Do all peaks need to be present in "every experimental run"? (no)
  - No.
  - "the plain and ordinary meaning of "characterized by" does not require all of the recited d-values to be present in every experimental run (i.e., an exact one-to-one match). Rather, as the broad claim language (drafted by the applicants and approved by the PTO) sets out, the claim limitation is satisfied as long as the crystal form can be "characterized by" — that is, identified by reference to the characteristic lines set forth in the claim"
- (3) Are relative intensities necessary to characterize the claimed crystal modifications?
  - "the plain language of the claims does not require inclusion of "relative intensities," and Roxane has failed to demonstrate that the prosecution history evidences a clear and unambiguous disavowal of claim scope such that the issued claims' reference to "XRPD" necessarily requires relative intensity values"

Otsuka Pharmaceutical Co., Ltd. V. Torrent Pharmaceuticals Limited, Inc. (DCt. NJ. November 16, 2015)

"Anhydrous Aripiprazole Crystals B"

Otsuka	Defendants	Court
AACB identifiable by reference to one or more of the features described in, for example, the '615 patent at col. 9:37-61 [or the '796 patent at col. 9:34-58].	AAC substance having the 1H-NMR spectrum, powder-x-ray diffraction spectrum, infrared absorption bands, endothermic peak in thermogravimetric/differential thermal analysis, endothermic peak in differential scanning calorimetry, and low hygroscopicity, as defined in the specification of the '615 patent at 9:37-63 [or the '796 patent at 9:34-60].	AAC having: 1) a proton nuclear magnetic resonance spectrum (DMSO-d6, TMS) having characteristic peaks at [specified levels]; 2) a powder x-ray diffraction spectrum having characteristic peaks at [specified levels]; 3) clear infrared absorption bands at [specified levels] on the IR (Mar) spectrum; [] 4) an endothermic peak near about 141.5° C. in thermogravimetric/ differential thermal analysis (heating rate 5° C./min); 5) an endothermic peak near about 140.7° C. in differential scanning calorimetry (heating rate 5° C./min); and 6) low hygroscopicity, all as specifically defined in the specification of the '615 patent at 9:37-63 [or the '796 patent at 9:34-60]"

- Disjunctive v. Conjunctive
- Same issue seen earlier – how much data is necessary to claim the solid form?

Otsuka Pharmaceutical Co., Ltd. V. Torrent Pharmaceuticals Limited, Inc. (DCt. NJ. November 16, 2015)

"Anhydrous Aripiprazole Crystals B"

Note - (12) deals with particle size

"Anhydrous Aripiprazole Crystals B" of the present invention as used herein have the physicochemical properties given in (6)-(12) below.

(6) They have an ^{1}H-NMR spectrum which is substantially the same as the ^{1}H-NMR spectrum (DMSO-d_6, TMS) shown in FIG. **4**. Specifically, they have characteristic peaks at 1.55-1.63 ppm (m, 2H), 1.68-1.78 ppm (m, 2H), 2.35-2.46 ppm (m, 4H), 2.48-2.56 ppm (m, 4H+DMSO), 2.78 ppm (t, J=7.4 Hz, 2H), 2.97 ppm (brt, J=4.6 Hz, 4H), 3.92 ppm (t, J=6.3 Hz, 2H), 6.43 ppm (d, J=2.4 Hz, 1H), 6.49 ppm (dd, J=8.4 Hz, J=2.4 Hz, 1H), 7.04 ppm (d, J=8.1 Hz, 1H), 7.11-7.17 ppm (m, 1H), 7.28-7.32 ppm (m, 2H) and 10.00 ppm (s, 1H).

(7) They have a powder x-ray diffraction spectrum which is substantially the same as the powder x-ray diffraction spectrum shown in FIG. **5**. Specifically, they have characteristic peaks at 2θ=11.0°, 16.6°, 19.3°, 20.3° and 22.1°.

(8) They have clear infrared absorption bands at 2945, 2812, 1678, 1627, 1448, 1377, 1173, 960 and 779 cm^{-1} on the IR (KBr) spectrum.

(9) They exhibit an endothermic peak near about 141.5° C. in thermogravimetric/differential thermal analysis (heating rate 5° C./min).

(10) They exhibit an endothermic peak near about 140.7° C. in differential scanning calorimetry (heating rate 5° C./min).

(11) Anhydrous Aripiprazole Crystals B of the present invention have low hygroscopicity. For example, Anhydrous

Forest Laboratories v. Sigmapharm Laboratories (Civ. No. 14-1119-SLR-SRF) (Del. January 29, 2016)

"Asenapine maleate"

Claim	Plaintiffs	Court
Orthorhombic asenapine maleate with various data	A crystalline form of asenapine maleate distinguishable from the monoclinic form, that can be characterized by several analytical techniques known in the art such as Infrared Spectroscopy, Raman Spectroscopy, Solid State Nuclear Magnetic Resonance Spectroscopy, Differential Scanning Calorimetry, x-ray powder diffraction patterns (XRPD) and many others.	"[A] construction that merely characterizes a substance by listing techniques which could be used to characterize it, without any information concerning what findings would confirm the presence of the orthorhombic crystal form, does not sufficiently define it" Asenapine maleate crystalline form characterized by at least one of the following: the XRPD pattern at Fig. 1 (lower pattern), the Raman spectrum at Fig. 2 (lower spectrum), a melting point in the range of 138-142°C, the unit cell as reported in Table 1A and the atomic positions reported in Table 1B.

Consider making explicit the distinctions over the prior art form in the specification.

Pioglitazone Hydrochloride

U.S. Patent Number
7,135,485

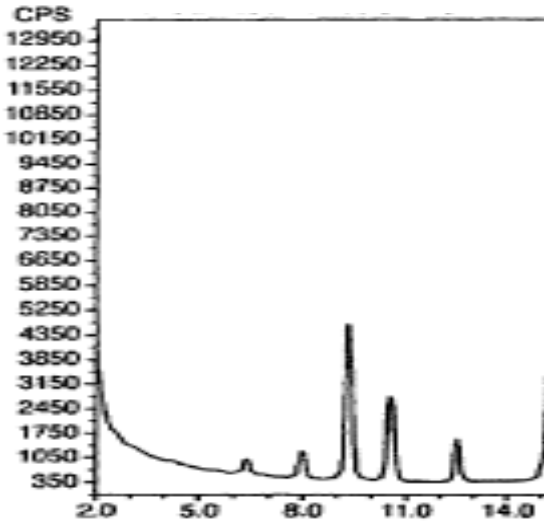

FIG. 1

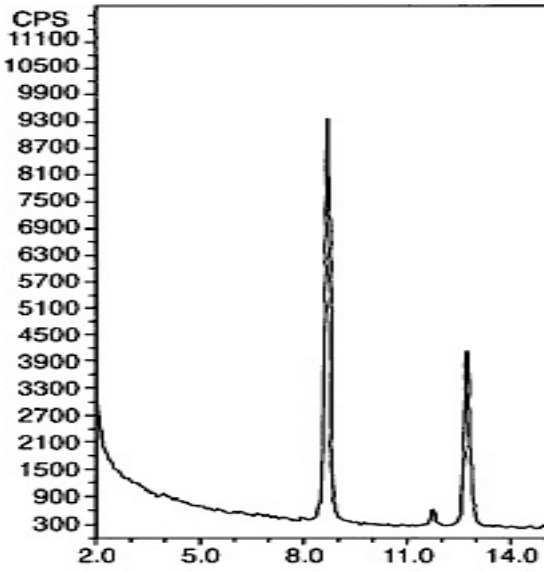

FIG. 4

Inspired by Sury et al., PPXRD-14,
June 7, 2016 at 9:47 AM

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Pfizer v. Mylan
(Civ. No. 15-526-SLR) (Del. May 6, 2016)
"About"

Claim	Specification	Court
Form I tigecycline having X-ray powder diffraction peaks at about …	"Due to differences in instruments, samples, and sample preparation, peak values are reported with the modifier "about" in front of the peak values. This is common practice in the solid-state chemical arts because of the variation inherent in peak values. A typical precision of the 2θ x-axis value of a peak in a powder pattern is on the order of plus or minus 0.2° 2θ. Thus, a powder diffraction peak that appears at "about 9.2° 2θ," means that the peak could be between 9.0° 2θ and 9.4° 2θ when measured on most X-ray diffractometers under most conditions." "T]he single peak at about 5.2° 2θ in Form I uniquely characterizes Form [I] because the nearest Form II peak to about 5.2° 2θ is found at about 9.2° 2θ, 4 degrees 2θ away. This 4° 2θ difference is significantly greater than the 0.4 ° 2θ obtained by combining the variability (0.2° 2θ) in any two peaks. In other words, so long as a peak in one sample is more than 0.4° 2θ away from any peak in another sample, then those represent different crystalline solid forms because the chance that any given peak in a crystalline solid form would vary by more than 0.4° 2θ from sample to sample and/or instrument to instrument is extremely small. Therefore, in a system that contains only Form I and Form II, a tigecycline powder pattern containing a peak at about 5.2° 2θ characterizes Form I tigecycline and the presence of that peak may be used to identify Form I. Similarly, when characterizing From II, one could use just the peak at about 9.2° 2θ because there is no Form I peak within 0.4 ° 2θ of that peak	A crystalline tigecydine called Form I having X-ray powder diffraction peaks at± 0.2° 2θ of the recited peaks ..."

Clear Guidance given on definition of "about" in Specification

U.S. Patent Number 9,315,450

1. A succinate salt of Desfesoterodine.

2. The succinate salt of Desfesoterodine of claim **1**, wherein the succinate salt of Desfesoterodine is isolated.

3. The succinate salt of Desfesoterodine of claim **1**, wherein the succinate salt is in an anhydrous form.

4. The succinate salt of claim **1**, wherein the succinate salt of Desfesoterodine is in solid form.

5. The succinate salt of Desfesoterodine of claim **1**, wherein the molar ratio between Desfesoterodine and succinic acid is 1:1 to 1:1.5, respectively.

6. The succinate salt of Desfesoterodine of claim **1**, having a chemical purity of at least 95%, >98%, or >99% by HPLC/UV (area %).

7. The succinate salt of Desfesoterodine of claim **1**, wherein the salt is in a crystalline form.

U.S. Patent Number 9,101,620

The invention claimed is:

1. A Crystalline Form I of 3-(4-amino-1-oxo-1,3-dihydro-2H-isoindole-2-yl)-piperidine-2,6-dione hemihydrate, characterized by diffraction peaks at in its X-ray powder diffraction pattern using Cu—Ka radiation as follows:

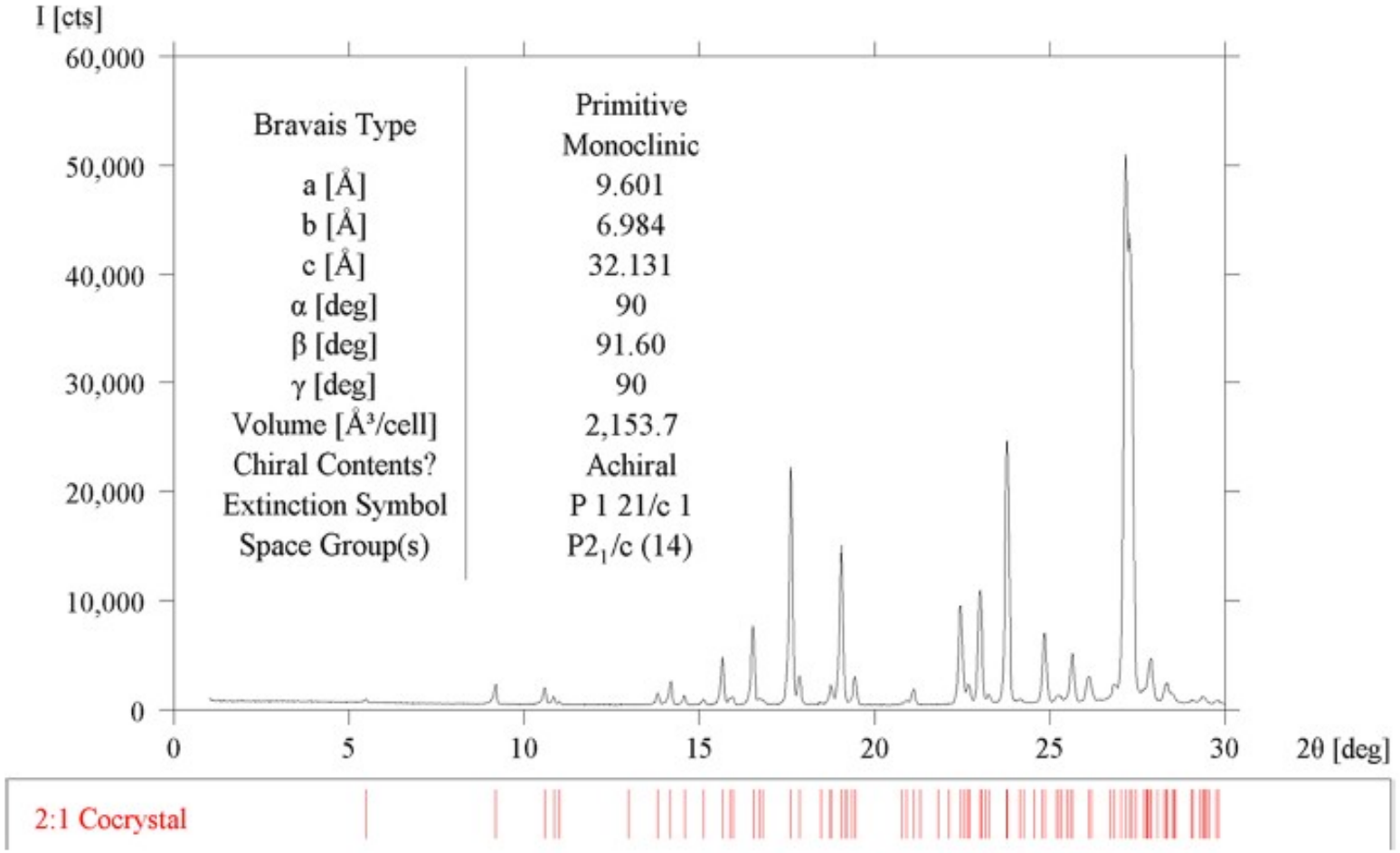
Peak Number	2θ	Flex Width	d-Value	Intensity	L/LO
1	11.940	0.212	7.4060	17891	84
2	13.020	0.235	6.7940	5996	28
3	13.780	0.188	6.4210	6550	31
6	15.620	0.235	5.6685	9017	42

Cont.

-continued

Peak Number	2θ	Flex Width	d-Value	Intensity	L/LO
9	17.960	0.259	4.9349	5895	28
10	19.080	0.235	4.6476	8374	39
11	19.480	0.235	4.5531	6273	30
12	20.580	0.235	4.3121	6162	29
15	21.980	0.235	4.0405	21530	100
16	22.520	0.259	3.9449	13747	64
18	23.760	0.259	3.7417	15053	70
19	24.400	0.212	3.6450	5016	24
21	26.440	0.282	3.3682	15819	74
22	27.520	0.353	3.2384	11455	54
23	29.060	0.306	3.0702	11190	52
24	30.980	0.306	2.8842	6238	29
25	32.000	0.376	2.7945	4934	23
26	33.040	0.306	2.7089	5313	25
28	34.440	0.259	2.6019	5469	26

TRIADS®
U.S. Patent Number 8,576,985
2:1 p-Coumaric Acid:Nicotinamide



M. Bevill,P. Vlahova, and J Smit, Cryst. Growth Des. 2014, 14, 1438−1448

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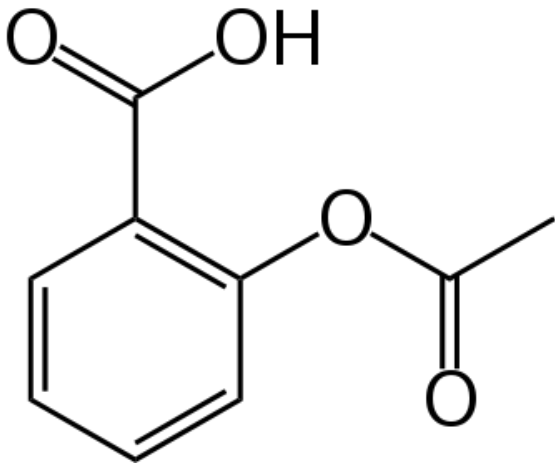
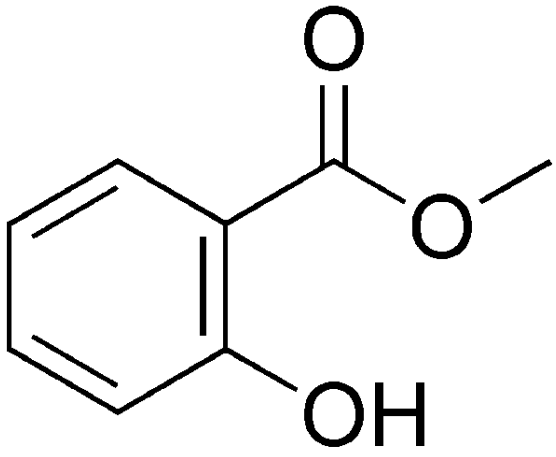
Qualities of the Invention Cannot be Obvious



Aspirin



Methyl Salicylate

Q: Would aspirin be obvious over Methyl Salicylate?

Obviousness

- Establishing a “prima facie case”
  - By using known organic texts, one could convert the closest prior art (methyl salicylate) to aspirin with a reasonable expectation of success
- Perhaps, but what about “secondary considerations”
  - Suppose methyl salicylate is a poison, but aspirin is a wonder drug, that is an unexpected result which rebuts the prima facie case!
  - Which is why patent attorneys will hound you (inventors) for data such as evidence of “synergy” or other unexpected results

Board of Appeals of the European Patent Office – T 1555/12 – 3.3.01 (April 29, 2015)

- Relates to Aripiprazole (Abilify®)
- Multiple claims at issue (Main and auxiliary requests)
- Main – "Crystals C" having specific characteristic peaks
- Auxiliary 1 – Same but also with selected data from IR, solid-state NMR and DSC
- Auxiliary 2 – Claim directed to an entire XRPD pattern
- Main claim held invalid for novelty whereas Auxiliary 1 (and 2) found novel due to added data not in prior art (hint hint more data can be better!!)
  - Auxiliary 1 found lacking in inventive step, however

Board of Appeals of the European Patent Office – T 1555/12 – 3.3.01 (April 29, 2015)

- Inventive Step of Auxiliary 1 Claim
  - Start with Problem-solution approach
    - What was the problem to be solved in the prior art?
    - Was it solved?
    - What that solution obvious?
  - Here, problem was "the provision of a thermally stable crystalline form of aripiprazole which can be obtained in high purity in a reliable manner"
    - Fact – the prior art "type 2" crystal was found to be unsuitable for use due to thermal instability leading to problems with consistent quality
    - Board ruled that the patentee had NOT solved the problem because the claim as drafted includes mixtures of Type 2 crystals. Why?
      - Because the additional data added in the claim is "not an indication of purity of a crystalline form" and the original XRPD data in the main claim did not distinguish Crystals C from Type 2 and thus could encompass mixtures of both.

Board of Appeals of the European Patent Office – T 1555/12 – 3.3.01 (April 29, 2015)

- Back to inventive step
  - Since forming a thermally stable form was not achieved, the less ambitious problem, finding simply a new crystalline form became the problem to solve, and it was achieved.
  - However, “the mere provision of a crystalline form is not regarded as involving an inventive step.”
- With respect to auxiliary request 2, where the claims were limited to an entire diffraction pattern (a lot of limitations), the Board found the claims novel (a single form) and inventive (because no Type 2 would be covered by such a claim)….But, enforcing such claims may be challenging….

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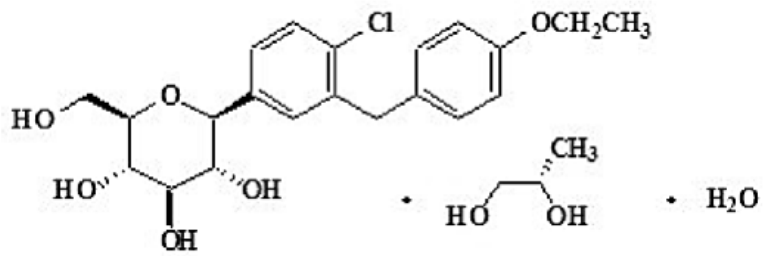
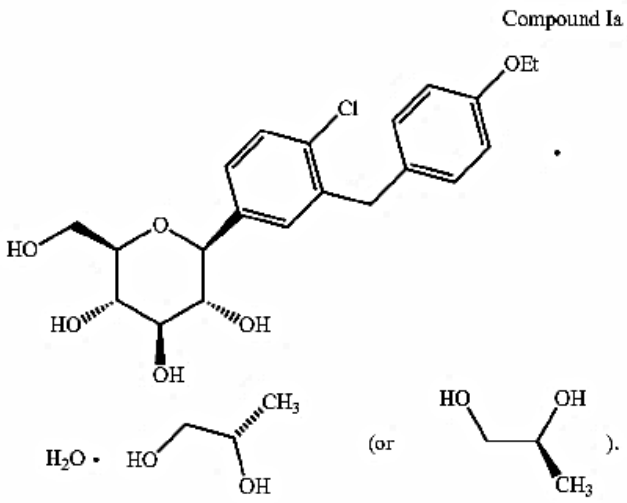
From Label



Claim 1 of 7,919,598 – expires December 16, 2029

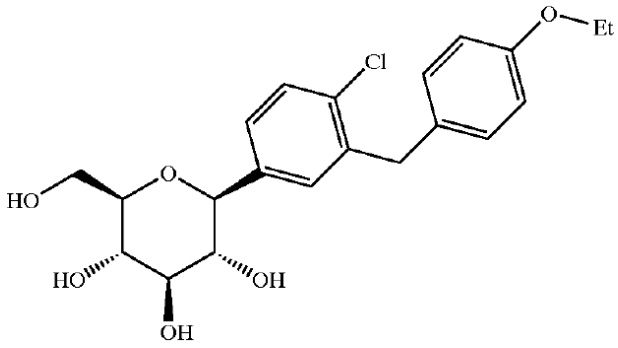
1. A crystalline (S)-propylene glycol ((S)-PG) solvate compound Ia (form SC-3)

Compound Ia



Claim 1 of 6,515,117 – expires October 4, 2020

1. A compound having the structure



or a pharmaceutically acceptable salt, a stereoisomer thereof, or a prodrug ester thereof.

THE CRYSTALLIZATION EXPERTS®

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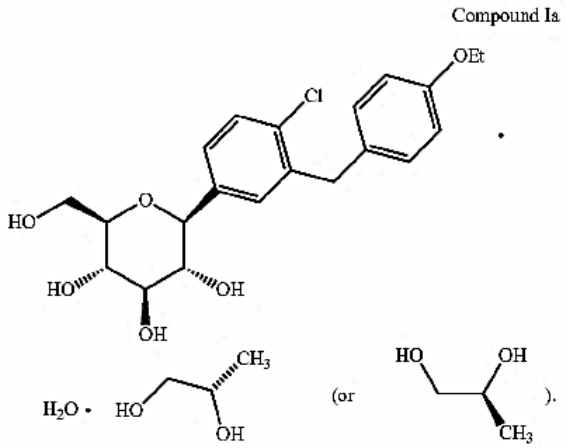
Solid Form Patent – 7,919,598

Claims 1 of 7,919,598 – expires December 16, 2029

1. A crystalline (S)-propylene glycol ((S)-PG) solvate compound Ia (form SC-3)



Claim 4-7 of 7,919,598 – expires December 16, 2029

4. The crystalline (S)-PG compound Ia (form SC-3) according to claim **1** characterized by peaks in the powder x-ray diffraction pattern at 2θ values of 3.8±0.1, 7.6±0.1, 8.1±0.1, 8.7±0.1, 15.2±0.1, 15.7±0.1, 17.1±0.1, 18.9±0.1 and 20.1±0.1.

5. The crystalline (S)-PG compound Ia (form SC-3) according to claim **1** characterized by a solid state ^{13}C NMR spectrum having substantially similar peak positions at 16.2, 17.6, 39.3, 60.9, 63.3, 69.8, 76.9, 78.7, 79.4, 113.8, 123.6, 129.3, 130.5, 132.0, 135.7, 139.1 and 158.0 ppm.

6. The crystalline (S)-PG compound Ia (form SC-3) according to claim **1** characterized by a differential scanning calorimetry thermogram having an endotherm in the range of about 50° C. to about 78° C. or as shown in FIG. **7**.

7. The crystalline (S)-PG compound Ia (form SC-3) according to claim **1** characterized by a thermal gravimetric analysis curve with about 18.7% weight loss from about room temperature up to about 240° C. or as shown in FIG. **5**.

Pharma Products with Solid Form Patents Expiring After Composition of Matter

- Ofev (Boehringer)
  - NCE to 10/15/2019
  - Composition of matter patent 6,762,180 set to expire 12/10/2020
  - Crystal form patent 7,119,093 set to expire 2/21/2024
- Jardiance (Boehringer)
  - NCE to 8/1/2019
  - Composition of matter patent 7,579,449 set to expire 11/15/2025
  - Crystal form patent 7,713,938 set to expire 4/15/2027
- Sivextro (Cubist)
  - NCE to 6/20/19
  - Composition of matter patents 7,816,379 and 8,420,676 set to expire 2/23/2028
  - Crystal form patent set to expire 12/31/2030

Pharma Products with Solid Form Patents Expiring After Composition of Matter

- Otezla (Celgene)
  - NCE to 3/21/2019
  - Composition of matter patents 6,020,358 and 7,427,638 set to expire 10/30/2018 and 11/17/2024
  - Crystal form patent 7,893,101 set to expire 12/9/2023
- Farxiga (AstraZeneca)
  - NCE to 1/8/2019
  - Composition of matter patents 6,414,126 and 6,515,117 set to expire 10/4/2020
  - Crystal form patent 7,919,598 set to expire 12/16/2029

Thank You