IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	Civil Action No. 20-md-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, Defendants.	Civil Action No. 22-cv-1395-RGA

TRIAL OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

This case is part of the multi-district litigation of patent infringement claims regarding Plaintiff Novartis Pharmaceuticals Corporation's Entresto. Novartis brought C.A. No. 22-1395 against MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited (together, "MSN"), alleging infringement of its U.S. Patent No. 11,096,918 (the "'918 patent"). (Docket No. 22-1395, D.I. 1 ¶ 1). Novartis accuses MSN of infringing claim 1 of the '918 patent, which MSN disputes. (D.I. 1705 at 1; D.I. 1757 at 1).[1]

I held a four-day bench trial from December 10, 2024 to December 13, 2024. (D.I. 1701, 1702, 1703, 1704, hereinafter cited "Tr.__"). I have reviewed the parties' post-trial briefing. (D.I. 1705, 1757, 1764). Having considered the evidence and testimony, I make the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a). I find that Novartis has not proved that MSN infringes the '918 patent.

I. BACKGROUND

Novartis is the holder of New Drug Application ("NDA") No. 207620 for Entresto, a tablet with active ingredients sacubitril and valsartan, used to treat heart failure. (Docket No. 22-1395, D.I. 1 ¶ 113). The '918 patent is not listed in the FDA Orange Book for Entresto. (*See* D.I. 1185 at 2). The priority date of the '918 patent is April 4, 2006. ('918 patent). The '918 patent is directed to the chemical compound that comprises Entresto, which is the amorphous solid form of sacubitril, valsartan, and sodium cations ("amorphous TVS"). (*Id.* at Abstract).

MSN submitted an Abbreviated New Drug Application ("ANDA") for approval to market generic versions of Entresto. (Docket No. 22-1395, D.I. 1 ¶ 31). Novartis then initiated this lawsuit.

[1] Unless otherwise specified, the docket referred to is C.A. No. 20-md-2930.

II. LEGAL STANDARD

A patent is directly infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent." 35 U.S.C. § 271(a). Determining infringement is a two-step analysis. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). First, the court must construe the asserted claims to ascertain their meaning and scope. *Id.* The trier of fact must then compare the properly construed claims with the accused infringing product. *Id.* This second step is a question of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). The patent owner bears the burden of proving infringement by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Lab'ys Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

In a Hatch-Waxman case, the plaintiff's infringement claim is based on the accused infringer's future conduct, rather than past acts of infringement. Under § 271(e)(2), the "infringement inquiry . . . is focused on the product that is likely to be sold following FDA approval." *Abbott Lab'ys v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). "Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry." *Id.*

III. ANALYSIS

The '918 patent is directed to amorphous TVS. ('918 patent at Abstract). The only claim at issue is Claim 1 of the '918 patent, which recites:

> 1. An amorphous solid form of a compound comprising anionic [valsartan[2]], anionic [sacubitril[3]], and sodium cations in a 1:1:3 molar ratio.

(*Id.* at 32:42–46).

I issued a claim construction opinion on May 31, 2024, where I construed "[a]n amorphous solid form of a compound" as "a solid form of a compound in which the amorphous form of the compound predominates. An amorphous solid form is mutually exclusive from a crystalline solid form, but not necessarily mutually exclusive from a partially crystalline solid form."[4] (D.I. 1374 at 5).

The only issue is whether Novartis successfully proved MSN's ANDA infringes claim 1 of the '918 patent by a preponderance of the evidence. MSN withdrew its invalidity arguments at trial. (Tr. 1035:17–19).

A. Findings of Fact

1. Level of Ordinary Skill in the Art

The parties agree on the definition of a person having ordinary skill in the art ("POSA"). A POSA for claim 1 of the '918 patent "is a person with a Ph.D. in chemistry or related field and two or more years of experience with solid forms of pharmaceutical compounds, such as

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[2] The chemical name "(S)-N-valeryl-N-{[2'-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine" recited in claim 1 describes valsartan.

[3] The chemical name "(2R,4S)-5-biphenyl-4-yl-4-(3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester" recited in claim 1 describes sacubitril.

[4] The Federal Circuit called this construction into question in an appeal of my denial of Novartis' motion for a preliminary injunction. *Novartis Pharms. Corp. v. MSN Pharms., Inc.*, 2024 WL 4969281, at *5 (Fed. Cir. Dec. 4, 2024). Even if I had adopted a different construction (like Novartis' proposal that no construction was needed, and thus any amount of amorphous TVS could infringe), I would still find that Novartis failed to prove MSN infringes. Novartis failed to prove MSN's ANDA contains any amorphous TVS due to the unreliability of Dr. Park's Raman spectrum.

synthesizing, crystallizing, and characterizing solid forms of pharmaceutical compounds." (Tr. 375:1–6).

2. Raman Spectroscopy

The parties generally agree about how Raman spectroscopy works. Raman spectroscopy provides a way to classify and identify molecular compounds and materials. (*See* Tr. 385:24–386:5). A Raman instrument shines a laser beam into a sample and records the energy levels produced by the sample. (Tr. 385:11–17, 718:8–15). The sample will "scatter" some of the light shined into it. (Tr. 718:8–24). The energy levels measured by the Raman instrument are the differences between the energy of the light shone into the material and the energy of the scattered light. (*Id.*; Tr. 720:10–12). The energy differentials will depend on the vibration of the bonds in the molecules, which will depend on the types of bonds in the molecules. (Tr. 385:11–17, 718:19–24, 720:18–22).

Conducting a Raman spectroscopy test on a sample will produce a Raman spectrum. (*See* Tr. 718:6–24, 720:10–12). A Raman spectrum is a graph with "Raman Shift" (in units of cm^{-1}) on the x-axis and "Intensity" or "Counts" on the y-axis, and it has peaks reflecting the recorded energy levels. (*See, e.g.*, PTX-1709; DTX-780 at 1). The peaks vary in intensity. (*See* Tr. 722:20–22).

A certain molecule, compound, or complex will produce a unique Raman spectrum. (Tr. 385:24–386:5, 719:19–24). The Raman spectrum can be thought of as a "fingerprint." (*Id.*). A Raman spectrum for a sample of a compound should be the same as a Raman spectrum for a different sample of the same compound. (*See id.*).

The Raman spectrum of a physical mixture of multiple compounds will be different from the Raman spectrum of an amorphous complex of the same multiple compounds. (*See* Tr. 730:20–24; '918 patent at 28:64–67).

An unknown compound can be identified by creating a Raman spectrum of the unknown compound and comparing it to reference Raman spectra of known compounds. (*See* Tr. 498:1–3, 829:16–18). If the spectrum of the unknown compound and the spectrum of a known compound generally contain the same peaks and intensity of peaks, one can conclude the unknown compound is the same as the known compound. (*See id.*).

3. Physical Mixtures and Amorphous Complexes

A physical mixture is the combination of two or more compounds with no significant chemical interactions among the compounds. (Tr. 376:9–11). An amorphous complex is the combination of two or more compounds with chemical interactions among the compounds, like "covalent-noncovalent" bonds. (Tr. 376:12–16).

Novartis' expert witness, Dr. Park, created a spectrum of an amorphous physical mixture by making amorphous valsartan disodium and amorphous sacubitril sodium, creating spectra of the two, normalizing the two spectra, then adding the two spectra together. (Tr. 383:11–15, 387:17–19).

MSN argues that the mathematically-created amorphous physical mixture spectrum is unreliable. (D.I. 1757 at 7 n.2). I disagree. Dr. Park testified that adding together the spectra of two components in a physical mixture is an accepted way to create the spectrum of that physical mixture, citing literature to support her testimony. (Tr. 387:24–388:10; JTX-138; JTX-127;

JTX-130). MSN's expert, Dr. McCreery,[5] said, "I don't like that practice, and I would far rather have a real physical mixture." (Tr. 723:14–15). But Dr. McCreery admitted that adding together two spectra to create a physical mixture spectrum is a method used by those in the field and described in relevant literature. (Tr. 723:7–8). Dr. McCreery described the potential distortion in intensity that may result from adding two spectra together (Tr. 722:20–24), but Dr. Park testified extensively that she normalized the spectra before adding them together, and cited literature to support her normalization procedures. (Tr. 425:19–429:23). Dr. McCreery did not say that Dr. Park's methods were inappropriate. He said he did not like it. I think Dr. Park's mathematically-created amorphous physical mixture spectrum is reliable.

4. Dr. Park's Glassy Solid

The parties dispute whether MSN's ANDA is predominately amorphous TVS. Dr. Park created a reference sample (also called the "glassy solid") of purportedly amorphous TVS to compare with MSN's ANDA. The parties dispute whether that reference sample and the corresponding Raman spectrum of the sample are sufficiently reliable.[6]

Amorphous TVS is different from an amorphous physical mixture of valsartan and sacubitril; this the parties agree on. (D.I. 1705 at 1; D.I. 1757 at 1). The parties disagree about

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[5] Novartis alleges that Dr. McCreery is not a POSA. (D.I. 1705 at 11). MSN makes no responsive arguments in its post-trial brief. This issue was the subject of a pre-trial *Daubert* motion. (*See* D.I. 1625 at 6 n.6). While true that "testimony on any issue that is analyzed through the lens of an ordinary skilled artisan" must come from an expert qualified as a POSA, *Kyocera Senco Indus. Tools Inc. v. ITC*, 22 F.4th 1369, 1377–78 (Fed. Cir. 2022), the opinions from Dr. McCreery that I rely on are not POSA opinions. I rely on his opinions about Raman spectroscopy. Dr. McCreery is an expert in Raman spectroscopy. (*See* Tr. 716:14–717:21).

[6] Though the parties argue about whether Novartis' reference spectrum is sufficiently "reliable," and I ultimately find the spectrum is not "reliable," the crux of the dispute is credibility of expert testimony. "[D]isputes over the expert's credibility or over the accuracy of the underlying facts" are questions of fact. *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1299 (Fed. Cir. 2015).

whether Dr. Park successfully made amorphous TVS, as opposed to an amorphous physical mixture. The parties point to the Raman spectrum of Dr. Park's glassy solid. Novartis says it is different from the Raman spectrum of an amorphous physical mixture of sacubitril and valsartan; MSN says it is not.

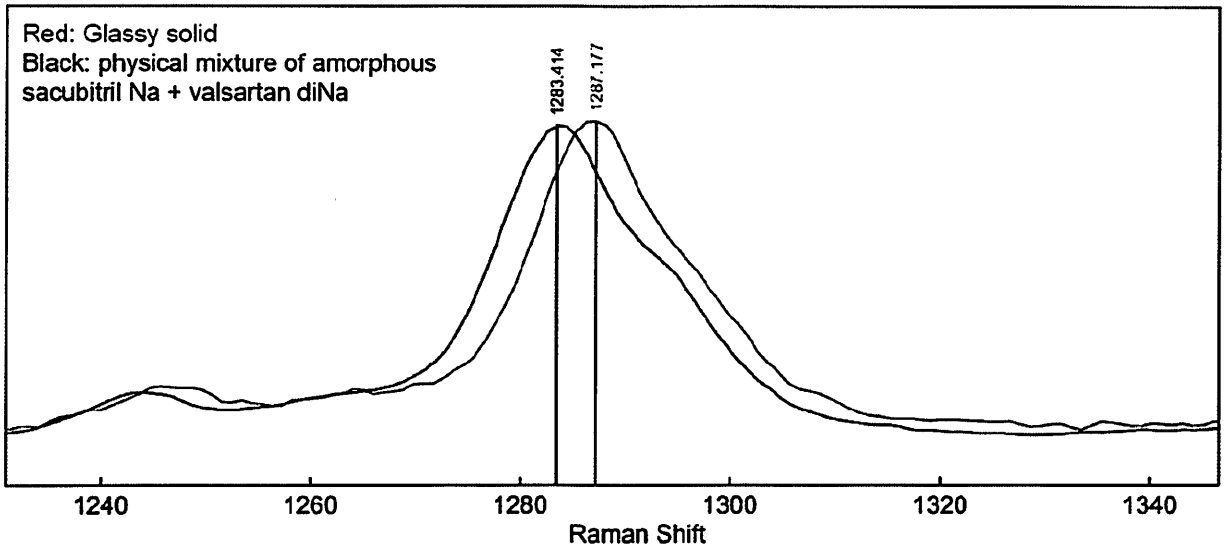
I think the Raman spectrum of Dr. Park's glassy solid is not reliable. That is, I do not think Novartis has shown by a preponderance of the evidence that the reference Raman spectrum is of amorphous TVS.

Dr. Park is the chief operating officer at Triclinic Labs. (Tr. 371:14–15). Dr. Park testified that she created, with assistance from those that work at Triclinic, amorphous TVS according to Example 1 of the '918 patent. (Tr. 373:12–19).[7] Dr. Park then ran tests on her sample to confirm that what she created was, in fact, amorphous TVS. (Tr. 386:13–18). Dr. Park created spectra of her sample from three spectroscopy methods: solid-state nuclear magnetic resonance ("ssNMR"), infrared ("IR"), and Raman. (*Id.*). To confirm that what she made was amorphous TVS, she compared the spectra of her sample to her spectra of an amorphous physical mixture and noted the differences between the two sets of spectra. (Tr. 387:1–11, 388:21–396:18).

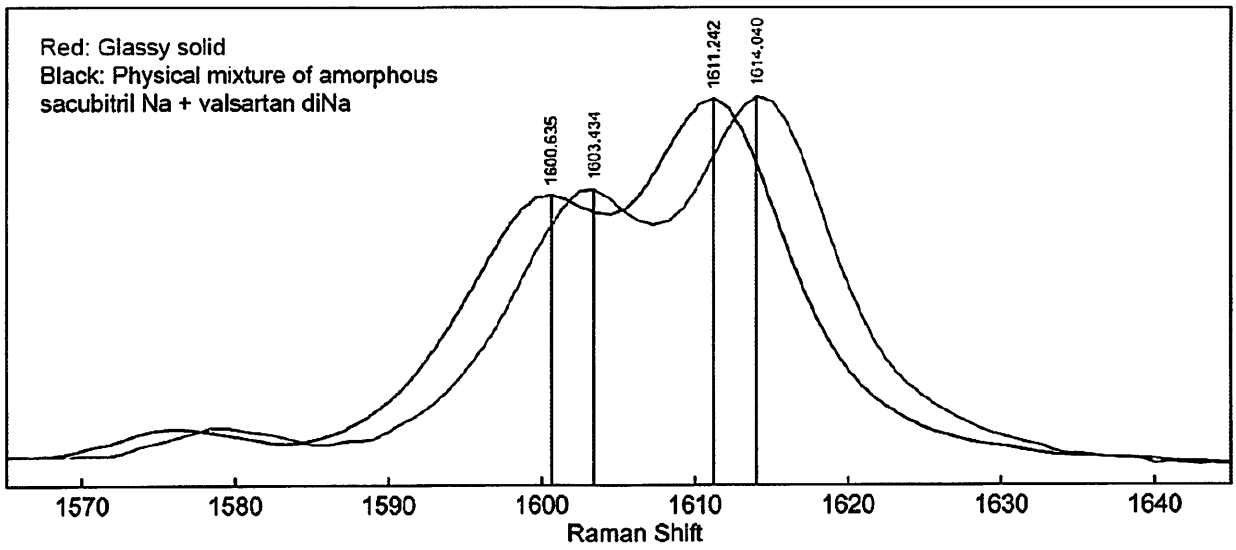
[7] MSN attempts to poke holes in how the glassy solid was made, chiefly arguing that the Triclinic technicians performed more steps than those listed in Example 1 of the '918 patent. (*See* D.I. 1757 at 17). Dr. Park was cross-examined on the issue (*see* Tr. 445:6–448:11), but MSN offered no expert of its own to testify that those extra steps so contaminated the process that the final product could not be amorphous TVS. MSN gives no explanation on how any extra steps affected the process. Though I do find the reference spectrum to be unreliable, I have no reason to doubt Dr. Park's testimony that Triclinic followed Example 1 as faithfully as possible. (*See* Tr. 379:15–17, 445:6–13).

MSN argues that Dr. Park created an amorphous physical mixture, not amorphous TVS, pointing to the similarities between Dr. Park's glassy solid Raman spectrum and her mathematically calculated amorphous physical mixture Raman spectrum. (D.I. 1757 at 7–8).

The reference glassy solid Raman spectrum, purportedly showing a spectrum of amorphous TVS, is strikingly similar to the amorphous physical mixture spectrum. Below are two "zoomed in" portions of the overlaid spectra, as presented by Novartis:



(PTX-1277 at 1 of 2).

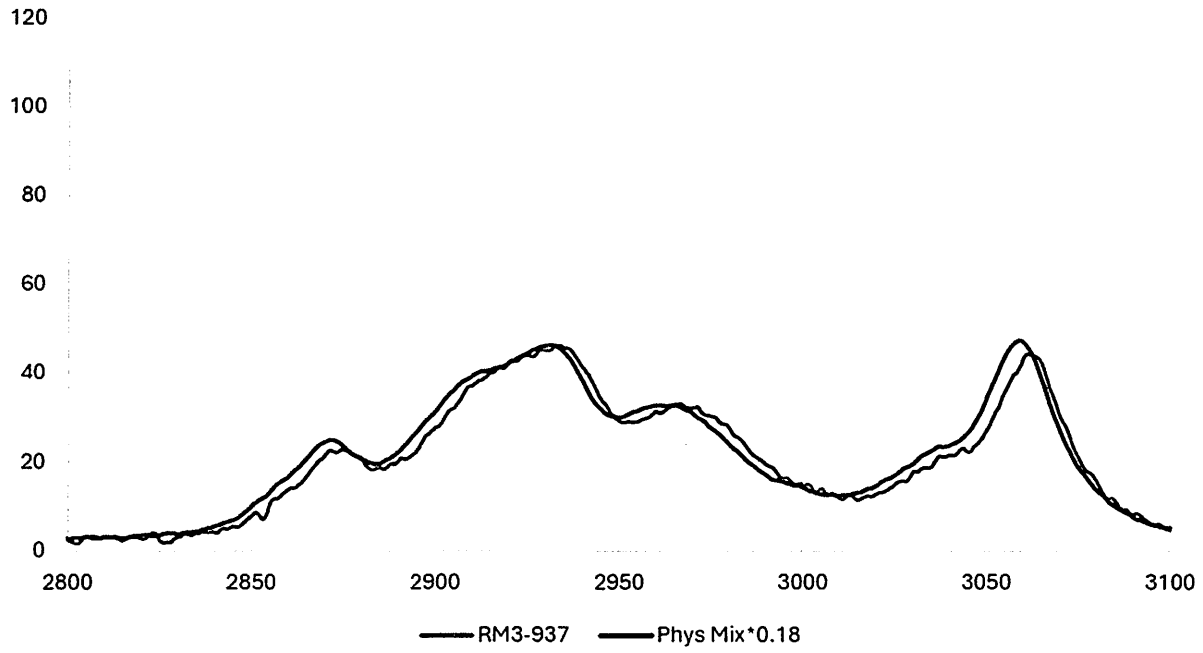


(*Id.* at 2 of 2).

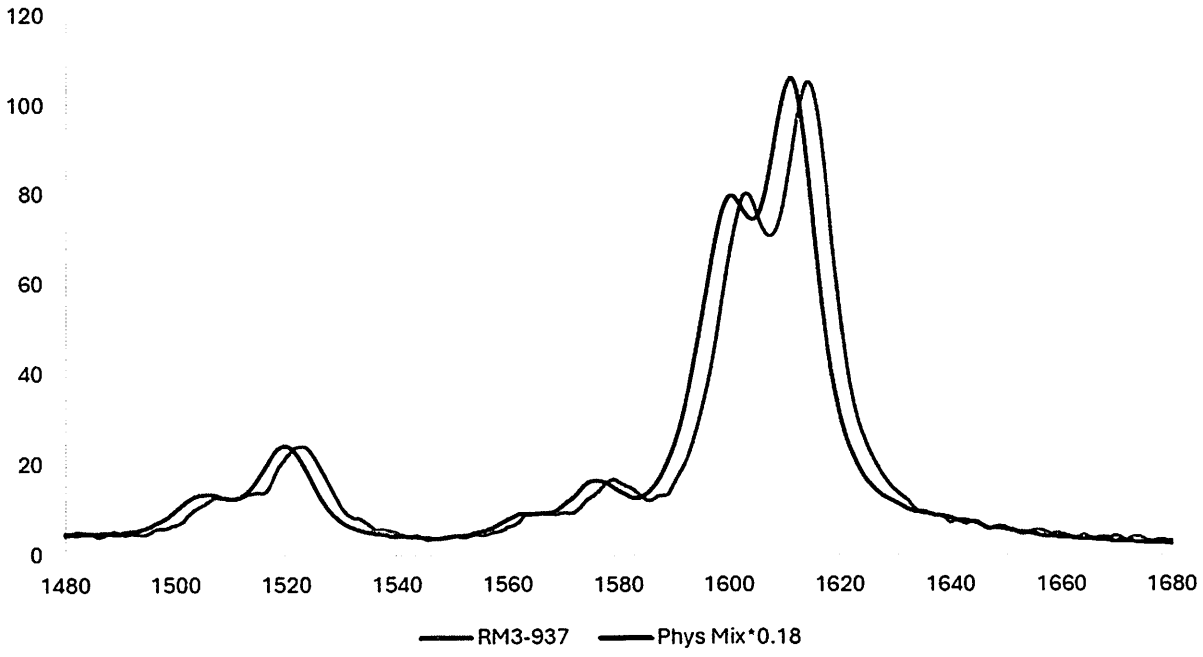
The peaks are at approximately the same height,[8] but the peaks are slightly shifted. That is, the spectrum for Dr. Park's glassy solid is shifted to the right of the amorphous physical mixture spectrum. Novartis points to three peak shifts (which can be seen in the images above) to show that the two spectra are different and that Dr. Park's glassy solid is amorphous TVS. The peak shifts are as follows (listed physical mixture first, Dr. Park's glassy solid second): 1283.4 cm^{-1} to 1287.2 cm^{-1} (difference of 3.8 cm^{-1}), 1600.6 cm^{-1} to 1603.4 cm^{-1} (difference of 2.8 cm^{-1}), and 1611.2 cm^{-1} to 1614.0 cm^{-1} (difference of 2.8 cm^{-1}).[9] (Tr. 394:21–395:5).

But, as testified to by Dr. McCreery, when looking at the Raman spectra as a whole, not just the two zoomed in portions, it appears that the entire Raman spectrum of the glassy solid is shifted approximately 3 cm^{-1} to the right of the Raman spectrum of the physical mixture. (Tr. 725:7–726:15). Below are MSN's depictions of several other regions of the two spectra:[10]

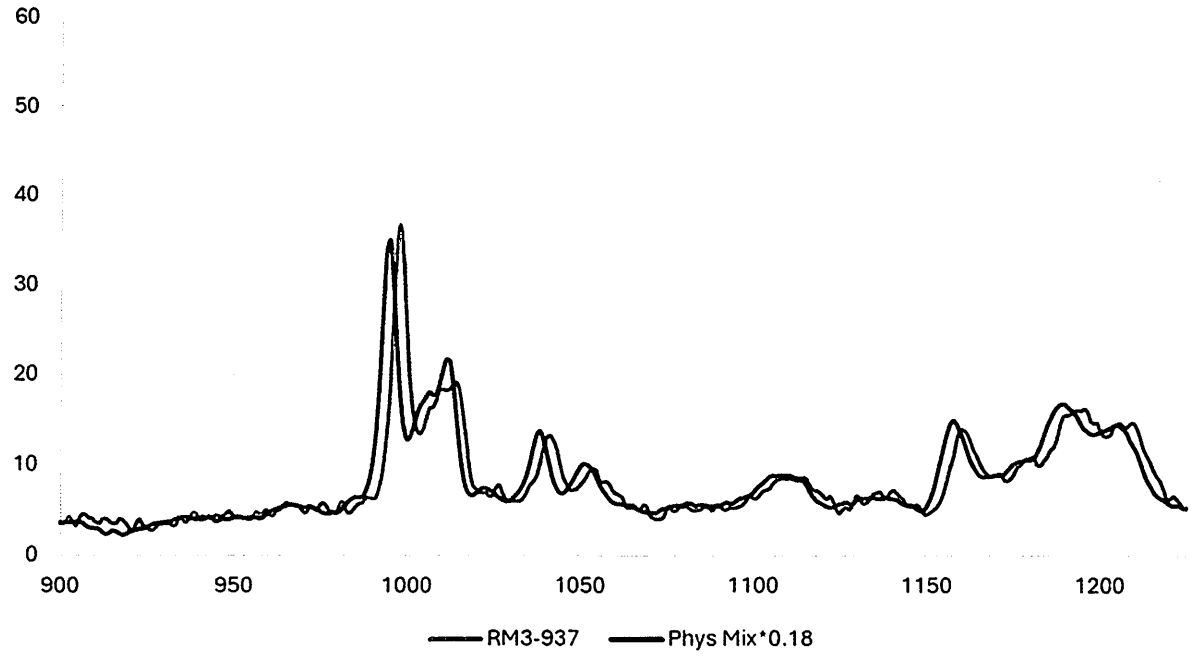
[8] The parties do not address the similarity in peak heights. This is merely my observation.
[9] When asked why the shifts all end in .8 or .7, Dr. Park responded, "[M]y Raman data was collected at about almost one wavenumbers, close to one. So that's why the difference [always ends in] about .8 or .7 because it's close to about 0.9 wavenumber . . . . That's the number of data points." (Tr. 409:18–22). MSN does not raise any issues about this testimony.
[10] MSN did provide a graph with the entirety of the two spectra overlaid, but with Dr. Park's glassy solid spectrum shifted 3 cm^{-1} to show that the spectra are substantially the same. (*See* DTX-646A at 3 of 11). It is nearly impossible to distinguish the two spectra. Perhaps that was MSN's intention, but I think several additional "zoomed in" areas on the spectra, without MSN's 3 cm^{-1} shift, are more informative.



(DTX-646A at 4 of 11).



(*Id.* at 5 of 11).



(*Id.* at 6 of 11).

Novartis argues the peak shifts show that the glassy solid is amorphous TVS, not an amorphous physical mixture, pointing to Redenti, a paper published in 1996. (D.I. 1705 at 3; D.I. 1764 at 7; Tr. 395:7–11). Indeed, Redenti says and shows that, at least with respect to the compounds at issue there, an amorphous complex and an amorphous physical mixture of the components in that complex will display different Raman peaks. (*See* JTX-121 at 3, 5 of 6). But Redenti points to more than just peak shifts. It describes the broadening and weakening of various peaks and bands as other notable differences observed between an amorphous complex and an amorphous physical mixture. (*Id.* at 3 of 6). Redenti does point to peak shifts, too, but no systematic shift of an entire Raman spectrum. (*See id.*). The visual comparing the two Raman spectra in Redenti is shown below:

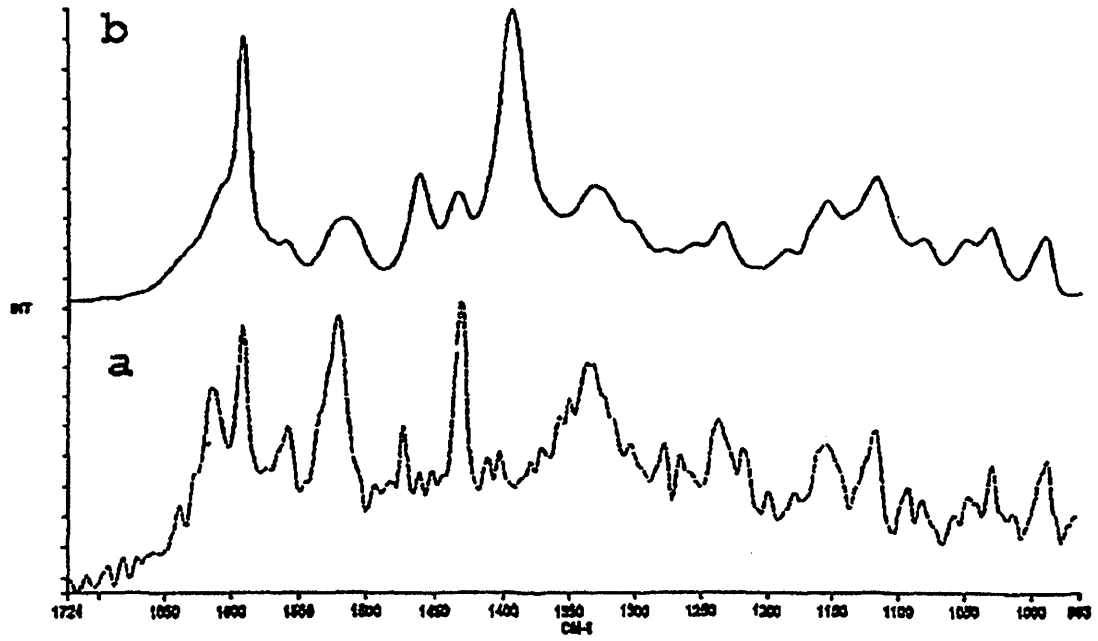


Fig. 3. Diagnostic region of NIR FT-Raman spectra of: (a) physical mixture of the two amorphous components and (b) freeze-dried P:β-CD (laser power: 30 mW/mm^2).

(*Id.* at 5 of 6). Dr. McCreery testified that the changes in peak intensity and shift of some, but not all, peaks show a difference between the two samples in Redenti. (Tr. 730:11–731:17). Redenti itself supports this. (*See* JTX-121 at 3 of 6).

Dr. McCreery testified that the type of systematic shift observed between the amorphous physical mixture Raman spectrum and Dr. Park's glassy solid Raman spectrum is simply "impossible." (Tr. 727:5). He testified that, in considering the bonds and molecular interactions present in an amorphous complex that are not present in an amorphous physical mixture, "most of the molecules shouldn't be affected," and there thus should be no systematic shift between the two spectra. (Tr. 727:5–11). Dr. McCreery testified that, though one spectrum of a sample is typically all that is needed to classify that sample, he would have run several tests and generated several Raman spectra of Dr. Park's glassy solid so he could statistically analyze the spectra and determine if the small changes are indeed significant. (Tr. 736:21–737:6). Dr. McCreery's testimony, combined with Novartis' own reference tending to support his testimony, convince

me that Novartis failed to show by a preponderance of the evidence that MSN's ANDA infringes based on the reference spectrum of Dr. Park's glassy solid.

Novartis has five main arguments in response.

First, Novartis points out that the glassy solid Raman spectrum is not uniformly shifted by precisely 3 cm^{-1}. (D.I. 1705 at 13). That is true. The peak shifts, as calculated by Novartis, are between 1.8 cm^{-1} and 5.7 cm^{-1}. (Tr. 409:7–11). Dr. McCreery testified that a calculated peak shift will depend on how the peak is selected. (Tr. 734:24–735:2). Dr. McCreery testified that most peak-picking software will pick the maximum height of a peak, which is not always the true normalized center of the peak. (*Id.*). He testified that small differences in peaks, like the ones at issue here, need rigorous evaluation to ensure accuracy. (Tr. 735:6–15). Dr. McCreery further testified that most of the peaks selected by Dr. Park were within Dr. Park's margin of error (1 cm^{-1}) of 3 cm^{-1}, and that the largest peak difference (5.7 cm^{-1}) was on a broad band where the peak could have plausibly been selected differently (as shown by Dr. McCreery shifting the glassy solid Raman spectrum 3 cm^{-1} and showing how closely the two spectra line up, including at the purported 5.7 cm^{-1} shift). (Tr. 733:20–737:6). Dr. Park testified that she accurately selected peak points. (Tr. 411:6–413:2). Dr. Park did not testify about how she picked her peaks or what software she used to pick her peaks. (*See* Tr. 411:24–413:2). While true that Dr. McCreery did not perform an analysis showing a peak selection where all peaks are uniformly shifted by 3 cm^{-1}, his testimony sows doubt about Novartis' reference Raman spectrum.

Second, Novartis argues that Dr. Park's instrument was properly calibrated when she conducted Raman spectroscopy on her glassy solid, and MSN has provided no explanation for what would cause a systematic shift in the spectrum other than actual differences between

amorphous TVS and an amorphous physical mixture of sacubitril and valsartan. (D.I. 1705 at 13).

Dr. Park testified that the Raman instrument she used is routinely calibrated using polystyrene, in accordance with American Society of Testing and Materials ("ASTM") standards. (Tr. 414:2–7). That is, the Raman instrument scans polystyrene and produces a spectrum, three peaks in that spectrum are compared to three known polystyrene peaks, and the instrument is calibrated accordingly. (Tr. 414:2–14). Dr. Park's Raman instrument was calibrated three times around the time of her testing her glassy solid: April 13, 2023, June 7, 2023, and August 3, 2023. (Tr. 415:5–7). She tested the glassy solid on April 28, 2023. (Tr. 373:4–8). Dr. Park testified that her "Raman instrument was accurate within plus/minus one wavenumber during [her] testing" and that there were no systematic shifts in the calibration data. (Tr. 414:25–415:2; Tr. 415:15–19). For example, on one calibration day, one peak was off by +1 cm^{-1}, another peak was off by +0.2 cm^{-1}, and another was off by 0.0 cm^{-1}. (Tr. 415:8–14). Dr. Park opined that any difference in peaks among two samples greater than one wavenumber is thus a "real difference between the two samples." (Tr. 415:20–25).

Dr. McCreery led the development of the ASTM standards followed by Dr. Park in calibrating her Raman instrument. (Tr. 737:14–16). He opined that Dr. Park did not do enough to ensure the accuracy of her Raman instrument. (Tr. 738:9–13). Dr. McCreery testified that, after seeing the striking similarities and small differences between the physical mixture and the glassy solid Raman spectra, he would have conducted further testing to ensure that the two spectra were in fact different. (*Id.*). Dr. McCreery did not pinpoint a systemic error that caused the 3 cm^{-1} shift; "It could have various sources." (Tr. 752:20–24).

Though Dr. McCreery and MSN do not point out a specific error in Dr. Park's Raman instrument that caused a uniform shift of 3 cm^{-1}, I do not think that is necessary for MSN to sow doubt about Novartis' reference Raman spectrum. For the reasons explained above, I think the reference Raman spectrum is unreliable. I do not doubt the accuracy of the calibration tests conducted on Dr. Park's Raman instrument. But I credit Dr. McCreery's testimony that such abnormally close and uniformly shifted spectra warrant further testing to confirm that the two spectra are in fact different. This is supported by Novartis' reference, Redenti, that shows that differences in peak positions and intensities among Raman spectra can be used to differentiate between an amorphous complex and a physical mixture, but is silent on a systematic shift with virtually no change in intensity. (*See* JTX-121 at 3, 5 of 6).

Third, Novartis points to other spectroscopy tests that purportedly show Dr. Park's Raman spectrum is of amorphous TVS, not an amorphous physical mixture. (D.I. 1705 at 3). Novartis points to ssNMR and IR spectra. (*Id.*). MSN addressed those spectra in a footnote and offered no expert testimony at trial to counter Dr. Park's testimony that the ssNMR and IR spectra show her glassy solid is amorphous TVS. (D.I. 1757 at 5 n.1; Tr. 743:3–17). MSN's arguments about the purported unreliability of the ssNMR and IR spectra are forfeited. *See Higgins v. Bayada Home Health Care Inc.*, 62 F.4th 755, 763 (3d Cir. 2023). I thus credit Dr. Park's testimony that the ssNMR and IR spectra tend to show that her glassy solid is amorphous TVS. Regardless, I think the Raman spectrum of Dr. Park's glassy solid is unreliable, for the reasons I explain above. Novartis used Dr. Park's Raman spectrum to show MSN's ANDA infringes, not the ssNMR or IR spectra. It is the Raman spectrum, not the glassy solid sample or the ssNMR and IR spectra, that I think is unreliable.

Fourth, Novartis offered testimony from Dr. Park to counter Dr. McCreery's testimony that the systematic shift was "impossible." (D.I. 1705 at 16). Dr. Park testified that it was not impossible for amorphous TVS to generate over twenty Raman peak shifts, pointing to the complexity of amorphous TVS. (Tr. 436:18–437:4). But Dr. Park did not address the crux of Dr. McCreery's testimony: that it was impossible for the entire amorphous Raman spectrum to shift by approximately the same amount. I do not think Dr. Park's testimony helps establish the reliability of her glassy solid Raman spectrum.

Fifth, Novartis argues multiple spectra are not needed to classify a compound, contrary to Dr. McCreery's opinion. (D.I. 1705 at 14–15). Dr. Park testified that a pharmaceutical compound can be classified with one spectrum, citing several pieces of literature for support. (Tr. 422:20–423:20). I do not doubt this. But I credit Dr. McCreery's testimony that when two spectra of two supposedly different materials are "very similar" (Tr. 728:6), multiple spectra would be beneficial so one could run statistical tests to determine if those small differences are significant enough to conclude the two materials are in fact different. (Tr. 736:21–737:6). I note that the sources cited by Dr. Park contain more obvious differences in the Raman spectra (like the emergence of new peaks and changes in intensity). (*See* JTX-121 at 5 of 6; PTX-1225 at 4 of 5; PTX-1228 at 4 of 5; PTX-1223 at 2 of 4).

To further support its position, MSN points to a spectrum from Novartis that MSN alleges is of amorphous TVS, but which is different from Dr. Park's glassy solid spectrum. (D.I. 1757 at 15–16).

Novartis had previously developed "LCZ-696," an amorphous compound; it had spectra of that compound. (*See* Tr. 430:9–11; JTX-104 at 8 of 33). MSN argues amorphous LCZ-696 is amorphous TVS, pointing to deposition testimony of a Novartis employee, Dr. Motto, who was

in charge of the Pharmaceutical and Analytical Development group working on Entresto. (D.I. 1757 at 15–16; *see* Tr. 692:13–25, 693:22–694:2). When asked if Novartis had ever characterized a material as amorphous TVS, Dr. Motto said, "Novartis was able to determine that material they had was amorphous [TVS] based on analytical testing of the next step product [(crystalline LCZ-696)] and physical evaluation of the material that they isolated [(LCZ-696 amorphous to glassy solid)]." (Tr. 695:11–22). Dr. Motto's testimony could be clearer. I understand him to say that Novartis determined amorphous TVS was in fact amorphous by comparing crystalline LCZ-696 to amorphous LCZ-696. Dr. Motto later testified that the glassy solid of Example 1 "was characterized as amorphous LCZ-696 or amorphous [TVS]," seeming to equate the two. (Tr. 697:2–5). Though Dr. Motto does not say so explicitly, it seems quite likely that he equated LCZ-696 with amorphous TVS.

Novartis had an internal presentation discussing, among other things, amorphous LCZ-696. (JTX-104). The presentation has a graph displaying Raman spectra of several materials, including amorphous LCZ-696. (*Id.* at 8 of 33). The amorphous LCZ-696 Raman spectrum is different from Dr. Park's glassy solid Raman spectrum. (Tr. 741:8–16). Peak intensities are different and some peaks are present in one and not in the other. (*Id.*). According to Dr. McCreery, "[S]pectroscopy would never claim those were the same material." (Tr. 741:14–15). Dr. Park agreed that the two spectra were different. (Tr. 462:7–10).

The author of the presentation, Charles Pan, is not an inventor of the '918 patent, and the presentation is dated April 21, 2009 while the '918 patent's priority date is April 4, 2006. (Tr. 430:22–431:10; *see* JTX-104 at 1 of 33; '918 patent). The Raman spectrum for amorphous LCZ-696 in the presentation was produced on February 6, 2007. (Tr. 431:17–19). The presentation

does not say amorphous LCZ-696 is amorphous TVS. (Tr. 431:23–25). None of these things foreclose the possibility that LCZ-696 is amorphous TVS.

Novartis argues that the LCZ-696 in its presentation is not Dr. Park's glassy solid. (D.I. 1764 at 4–5). True. That does not matter. Raman spectroscopy is like a fingerprint; the spectrum of one sample of a compound should be the same as the spectrum of a different sample of the same compound. (*See* Tr. 385:24–386:5, 719:19–24). If amorphous LCZ-696 and Dr. Park's glassy solid are both amorphous TVS, the two spectra should be substantially the same. I note that Novartis offered no testimony saying amorphous LCZ-696 is not amorphous TVS. Novartis merely argues Dr. Motto did not explicitly say the two were the same. (D.I. 1764 at 5).

Based on the timing and Dr. Motto's testimony, I think there is a reasonable likelihood that amorphous LCZ-696 is amorphous TVS. Since the amorphous LCZ-696 spectrum is quite different from Dr. Park's glassy solid spectrum, it too causes me to doubt that Dr. Park's glassy solid Raman spectrum is reliable to use as a reference to compare with MSN's ANDA.

B. Conclusions of Law

1. Adverse Inference

The parties dispute the applicability of an adverse inference. Before trial, I heard a discovery dispute between Novartis and MSN's co-defendants, Gerbera Therapeutics, Inc. and Nanjing Noratech Pharmaceutical Co., Limited (together, "Noratech"). (*See* D.I. 1634 at 3). Noratech went to trial with MSN, but settled its case after trial, and I entered a consent judgment and injunction against Noratech on June 17, 2025. (D.I. 1902). At the discovery dispute, Noratech asserted that Novartis failed to produce Dr. Park's glassy solid sample in violation of Federal Rule of Civil Procedure 26. (*See* D.I. 1634 at 3). At the pretrial conference, I indicated I would take an adverse inference against Novartis for failing to produce the sample. (D.I. 1667 at

31:21–32:4). Novartis re-argues the applicability of an adverse inference, and it argues that any adverse inference does not apply to MSN because MSN was not the defendant that requested the glassy solid. (D.I. 1705 at 34–35).

Whether to impose sanctions, and which sanctions to impose, for discovery violations is in the discretion of the trial court. FED. R. CIV. P. 37(c); *see Grider v. Keystone Health Plan Cent., Inc.*, 580 F.3d 119, 134 (3d Cir. 2009). Novartis gives three reasons for why an adverse inference is not warranted. As I explained at the pretrial conference, I think an adverse inference is warranted, but I address Novartis' arguments. (D.I. 1667 at 31:21–32:4).

First, Novartis argues a sanction for a discovery violation requires prejudice. (D.I. 1705 at 34). I think there is prejudice here. MSN wanted to test the sample Novartis used to show MSN's ANDA infringes but could not. Indeed, counsel for Novartis asked Dr. Park if "Defendants' experts test[ed] the glassy solid of Example 1." (Tr. 397:7–9). Counsel may have been asking if Defendants' experts tested any glassy solid, not just Dr. Park's, but again, Defendants wanted to test Dr. Park's sample in particular.

Second, Novartis argues there must be bad faith for sanctions to be warranted, citing *Robocast v. Microsoft Corp.*, 2014 WL 789086, at *2 (D. Del. Feb. 25, 2014). *Robocast* dealt with spoliation and a party failing to issue a litigation hold to preserve evidence. *Id.* at *1. The case cited in *Robocast*, a Third Circuit case, dealt with spoliation and the sanction of dismissal with prejudice. *Bull v. United Parcel Serv., Inc.*, 665 F.3d 68, 72 (3d Cir. 2012). *Bull* says, "Withholding requires intent," and that sanctions are appropriate only for withheld evidence, not evidence accidentally misplaced. *Id.* at 79. Novartis does not contend the glassy solid was misplaced; indeed, Dr. Park still had it at the time of trial. (Tr. 448:25–449:3). The glassy solid fell under the scope of requested production. Novartis agrees. (D.I. 1667 at 15:5–6). Novartis

argued only that Nanjing Noratech brought up the issue too late. (*Id.* at 14:3–6). There is evidence that Novartis knew the sample existed, knew the sample fell within the scope of requested discovery, and did not provide it. I think that is sufficient to show that Novartis acted with "intent" to withhold the sample, and that a sanction is warranted.

Third, Novartis argues complete foreclosure of its claim is a harsh penalty when MSN did not seek to compel production. (D.I. 1705 at 34). An adverse inference is a not complete foreclosure of Novartis' claim.

I think this adverse inference applies not just in relation to Noratech, but to MSN, too.

Novartis argues that the adverse inference should not apply to MSN's case. While true that MSN was not the party that sought production of Dr. Park's glassy solid, this is discovery common to both Defendants. Indeed, the Scheduling Order says, "The parties shall coordinate activities to reduce duplicative and cumulative discovery that is common to all Defendants." (D.I. 1098 at 5). Dr. Park created a Raman spectrum from her glassy solid that was used by Novartis to show that both Defendants' ANDAs infringe. The Defendants would have had their shared expert witness, Dr. McCreery, test Dr. Park's glassy solid. (Tr. 711:1–3; D.I. 1667 at 27:12–19). Novartis points out that MSN never made a glassy solid (*see* Tr. 397:4–6; D.I. 1705 at 34), but MSN wished to test Dr. Park's glassy solid, the material against which its ANDA was compared. I thus think it is appropriate to take an adverse inference against Novartis for failing to produce Dr. Park's glassy solid to Noratech.

In an analogous setting, the Ninth Circuit came to a similar conclusion. *See Payne v. Exxon Corp.*, 121 F.3d 503, 510 (9th Cir. 1997). In *Payne*, the Ninth Circuit affirmed the district court's dismissal of a case against two defendants as a sanction for the plaintiff failing to comply with a discovery order, even though only one of the defendants requested and filed a motion on

the discovery at issue. *Id.* at 507, 510. The court explained, "If Congress had intended to limit the district court's dismissal authority to claims against the party who propounded discovery, it would not have chosen such sweeping language [under Rule 37(b)(2)]."[11] *Id.* at 510. Further, "The district court could reasonably conclude that plaintiffs' failure to comply with court orders prejudiced both parties." *Id.* Here, Novartis' failure to produce Noratech's requested discovery prejudiced both defendants.

I will assume that, had Novartis produced the glassy solid sample to Defendants, it would have been unfavorable to Novartis' case. *See Gronquist v. Nicholas*, 2011 WL 4001103, at *8 (W.D. Wash. Aug. 12, 2011).

2. Infringement

Novartis must prove MSN's ANDA infringes by a preponderance of the evidence. *SmithKline*, 859 F.2d at 889. For all the foregoing reasons, I think Novartis did not. The reference Raman spectrum that Novartis used to compare to a Raman spectrum of MSN's ANDA is unreliable as a reference spectrum. Thus, an infringement analysis based on that "reference spectrum" is insufficient. The unreliability of Novartis' reference Raman spectrum, combined with an adverse inference due to Novartis' failure to produce the glassy solid sample reflected in the reference Raman spectrum, leads me to conclude that Novartis did not meet its burden to show MSN's ANDA infringes by a preponderance of the evidence.

IV. CONCLUSION

For the foregoing reasons, I find that Novartis did not prove that MSN's ANDA infringes by a preponderance of the evidence. I will enter a final judgment consistent with this opinion.

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[11] At issue here is a violation under Rule 37(c)(1), which allows for the sanctions listed in Rule 37(b)(2). FED. R. CIV. P. 37(c)(1)(C).