

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

FERRING B.V.,

Plaintiff,

vs.

WATSON LABORATORIES, INC. - (FL) et al.,

Defendants.

3:11-cv-00481-RCJ-VPC

ORDER

FERRING B.V.,

Plaintiff,

vs.

APOTEX, INC. et al.,

Defendants.

3:11-cv-00485-RCJ-VPC

ORDER

FERRING B.V.,

Plaintiff,

vs.

WATSON PHARMACEUTICALS, INC. et al.,

Defendants.

3:11-cv-00853-RCJ-VPC

ORDER

FERRING B.V.,

Plaintiff,

vs.

APOTEX, INC. et al.,

Defendants.

3:11-cv-00854-RCJ-VPC

ORDER

1 These four consolidated cases arise out of Defendants’ application with the Food and
2 Drug Administration (“FDA”) to manufacture and sell generic versions of a patented drug.
3 Pending before the Court are the parties’ claim construction briefs.

4 **I. FACTS AND PROCEDURAL HISTORY**

5 These cases arise out of the alleged infringement of Plaintiff Ferring B.V.’s (“Ferring”) U.S. Patent No. 7,947,739 for tranexamic acid tablets sold under the trademark Lysteda® (the
6 “‘739 Patent” or “Tablet Patent”), (*see* Compl. ¶¶ 13–17, July 7, 2011, ECF No. 1; Compl. ¶¶
7 9–13, July 8, 2011, ECF No. 1 in Case No. 3:11-cv-00485), and the alleged infringement of
8 Ferring’s U.S. Patent No. 8,022,106 for tranexamic acid formulations and methods of treating
9 menorrhagia therewith (the “‘106 Patent” or “Formulas and Treatment Patent”), (*see* Compl. ¶¶
10 13–17, Nov. 25, 2011, ECF No. 1 in Case No. 3:11-cv-00853; Compl. ¶¶ 9–13, Nov. 25, 2011,
11 ECF No. 1 in Case No. 3:11-cv-00854).¹ In the ‘481 and ‘485 Cases, respectively, Ferring sued
12 several Watson Labs entities (collectively, “Watson Defendants”) and several Apotex entities
13 (collectively, “Apotex Defendants”) in this Court for infringing the ‘739 Patent. In the ‘853 and
14 ‘854 Cases, respectively, Ferring sued several Watson Defendants and several Apotex
15 Defendants in this Court for infringing the ‘106 Patent.

16 The Court consolidated the four cases, with the ‘481 Case as the lead case. It also
17 granted motions to dismiss the counterclaims for invalidity and to strike affirmative defenses for
18 invalidity in the ‘481 and ‘854 Cases, with leave to amend. The Court ruled that affirmative
19 defenses must specify a distinct legal theory of invalidity under Rule 8(c) but need not be pled
20 according to the *Iqbal* plausibility standard, as the counterclaims must be under Rule 8(a).
21 Watson Defendants and Apotex Defendants amended their answers and counterclaims,
22 accordingly. (*See* ECF Nos. 93, 94). Apotex Defendants later further amended its answer and
23

24
25 ¹Unless otherwise noted, the docket numbers in this document refer to Case No. 3:11-cv-00481.

1 counterclaim. The Court has denied motions to dismiss the amended counterclaims for
2 invalidity.

3 In preparation for the *Markman* hearing, and in accordance with the local rules, the
4 parties submitted a Joint Claim Construction and Prehearing Statement (“JCCPHS”), in which
5 they claim to have exchanged proposed terms for claim construction, met and conferred
6 regarding those proposed terms, and exchanged preliminary constructions and supporting
7 evidence. The parties agreed on none of the terms that they believe the Court must construe.
8 The Court held a *Markman* hearing.

9 **II. LEGAL STANDARDS**

10 “[T]he interpretation and construction of patent claims, which define the scope of the
11 patentee’s rights under the patent, is a matter of law exclusively for the court.” *Markman v.*
12 *Westview Instruments, Inc.*, 52 F.3d 967, 970–71 (Fed. Cir. 1995) (en banc) (affirming a district
13 court’s grant of a motion for judgment as a matter of law after a jury found infringement based
14 upon its incorrectly broad construction of a patent claim).² Despite pre-*Markman* inconsistencies
15 in the Federal Circuit’s case law on the question of whether a jury properly had any role in
16 construing patent claims, the Supreme Court had consistently ruled that claim construction was a
17 purely legal issue. *Id.* at 977–78 (collecting cases). This is because a patent claim, like a
18 contract, is a written instrument uniquely suited to interpretation by a court as a matter of law.
19 *Id.* at 978.

20 A “*Markman* hearing” is an extended evidentiary hearing culminating in a claim
21 construction order, the language of which will inform the jury as to its determination of
22 infringement at the trial itself. At the hearing, a district court hears evidence concerning the
23 claims, the specifications, the prosecution history, and any extrinsic evidence helpful to the court

24
25 ²“Claim construction” and “claim interpretation” are synonymous in the patent law
context. *Id.* 52 F.3d at 976 n.6.

1 in understanding the patent:

2 To ascertain the meaning of claims, we consider three sources: The claims,
3 the specification, and the prosecution history. Expert testimony, including evidence
4 of how those skilled in the art would interpret the claims, may also be used. . . .

4 Claims must be read in view of the specification, of which they are a part.
5 The specification contains a written description of the invention that must enable one
6 of ordinary skill in the art to make and use the invention. For claim construction
7 purposes, the description may act as a sort of dictionary, which explains the
8 invention and may define terms used in the claims. As we have often stated, a
9 patentee is free to be his own lexicographer. The caveat is that any special definition
10 given to a word must be clearly defined in the specification. The written description
11 part of the specification itself does not delimit the right to exclude. That is the
12 function and purpose of claims.

9 To construe claim language, the court should also consider the patent's
10 prosecution history, if it is in evidence. This undisputed public record of
11 proceedings in the Patent and Trademark Office is of primary significance in
12 understanding the claims. The court has broad power to look as a matter of law to
13 the prosecution history of the patent in order to ascertain the true meaning of
14 language used in the patent claims. . . . Although the prosecution history can and
15 should be used to understand the language used in the claims, it too cannot enlarge,
16 diminish, or vary the limitations in the claims.

13 Extrinsic evidence consists of all evidence external to the patent and
14 prosecution history, including expert and inventor testimony, dictionaries, and
15 learned treatises. This evidence may be helpful to explain scientific principles, the
16 meaning of technical terms, and terms of art that appear in the patent and prosecution
17 history. Extrinsic evidence may demonstrate the state of the prior art at the time of
18 the invention. It is useful to show what was then old, to distinguish what was new,
19 and to aid the court in the construction of the patent.

18 The court may, in its discretion, receive extrinsic evidence in order to aid the
19 court in coming to a correct conclusion as to the true meaning of the language
20 employed in the patent.

20 Extrinsic evidence is to be used for the court's understanding of the patent,
21 not for the purpose of varying or contradicting the terms of the claims. When, after
22 considering the extrinsic evidence, the court finally arrives at an understanding of the
23 language as used in the patent and prosecution history, the court must then
24 pronounce as a matter of law the meaning of that language. This ordinarily can be
25 accomplished by the court in framing its charge to the jury, but may also be done in
26 the context of dispositive motions such as those seeking judgment as a matter of law.

24 Through this process of construing claims by, among other things, using
25 certain extrinsic evidence that the court finds helpful and rejecting other evidence as
unhelpful, and resolving disputes en route to pronouncing the meaning of claim
language as a matter of law based on the patent documents themselves, the court is

1 not crediting certain evidence over other evidence or making factual evidentiary
2 findings. Rather, the court is looking to the extrinsic evidence to assist in its
3 construction of the written document, a task it is required to perform. The district
4 court’s claim construction, enlightened by such extrinsic evidence as may be helpful,
5 is still based upon the patent and prosecution history.

6 *Id.* at 979–81 (internal quotation marks, footnotes, and citations omitted). The Supreme Court
7 unanimously affirmed. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996)
8 (“We hold that the construction of a patent, including terms of art within its claim, is exclusively
9 within the province of the court.”).

10 Certain kinds of evidence are given more weight than other kinds, in the following order:
11 terms as used within the claims themselves, the descriptive part of the specifications, the patent
12 prosecution history, and finally, extrinsic evidence, which is inherently less reliable than intrinsic
13 evidence and is therefore only viable for use in interpreting claims directly where the available
14 intrinsic evidence is insufficient. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314–19 (Fed. Cir.
15 2005) (en banc). Claims are given their ordinary meaning as they would be understood by a
16 person of ordinary skill in the relevant art at the time of the effective filing date of the patent. *Id.*
17 at 1312–13.

18 **III. ANALYSIS**

19 In Exhibits A, B, and C to the JCCPHS, respectively, Plaintiff, Watson Defendants, and
20 Apotex Defendants have adduced their proposed claim constructions and specified supporting
21 evidence. Plaintiff has used a memorandum format, and Defendants have used table formats.
22 Although styled as “claim constructions,” the parties have not adduced proposed claim
23 constructions as to entire claims but have proposed definitions for certain terms included within
24 the claims.

25 **A. The ‘739 Patent**

1. The Claims

The purpose of the ‘739 Patent is to create “modified release oral tranexamic acid

1 formulations that preferably minimize or eliminate undesirable side effects and methods of
2 treatment with these formulations.” (See ‘739 Patent col. 1, ll. 16–19, ECF No. 204 Ex. 1).
3 Tranexamic acid is used to control bleeding during dental surgery on hemophiliacs and during
4 menstruation. (See *id.* col. 1, ll. 33–36). Women using the drug typically ingest 3–6 grams a day,
5 but this dosage can cause negative gastrointestinal side effects—effects the ‘739 Patent aims to
6 minimize or eliminate via a modified release mechanism that prevents excess tranexamic acid
7 from collecting in the stomach and intestinal tract. (See *id.* at col. 1, ll. 36–51; *id.* col. 6, ll.
8 3–18). The ‘739 Patent makes nineteen claims, three of which are independent (Claims 1, 11,
9 and 16), ten of which depend on Claim 1 (Claims 2–6, 8–10, 12–13), two of which depend in
10 turn on Claim 5 (Claims 7 and 14), one of which depends further in turn on Claim 14 (Claim 15),
11 one of which depends on Claim 11 (Claim 18), one of which depends in turn on Claim 18 (Claim
12 19), and one of which depends on Claim 16 (Claim 17). Plaintiff has not specified which of the
13 claims Defendants are alleged to have infringed but only that they have infringed “at least one of
14 the claims.”

15 Claim 1 reads:

16 A tranexamic acid tablet formulation, comprising:

17 tranexamic acid or a pharmaceutically acceptable salt thereof; and

18 a modified release material, wherein the modified release material comprises
19 a polymer selected from the group consisting of hydroxyalkylcelluloses,
alkylcelluloses, cellulose ethers, partial esters thereof, and mixtures thereof;

20 wherein the modified release material is present in the formulation in an
21 amount from about 10% to about 35% by weight of the formulation;

22 wherein the formulation provides an in-vitro dissolution release rate of the
23 tranexamic acid or pharmaceutically acceptable salt thereof, when measured
24 by the USP 27 Apparatus Type II Paddle Method @ 50 RPM in 900 mL
25 water at $37\pm 0.5^{\circ}\text{C}$, of less than about 70% by weight tranexamic acid or
pharmaceutically acceptable salt thereof released at about 45 minutes, and
about 100% by weight tranexamic acid or pharmaceutically acceptable salt
thereof released by about 120 minutes; and

1 wherein each tablet of the formulation provides a dose of about 650 mg of
2 tranexamic acid.

3 (*See id.* col. 69, ll. 45–67). First, the claim includes any “pharmaceutically acceptable salt” of
4 tranexamic acid within its definition of “tranexamic acid” in the first limitation, in order to allow
5 for tablets comprised of various salts of tranexamic acid. The Claim therefore covers tablets not
6 only with tranexamic acid itself, but tablets with any salt of tranexamic acid that is suitable for
7 human ingestion. Second, the claim includes the significant limitation that the “modified release
8 material” in the tablet must be “a polymer selected from the group consisting of
9 hydroxyalkylcelluloses, alkylcelluloses, cellulose ethers, partial esters thereof, and mixtures
10 thereof.” Tablets with modified release materials comprised of other substances are therefore
11 not claimed. Third, only tablets where the modified release material is present between “about”
12 10% and 35% are covered. Because the term “about” is not readily capable of mathematical
13 translation, unless the term is addressed in the specifications, which it is not, expert testimony
14 may be relevant to understand the scope of the range claimed. Fourth, the claim is limited to
15 tablets where less than “about” 70% of the weight of the tranexamic acid in the tablet is
16 released after “about” 120 minutes under the specified laboratory conditions. Fifth, the claim is
17 limited to tablets that deliver a dose of “about” 650 mg of tranexamic acid. Also, the phrase “or
18 a pharmaceutically acceptable salt thereof” does not appear in the fifth limitation, likely because
19 once administered, the acid (the positive ion) dissociates from the negative ion (a chloride or the
20 like), whereas the solid tablet as described in the first limitation may exist as a “salt,” i.e.,
21 molecules or matrices of positive acid ions and negative ions such as halogens, as opposed to
22 hydroxide.

23 Claim 2 adds a sixth limitation to Claim 1 wherein about 15-29% by weight of the acid is
24 released under the specified laboratory conditions by about 15 minutes, about 56-69% is released
25 by about 45 minutes, and about 89-100% by about 90 minutes.

1 Claim 3 adds a sixth limitation to Claim 1 wherein the tablet consists of a “matrix tablet,”
2 i.e., “a pregranulated drug mixed together with the modified release material.”

3 Claim 4 adds a sixth limitation to Claim 1 wherein the modified release material
4 comprises a hydroxyalkylcellulose or a cellulose ether.

5 Claim 5 adds a sixth limitation to Claim 1 wherein the modified release material
6 comprises hydroxypropylmethylcellulose.

7 Claim 6 adds a sixth limitation to Claim 1 wherein the modified release material is
8 present in about 15% by weight of the formulation.

9 Claim 7 adds a seventh limitation to Claim 5 wherein the modified release material is
10 present in about 15% by weight of the formulation.

11 Claim 8 adds a sixth limitation to Claim 1 wherein a single administration of a dose of
12 1300 mg (two tablets) provides a maximum plasma concentration of tranexamic acid from about
13 9 to 14.5 mcg/mL.

14 Claim 9 adds a sixth limitation to Claim 1 wherein a single administration of a dose of
15 1300 mg (two tablets) provides a maximum plasma concentration of tranexamic acid from about
16 12.5 to 25 mcg/mL.

17 Claim 10 adds a sixth limitation to Claim 1 wherein the time to the maximum plasma
18 concentration of tranexamic acid is about two to three-and-a-half hours after a single dose.

19 Claim 11 is a variation of Claim 1 also containing five limitations. The second limitation
20 is modified to specify an “effective amount of” a modified release material, and the fourth
21 limitation is modified to specify that the formulation releases about 10% to 25% by weight of the
22 tranexamic acid or salt thereof every 15 minutes, and all of the acid within 120 minutes.

23 Claim 12 adds a sixth limitation to Claim 1 wherein the administration of a dose of 1300
24 mg (two tablets) three times daily provides a mean maximum plasma concentration of
25 tranexamic acid from about 10 to 20 mcg/mL after multi-dose administration.

1 Claim 13 adds a sixth limitation to Claim 1 wherein a single administration of a dose of
2 1300 mg (two tablets) provides a mean maximum plasma concentration of tranexamic acid from
3 about 9 to 17.5 mcg/mL.

4 Claim 14 adds a seventh limitation to Claim 5 wherein the hydroxypropylmethylcellulose
5 is present in about 10% to 35% by weight of the formulation.

6 Claim 15 adds an eighth limitation to Claim 14 wherein the
7 hydroxypropylmethylcellulose is present in about 15% by weight of the formulation.

8 Claim 16 is a variation of Claim 1 containing four limitations. The second and third
9 limitations of Claim 1 are modified into a single second limitation of Claim 16 requiring that
10 hydroxypropylmethylcellulose is present in about 10% to 35% by weight of the formulation.

11 Claim 17 adds a fifth limitation to Claim 16 wherein the hydroxypropylmethylcellulose is
12 present in about 15% by weight of the formulation.

13 Claim 18 adds a sixth limitation to Claim 11 wherein hydroxypropylmethylcellulose is
14 present in about 10% to 35% by weight of the formulation.³

15 Claim 19 adds a seventh limitation to Claim 18 wherein hydroxypropylmethylcellulose is
16 present in about 15% by weight of the formulation.

17 **2. The Parties' Proposed Claim Constructions**

18 **a. "tablet formulation"**

19 Plaintiff proposes that this term means "active pharmaceutical ingredient and excipients
20 compressed together." In other words, according to Plaintiff, "tablet formulation" means the
21 entire pill, including inactive substances that are a part of the tablet a patient swallows.

22 Defendants propose that this term means "a finished oral dosage form in tablet form." It is not
23

24 ³Although written as dependent on Claim 11, it appears that Claim 18 was originally
25 intended to be independent, because it includes four of its own limitations, three of which are
redundant with limitations already present under Claim 11. The result is the same.

1 clear what the difference between these two definitions is, but Plaintiff's definition is clearer. It
2 is also a more straightforward and commonsense definition. The term "dosage" would appear to
3 refer to the amount of active ingredient to be given to a patient (in some form), and the term
4 "tablet dosage" would appear to refer to this amount of active ingredient compressed into a
5 tablet, together with any amount of inactive substance. But the term "tablet formulation" would
6 appear to refer to the formula of a tablet as a whole, i.e., the percentages of active and inactive
7 ingredients in the entire tablet. As such, Plaintiff's construction appears to be correct, and
8 Defendants' construction does not appear to contradict it, though it is unnecessarily confusing
9 and unclear. What is "a finished oral dosage form in tablet form?" The "form" of the object is a
10 tablet. A dosage is not a "form" but a quantity, i.e., a mass or a volume of active ingredient.
11 Therefore, a better construction in Defendants' style would read, "a finished oral dosage in tablet
12 form." But what is a "finished" dosage as opposed to an "unfinished" dosage? Do Defendants
13 simply mean to imply that "tablet formulation" applies only to tablets that have been completely
14 manufactured and not those that have only been partially manufactured? How could such a
15 construction aid Defendants? Do they intend to argue that they sell or intend to sell only
16 "unfinished" tablets, as opposed to "finished" tablets? Aren't the tablets they allegedly sell or
17 intend to sell "finished" by definition once they are taken off the assembly line? An even better
18 construction in Defendants' style would therefore read, "an oral dosage in tablet form." And
19 how is this different from "active pharmaceutical ingredient and excipients compressed
20 together?" Plaintiff's construction better explains what "tablet formulation" means. The
21 common meanings of these words as used in the claims are sufficient to construe the term, and
22 the Court need not examine the specifications, patent prosecution history, or extrinsic evidence.

23 **b. "modified release material"**

24 Plaintiff proposes that this term means "a material that modifies the release of the active
25 pharmaceutical ingredient." In other words, an excipient material in a tablet that alters the rate

1 of release of the active pharmaceutical ingredient. Defendants propose that this term means “a
2 polymer selected from the group of hydroxyalkylcelluloses, cellulose ethers, or partial esters
3 thereof that act to slow the release of tranexamic acid in the water medium used in the 27 USP
4 Apparatus Type II test.” In other words, Defendants’ wish to limit the term to very particular
5 kinds of materials (hydroxyalkylcelluloses, cellulose ethers, or partial esters thereof) and also to
6 note that the rate refers specifically to the rate achieved under particular test conditions.

7 The Court adopts Plaintiff’s construction. Each of the independent claims that include
8 the present term contain limitations that make Defendants’ proposed construction either partially
9 redundant or plainly incorrect. For example, the independent claims already indicate as a
10 limitation that the modified release material must be made of the substances Defendants specify
11 in their proposed construction of the term “modified release material,” or some other more
12 specific substance. And in some of the claims, the composition of the modified release material
13 is further limited in such a way that the independent claims would be rendered internally
14 inconsistent if the term “modified release material” were to be construed always to imply the
15 limitations on composition separately identified in the limitations of the independent claims.
16 Defendants’ language about the function of the modified release material is also redundant in
17 light of the separate limitations in the independent claims indicating the function.

18 **c. “release rate”**

19 Plaintiff proposes that this term means “the percentage of active pharmaceutical
20 ingredient released in a given time.” Defendants propose that this term means “the rate at which
21 tranexamic acid or a pharmaceutically acceptable salt thereof is released from the tablet
22 formulation in the water medium used in the 27 USP Apparatus Type II test.”

23 Defendants are correct that the summary of the invention in the specifications indicates
24 that release rate is measured specifically. (*See, e.g.*, ‘739 Patent col. 6, ll. 56–60). In fact, the
25 release rate is defined in the claims and throughout the specifications even more specifically as

1 “when measured by the USP 27 Apparatus Type II Paddle Method @ 50 RPM in 900 mL water
2 at $37\pm 0.5^{\circ}\text{C}$.” (*See id. passim*). The Court adopts Plaintiff’s construction. The construction
3 Defendants propose unnecessarily imports additional information from the specifications and is
4 redundant with limitations in the claims.

5 **d. “about 10% to about 35% by weight of the formulation”**

6 Plaintiff proposes that this term includes quantities within 10% of the specified value. It
7 is not clear whether Plaintiff means 0% to 45%, which is an unlikely interpretation of “about
8 10% to about 35%,” or whether it means 9% to 38.5%, which is obtained by subtracting or
9 adding 10% of the limits of the range, respectively. Defendants propose that this term includes a
10 range of 9.5% to 36.75% by weight, which corresponds to the subtraction or addition of 5% to
11 the limits of the range, respectively.

12 The claims and the specifications use the term “about” often but never attempt to define it
13 numerically. In 2007, the Federal Circuit was faced with the task of construing the term “about
14 1:5” in the context of the ratio of tramadol to acetaminophen in a pain reliever pill. *See Ortho-*
15 *McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321 (Fed. Cir. 2007). The parties
16 agreed that the term meant “approximately,” but the stipulation to a synonym still left the court
17 with no mathematically useful interpretation. *See id.* at 1326. The defendant argued that the
18 scope of the claim was no more than 5–10% of the specified ratio (1:5) due to the confidence
19 levels reported in the specifications of the patent, but the plaintiff argued that the scope of the
20 claim was a ratio from at least 1:3.6 to 1:7.1. *Id.* at 1324. The district court adopted the
21 plaintiff’s proposed construction based upon the claims and specifications, as well as the
22 extrinsic testimony of two medical doctors that the outer ratios argued by the plaintiff would be
23 statistically indistinguishable from 1:5 to a person of ordinary skill in the art. *Id.* The Court of
24 Appeals noted that words such as “about” are to be construed consistently with the technological
25 facts of a particular case. *See id.* at 1326 (quoting *Pall Corp. v. Micron Separations, Inc.*, 66

1 F.3d 1211, 1217 (Fed. Cir. 1995)). The court concluded that in the case before it, the plaintiff's
2 patent used ratios both alone and in ranges, and the court therefore concluded that "one of
3 ordinary skill in the art would understand the inventors intended a range when they claimed one
4 and something more precise when they did not." *Id.* at 1327. Two concise paragraphs of the
5 specifications of the patent at issue discussed common ranges of tramadol–acetaminophen ratios
6 in pills, optimal ranges of tramadol–acetaminophen ratios, and then concluded by noting that the
7 patent included the discrete ratios of 1:1 and 1:5. *Id.* The Court of Appeals reasoned:

8 These paragraphs suggest that the qualifier "about" is narrow because to find
9 otherwise would allow the scope of the more specifically identified ratio, 1:5, to
10 encompass a range of ratios that could potentially render meaningless another
11 claim's limitation, namely the 1:1 limitation.

12 Furthermore, the data points from the experiments described in the
13 specification support a conclusion that the more specifically identified ratio of 1:5
14 was meant to encompass compositions very close to that ratio. The experiments
15 disclosed in the specification show data points for ratios of tramadol to
16 acetaminophen in the lower ratio quadrant of 1:1, 1:3, 1:5, 1:5.7, and 1:15. Yet, the
17 patentees chose to specifically claim ratios of 1:1 and 1:5. If the data suggested to
18 the inventors that a range of ratios in this lower ratio quadrant was desirable, they
19 could easily have claimed a ratio range of "about 1:1 to about 1:5," or even a ratio
20 range of "about 1:3 to about 1:5," but they did not. Instead, they chose a specific
21 data point for claim 6 of precisely 1:5. Moreover, the identification of the 1:5 ratio
22 in both claim 6 and the specification is especially important when the only other
23 specifically identified ratio is close to it, 1:1, and the other claims point to a broad
24 range of ratios. This dichotomy between the specific ratio of 1:5 and the broader
25 ratio ranges of the other claims points to a narrow scope for the "about 1:5"
limitation.

Id. at 1327–28 (citations omitted).

19 Here, the parties dispute the meaning of "about" in the context of a claim limitation that
20 the modified release material is present in "about" 10% to 35% by weight of the tablet. In
21 support of its position, Plaintiff points to the claims themselves and to specifications within the
22 patent that recount the preparation of 84.5 kg batches of 650 mg tablets, but which do not
23 indicate any variation in the concentration of modified release material either by batch or by
24 tablet. (*See* '739 Patent col. 28, l. 23 to col 29., l. 3). The ingredients in the "Example 1" batch
25

1 that appear to be polymers corresponding to the list in Claim 1 are Microcrystalline Cellulose NF
2 (Avicel PH 101) and Hypromellose, USP (Methocol K3 Premium LV), which are present in each
3 650 mg tablet in amounts of 44.25 mg and 147.00 mg, respectively, for a total modified release
4 material of 29.42% by weight, which is well within the 10% to 35% range of the third limitation
5 of Claim 1. (*See id.* tbl.1). In Example 2, the modified release materials are present at 21.73%.
6 (*See id.* tbl. 2). In Example 3, the modified release materials are present at 29.42%. (*See id.* tbl.
7 3). In Example 3a, the modified release materials are present at 21.73%. (*See id.* tbl. 3A). The
8 examples do not include error ranges. The percentage of each ingredient in each batch of tablets
9 is very precisely given, much more precisely than the ratios given in *Ortho-McNeil*, and no
10 ranges are suggested, either by design or as a result of error calculations. Defendants recount
11 much of this and then suggest a 5% variation down from 10% and up from 35%, i.e., a range of
12 9.5% to 36.75%, based upon the declarations of their expert and an FDA manual.

13 In summary, the 10% to 35% limitation appears to claim more than what was reported as
14 having been tested in the specifications, and this limitation already provides a large “about”-type
15 buffer for variation well beyond Defendants’ claimed industry-standard 5% variation and
16 Plaintiff’s claimed industry-standard 10% variation. Under these circumstances, where the
17 specifications indicate a level of precision far beyond that given in the claim, and where the
18 relevant limitation in the claim is already significantly broader than the range of precise
19 percentages given in the tests reported in the specifications, the Court might read the term
20 “about” in the claims to be superfluous, except to the extent it may refer to error extrinsic to the
21 intended design of the invention, such as manufacturing error. The Court will not ignore a term
22 in a claim, however. The Court rules that “about” means “approximately” and will instruct the
23 jury no more specifically. The jury can determine what the word “approximately” means.

24 ///

25 ///

1 **e. “about” as used in connection with an amount of active pharmaceutical**
2 **ingredient released**

3 Plaintiff proposes that this term includes quantities within 10% of the specified value.

4 Defendants propose that the term means “plus or minus 5% by weight of the stated value.” The
5 specifications include Table 10A, which lists percentages of dissolution at 15, 45, and 90
6 minutes for eleven batches of the formula represented in Example 1. (*See* ‘739 Patent tbl.10A).
7 As Defendants note, the greatest standard deviation within any batch was the standard deviation
8 for batch 3 at 45 minutes, which was 4.366%. (*See id.*). Most of the standard deviations are
9 between 2–3%. (*See id.*). Claim 1 claims dissolution of less than “about” 70% by weight by
10 “about” 45 minutes and “about” 100% by “about” 120 minutes. Table 10A indicates that in the
11 eleven tested batches, between 56% and 69% dissolution by 45 minutes.

12 The Court might adopt something more like Plaintiff’s construction of “about” in the
13 present context, because the specifications indicate that “about” in this context means anywhere
14 from 56% to 69%. (*See id.*). In fact, based upon the specifications, Plaintiff could plausibly
15 argue that the term “about” in the present context means up to a 20% variation in the specified
16 value, because 70% reduced by 20% is 56%, which is one of the results within the range given in
17 the relevant tests in the specifications. However, “about” in the present context could also be
18 interpreted to include only downward variations, not upward variations, because the claim uses
19 the upper level (in fact, one percentage point above the upper level) of the relevant tests in the
20 specifications as a starting point, as opposed to the midpoint. In light of the specifications,
21 “about 70%” in Claim 1 could be read to mean something like “51% to 76%,” which would
22 represent the 56% to 69% results in the specifications, with the USP-standard 10% variation
23 added for error. The term “about 100%” could likewise be read to mean something like “at least
24 89%.” There is no indication in Table 10A of the results at 120 minutes, which is relevant to
25 Claim 1, but the results at 90 minutes are between 89% and 100% dissolution. (*See id.*).

1 Although the specifications include no 120-minute results, because of the scientific principle of
2 entropy, there is no danger that the amount dissolved at 120 minutes is less than the amount
3 dissolved at 90 minutes. If anything, the patentee has claimed less than he might have based
4 upon the specifications.

5 On the other hand, the 56% to 69% numbers and the 89% to 100% numbers are
6 accounted for in the additional limitation given to Claim 1 by Claim 2, which claim itself uses
7 the term “about” to further modify those numbers, indicating that the term “about” in this context
8 has a broader meaning. This brings the Court back to a choice between a 5% and 10% variation.
9 The Court will rule as it has, *supra*, that “about” means “approximately,” and allow the parties to
10 argue the issue to the jury on this basis.

11 **f. “about” as used in connection with time values**

12 Plaintiff proposes that this term includes quantities within 10% of the specified value.
13 Defendants propose that the term means “plus or minus 2% of the stated point in time.” Plaintiff
14 points to the claims themselves and to Example 1 in the specifications, none of which is helpful
15 in interpreting the term.

16 The Court could find that the word “about” as it relates to time values leaves very little
17 room for variation. Although concentrations of chemicals at given times may vary from test to
18 test because of the difficulties in conducting complex chemical experiments, there is no reason
19 there should necessarily be significant variations in time values. Presumably, an experimenter is
20 capable of timing an experiment to at least the nearest second. There may be some experimental
21 variation in time measurements if the apparatus used to take the reading requires the
22 experimenter to do some “fidgiting” to remove a sample, insert a test probe, or the like. But the
23 specifications do not indicate what this time variation might be in the present context.

24 Defendants point out that the USP standards require measurements to be taken within 2% of the
25 stated time points. It is unclear where Plaintiff obtained its 10% figure. The Court will rule as it

1 has, *supra*, that “about” means “approximately,” and allow the parties to argue the issue to the
2 jury on this basis.

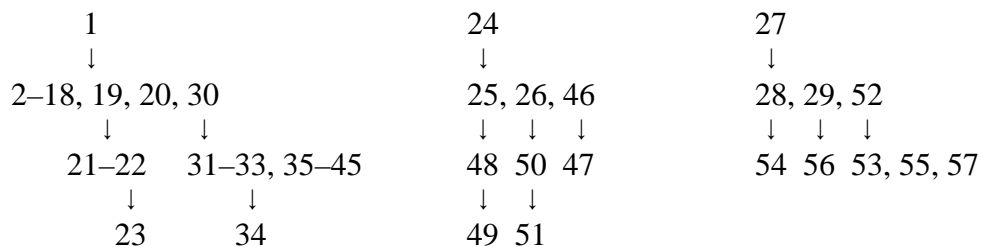
3 **g. “about” as used in connection with the maximum concentration of**
4 **tranexamic acid in blood plasma (“C_{max}”) and the time to reach C_{max} (“T_{max}”)**

5 Plaintiff proposes that this term includes quantities within 20% of the specified value.
6 Defendants propose, contrary to the presumption of validity, that “no construction [is] possible”
7 for this term. Plaintiff points to the specifications and industry standards indicating that if the
8 90% confidence interval of the mean ratio of C_{max} is within 80% to 125%, the formulations are
9 bioequivalent because of the inherent degree of variability between persons. Plaintiff argues that
10 this means the claims for C_{max} and T_{max} include a 20% variation. Defendants point to the
11 declaration of a doctor expert who claims that “about” in this context is insolubly vague and
12 not understandable to persons of skill in the art. The term “about” are not any vaguer as used
13 here than in the other instances. The Court will rule as it has, *supra*, that “about” means
14 “approximately,” and allow the parties to argue the issue to the jury on this basis.

15 **B. The ‘106 Patent**

16 **1. The Claims**

17 The purpose of the ‘106 Patent is the same as that of the ‘739 Patent. The claims in the
18 ‘106 Patent consist of variations of the claims in the ‘739 Patent, but the claims are more
19 numerous and further refined. The ‘106 Patent makes fifty-seven claims, the dependence of
20 which is illustrated in the following diagram:



24 ///

1 **2. The Parties' Proposed Claim Constructions**

2 **a. “dosage form”**

3 Plaintiff proposes that this term means “active pharmaceutical ingredient and excipients
4 together.” In other words, the physical state and chemical composition of the entire mass
5 intended to be ingested by the patient. Defendants do not address this term. The Court adopts
6 Plaintiff’s construction.

7 **b. “oral dosage form”**

8 Plaintiff proposes that this term means “active pharmaceutical ingredient and excipients
9 together, suitable for ingestion by mouth.” In other words, the physical state and chemical
10 composition of the entire mass intended to be ingested by the patient by mouth, which is a
11 logical extension of Plaintiff’s proposed interpretation of “dosage form.” Defendants propose
12 that the term means “a finished oral dosage form in which a drug is produced and dispensed.”
13 The Court adopts Plaintiff’s construction.

14 **c. “suitable for administration”**

15 Plaintiff proposes that this term means “capable of being given, taken, dosed, or
16 ingested.” Defendants propose that this term means “in a form approved by the FDA to be
17 administered to a human.” Plaintiff points to portions of the specifications concerning oral
18 dosages, ingestion by mouth in tablets of 0.5 to 1.0 grams, and dissolution in the stomach fluids.
19 Defendants point to no evidence indicating that this term implies approval by the FDA. The
20 Court adopts Plaintiff’s construction.

21 **d. “formulation”**

22 Plaintiff proposes that this term means “active pharmaceutical ingredient and excipients
23 together.” This is the same as Plaintiff’s proposed interpretation of “tablet formulation” under
24 the ‘739 Patent, minus the word “compressed,” and the same as its proposed interpretation for
25 “dosage form.” Defendants propose that the term means the same as “an oral dosage form.” The

1 Court adopts Plaintiff's construction.

2 **e. Remaining Terms**

3 The six remaining disputed terms under the '106 Patent are the same as six of the seven
4 disputed terms under the '739 Patent *supra*, excluding "tablet formulation," and the parties make
5 the same arguments as to their proper construction. The Court rules as it rules under the '739
6 Patent.

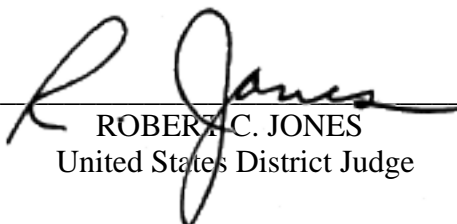
7 **CONCLUSION**

8 IT IS HEREBY ORDERED that the disputed terms are construed as follows:

Term	Construction
tablet formulation	active pharmaceutical ingredient and excipients compressed together
modified release material	a material that modifies the release of the active pharmaceutical ingredient
release rate	the percentage of active pharmaceutical ingredient released in a given time
about (in all challenged contexts)	approximately
oral dosage form	active pharmaceutical ingredient and excipients together, suitable for ingestion by mouth
dosage form	active pharmaceutical ingredient and excipients together
suitable for administration	capable of being given, taken, dosed, or ingested
formulation	active pharmaceutical ingredient and excipients together

9 IT IS SO ORDERED.

10 Dated this 6th day of February, 2013.

11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

ROBERT C. JONES
United States District Judge