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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
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NORTHERN DISTRICT OF CALIFORNIA

TAKEDA PHARMACEUTICAL CO., LTD.,
et al.,
Plaintiffs,
v.
IMPAX LABORATORIES, INC.,
Defendant.

Case No.C-11-01610 JCS

**ORDER RE SUMMARY JUDGMENT
MOTIONS [Docket Nos. 167, 174 (redacted
publicly filed versions); 169, 203 (sealed
versions)]**

~~FILED UNDER SEAL~~
[REDACTED VERSION]



United States District Court
Northern District of California

I. INTRODUCTION

Takeda Pharmaceutical Co., Ltd., Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (hereinafter, referred to collectively as "Takeda") initiated this action under 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, in response to Abbreviated New Drug Applications ("ANDA") 202-576 of Defendant Impax Laboratories, Inc. ("Impax") seeking approval of the United States Food and Drug Administration ("FDA") to manufacture and sell 30-mg and 60-mg generic versions of Takeda's drug DEXILANT (dexlansoprazole) ("the ANDA products"). Takeda alleges that Impax's ANDA products infringe U.S. Patent No. 6,462,058 ("the '058 Patent"), U.S. Patent No. 6,664,276 ("the '276 Patent"), U.S. Patent No. 6,939,971 ("the '971 Patent") and U.S. Patent No. 7,790,755 ("the '755 Patent") (collectively, "the Asserted Patents").¹

¹ In its complaint, Takeda also alleged that Impax's ANDA products infringed U.S. Patent No. 7,285,668 ("the '668 Patent"). However, on November 28, 2012, the Court dismissed Takeda's claims based on the '668 Patent, as well as Impax's counterclaims based on that patent, pursuant to the stipulation of the parties. See Docket No. 171.

1 Impax, in turn, asserts counterclaims seeking declaratory judgment that no valid claims of the
2 Asserted Patents are infringed.

3 Presently before the Court are the parties' cross-motions for summary judgment. [REDACTED]

4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
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15 [REDACTED]
16 [REDACTED]
17 [REDACTED] and 3) claims 6 and 7 of the '971 Patent are invalid because they lack adequate
18 written description. *See* Motion for Partial Summary Judgment ("Impax SJ Motion").

19 Hearings on the motions were held on February 8, 2013 and February 22, 2013. For the
20 reasons set forth below, Takeda's summary judgment motion is GRANTED. Impax's summary
21 judgment motion is GRANTED in part and DENIED in part.³
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25 [REDACTED]
26 [REDACTED] *See* Impax Opposition at 1 n. 1. Therefore, Takeda's request for
27 summary judgment of infringement is GRANTED as to those claims.

28 ³ The parties have consented to the jurisdiction of a United States Magistrate Judge pursuant to 28
U.S.C. § 636(c).

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II. BACKGROUND

A. The Accused Products

Impax is the owner of ANDA No. 202-576, which has been submitted to the FDA and which seeks approval to market dexlansoprazole delayed-release capsules in 30-mg and 60-mg dosage forms. Joint Statement of Undisputed Facts in Support of Impax Laboratories, Inc.’s Motion for Partial Summary Judgment (“JSUF (Impax Motion)”) ¶¶ 5-6.



B. The Asserted Claims of the '058 Patent

Takada asserts claims 1 and 3 of the '058 Patent against Impax. JSUF (Impax Motion) ¶ 2. Claim 1 of the '058 Patent requires “[a] crystal of (R)-2-(((3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl)methyl)sulfinyl)-1 H-benzimidazole wherein the X-ray powder diffraction analysis pattern has characteristic peaks at interplanar spacings (d) of 11.68, 6.77, 5.84, 5.73, 4.43, 4.09, 3.94, 3.89, 3.69, 3.41 and 3.11 Angstrom.” The parties have agreed that the term “(R)-2-(((3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl)methyl)sulfinyl)-1 H-benzimidazole” in the asserted patents refers to dexlansoprazole. JSUF (Takeda Motion) ¶ 7. The two-theta values that correspond to the d-spacings given in claim 1 of the '058 patent for the anhydrous crystal are listed in Table 2 of the '058 Patent and are as follows: 7.56, 13.06, 15.16, 15.44, 20.04, 21.72, 22.56, 22.82, 24.08, 26.12, and 28.68. *Id.* ¶ 8; '058 patent, col.11, tbl.2; Jorjani Motion Decl., Ex. 2 (Myerson Report (Impax)) ¶ 62. Claim 3 of the '058 Patent depends from claim 1 and requires “[a] pharmaceutical composition which comprises the crystal according to claim 1 and a pharmaceutically acceptable excipient, carrier or diluent.” Because claim 1 is directed at an isolated crystal, the infringement analysis as to that claim encompasses both the API and the formulated ANDA products; claim 3, however, requires a “pharmaceutical composition,” and therefore, the infringement inquiry addresses only the formulated ANDA products.

The Court has construed the term “a crystal of” in claims 1 and 3 of the '058 Patent to mean a “regularly repeating pattern of molecules with long range order extending in three dimensions.” Claim Construction Order at 70. The Court has construed the term “characteristic peaks at interplanar spacings (d)” in claim 1 of the '058 patent (and claim 7 of the '971 patent, described further below) to mean “peaks in the X-ray powder diffractogram of a crystal that uniquely identify that crystal, denoted by distances between lattice planes in a crystal as measured by a diffraction experiment and defined by Bragg’s law, within normal experimental error of X-ray powder diffraction.” *Id.* It is undisputed that Impax’s ANDA products are “pharmaceutical composition[s]” that contain at least one “pharmaceutically acceptable excipient.”

1 **C. The Asserted Claims of the '971 Patent**

2 Takeda asserts claims 6 and 7 of the '971 patent against Impax. JSUF (Impax Motion) ¶ 3.
3 Both claims depend from claim 5, which requires “[a] method of treating reflux esophagitis in a
4 mammal in need thereof which comprises administering to said mammal an effective amount of a
5 crystalline compound of (R)-2-(((3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl)methyl)sulfinyl)-
6 1 H-benzimidazole or a salt thereof and a pharmaceutically acceptable excipient, carrier or
7 diluent.” The Court has construed the term “effective amount” in claim 5 to mean “an amount
8 sufficient to help ameliorate or cure reflux esophagitis.” Claim Construction Order at 71.

9 Claim 6 depends directly from claim 5 and further specifies that “said crystalline compound
10 is (R)-2-(((3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl)methyl)sulfinyl)-1 H-benzimidazole.”
11 Claim 7 depends directly from claim 6 (and thus indirectly from claim 5), and specifies that “said
12 crystalline compound has an X-ray powder diffraction analysis pattern with characteristic peaks at
13 interplanar spacings (d) of 11.68, 6.77, 5.84, 5.73, 4.43, 4.09, 3.94, 3.89, 3.69, 3.41 and 3.11
14 Angstrom.” The d-spacings listed in claim 7 are the same d-spacings listed in claim 1 of the '058
15 patent. Because these claims require a “pharmaceutically acceptable excipient, carrier or
16 diluent,” Takeda’s allegation that they are infringed is aimed at Impax’s formulated ANDA
17 products, not the dexlansoprazole API. See JSUF (Impax Motion) ¶ 54.

18 **D. The Asserted Claims of the '755 Patent**

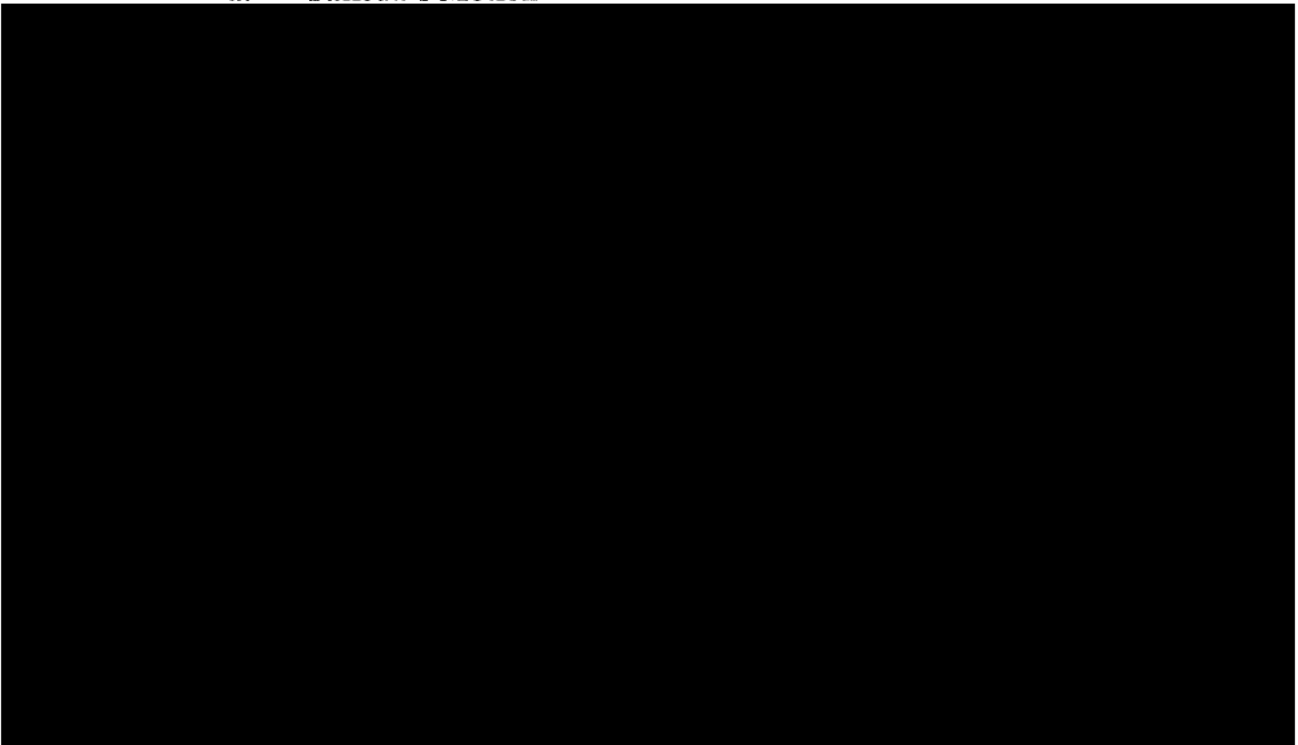
19 Takeda alleges that Impax’s ANDA products infringe claims 2, 4 and 6 of the '755 Patent,
20 each of which depends from claim 1. JSUF(Impax Motion) ¶ 4. Claim 1 describes a capsule
21 comprising two compositions, composition (i) and (ii). Composition (i) is comprised of a “tablet,
22 granule, or fine granule” with polymeric coating that is “soluble in the pH range of 6.0 to 7.5”
23 (the “dissolution limitation”). Composition (ii) comprises “a tablet, granule or fine granule” with
24 a core particle and an enteric coat such that the active ingredient is “released in the pH range of
25 no less than 5.0 to no more than 6.0” (the “release limitation”). At the claim construction stage of
26 the case, the key dispute regarding the construction of the release limitation focused on whether
27 the specified pH range refers to the pH at which release of the active ingredient begins, as Takeda
28 asserted, or rather, represents the only pH values at which release or dissolution occurs. The

1 Court adopted Takeda’s proposed construction, construing the claim term “released in the pH
2 range of no less than 5.0 to no more than 6.0” to mean that the dexlansoprazole “begins to be
3 released from the tablet, granule or fine granule at pH values within the range from 5.0 to 6.0.”
4 Claim Construction Order at 70. In response to the argument that the release limitation is
5 indefinite because a person skilled in the art would not know what percentage of the drug needs to
6 be released to satisfy the “begins to be released” requirement, the Court noted that “the phrase
7 ‘begins to release’ is not a claim term but merely a proposed construction intended to convey the
8 idea that the pH values in the term represent a threshold.” Claim Construction Order at 67. The
9 Court went on to find that the question of what amount of drug release satisfies this requirement
10 does not render the claim term insolubly ambiguous to a person of ordinary skill in the art. *Id.*

11 **E. The Parties’ Contentions**

12 **1. Infringement of the ‘058 and ‘971 Patents**

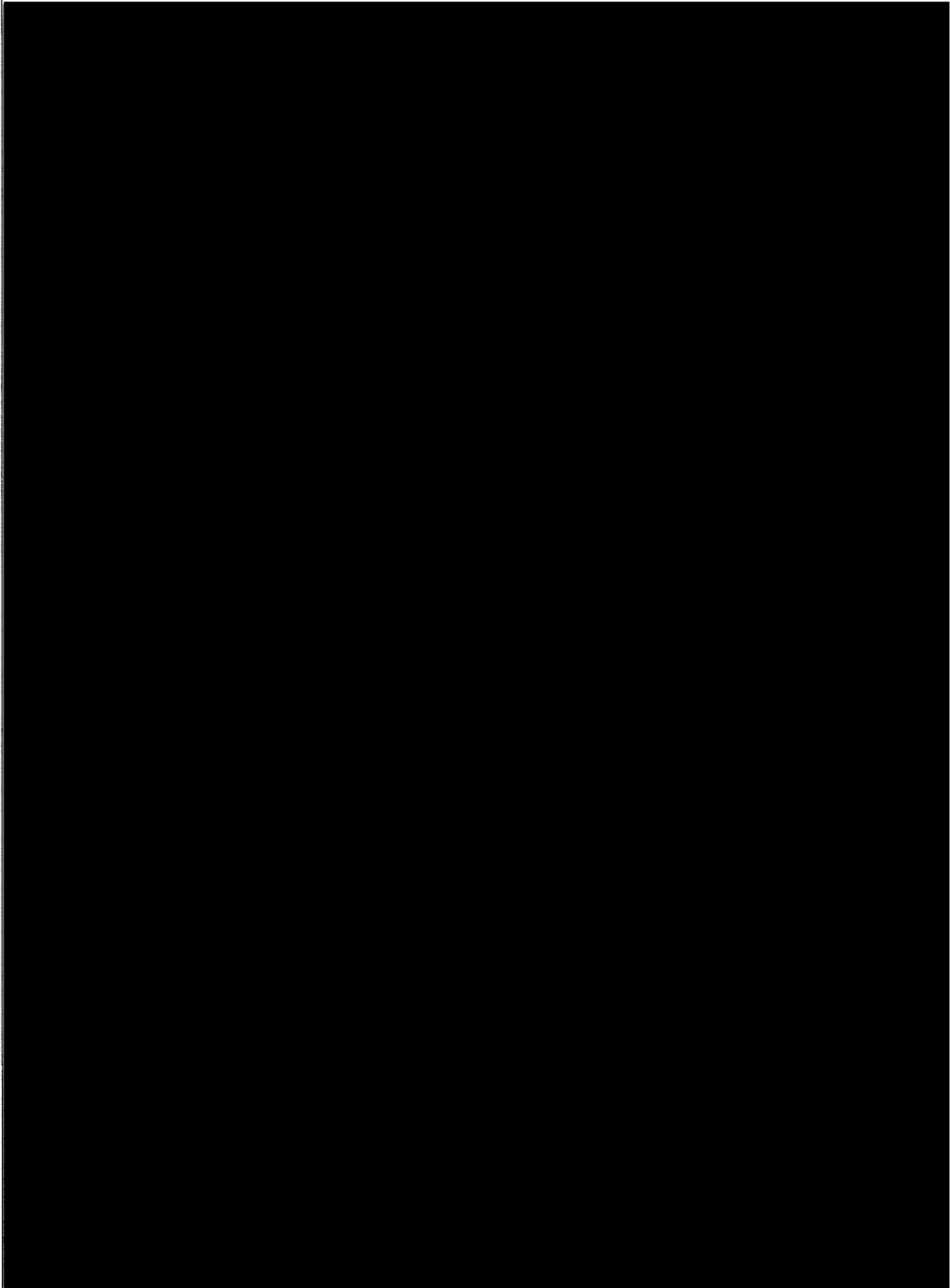
13 **a. Takeda’s Motion**



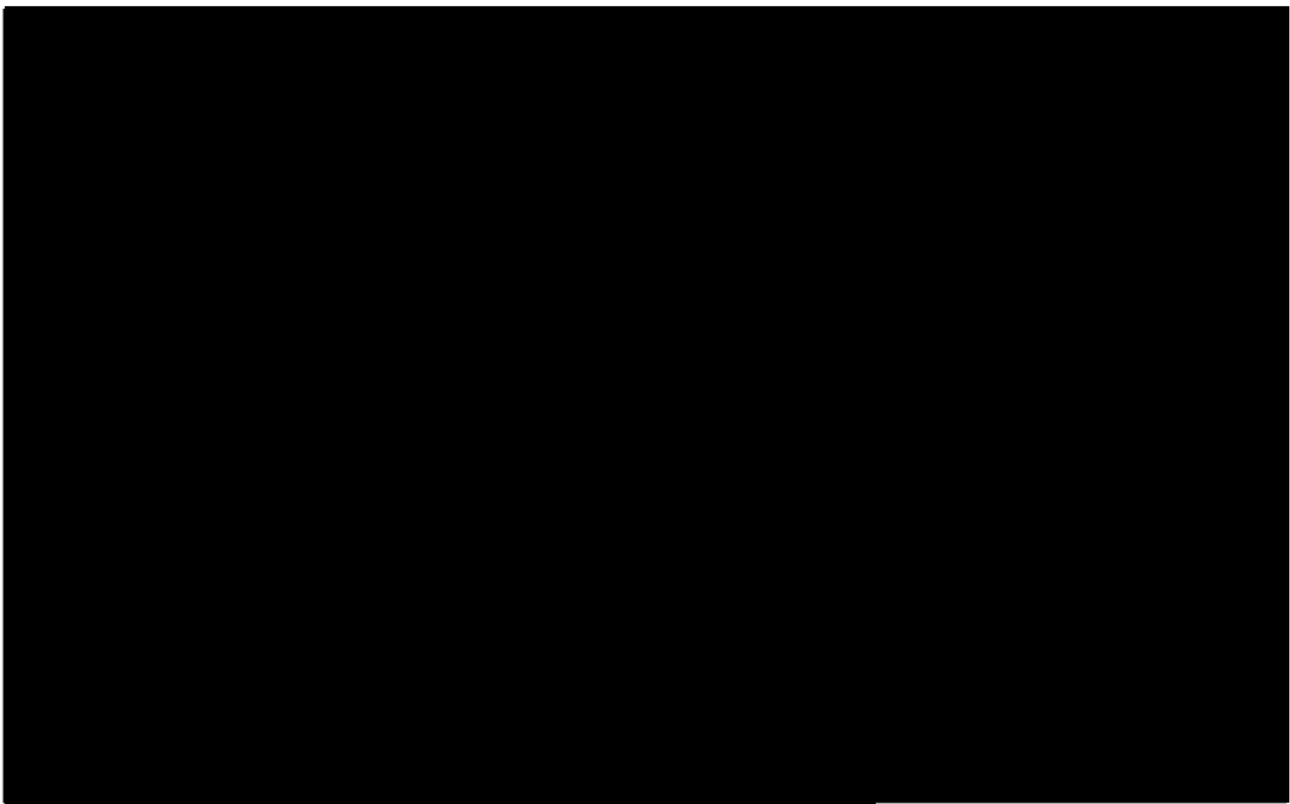
26 _____
27 ⁴ Takeda also seeks summary judgment of infringement of claim 6 of the ‘971 Patent and claims 2
28 and 2 of the ‘276 Patent. As noted above, Impax does not oppose summary judgment of
infringement as to those claims and therefore, the Court does not include Takeda’s infringement
arguments as to those claims in its summary of Takeda’s motion.

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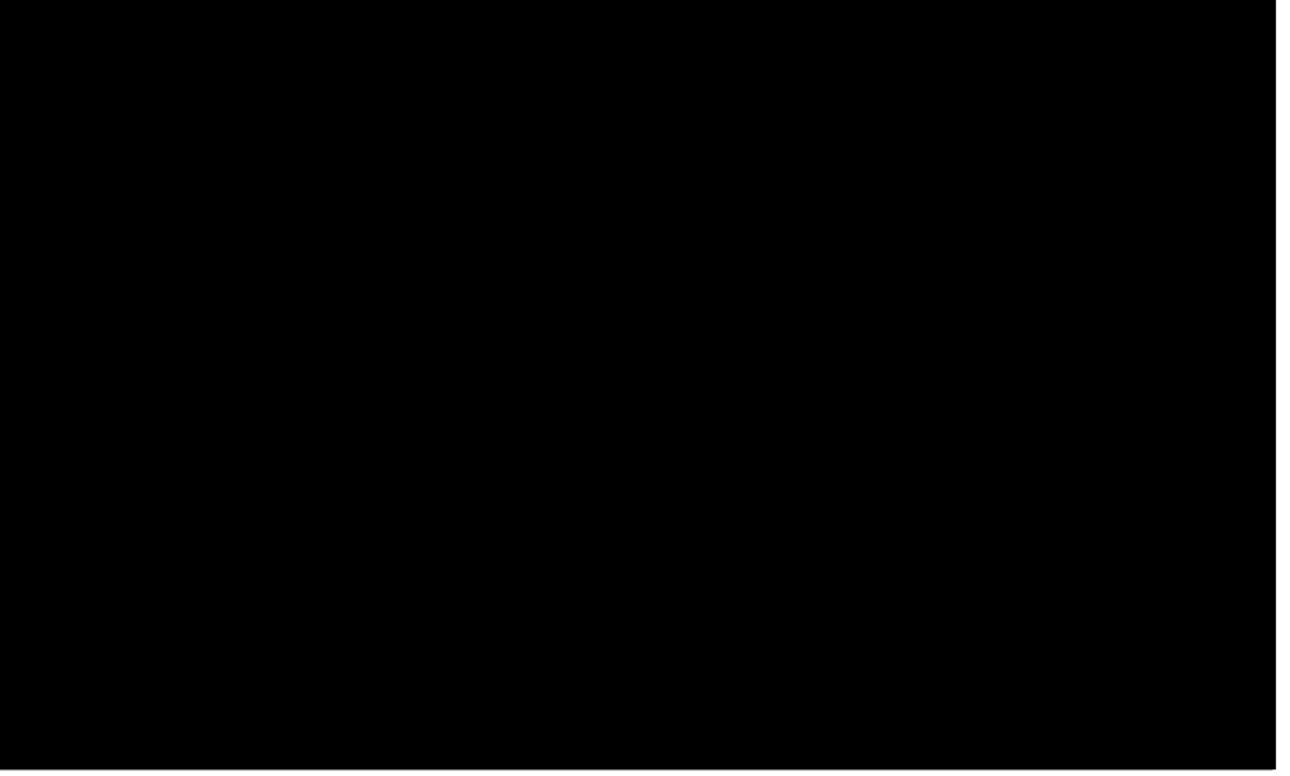
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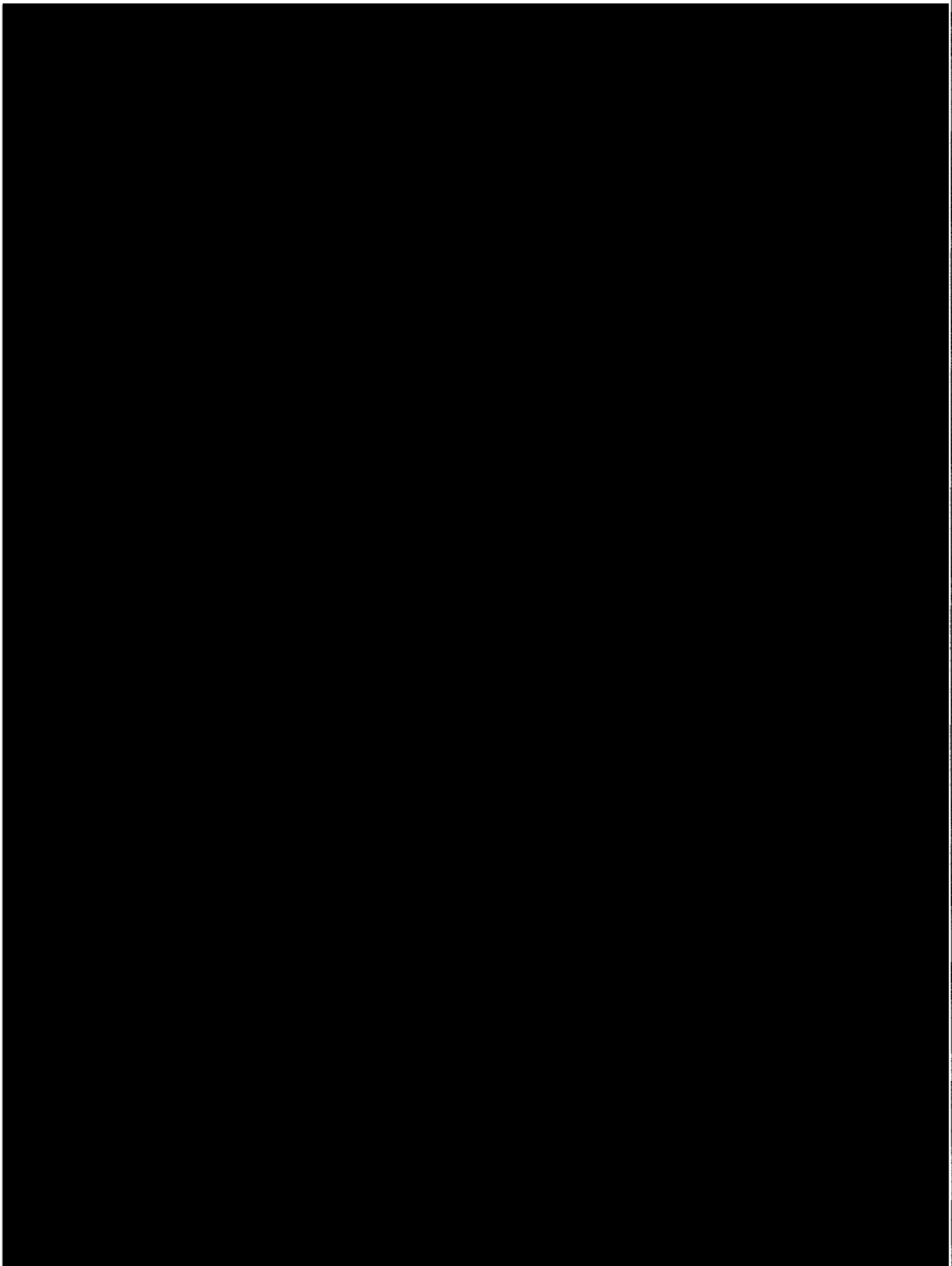


Id. at 19 (citing *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002); JSUF (Takeda Motion) ¶ 23; Myerson Decl., Ex. 9 (Siew Dep. Ex. 41) at IPXL-0000475



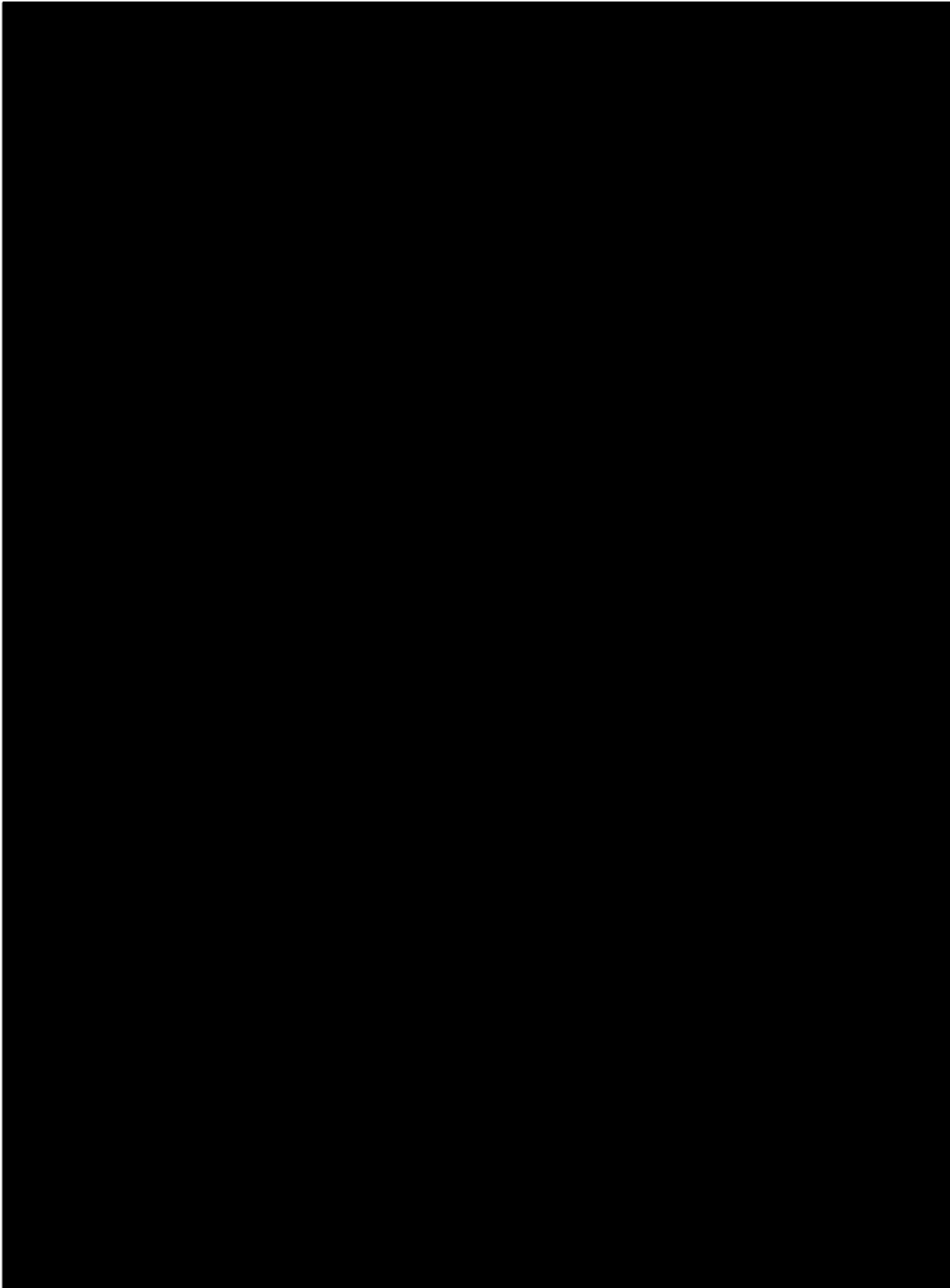
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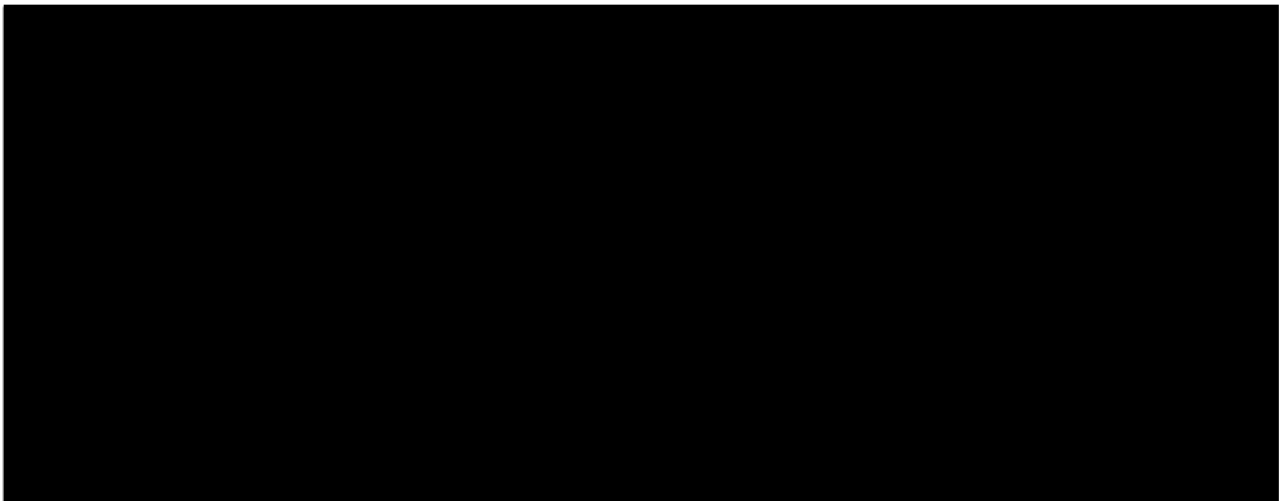


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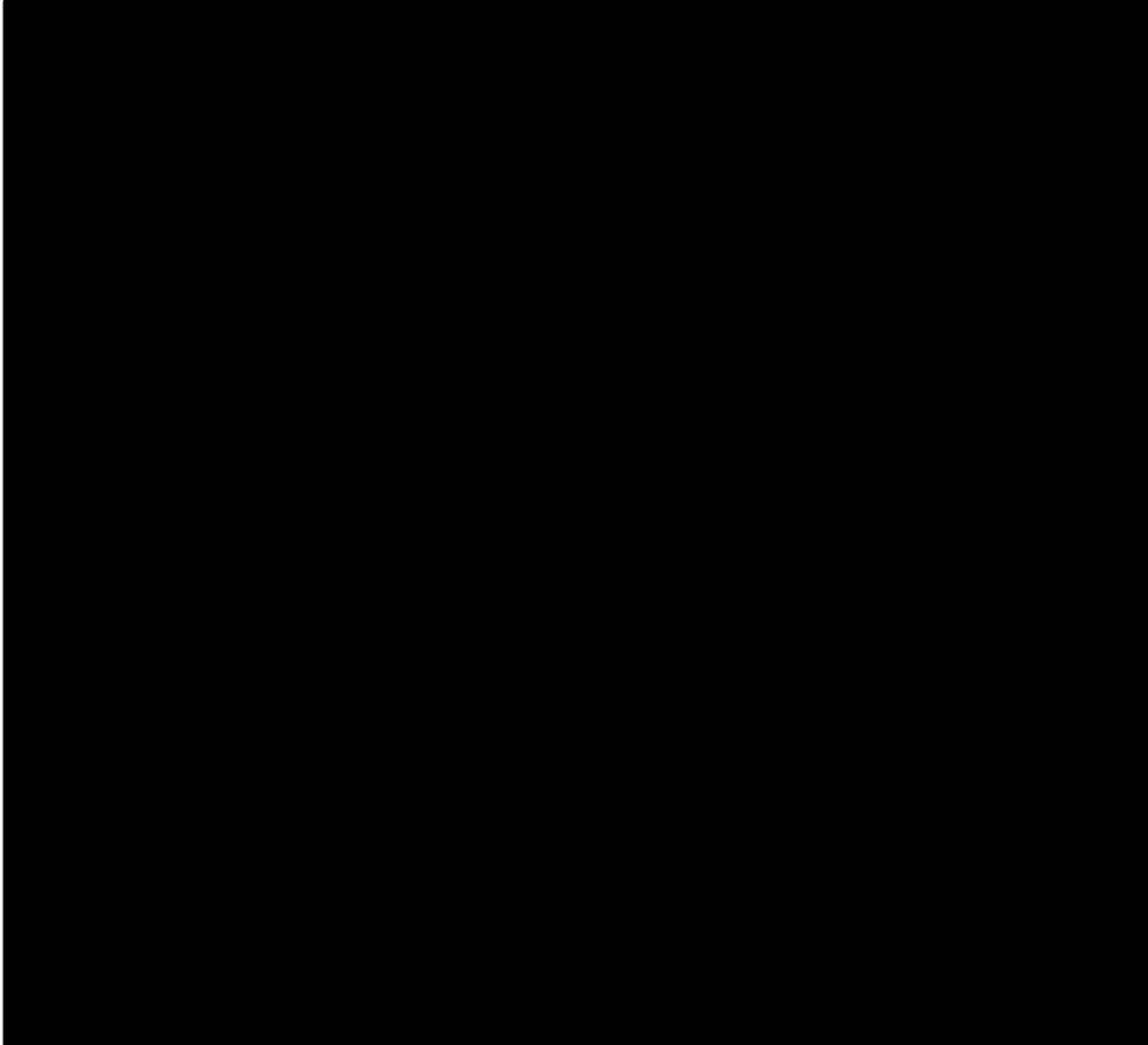
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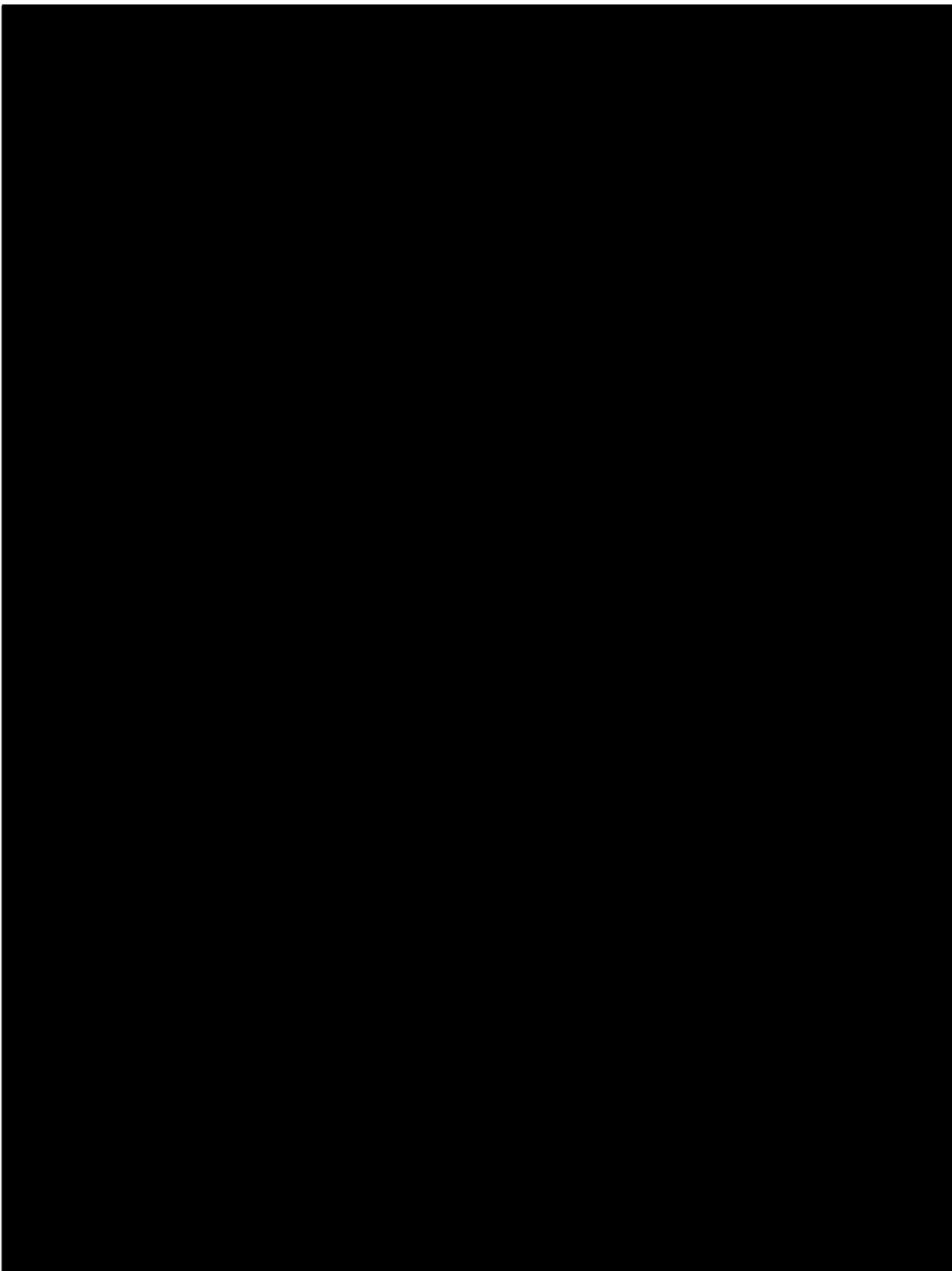


b. Impax's Opposition

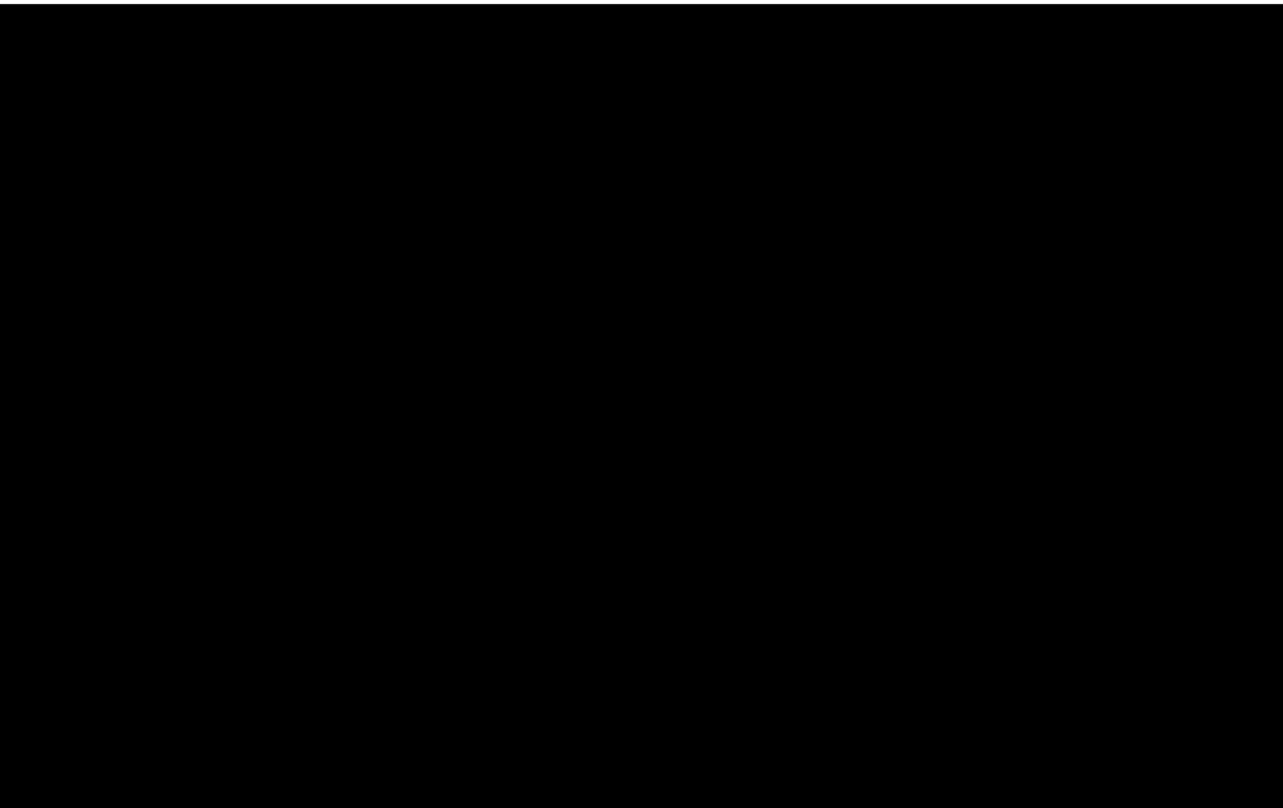


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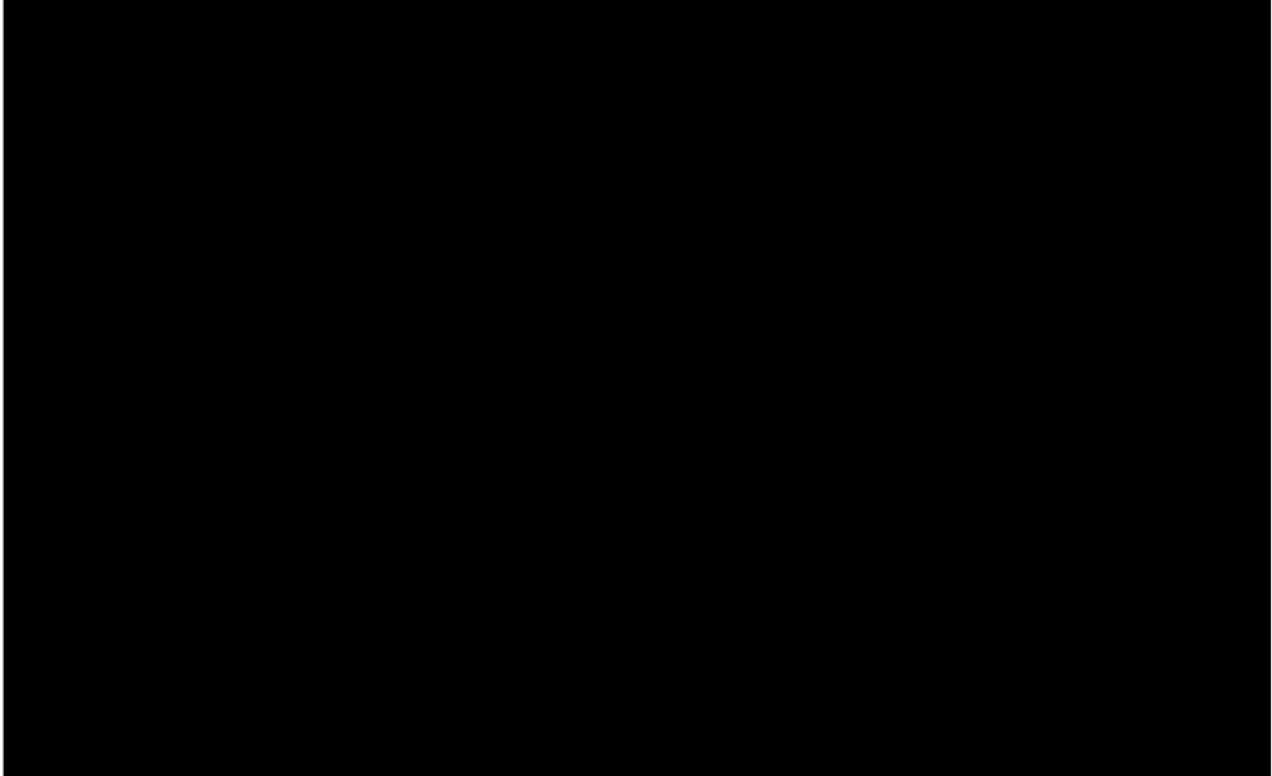
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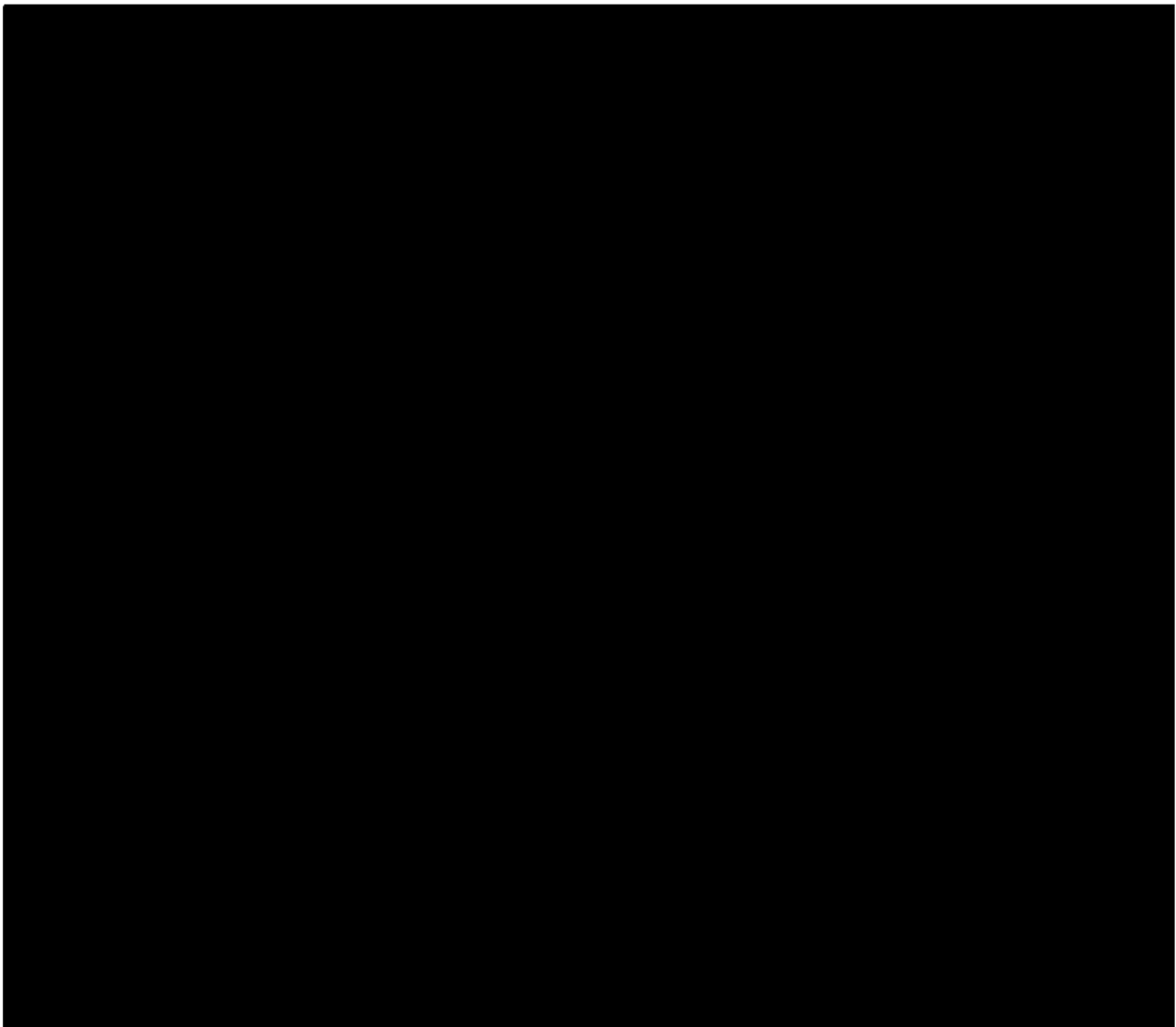
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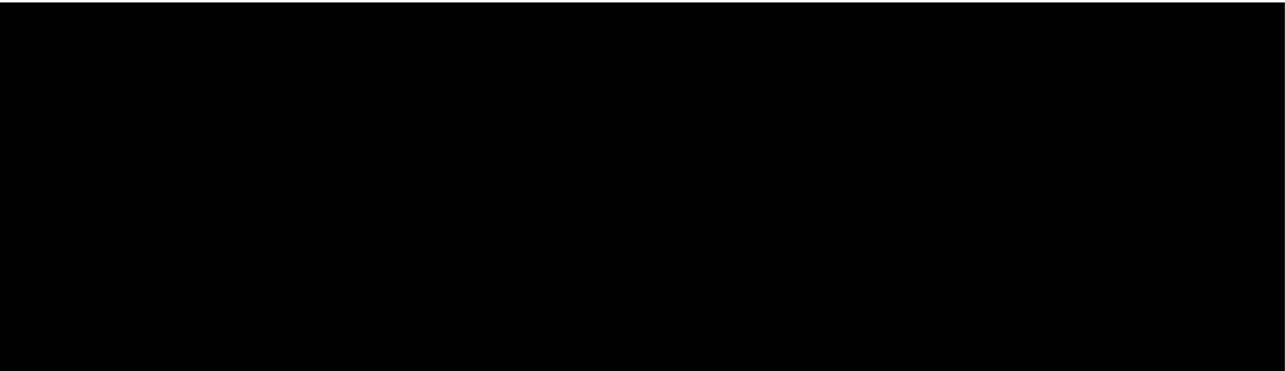
[REDACTED] *Id.* at 10 (citing *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1288-89 (Fed. Cir. 2010); *Zenith Lab. Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994)). [REDACTED]



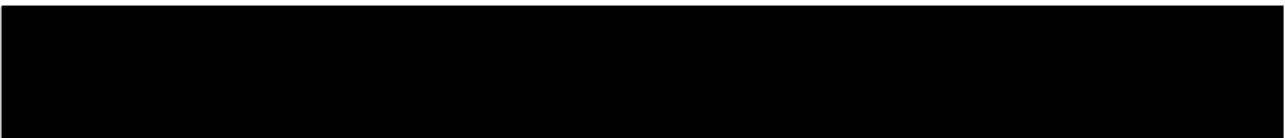
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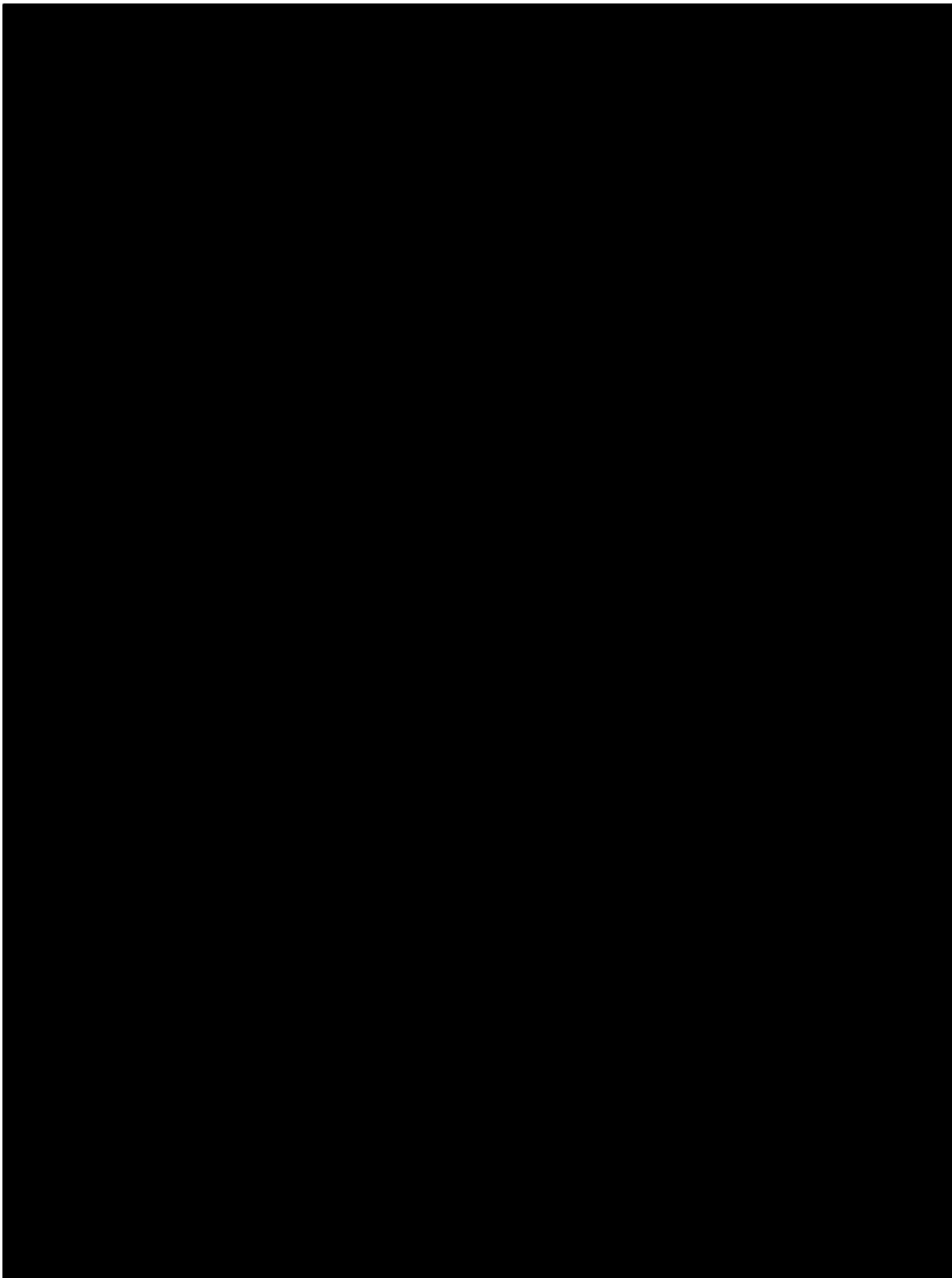
c. Takeda's Reply



(citing *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1193 (Fed. Cir. 2006)).

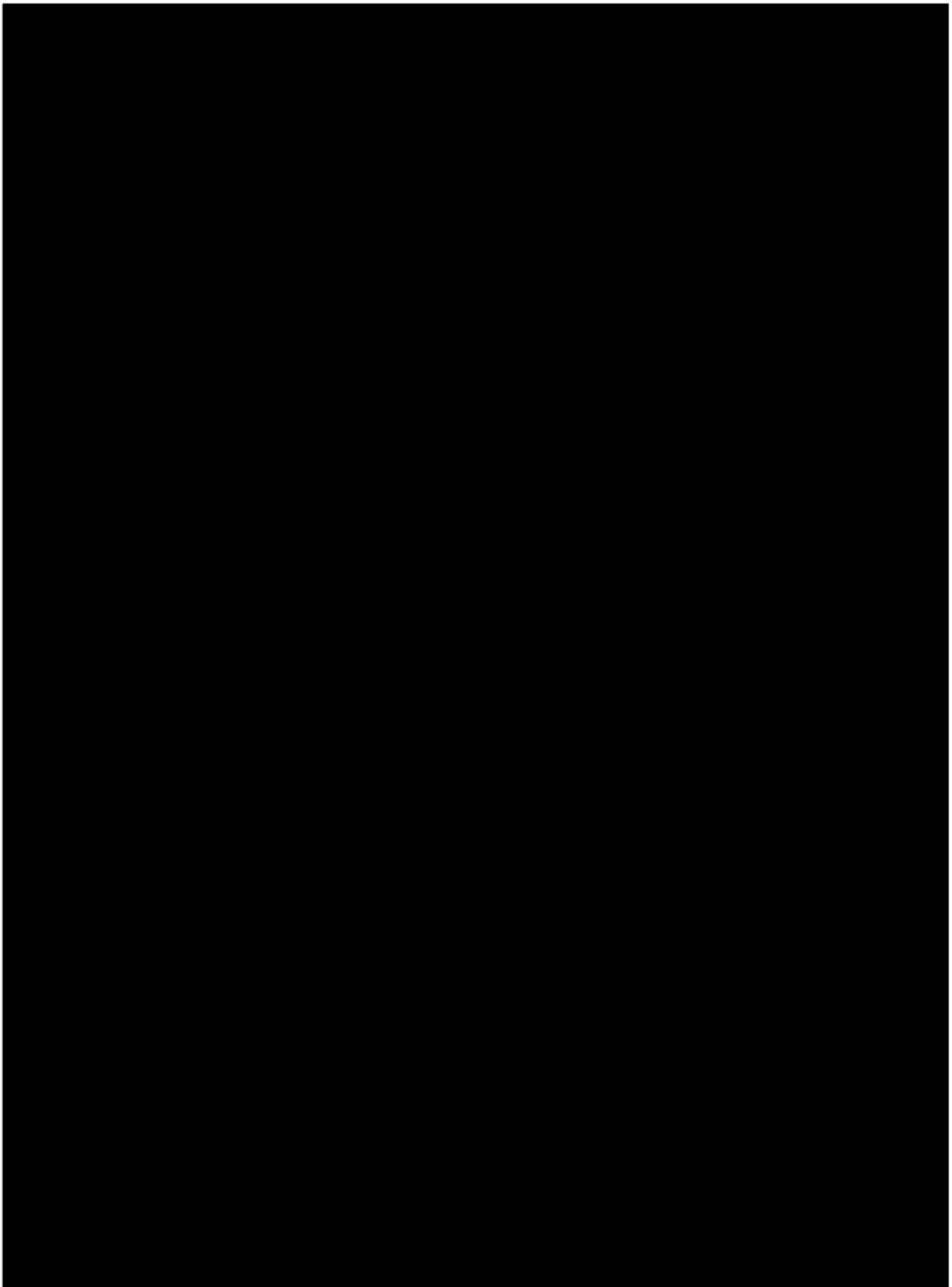


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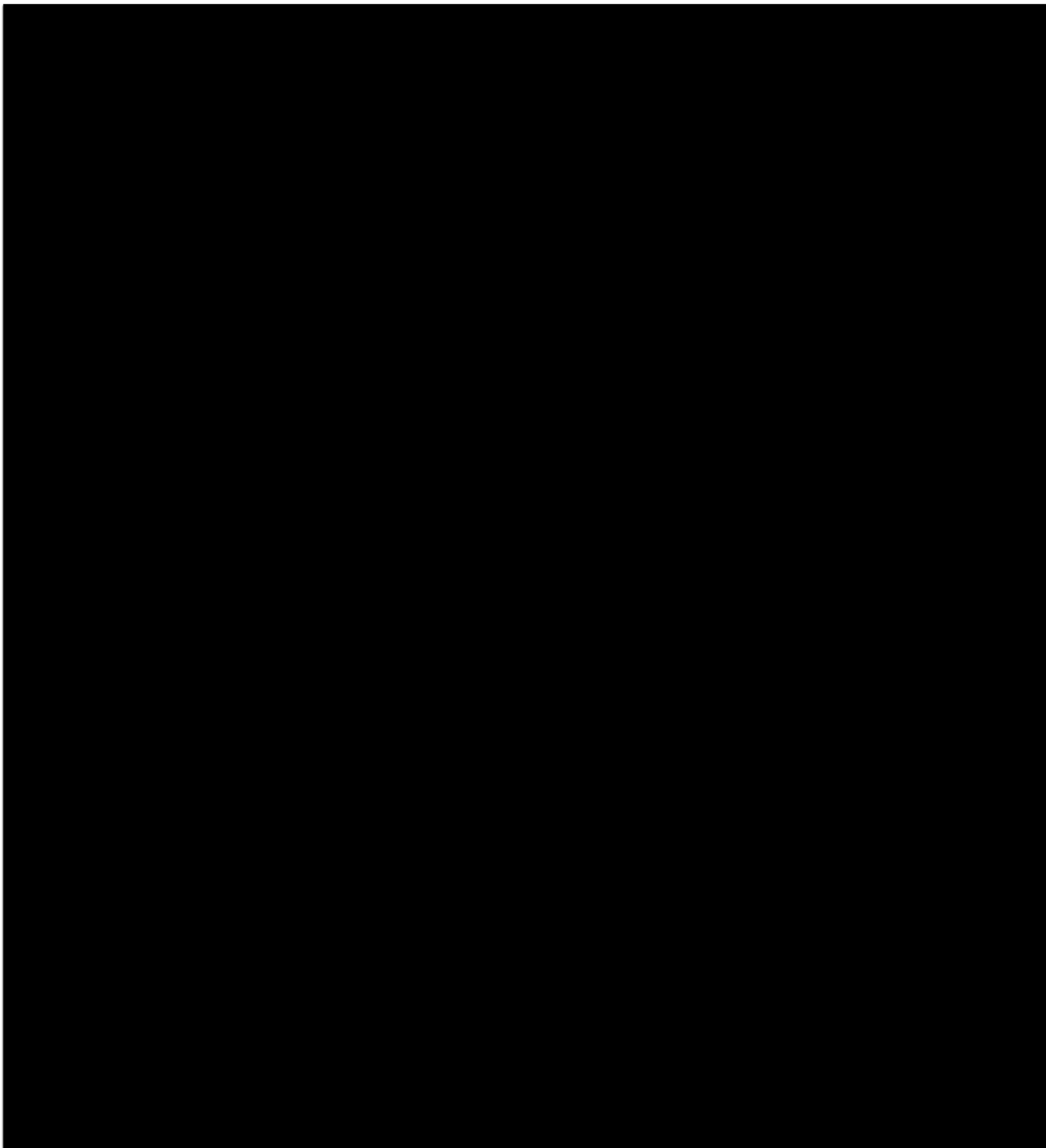


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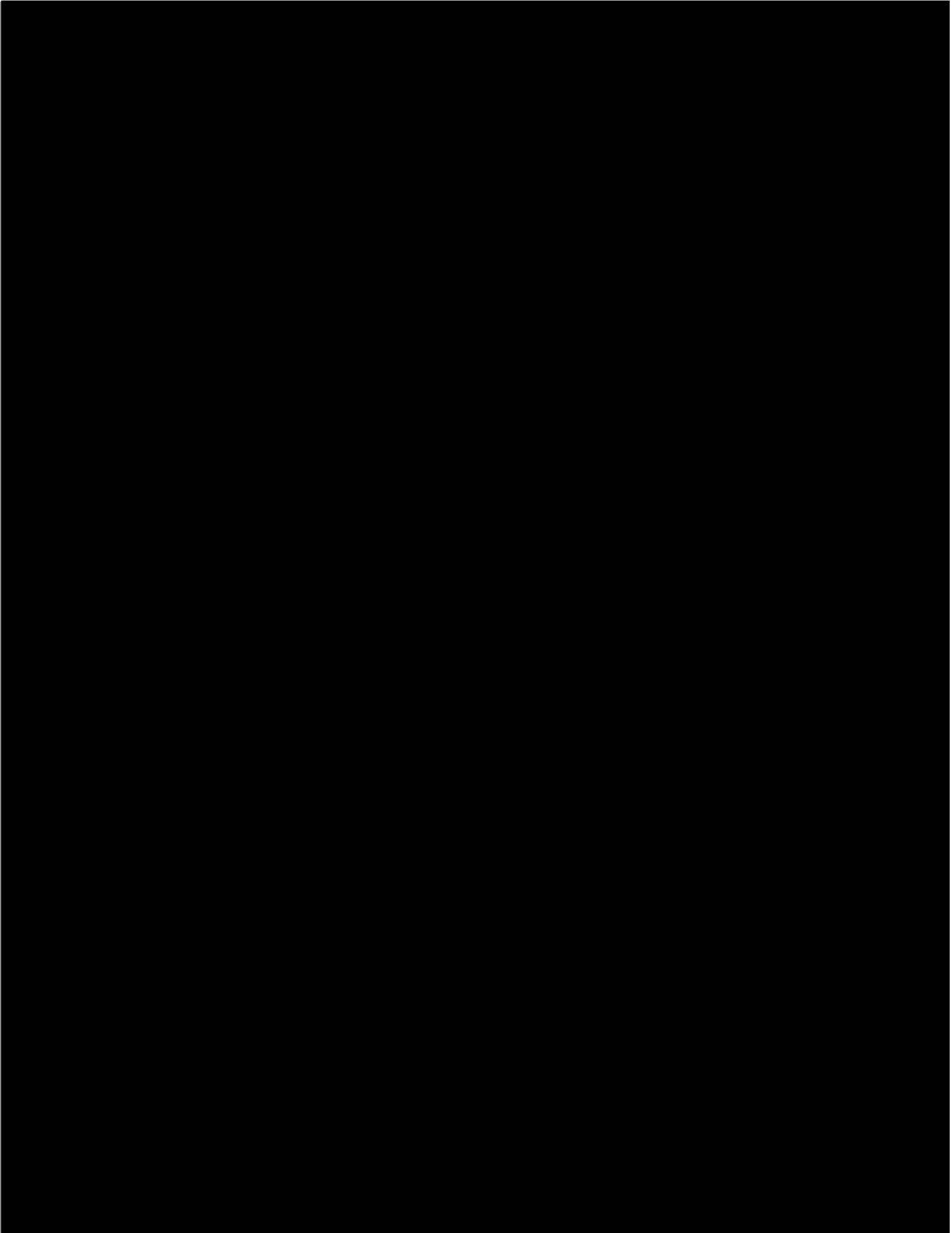
Id. (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1341 (Fed. Cir. 2005)).

d. Impax's Motion

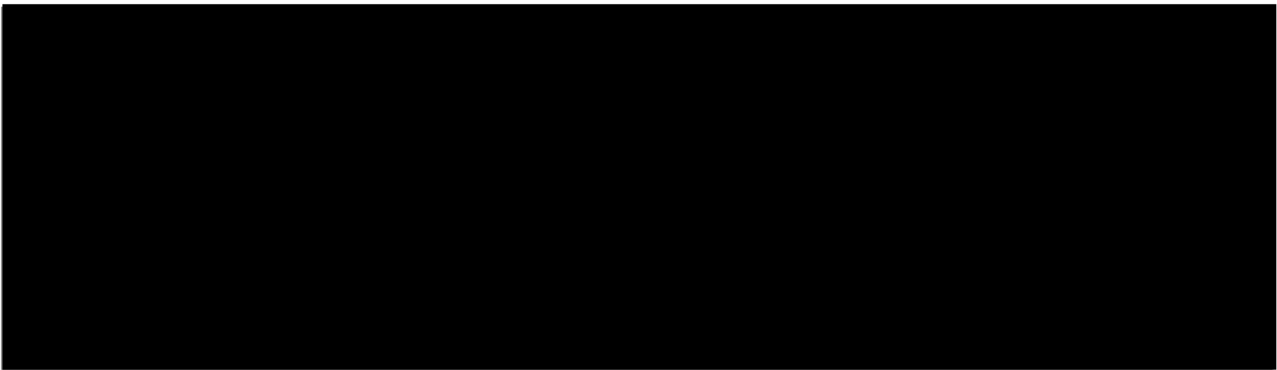


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e. Takeda's Opposition



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f. Impax's Reply



2. Validity of Claims 6 and 7 of the '971 Patent

a. Impax's Motion

Impax contends claims 6 and 7 of the '971 Patent are invalid for lack of written description because the claim limitation "effective amount," as construed by the Court ("an amount sufficient to help ameliorate or cure reflux esophagitis") is not supported by any specific description in the specification that would allow a person of skill in the art to determine the amount of dexlansoprazole that would meet this limitation. Impax Motion at 21-22. According to Impax, it is undisputed that there is only a general disclosure in the patent that would serve as a starting point for experimentation. *Id.* at 22 (citing Jorjani Motion Decl., Ex. 13 (Expert Report of M. Brian Fennerty, M.D., in Response to the Expert Report of George Triadafilopoulos, Ph.D., Regarding the Validity of the '971 Patent ("Fennerty Report"))) ¶¶ 21, 23, 32-33, 37; *id.*, Ex. 14

1 (Nov. 2, 2012 Fennerty Dep. Tr.) at 48:9-50:16). In particular, Takeda’s expert relies on the
2 following passage in the specification in support of its position that claims 6 and 7 are not
3 indefinite:

4 The content of the crystal of the present invention in the
5 pharmaceutical composition of the present invention is about 0.01
6 to 100% by weight relative to the entire composition. Varying
7 depending on subject of administration, route of administration,
8 target disease etc., its dose is normally about 0.5 to 1,500 mg/day,
9 preferably about 5 to 150 mg/day, based on the active ingredient,
10 for example, when it is orally administered as an antiulcer agent to
11 an adult human (60 kg).

12 *Id.* (quoting ‘971 Patent, col. 4, ll. 15-22). To the extent that Takeda’s expert opines that a person
13 of skill in the art would have to first test the drug in healthy subjects and then test a potential dose
14 in sick patients to determine an effective amount, Impax asserts, this disclosure does not provide
15 adequate written description. *Id.* Rather, the ’271 Patent should have provided the results of
16 pharmacodynamics studies indicating whether the drug has the potential to treat acid related
17 diseases, Impax asserts. *Id.* at 22-23.

18 Impax also argues that Experimental Example 1 of the ‘971 Patent “does not disclose an
19 amount of crystalline dexlansoprazole effective for treating any disease, let alone specifically
20 reflux esophagitis.” *Id.* at 23 (citing Jorjani Motion Decl., Ex. 15 (Expert Report of George
21 Triadafilopoulos, M.D. (“Triadafilopoulos Report”)) ¶¶28-31). Impax contends that Takeda’s
22 expert, Dr. Fennerty, recognized that Experimental Example 1 was offered only to show that
23 crystalline dexlansoprazole has potential as a therapeutic agent and that its results “do not actually
24 disclose an amount of dexlansoprazole effective for treating or ameliorating any disease.” *Id.*
25 (citing Jorjani Motion Decl., Ex. 13 (Fennerty Report ¶ 37); *id.*, Ex. 14 (Nov. 2, 2012 Fennerty
26 Dep. Tr.) at 58:17-60:15).

27 Impax argues that where a patent includes broad genus claims defined by functional
28 language, the specification must contain adequate species to demonstrate that the inventors
invented the genus and that the specification of the ‘971 Patent does not meet this requirement.
Id. at 23-24 (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010)
(*en banc*)). According to Impax, the ‘971 Patent discloses no species at all and therefore there is

1 not adequate written description. *Id.* at 24. Further, to the extent Dr. Fennerty emphasizes that
 2 the experiments required to determine an “effective amount” would be easy, Impax argues, this
 3 goes to the question of whether the specification is enabling, not whether it contains adequate
 4 written description. *Id.* (citing *Ariad*, 598 F.3d at 1352). According to Impax, the Federal Circuit
 5 has repeatedly invalidated claims for inadequate written description in similar situations. *Id.*
 6 (citing *Boston Scientific Corp.*, 647 F.3d 1353, 1362-1367 (Fed. Cir. 2011); *Ariad*, 598 F.3d at
 7 1355-1358; *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 918-919 (Fed. Cir.
 8 2004); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567-68 (Fed. Cir. 1997)).
 9 In short, Impax asserts, claims 6 and 7 are invalid for lack of written description because the
 10 specification does no more than provide an invitation for further research. *Id.* at 25 (citing
 11 *Centocor Ortho Biotech, Inc. v. Abbott Labs*, 636 F.3d 1341, 1348 (Fed. Cir. 2011); *Ariad*, 598
 12 F.3d at 1356; *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997)).

13 **b. Takeda’s Opposition**

14 Takeda contends that Impax has failed to take into account that the adequacy of the
 15 written description supporting a claim is viewed from the perspective of a person skilled in the
 16 art. Takeda Opposition at 19 (citing *Boston Scientific Corp.*, 647 F.3d at 1366). According to
 17 Takeda, such a person would be familiar with its drug Prevacid®, which contains the related
 18 racemic molecule lansoprazole and was approved for the treatment of reflux esophagitis in 1995,
 19 four years before the application leading to the ’971 Patent was filed. *Id.* at 20. Further, Takeda
 20 asserts, the ’971 Patent discloses a potential therapeutic dosage amount at column 4, ll. 18-22,
 21 indicates at col. 3, ll. 54-59 that one “target disease” is the “treatment and prevention of . . . reflux
 22 esophagitis,” and provides an experimental example (Experimental Example 1) showing that
 23 dexlansoprazole (like lansoprazole) can be used to suppress acid production in the stomach. *Id.*
 24 at 20-21. Takeda argues that these disclosures, when considered together with the prior art, are
 25 sufficient to demonstrate that the inventors possessed the claimed invention at the time of the
 26 priority date. *Id.* at 21. Takeda points out that in determining whether the written description
 27 requirement is met, the court must apply a clear and convincing evidence standard because of the
 28 presumption that patents are valid. *Id.* at 20.

1 Takeda rejects Impax's position that in order to meet the written description requirement
2 the '971 Patent must disclose results of clinical trials and other studies. *Id.* at 21. This argument,
3 Takeda contends, is contradicted by Federal Circuit authority holding that a claim should not be
4 invalidated simply because the embodiments of the specification do not contain examples
5 explicitly covering the full scope of the claim language. *Id.* at 21-22 (citing *LizardTech, Inc. v.*
6 *Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005)). Further, Takeda asserts,
7 patents are not required to include information that is well-known in the prior art. *Id.* at 22 (citing
8 *Volterra Semiconductor Corp. v. Primarion, Inc.*, 796 F. Supp. 2d 1025, 1064 (N.D. Cal. 2011);
9 *Boston Sci. Corp.*, 647 F.3d at 1366; *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005)).

10 Here, Takeda argues, a person of ordinary skill in the art at the priority date would have
11 known how to determine the effective amount of dexlansoprazole for treating reflux esophagitis
12 based on the disclosures in the '971 patent in light of the prior art. *Id.* at 22. In particular,
13 Takeda cites the testimony of its expert, Dr. Fennerty, that the effective amount of racemic
14 lansoprazole (which contains both (R+)- and (S-)-lansoprazole) for the treatment of reflux
15 esophagitis was known well before the filing date, because Prevacid® had already been approved
16 by the FDA. *Id.* (citing Jorjani Motion Decl., Ex. 13 (Fennerty Report) at ¶ 31). Dr. Fennerty
17 further opines that a skilled person would have recognized the FDA-approved dosage amounts for
18 lansoprazole as reasonable approximations of the effective dosage amounts for dexlansoprazole.
19 *Id.* (citing Jorjani Motion Decl., Ex. 13 (Fennerty Report) at ¶ 35) ("studies have been done to
20 determine the effectiveness of lansporazole at dosages of 15, 30 and 60 mg. [which] would have
21 suggested to one skilled in the art that a drug product containing only dexlansoprazole as an
22 active ingredient, with no levolansoprazole, might also be suitable for dosages in the 15 to 60 mg
23 range. It would certainly have suggested that such dosages would be reasonable ones to which to
24 direct experimentation. And, in fact, Dexilant is marketed at 30 mg and 60 mg doses."). Takeda
25 contends that Impax's expert, Dr. Triadafilopoulos, admitted as much in his deposition. *Id.*
26 (citing Purles Opp'n Decl., Ex. 15 (Oct. 19, 2012 Triadafilopoulos Dep. Tr.) at 29:8-30:15).

27 Takeda further notes that both Impax and Takeda's experts have acknowledged that the
28 prior art contained numerous studies directed towards determining the proper dosage amounts for

1 lansoprazole and other proton pump inhibitors. *Id.* at (citing Jorjani Motion Decl., Ex. 15
 2 (Triadafilopoulos Rep.) ¶¶ 14, 42-50; *id.*, Ex. 13 (Fennerty Rep.) ¶¶ 24-29, 35; Purles Opp’n
 3 Decl., Ex. 15 (Oct. 19, 2012 Triadafilopoulos Dep. Tr.) at 41:1-42:21; *id.*, Ex. 16 (Nov. 2, 2012
 4 Fennerty Dep. Tr.) at 44:21-45:3, 47:15-48:8). In light of this prior art, Takeda argues, it would
 5 have been “very easy . . . to determine the optimal dose of dexlansoprazole” for the treatment of
 6 reflux esophagitis. *Id.* at 22-23 (quoting Purles Opp’n Decl., Ex. 16 (Nov. 2, 2012 Fennerty Dep.
 7 Tr.) at 44:21-45:3, 47:15-48:8).

8 Takeda argues that the law does not require that a patentee disclose the dosage amount of
 9 a claimed compound. *Id.* at 23. Rather, according to Takeda, “[c]ourts recognize that
 10 pharmaceutical patents often ‘will require experimentation such as clinical trials to determine
 11 “effective amounts,” but [that] clinical trials are not considered “undue” experimentation.’” *Id.*
 12 (citing *King Pharms. v. Purdue Pharma, L.P.*, 718 F. Supp. 2d 703, 718 (W.D. Va. 2010); *Ortho-*
 13 *McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358 (Fed. Cir. 2008); *Kao Corp. v. Unilever*
 14 *U.S., Inc.*, 334 F. Supp. 2d 527, 551 (D. Del. 2004)). Takeda further contends that Impax
 15 attempts to “mislead” the Court when it characterizes the claims of the ‘971 Patents as “broad
 16 genus claims” that merely invite further research. *Id.* According to Takeda, the cases cited by
 17 Impax are factually distinguishable because in those cases, “the claims covered a broad range of
 18 chemical compounds or DNA materials even though the relevant specifications disclosed, at
 19 most, only one type of compound and there was minimal, if any, prior art discussing the claimed
 20 subject matters.” *Id.* at 23 & n. 16 (distinguishing the facts of *Boston Scientific*, 647 F.3d at 1364-
 21 1367; *Ariad Pharms., Inc.*, 598 F.3d at 1354-58; *Univ. of Rochester v. G.D. Searle & Co., Ltd.*,
 22 358 F.3d 916, 918-19 (Fed. Cir. 2004); *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559,
 23 1566-69 (Fed. Cir. 1997)). In contrast, Takeda argues, the ‘971 Patent covers only a single
 24 compound and it is undisputed that that compound is fully disclosed in the specification. *Id.* at
 25 24. Given the narrow dosing range in the patent and the prior art, a person skilled in the art would
 26 know how to determine the claimed “effective amount,” Takeda asserts. *Id.*

27 Finally, Takeda contends that Impax has attempted to disguise an enablement argument as
 28 a written description challenge by suggesting that the scope of the disclosure as to “effective

1 amount” is too broad and imprecise and thus requires further experimentation. *Id.* (citing *Capon*,
2 418 F.3d at 1360 (“The Board’s position that the patents at issue were merely an ‘invitation to
3 experiment’ . . . concerns enablement more than written description.”)).

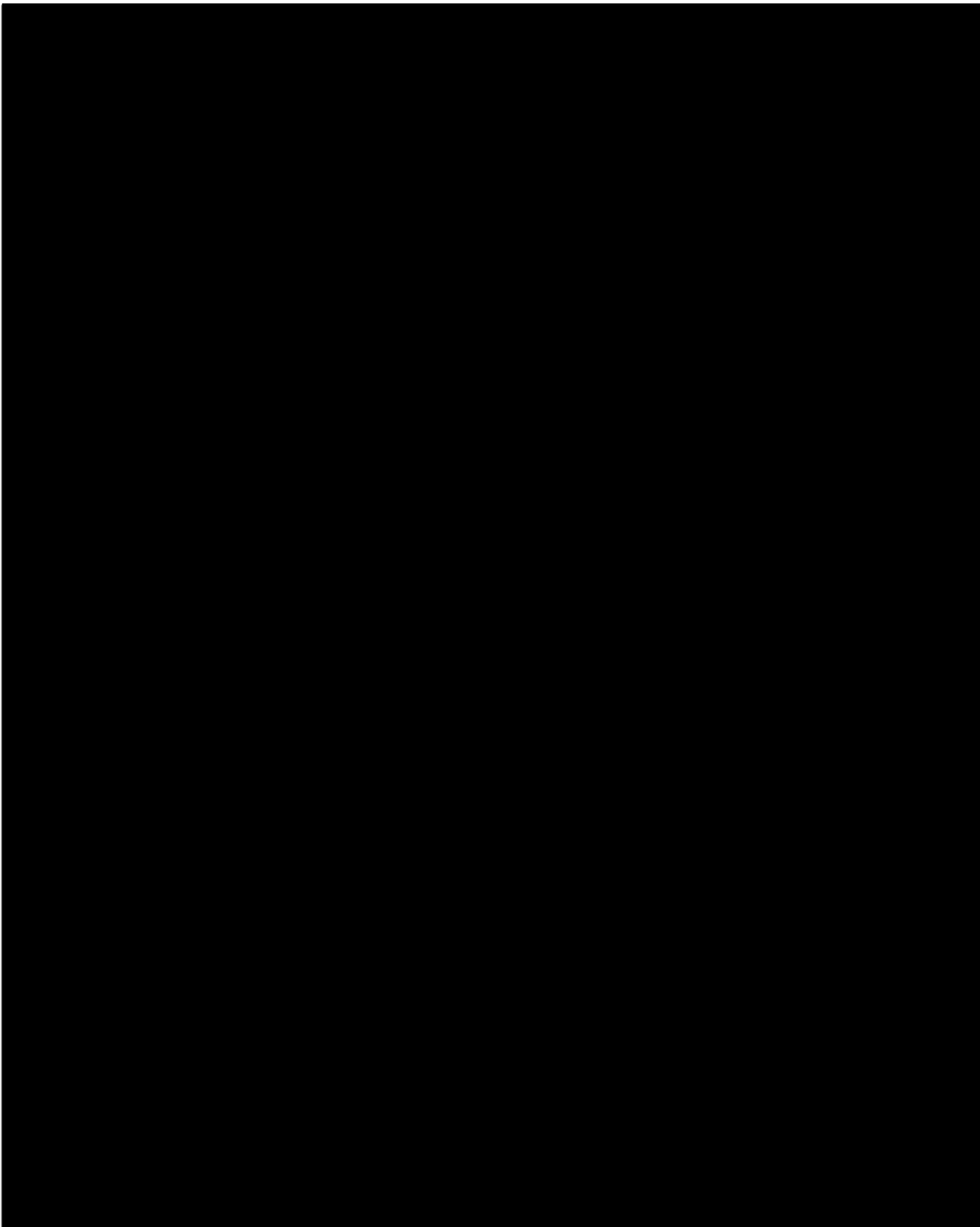
4 **c. Impax’s Reply**

5 In its reply brief, Impax states that it “agrees with Takeda, and Takeda’s expert Dr.
6 Fennerty, that it is obvious and well within the ability of a person of ordinary skill to determine an
7 amount of dexlansoprazole crystal effective for treating reflux esophagitis, at least in humans,
8 based on what was known in the art about other proton pump inhibitors.” Impax Reply at 7.
9 However, according to Impax, this goes to obviousness and enablement rather than the
10 sufficiency of the written description and whether the inventors were in possession of the claimed
11 invention. *Id.* (citing *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)).
12 Impax contends that the inventors were not in possession of the invention, arguing that even Dr.
13 Fennerty concedes that the specification of the ‘971 Patent merely provides a starting point for
14 further experimentation. *Id.* (citing Jorjani Motion Decl., Ex. 13 (Fennerty Report) ¶ 21-24, 32-
15 33, 37; *id.*, Ex. 14 (Nov. 2, 2012 Fennerty Dep. Tr.) at 43:6-46:9, 48:9-50:16). As the
16 specification is only an invitation for further experimentation, Impax asserts, the written
17 description requirement is not met. *Id.* (citing *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636
18 F.3d 1341, 1348 (Fed. Cir. 2011)). Impax rejects Takeda’s reliance on the dosage range in the
19 specification, arguing that this broad range is only a starting point and would, according to Dr.
20 Fennerty, require at least two rounds of trials. *Id.* Such disclosure is too vague and general to
21 satisfy the written description requirement, Impax asserts. *Id.* (citing *Boston Scientific Corp.*,
22 647 F.3d at 1362-67). Similarly, it argues that the Experimental Example and the disclosure that
23 dexlansoprazole might be useful for treating reflux esophagitis is not sufficient to satisfy the
24 written description requirement. *Id.* at 8. Impax points to testimony of Dr. Fennerty in which he
25 admits that treating reflux esophagitis is an expected characteristic of all proton pump inhibitors,
26 not just dexlansoprazole. *Id.* (citing Jorjani Motion Decl., Ex. 13 (Fennerty Report) ¶¶ 24-31).
27 It also reiterates its point that results relating to the treatment of ulcers in rats disclosed in the
28 patent are not sufficient to show that the inventors had possession of the claimed invention. *Id.*

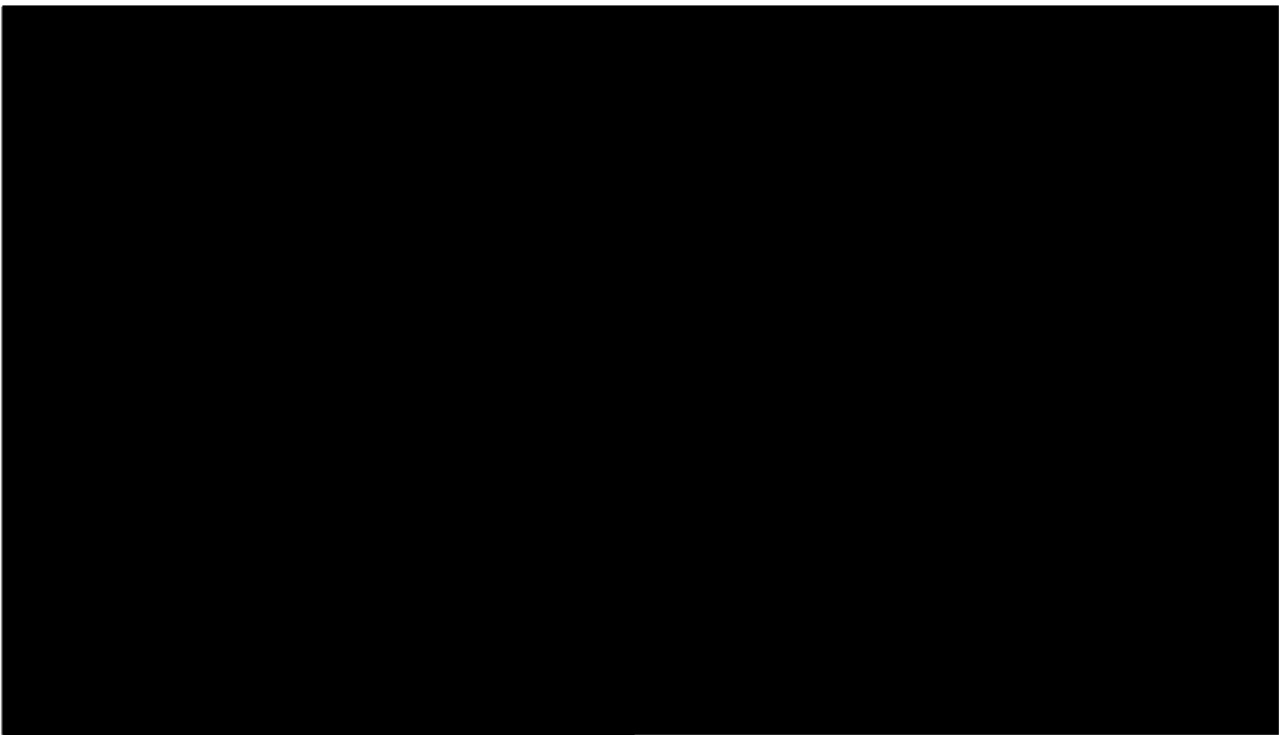
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3. Infringement of the '755 Patent

a. Impax's Motion



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Impax cites the opinions of its own expert, Dr.

Augsburger, as to when a person of ordinary skill in the art would determine that the dexlansoprazole “begins to be released” (release limitation) or the enteric coat “begins to dissolve”⁶ (dissolution limitation). *Id.* (citing Jorjani Motion Decl., Ex. 8 (Nov. 6, 2012 Augsburger Dep. Tr.) at 108:1-14, 109:14-24). According to Dr. Augsburger, a person of ordinary skill in the art would interpret these terms with reference to the sensitivity of the testing conditions. *Id.* The testing conditions chosen by Dr. Charman are sufficiently sensitive to detect release of 1% of the total dexlansoprazole content of the capsules. *Id.* (citing JSUF (Impax Motion) ¶ 18; Jorjani Motion Decl., Ex. 16 (August 1, 2012 Advantar Report) at DEX1668403). Thus, Dr. Augsburger opines that dexlansoprazole “begins to be released” and a polymer coat “begins to dissolve” when 1% of the total dexlansoprazole content of a capsule is detectable. *Id.*

⁶ The Court notes that while Impax’s expert describes the dissolution limitation as establishing a threshold pH at which drug “begins to dissolve,” the Court did not construe the dissolution limitation, which states that the polymeric coating of composition (i) is “soluble in the pH range of 6.0 to 7.5.” The parties’ experts appear to agree, however, that the dissolution limitation, like the release limitation, sets a threshold at which the enteric coating “begins to dissolve.” *See* Charman Report (Impax) ¶ 91 (“The final limitation of claim 1 is that requiring that the polymeric substance in the delayed-release coating “begin[] to dissolve at pH values within the range from 6.0 to 7.5.”).

1 (citing Jorjani Motion Decl., Ex. 8 (Nov. 6, 2012 Augsburger Dep. Tr.) at 108:1-14, 109:14-24).
2 Dr. Augsburger does not adopt a specific time at which the measurement should be cut off, but
3 instead opines that the test should be run for a reasonable period. *Id.* (citing Jorjani Motion Decl.,
4 Ex. 8 (Nov. 6, 2012 Augsburger Dep. Tr.) at 107:23-25, 108:24-109:13). [REDACTED]

5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 Impax also challenges Dr. Charman's opinion that the release that is claimed in the release
17 and dissolution limitations must be "rapid and significant," requiring a 10% or greater release
18 over a period of two hours. *Id.* (citing Charman Report (Impax) ¶¶ 88-90, 94). Impax points out
19 that there are no time or extent limitations in the claim language and argues that Dr. Charman's
20 approach does not find support in the '755 Patent or prosecution history. *Id.* Instead, Impax
21 contends, Dr. Charman relies only on extrinsic evidence in support of his position, namely, part of
22 the acceptance criteria for a general protocol for testing delayed release capsules from the United
23 States Pharmacopeia ("USP"), and a draft FDA Guidance for dexlansoprazole. *Id.* (citing Jorjani
24 Motion Decl., Ex. 3 (Oct. 31, 2012 Charman Dep. Tr.) at 72:12-73:17; *id.*, Ex. 10 (USP protocol)
25 at 301; Charman Report (Impax) ¶ 89). According to Impax, however, neither the extrinsic nor
26 the intrinsic evidence supports Dr. Charman's approach. *Id.*

27 With respect to the USP protocol, Impax cites Dr. Augsburger's testimony that
28

1 “the USP specification is for confirming manufacturing uniformity, not for determining if
2 something is a delayed release product or satisfies a patent claim.” *Id.* at 9-10 (citing Jorjani
3 Motion Decl., Ex. 8 (Augsburger Dep.) at 37:12-40:2). Impax also points to Dr. Charman’s
4 deposition testimony, asserting that [REDACTED]
5 [REDACTED]
6 [REDACTED] *Id.* at
7 10 (citing JSUF (Impax Motion) ¶ 24; Jorjani Motion Decl., Ex. 3 (Oct. 31, 2012 Charman Dep.
8 Tr.) at 196:2-17, 198:3-203:21). Impax also cites Dr. Charman’s testimony that the USP protocol
9 has not been accepted by the Japanese Pharmacopeia. *Id.* (citing Jorjani Motion Decl., Ex. 3 (Oct.
10 31, 2012 Charman Dep. Tr.) at 203:22-204:1). Impax contends that in light of this fact, it is
11 unlikely that “Japanese scientists, like the inventors of the ‘755 patent” would have followed the
12 USP protocol for evaluating dissolution or release of their invention. *Id.* Finally, Impax argues
13 that Dr. Charman “cherry-picked” the 10% release in two hours limitation from the USP protocol.

14 *Id.* [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]

19 Impax also challenges Dr. Charman’s reliance on the FDA Draft Guidance on
20 Dexlansoprazole (“FDA Draft Guidance”). *Id.* In addition to the fact that it is only a draft and
21 has not yet been adopted by the FDA, Impax points out that it was not issued by the FDA until
22 June 2011, “years after the filing of the ‘755 patent.” *Id.* (citing Jorjani Motion Decl., Ex. 9 at
23 footer (“Recommended Jun[e] 2011”). [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]

27 Turning to the intrinsic evidence, Impax contends the ‘755 Patent specification offers
28 some guidance, disclosing a preferred set of dissolution conditions for composition (i) where

1 testing is conducted for at least five, and up to eight, hours. *Id.* at 11. In particular, the
2 specification includes the following passage:

3 The rate of elution of active ingredient from the active ingredient
4 release-controlled tablet, granule or fine granule thus obtained is
5 desirably 10% or less for 5 hours in a solution of pH 6.0, and 5% or
6 less for one hour and 60% or more for 8 hours in a solution of pH
7 6.8.

8 '755 Patent, col. 10, ll. 13-17. According to Impax's expert, Dr. Augsburger, these rates
9 "indicate that the inventors considered a relatively slow, extended release to be part of their
10 invention, and that the claims are not limited to the rapid release Dr. Charman suggests." Impax
11 Motion at 11 (citing Jorjani Motion Decl., Ex. 8 (Nov. 6, 2012 Augsburger Dep. Tr.) at 154:19-
12 157:2).

13 The prosecution history also contradicts Dr. Charman's approach, Impax contends. *Id.* at
14 12. In particular, Impax cites the declaration of Takashi Kurasawa, one of the inventors,
15 submitted to the PTO during prosecution of the '755 Patent in order to overcome an obviousness
16 rejection over a prior art patent to Beckert. *Id.* (citing Sharp Decl., Ex. 8). According to Impax,
17 Dr. Kurasawa submitted dissolution testing of a specific embodiment of the invention of claim 1,
18 consisting of pellets according to patent Example 53 (Granules L-S, low pH) and patent Example
19 56 (Granules H, high pH). *Id.* The applicants relied on Kurasawa's results to make the following
20 argument:

21 As shown in Fig. 1 of the attached Declaration of Mr. Takashi
22 KURASAWA, who is one of the inventors of the present
23 application, composition (i) of claim 41, i.e., Granule H in the
24 Declaration, dissolves at pH 6.8 almost 100% in 6 hours and more
25 than 30% in 4 hours... Further, the composition (i) of claim 41
26 dissolves at pH 6.0-7.5, and dissolves completely at pH 6.8 in 6
27 hours (See Fig. 1 of the Declaration). The [Beckert] reference,
28 however, discloses that not more than 20% of the active ingredient
in pellet B is released at pH 6.8 after 6 hours...

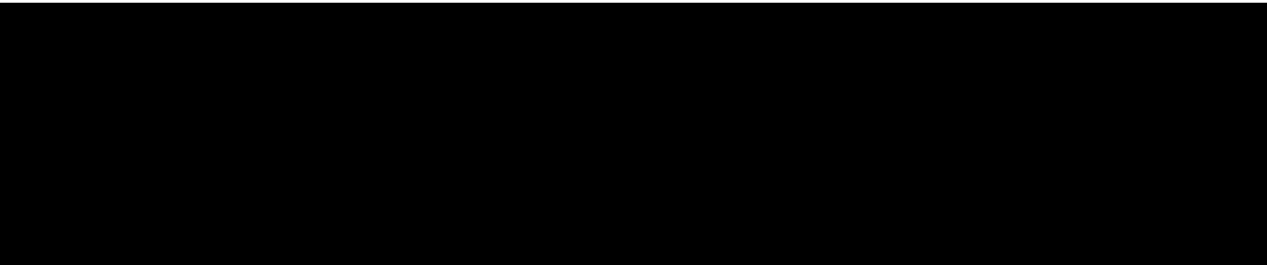
29 *Id.* (quoting Sharp Decl., Ex. 8 at DEX0007130-31). Impax emphasizes that the applicants
30 argued that the release behavior after six hours was critical, thus contradicting Dr. Charman's
31 approach. *Id.* Impax also points out that Mr. Kurasawa's dissolution testing was conducted for

1 eight hours, and that pellets of composition (i) released less than 10% in three hours. *Id.* at 12-13.

2 In other words, Impax contends, a preferred embodiment of the invention would fall outside of
3 the scope of the claims under Dr. Charman's approach. *Id.* at 13-14.



22 **b. Takeda's Opposition**



27 Takeda notes that the Court explicitly
28 declined to specify at the claim construction stage of the case what type of testing would be

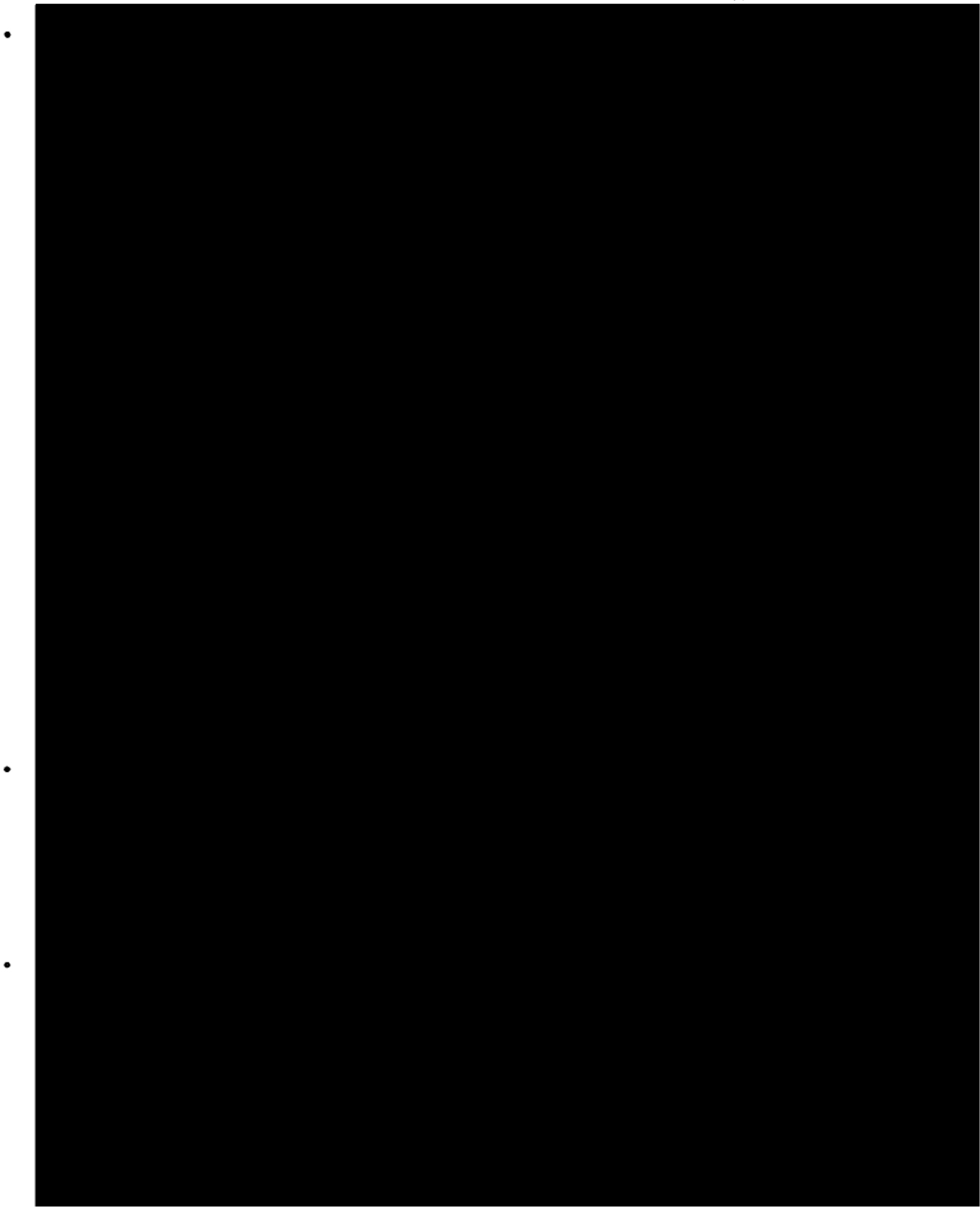
1 required to determine whether the release term was satisfied, leaving this question to be addressed
2 at trial through expert testimony. *Id.* at 4. This approach is consistent with Federal Circuit
3 precedent, Takeda asserts, pointing to cases holding that courts need not eliminate all ambiguity
4 in construing claim terms but rather, should only define terms to the level of specificity that is
5 warranted by the language of the claim and the evidence. *Id.* at 4-5 (citing *Acumed LLC v.*
6 *Strkyer Corp.*, 483 F.3d 800 (Fed. Cir. 2007); *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d
7 1351 (Fed. Cir. 1998); *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc.*, 249
8 F.3d 1341 (Fed. Cir. 2001); *Modine Mfg. Co. v. Int'l Trade Comm'n*, 75 F.3d 1545 (Fed. Cir.
9 1996)). According to Takeda, “where ‘the claim language does not require a particular form of
10 testing, this inquiry is not a claim construction question’ but is ‘review[ed] . . . as a question of
11 fact.’” *Id.* at 5 (quoting *Union Carbide Chems. and Plastics Tech. Corp. v. Shell Oil Co.*, 425 F.3d
12 1366, 1377 (Fed. Cir. 2005), overruled on other grounds by *Cardiac Pacemakers, Inc. v. St. Jude*
13 *Med., Inc.*, 576 F.3d 1348 (Fed. Cir. 2009)).

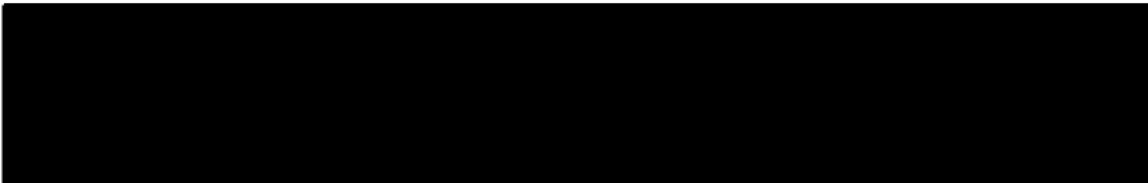
14 Takeda argues further that there is a genuine dispute of material fact as to the testing
15 criteria that should be used to decide whether Impax’s ANDA products meets the release
16 limitation and that substantial evidence supports Dr. Charman’s approach. *Id.* Takeda points to
17 the following evidence in support of Dr. Charman’s approach:

- 18 • the monograph on dissolution testing in the United States Pharmacopeia (“USP”),
19 which recognizes that for delayed-release dosage forms, a product passes a dissolution
20 test if no individual dosage unit shows more than 10% dissolution in acid medium and
21 prescribes a two-hour testing period for the acid stage. *Id.* at 6, 7-8 (citing Charman
22 Decl., Ex. C.20 (2012 USP section on dissolution) at 299, 301, Acceptance Table 3;
23 Takahashi Decl., Ex. F (1995 USP section on dissolution) at 1796, Acceptance Table
24 2).
- 25 • the USP section on delayed release lansoprazole (which is an enantiomer of
26 dexlansoprazole), which “permits dissolution of less than 10% in the acid stage in a
27 two-stage experiment designed to simulate passage through an acidic stomach (in the
28 first stage) followed by simulated intestinal dissolution (in the second stage).” *Id.*


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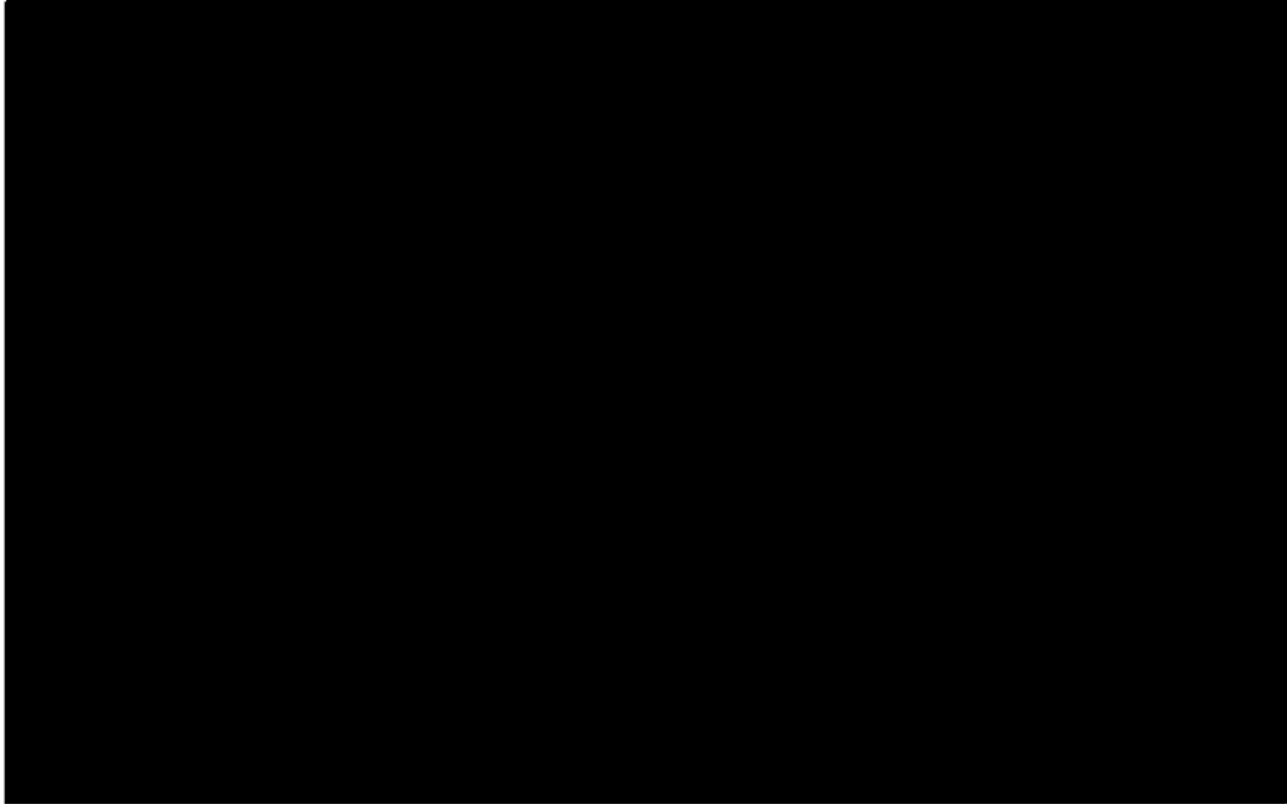
(citing Takahashi Decl., Ex. G (2009 USP section on lansoprazole delayed-release capsules) at 2753 (stating as to acid stage “[t]olerances” that “[n]ot more than 10% of the labeled amount of [lansoprazole] is dissolved in 60 minutes”)).



- 1 • A statement in United States Patent No. 6,897,205 (hereinafter, “Beckert”) that
2 Takeda contends is representative of the general understanding of those skilled in the
3 art indicating that release of under 10% is considered insignificant. *Id.* (citing Purles
4 Opp’n Decl., Ex. 3 (Dep. Ex. 524 (Beckert)) at col.4, ll.6-10 (“The outer polymer
5 coating is an enteric coating which rapidly dissolves only above about pH 5.5. The
6 coating is thus intended to prevent release of active ingredient in the substantially [sic]
7 stomach, i.e., this is intended to be no more than 10, preferably only 5, % according to
8 USP 23”).
- 9 • testimony of Handa’s expert, Dr. Mansoor Amiji, that the typical transit time through
10 the small intestine is 3.5 to 4.5 hours, with the pH level rising continuously through
11 the length of the intestine. *Id.* (citing Purles Opp’n Decl., Ex. 4 (Nov. 14, 2012 Amiji
12 Dep. Tr.) at 127:7-129:24) & Ex. 5 (Dep. Ex. 105) at 5). Takeda asserts that in light of
13 the fact that the ‘755 Patent envisions two distinct releases, one at the upper end of the
14 small intestine and another at the lower end of the small intestine, this testimony offers
15 further support for the time period suggested by Dr. Charman for measuring
16 dissolution. *Id.* (citing ‘755 Patent, col. 1, ll. 53-57 (“After administered orally, the
17 tablet, granule or fine granule migrates through gastrointestinal tract with releasing an
18 active ingredient to stomach, duodenum, jejunum, ileum and colon sequentially”).
- 19 • the FDA’s Dissolution Methods Database entry for dexlansoprazole, recommending
20 that in testing dexlansoprazole dissolution, sampling for the acid stage should be
21 conducted at 120 minutes. *Id.* (citing Takahashi Decl., Ex. P (Dissolution Methods)).
- 22 • 
- 23
24
25 • Dr. Charman’s deposition testimony that “any meaningful test for infringement must
26 have an amount limitation to account for small amounts of dissolution that inevitably
27 occur in any in vitro dissolution test of any significant duration,” especially in light of
28 manufacturing defects that commonly result in inappropriately coated or uncoated

1 drug in the formulation. *Id.* (citing Purles Opp'n Decl., Ex. 1 (Oct. 31, 2012 Charman
2 Dep. Tr.) at 254:20-260:23 (rejecting the 1% criterion put forward by Impax's expert,
3 Dr. Augsburger, on the grounds that there could be poorly-coated particles,
4 unencapsulated drug, or diffusion), 180:20- 181:8, 182:22-184: 12; *id.*, Ex. 7 (Nov. 1,
5 2012 Charman Dep. Tr.) at 58:16-59:8).

6 Takeda rejects Impax's arguments that Dr. Charman's reliance on the USP and FDA Draft
7 Guidance is inappropriate. *Id.* at 9. As to the USP protocol, Takeda argues that Impax has
8 mischaracterized the deposition testimony of Dr. Charman, 

9 

22 With respect to the FDA Draft Guidance, Takeda argues that it is "relevant and
23 informative to dissolution methods," pointing out that the Draft Guidance is currently available on
24 the FDA's website and is described as "[c]ontain[ing] [n]onbinding [r]ecommendations." *Id.* at
25 10-11 (citing Takahashi Decl., Ex. O (FDA Draft Guidance)). Takeda further asserts that while
26 the Draft Guidance is not mentioned in the '755 Patent and was issued after the filing of the
27 application leading to the '755 Patent, this does not preclude Dr. Charman from relying on it, as
28 the Federal Circuit has held that proof of infringement is not limited to methods in existence on

1 the date of the invention. *Id.* at 11 (citing *Am. Cyanamid Co. v. U.S. Surgical Corp.*, 833 F. Supp.
2 92, 130-31 (D. Conn. 1992); *Cosden Oil & Chem. Co. v. Am. Hoechst Corp.*, 543 F. Supp. 522,
3 530 (D. Del. 1982); *SmithKline Beecham Corp. v. Apotex Corp.*, 286 F. Supp. 2d 925, 942 (N.D.
4 Ill. 2001)).

5 Takeda contends that the intrinsic evidence does not contradict Dr. Charman's approach,
6 contrary to Impax's assertion. *Id.* at 11. First, it disagrees with Impax's position regarding the
7 significance of the passage in the '755 specification referring to a test that is between 5 and 8
8 hours in duration. *Id.* at 11-12 (citing '755 Patent, col. 10, ll. 13-17). According to Takeda, this
9 passage does not support the conclusion that testing should be performed over a longer time
10 period than two hours, as Impax contends. *Id.* Rather, Takeda argues, this passage must be
11 understood in context; in particular, Takeda asserts it is "clear from this portion of the
12 specification, the threshold pH for the formulation described therein was '6.75 or above.'" *Id.*
13 (citing '755 Patent, col.10, l.2). According to Takeda, this supports the conclusion that "the
14 'rapid and significant' release for this particular embodiment would only be expected at a pH of
15 6.75 or higher. That release was relatively slow and minimal at pH 6.0, a pH level significantly
16 below the target pH of this particular embodiment, is in no way inconsistent with Dr. Charman's
17 opinion that the claimed formulation should show rapid and significant dissolution above its
18 target pH." *Id.* at 12. [REDACTED]

19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 Takeda also rejects Impax's reliance on the Kurasawa affidavit and the remarks of the
23 inventors based upon the Kurasawa testing in the prosecution history. *Id.* Takeda argues that the
24 Kurasawa testing does not contradict Dr. Charman's approach because in that experiment,
25 Granule H did not begin "significantly to release drug until after 3.5 hours" but the test was
26 conducted at pH 6.8, that is, at a pH that was "much lower" than the upper end of the pH range
27 for the high pH granule described in claim 1 (which is 7.5). *Id.* (citing Purles Opp'n Decl., Ex.
28 10 (Dep. Ex. 108) at DEX0007124). According to Takeda, "that the granule released drug slowly

1 at pH level of 6.8 does not indicate how rapidly the drug would release within two hours at the
2 higher pH of 7.5, and thus in no way undermines Dr. Charman's opinion." *Id.* "In other words,
3 because the granule need only meet the claim limitation for one or more pH levels within the
4 claimed range, the fact that the granule did not begin to release drug within two hours at a
5 different pH value within the range does not undermine the validity of Dr. Charman's
6 interpretation of Takeda's infringement testing." *Id.*

7 Takeda further asserts that Impax's reading of the prosecution history would not have led
8 to the issuance of the patent because Takeda's arguments to the PTO would have made no sense.
9 *Id.* In particular, Takeda points to the remarks by the inventors, in response to the PTO's
10 rejection of the claims based on obviousness, distinguishing the Beckert prior art based on the
11 Kurasawa testing, comparing the release profile for Granule H of the invention to that of
12 Beckert's Pellet B. *Id.* at 12-13. This comparison showed that Granule H achieved 30%
13 dissolution after four hours, and nearly 100% after six hours, at pH 6.8, while Pellet B released
14 not more than 20% after six hours at pH 6.8. *Id.* (citing Purles Opp'n Decl., Ex. 10 (Dep. Ex.
15 108) at DEX0007130; Charman Decl. ¶ 26). According to Takeda, "under Impax's view of
16 infringement, this minimal and slow release from the Beckert Pellet B would still have satisfied
17 the claim limitations of the '755 patent." *Id.* at 13. Takeda argues that the fact that the patent
18 Examiner understood the release profile of the invention to be patentably distinct from that of the
19 Beckert formulation supports Dr. Charman's opinion that the amount and rate of release is
20 critical to determining whether the limitations of the '755 Patent are satisfied. *Id.*

21 Takeda also rejects Impax's reliance on Takeda's claim construction reply brief to suggest
22 that Takeda took an inconsistent position by citing the Kurasawa testing to show that the release
23 limitation was not indefinite and that a person of ordinary skill in the art would know how to
24 assess infringement based, in part, on the prosecution history. *Id.* Takeda asserts that it pointed
25 to the Kurasawa testing only to show that a person skilled in the art would know to perform
26 dissolution testing *like* that performed by Kurasawa, not identical to those tests. *Id.* Takeda
27 points out that performing the identical tests would not allow for an assessment of infringement in
28 any event as the Kurasawa tests were conducted at 6.8 pH; according to Takeda, tests conducted

1 at that pH would provide only incomplete information about how the high pH granule would
2 behave at the upper end of the pH range and no information concerning the behavior of the low-
3 pH granule in the claimed 5.0 to 6.0 pH range. *Id.*

4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED] Takeda also notes that Impax has
16 not cited any expert testimony or scientific literature in support its position. *Id.* Nor is Impax's
17 reliance on the prosecution history justified, Takeda contends. *Id.* Although Impax relies on the
18 fact that the Kurasawa testing focused on the high-pH granule, Takeda argues that that testing
19 was conducted only to distinguish the Beckert prior art and did not go to the infringement
20 analysis. *Id.* [REDACTED]
21 [REDACTED]
22 [REDACTED]

23 **c. Impax's Reply**

24 [REDACTED]
25 [REDACTED]
26 [REDACTED]
27 [REDACTED] Impax again argues that the intrinsic evidence
28 contradicts Dr. Charman's position and points to statements made by Takeda at claim

1 construction in which it argued that the release term was not indefinite because the Kurasawa
2 testing described in the prosecution history “provides a specific dissolution methodology that one
3 skilled in the art could use to assess ‘release.’” *Id.* at 2 (quoting Takeda’s Reply Brief on Claim
4 Construction at 15). According to Impax, Takeda has changed its position on this point to the
5 extent it now contends that because the Kurasawa tests were performed at pH 6.8 and Granule H
6 might dissolve faster at pH 7.5, the methodology would have to be modified. *Id.* at 2-3. Impax
7 rejects this reasoning, arguing that there is no evidence that Granule H would have dissolved
8 faster at a higher pH. *Id.* at 3. Moreover, regardless of how Granule H performed, to the extent
9 that the applicants sought allowance using a six hour test, Impax asserts, the Court cannot now
10 interpret the claims in an entirely different way, using a two-hour test. *Id.* (citing *Chimie v. PPG*
11 *Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005); *Springs Window Fashions LP v. Novo Indus.*
12 *L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003); *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d
13 1366, 1379 (Fed. Cir. 2008)).

14 Impax also rejects Takeda’s reliance on the Federal Circuit’s decisions in *Acumed LLC v.*
15 *Stryker Corp.*, 483 F.3d 800, 805-6 (Fed. Cir. 2007), *Biotec Biologische Naturverpackungen*
16 *GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1349 (Fed. Cir. 2001), and *Modine Mfg. Co. v.*
17 *Int’l Trade Comm’n*, 75 F.3d 1545, 1554-55 (Fed. Cir. 1996), arguing that these cases merely
18 stand for the proposition that “in construing claims, the Court should provide as much specificity
19 as the claim language and intrinsic evidence permit, while the trier of fact must resolve any
20 further ambiguity as a question of fact in the infringement analysis.” *Id.* at 4. Still, Impax argues,
21 “[t]he Federal Circuit consistently has held that district courts should resolve disputes about claim
22 scope as an issue of claim construction, not leave them for the trier of fact.” *Id.* at 5-6 (citing
23 *Every Penny Counts, Inc. v. Am. Express Co.*, 563 F.3d 1378, 1382-83 (Fed. Cir. 2009); *O2 Micro*
24 *Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008); *AK Steel Corp.*
25 *v. Sollac*, 344 F.3d 1234, 1239-40 (Fed. Cir. 2003); *Creative Internet Adver. Corp. v. Yahoo!,*
26 *Inc.*, 476 Fed. Appx. 724, 728 (Fed. Cir. 2011)).

27 Impax argues that *O2 Micro* involved a dispute similar to the one in this case. *Id.* at 6.
28 There, the parties disagreed about the scope of the claim term “only if said feedback signal is

1 above a predetermined threshold,” and particularly, whether the words “only if” applied only at
2 certain times or at all times. *Id.* The district court declined to construe the words “only if” on the
3 basis that those words have a well understood meaning, but the Federal Circuit reversed, holding
4 that the dispute went to the scope of the claims rather than the meaning of the particular words,
5 which is a question for the court. *Id.* Similarly, Impax asserts, the Court here should determine
6 the scope of the claims, reject Dr. Charman’s two hour limitation and find in favor of Impax on
7 that basis. *Id.*



11 **d. Supplemental Briefs**

12 Following the February 8, 2013 hearing, the parties in this case and the related cases
13 submitted supplemental briefing at the request of the Court addressing whether it should engage
14 in additional construction of the release term of the ‘755 Patent. *See* Case No. C-11-0840 JCS,
15 Docket Nos. 251 (Takeda), 252 (Handa); Case No. 11-1609, Docket No. 223 (TWi); Case No. C-
16 11-1610, Docket No. 228 (Impax).

17 **III. ANALYSIS**

18 **A. Legal Standards**

19 **1. Legal Standard Governing Summary Judgment**

20 Summary judgment on a claim or defense is appropriate “if the movant shows that there is
21 no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of
22 law.” Fed. R. Civ. P. 56(a). In order to prevail, a party moving for summary judgment must
23 show the absence of a genuine issue of material fact with respect to an essential element of the
24 non-moving party’s claim, or to a defense on which the non-moving party will bear the burden of
25 persuasion at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the movant has
26 made this showing, the burden then shifts to the party opposing summary judgment to designate
27 “specific facts showing there is a genuine issue for trial.” *Id.* “[T]he inquiry involved in a ruling
28 on a motion for summary judgment . . . implicates the substantive evidentiary standard of proof

1 that would apply at the trial on the merits. *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 252
 2 (1986). On summary judgment, the court draws all reasonable factual inferences in favor of the
 3 non-movant. *Id.* at 255.

4 **2. Legal Standard Governing Patent Infringement**

5 A determination of infringement is a two-step process. *Wright Med. Tech., Inc. v.*
 6 *Osteonics Corp.*, 122 F.3d 1440, 1443 (Fed. Cir. 1997). The first step is claim construction,
 7 which is a question of law to be determined by the court. *Id.* The second step is an analysis of
 8 infringement, in which it must be determined whether a particular device infringes a properly
 9 construed claim. *Id.* A device literally infringes if each of the limitations of the asserted claim is
 10 found in the accused device. *Id.* The patentee always bears the burden of proof on infringement.
 11 *Under Sea Industries, Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987). Thus, a
 12 patentee is entitled to summary judgment if it can show that it is “more likely than not” that the
 13 accused product possesses all of the elements of the asserted claim. *Warner-Lambert Co. v. Teva*
 14 *Pharms. USA, Inc.*, 418 F.3d 1326, 1341 (Fed. Cir. 2005) (citing *Anderson v. Liberty Lobby Inc.*,
 15 477 U.S. at 252). Once the patentee has made a prima facie showing that it is more likely than
 16 not that all the claim limitations are met, the accused infringer must come forward with more than
 17 a scintilla of evidence to create a genuine issue of material fact as to non-infringement. *Id.*
 18 Conversely, an accused infringer is entitled to summary judgment of non-infringement where it
 19 shows “that the patentee failed to put forth evidence to support a finding that a limitation of the
 20 asserted claim was met by the structure in the accused devices.” *Johnston v. IVAC Corp.*,
 21 885 F.2d 1574, 1578 (Fed. Cir. 1989).

22 Takeda asserts its infringement claims under 35 U.S.C. § 271(e)(2); it also seeks a
 23 declaratory judgment of infringement and injunctive relief under 35 U.S.C. § 271(a) and the
 24 Declaratory Judgment Act. Section 271(e)(2) provides that:

25 [i]t shall be an act of infringement to submit . . . an [ANDA
 26 application to the FDA] . . . if the purpose of such submission is to
 27 obtain approval under such Act to engage in the commercial
 28 manufacture, use, or sale of a drug, veterinary biological product, or
 biological product claimed in a patent or the use of which is
 claimed in a patent before the expiration of such patent.

1 35 U.S.C. § 271(e)(2). Section 271(a) provides that “whoever without authority makes, uses,
2 offers to sell, or sells any patented invention, within the United States or imports into the United
3 States any patented invention during the term of the patent therefor, infringes the patent.” 35
4 U.S.C. § 271(a).

5 3. Legal Standards Governing Invalidity Based on Lack of Written Description

6 The Patent Act requires that every patent must contain a written description and be
7 enabled, as stated in 35 U.S.C. § 112 ¶ 1, which provides as follows:

8 The specification shall contain a written description of the
9 invention, and of the manner and process of making and using it, in
10 such full, clear, concise, and exact terms as to enable any person
11 skilled in the art to which it pertains, or with which it is most nearly
12 connected, to make and use the same, and shall set forth the best
13 mode contemplated by the inventor of carrying out his invention.

14 To satisfy the written description requirement, “the description ‘must clearly allow persons of
15 ordinary skill in the art to recognize that [the inventor] invented what is claimed.’” *Id.* at 1351
16 (quoting *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). “In other words, the test for
17 sufficiency is whether the disclosure of the application relied upon reasonably conveys to those
18 skilled in the art that the inventor had possession of the claimed subject matter as of the filing
19 date.” *Id.* (quoting *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir.
20 1985)).

21 The Federal Circuit in *Ariad* acknowledged that the term “possession” “has never been
22 very enlightening.” *Id.* It explained that “the hallmark of written description is disclosure” and
23 that the “test requires an objective inquiry into the four corners of the specification from the
24 perspective of a person of ordinary skill in the art.” *Id.* “For generic claims, [the Federal Circuit
25 has] set forth a number of factors for evaluating the adequacy of the disclosure, including ‘the
26 existing knowledge in the particular field, the extent and content of the prior art, the maturity of
27 the science or technology, [and] the predictability of the aspect at issue.’” *Id.* Thus, the inquiry
28 is a question of fact and is context-specific. *Id.* (citing *Ralston Purina*, 772 F.2d at 1575; *Capon*
v. Eshhar, 418 F.3d 1349, 1357–58 (Fed.Cir.2005)). However, certain “broad principles . . . hold
true across all cases.” *Id.* at 1352. The Federal Circuit described these principles as follows:

1 We have made clear that the written description requirement does
 2 not demand either examples or an actual reduction to practice; a
 3 constructive reduction to practice that in a definite way identifies
 4 the claimed invention can satisfy the written description
 5 requirement. *Falko–Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366–
 6 67 (Fed.Cir.2006). Conversely, we have repeatedly stated that
 7 actual “possession” or reduction to practice outside of the
 8 specification is not enough. Rather, as stated above, it is the
 9 specification itself that must demonstrate possession. And while the
 10 description requirement does not demand any particular form of
 11 disclosure, *Carnegie Mellon Univ. v. Hoffmann–La Roche Inc.*, 541
 12 F.3d 1115, 1122 (Fed.Cir.2008), or that the specification recite the
 13 claimed invention in haec verba, a description that merely renders
 14 the invention obvious does not satisfy the requirement, *Lockwood v.*
 15 *Am. Airlines*, 107 F.3d 1565, 1571–72 (Fed.Cir.1997).

16 *Id.* at 1352.

17 In cases involving a chemical genus, the written description requirement is met where the
 18 specification “discloses either a representative number of species falling within the scope of the
 19 genus or structural features common to the members of the genus so that one of skill in the art can
 20 ‘visualize or recognize’ the members of the genus.” *Id.* at 1350. The Federal Circuit further
 21 explains in *Ariad* that “[t]he written description requirement . . . ensures that when a patent
 22 claims a genus by its function or result, the specification recites sufficient materials to accomplish
 23 that function—a problem that is particularly acute in the biological arts.” *Id.* Thus, in *University*
 24 *of Rochester v. G.D. Searle & Co., Inc.*, for example, the Federal Circuit invalidated claims
 25 directed to a method of selectively inhibiting the COX–2 enzyme by administering a non-steroidal
 26 compound that selectively inhibits the COX–2 enzyme because the specification did not describe
 27 any specific compound capable of performing the claimed method and the skilled artisan would
 28 not be able to identify any such compound based on the specification’s function description. 358
 F.3d 916, 927-928 (Fed. Cir. 2004).

Finally, to meet the written description requirement, “[a]n applicant is not required to
 describe in the specification every conceivable and possible future embodiment of his invention.”
Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1365 (Fed. Cir. 2003) (quoting *Rexnord*
Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed. Cir. 2001)). Thus, “[a] specification may,
 within the meaning of 35 U.S.C. § 112 para. 1, contain a written description of a broadly claimed

1 invention without describing all species that [the] claim encompasses.” *Id.* (quoting *Utter v.*
2 *Hiraga*, 845 F.2d 993, 998 (Fed. Cir.1988)). Further, “[a] patent need not teach, and preferably
3 omits, what is well known in the art.” *Epistar Corp. v. International Trade Commission*, 566
4 F.3d 1321, 1336 (Fed. Cir. 2009) (quoting *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524,
5 1534 (Fed. Cir. 2009)).


6 In *Ariad*, the Federal Circuit made clear that the written description requirement is distinct
7 from the enablement requirement, although the two “often rise and fall together.” 598 F.3d at
8 1352. The test for enablement is whether a person “skilled in the art, after reading the
9 specification, could practice the claimed invention without undue experimentation.” *Sitrick v.*
10 *Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008) (citation omitted). In determining
11 whether a disclosure requires undue experimentation, courts may consider the following factors:

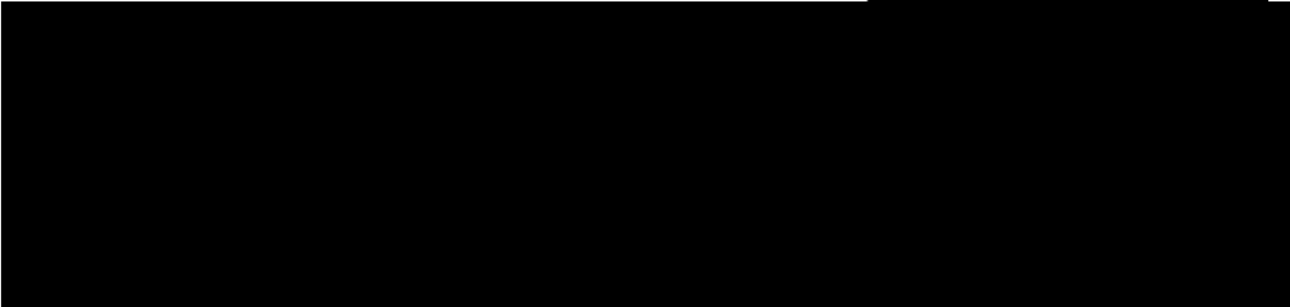
12 (1) the quantity of experimentation necessary, (2) the amount of
13 direction or guidance presented, (3) the presence or absence of
14 working examples, (4) the nature of the invention, (5) the state of
15 the prior art, (6) the relative skill of those in the art, (7) the
predictability or unpredictability of the art, and (8) the breadth of
the claims.

16 *ALZA Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (quoting *In re*
17 *Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)).

18 **B. The ‘058 and ‘971 Patents**

19 **1. Infringement**

20 Both Takeda and Impax seek entry of summary judgment on the question of infringement
21 of claims 1 and 3 of the ‘058 Patent and claim 7 of the ‘971 Patent. 

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27 The Court need not reach these questions, however, because it finds that Takeda is entitled to
28 summary judgment based on the facts that are not in dispute.

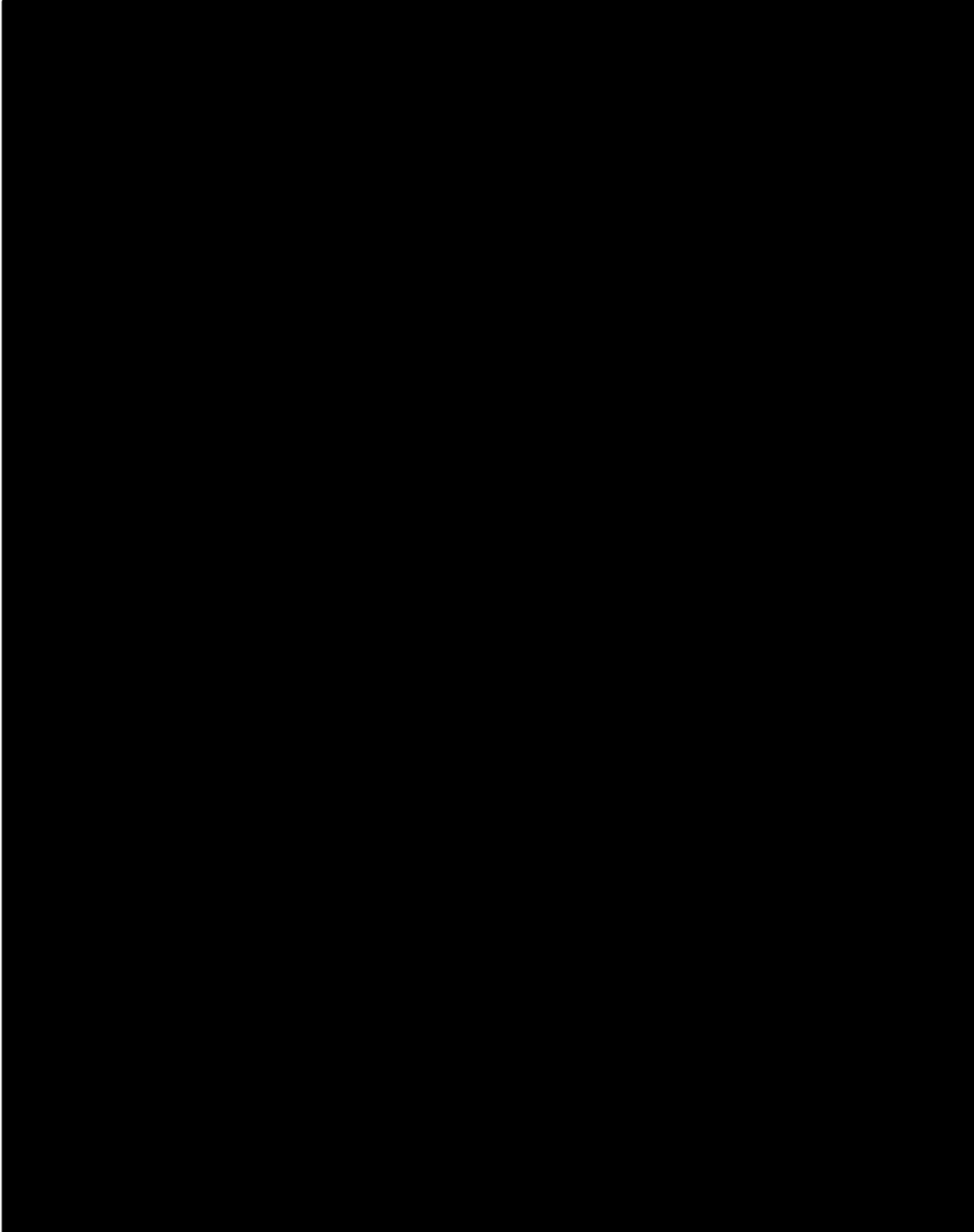
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[REDACTED] the Court

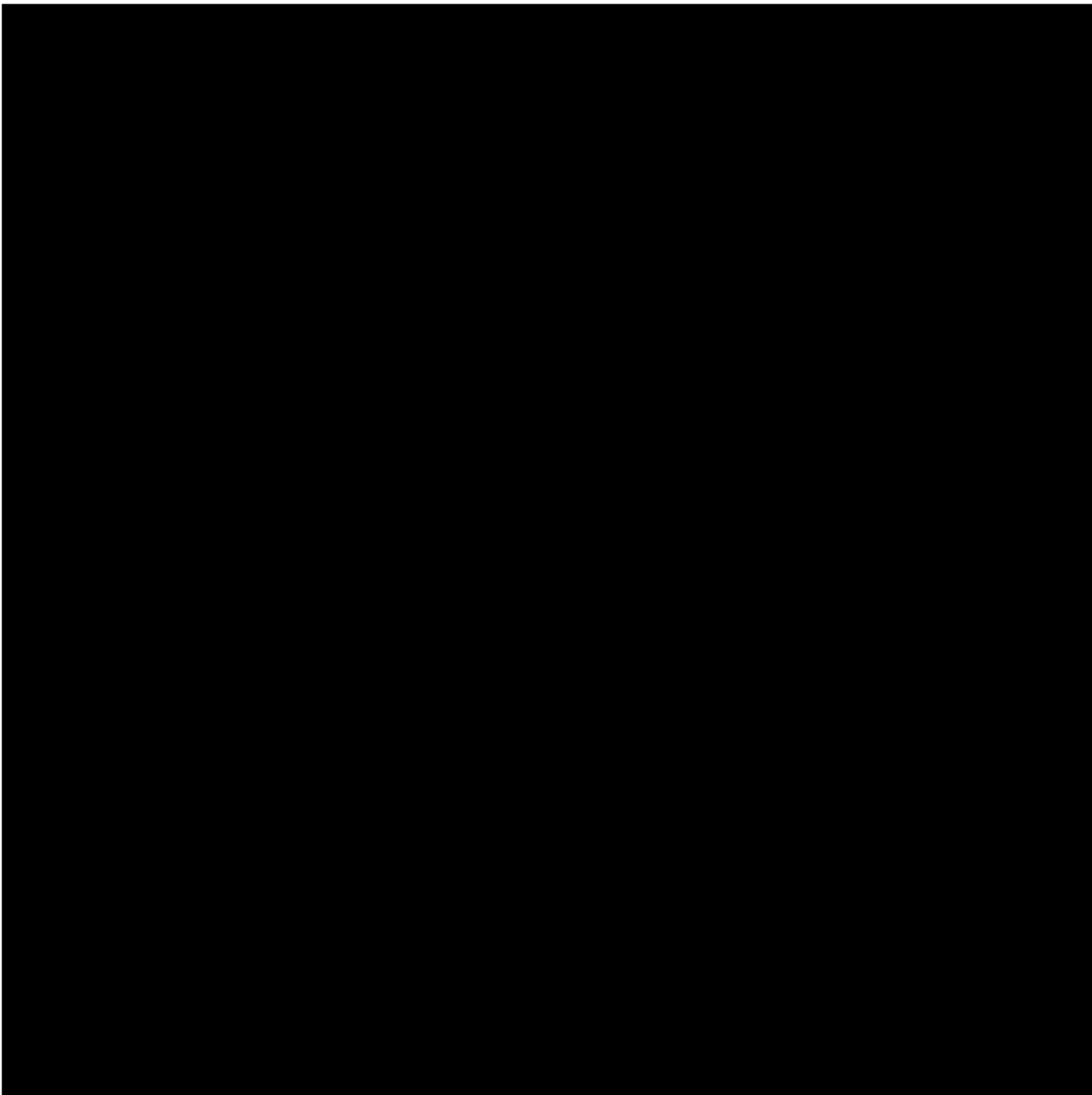
addresses an issue that was not briefed by the parties, namely, whether Takeda has established standing under the Declaratory Judgment Act. Takeda’s claim of infringement of the ‘058 Patent is based, in part, on the theory that the API used by Impax meets all the limitations of claim 1. Takeda asserts that claim under the Declaratory Judgment Act and §271(a) rather than under the Hatch-Waxman Act.

To establish a case or controversy under Article III of the U.S. Constitution, a claim must be “‘definite and concrete, touching the legal relations of parties having adverse legal interests’; and that it be ‘real and substantial’ and ‘admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.’” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)(quotations omitted). Some courts have permitted claims under §271(a) seeking declaratory judgment of infringement based on the filing of an ANDA. *See, e.g., Cephalon v. Sandoz, Inc.*, 2012 WL 682045 , at *5 (D. Del. Mar. 1, 2012); *Bayer Healthcare, LLC v. Norbrook Labs., Ltd.*, 2009 WL 6337911, at *13-14 (E.D. Wis. Sept. 24, 2009) . Other courts, however, have held that such claims are not sufficiently real and immediate to satisfy the requirements of *MedImmune*. *See, e.g., Eisai*, 2007 WL 4556958 (D.N.J. Dec. 20, 2007); *see also Abbott Las. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 983 (N.D. Ill. 1995) (questioning whether such a claim is consistent with Congress’ intent in providing a safe haven for generic manufacturers under the Hatch-Waxman Act). As the parties have not briefed this issue, the Court does not reach the questions of whether Takeda can establish the existence of a “definite and concrete” controversy on its infringement claims under § 271(a) and the Declaratory Judgment Act, or whether its claim may run afoul of the safe haven provisions of the Hatch-Waxman Act. [REDACTED]

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2. Invalidity

Impax contends that the “effective amount” limitation in claims 6 and 7 of the ‘971 Patent lacks sufficient written description, thus rendering these claims invalid, because the specification does not describe any clinical trials or testing from which a person skilled in the art could determine the amount that would be needed to meet this limitation for any particular disease or mammal. There appears to be no dispute between Takeda and Impax that although a person skilled in the art could determine the specific dosages that would constitute an effective amount

1 for different diseases and mammals fairly easily, the '971 specification does not provide the
 2 results of clinical studies showing what these dosages would be. Thus, resolution of this issue
 3 turns on whether the inventors' failure to disclose specific testing or amounts in the specification
 4 is sufficient to demonstrate, by clear and convincing evidence, that the inventors did not have
 5 possession of the claimed invention. The Court finds that it is not.

6 As discussed above, the clear and convincing evidence standard is applied to invalidity
 7 challenges because a patent is presumed to be valid. Nonetheless, if the written description in the
 8 specification is insufficient to demonstrate that the inventors had possession of the invention, that
 9 presumption is rebutted. Impax relies heavily on a series of cases in which a claimed chemical
 10 genus was found not to be supported by adequate written description. *See Boston Scientific Corp.*
 11 *v. Johnson & Johnson*, 647 F.3d at 1363; *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336,
 12 1349 (Fed. Cir. 2010) (*en banc*); *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916,
 13 918-919 (Fed. Cir. 2004); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567-68
 14 (Fed. Cir. 1997)). Not one of these cases involves a limitation calling for an "effective amount"
 15 of a particular chemical compound. Rather, all claimed a broad range (or genus) of chemical
 16 compounds -- or in the case of *Regents of the Univ. of Cal. v. Eli Lilly & Co* -- DNA material,
 17 where there was little prior art discussing the subject matter. Under these circumstances, a
 18 person of skill in the art would not be able to "visualize or recognize" a member of the claimed
 19 genus. The facts here are markedly different -- a person skilled in the art could certainly
 20 visualize or recognize a particular amount of dexlansoprazole as being within the claim limitation,
 21 particularly as there is no dispute that there was prior art as of the priority date addressing the
 22 proper dosages for Prevacid[®] and for lansoprazole.


23 The Court also rejects Impax's assertion that the ease with which a person of skill in the
 24 art could determine an "effective amount" is not relevant to the question of whether a patent
 25 provides adequate written description and goes only to enablement. While the amount of testing
 26 required to practice the invention is indeed relevant to the question of enablement, it is also a
 27 consideration in determining whether there is adequate written description to the extent that courts
 28 are instructed to take into account the context of the invention and "the state of the knowledge" in

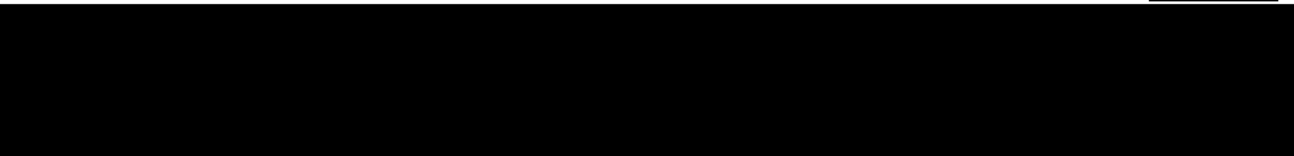
1 the relevant art in addressing this question. *See Capon*, 418 F.3d at 1358. The fact that the
2 clinical trials that would be necessary to determine an “effective amount” of dexlansoprazole
3 would be easily understood by a person skilled in the art thus supports the conclusion that the
4 inventors possessed the invention even though they did not include specific clinical testing results
5 in the specification of the ‘971 Patent.

6 The Court concludes that the ‘971 Patent contains adequate written description to support
7 claims 6 and 7 of the ‘971 Patent.

8 **C. The ‘755 Patent**



17 As noted above, at the claim construction stage of the case, the Court construed the phrase
18 “released in the pH range of no less than 5.0 to no more than 6.0” to mean “begins to be released
19 from the tablet, granule or fine granule at pH values within the range from 5.0 to 6.0.” The
20 Court’s construction makes clear that the range set forth in the release term is a threshold at which
21 release begins. The Court acknowledged in its claim construction order that the parties disagree
22 about what testing should be conducted to determine infringement but found that this
23 disagreement goes to infringement rather than indefiniteness, rejecting the defendants’ argument
24 that a person skilled in the art would not know how to determine when release “begins.” 



28 ⁷ The general legal standards governing claim construction are set forth in the Court’s claim
construction order. *See* Docket No. 106. Therefore, the Court does not repeat them here.

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6 First, the Court looks to the claim language. “Absent an express intent to impart a novel
7 meaning, claim terms take on their ordinary meaning.” *Elekta Instrument S.A. v. O.U.R. Scientific*
8 *International, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000) (citation omitted). The plain language
9 of the release term of claim 1 sets forth a specific range of pH values in which release of the API
10 must begin. This range captures the idea set forth in the specification that composition (ii)
11 dissolves at a pH of “about 5.5.” See ‘755 Patent, col. 2, ll. 48-53 (stating in the “Disclosure of
12 Invention” section that the invention provides a “capsule . . . which comprises a tablet, granule or
13 fine granule having an enteric coat that releases an active ingredient at the pH of about 5.5”). In
14 other words, the claim language *already* allows for some dissolution to occur below the 5.5 target
15 pH level for composition (ii) while remaining within the scope of the claim. Were the Court to
16 insert further qualifying language in its construction that allowed release *below* the lower end of
17 the range claimed by the inventors, it would not only be ignoring the ordinary meaning of the
18 claim term but would also be rendering the lower end of the range in the claim superfluous to the
19 extent that release would be permitted both below 5.0 *and* above 5.0. See *Elekta*, 214 F.3d at
20 1307 (reversing district court’s construction of the term “only within a zone extending between
21 latitudes 30° - 45°” as meaning “beginning at the edge of the helmet (0°) and extending to a point
22 between 30° - 45°” on the basis that it was inconsistent with ordinary meaning of claim language
23 and rendered lower end of the range superfluous); *U.S. Philips Corp. v. Isasaki Elec. Co.*, 505
24 F.3d 1371, 1376 (Fed. Cir. 2007) (affirming district court’s construction of term “between 10^{-6}
25 and 10^{-4} <<mu>>mol/mm³” as meaning “between 1×10^{-6} and 1×10^{-4} <<mu>>mol/mm³” and
26 noting that district court was correct that “the overall phrase - ‘a quantity between -- and --’ - is a
27 construction that ‘implies a specific range . . . it does not imply a range between two values which
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1 are themselves ranges”). Thus, the unambiguous language of the claim supports a construction
2 that does not permit release of the API outside of the claimed range.

3 Further, nothing in prosecution history or the specification of the ‘755 Patent persuades the
4 Court that it is appropriate to read into the release term a requirement that release must be
5 significant and rapid (or to state it somewhat differently, that the claim covers embodiments in
6 which there is no *significant* release below the lower end of the range, pH 5.0). The parties hotly
7 dispute the significance of: 1) the applicants’ reliance on the Kurasawa testing during patent
8 prosecution; and 2) the disclosure in columns 9 and 10 of the ‘755 Patent. Beyond the fact that
9 both describe testing that was conducted over a longer period of time than Takeda asserts is
10 appropriate for determining whether the release limitation is satisfied, suggesting that the two-
11 hour limitation proposed by Takeda is incorrect, the Court finds that neither the prosecution
12 history nor the passage in the specification offers significant guidance as to the construction of the
13 release term.

14 On one hand, the Kurasawa testing revealed a dissolution rate of less than 5% dissolution
15 after 2 hours and thus, the embodiment of the invention tested by Kurasawa would not have
16 satisfied the “significant and rapid” requirement that Takeda asks the Court to read into the
17 release term.⁸ On the other hand, the single example describing testing in the specification, found
18 in columns 9 and 10, arguably supports Takeda’s position that claim 1 allows some release below
19 the claimed pH ranges. That passage states as follows:

20 It is desirable that the coating material is used alone or, if necessary,
21 in combination so that the polymer is dissolved, preferably at a pH
22 of 6.0 or above, more preferably at a pH of 6.5 or above, and further
23 more preferably at a pH of 6.75 or above. . . . The rate of elution of
24 active ingredient from the active-ingredient release-controlled
25 tablet, granule or fine granule thus obtained is desirably 10% or less
26 for 5 hours in a solution of pH 6.0, and 5% or less for one hour and
27 60% or more for 8 hours in a solution of pH 6.8.

28 ⁸The Court notes that the Kurasawa testing involved the high pH granule rather than the low pH granule that is the subject of the release term. Nonetheless, at claim construction Takeda argued that the Kurasawa testing would have offered guidance to a person of ordinary skill in the art as to how to measure whether the release term was satisfied.

1 '755 Patent, col. 9, l. 65 - col. 10, l. 17. Neither of the examples, however, addresses whether (or
2 when) the release described in them falls within the range set forth in the release term. Moreover,
3 even if Takeda is correct that the passage in the specification describes an embodiment that is
4 excluded under the Court's current construction of the release term, this does not justify
5 modifying the construction as "the unambiguous language of the . . . claim controls over any
6 contradictory language in the written description." *Elekta*, 214 F.3d at 1308. Finally, to the
7 extent that the Court finds that the claims themselves are unambiguous, reliance on extrinsic
8 evidence, such as the USP, is not a proper basis for varying the meaning of the term. *See*
9 *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In most situations,
10 an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In
11 such circumstances, it is improper to rely on extrinsic evidence.").

12 For these reasons, the Court concludes that it is not appropriate to revise its construction of
13 the release term to insert qualifying language requiring that release must be rapid and significant.
14 Rather, the Court finds that a product falls outside of the ambit of claim 1 if there is any
15 measurable release of the API from the low pH granule below the range specified in the release
16 term.

[REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

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27 9 [REDACTED]

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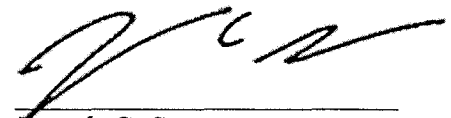
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IV. CONCLUSION

For the reasons stated above, Takeda's Motion is GRANTED. Impax's Motion is GRANTED in part and DENIED in part.

IT IS SO ORDERED.

Dated: April 8, 2013



Joseph C. Spero
United States Magistrate Judge

UNITED STATES DISTRICT COURT
FOR THE
NORTHERN DISTRICT OF CALIFORNIA

TAKEDA PHARMACEUTICALS et al,

Plaintiff,

v.

IMPAX LABORATORIES et al,

Defendant.

Case Number: CV11-01610 JCS

SEALED CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that I am an employee in the Office of the Clerk, U.S. District Court, Northern District of California.

That on April 8, 2013, I SERVED a true and correct copy(ies) of the attached, by placing said copy(ies) in a postage paid envelope addressed to the person(s) hereinafter listed, by depositing said envelope in the U.S. Mail, or by placing said copy(ies) into an inter-office delivery receptacle located in the Clerk's office.

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Dated: April 8, 2013

Karen L. Hom

Richard W. Wieking, Clerk
By: Karen Hom, Deputy Clerk