United States Court of Appeals for the Federal Circuit

MERCK SHARP & DOHME CORP.,
Plaintiff-Appellant

v.

AMNEAL PHARMACEUTICALS LLC,
Defendant-Appellee

2017-1560

Appeal from the United States District Court for the District of Delaware in No. 1:15-cv-00250-SLR-SRF, Judge Sue L. Robinson.

Decided: February 9, 2018

NICOLAS BARZOUKAS, Reed Smith LLP, Houston, TX, argued for plaintiff-appellant. Also represented by JOSHUA DAVIS, LISA M. THOMAS.

THOMAS J. MELORO, Willkie Farr & Gallagher LLP, New York, NY, argued for defendant-appellee. Also represented by DEVON EDWARDS, MATTHEW S. FREIMUTH, MICHAEL JOHNSON.

Before TARANTO, CLEVENGER, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

Merck Sharp & Dohme Corp. ("Merck") owns U.S. Patent No. 6,127,353, which claims mometasone furoate monohydrate, the active ingredient in Merck's Nasonex® nasal product. Amneal Pharmaceuticals LLC ("Amneal") submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food & Drug Administration ("FDA") seeking approval to market a generic mometasone furoate nasal spray. Merck filed an infringement suit in the District of Delaware alleging that Amneal's proposed ANDA product would infringe the '353 patent if approved by the FDA.

Following a bench trial, the district court found that Merck failed to prove by preponderant evidence that Amneal's ANDA product will infringe the '353 patent. On appeal, Merck argues that the district court abused its discretion by not compelling Amneal to produce additional samples of its ANDA product for testing before trial. Merck also argues that the district court's noninfringement finding must be reversed because it was not based on Amneal's final commercial product. Merck also challenges the district court's fact-finding that a Raman spectroscopy three-peak analysis was required to confirm the infringing form of mometasone furoate in Amneal's product.

For the reasons explained below, we conclude that the district court did not abuse its discretion in denying Merck's request for additional samples and a new trial. Further, we hold that the district court did not err in finding that Merck failed to demonstrate that Amneal's ANDA product, which formed the basis for the district court's noninfringement finding, was not representative of Amneal's final commercial product. Finally, we conclude that the district court did not clearly err in finding that

three Raman peaks were required to prove infringement. Accordingly, we affirm.

BACKGROUND

In the early 1980s, Merck scientists discovered and synthesized the corticosteroid anhydrous mometasone furoate or "MFA." After initial setbacks with dissolving MFA in water and pharmaceutical compositions, Merck discovered a solvent that eventually allowed it to develop MFA for the treatment of psoriasis.

In the late 1980s, Merck sought to further develop MFA into nasal formulations. That research led to the discovery of a polymorph of MFA, mometasone furoate monohydrate, also referred to as "MFM." MFM and MFA differ in that every molecule of MFM is associated with water, whereas no water is present in the crystal lattice structure of MFA. These differences cause conformational changes to the solid crystal lattice structure in the two crystalline forms. In certain aqueous suspensions, MFM is the more stable polymorphic form.

The discovery of MFM led to the development of Merck's Nasonex® nasal product, which is approved for the treatment of perennial allergic rhinitis, seasonal allergic rhinitis, nasal polyps, and congestion associated with nasal symptoms of allergic rhinitis. The '353 patent claims MFM and pharmaceutical compositions comprising MFM.

In November 2014, Amneal filed ANDA No. 207989, seeking approval to market a generic mometasone furoate nasal spray comprising MFA (as opposed to MFM) as the active ingredient. In February 2015, Amneal sent Merck a notice letter, informing Merck of its ANDA filing and certifying that its proposed product would not infringe the '353 patent and that the '353 patent was invalid. As a result, in March 2015, Merck filed an infringement suit against Amneal asserting claims 1, 6, and 9–12 of the '353

patent. Merck alleged that although Amneal's ANDA product contained MFA, its ANDA product would convert to the infringing MFM form over time. Thus, the issue of infringement before the district court was whether Amneal's ANDA product would contain any patented MFM during Amneal's product's two-year shelf-life.

Relevant to the issues in this case, Amneal manufactured three 100 kilogram ANDA submission batches ("Exhibit Batches") of its proposed ANDA product and provided the FDA data on those samples. Amneal produced samples of the Exhibit Batches to Merck. Although Amneal also gave the FDA data on samples from a 1,000 kilogram commercial-sized batch ("Commercial 157 Batch"), Amneal did not produce those samples to Merck. As a result, Merck moved to compel production of the Commercial 157 Batch samples, which the district court ordered on November 24, 2015.

On December 10, 2015, the district court ordered that the case would be stayed unless Amneal filed a declaration attesting that the Exhibit Batch samples provided to Merck were representative of Amneal's commercial ANDA product. The district court further ordered "Amneal [to] immediately make available to Merck samples of any further representative commercial batches sent to the FDA." J.A. 82. On December 21, 2015, Amneal filed a declaration, representing that its Exhibit Batch samples were representative of its commercial ANDA product. Amneal's declaration indicated, however, that Amneal amended its ANDA to change its commercial batch size from 1,000 kg to 100 kg and would manufacture its commercial ANDA products using the same formulation and manufacturing process as the Exhibit Batch samples provided to Merck. Based on this amendment, the district court later excluded the Commercial 157 Batch samples from trial, concluding that Amneal "has identified the Exhibit Batches as its Generic Product to the FDA and there is no credible indication that [Amneal] could realis-

tically use the [Commercial] 157 Batch manufacturing process instead." J.A. 149.

Because Amneal's ANDA specification allowed for a maximum bulk suspension hold of up to four days, the FDA required Amneal to complete a bulk-hold study, in which Amneal's commercial batch would be held for a four-day period before being packaged into nasal spray bottles. On January 11, 2016, Amneal manufactured another 100 kilogram commercial batch for the bulk-hold study ("Batch 16001"). Amneal drew samples from the batch on the first day ("Day 1 Batch") and again on the fourth day ("Day 4 Batch"). Before sampling the Day 4 Batch, Amneal additionally mixed the batch at 840 revolutions per minute ("RPM") for 30 minutes. After the bulk-hold study was completed, Amneal again mixed the Batch 16001 mixture and bottled it for storage, redesignating the batch as "Batch 16001A" (hereinafter referred to as the "A Batch"). On February 29, 2016, Amneal responded to the FDA, providing data on samples from the Day 1 and Day 4 Batches from the requested bulk-hold study. Amneal did not provide the FDA data on samples from the A Batch.

On January 12, 2016 and February 11, 2016, Amneal produced samples from the Day 1 Batch to Merck, indicating that they were representative of Amneal's finished commercial product. On March 10, 2016, Amneal completed its document production to Merck, which included its February 29, 2016 response to the FDA providing the results of the bulk-hold study. On April 25, 2016, Amneal served a rebuttal expert report on infringement, in which Amneal's expert opined regarding samples from the Day 4 Batch. Merck represents that this was the first time it became aware of the Day 4 and A Batch samples.

This led to a discovery dispute close to trial regarding whether samples of Amneal's Day 1 Batch were representative of Amneal's final commercial product and

whether Amneal should have produced the Day 4 and A Batch samples. On May 9 and 13, 2016—six weeks before trial—Merck sought emergency relief from the district court, arguing that Amneal should have produced samples from the Day 4 and A Batches. Merck argued that because the Day 4 and A Batches underwent additional mixing, which can promote conversion of MFA to the infringing MFM form, Amneal should have produced samples from those batches for testing. Amneal argued that additional samples would have been cumulative of the Day 1 Batch samples already produced and maintained its representation that the Day 1 Batch samples were representative of its ANDA product. The parties and the district court recognized the link between the requested production and the trial date: the upcoming trial would have to be materially postponed if the Day 4 and A Batch samples were produced and Merck were given a full opportunity to test those samples before trial.

Following two discovery hearings on the issue, the district court became aware of Amneal's discovery violation and acknowledged that ideally Amneal should have produced samples of the Day 4 and A Batches. The district court determined, however, that it did not have enough information at the time to determine whether the Day 4 and A Batch samples were materially different from the Day 1 Batch samples. The district court concluded that it was "not persuaded sitting right here that mixing [] makes a substantive difference, and if it doesn't, then it doesn't matter that Amneal didn't give [Merck] a sample of both [the Day 4 and A Batches] . . . [and] only gave [Merck the Day 1 Batch]." J.A. 128 at 27:7–12. The district court did not compel Amneal to produce the additional samples. Nor did the court postpone trial. Instead, the district court gave Merck the opportunity to prove at trial that the Day 4 and A Batch samples were substantively different than the Day 1 Batch samples and

warned Amneal that it was at risk of incurring costs if Merck prevailed on the issue.

At trial, Merck's expert, Dr. Matzger, testified that he tested samples of Amneal's ANDA product using Raman spectroscopy.[1] Dr. Matzger tested samples of Amneal's Exhibit Batches and did not identify any MFM crystals. But Dr. Matzger also tested samples from the Day 1 Batch and testified that he identified a single Raman peak at 1709 cm^{-1}, which is characteristic of MFM. Dr. Matzger testified that although he tested the Exhibit and Day 1 Batch samples, he would have preferred to test samples of Amneal's Day 4 and A Batches because they underwent additional mixing and thus were more representative of the final ANDA product.

Amneal's expert, Dr. Marquardt, testified that Dr. Matzger misinterpreted the data as identifying MFM in Amneal's Day 1 Batch samples and opined that MFM was not present in Amneal's final ANDA product. Dr. Marquardt further opined that three Raman peaks were required to confirm the presence of MFM rather than a single Raman peak. Amneal's other expert, Dr. Rogers, disagreed with Dr. Matzger's opinion regarding the relevance of the Day 4 and A Batches. Dr. Rogers opined that the likelihood of conversion of MFA to MFM was merely theoretical and unlikely due to the high energy required to convert between forms.

Based on this competing testimony regarding sample production and whether the Day 1 Batch samples were representative of Amneal's ANDA product, the district court summarized the parties' positions and its fact-findings as follows:

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[1] Raman spectroscopy is a vibrational spectroscopy technique. A laser is used to generate a Raman spectrum, which indicates the vibrational modes of molecules and can be used to differentiate crystalline forms.

> The parties dispute whether Amneal should have provided samples from [the Day 4 and A Batches] ("additional samples") to Merck. Amneal asserts that the additional samples would be cumulative to those provided ([the Day 1 Batch] and the Exhibit Batches). Merck requests that the court conclude that the additional samples would have contained MFM because of the additional mixing. From the expert testimony, the court concludes that generally additional (or faster) mixing tends to promote conversion of MFA to MFM. Neither party, however, has offered a quantification of how the additional (or faster) mixing might affect the dissolution of MFA, or the nucleation and crystal growth of MFM in Amneal's ANDA product . . . . The expert testimony—that conversion is system-dependent and the additional mixing performed on Batch 16001 likely would have promoted conversion—renders any conclusion regarding [the Day 4 and A Batches] theoretical. On the evidence presented, the court concludes that Merck has not demonstrated that the additional samples would yield different results. Consequently, the court denies Merck's alternative request for the production of [the Day 4 and A Batch] samples and a new trial.

Merck Sharp & Dohme Corp. v. Amneal Pharm. LLC, 235 F. Supp. 3d 625, 631–32 (D. Del. 2017) ("*District Court Decision*") (footnotes omitted).

Regarding infringement, the district court credited Amneal's expert that three Raman peaks were required to identify MFM in Amneal's ANDA product. As a result, the district court "assign[ed] little weight to Dr. Matzger's identification of MFM based on a single peak . . . ." *Id.* at 636. The district court concluded that based on the "lack of MFM in the Exhibit Batches and opposing conclusions on the same testing of the [Day 1 Batch]," Merck failed to

carry its burden of proving by a preponderance of the evidence that MFM is present in Amneal's ANDA product. *Id.* at 637–38.

Merck appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

I.

We start our analysis with the district court's discovery ruling. We review the district court's denial of additional discovery under regional circuit law. *Digeo, Inc. v. Audible, Inc.*, 505 F.3d 1362, 1370 (Fed. Cir. 2007). The Third Circuit will not disturb a denial of additional discovery absent an abuse of discretion and "a showing of actual and substantial prejudice." *Anderson v. Wachovia Mortg. Corp.*, 621 F.3d 261, 281 (3d Cir. 2010).

The district court's standing discovery order required Amneal to "immediately make available to Merck samples of any further representative commercial batches *sent to the FDA*." J.A. 82 (emphasis added). Amneal, however, did not produce samples of its Day 4 Batch that it submitted to the FDA, in violation of the discovery order. Merck argues that the district court abused its discretion by not compelling Amneal to produce samples of its Day 4 and A Batches and by not postponing trial.

The question before us is a close one. Amneal's failure to abide by the standing discovery order resulted in a trial situation that was less than ideal. Because Amneal did not produce samples of the Day 4 and A Batches, the district court faced a very difficult situation a mere six weeks prior to trial. The district court held two hearings in which it tried to ascertain whether the Day 4 and A Batches were materially different from the produced Day 1 Batch samples. After concluding that Merck had not shown that the Day 1 Batch samples were insufficient to represent Amneal's finished ANDA product, the district court decided to proceed to trial, but also allowed Merck

the opportunity to present evidence on the issue at trial. The question on appeal is thus whether the district court abused its discretion in choosing this particular approach as opposed to ordering additional discovery and delaying trial. We hold that it did not.

The district court took adequate steps to ensure that proceeding with trial would not prejudice Merck. Because the court allowed Merck the opportunity to prove at trial that the Day 4 and A Batch samples were different than the Day 1 Batch samples for purposes of infringement, we cannot say that Merck was prejudiced by the district court's decision to proceed to trial. The district court's offer to Merck was not illusory. At trial, Merck attempted to prove that mixing promotes conversion of MFA to MFM such that the additional mixing of Amneal's Day 4 and A Batches would likely convert the MFA to MFM.

Merck's expert, Dr. Matzger, testified that he performed a thermodynamic stability study, which demonstrated the conversion of MFA to MFM. In the study, Dr. Matzger added MFM to Amneal's Exhibit Batch of MFA. Dr. Matzger then subjected the mixture to vigorous shaking (at 500 RPM) for 27 days and sampled the mixture at various stages during the shaking. Dr. Matzger testified that at the end of the 27-day process, the mixture converted to MFM. He also testified that he "intentionally added [MFM] so that the conversion could take place with both forms present, and so [he] wouldn't know if [MFM] would become present or when it would become present if [he] hadn't added it." J.A. 166 at 63:6–12.

Additionally, Dr. Matzger testified at trial that he was aware of Amneal's Day 4 and A Batches and that he would have preferred to test samples of those batches because they were "more representative" of Amneal's final product in that they went through additional mixing. J.A. 178 at 111:6–25. Based on his analysis of the additional mixing steps, Dr. Matzger stated that he would

have expected to find MFM in the Day 4 and A Batch samples.

Merck's other expert, Dr. Trout, also opined that generally additional mixing increases the likelihood of polymorphic conversion to MFM. Dr. Trout testified that additional vigorous mixing on an industrial scale imparts more energy into the system, which increases the likelihood of polymorphic conversion. Dr. Trout admitted, however, that this conversion concept was based on general chemical, thermodynamic, and kinetic principles and that to determine whether conversion occurs in a given sample, the sample would need to be tested. But Dr. Trout did not test Amneal's product, including the Day 1 Batch samples.

Amneal's expert, Dr. Rogers, disagreed that the amount of mixing Amneal did to arrive at the Day 4 and A Batch samples would have increased the likelihood of conversion. Dr. Rogers testified that Dr. Trout's opinion was based on a scientific reference involving a different drug, which did not provide any relevant information on MFM or MFA. Dr. Rogers also testified that increased mixing does not necessarily result in increased polymorphic conversion. Finally, Dr. Rogers explained his view that conversion of MFA in Amneal's ANDA product would be difficult due to the high energy required to convert to MFM.

In light of the competing evidence in the record before us, we discern no clear error in the district court's finding that the trial evidence failed to demonstrate that the MFA in Amneal's product would have converted to MFM based on Amneal's additional mixing. As the district court found, Merck presented little more than theoretical evidence to show that the Day 4 and A Batch samples would be more likely to undergo conversion than the Day 1 Batch samples. Merck's evidence merely supported that MFA *could* convert to MFM by additional mixing.

Merck made no attempt to prove that Amneal's product *would* convert simply by the additional mixing Amneal performed on the produced Day 1 samples. While Merck's expert, Dr. Matzger, attempted to show conversion from MFA to MFM in the Exhibit Batch samples produced by Amneal, he did so by, among other steps, adding MFM to the Exhibit Batch samples and mixing for 27 days. As the district court explained, Dr. Matzger's study was "not representative of the ANDA product (because of the addition of MFM) and did not measure the effect of mixing speed or time on the rate of conversion." *District Court Decision*, 235 F. Supp. 3d at 631.

We reject Merck's argument that it could not prove conversion without testing the Day 4 and A Batch samples. Merck had samples of Amneal's Exhibit and Day 1 Batches, but made no attempt to experiment with Amneal's ANDA product to demonstrate conversion by additional mixing and passage of time alone, let alone by matching the mixing, in both speed and duration, that Amneal carried out to arrive at the Day 4 and A Batch samples. For example, Merck could have tested whether mixing an MFA solution (e.g., the Day 1 Batch solution) at 840 RPM for 30 minutes (the additional mixing steps of the Day 4 or A Batches) would result in conversion of MFA to MFM. Based on such lack of conclusive evidence, we cannot say that the district court clearly erred in finding that Merck failed to show that the Day 4 and A Batch samples would have differed from the Day 1 Batch samples. We are not "left with a definite and firm conviction that the district court was in error" to overturn its fact-finding. *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006).

We recognize, as did the district court, that it would have been better for the process if Amneal had provided samples of the Day 4 and A Batches. Uncertainties in pharmaceuticals provide sufficient reason for ANDA filers to produce samples that are provided to the FDA for

which they seek approval, as Amneal had been ordered to do. In this case, however, we hold that the district court did not err given the steps it took to allow Merck to prove that Amneal's discovery violation was prejudicial.

II.

Having concluded that the district court did not abuse its discretion in denying discovery of the Day 4 and A Batch samples, we next turn to Merck's argument that the district court erred in relying on Amneal's Day 1 Batch samples to find that Amneal will not infringe the '353 patent. Following a bench trial, we review the district court's conclusions of law de novo and its fact-findings for clear error. *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1058 (Fed. Cir. 2004). The ultimate determination of infringement is a question of fact, which we review for clear error. *Id.* A fact-finding is clearly erroneous if the court "is left with a definite and firm conviction that the district court was in error." *Alza*, 464 F.3d at 1289.

Merck argues that the district court's finding of non-infringement must be reversed as a matter of law because the district court improperly based its noninfringement finding on Amneal's intermediate product (the Day 1 Batch samples) rather than its final, commercial-sized product (the A Batch samples). In this regard, Merck argues that the proper adjudication of an ANDA infringement inquiry must focus on what will be or is likely to be sold. Merck avers that Amneal's A Batch samples were the only final commercial ANDA product and thus should have been the focus of the infringement question. As Merck posits the argument, "[a]lthough the district court's error started as a discovery dispute, the district court's failure to recognize the proper subject of the infringement inquiry according to 35 U.S.C. § 271(e)(2) and this [c]ourt's precedent resulted in a complete misapplica-

tion of law under the Hatch-Waxman Act's framework." Appellant Br. 37.

As we explained above, Merck was allowed an opportunity to prove at trial that samples of the Day 4 and A Batches would have materially differed from the Day 1 Batch samples. But Merck failed to do so. Based on the lack of conclusive evidence that Amneal's additional mixing would have caused conversion in the Day 4 and A Batches, we cannot say that the district court erred in finding that Amneal's Day 1 Batch samples were adequate to represent Amneal's final ANDA product for purposes of determining infringement.

We do not agree with Merck that our law requires otherwise. In arguing that only the A Batch samples should have been the focus of infringement, Merck seeks to impose a heightened evidentiary standard in ANDA cases not supported by our case law. We agree with Merck that infringement under 35 U.S.C. § 271(e)(2) "must focus on what the ANDA applicant will likely market if its application is approved . . . ." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). But we have not said that the proof of infringement in the ANDA context must necessarily be based on any particular sample. To the contrary, we have "endorsed the district court's reference to relevant evidence, including biobatch data and actual samples of the proposed generic composition that the ANDA filer had submitted to the FDA." *Ferring B.V. v. Watson Labs, Inc.-Fla.*, 764 F.3d 1401, 1409 (Fed. Cir. 2014). Regardless of the type of sample (e.g., commercial or batch), the critical inquiry is whether it is representative of what is likely to be approved and marketed.

Here, we disagree with Merck that Amneal's Day 1 Batch samples were merely an intermediate product and not representative of its final commercial product. Amneal represented to the FDA and the district court that its

Day 1 Batch samples were representative of its ANDA product. Moreover, we note that Amneal's ANDA specification allows up to a four-day batch-hold period. Thus, samples drawn from the Day 1 Batch met Amneal's ANDA specification and thus represented its ANDA product.

Merck's reliance on *Ferring* is misplaced. In *Ferring*, we held that infringement could not be based on Watson's uncoated tablets, but rather had to be based on the "final, coated commercial . . . tablets for which Watson sought and was granted FDA approval to market as a generic version . . . ." 764 F.3d at 1409. In so holding, we emphasized the fact that Watson could not sell uncoated tablets because they did not comply with Watson's ANDA specification. *Id.* Here, however, Amneal's Day 1 Batch samples comply with its specification, and despite Merck's insistence that the A Batch samples are the most representative of Amneal's final product, Merck concedes that no data on the A Batch samples was submitted to the FDA for approval. *See* Oral Arg. at 10:00–10:35. Thus, we conclude that the district court did not err in relying on Amneal's Day 1 Batch samples.[2]

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[2] In addition to finding that Amneal's Day 1 Batch samples did not infringe, the district court also supported its noninfringement finding on the lack of MFM found in Amneal's Exhibit Batch samples. Merck argues that the district court also erred in relying on the Exhibit Batch samples because the Exhibit Batches were not manufactured according to Amneal's ANDA specification. We need not resolve this issue because we conclude that the district court did not clearly err in relying on the Day 1 Batch samples to conclude that Amneal does not infringe.

III.

We also discern no clear error in the district court's fact-finding of noninfringement. Although Dr. Matzger testified that he identified a single Raman peak characteristic of MFM in Amneal's Day 1 Batch samples, his testimony was rebutted. Amneal's expert, Dr. Marquardt, opined that Dr. Matzger misinterpreted his data and testified that MFM was not present in the Day 1 Batch samples. Dr. Marquardt also disagreed that a single Raman peak was sufficient to distinguish between MFA and MFM. The district court found Amneal's expert evidence "at least as consistent and credible" as Merck's expert and concluded that Merck failed to prove infringement by preponderant evidence. *District Court Decision*, 235 F. Supp. 3d at 637. Because its noninfringement finding is supported by the record, we conclude that the district court did not clearly err in its noninfringement finding.

On appeal, Merck argues that the district court clearly erred in finding that three Raman peaks were required to confirm the presence of MFM in Amneal's ANDA product. Specifically, Merck argues that the district court ignored Amneal's admission to the FDA that a single peak at 1705 cm^{-1} is sufficient to identify MFM. Merck also references portions of Amneal's ANDA suggesting that the Raman spectra peaks at 1705 cm^{-1} and 1725 cm^{-1} are quick references to distinguish between MFM and MFA. Merck further cites the deposition testimony of one of Amneal's scientists who testified that Amneal would look for the 1705 cm^{-1} peak for MFM and the 1725 cm^{-1} peak for MFA.

The district court heard testimony from Amneal's expert, Dr. Marquardt, however, that although a single peak can be used at times, three Raman peaks are typically used to absolutely confirm the presence of molecules in complex mixtures like MFM. Because the district court's finding that three Raman peaks were required to

identify MFM is supported by Dr. Marquardt's testimony, we conclude that the district court did not clearly err in so finding.

In concluding that three Raman peaks were required, the district court also noted that the district court in *Schering Corp v. Apotex Inc.*, No. 09-6373, 2012 WL 2263292 (D.N.J. June 15, 2012), likewise concluded that three peaks were required to confirm MFM. *Schering* dealt with a similar generic version of Nasonex® manufactured by Apotex, which also comprised MFA. The district court there addressed the same issue of whether a single peak or three peaks were required to identify MFM. *Schering* involved Merck's same expert, Dr. Matzger. In *Schering*, the district court gave Dr. Matzger's evidence "little weight because it [did] not identify three peaks," and concluded that Apotex did not infringe. *Id.* at *10. The three-peak issue was raised on appeal to this court, and we affirmed the district court's judgment without opinion. *See Merck Sharp & Dohme Corp. v. Apotex Inc.*, 517 F. App'x 939 (Fed. Cir. 2013).

Merck suggests that the district court improperly relied on *Schering* to find that three peaks were required to confirm the presence of MFM in Amneal's ANDA product. We disagree. While the district court noted the holding in *Schering*, it is clear from the district court's opinion that it independently relied on Dr. Marquardt's credible testimony that three peaks were required. Based on this record, we see no clear error in the district court's fact-finding that three peaks were required and that Amneal's ANDA product will not infringe.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm.

AFFIRMED

COSTS

Costs to Appellee.