Ferring Pharmaceuticals Inc. et al v. Par Pharmaceutical Inc. Doc. 192

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC. and FERRING INTERNATIONAL CENTER S.A.,

Plaintiffs;

v.

PAR PHARMACEUTICAL, INC.,

Defendant.

Civil Action No. 1:15-cv-173-RGA

TRIAL OPINION

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July 11, 2017

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**ANDREWS, U.S. DISTRICT JUDGE:**

Plaintiffs brought this patent infringement action against Par Pharmaceutical, Inc. on February 20, 2015. (D.I. 1). Defendant filed an Abbreviated New Drug Application ("ANDA"), seeking to engage in the commercial manufacture, use, and sale of a generic version of Ferring's Prepopik product. (D.I. 170-1 at 3, ¶¶9-10). Plaintiffs allege that Defendant's submission of this ANDA infringes U.S. Patent Nos. 8,450,338 ("the '338 patent") and 8,481,083 ("the '083 patent"). (D.I. 170 at 3, ¶1)

The product at issue in this case is a treatment used as preparation for colonoscopy. (D.I. 170-1 at 2, ¶8). Plaintiffs' Prepopik product is comprised of sodium picosulfate, magnesium oxide, and citric acid. (*Id.* at 2, ¶5). The Court held a bench trial on November 8-9, 2016. (D.I. 178, 179) ("Tr."). Prior to trial, Defendants dismissed all invalidity defenses with prejudice. (D.I. 165). Therefore, the only issue addressed at trial was whether Defendant's proposed ANDA product and process infringe the '338 and '083 patents.

## I. LEGAL STANDARDS

A patent is infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent . . . ." 35 U.S.C. § 271(a). A two-step analysis is employed in making an infringement determination. *See 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. *See id.* The trier of fact must then compare the properly construed claims with the accused infringing product. *See id.* This second step is a question of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). "Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device." *Kahn v. Gen. Motors Corp.*, 135

F.3d 1472, 1477 (Fed. Cir. 1998). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). The patent owner has the burden of proving infringement by a preponderance of the evidence. *See SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

## II. INFRINGEMENT OF THE '083 AND '338 PATENTS

Plaintiffs assert claims 1, 4-6, 8, 9-12, and 17-18 of the '338 patent and claims 1 and 7-11 of the '083 patent. The parties agree that if Defendant's ANDA product meets all limitations of claim 1 of the '338 patent and if the process by which it makes its ANDA product meets all limitations of claim 8 of the '338 patent, then all limitations of the asserted dependent claims of the '338 patent are met. (D.I. 170-1 at 6-7, ¶¶34-35). Claim 1 is a composition claim and reads as follows:

> 1. A composition comprising sodium picosulphate coated granules having a spray-coated layer of sodium picosulphate coating a potassium bicarbonate core.

('338 patent, claim 1). Claim 8 is a process claim and reads as follows:

> 8. A process for the preparation of a composition according to claim 1 wherein said process comprises steps of:
>
> (a) spray coating a solution of sodium picosulfate on to potassium bicarbonate; and
>
> (b) drying the sodium picosulfate and potassium bicarbonate thereby obtaining sodium picosulphate coated granules,
>
> Wherein the sodium picosulfate coated granules have a layer of sodium picosulfate coating a potassium bicarbonate core.

('338 patent, claim 8). There is no dispute that Defendant's ANDA product is a composition comprising sodium picosulfate and potassium bicarbonate. (D.I. 170-1 at 6, ¶¶29, 31). There is also no dispute that Defendant's ANDA product contains granules. (*Id.* at 6, ¶32).

The parties also agree that if Defendant's ANDA product meets all limitations of claim 1

of the '083 patent, then all limitations of the asserted claims of the '083 patent are met. (*Id.* at 7, ¶36). Claim 1 is a composition claim and reads as follows:

> 1. A pharmaceutical composition comprising:
>  (a) magnesium oxide coated granules which have a layer of magnesium oxide coated on a core of citric acid; and
>  (b) sodium picosulphate coated granules having a spray-coated layer of sodium picosulphate coating a potassium bicarbonate core.

('083 patent, claim1). There is no dispute that Defendant's ANDA product is a pharmaceutical composition comprising magnesium oxide coated granules which have a layer of magnesium oxide coated on a core of citric acid. (D.I. 170-1 at 6, ¶¶30, 33).

The only disputed issue, therefore, is whether Defendant's ANDA product comprises a "spray-coated layer of sodium picosulfate coating a potassium bicarbonate core."

**A. Findings of Fact**

1. The plain and ordinary meaning of "coating" is "a layer of a substance, which is on the outer surface of another substance or material."
2. Defendant's proposed ANDA product has a layer of sodium picosulfate coating a potassium bicarbonate core.
3. Defendant's proposed ANDA product is produced using a spray-coating process.
4. Defendant's proposed ANDA product meets all limitations of claims 1, 4-6, 8, 9-12, and 17-18 of the '338 patent.
5. Defendant's proposed ANDA product meets all limitations of claims1 and 7-11 of the '083 patent.

**B. Conclusions of Law**

Defendant argues that Plaintiffs have not proven 1) Defendant's ANDA product has a layer of sodium picosulfate coating a bicarbonate core; and 2) Defendant's ANDA product is produced

using a spray-coating process. The essence of the parties' disputes as to both limitations revolves around the plain and ordinary meaning of the terms "coated," "coating," and "layer."

*1. The Plain and Ordinary Meaning of Coated, Coating, and Layer*

During claim construction, I declined to construe the disputed terms "coated" and "coating," finding that the terms "have a meaning to people of ordinary skill in the art" and directing the parties to provide expert opinions at trial as to whether Defendant's proposed ANDA product has a coating. (D.I. 74 at 32:24-33:23). I specifically prohibited the parties from engaging in claim construction at trial. (*Id.* at 33:14-15). I reiterated the prohibition on further claim construction when I ruled on the parties' Motions in Limine. (D.I. 172 at 2) ("Both parties' experts are, therefore, precluded from testifying that the specification and prosecution history support their views regarding the plain and ordinary meaning of the claim terms."). The term "layer" was not identified as a disputed term during claim construction. Much of the trial testimony was directed to the parties' competing plain and ordinary meanings for these terms.

Plaintiffs' expert, Dr. Davies, opined that "coated" and "coating" mean "a layer of a substance, which is on the outer surface of another substance or material." (Tr. at 50:16-22). Defendant's expert, Dr. Augsburger, disagreed, opining that these terms mean a "process resulting in the production of a layer of sodium picosulfate substantially evenly surrounding the potassium bicarbonate core." (Tr. at 415:10-19). Dr. Augsburger further opined that a "layer" is "a structural component of the sodium picosulfate/potassium bicarbonate granules that substantially evenly surrounds the potassium bicarbonate core." (*Id.* at 419:20-420:12).

Plaintiffs argue that Defendant is attempting to reargue claim construction. (D.I. 177 at 29). Defendant counters that its expert, Dr. Augsburger, relied on "the Court's *Markman* hearing transcript, the context of the patents-in-suit, his experience and the relevant scientific literature."

(D.I. 181 at 8). Defendant argues that the term "coated" is used in the claims as an adjective while the term "coating" is used as a verb. (*Id.* at 9). This means, according to Defendant, that Plaintiffs' proposed plain and ordinary meaning "cannot be correct" because Plaintiffs' meaning requires these terms to be nouns. (*Id.*). I do not think that this grammatical inconsistency necessarily means that Defendant's meaning is correct. While Defendant's argument has merit, based solely on the question of proper grammar, the relevant issue for infringement is not what part of speech "coated" or "coating" is. Rather, the dispute is whether the sodium picosulfate layer must "substantially evenly surround" the core, as Defendant contends. Based on the record, I am not persuaded that it must.

I am dubious about Dr. Augsburger's purported reliance on scientific literature for arriving at his plain and ordinary meaning. Plaintiffs established at trial that Dr. Augsburger did not rely on technical dictionaries or other treatises in his expert report. (Tr. at 500:13-18). At trial, several scientific treatises were admitted into evidence without any meaningful discussion from Dr. Augsburger as to their relevance. (Tr. 422:4-424:22). No relevant passages were cited during direct examination. In post-trial briefing, however, Defendant's attorneys call out specific passages from these treatises that allegedly provide support for Dr. Augsburger's opinion. (D.I. 181 at 11-12). This post hoc attorney argument is inappropriate. Furthermore, none of Defendant's citations support Dr. Augsburger's proposal that the layer must "substantially evenly surround" the core.

I agree with Plaintiffs that Dr. Augsberger's opinion amounts to an attempt to reargue claim construction. It seems clear to me that Dr. Augsburger did not, in fact, rely on the scientific treatises Defendant cites in post-trial briefing in developing his plain and ordinary meaning for these terms. (Tr. at 487:9-493:22). Plaintiffs established on cross-examination that the only

evidence Dr. Augsburger consulted to arrive at his definition were the patent specification and the inventor's declaration. (*Id.* at 493:4-22). I considered this same intrinsic evidence during claim construction and rejected Defendant's attempt to use them to narrow the scope of the terms "coated" and "coating." (D.I. 74 at 32:6-10). In fact, Defendant's current proposal is not materially different from the construction it proposed, and I rejected, at claim construction.

Plaintiffs' expert, Dr. Davies proposed that the plain and ordinary meaning of these terms is "a layer of a substance, which is on the outer surface of another substance or material." (Tr. 50:16-22). Dr. Davies testified about his extensive experience doing research and consulting in the field of pharmaceuticals, including a substantial focus on different types of coatings used in pharmaceutical products. (*Id.* at 51:5-14). Dr. Davies further testified that there are many different types of coatings used in pharmaceutical products and that not all coatings look the same. (*Id.* at 51:14-53:6).

The claims of the '083 patent call for two types of coated granules: 1) citric acid granules coated with a layer of magnesium oxide; and 2) potassium bicarbonate granules coated with a layer of sodium picosulfate. ('083 patent, claim 1). The claims of the '338 patent call for potassium bicarbonate granules coated with a layer of sodium picosulfate. ('338 patent, claim 1). Dr. Davies explained that a person of ordinary skill in the art would expect the magnesium oxide layer coated on the citric acid core to be continuous because of the relative proportions of the two compounds given in the patent. (Tr. 56:5-10). On the other hand, because of the relative proportions of potassium bicarbonate and sodium picosulfate, a person of ordinary skill would expect the sodium picosulfate layer to be discontinuous. (*Id.* at 56:14-17). Dr. Davies opined that a person of ordinary skill in the art would still understand this to be a granule coated with a layer. (*Id.* at 56:18-57:6). Dr. Davies further explained that it would be impossible to create a layer of sodium

picosulfate "substantially evenly surrounding" the core because of the random nature of the spray-coating process. (*Id.* at 59:10-60:11).

I find Dr. Davies more credible than Dr. Augsburger both because his expertise is more closely aligned with the technology at issue than Dr. Augsberger's, and because he provided a more persuasive explanation for his proposal. I will adopt Dr. Davies' proposed plain and ordinary meanings of "coating" and "coated."

*2. Spray-Coating*

The parties dispute whether Defendant's process involves spray-coating or wet granulation. While both processes can be performed using the same equipment, they are distinct processes that produce different sized particles. (Tr. 198:5-200:14). Spray-coating involves spraying small droplets of a solution containing the coating material onto the core material. (Tr. 198:9-15). To achieve a spray-coating, the process conditions are such that the coating will dry very quickly. (Tr. 198:16-20). In wet granulation, on the other hand, the process conditions are such that the coating solution does not dry quickly, so that the granules remain wet and stick together to form agglomerates. (Tr. 199:5-20).

Plaintiffs' expert, Dr. Johnson, opined that Defendant's ANDA product is made using a spray-coating process. (D.I. 177 at 22). Dr. Johnson evaluated Defendant's process conditions and equipment configuration in arriving at his opinion. (*Id.* at 22-24). Dr. Johnson is an expert in powder mixing techniques and is qualified to opine on these issues. (*Id.* at 20). Plaintiffs argue Dr. Johnson is better qualified to opine on this issue than Defendant's expert, Dr. Augsburger, whose expertise is not in powders, but rather in tablet coating. (D.I. 182 at 4). Defendant argues in response that its product is manufactured by "agglomeration via a wet granulation process." (D.I. 181 at 15). Defendant makes a number of arguments in support of this contention, none of

which I find persuasive.

Defendant first argues that its ANDA characterizes the process as wet granulation, evidence Defendant believes is dispositive of the issue. (*Id.* at 16). I disagree. The word Defendant uses to characterize its own process is neither dispositive, nor even persuasive in the face of substantial evidence that its process employs spray-coating rather than wet granulation. The process must be considered as a whole, as Dr. Johnson persuasively opined during direct examination. (Tr. 229:12-230:9). Furthermore, while Defendant sometimes refers to the process as wet granulation, Plaintiffs pointed out at trial that some of Defendant's own lab notebooks reference using a spray-coating process. (Tr. 241:1-243:7).

Defendant next argues that its manufacturing equipment is configured for agglomeration via wet granulation, and that this configuration is not appropriate for spray-coating. (D.I. 181 at 16). There is no dispute that the equipment is used in a "top spray configuration." (Tr. 240:4-9, 452:18-21). Defendant suggests that this configuration "is known to agglomerate granules via wet granulation." (D.I. 181 at 16). Defendant's own expert, Dr. Augsburger, admitted during cross-examination, however, that this piece of equipment can be used in the top spray configuration for granulation or coating. (Tr. 507:12-508:6). Dr. Augsburger also admitted determining whether the process employs coating or wet granulation requires examining the processing conditions. (Tr. 508:7-19). It seems clear to me that the fact that this equipment is used in the "top spray configuration" does not prove anything about whether Defendant's process is wet granulation or spray-coating.

Defendant next argues that its process parameters, including temperature and humidity, indicate that the process is wet granulation. (D.I. 181 at 17). Specifically, Defendant argues that its temperature and humidity conditions "closely track" exemplary conditions for wet granulation

disclosed in the scientific literature. (*Id.*). Defendant contends that this "objective evidence" for wet granulation "went unrebutted at trial." (*Id.*). Defendant further argues that the amount of drug solution used in its process also points to wet granulation. (*Id.* at 17-18). I am not persuaded that a single reference from the scientific literature that shows a set of "exemplary" conditions is sufficient evidence to prove Defendant's process is wet granulation. I also do not think this evidence was "unrebutted." Plaintiff's expert, Dr. Johnson, testified in detail about Defendant's processing conditions and why those conditions indicate to a person of ordinary skill in the art that Defendant's process is spray-coating rather than wet granulation. (Tr. 220:7-239:2). Dr. Johnson emphasized that the process must be considered as a whole, rather than looking to each process setting individually, in order to determine whether the process is spray-coating or wet granulation. (Tr. 238:10-16). Dr. Johnson opined that the process parameters, taken together, indicated that Defendant's process did not produce large enough droplets and the end product did not have a high enough residual moisture content for wet granulation. (Tr. 237:14-19). Dr. Johnson emphasized that Defendant's process is "very dry," involving "rapid evaporation and rapid drying" and these conditions are not favorable to wet granulation, which requires "much wetter" conditions. (Tr. 237:20-238:2). I do not think that Defendant's reliance on a single graph from the literature that purportedly represents "exemplary" wet granulation conditions is sufficient to rebut Dr. Johnson's detailed testimony about Defendant's process.

Defendant next argues that the separate drying step it employs is evidence that its process is wet granulation. (D.I. 181 at 18). I am not persuaded. Dr. Augsburger did not opine that a spray-coating process never involves a separate drying step. Rather, he testified that "it's not uncommon in a granulation to have a step like that." (Tr. 471:18-10). This is insufficient to rebut Dr. Johnson's credible testimony that Defendant's ANDA process, viewed as a whole, is spray-

coating rather than wet granulation.

Defendant attempts to discredit Dr. Johnson by arguing that he did no physical analysis on Defendant's products, his opinions are not supported by the scientific literature, and there are "gaps" in his reasoning process. (D.I. 181 at 19-22). Defendant suggests that it is "improper" for Dr. Johnson to base his opinion on the information in Defendant's ANDA and his knowledge and experience as a person of ordinary skill in the art. (*Id.* at 19). I disagree. As Dr. Johnson explained, the information he needed to form his opinion was present in the batch processing records. (Tr. 206:22-207:7). Furthermore, Plaintiffs' other expert, Dr. Davies, did conduct physical testing and Dr. Johnson referred to the results of those tests as evidence supporting his infringement opinion. (Tr. 236:18-237:4).

Defendant also criticizes Dr. Johnson for failing to cite to scientific literature that would show how a person of skill in the art would distinguish between spray-coating and wet granulation. (D.I. 181 at 20). I am not persuaded. Dr. Johnson has significant experience in spray-coating pharmaceutical products and he provided a detailed explanation of Defendant's process, including an explanation of how he would change the process parameters to achieve wet granulation instead of spray-coating.

Finally, I fail to see the purported "gaps" in Dr. Johnson's reasoning process. Defendant suggests that because Dr. Johnson did not opine on whether Defendant's product has a "coating," he had no basis for concluding that Defendant's process employs spray-coating. (*Id.* at 21). What Defendant fails to recognize, however, is that Dr. Davies testified that Defendant's product has a coated layer. (Tr. 113:22-115:1). Dr. Johnson adopted this finding and further analyzed Defendant's process to determine that this process employs spray-coating. (Tr. 264:10-24). There is nothing improper about Dr. Johnson's adoption of Dr. Davies' conclusion. The other "gaps"

Defendant points to are not gaps at all, but rather attacks on Dr. Johnson's testimony regarding individual process parameters. (D.I. 181 at 19). These arguments misconstrue Dr. Johnson's testimony and focus on individual parameters instead of the process as a whole. Defendant has not persuaded me that Dr. Johnson's analysis suffers from any "gaps."

I find Dr. Johnson's detailed testimony about Defendant's ANDA manufacturing process persuasive and more credible than Dr. Augsburger's. I hold that Defendant's process employs spray-coating.

*3. Layer of Sodium Picosulfate Coating a Potassium Bicarbonate Core*

Defendant contends that Plaintiffs have not established that the proposed ANDA product meets the "layer of sodium picosulfate" limitation of the asserted claims. (D.I. 181 at 23). Defendant first argues that the images presented by Plaintiffs show "only the presence of five small, discrete spots of sodium picosulfate," rather than a layer "substantially evenly surrounding" the core as Defendant contends is required. (*Id.*). I have already rejected Defendant's argument that the layer must "substantially evenly surround" the core. As Defendant makes no argument that their ANDA product does not meet this limitation under Plaintiffs' proposed plain and ordinary meaning, which I find credible, this first argument is moot.

Defendant next argues that Plaintiffs' Raman images show the presence of sodium picosulfate inside the potassium bicarbonate core rather than only on the surface of the core. (*Id.* at 25). Defendant's expert, Dr. Augsburger, testified that these images are "highly suggestive . . . of a crystal bridge connecting those, which is what happens in an agglomeration process." (Tr. 449:24-450:3). Defendant's other expert, Dr. Griffiths, also stated his conclusion that the images show sodium picosulfate inside the core. (Tr. 389:7-24). I am not persuaded.

Dr. Davies analyzed the images Defendant's experts pointed to as evidence of sodium

picosulfate inside the granule and opined on why he, as a person of ordinary skill in the art, concluded the sodium picosulfate was actually on the surface. (Tr. 99:14-102:24). For example, Dr. Davies explained that the granules are not smooth, but rather have crevices and cracks in which sodium picosulfate can lodge. (Tr. 99:22-100:1). Dr. Davies also discussed what a Raman image would look like if the particles being imaged were aggregates formed by wet granulation, as Defendant's experts opined. (Tr. 101:21-102:24). None of the images were consistent with aggregates. (Tr. 102-13-24).

Dr. Davies is an expert in Raman spectroscopy, the technique used to produce the images. (Tr. 34:16-35:4; PTX0002). Dr. Augsburger, on the other hand, is not an expert in Raman spectroscopy and, in fact, has never performed Raman spectroscopy. (Tr. 501:13-18). I find Dr. Davies' explanations of the Raman images and his rebuttal of Dr. Griffiths' analysis credible. I hold that Plaintiffs have established that Defendant's ANDA product contains a layer of sodium picosulfate.

*4. Downstream Processing*

At trial, Defendant argued that its product is materially changed during downstream processing such that any layer of sodium picosulfate that may have been formed would be subsequently destroyed. (Tr. 480:2-484:4). Defendant makes only passing reference to this argument in a single footnote in its post-trial briefing. (D.I. 181 at 23 n.15). Defendant cites Dr. Augsburger's testimony at trial that he "would feel that the layer would have been disrupted," and he "would expect any coating to be also fractured, rubbed off or somehow changed." (Tr. 481:2-3; 482:5-9). I find this purely speculative testimony unconvincing. Dr. Davies testified that the experimental data showed the presence of sodium picosulfate on the outer surface of the granules after the downstream processing steps. (Tr. 146:6-13). I find there is no evidence that downstream

processing alters the layer of sodium picosulfate on Defendant's proposed ANDA product.

## III. CONCLUSION

Plaintiffs have met their burden of proving by a preponderance of the evidence that Defendant's proposed ANDA product infringes claims 1, 4-6, 8, 9-12, and 17-18 of the '338 patent and claims 1 and 7-11 of the '083 patent.

Plaintiffs should submit an agreed upon form of final judgment within two weeks.