IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-691 (GBW)
	)	
AVADEL CNS PHARMACEUTICALS LLC,	)	PUBLIC VERSION
	)	
Defendant.	)	

JAZZ PHARMACEUTICALS, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR A STAY PENDING APPEAL OR, IN THE ALTERNATIVE, A STAY PENDING APPLICATION TO THE FEDERAL CIRCUIT FOR A STAY PENDING APPEAL

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INTRODUCTION

Avadel seeks to prevent Jazz from obtaining meaningful appellate review of the novel legal questions underlying Jazz's appeal of the Court's mandatory injunction. While Avadel disputes the merits of Jazz's arguments and Jazz's ability to raise them, the case that Avadel relies upon (*Newimar*) confirms that novel legal questions satisfy the first requirement for a stay pending appeal. That same case—in which the party delayed five months in seeking a stay and failed to expedite the appeal—also confirms that Jazz's filing of its stay request two business days after the Court's order provides no reason to deny the request. Indeed, the Federal Circuit recognized as much, issuing a temporary stay to afford time for this Court and, if necessary, the Federal Circuit to consider Jazz's stay request before Jazz loses the opportunity to obtain meaningful relief.

Beyond the presence of novel legal issues, Jazz has shown a serious question as to whether delisting is required. Neither Avadel in its briefing on the motion for judgment on the pleadings nor the Court in its Order addressed the retroactivity question or the need to reconcile various statutory provisions. While Avadel incorrectly argues that Jazz waived certain merits arguments dependent on the Court's claim construction, it also overlooks that Jazz did not have the benefit of the Court's claim construction in briefing Avadel's motion for judgment on the pleadings.

Finally, in contrast to Jazz's demonstrated loss of its pediatric exclusivity and inability to obtain meaningful relief on appeal absent a stay, recent [redacted]. By agreement, the appeal will be fully briefed in the next 60 days, and thus Avadel cannot show any harm from a stay during that time. Further, because any harm to Avadel is speculative at best, Avadel is not entitled to a bond, although Jazz would be willing to provide one if ordered to do so.

ARGUMENT

I. THIS COURT SHOULD STAY ITS INJUNCTION PENDING APPEAL

A. Jazz Acted Promptly And In Good Faith

Jazz's conduct in connection with its stay request has focused on one goal: preserve the status quo so that the Federal Circuit can meaningfully assess the merits of Jazz's appeal. Jazz acted swiftly to achieve that goal, filing an appeal and a stay motion in this Court two business days after this Court's entry of an injunction (*compare* D.I. 232 *with* D.I. 235), and then seeking a short administrative stay when this Court entered a briefing schedule that would not give the Federal Circuit sufficient time to address a stay motion on appeal, if necessary (*see* D.I. 238).

Avadel accuses Jazz of "strategic machinations," exploiting Thanksgiving, and "feign[ing] impracticability" (Opp. 4). But the only case Avadel cites on this point highlights the weakness of Avadel's position. *See Newimar, S.A. v. United States*, 2022 WL 17072803 (Fed. Cl. Nov. 14, 2022) (cited at Opp. 4). The *Newimar* court rejected a stay request filed *five months* after the entry of judgment, reasoning that the failure to seek an earlier stay (and the failure to "pursue an expedited appeal *before the Federal Circuit*") belied its assertion of "imminent and irreparable harm." *Id.* at *4 (emphasis added). Here, Jazz acted in *two business days* and pursued an expedited appeal. *See* Ex. A. Jazz did exactly what *Newimar* suggests a party should do.

Jazz also acted consistently with Rule 8 of the Federal Rules of Appellate Procedure—which Avadel fails to address. Rule 8 expressly contemplates that a party may do *exactly* what Jazz has done here—first seek a stay from the district court, and then, if necessary, seek a stay from the court of appeals if the initial stay motion has not been resolved. Any other approach would risk leaving the court of appeals with insufficient time to consider the merits of a stay motion, thus inconveniencing the appellate courts and disserving judicial economy.

B. Jazz Presents, At A Minimum, A Substantial Case On The Merits

Jazz has demonstrated (Br. 6-15) a substantial case on the merits and Avadel does not undermine this showing. *First*, given that the scope of the delisting statute is a question of first impression that the Federal Circuit will review *de novo* as a question of statutory construction, Jazz has satisfied this first factor the stay inquiry. Br. 14. Avadel's cited case confirms this factor is met by the presence of a novel issue. *Newimar*, 2022 WL 17072803, at *3 ("The movant must demonstrate that *the question raised is novel* …." (emphasis added)).

Second, Avadel wrongly contends (Opp. 4-6) that Jazz cannot show a substantial question on the merits because "[t]he statute does not require an inquiry into whether the NDA holder was authorized to list the patent in the first instance." (emphasis omitted). Avadel cites no case supporting that position—neither *Lantus* nor *Caraco* addressed it. And Avadel's reliance (Opp. 5-6) on case law regarding the general contours of statutory interpretation leads to the statutory interpretation principles on which Jazz relies—including those requiring newly-enacted statutory provisions to have meaning and foreclosing retroactive application absent express language.

Although Avadel argues (Opp. 7-8) that the listing statute is in "perfect harmony" with the delisting statute because the listing statute authorizes an exclusive category of permissibly-listable patents, and all other categories cannot be listed, the statutory text is silent on that issue. Notably, if Avadel's interpretation were accurate, the provision of the OBTA that amends section 505(c)(2) of the FDCA, and which states that "[p]atent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph," 21 U.S.C. § 355(c)(2), would be superfluous. Such an interpretation is disfavored under the law Avadel cites. *See Nat'l Ass'n of Mfrs v. Dep't of Defense*, 138 S. Ct. 617, 632 (2018) (rejecting "an interpretation of the statute that would render an entire subparagraph [of the statute] meaningless")).

Moreover, the FDA has rejected Avadel's interpretation by promulgating regulations that enumerate the categories of patents that "must" and "must not" be listed and declining to include in the "must not" category the type of patent into which the '963 patent falls (under either party's construction). 21 C.F.R. § 314.53(b)(1). At a minimum, the FDA's rejection of Avadel's interpretation establishes a substantial question, given that responsibility for implementation of the FDCA and interpretation of the corresponding regulations lies primarily with that agency.[1] While Avadel argues that *Lantus* rebuts this point, *Lantus* supports Jazz, because the court there delisted a patent that purported to, but in fact did not, claim (let alone mention) the drug for which the application was approved. *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 7-10 (1st Cir. 2020).

Avadel next asserts (Opp. 8-9) that the OBTA should be construed as merely a clarification of the original listing statute. But the fact that Congress, through the OBTA, later "demonstrated its ability to specify a statute's applicability … and indeed to make explicit refence," instead renders it "unreasonable to infer" that Congress intended the initial listing statute to prohibit the listing of all categories of patents that were not required to be listed. *Canadian Lumber Trade All. v. United States*, 517 F.3d 1319, 1343 (Fed. Cir. 2008). As the existence of the OBTA demonstrates, Congress understands how to *prohibit* the listing of all patent information that is not required to be listed if Congress so intends, and it did not do so in the initial listing statute.

Third, Jazz also has strong arguments that the '963 patent belongs in the Orange Book because it claims an approved condition of use for Xyrem. *See* Br. 8-15. Contrary to Avadel's

[1] Nor does Jazz's interpretation of the listing statute render meaningless the delisting statute: under Jazz's construction, delisting remains an available remedy for the categories of patents that the FDA interpreted the listing statute to prohibit. Those categories include "process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates," 21 C.F.R. § 314.53(b)(1), all of which could be subject to delisting if they were improperly included.

argument (Opp. 11), Jazz preserved this argument, maintaining that the '963 patent covers "FDA-required conditions of use for Xyrem®" and thus "claims an approved 'method of using the drug' under both the relevant statute and FDA regulations." D.I. 159 at 13 (brackets omitted); *see also id.* at 9 (invoking "FDA's Orange Book listing rules"). The FTC responded to these very points, contesting Jazz's argument that "a REMS distribution patent claim[s] … 'other conditions of use' for [a] drug." D.I. 227 at 23.[2] Particularly given that Jazz did not have the benefit of the Court's claim construction in briefing Avadel's delisting motion or an opportunity to respond to the substance of FTC's position, Jazz sufficiently preserved this argument.

Preservation aside, Avadel faults Jazz (Opp. 13) for "rel[ying] on so-called 'ordinary speech'" to interpret the word "method" in 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb). But Jazz has good company. *See Ysleta Del Sur Pueblo v. Texas*, 142 S. Ct. 1929, 1938 (2022) (interpreting statute in light of "ordinary speech"). There is also nothing "haphazard" (Opp. 13) about the sources Jazz cited. The Supreme Court followed the same approach in *Wisconsin Central Limited v. United States*, 138 S. Ct. 2067, 2071 (2018), consulting Black's Law Dictionary, Webster's New International Dictionary, and a contemporaneous state-court decision in deriving the "ordinary meaning" of a statutory term. Far from being "cherry-picked" (Opp. 14), those sources—and many others[3]—show here that "system" can mean "method," and vice-versa. In other words: even if the

[2] Even were this argument "entirely new," because it concerns purely legal questions of statutory interpretation, the Federal Circuit can—and should—consider it. *See Cemex, S.A. v. United States*, 133 F.3d 897, 902 (Fed. Cir. 1998) ("Ordinarily, when a party fails to make an argument in proceedings below, the argument is waived, and [the court] will not hear it on appeal," but where "an issue of statutory interpretation is involved," a court will address the waived argument).

[3] *Compare Webster's Third New International Dictionary* 1422-23 (2002) ("method" can mean "system") *with id.* at 2322 ("system" can mean "method"); *compare The American Heritage Dictionary of the English Language* 1105-06 (2006) ("method" and "system" as synonyms) *with id.* at 1757 ("system" as an "organized and coordinated method"); *compare The New Oxford American Dictionary* 1067 (2005) (a "method" is a "systematic" procedure) *with id.* at 1714 ("system" can mean "method"); *see also* Opp. Ex. H at 2 ("method" and "system" as synonyms).

'963 patent claimed a "system" for patent-law purposes, it could still claim a "method of using" Xyrem under the "ordinary, contemporary, common meaning" of section 355(c)(3)(D)(ii)(I)(bb). *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2362 (2019) (citation omitted).

Avadel retorts (Opp. 13-14) that "the term 'method' in the delisting statute" cannot diverge from its meaning in patent law. But "identical language may convey varying content when used in different statutes." *Yates v. United States*, 574 U.S. 528, 537 (2015) (plurality opinion). Nor is Avadel right that "patent law principles" oust ordinary meaning because 21 U.S.C. 355(c)(3)(D)(ii)(I) uses the word "claims." Opp. 12. Read as a whole, the phrase "approved method of using the drug" shows that Congress did not use "method" in a patent-law sense.

Avadel's remaining arguments fail. To start, Jazz did not suggest that FDA's regulation "trump[s]" the statute. Opp. 12. Far from it: the point is that FDA's "reasonable interpretation" resolves any ambiguity in Jazz's favor, thereby confirming that REMS patents like the '963 patent can be Orange Book listed. Br. 8-9, 11. Avadel has not challenged that regulation, so "a court may not second-guess [FDA's] policy choices." *Schnall v. Amboy Nat. Bank*, 279 F.3d 205, 212 (3d Cir. 2002). Moreover, Avadel's argument confirms that FDA did not use patent terminology in 21 C.F.R. § 314.53(b)(1). Avadel attempts to rewrite the regulation to argue that "the term 'process' as used in 21 C.F.R. § 314.53(b)(1)" refers to "patents for manufacturing processes." Opp. 12. The rule speaks of "[p]rocess patents"—not "manufacturing-process patents"—and Avadel "may not narrow a provision's reach by inserting words [FDA] chose to omit." *Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020). Finally, Avadel is silent on Jazz's and FDA's explanation why *ViroPharma, Inc. v. Hamburg* does not help Avadel. *See* Br. 12-13 & n.3.

C. The Equities Favor Granting A Stay

1. Jazz Will Be Irreparably Harmed Absent A Stay

As Jazz showed, if the Order is not stayed pending appeal, the right to pediatric exclusivity that Jazz seeks to protect will be destroyed. (*See* Br. 15-16.) Avadel downplays the significance of Jazz's loss of a statutory right to exclusivity and disregards the inability of Jazz to obtain meaningful appellate review absent a stay.

To start, Avadel suggests that Jazz's only potential injury is "the possibility that [its] appeal may become moot." (Opp. 14). Of course, stays to preserve the possibility of meaningful appellate relief are routine, but Jazz also has shown that, without a stay, its statutory right to pediatric exclusivity likely will evaporate. Stays are designed for precisely this context, where "necessary to mitigate the damage that can be done during the interim period before a legal issue is finally resolved on its merits." *In re A & F Enters., Inc. II*, 742 F.3d 763, 766 (7th Cir. 2014).

Avadel also tries to blame Jazz for creating the circumstances that give rise to a need for a stay. (Opp. 14 (asserting that Jazz "has only itself to blame").) But the need for a stay arises from the potential irreversible loss of pediatric exclusivity, which has nothing to do with when the Court addressed delisting and everything to do with the effect of submitting a delisting request to the FDA. Moreover, unlike the movant in *Otsuka Pharm. Co. v. Torrent Pharms. Ltd.*, 99 F. Supp. 3d 461 (D.N.J. 2015) (cited at Br. 14), Jazz did not wait a year to seek equitable relief. *See id.* at 505. Instead, Jazz sought a stay within two business days.

Unable to contest Jazz's showing that its loss of a statutory right will result in irreparable harm absent a stay, Avadel attempts to conjure a paradox: how could Jazz's loss of pediatric exclusivity constitute harm if Avadel cannot launch now? (Opp. 15.) The answer is two-fold.

First, the fact that Avadel cannot currently launch does not preclude the possibility that it will be able to launch at some point before pediatric exclusivity expires on June 17, 2023. If a stay is denied, and assuming for present purposes that Jazz would have won the appeal, then the denial

of a stay will mean that Jazz will be harmed by the loss of pediatric exclusivity that it should have retained during the period from the commencement of FT218 marketing through June 17, 2023.

Second, Avadel's myopic focus on itself skews its vision. Jazz's statutory exclusivity is not specific to Avadel; it is a right good against the world, grounded in a legislative policy of encouraging investment in pediatric studies. Jazz's pediatric exclusivity could apply equally to another entrant, other than Avadel, that has not revealed itself to Jazz. The irreversible loss of that exclusivity is a substantial harm that cannot be remedied with damages—it is irreparable.

2. Avadel Will Not Suffer Irreparable Harm As A Result Of The Stay

Nor has Avadel shown that any harm it may suffer will outweigh the harm to Jazz. To start, Avadel's claim of harm from a delayed launch of FT218 is contradicted by Avadel's correspondence just last week with the FDA, which Avadel neglected to submit here. After informing the FDA of the Court's delisting order, [redacted].

Likewise, while Avadel characterizes Jazz as pursuing a strategy of delay, Avadel disregards the relevant history. In addition to Avadel's belated certification to the '963 patent, this Court (Judge Noreika) denied Avadel's motion for judgment on the pleadings as premature. Avadel cannot dispute that the claim construction ruling was a necessary predicate to its delisting counterclaim. Avadel then mischaracterizes (Opp. 5) Jazz's decision to accept for purposes of the stay motion the Court's "system" construction as opposed to a "method of use." Jazz made clear that it did not abandon claim construction on appeal, but rather elected not to rely on any challenge to claim construction for purposes of the stay motion. *See* Br. 2.

Regardless, Avadel wrongly argues (Opp. 1) that "Jazz's proposal would effectively block delisting for the remaining lifetime of the '963 patent." Avadel agreed to a Federal Circuit argument in February 2023 (Ex. B), which provides time to decide the appeal before expiration.

D. The Public Interest Favors A Stay

Avadel's assessment of the public interest (Opp. 17-19) attacks a strawman by arguing that patent rights are always subordinate to the rights of patients. But the question of how best to balance the need to encourage the research and development of new drugs and the development of generics is a question for Congress. Congress answered that question through the Hatch-Waxman Act, which strikes a "better balance" between those "two competing interests." *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (D.C. Cir. 2008). *See also* Br. 17-18 (collecting cases). Absent a stay, the Court's order upsets that balance by removing statutory protections for a patent without which the FDA would not have approved the drug. Br. 18. Moreover, the second of those competing interests is not in play here, as Avadel is not seeking to market a lower-cost, generic version of Xyrem – rather, it has stated repeatedly it will price its product at parity with Jazz's two oxybate products. Ex. C at 10.

Nor will patients suffer any harm pending a stay. The stay will not impact patients because FT218 is at least months away from the market. *Infra* 8. And Avadel's assertion that its product is "revolutionary" (Opp. 1) is belied by the record, [redacted]. Ex. F. [redacted] Avadel's assertion that its product will enhance patient outcomes because the FDA would have granted priority review if it had thought FT218 would enhance "patient compliance" in a way that "is expected to lead to an

improvement in serious outcomes." *Id.* [redacted] *See* 21 U.S.C. § 356(a)(1) (breakthrough therapies are "substantial improvement over existing therapies"); *id.* § 356(b)(1) (fast track products have "the potential to address unmet medical needs").[4]

E. Jazz Is Prepared To Provide Sufficient Security Under Rule 62(d)

Avadel cites no authority holding that absence of discussion in an opening brief of Rule 62(d)'s security requirement warrants denial of Jazz's motion. *See* Opp. 20. Indeed, courts in this district have granted a stay where the movant first addressed the bond in reply. *Caroleng Inv. Ltd. v. Bluestone Res., Inc.*, 2021 WL 1820476, at *4 (D. Del. May 6, 2021).

Because bonds for injunctions and other equitable relief are designed to protect the non-moving party from the harms they may suffer as a result of the equitable relief, *see, e.g.*, Fed. R. Civ. P. 65(c), the amount of security should be tied to the harms *Avadel* may suffer. *See, e.g.*, *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 2010 WL 817519, at *7 (M.D. Pa. Mar. 9, 2010). Here, given the expedited appeal and the FDA's indications that approval is not imminent, any harm to Avadel is speculative, so no bond should be required. *See Thiry v. Carlson*, 891 F. Supp. 563, 568 (D. Kan. 1995) (declining to impose bond where harm was speculative). Indeed, Avadel told its investors FT218 will not launch until the third quarter of 2023. Ex. G at 5.

Jazz, however, is prepared to post a reasonable security tied to Avadel's purported losses during the pendency of the appeal on the merits if the Court determines one is needed. That bond should not exceed $24,500 per day, which corresponds to [redacted]. Ex. H at 54.

[4] *Baxalta Inc. v. Genentech, Inc.*, 2018 WL 3742610 (D. Del. Aug. 7, 2018), is therefore distinguishable because it involved access to an approved drug that was *already on the market* and had received breakthrough designation from the FDA for the disputed use. *Id.* at *3.

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December 1, 2022

EXHIBIT A

No. 23-1186

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

JAZZ PHARMACEUTICALS, INC.,
Plaintiff-Appellant,

v.

AVADEL CNS PHARMACEUTICALS LLC,
Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware in No. 21-691, Honorable Gregory B. Williams

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PLAINTIFF-APPELLANT'S MOTION TO EXPEDITE PROCEEDINGS

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November 28, 2022

Counsel for Plaintiff-Appellant Jazz Pharmaceuticals, Inc.

CERTIFICATE OF INTEREST

Counsel for Jazz Pharmaceuticals, Inc., F. Dominic Cerrito, certifies the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

   Jazz Pharmaceuticals, Inc.

2. **Real Party in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

   None

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

   Jazz Pharmaceuticals plc.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. **Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, No. 1:22-cv-00941-GBW (D. Del.) (filed July 15, 2022).

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not applicable

November 28, 2022

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INTRODUCTION

Plaintiff-Appellant Jazz Pharmaceuticals, Inc. hereby moves to expedite briefing and consideration of Jazz's emergency motion for a stay pending appeal, filed concurrently with this motion, and for expedited briefing and consideration of the merits of the appeal.[1] Jazz appeals from an interlocutory order imposing a mandatory injunction. That injunction requires Jazz to request, on or before December 2, 2022, that the Food and Drug Administration de-list Jazz's '963 patent from FDA's Orange Book. Expedition is necessary to preserve the ability of this Court to provide meaningful relief given that Jazz's six-month pediatric exclusivity period—which the appealed-from order implicates—will evaporate and could not be revived in time before the appeal could be

[1] Pursuant to Federal Circuit Rule 27(a)(2), counsel for Jazz informed counsel for Defendant-Appellee Avadel CNS Pharmaceuticals LLP of Jazz's intent to file this motion. Counsel for Avadel informed counsel for Jazz that it does not oppose Jazz's request for an expedited briefing schedule on the merits of the appeal (or the specific schedule proposed), but it opposes the request for expedited briefing of the motion to stay, and it intends to file a response. Counsel for Avadel also asked that Jazz attach to this motion a copy of an email between counsel. That email is attached as Exhibit 1. Jazz disagrees with the characterizations made by counsel for Avadel in that email. In particular, there is no merit to Avadel's suggestion that Jazz somehow delayed seeking relief from the district court's 14-day deadline.

briefed and decided under the typical appeal schedule. Expediting the appeal will provide certainty to both parties regarding the listing of Jazz's '963 patent in the Orange Book.

BACKGROUND

This case arises out of Avadel's filing of an application for FDA approval of its proposed sodium oxybate drug product ("FT218"[2]) before the expiration of a number of Jazz-owned patents. Avadel's New Drug Application for its FT218 product was filed under 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b)(2), relying in part on FDA's prior approval of Jazz's Xyrem® product, which has the same active ingredient—sodium oxybate—as FT218.

Oxybate is a controlled substance (also known as gamma hydroxybutyrate or "GHB") and a strong central nervous system depressant. Today, to obtain FDA approval of a drug containing oxybate, the agency requires new drug applications to include a Risk Evaluation and Mitigation Strategy ("REMS"). Years ago, when Jazz first sought

[2] "LUMRYZ" is the proposed brand name for FT218. Because an unapproved new drug product like FT218 cannot be marketed in the United States, *see* 21 U.S.C. §§ 331(a), 355(d), it is more appropriate to refer to the drug by its investigational moniker.

FDA approval for Xyrem®, it developed a risk management program that was approved by FDA as a condition of use to ensure that Xyrem® could be safely brought to market. In 2007, Congress deemed that risk management program to be a REMS when it enacted the REMS statute, 21 U.S.C. § 355-1.

Jazz obtained a patent (U.S. Patent No. 8,731,963, or the "'963 patent") covering various elements of the risk management program (now REMS) for Xyrem®. The '963 patent has been included in FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication (the "Orange Book") since 2014. The '963 patent is listed in the Orange Book under use code 1110 ("U-1110"), thereby protecting a "method of treating a patient with a prescription drug using a computer database in a computer system for distribution." *Avadel CNS Pharms., LLC v. Becerra*, No. 22-cv-02159 (APM), 2022 WL 16650467, at *3 (D.D.C. Nov. 3, 2023). Pursuant to a six-month extension as a result of the exclusivity Jazz received as a reward for establishing that sodium oxybate is safe and effective for use in pediatric patients, *see* 21 U.S.C. § 355a(b)(1)(B), the exclusivity associated with the '963 patent will last into June 2023, six months after the '963 patent itself expires.

In December 2020, Avadel applied for FT218's approval under FDCA section 505(b)(2) and relied on Xyrem® as the "listed drug" for that application. Avadel's strategy allowed it to rely on FDA's prior finding that Jazz's product is safe and effective, but it also required Avadel to provide a patent certification regarding each patent listed in the Orange Book for Xyrem®, including the '963 patent. *See* 21 U.S.C. § 355(b)(2)(A); 21 C.F.R. § 314.54(a)(1)(vi). Rather than submit such a patent *certification*, however, Avadel submitted a patent *statement*, declaring to FDA that its application did not seek approval for any protected use. *See* 21 U.S.C. § 355(b)(2)(B).

FDA rejected Avadel's filing strategy, concluding that Avadel's patent statement was not accurate. On May 24, 2022 the agency issued a decision explaining that Avadel sought "approval of a condition of use that is claimed by the '963 patent, as described by the U-1110 use code." *Avadel*, 2022 WL 16650467, at *3. Further, FDA explained that it would not approve Avadel's application unless Avadel replaced its inappropriate statement with a patent certification. *Id.* at *1, *3; *see* 21 U.S.C. § 355(d)(6); 21 C.F.R. § 314.125(b)(7). Avadel submitted the missing patent certification—and, as the statute requires, notified the

listed drug's patentholder, Jazz—and FDA provided a "tentative approval" on July 18, 2022. Complaint For Declaratory And Injunctive Relief at 5, *Avadel*, 2022 WL 16650467, ECF No. 1.

Jazz's receipt of Avadel's patent certification notice opened a 45-day window within which Jazz could allow the application's approval to be "made effective immediately," or else sue Avadel for patent infringement. 21 U.S.C. § 355(c)(3)(C). Jazz sued within the window, *see Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 1:22-cv-00941-GBW (D. Del.) (filed July 15, 2022), triggering a statutory thirty-month stay of approval. 21 U.S.C. § 355(c)(3)(C). The stay precludes approval of FT218 until expiration of the '963 patent's term and the related pediatric exclusivity in June 2023. *Id.* Jazz had previously sued Avadel on the '963 patent in the matter *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*, No. 1:21-cv-00691-GBW (D. Del.) (filed May 12, 2021), and Avadel responded by (among other things) asserting a counterclaim seeking de-listing of the '963 patent. This appeal arises out of that Delaware case.

After Avadel's back-and-forth with (and patent certification to) FDA, Avadel filed claims in the U.S. District Court for the District of Columbia against multiple federal agencies and agency heads, including

FDA, seeking equitable relief. *See* Complaint For Declaratory And Injunctive Relief, *Avadel*, 2022 WL 16650467, ECF No. 1. Avadel claimed that FDA violated the Administrative Procedure Act by (1) "second-guess[ing] Avadel's decision to file a patent statement" and "compelling Avadel to submit a patent certification instead," *id.* at 24, and (2) unreasonably delaying approval of FT218, *see id.* at 25–26. Jazz intervened. Ultimately, the D.C. district court entered judgment against Avadel on its claims because of the "availability of adequate alternative relief" in the ongoing patent suit in the District of Delaware, *i.e.*, the proceedings below here. *See Avadel*, 2022 WL 16650467, at *2. Specifically, the D.C. district court observed that Avadel had available to it, and was already pursuing in the patent litigation, a statutory counterclaim seeking the delisting of the '963 patent.

About two weeks later, following Avadel's earlier request for expedited consideration of its delisting counterclaim, the Delaware district court in this case entered a mandatory injunction directing Jazz to submit to the FDA a request to delete the '963 patent from the Orange Book, on the ground that, in the district court's view, the '963 patent "does not claim … an approved method of using the drug" under 21 U.S.C.

§ 355(c)(3)(D)(ii)(I). As explained more fully in Jazz's concurrently filed motion to stay, the district court's decision was based on an erroneous interpretation of the relevant statutes, and its injunction—if not stayed—will cause Jazz irreparable harm.

Moreover, time is of the essence: The resolution of this dispute will determine whether Jazz will retain its statutory entitlement to a six-month period of pediatric exclusivity, running through June 17, 2023, based on expensive and valuable pediatric studies that Jazz conducted. As a practical matter, the appeal concerning Jazz's remaining six-and-a-half-months of exclusivity must be resolved expeditiously. That exclusivity period would be mostly or entirely consumed by the typical schedule for an appeal in this Court. Even more pressing is the deadline for Jazz to comply with the district court's injunction: absent further action by the district court or this Court, Jazz will need to send the request to "de-list" the '963 patent to the FDA by this Friday, December 2, 2022.[3] And if FDA were to act on that compelled de-listing request, Jazz's pediatric exclusivity would dissolve and likely could not be revived

[3] Jazz has moved the District Court for a stay but that court has not yet ruled.

even if this Court were to conclude on appeal that the injunction never should have been ordered.

ARGUMENT

Jazz respectfully requests expedited briefing and consideration of both its emergency motion for a stay and the merits of the appeal. Expedition is warranted because the standard timelines for briefing and consideration are impracticable in this case.

With respect to the emergency motion to stay, the standard briefing timeline would render the motion moot before it could be considered. Under Federal Rule of Appellate Procedure 27(a)(3)(A), Avadel's response would be due 10 days after service of the motion, *i.e.*, by December 8, 2022. But the injunction that Jazz seeks to stay requires Jazz to act by December 2, 2022.

Further, as explained more fully in Jazz's motion to stay the district court's mandatory injunction, if FDA *does* de-list the '963 patent in response to the action directed by district court, then Jazz's pediatric exclusivity will evaporate, and the patent and any associated exclusivity will expire on December 17, 2022 (before an appeal could plausibly be resolved). *See* Fed. R. App. P. 2 ("On its own or a party's motion, a court

of appeals may—to expedite its decision or for other good cause—suspend any provision of these rules in a particular case and order proceedings as it directs . . . .").

Accordingly, Jazz respectfully requests entry of the following briefing schedule for the motion to stay, or any other expedited schedule that the Court may order:

- Avadel's response: November 30, 2022
- Any reply by Jazz: December 1, 2022.

With respect to the merits of the appeal, expedition is warranted because the dispute concerns a six-month period of exclusivity—and thus a period that would likely begin and end during the course of an appeal briefed and argued on a typical schedule. As this Court recognizes, a motion to expedite "is appropriate where the normal briefing and disposition schedule may adversely affect one of the parties, as in appeals involving preliminary or permanent injunctions . . . ." Practice Notes to Fed. Cir. R. 27. Jazz already has taken steps to expedite by filing a notice of appeal within days of the entry of the injunction below, and Jazz is prepared to submit its briefs on an accelerated schedule to allow the appeal to be set for argument promptly (during the Court's February

2023 session, for example). To that end, Jazz respectfully requests entry of the following expedited schedule for briefing and consideration of the merits of this appeal or any other expedited schedule that the Court may order:

- Jazz's opening brief: December 16, 2022
- Avadel's response brief: January 13, 2023
- Jazz's reply brief: January 20, 2023
- Oral argument: during the Court's February session.

CONCLUSION

Jazz respectfully requests that its motion to expedite the proceedings on appeal be granted.

November 28, 2022

/s/ F. Dominic Cerrito

F. Dominic Cerrito
Frank C. Calvosa
Ellyde R. Thompson
Gabriel P. Brier
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

Counsel for Plaintiff-Appellant Jazz Pharmaceuticals, Inc.

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

This motion complies with the word limit set forth in Fed. R. App. Pr. 27(d) because this motion contains 1,927 words.

This motion complies with the typeface requirements of Fed. R. App. Pr. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 365 in 14-point Century Schoolbook font.

November 28, 2022

/s/ F. Dominic Cerrito

F. Dominic Cerrito
QUINN EMANUEL URQUHART & SULLIVAN, LLP
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New York, NY 10010
(212) 849-7000

Counsel for Plaintiff-Appellant Jazz Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on November 28, 2022, I electronically filed the foregoing using the Court's CM/ECF system, which will send notifications to all counsel registered to receive electronic notices, and served the foregoing by electronic mail to all counsel of record, at the addresses below.

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Sarah W. Wang, Esquire
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Alan J. Devlin, Esquire
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DURIE TANGRI LLP
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Los Angeles, CA 90013
Attorneys for Defendant-Appellee

November 28, 2022

/s/ F. Dominic Cerrito

F. Dominic Cerrito
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

Counsel for Plaintiff-Appellant Jazz Pharmaceuticals, Inc.

Exhibit

Exhibit

Document	Description
Exhibit 1	E-mail from Audra Sawyer, Latham & Watkins, to Gabriel P. Brier, Quinn Emanuel Urquhart & Sullivan (Nov. 28, 2022, 2:55 p.m. EST)

Exhibit 1

Gabriel Brier

From: Audra.Sawyer@lw.com
Sent: Monday, November 28, 2022 2:55 PM
To: Gabriel Brier; Herman.Yue@lw.com
Cc: KENNETH.SCHULER@lw.com; Marc.Zubick@lw.com; Sarah.Wang@lw.com; Sunnie.Ning@lw.com; Sarah.Propst@lw.com; DDurie@durietangri.com; KDavis@durietangri.com; ajoyce@mccarter.com; Nick Cerrito; Eric Stops; Evangeline Shih; Andrew Chalson; AJones@durietangri.com; Frank Calvosa; JBlumenfeld@morrisnichols.com; JTigan@morrisnichols.com; JazzAvadel; DSilver@McCarter.com; Alex.Grabowski@lw.com; jazzpatentlitigation.lwteam@lw.com
Subject: RE: Jazz v. Avadel, No. 21-691

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Gabe,

We are fine with the expedited schedule for briefing and consideration of the merits of Jazz's appeal that you set forth below—subject to the preferences of the Federal Circuit.

We otherwise object to your proposals for an emergency stay or an expedited briefing schedule thereon—especially given the very low likelihood of success on the merits of the appeal and Jazz's failure to exhaust its remedies in district court—and will respond in due course. We also reiterate our position that if Jazz truly wanted to seek all avenues of relief before the district court, it should have asked that court for expedited briefing and/or expedited relief. Jazz didn't do that. Instead, Jazz waited for the district court itself to propose an expedited schedule and only then decided that was not good enough. That does not justify emergency/expedited intervention by the Federal Circuit.

We ask that you attach this email to your Federal Circuit motion papers to accurately represent our position.

Thanks,

Audra

From: Gabriel Brier <gabrielbrier@quinnemanuel.com>
Sent: Monday, November 28, 2022 10:03 AM
To: Sawyer, Audra (DC) <Audra.Sawyer@lw.com>; Yue, Herman (NY) <Herman.Yue@lw.com>
Cc: Schuler, Kenneth (CH) <KENNETH.SCHULER@lw.com>; Zubick, Marc (CH/NY) <Marc.Zubick@lw.com>; Wang, Sarah (CH) <Sarah.Wang@lw.com>; Ning, Sunnie (BN) <Sunnie.Ning@lw.com>; Propst, Sarah (DC) <Sarah.Propst@lw.com>; DDurie@durietangri.com; KDavis@durietangri.com; ajoyce@mccarter.com; Nick Cerrito <nickcerrito@quinnemanuel.com>; Eric Stops <ericstops@quinnemanuel.com>; Evangeline Shih <evangelineshih@quinnemanuel.com>; Andrew Chalson <andrewchalson@quinnemanuel.com>; AJones@durietangri.com; Frank Calvosa <frankcalvosa@quinnemanuel.com>; JBlumenfeld@morrisnichols.com; JTigan@morrisnichols.com; JazzAvadel <jazzavadel@quinnemanuel.com>; DSilver@McCarter.com; Grabowski, Alex (CH) <Alex.Grabowski@lw.com>; #C-M JAZZ PATENT LITIGATION - LW TEAM <jazzpatentlitigation.lwteam@lw.com>
Subject: RE: Jazz v. Avadel, No. 21-691

Audra,

We are available to meet and confer at 12:00 pm EST today. Please use the conference call information below:

Dial-in: (646) 518-9805
Meeting ID: 832 7728 4310
+16465189805,,83277284310#

Regards,

Gabe

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Avadel is considering your proposed schedules for an expedited appeal and an emergency motion to stay at the Federal Circuit. So that we can better understand Jazz's positions, we believe the parties should meet and confer today. Please be prepared to address why Jazz believes an emergency motion to the Federal Circuit is appropriate given that Jazz did not ask the district court for expedited briefing of its stay motion or propose a schedule for briefing of that motion to Avadel and further given Judge Williams' Order requiring Avadel to file its opposition on Thursday December 1, and Avadel's subsequent offer to file its opposition on Tuesday November 29.

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To: Yue, Herman (NY) <Herman.Yue@lw.com>
Cc: Schuler, Kenneth (CH) <KENNETH.SCHULER@lw.com>; Zubick, Marc (CH/NY) <Marc.Zubick@lw.com>; Wang, Sarah (CH) <Sarah.Wang@lw.com>; Ning, Sunnie (BN) <Sunnie.Ning@lw.com>; Propst, Sarah (DC) <Sarah.Propst@lw.com>; DDurie@durietangri.com; KDavis@durietangri.com; ajoyce@mccarter.com; Nick Cerrito <nickcerrito@quinnemanuel.com>; Eric Stops <ericstops@quinnemanuel.com>; Evangeline Shih <evangelineshih@quinnemanuel.com>; Andrew Chalson <andrewchalson@quinnemanuel.com>; AJones@durietangri.com; Frank Calvosa <frankcalvosa@quinnemanuel.com>; JBlumenfeld@morrisnichols.com; JTigan@morrisnichols.com; JazzAvadel <jazzavadel@quinnemanuel.com>; Sawyer, Audra (DC) <Audra.Sawyer@lw.com>; DSilver@McCarter.com; Grabowski, Alex (CH) <Alex.Grabowski@lw.com>; #C-M JAZZ PATENT LITIGATION - LW TEAM <jazzpatentlitigation.lwteam@lw.com>
Subject: Jazz v. Avadel, No. 21-691

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As we have previously informed you, Jazz intends to file a motion for an expedited appeal of the Court's delisting order with the Federal Circuit. Please let us know as soon as possible whether Avadel will oppose Jazz's motion to expedite or file a response.

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Regards,

Gabe

Gabe Brier | **quinn emanuel urquhart & sullivan, llp**
51 Madison Avenue, 22nd Floor, New York, NY 10010 | Office: (212) 849-7000 | Direct: (212) 849-7486 | Mobile: (917) 576-3454 | Fax: (212) 849-7100 | gabrielbrier@quinnemanuel.com

EXHIBIT B

Gabriel Brier

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Sent: Monday, November 28, 2022 2:55 PM
To: Gabriel Brier; Herman.Yue@lw.com
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Gabe

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51 Madison Avenue, 22nd Floor, New York, NY 10010 | Office: (212) 849-7000 | Direct: (212) 849-7486 | Mobile: (917) 576-3454 | Fax: (212) 849-7100 | gabrielbrier@quinnemanuel.com

EXHIBIT C

REFINITIV STREETEVENTS

PRELIMINARY TRANSCRIPT

AVDL.OQ - Q2 2022 Avadel Pharmaceuticals PLC Earnings Call

EVENT DATE/TIME: AUGUST 09, 2022 / 12:00PM GMT

REFINITIV

CONFERENCE CALL PARTICIPANTS

>>Ami Fadia - Needham & Company, LLC, Research Division

>>Brandi Robinson - Senior Key Executive

>>Gregory Divis - CEO

>>Jennifer Gudeman

>>Richard Kim - Senior Key Executive

>>Thomas McHugh - CFO

>>François Brisebois - Oppenheimer & Co. Inc., Research Division

>>Oren Livnat - H.C. Wainwright & Co, LLC, Research Division

>>Eason Lee - SVB Securities LLC, Research Division

>>David Amsellem - Piper Sandler & Co., Research Division

>>Adam Evertts - LifeSci Capital, LLC, Research Division

>>Chase Knickerbocker - Craig-Hallum Capital Group LLC, Research Division

TRANSCRIPT

PRESENTATION

>>Ami Fadia - Needham & Company, LLC, Research Division

Greetings, and welcome to Avadel Pharmaceuticals Second Quarter 2022 Earnings Call. (Operator Instructions) It is now my pleasure to introduce Brandi Robinson. Thank you. You may begin.

>>Brandi Robinson - Senior Key Executive

Good morning, and thank you for joining us on our conference call to discuss second quarter 2022 earnings.

As a reminder, before we begin, the following presentation includes several matters that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. These risks include risks that products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements, uncertainties regarding market entry and acceptance of products and the impact of competitive products and pricing. These and other risks are described more fully in Avadel's public filings under the Exchange Act included in the Form 10-K for the year ended December 31, 2021, which was filed on March 16, 2022, and subsequent SEC filings. Except as required by law, Avadel undertakes no obligation to update or revise any forward-looking statements contained in this presentation to reflect new information, future events or otherwise.

On the call today are Greg Divis, Chief Executive Officer; Dr. Jennifer Gudeman, Vice President of Medical and Clinical Affairs; Richard Kim, Chief Commercial Officer; and Tom McHugh, Chief Financial Officer.

At this time, I'll turn the call over to Greg.

>>Gregory Divis - CEO

Good morning, everyone, and thank you for joining us to discuss our second quarter 2022 results. .

This was an important quarter for Avadel, where we continue to make progress in our mission to bring LUMRYZ to all once-at-bedtime eligible patients living with narcolepsy, which included the receipt of a notable and important regulatory milestone for LUMRYZ in the form of a tentative approval, the active pursuit of additional legal and regulatory strategies to accelerate a final FDA decision for LUMRYZ prior to June of 2023 or when the REMS patent we certified on will expire and the continued execution of our commercial preparations with a focus on shortening the time between final approval and launch while we took the necessary actions to ensure, as required, we have the liquidity to carry us to the potential outer date of a final FDA approval decision.

With that, I will start by commenting on our most recent company update. On July 19, we announced that the FDA granted tentative approval of LUMRYZ, formerly known as FT218, our investigational once at bedtime oxybate therapy for the treatment of cataplexy or excessive daytime sleepiness in people with narcolepsy. Receiving tentative approval is an important step toward a final approval. By granting tentative approval, the FDA has validated the clinical and safety profile of LUMRYZ and confirms that LUMRYZ is approvable as a once at bedtime therapy for eligible patients living with narcolepsy, which we believe is a meaningful derisking regulatory event for the company.

LUMRYZ is has a demonstrably strong clinical profile with an improved dosing regimen that, per our extensive research, is preferred by patients and sleep specialists. This, along with our comprehensive launch strategy, gives us the confidence in the potential significant role LUMRYZ can play in the $3 billion-plus market opportunity.

Further and perhaps most importantly, receiving tentative approval confirms that the potential latest date we could receive a final approval decision for LUMRYZ is after expiry of the REMS patent, which is June 17, 2023, or just 10 months and 8 days from today. As previously stated, we are and will continue to aggressively pursue legal and regulatory strategies with a clear objective of potentially leading to a final approval decision prior to June 2023 and, depending on timing and results of these legal actions, possibly by the end of this year. In this regard, we filed a motion in the U.S. District Court for the District of Delaware to delist the REMS patent from the FDA's Orange Book on June 23 as we do not believe the substance of the REMS patent qualifies as an eligible Orange Book listable patent. A court order requiring the patent holder to delist the REMS patent from the Orange Book could provide a pathway for a final approval of LUMRYZ prior to June 2023. As the court previously stated that a claim construction hearing is required before ruling on the motion to delist, the next step in this process is the Markman or claim construction hearing, which is scheduled for August 31. Additionally, we recently announced that we filed an Administrative Procedure Act lawsuit against FDA alleging that their decision requiring us to file a patent certification on the REMS patent was arbitrary, capricious and contrary to applicable law. In this lawsuit, we are asking the court to vacate the FDA's patent certification decision and order FDA to take final action on the LUMRYZ NDA within 14 days after vacating their decision.

A successful outcome in this APA suit could also lead to a potential final approval of LUMRYZ prior to June of 2023. An accelerated briefing schedule order has been approved by the court, and we currently expect this case to be heard at the end of September 2022.

In addition to these opportunities to accelerate a potential final approval, we are also focusing on launch preparation activities that will shorten the time to launch following final approval. This includes completion of manufacturing and primary packaging for our commercial supply and operationalizing our REMS program both in advance of a final approval and before the end of this calendar year.

In summary, we are well positioned to execute on all of these priorities to potentially accelerate bringing LUMRYZ to a final approval prior to June 2023 and subsequent launch as soon as possible thereafter. As you will hear next, Jennifer will provide details on the data we presented this quarter at SLEEP 2022. And following, Richard will give an update on our launch readiness actions now with the tentative approval in hand.

With that, I'll turn the call over to Jennifer.

>>Jennifer Gudeman

Thanks, Greg, and good morning.

As Greg said, this was an important quarter for Avadel. Tentative approval for LUMRYZ is a significant milestone that validates its efficacy and safety profile and also has facilitated us starting our REMS build-out, which will shorten our time to launch following final approval. Furthermore, we had

a strong presence at SLEEP 2022 with considerable interest in the body of evidence supporting LUMRYZ, as described in our 9 posters. The poster that we had the most engagement with described the new interim data on dosing and titration from the ongoing RESTORE open-label extension SWITCH study of our LUMRYZ drug candidate. 62% of participants switching from twice-nightly oxybate formulations had a stable dose equal to their starting dose, which will help clinicians understand that switching to LUMRYZ is a straightforward process. Additionally, participants not currently taking oxybate formulations or oxybate naive participants reached a stable dose with 2 to 4 dose titrations within 4 weeks. This is particularly relevant as we hear anecdotes of patients having to spend months trying to find a stable and consistent dosing regimen of twice-nightly oxybate.

We also presented updated results from patient preference and the nocturnal adverse event questionnaire with patients switching from twice-nightly oxybate in the RESTORE study. These interim data confirmed previous data we have presented showing that a high proportion of patients switching from twice-nightly oxybate formulations experience difficulty in taking the second dose, with nearly 2/ 3 reporting accidentally missing their second dose at least once in the past 3 months and more than 80% of those reporting that they experienced worse narcolepsy symptoms the next day.

Also consistent with data we have previously presented 92.5% stated a preference for the once-nightly dosing regimen. As we talk about RESTORE, I want to highlight that we have extended this study so participants can stay in RESTORE through FDA approval and up to launch of LUMRYZ to then transition to commercially available product. I have had the opportunity to speak directly with a number of participants in RESTORE who have expressed their gratitude for this extension specifically because they don't want to go back to waking up in the middle of the night after successfully taking Avadel's investigational once at bedtime sodium oxybate.

Going back to our posters, we had 5 posters from Reston which continue to reinforce the strong efficacy demonstrated in this pivotal trial, including in subgroups of both NT1 and NT2 and those with and without concomitant stimulant on measures of disrupted nighttime sleep.

Lastly, we published results from our second discrete choice experiment, or DCE. As some may recall, we have published the results of our first DCE in patient preference and adherence which clearly showed that the most important driver of patient choice for sodium oxybate is a single bedtime dose. The second DCE was expanded to include clinicians and the mixed salt oxybate and affirmed our first DCE. Patients clearly placed the highest priority of treatment selection among the 3 oxybate profile for once at bedtime dosing.

For the 100 clinicians participating in the DCE, the data also demonstrated that the most important driver of clinician choice is once at bedtime dosing. The SLEEP meeting provided us the opportunity to connect directly with KOLs and explain the delay in FDA decision on approval of LUMRYZ. We have been communicating extensively with both the medical and patient communities following the tentative approval, including a fact sheet available at avadel.com about what this means and a letter to the community reiterating our commitment to bringing LUMRYZ to patients.

We recognize patients with narcolepsy will be critical in shared decision-making with their clinicians. To that end, we were thrilled to publish a plain language summary in future neurology describing the primary results from our pivotal trial, so people with narcolepsy can access these results. The totality of the data we continue to present supports the robust clinical efficacy, the well-established safety profile, ability to switch from twice-nightly oxybate and patient preference of LUMRYZ. Now that we have the tentative approval secured, the community is even more eager to see this potential treatment option receive final FDA approval and made available to patients.

We are proud of all of our hard work that continues to drive LUMRYZ forward. I will now turn the call over to Richard to provide details on the commercial opportunity and our preparations for launch. Richard?

>>Richard Kim - Senior Key Executive

Thank you, Jennifer. With the tentative approval in hand, we are well positioned to continue to advance our launch preparations as we work towards bringing once at bedtime LUMRYZ to adults with narcolepsy. Despite a longer-than-anticipated time for the final approval of LUMRYZ, one thing that has not changed is the fundamental belief in the potential for this drug candidate to help patients manage their excessive daytime sleepiness or cataplexy while also providing them with an opportunity for a more natural sleep cycle.

It has been an amazing journey spending time within our community, sleep specialists, medical societies and patient organizations. Throughout the year, we made significant progress in expanding our reach our reach with sleep specialists through major congresses like World Sleep in March and the SLEEP 2022 Conference in June along with one-on-one meetings.

This year alone, we estimate that we have been in front of over 1,000 people from the narcolepsy community. As a reminder, less than 1,600 sleep specialists make up 80% of the current overall oxybate prescription volume. As we get ready to transition from the summer to the fall, we are also preparing for a number of meetings and conferences that will give us continued exposure to patient organizations and sleep specialists. We have both the American Neurological Association and CHEST meetings continue to engage with sleep specialists this October along with key patient advocacy organization meetings in the next couple of months.

We also continue to see strong interest in our disease education campaign, Narcolepsy Disrupts. In June, we began to make a sleep diary available that helps patients charge how they are managing their narcolepsy. And we have already shipped more than 3, 000 to individuals across the country. After assessing all that we have accomplished to date with Narcolepsy Disrupts, we anticipate launching additional enhancements in the early fall.

Our actions this year have really put Avadel on the map with our key stakeholders as a patient's first company who will not relent until we can bring a new treatment option to people with narcolepsy. For the payers, we have made very good progress in our conversations this year. Now with the tentative approval in hand and, more importantly, the outer battery of a final approval decision now just over 10 months away, we are accelerating our actions with payers, including the 3 GPOs and the affiliate PBMs that represent over 85% of commercially insured lives.

Our team has done excellent work in establishing the clinical value proposition of once at bedtime LUMRYZ. And now we look forward to advancing contract discussions. The reception has been very positive as the payers look to gain post-approval access to a new therapy that we believe can go beyond the limitations of the current standards of care.

Now we continue to be nimble and dynamic in our readiness planning to ensure that we are ready to fully launch at the earliest time after receipt of a final approval. We retained relationships with our key partners, where the work takes the longest to prepare for launch. With the REMS requirements from the FDA being finalized, our program build-out is in full motion. The same can be said for the work being done by our team in advancing our commercial launch supply.

For product fulfillment, our patient services center will be ready to go live upon final approval. And now we will look to finalize our specialty pharmacy distribution agreements as we head towards a potential final approval.

In summary, the collective work that we have done across REMS, supply, distribution and fulfillment has put us on track to launch as soon as we can once we have final FDA approval for LUMRYZ. We know that once at bedtime LUMRYZ has the potential to address significant unmet need with patients and that our market research and data analytics shows the market potential for LUMRYZ to be roughly double that of the current twice-nightly oxybate market with more than 30,000 potential eligible narcolepsy patients. Recall, the total PAP patient population consists of 3 key segments: first, approximately 16, 000 actively treated twice nightly patients; second, an estimated 10,000 to 15,000 potential patients previously treated with oxybate who have discontinued therapy; and third, roughly 3,000 new oxybate patient starts. And in this segment, we expect robust yearly growth of 25% to 50% per year in the future.

All 3 patient segments have expressed high levels of interest in LUMRYZ. And physicians and patient groups both have indicated that once at bedtime dosing is the most important attribute in choosing an oxybate.

We are a forward-looking team. And now with the outer boundary timing for a final approval decision just over 10 months away, we are fully focused on executing our plans to deliver LUMRYZ to patients as effectively and as quickly as we can. I look forward to providing more updates on future calls.

Now let me turn the call to Tom for an update on the company's financials. Tom?

>>Thomas McHugh - CFO

Thank you, Richard. I'll provide a few highlights for the quarter and also note that full financial results are available in the press release and the 10-Q.

I'll start with the balance sheet, where we reported $104.1 million of cash, cash equivalents and marketable securities as of June 30, 2022. Also as of June 30, we had approximately $17 million of tax refunds pending, of which $10 million was received in July. We currently expect that the remaining $7 million will be received in the second half of 2022.

As a reminder, earlier this year, we completed an exchange and 8-month maturity extension of approximately 80% of $143.8 million of convertible notes. As a result, $117.4 million now matures in October 2023, and $26.4 million will mature in February of 2023.

R&D expenses were $4. 5 million in the quarter ended June 30, 2022, compared to $6.8 million for the same period in 2021. The period-over-period decrease was due primarily to lower purchases of active pharmaceutical ingredients used in the manufacture of LUMRYZ. SG&A expenses were $21.8 million in the quarter ended June 30, 2022, compared to $15.2 million for the same period in 2021. The period-over-period increase is primarily the result of fees associated with the exchange of the convertible notes. Higher legal and compensation costs were mostly offset by the reversal of previously accrued expenses due to the restructuring. This quarter, we recorded a restructuring charge of $3.6 million primarily for severance benefits associated with the reduction in the company's workforce. The workforce reduction will be completed during the third quarter 2022, and we expect to reduce quarterly cash operating expenses, excluding inventory purchases, to $12 million to $14 million.

Income tax expense was $3.2 million in the quarter ended June 30, 2022, compared to income tax benefit of $3.8 million for the same period in 2021. Income tax expense this quarter is due primarily to the valuation allowance recorded against deferred tax assets. The valuation allowance is noncash and does not impact our ability to utilize NOLs in the future when the company begins to generate taxable income.

Net loss for the second quarter of 2022 was approximately $63.4 million or $1. 07 per diluted share compared to net loss of approximately $19.6 million or $0.33 per diluted share in the same period in 2021. Finally, with $104 million of cash on hand at June 30, the $10 million of tax refunds received in July and the $7 million of tax refunds still to be received, together with the cost reductions we implemented, we believe that the cash runway extends to at least the middle of 2023. And with the tentative approval now granted and as we progress toward a final approval decision that could occur by June 2023 or earlier, we will seek opportunities to strengthen the balance sheet and ensure we have the capital resources available to prepare for the launch of LUMRYZ into what we believe is a greater than $3 billion market opportunity.

I'll now turn the call back to Greg for closing remarks.

>>Gregory Divis - CEO

Thanks, Tom. To summarize, we are pleased but certainly not satisfied with our recent milestone of receiving tentative approval for LUMRYZ, marking a critical step for Avadel.

With tentative approval in hand, we are committed to keep moving forward to unlock LUMRYZ's clear and intuitive value proposition with a once at bedtime treatment that could be transformative for people with narcolepsy by providing the potential of an uninterrupted night sleep while also managing daytime symptoms of narcolepsy. We look forward to keeping you up to date on our continued progress with our regulatory and legal actions as well as our ongoing efforts to prepare for and shorten the time to commercial launch upon receipt of final approval.

With that, we will open the call for questions, and I'll turn it back to the operator.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from François Brisebois with Oppenheimer.

>>François Brisebois - Oppenheimer & Co. Inc., Research Division

Just all right, so the time lines have changed a little bit. We've been tracking. We've got the potential REMS expiration. But you mentioned just between the filing of the lawsuit and the Markman hearing and what can come of that, you mentioned possibly having news by the end of '22. I just wanted to make sure I understood what that referred to. And also maybe hearing about -- I believe it was a lawsuit by the end of September, so maybe if you could just kind of put it all together and just make sure we know what to expect for a potentially earlier approval decision than June of '23.

>>Gregory Divis - CEO

Yes. Thanks, Frank. So both of them being the Markman hearing leading into the motion to delist on one track and, on the other track, the APA action against FDA. So taking the first one, again, in that case, we have asked the court assuming they agree with our position on the actual REMS patent not being eligible -- not being listed eligible -- Orange Book eligible to be listed, we are asking the court to order the delisting of that. Upon receipt of that delisting, we would then facilitate the process to, in essence, refile the necessary documents with FDA seeking their approval to move from a tentative approval to a final approval.

So obviously, the Markman hearing is on August 31. We certainly are seeking to have the motion to delist heard as quickly thereafter as possible. And depending on the timing of those decisions, whenever that occurs, that will set the time frame for us to then file the necessary documentation with the FDA to convert the tentative approval to final approval, which, again, per FDA guidance, generally speaking in that situation, is recommended anywhere from 2 months to 6 months. So depending upon when that occurs and how quickly the FDA acts in that setting could create a situation where a final approval decision could be had, depending on when that final delisting motion occurs.

On the APA case, what has occurred is a briefing schedule has been agreed to, which is we'll go through basically the middle of September. And currently, tentatively, that hearing is expected to be heard at the end of September. And again, what we're requesting from the court there is, if they agree with our position, that they vacate the requirement, the decision to require certification and ask the FDA to make a final decision within 14 days. So depending upon how long from the hearing to when the judge makes a final decision or ruling on that, if they rule in our favor, then a final decision could occur as early as 14 days after that point in time.

So again, both of those potentially provide windows where if the decisions happen relatively efficiently and they go in our favor, a decision could potentially occur prior to the end of the year.

>>François Brisebois - Oppenheimer & Co. Inc., Research Division

Perfect. That's very helpful. And then just maybe more for Richard. On the payer side, you guys obviously are doing a lot of work there. I was just wondering, any thoughts -- would you share any thoughts strategically of maybe giving out samples for free just to make sure that based on the fact that you have to titrate this medication, it can take time. In these patients, there is a high discontinuation rate for for these types of medicines. Any thoughts about from the script being prescribed to getting in the patient's hand to make sure that happens as quickly as possible, thoughts about just giving out some samples for free to make sure that patients get access quickly.

>>Richard Kim - Senior Key Executive

Yes. Frank, thanks for the question. It's an interesting thought. The one thing we are absolutely focused in on is making sure we can get patients a great experience with LUMRYZ as fast as possible upon final approval. So through our patient services center, we will offer a bevy of services. If it's a quick-start programs where you're waiting for insurance and other things for applicable patients to ensure that patients can get the experience with LUMRYZ with -- obviously, once they've been certified as quickly as possible. So we do know those initial experiences are going to be absolutely pivotal for us, which is why we have invested so heavily in ensuring that our patient services center will have not only that but other services aimed at both patients themselves and the offices as well.

So it's a good idea, Frank. There's obviously some legalities we'd have to work through, but we are working on making sure that we have a full suite of services to ensure that patients can get on therapy as fast as possible.

Operator

Our next question comes from Oren Livnat with H.C. Wainwright.

>>Oren Livnat - H.C. Wainwright & Co, LLC, Research Division

I have a couple. Just can you remind us upon FT218 or LUMRYZ tentative approval, did you get or do you expect to receive in due course, an indication regarding potential orphan exclusivity of your own product for -- that would apply to any future once-nightly sodium oxybate? I have a follow-up, sir.

>>Gregory Divis - CEO

Yes. Thanks, Oren. Again, as we've shared in the past, this is a topic we've had engagement with during the pendency of the review with FDA and fundamentally believe that the orphan exclusivity review was by and large complete although not decided upon formally because, technically, until there's a basis for a timing for a final decision, the FDA just isn't going to make that final decision -- that formal decision until the time is right.

And there's a lot of reasons for that, including that things could change in the marketplace or whatnot between now and that point in time. That being said, what's been communicated to us in our tentative approval letter, which I do believe is online now, you'll see what was noted in that approval letter was the REMS patent as we previously identified as the issue that we need to climb over.

So again, from our perspective, in our discussions with FDA, although not a formal decision, this issue is the same as it was prior to missing the PDUFA date and whatnot. And we believe both in the context of the robustness of our submission on the basis of clinical superiority that we provided to be granted orphan drug exclusivity. But as we've also stated based upon the statute, we don't necessarily believe orphan drug exclusivity is required to be granted a full and final approval.

>>Oren Livnat - H.C. Wainwright & Co, LLC, Research Division

Okay. And as we think about the launch scenarios and the timing to launch, Francois touched on this, but what -- how long do you think it would take to actually get this product out the door, which includes having to enroll physicians and REMS, et cetera, post approval? And if you were approved in fall or year-end, how many months do you think it would take to actually get some scripts rolling through the system and maybe even revenue producing?

>>Gregory Divis - CEO

Richard, do you want to start on that?

>>Richard Kim - Senior Key Executive

Yes. So on the great news with the tenant approval on hand under Jen's leadership, the REMS program is in full build-out right now as well. So previously, that would have been viewed as sort of one of the long poles in the tent. But now with us having the TA, that's going forward, so our belief is our work will be shortly after -- very shortly after our final approval, that will be up and going. And obviously, once the REMS is up and going, we can actually begin to certify both physicians and patients. .

So depending on timing, we'll either have time to do that a little bit before product is out there or it will be done concurrently. So that one element has really shrunk down a significant part of our prelaunch readiness here. So -- but it will still take us potentially a few months from the final approval before the first product is shipped out.

Greg, would you like to add on to that?

>>Gregory Divis - CEO

Yes, I think that's right. I think, Oren, the best way to think about it is, in the scenario where good news comes early and we have that as a tailwind and we're building toward a launch date on the back of an approval, there are certain things that will continue to be worked on that otherwise would have been completed if we go all the way until June of next year. So I think in the scenario where an approval comes by the end of this year, we may be launching a few months after that into the early part of next year into perhaps even depending on when the approval comes in the early part of maybe Q2. Unlike if a launch, if it goes all the way until after June 17, then we're likely towards the end of Q2 before final approval, we're obviously likely launching in the subsequent quarter.

>>Oren Livnat - H.C. Wainwright & Co, LLC, Research Division

Okay. And just if I may, you talked about your increased optimism for the oxybate market growth potential with several different buckets. Given all that work you've done in the interim, what's the latest view on the resources necessary to successfully launch the product, realize sort of those ambitions? What sort of footprint, marketing, I guess, just you probably wouldn't comment on total cost, but just as we try to understand the magnitude of investment necessary.

>>Gregory Divis - CEO

Go ahead, Richard.

>>Richard Kim - Senior Key Executive

Yes. No, Oren, it's a great question. I mean the 1 thing that's always really key for us to think about for the narcolepsy market is it's relatively compact, right? Once again, we know that as far as the treater base of oxybate prescribers are concerned for narcolepsy, there's only about 5,000, and 1,600 make up 80% of the total oxybate volume. So for us, it's been -- it's relatively compact. .

Our initial plans are still about the same where we're probably focusing at around 50 representatives that will allow us to cover that entire universe and add some. We've really invested very heavily in our data analytics platform so that we can really effectively target the right physicians at the right time. And a lot of the work that we've done up to this point is our foundation going forward, which is a great base for us. Everything from our disease education with Narcolepsy Disrupts to the engagement that we had with patients digitally, we have this to build upon.

So the great news for us is I don't think it's like we need a massive bolus. We're just going to keep building upon what we have. Clearly, we're going to have to spend more to hire sales force again and things like that. But the fact that this is a compact marketplace and then from making good inroads into those -- that core, there's clearly room to expand in the future. But that's what makes this marketplace, from my perspective, really

attractive to execute on is we don't have to do like multiple things. We can really focus on the physician engagement, the patient engagement and the payer engagement. And we've got great plans going against all 3 segments.

Operator

Our next question comes from Ami Fadia with Needham.

>>Eason Lee - SVB Securities LLC, Research Division

This is Eason Lee on for Ami. Just 2 from us. Maybe first, I'm curious, ahead of kind of the August 31 Markman hearing, is there any read-through that we could get from that in terms of potentially getting a favorable rule in regards to the delisting counterclaim?

And then maybe second, we just love your latest thoughts kind of on pricing of LUMRYZ and kind of in this market in general given the entry of authorized generics looking like they'll kind of start off in the beginning of next year.

>>Gregory Divis - CEO

Yes, thanks. As it relates to kind of any read-through from that perspective, it's probably not appropriate for us to speak on any of those specifics relative to this ongoing litigation other than the fact that when it comes to this specific 9, 6, 3 grams patent, again, I think what we're -- what we believe based upon the components of the patent that it is a computer system patent given it describes things such as processors and servers and screenshots and whatnot and believe that, that is not a listable -- Orange Book listable patent, which really is tied to formulation or method of use of that specific product, and therefore, again, we've asserted this because we believe in our position. And we look forward to the first step in this process in just a few weeks from now to advance it.

As it relates to pricing and the market dynamics, I'll turn it over to Richard.

>>Richard Kim - Senior Key Executive

Yes, Eason, thanks for the question. So obviously, when it comes to the marketplace, first and foremost, we've seen the oxybate market to be relatively flat as far as narcolepsy is concerned. And all of our plans that we've made in prelaunching our post-approval plans have actually been contemplating an AG in the marketplace. Now we don't really see the AG significantly impacting the potential for once a bedtime LUMRYZ at all. We've made plans whether not they make some further inroads or not here as well.

But regardless, when it comes to AG, it's always remember, important to remember that it's still going to be a twice-nightly product as are all the current oxybate as well. And we believe our work that we've done with the payers has really been to establish a clinical value proposition of the once at bedtime Lumeris as well.

So we definitely take that into account as well. We don't anticipate them really having significant pricing erosion, but we'll adjust our plans with whatever goes on there. And also keep in mind, the AG is really generally not attractive to payers as far as really increasing the uptake off of our assumptions today.

And as far as your question on pricing, we've stated right from the beginning, our goal with payers is to be sort of in a parity access position with the best of oxybates overall. And so our pricing, we've always stated to be sort of in the zone of where we believe the branded oxybate will be in the future as well.

Operator

Our next question comes from Chris Howerton with (inaudible).

>>Unidentified Analyst

This is A.J. for Chris at Jefferies. A quick housekeeping question. Do you have a target budget for API stocking? I just see it was the only item excluded from your expenditure guidance. .

>>Gregory Divis - CEO

Tom, do you want to answer that?

>>Thomas McHugh - CFO

You broke up a little bit. Your question was do we have guidance on the amount of our API purchases?

>>Unidentified Analyst

Yes.

>>Thomas McHugh - CFO

Yes, we're not providing a specific guidance around that. The API purchases are included in our R&D costs at this point?

>>Unidentified Analyst

Okay. Got you. And a quick follow-up question on the Narcolepsy Disrupts program. Do you have an update on what kind of engagement you're seeing with patients?

>>Gregory Divis - CEO

Yes. No, we've seen really great enrollment so far. We're closing at about 6,000 individuals who are registering to our program. And I think as I mentioned during the prepared remarks, what's been really cool to sort of see is we offered what we deem as a very simple but a very essential tool around a sleep diary. And in the first sort of month and a bit, we had over 3,000 individuals request getting it.

So our discussions with the patients, our engagement has been very good. And as I mentioned as well, we're sort of looking to sort of have a larger revamp to sort of take that next wave of engagement as we go into the early part of fall. But so far, we're super pleased with the impact that the campaign has really had and the continued engagement and dialogue that we're having with patients online.

Operator

Our next question comes from David Amsellem with Piper Sandler.

>>David Amsellem - Piper Sandler & Co., Research Division

So most of my questions have been answered, but I did want to ask you a couple of questions on commercialization. Number one, can you talk through where you think early adoption is going to come from? And in particular, do you expect that most of your earlier patients will have had exposure to the Xyrem authorized generic before they get on LUMRYZ? So that's number one.

Number two is, as you look at your IP runway, just makes sense for you to run a registration quality study in idiopathic hypersomnia. Is that something that's in the cards?

>>Gregory Divis - CEO

Thanks, David. Richard, do you want to take the first one?

>>Richard Kim - Senior Key Executive

Sure. No, great question, David. So as far as early adoption is concerned, I mean, first, I sort of think about it from the prescriber base. And clearly, our assumption is we'll have the earliest adoption from the most experienced oxybate prescribers. We know that there is less than 500 physicians that account for over 50% of the oxybate volume in the marketplace right now as well. .

And actually, what we see in our market research is a great opportunity for patients who are currently on twice nightly oxybate discontinued in de novo. But if you think about the SWITCH patients themselves, we actually know that wave patients tend to be the earliest adopters of innovative new therapies. So we absolutely do see a good opportunity for patients there to be attracted to the LUMRYZ value proposition as are the current Xyrem patients were potentially that -- which makes the most intuitive sense.

And as far as the AG is concerned, like I said, we still see it having limited impact in the marketplace. Now clearly, we'll have -- likely have some time to see that. But we absolutely do see the switch from existing twice nightly oxybate being a relatively large segment in the oxybate experienced physicians. We also see that opportunity with patients who tried twice nightly but are no longer on them for various reasons. And we also do believe we're going to get a good share of the de novo patients because, as many physicians have told me, when you offer the chance to not have to wake up in the middle of night with de novo patients, it's a pretty clear value proposition as well.

So we feel fortunate that we know that we have a great opportunity of the switch patients, but we absolutely sort of see the opportunity for growth in all 3 of those patient segments overall.

And Greg, I'll turn the IP question back to you.

>>Gregory Divis - CEO

Yes. Thanks, David. It's an important question because what's next is an important consideration for us in terms of how do we build the franchise around the innovation that is once-nightly LUMRYZ. And I think the short answer is there's a tremendous amount of interest from the clinician community amount of interest from the clinician community amount of interest from the clinician community to want to study a true once-nightly dose, once a bedtime administration for IH patients.

So yes, I think in short, we're evaluating that very seriously. We've done a tremendous amount of work in terms of understanding what that trial design could be like and whether or not should we consider a registration quality study or whatnot. I think you'll hear more about that as we go forward, but it is an important consideration as one of the tools in terms of building out the full value of LUMRYZ, whether that's in IH or whether that's in the work we're doing with the additional formulation work as well on our own low-sodium formulation -- no sodium formulations.

Operator

The next question comes from Adam Evertts with LifeSci Capital.

>>Adam Evertts - LifeSci Capital, LLC, Research Division

Question on the commercial side. On Jazz's earnings call, they reported that there are more patients on Xywav in Xyrwm. Of course, part of that is the idiopathic hypersomnia indication for Xywav. Just curious if that impacts your commercial strategy, perhaps messaging or otherwise.

>>Gregory Divis - CEO

Yes. And thanks for the question. Yes, you're right. I think what they reported is more patients for Xywav overall. But if we actually look at the narcolepsy market, it still slightly tilt towards Xyrem. The good news for us is we see the opportunity uniquely favorable for both of those segments. As I mentioned before, what we -- our research tells us is, in general, Xywav patients with narcolepsy tend to be earlier adopters, younger patients who have been diagnosed with narcolepsy for last years seeking more new innovative therapies as well. So we believe that bodes very well for the value proposition of LUMRYZ once it's available in the market as well.

And then once again, so it likely will be a bifurcated market between Xyrem and Xywav patients as far as oxybates are concerned. For Xyrem patients, our value proposition is probably the clearest and most intuitive overall there as well. So going from twice at night to a once at bedtime a once at bedtime therapy, that, in essence, is the same sort of compound. So we believe we're really well positioned for both. And a lot of it is also going to be driven by some of the patient engagement that we have overall as well. So despite the fact that there's about a 50-50 split in the marketplace right now, we believe we're positioned for both of those segments very well in addition to the discontinued patients and the de novo patients as well.

>>Adam Evertts - LifeSci Capital, LLC, Research Division

Fantastic. I appreciate that. And then one quick clarification. I think I know the answer to this, but will we get any more color on the label or we'll need to wait until full approval to see any more details there?

>>Gregory Divis - CEO

Yes, it won't be released until a final approval, Adam. But our view on it, where it stands today, it's in really good shape and, I think, gives us something really good to work within the marketplace.

Operator

The next question comes from Marc Goodman with SVB Securities.

>>Unidentified Analyst

This is (inaudible) for Marc. Similarly to the previous participant, I think most of the questions have been answered. But maybe just a follow-up on the last question. Do you expect any additional edits to the label or REMS upon the request for final approval?

>>Gregory Divis - CEO

Not at this time. We don't -- we believe that's complete. I would say that that's our expectation, unless new information or new data is learned during the pendency of the tentative approval period. But at this stage, we would expect that to be in its final form.

Operator

Next question comes from Matt Kaplan with Ladenburg Thalmann.

>>Unidentified Analyst

This is Raymond in for Matt. Just 2 quick questions. Impressive data showing that dosing is a key factor in patient preference. I was just wondering to ask, just digging deeper, is there alignment between patients and clinicians on the relative preference for sodium content in making treatment choice? And is that something maybe a patient education campaign or that might be helped in aligning patients with clinicians? And my second question is do you expect any update from RESTORE study later this year? Or is that more of a next year?

>>Gregory Divis - CEO

Jen, can you handle those?

>>Jennifer Gudeman

Yes, absolutely. Thank you for the question. So the poster that we had presented at sleep on the discrete choice experiment shows that both patients and clinicians do not place the same value on the sodium content as they do on the dosing frequency. So that came through very clearly for those patients and clinicians that the # 1 driver of treatment selection is the dosing frequency in preference of a once at bedtime dose as compared to twice-nightly dosing.

As far as it pertains to RESTORE, yes, we will be presenting more data at the upcoming congresses, both the CHEST and ANA Congress that are being held mid-October. We will have posters that continues to update our open-label data from RESTORE.

Operator

The next question comes from Chase Knickerbocker with Craig Hallum.

>>Chase Knickerbocker - Craig-Hallum Capital Group LLC, Research Division

Number one, just first for me, can you speak a bit to how your REMS program and the existing oxybate REMS would have to interact and would there have to be some cooperation between 2 of you to ensure oxybate patients properly managed between the 2 programs? If you could just speak to any challenges here as you are building out your REMS program sort of around there, so that would be helpful here.

>>Gregory Divis - CEO

Yes. Thanks, Chase. I think the first answer to that question is that upon a final approval, both REMS programs are going to have to communicate with each other and cooperate. So it's not just theirs cooperating with our or ours cooperating with theirs. Both companies are going to have the requirement to ensure a patient only has one active oxybate prescription at a time.

There is a process for which the FDA is approved and how that's going to work on our part. That's part of our REMS program and our design. And if you look at our tentative approval letter online, you'll see that components of the REMS document, the REMS program has been provided by FDA. And inclusive of that is Section 9, which is a section that basically requires us to report how the other party is responding to -- and the timeliness of those response -- the response in our inquiries to determine if a patient has an active prescription or not.

Our assumption is that will be reciprocal on their side as well, but I don't know that for sure. But clearly, there is a mechanism to report the responsiveness of the other REMS program to FDA at their request.

>>Chase Knickerbocker - Craig-Hallum Capital Group LLC, Research Division

Awesome. That's helpful color. Then just last for me, can you provide some details of what specific business functions were cut or reduced in the workforce reduction and cost optimization or what will need to be added or added back upon full approval?

>>Gregory Divis - CEO

Yes, I would say there was no area that was spared, so to speak, from that standpoint. And I would characterize it in really a couple of ways. The first way is, in part, it was part of the G&A organization that was built to prepare for an onboarding of a significant expansion of headcount in the organization, more than a doubling of it by far as we would -- as we were heading towards a potential final approval. And clearly, those aren't physicians we need in place right now, although the infrastructure and systems have been built to support that in the future.

And then secondly, I would say it's roles where there are certain roles that we've done a lot of work to get ready for launch, and now it is ready to go, and there's no really active work that's required from those functions. So we've made the decision on those sorts of roles to let them go but really keep critical roles that we need to continue to execute to shorten the time from approval -- from final approval to launch.

Operator

Next question comes from Paul Matteis with Stifel.

>>Unidentified Analyst

This is James on for Paul. I just wanted to understand the exact steps behind getting a full approval. It sounds like from the press release, you'll receive full approval kind of immediately following the expiry of the REMS patent. And I guess is that the case? Or is there anything that needs to happen at the FDA first? For example, will they need to make a decision on ODE following patent expiry? And I guess, what's the risk that could cause a further delay?

>>Gregory Divis - CEO

Yes. As previously shared, there is a process. If we're heading toward the situation where June 17 is the expiry of the patent and that's the last remaining item for us to move to from a tentative approval to a final approval decision, we would begin the process in notifying the FDA and filing all of our related documentation well in advance of that per FDA guidance such that upon that expiry or shortly thereafter, we would expect a final decision to be made on LUMRYZ.

So I think the short answer to the question is, not speaking directly for how long after June 17 that will occur, but we will take the necessary steps to file the necessary documentation and request the FDA to begin the process to make whatever final decision needs to be made to convert from a tentative approval to final approval in advance of that such that when that patent expires, the FDA should be in a position to do so.

Operator

This concludes our question-and-answer session. I would like to turn the conference back over to Greg Divis for any closing remarks.

>>Gregory Divis - CEO

Thank you, operator. Thank you, everyone, for joining us today. We look forward to keeping you up to date on our progress on a number of these fronts in these matters and wish you a great rest of the day and look forward to any follow-up necessary. Take care. Thank you.

Operator

The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.

EXHIBIT D

REQUEST FOR PRIORITY REVIEW DESIGNATION

for

Sodium Oxybate for Extended-Release Oral Suspension (FT218)

For the treatment of cataplexy and excessive daytime sleepiness in adults with narcolepsy

Contact Person: Marla Scarola
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Submitted to: Division of Neurology 1, CDER

NDA Number: 214755

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1. INTRODUCTION

Oxybate, also known as gamma-hydroxybutyric acid (GHB), was discovered in 1960. GHB is a metabolite of gamma-aminobutyric acid (GABA), which is synthesized by neurons in the brain and functions as a neurotransmitter. GHB is a central nervous system (CNS) depressant and produces dose-dependent sedation and anesthesia in laboratory animals (WHO 2012).

The sodium salt of GHB, sodium oxybate, has been described as a therapeutic agent with high medical value (Fuller et al. 2004; U.S. Xyrem® Multicenter Study Group 2004). In Europe and the United States (U.S.), sodium oxybate is currently approved for the treatment of cataplexy and excessive daytime sleepiness (EDS) in patients with narcolepsy at doses up to 9.0 g/night (Xyrem® Summary of Product Characteristics (SmPC) 2015; Xyrem® Prescribing Information 2020). A recent post hoc analysis confirmed that sodium oxybate treatment results in improved sleep continuity and nocturnal sleep quality in patients with narcolepsy (Roth et al. 2017). Moreover, sodium oxybate treatment is associated with improvements in resistance to sleep and sustained attention in narcoleptic patients (van Schie et al. 2016).

In the U.S., the Food and Drug Administration (FDA) approved Xyrem® (sodium oxybate) oral solution in 2002 as an orphan drug for the treatment of cataplexy in adult patients with narcolepsy. In 2005, this approval was extended to the treatment of EDS in adults with narcolepsy, and in 2018, it was further extended to the treatment of cataplexy and EDS in pediatric patients 7 years of age and older with narcolepsy. In 2020, FDA approved Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution for the treatment of cataplexy and EDS in patients 7 years of age and older with narcolepsy. The primary difference between these products is that Xyrem® bears a warning regarding use in patients sensitive to sodium intake due to its sodium content and Xywav® does not bear this warning.

Sodium oxybate has also been approved in different countries for various purposes, such as general anesthesia and treatment of alcohol withdrawal and addiction. Potential additional benefits of sodium oxybate include the treatment of symptoms of idiopathic hypersomnia (Leu-Semenescu et al. 2016).

Both Xyrem® and Xywav® are administered in two equal oral doses twice nightly. The first dose is administered prior to bedtime with the second dose requiring the patient to wake 2.5-4 hours later to take the second dose (Xyrem® Prescribing Information 2020). Requiring a second nightly dose is inconvenient and may jeopardize sleep structure architecture and sleep quality. It may also affect compliance, resulting in decreased efficacy and poorer quality of life. Additionally, the second dose can result in adverse events in the middle of the night, ranging from nausea/vomiting (potentially increasing aspiration risk) to falls (increasing fracture risk). Avadel CNS Pharmaceuticals, LLC (Avadel) has developed FT218, an extended-release formulation of sodium oxybate that allows for a single dose prior to bedtime. The single nightly dose of FT218 eliminates the need to interrupt sleep to take a second dose and provides a safer alternative by avoiding middle-of-the-night dosing and associated adverse events.

Avadel conducted a Phase 3 double-blind, randomized, placebo-controlled, two-arm, multicenter study to assess the efficacy and safety of the once nightly formulation of FT218 (sodium oxybate for extended-release oral suspension) for the treatment of EDS and cataplexy in subjects with narcolepsy (CLFT218-1501, the REST-ON study). In addition, Avadel is currently conducting an ongoing open-label extension and switching study intended to evaluate long-term safety and

tolerability of FT218 and the ability to switch from twice-nightly immediate release sodium oxybate to once-nightly FT218 for the treatment of EDS and cataplexy in subjects with narcolepsy (CLFT218-1901).

Avadel hereby requests priority review designation of its new drug application (NDA) for FT218 for treatment of cataplexy and EDS in adult patients with narcolepsy. As discussed below, narcolepsy is a serious condition associated with morbidity that has a substantial impact on day-to-day functioning; FT218, if approved, would provide a significant improvement in safety and effectiveness for the treatment of this serious condition.

2. SERIOUS CONDITION

2.1. Symptoms of Narcolepsy

The hallmark symptom of narcolepsy is EDS and is hence required for diagnosis. It is also the most troublesome symptom and the one for which patients most commonly seek treatment. EDS is defined as the inability to stay awake and alert during the day, resulting in periods of involuntary sleep episodes or unintended lapses into "drowsiness" during activities of daily living (Thorpy 2012). In narcolepsy, EDS can exist despite adequate nighttime sleep. The chronic and severe nature of EDS predisposes these patients to deficits in multiple areas of functioning. When alertness is compromised, performance may be diminished across a variety of cognitive functions, work-related safety may be compromised, and productivity and overall quality of life may suffer. In fact, quality of life scores in patients with narcolepsy mirror those of patients with multiple sclerosis, Parkinson's disease, and post-partum depression (Beusterien et al. 1999; Da Costa et al. 2006; Riazi et al. 2003). It is possible that performance deficits may precipitate reduced patient-reported quality of life and difficulty with achievement in work and/or school. Beyond this, the sleepiness can be so omnipresent as to cause patients to socially withdraw, making relationships with family and friends difficult and strained.

Cataplexy, in the presence of EDS, is suggestive of type 1 narcolepsy and an indication for objective testing to confirm the diagnosis (Sansa et al. 2016). Cataplexy is defined as a sudden muscle weakness episode and can affect a few muscles (for example, facial muscles) or all skeletal muscles at once (Dauvilliers et al. 2014). As a result of the muscle weakness, patients momentarily have head nodding from weakness in the neck muscles, sagging of the jaw, buckling of the knees, dropping of objects from hands, and/or dysarthria or inability to speak during the episode. Sometimes, they may slump or fall forward onto the ground, either all at once or more gradually.

Cataplexy attacks are typically brief, on average, lasting from milliseconds to 1-2 minutes. Cataplexy is typically triggered by emotions, most often by telling or hearing a joke, laughing, or becoming angry. These emotions have been combined to successfully identify cataplexy among cases and lack of cataplexy among controls with remarkable specificity. At initial presentation and close to symptom onset, and especially in children and teenagers, the onset of a cataplexy attack may not be precipitated by an emotional trigger and can happen almost spontaneously, termed atypical cataplexy. It is unclear as to how and why the frequency or severity of cataplexy varies across patients and may or may not change over time (Dauvilliers et al. 2014).

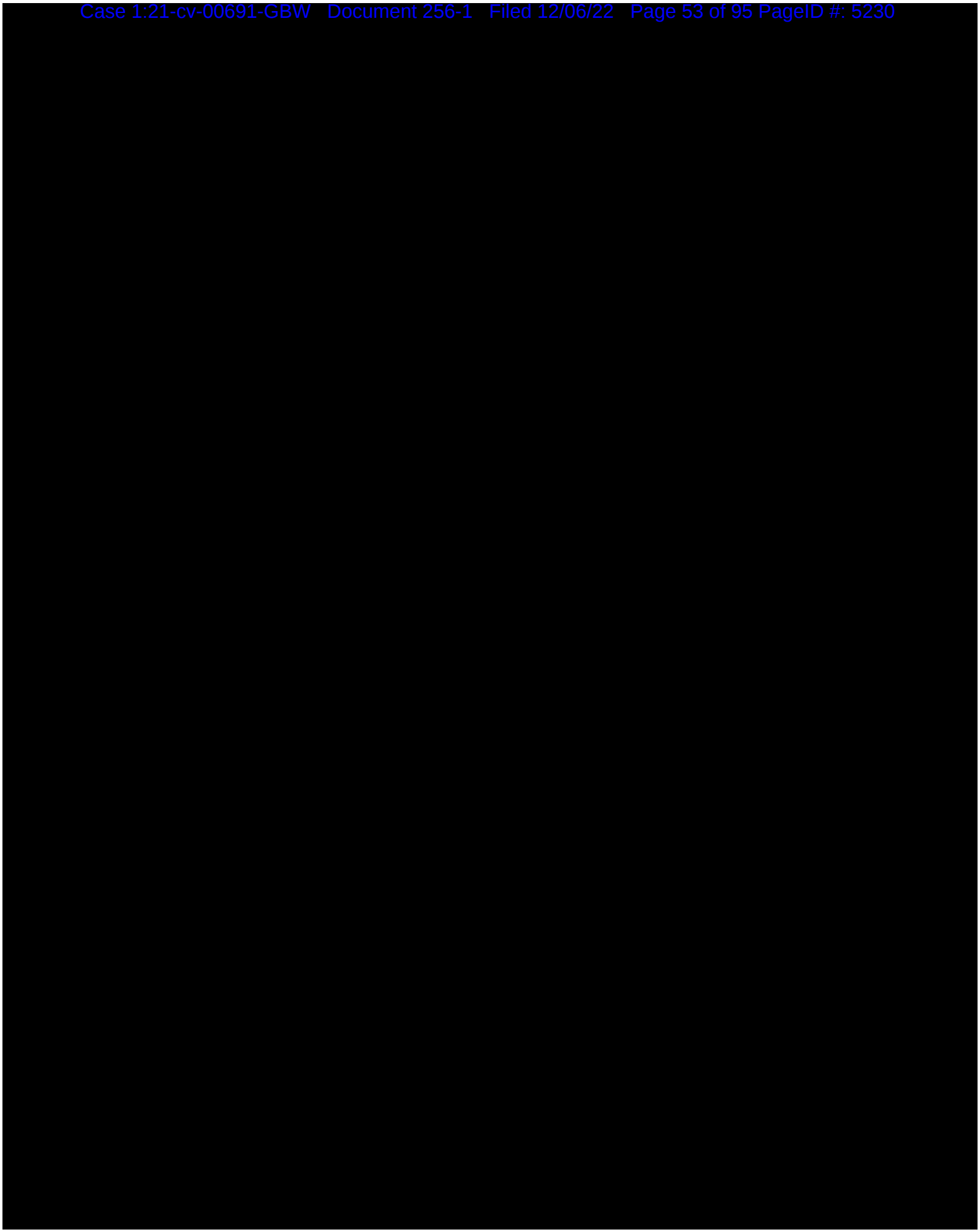
The onset of cataplexy typically occurs after the onset of EDS. Less frequently, it can occur years after the onset of EDS. Aside from the emotional triggers for cataplexy attacks, withdrawal from rapid eye movement (REM)-suppressing drugs may also cause them (Dauvilliers et al. 2014).

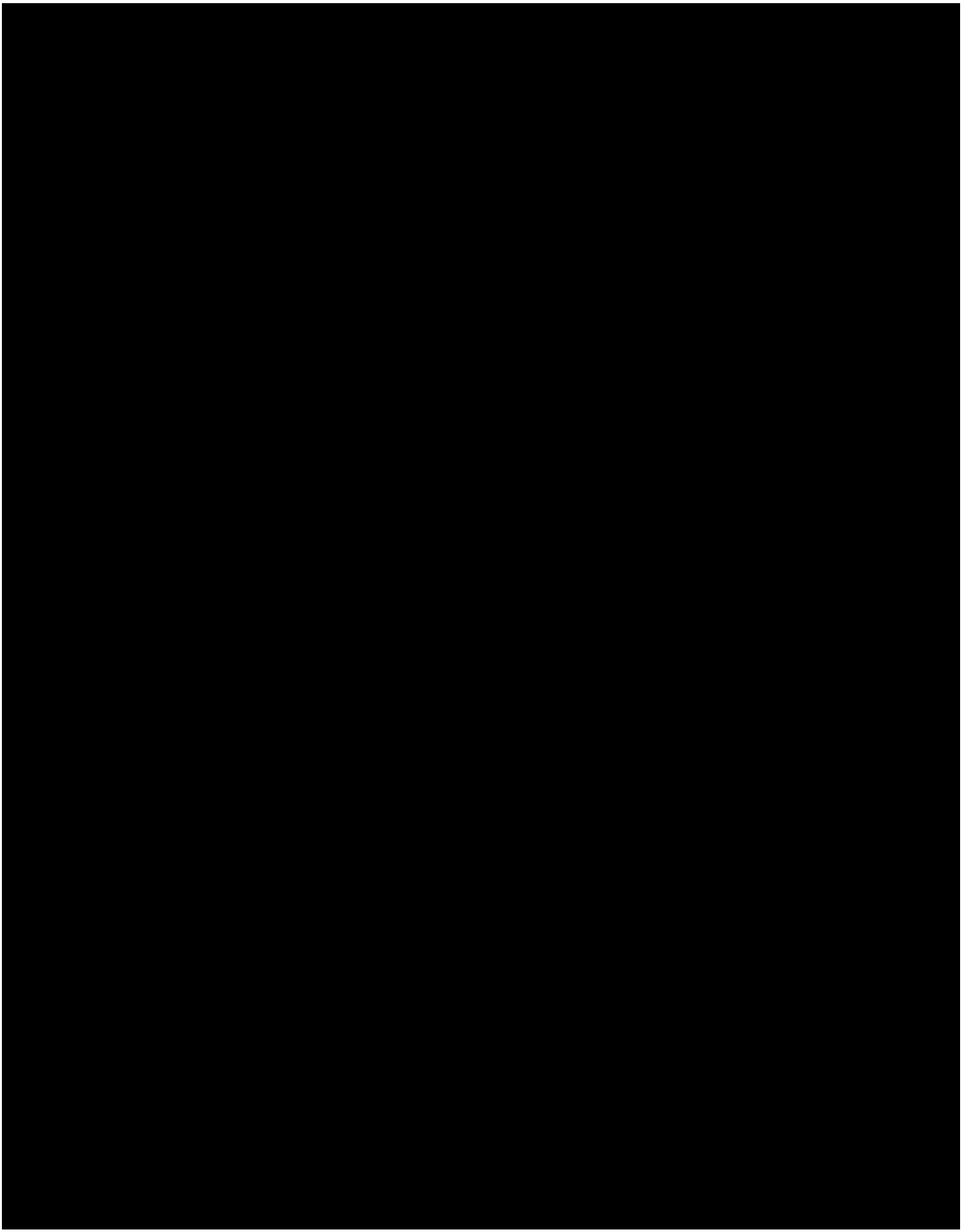
Disturbed nocturnal sleep (DNS) is the second most common symptom among narcolepsy patients after EDS (Mitler 1994). The DNS observed in narcolepsy is distinct from that seen in insomnia. While patients with insomnia have difficulty falling asleep at the beginning of the night and after nocturnal awakening, patients with narcolepsy fall asleep faster than insomniacs and even the general population. DNS in narcolepsy is characterized by frequent brief awakenings or shifts to lighter stages of sleep during the sleep period that are transient, with increased Stage 1 sleep, and

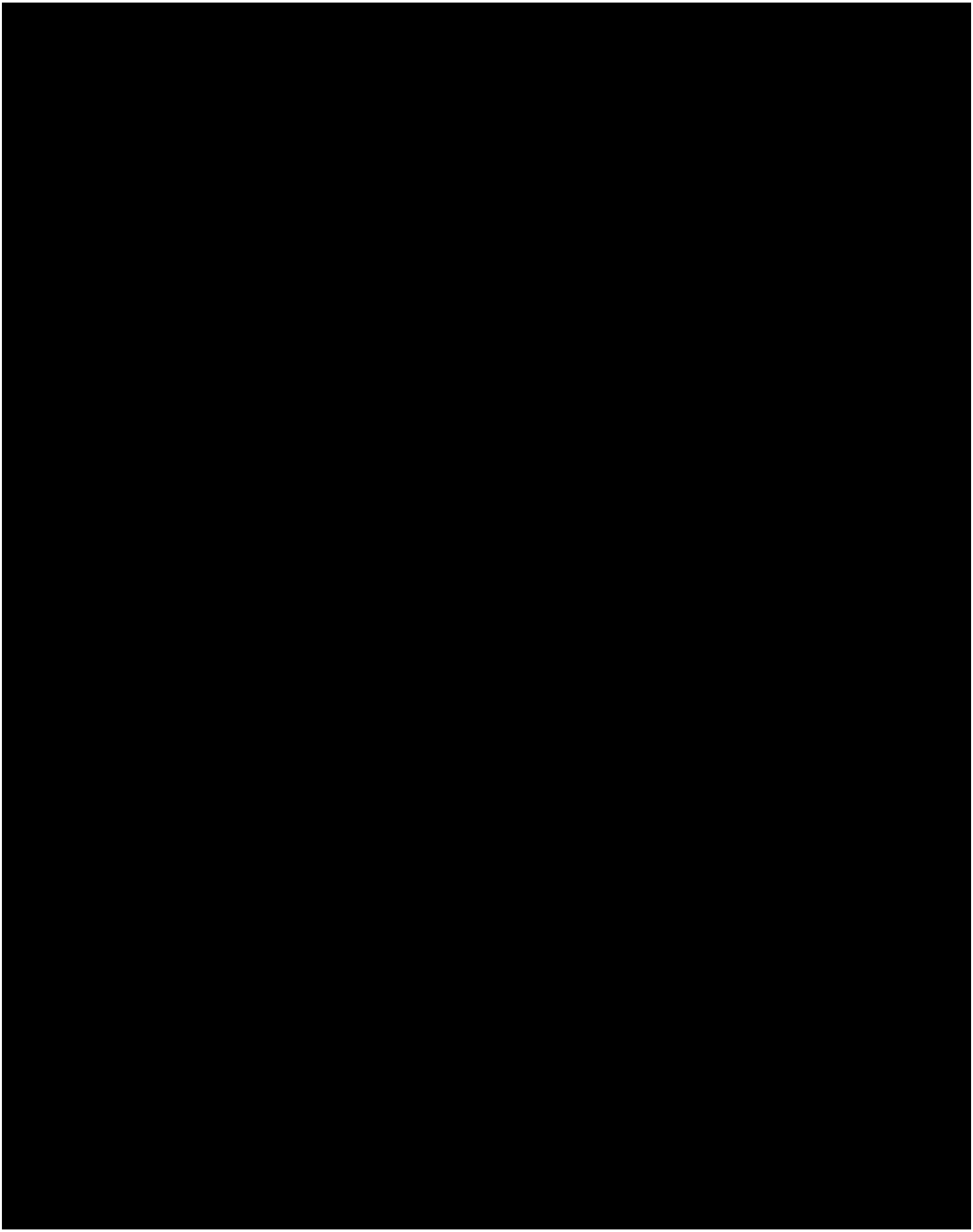
reduced deeper stages of sleep. Often this leaves patients feeling poorly rested or that their sleep was not refreshing. The contribution of DNS to the EDS in narcolepsy is not well understood.

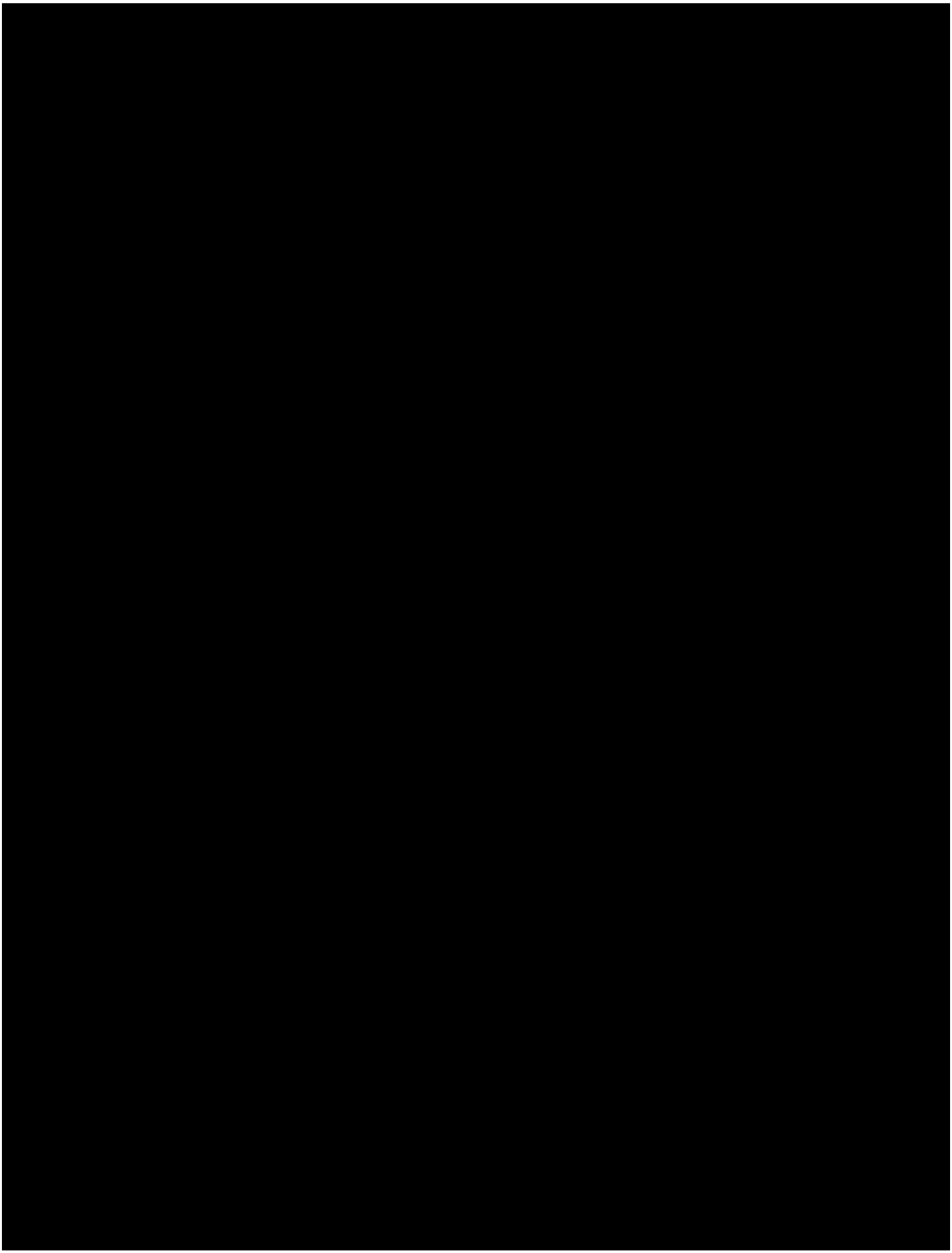
Additional symptoms completing the narcolepsy pentad include hypnagogic/hypnopompic hallucinations (HH) (vivid dreams at sleep onset or offset that are more often associated with negative emotions) and sleep paralysis (SP) (feeling unable to move the body during transition periods of sleep) (Roth et al. 2013). These may occur simultaneously and are often frightening to the patient. More specific for narcolepsy is their occurrence at sleep onset. Like cataplexy, SP and HH are REM-related phenomena. Thus, experiencing them at sleep onset is rare in the general population.

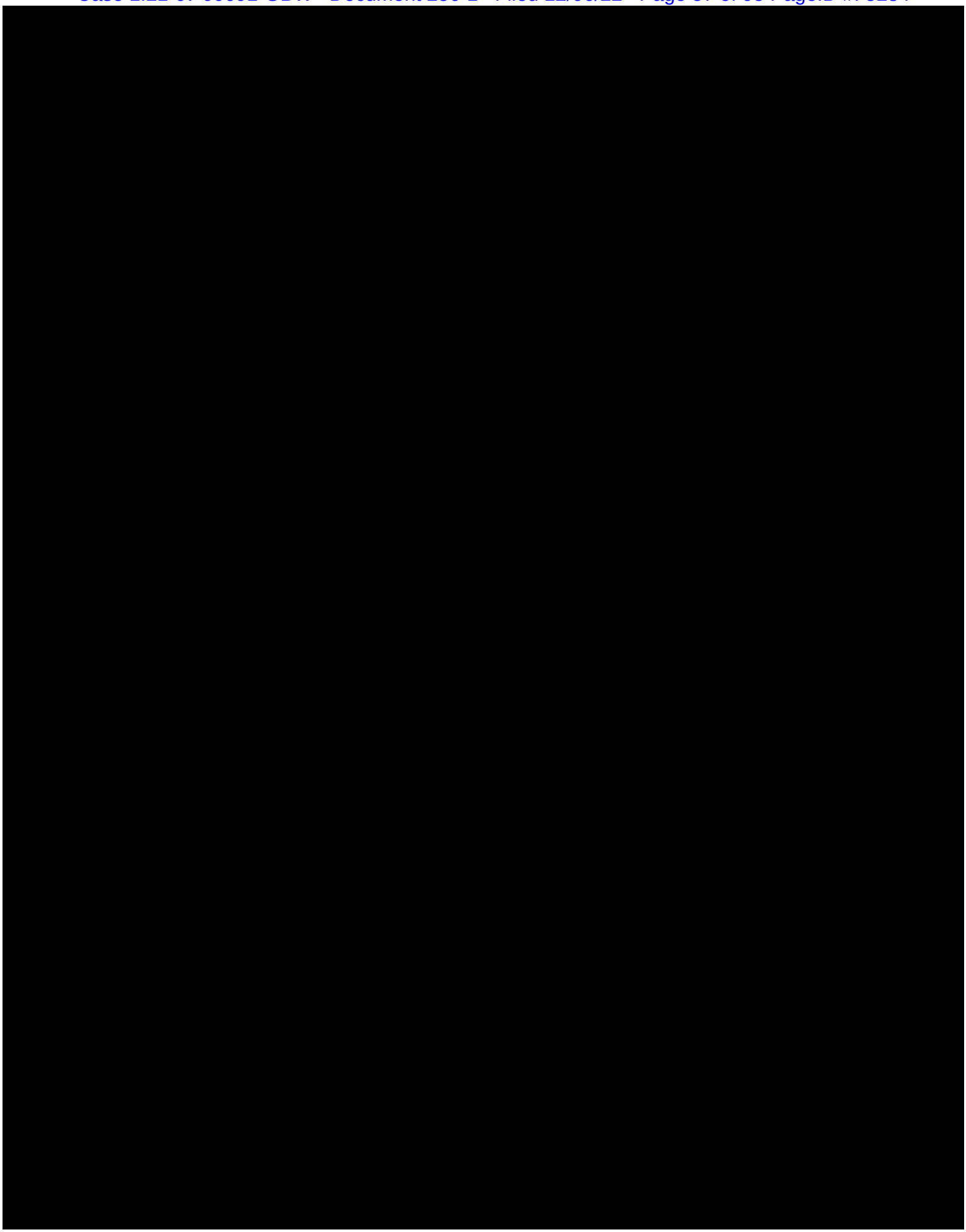
The significant symptoms associated with narcolepsy make it a very serious condition, with morbidity that severely impacts patients' day-to-day functioning.

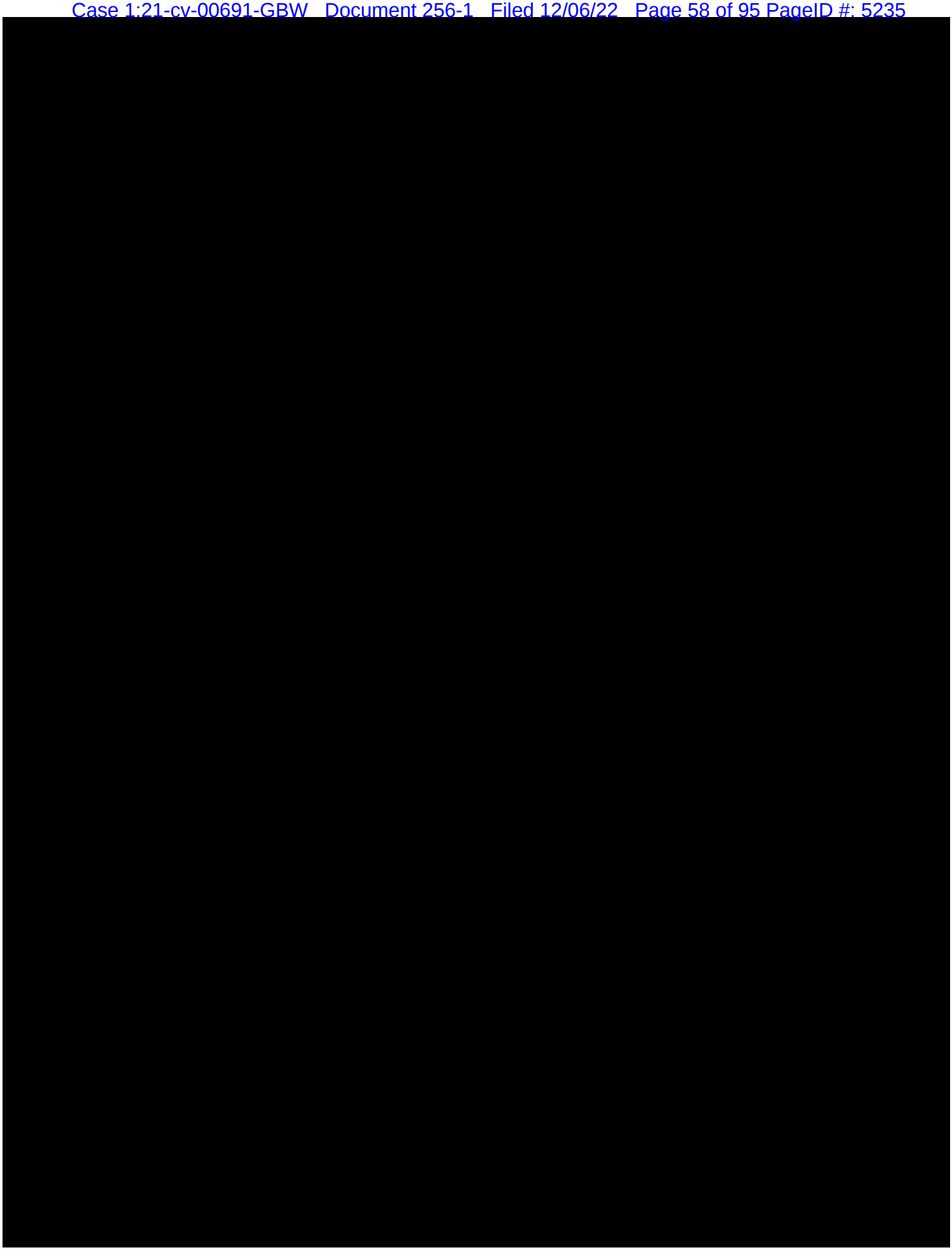


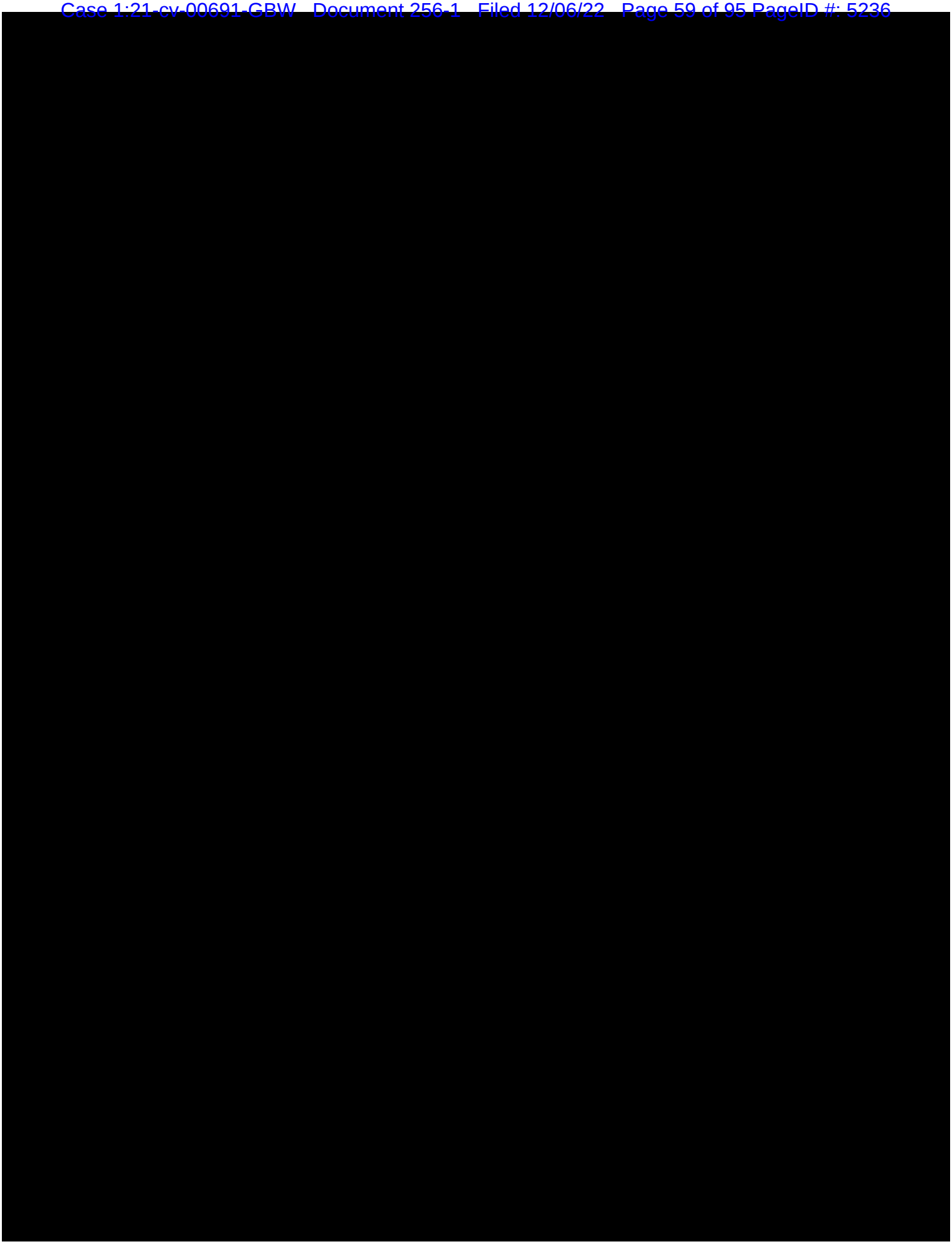


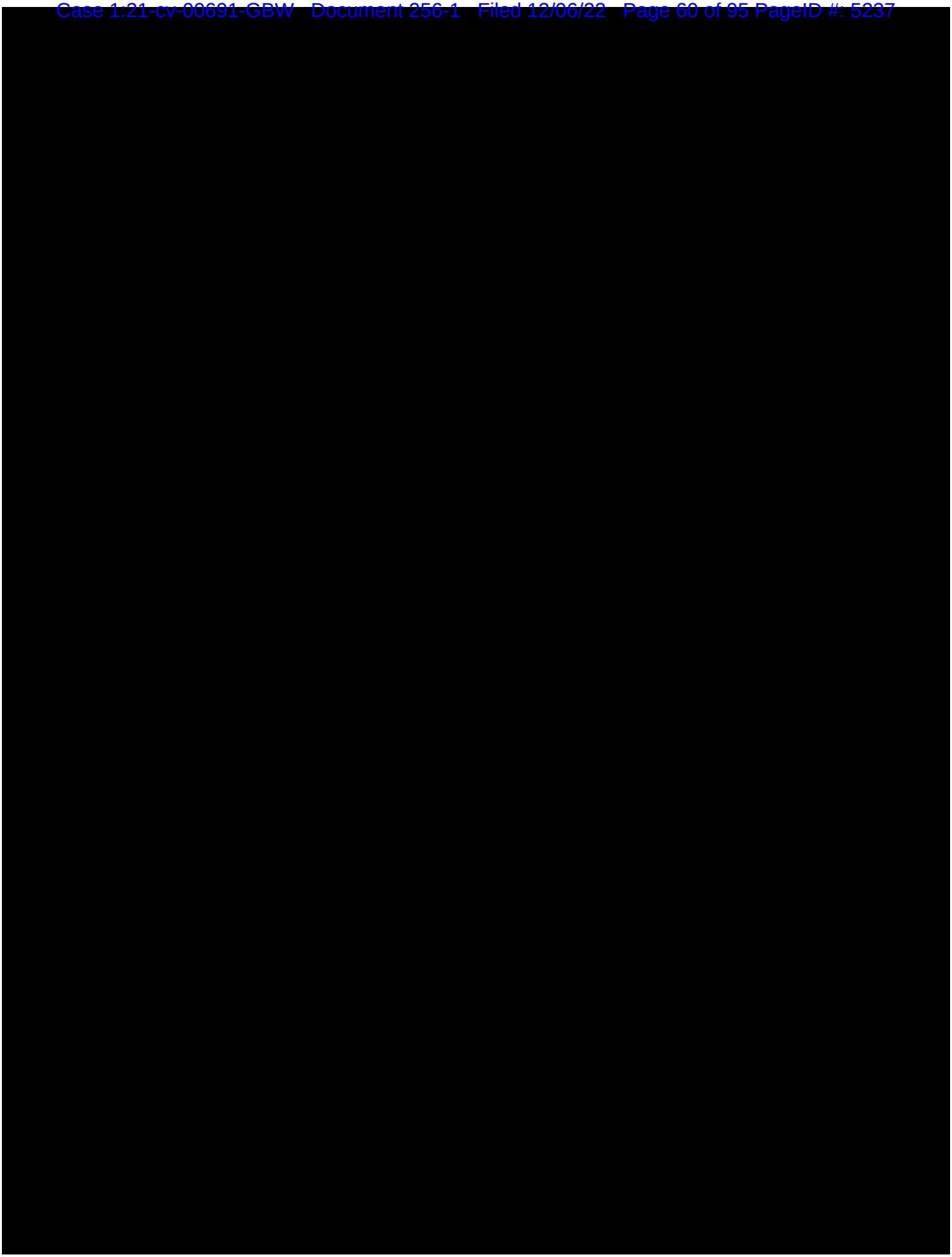


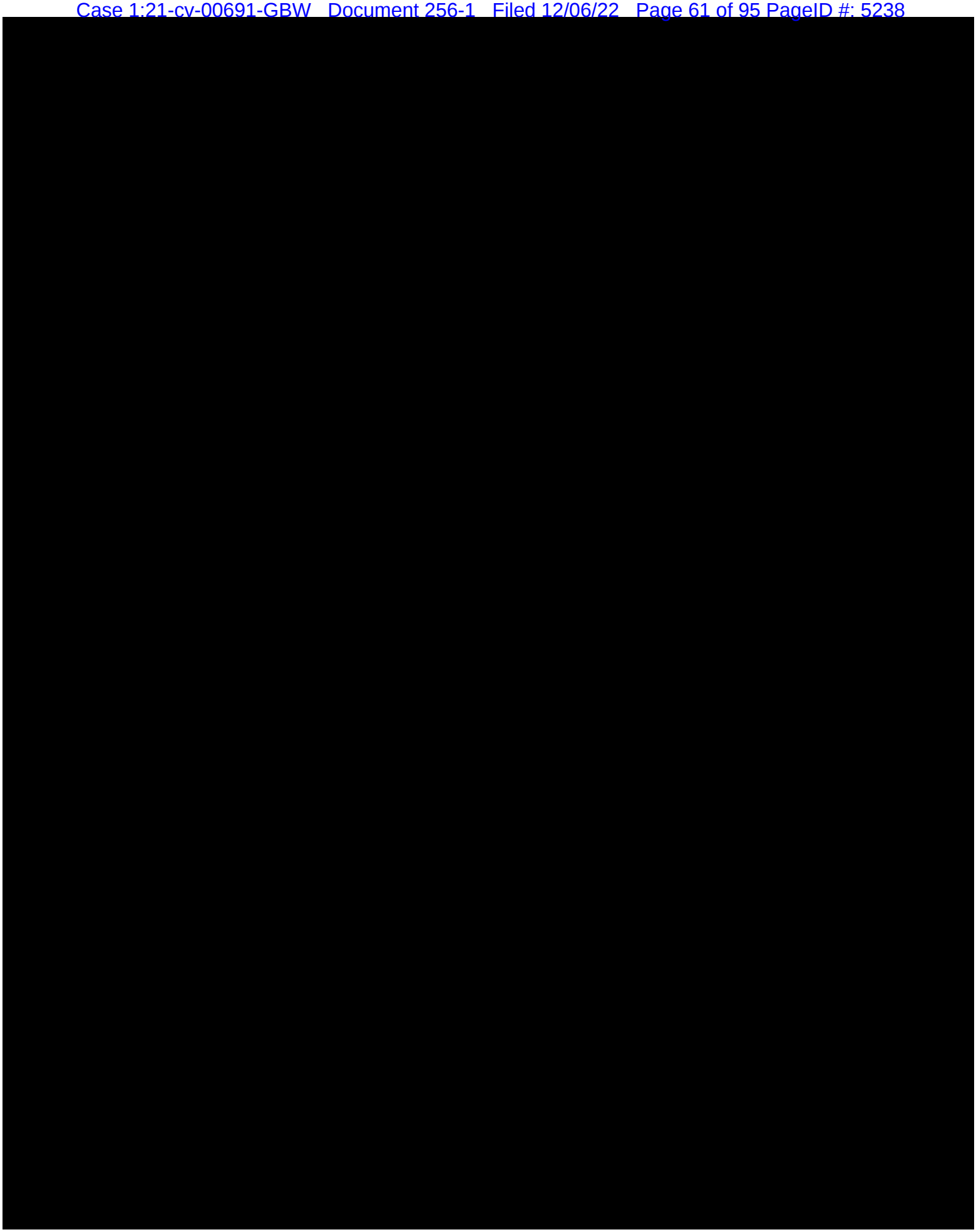


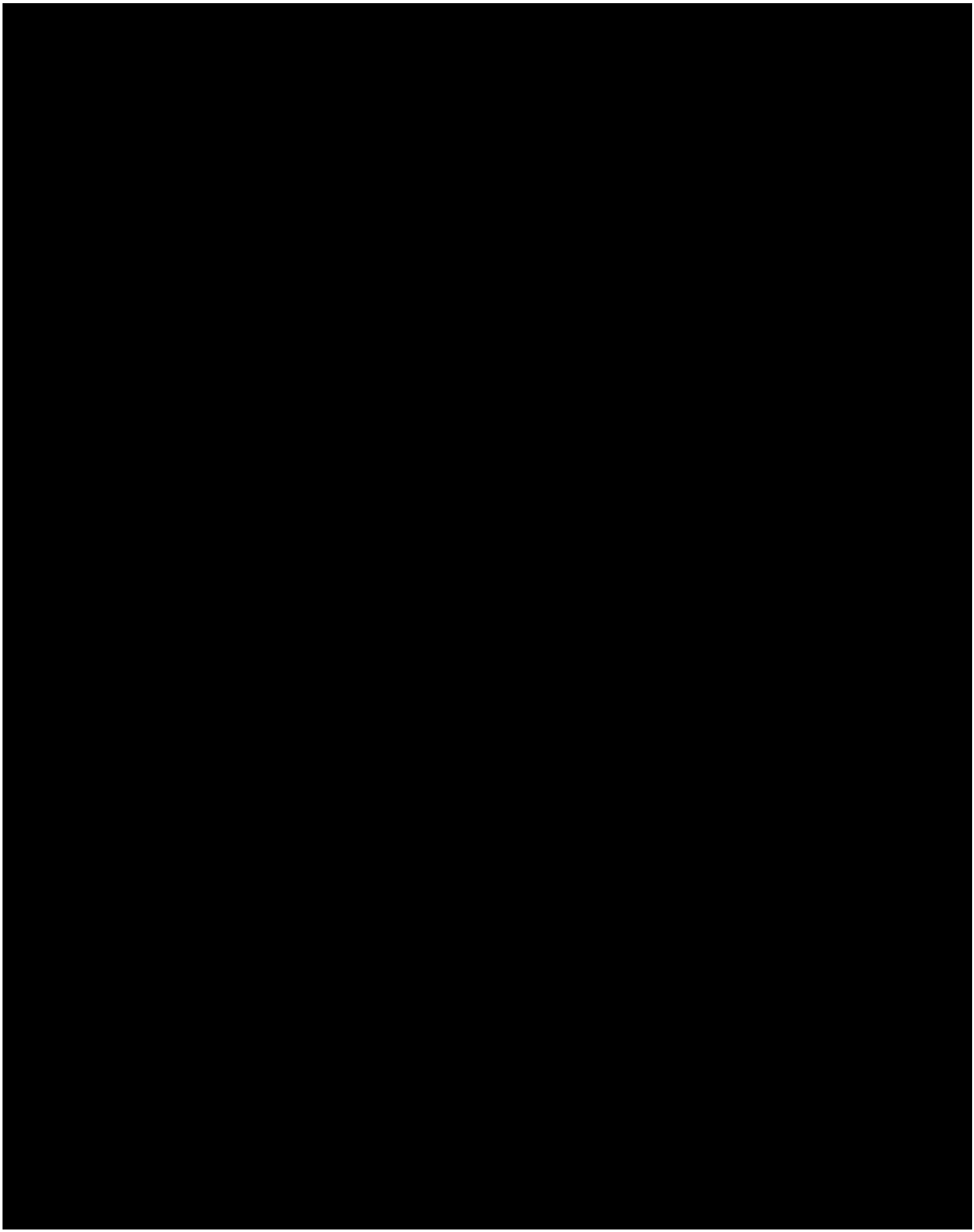


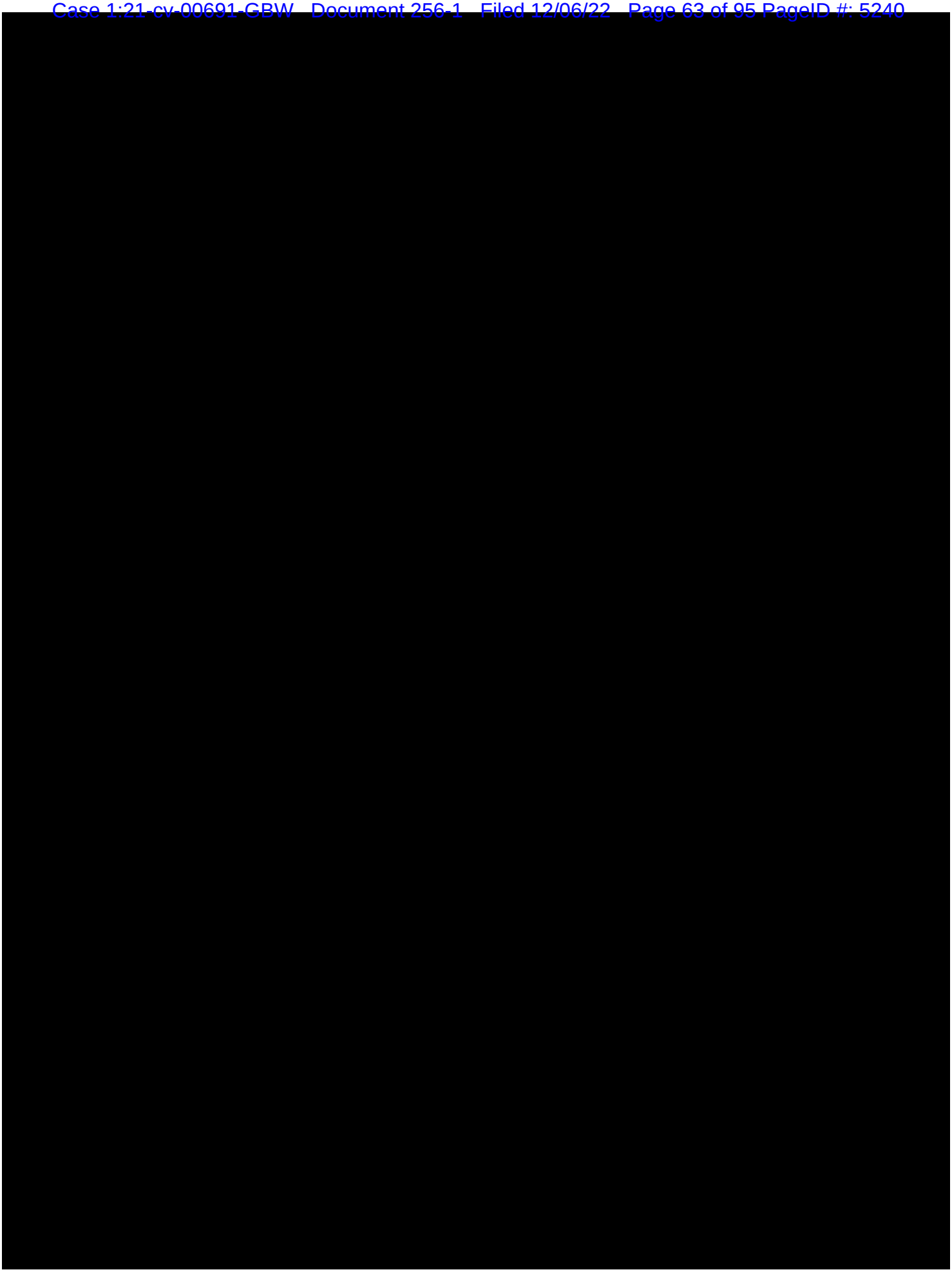


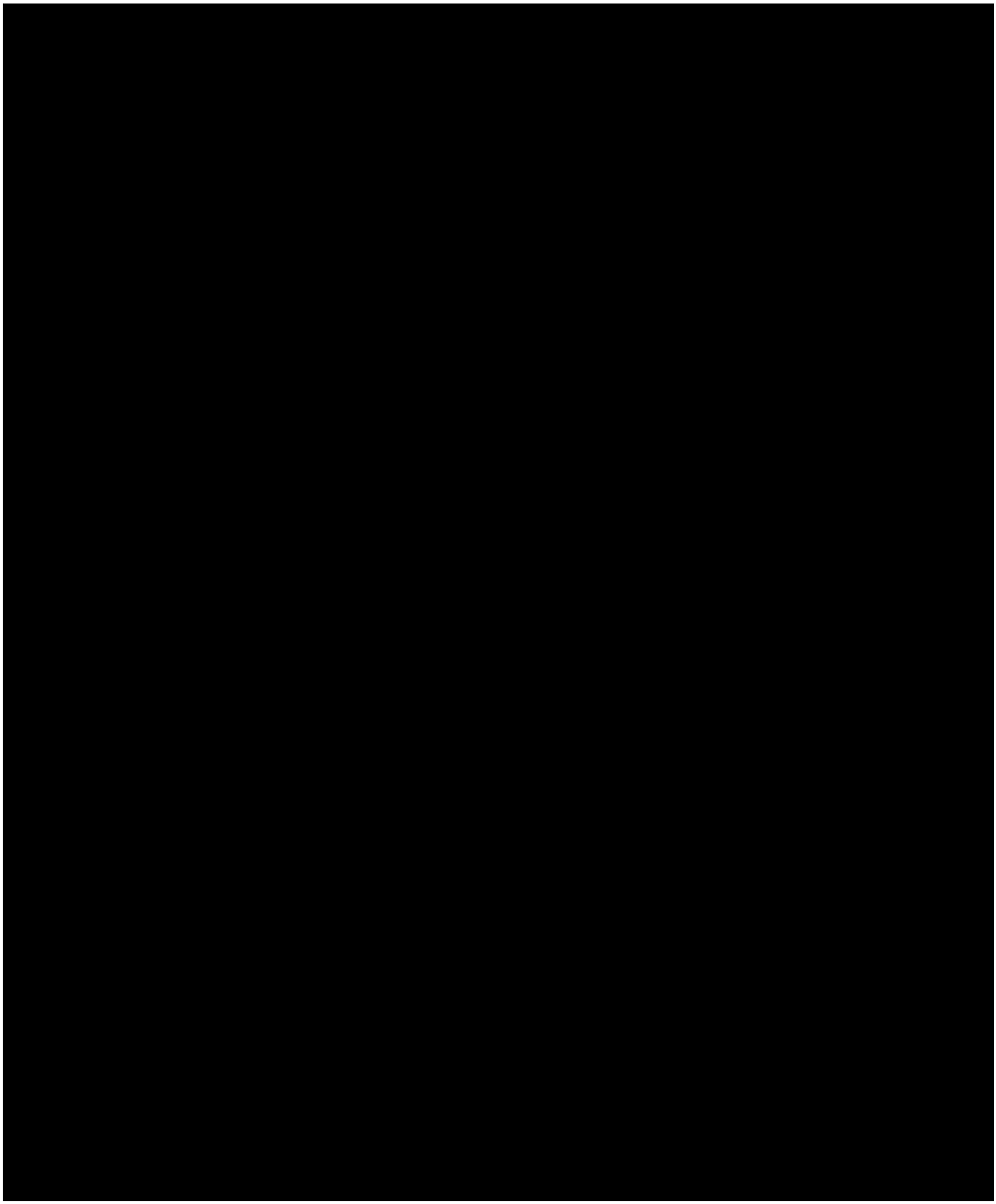


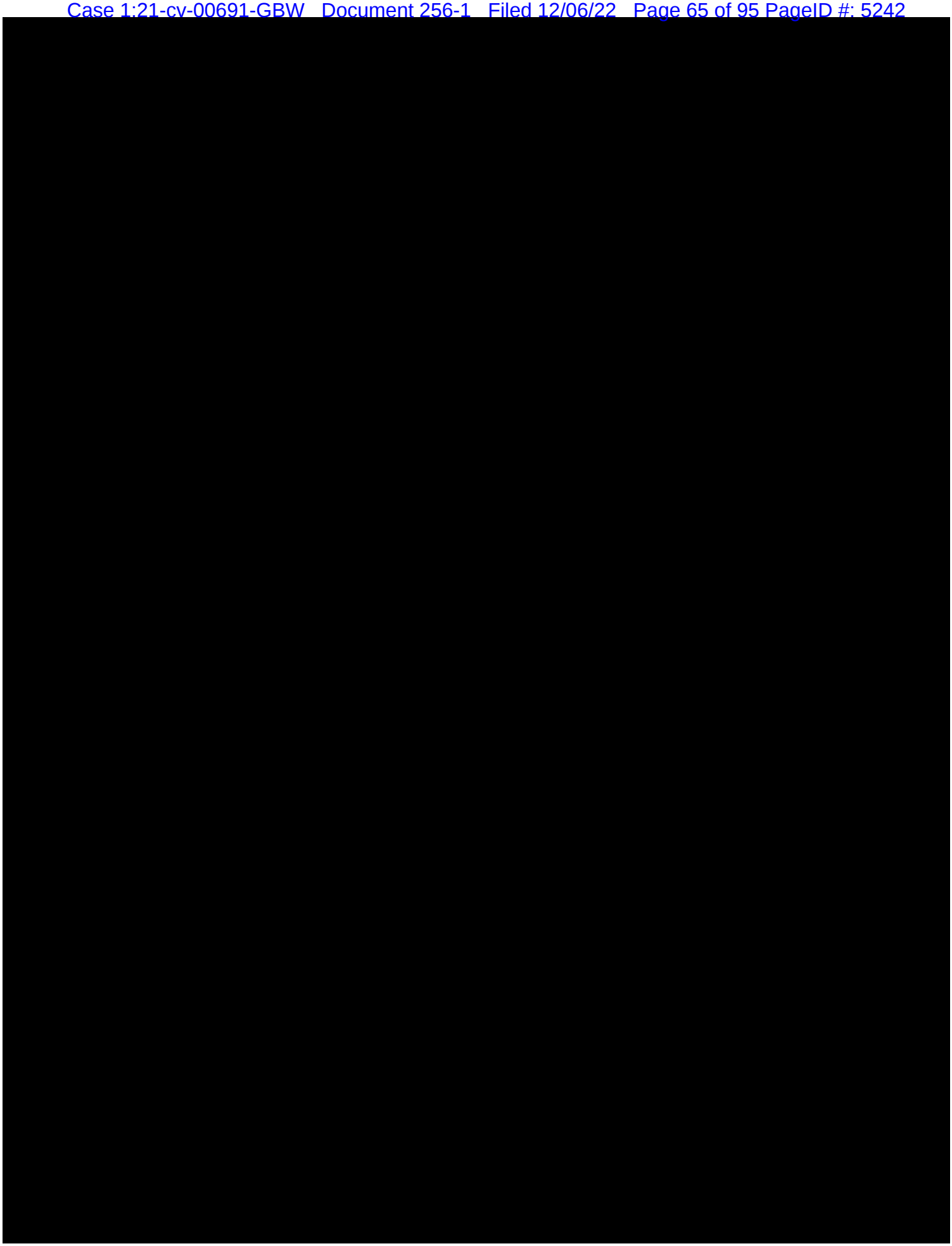


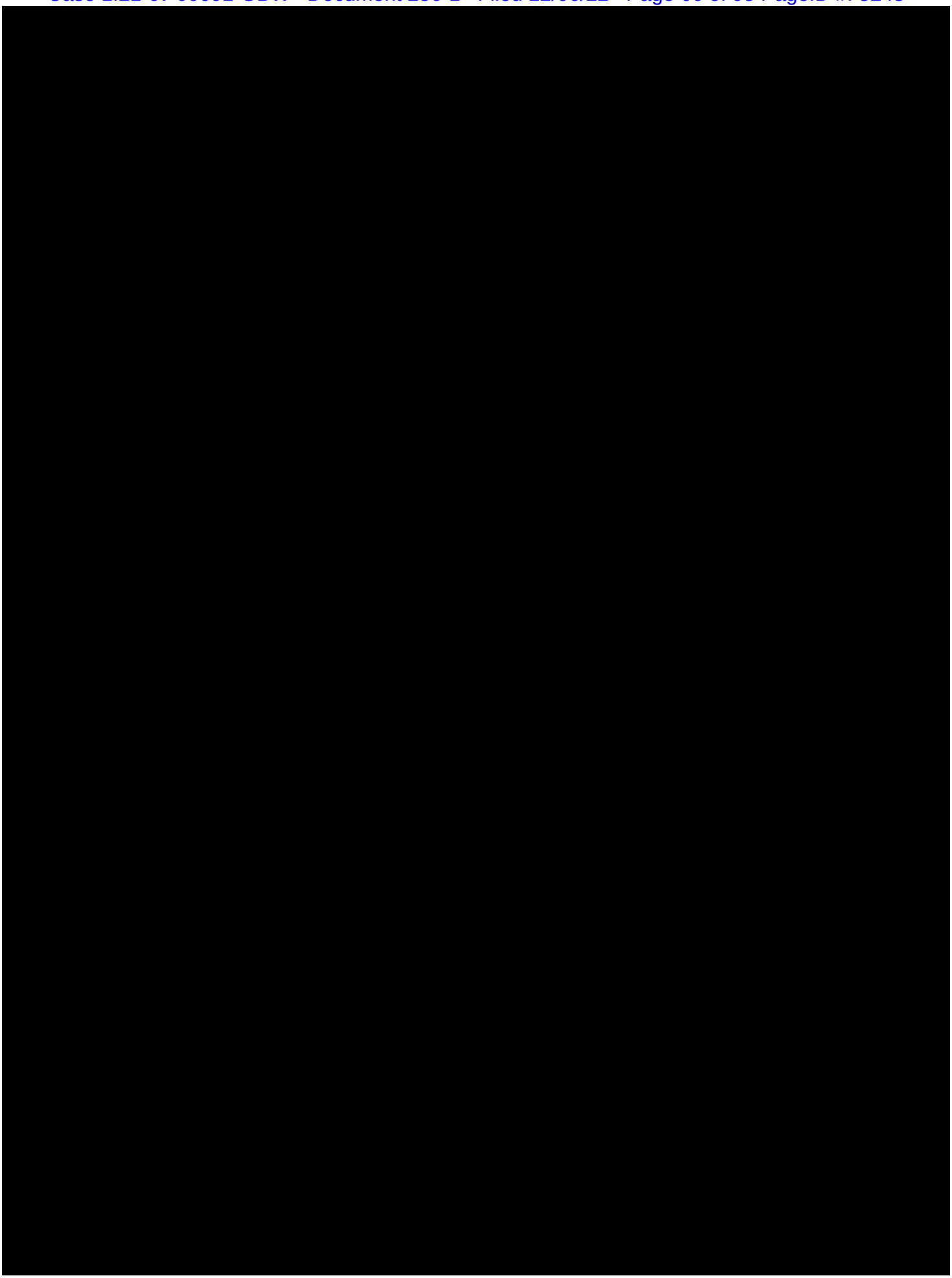


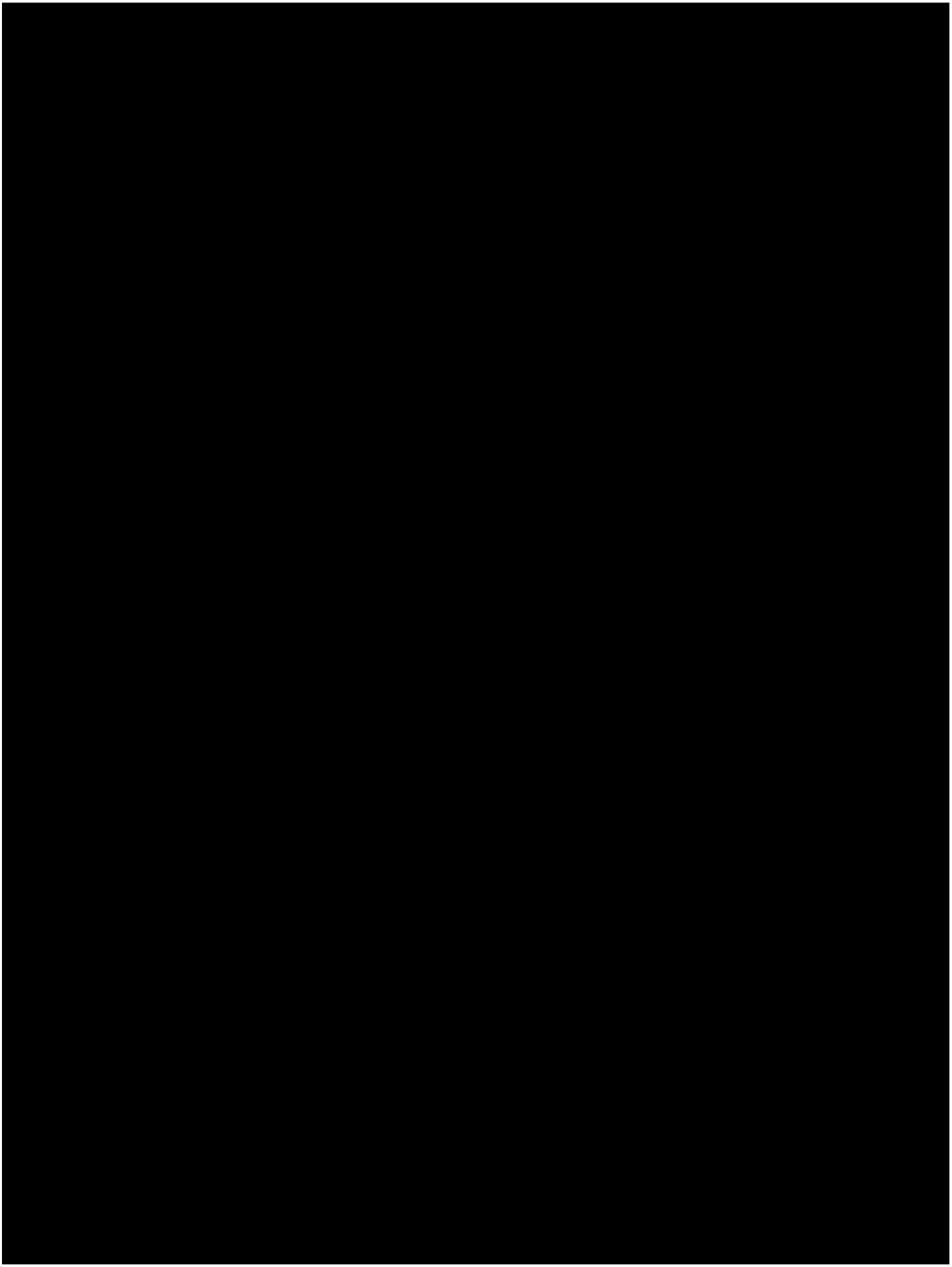


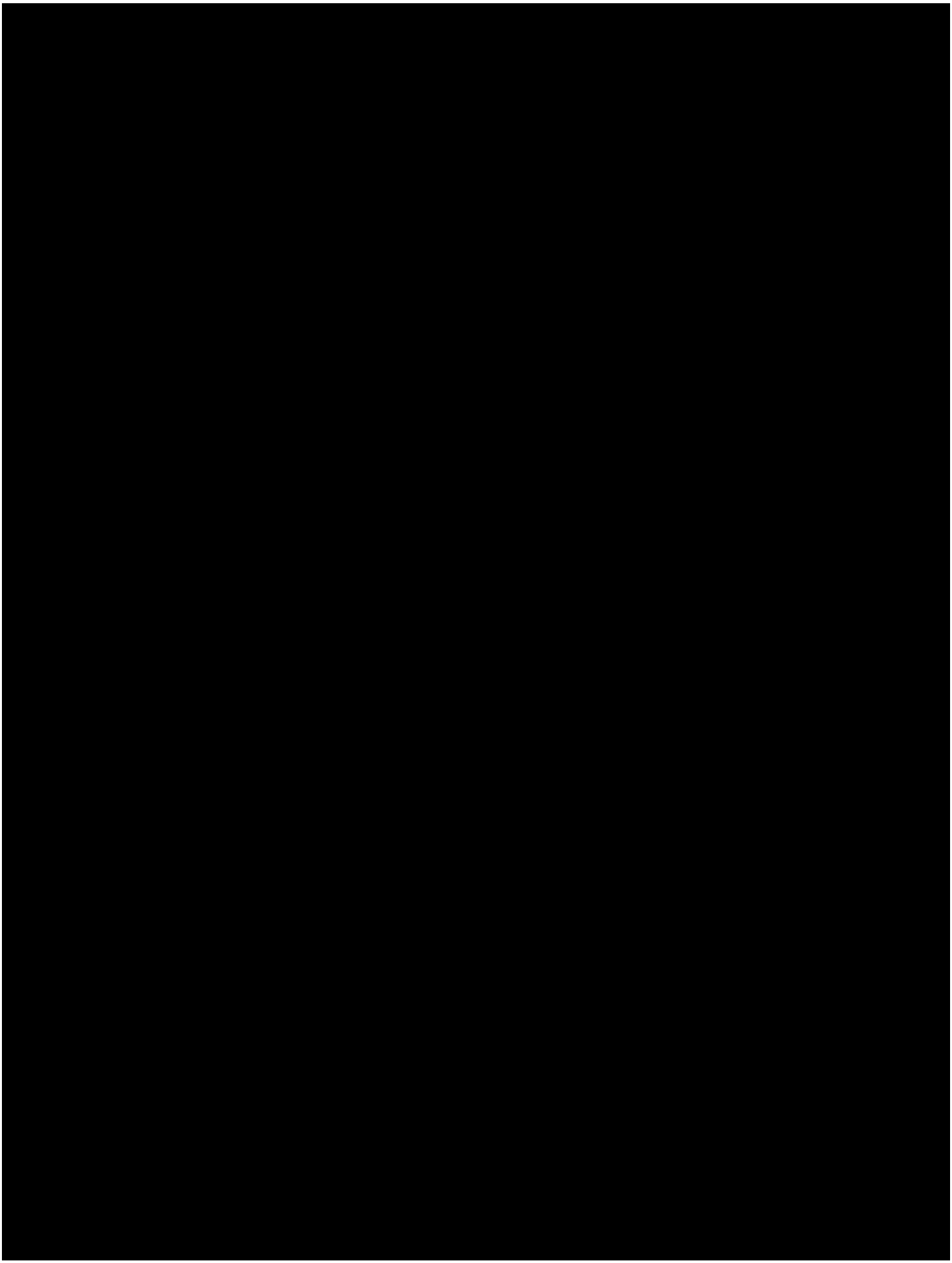


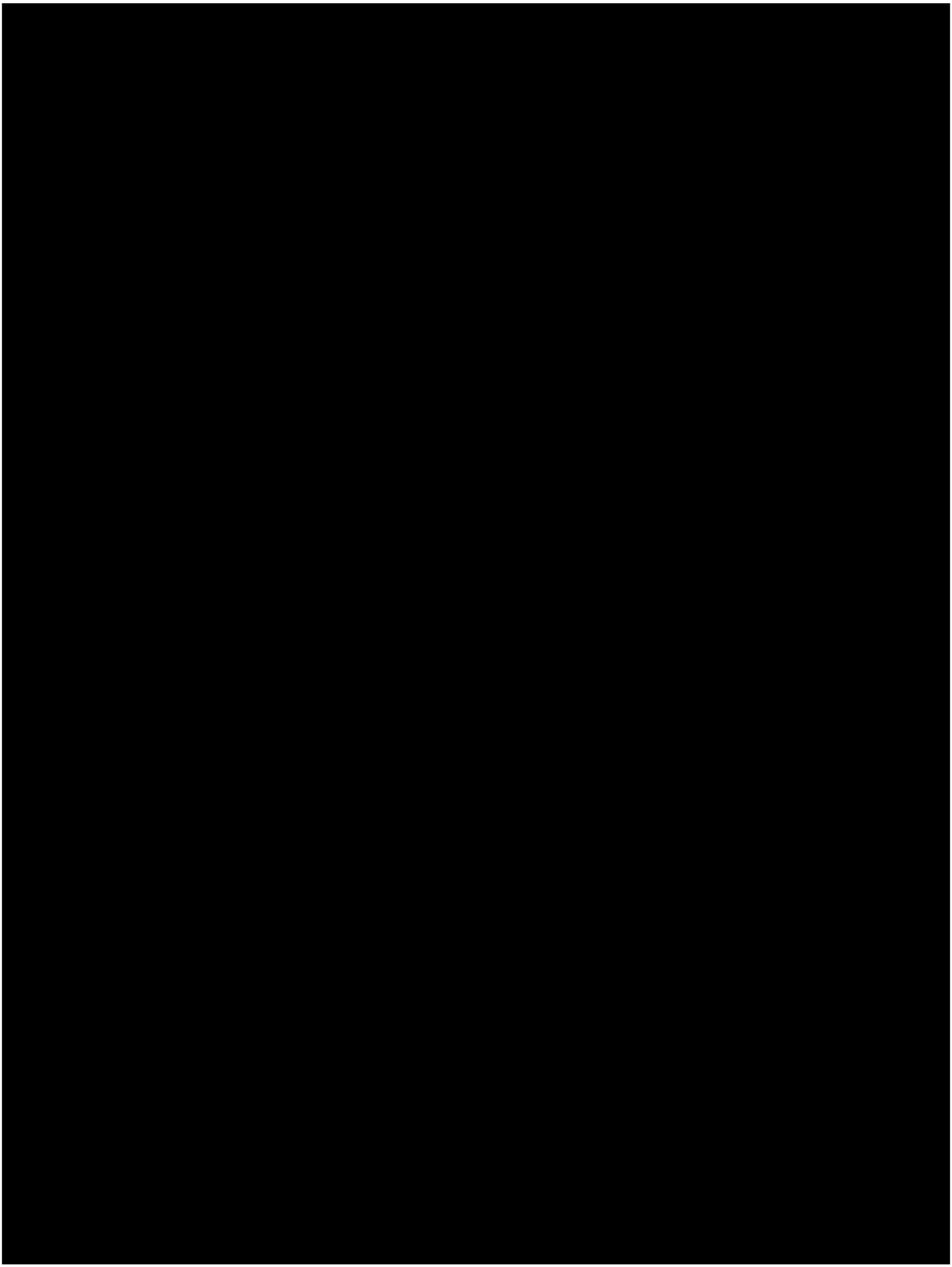












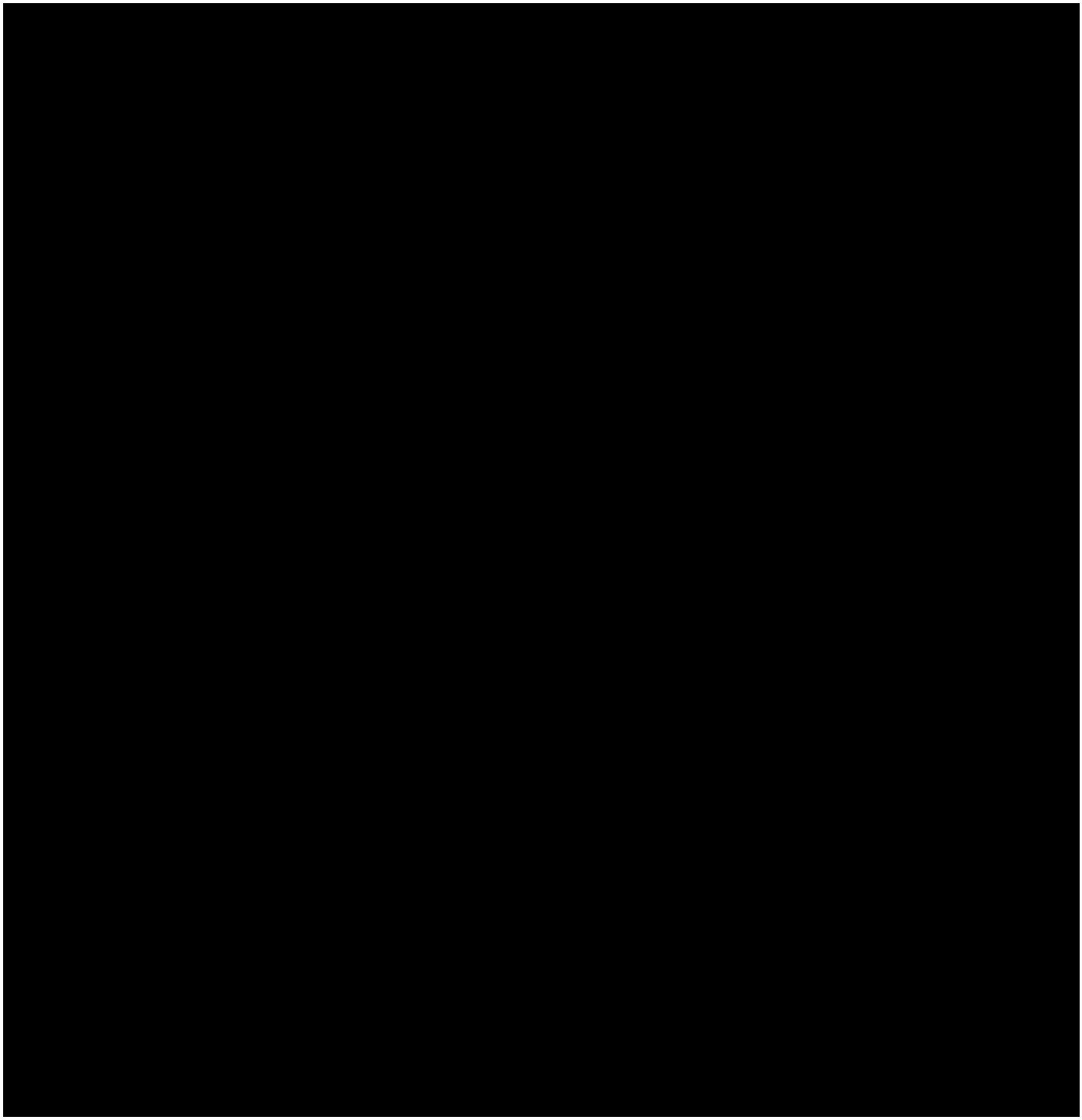


EXHIBIT E

THIS DOCUMENT HAS

BEEN REDACTED IN ITS

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EXHIBIT F

Priority Review

Prior to approval, each drug marketed in the United States must go through a detailed FDA review process. In 1992, under the Prescription Drug User Act (PDUFA), FDA agreed to specific goals for improving the drug review time and created a two-tiered system of review times – *Standard Review* and *Priority Review*. A Priority Review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review).

A *Priority Review* designation will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

Significant improvement may be demonstrated by the following examples:

- evidence of increased effectiveness in treatment, prevention, or diagnosis of condition;
- elimination or substantial reduction of a treatment-limiting drug reaction;
- documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes; or
- evidence of safety and effectiveness in a new subpopulation.

FDA decides on the review designation for every application. However, an applicant may expressly request priority review as described in the Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics. It does not affect the length of the clinical trial period. FDA informs the applicant of a Priority Review designation within 60 days of the receipt of the original BLA, NDA, or efficacy supplement. Designation of a drug as "Priority" does not alter the scientific/medical standard for approval or the quality of evidence necessary.

EXHIBIT G

REFINITIV STREETEVENTS

PRELIMINARY TRANSCRIPT

AVDL.OQ - Q3 2022 Avadel Pharmaceuticals PLC Earnings Call

EVENT DATE/TIME: NOVEMBER 09, 2022 / 1:00PM GMT

REFINITIV

CORPORATE PARTICIPANTS

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Jennifer Gudeman

Richard Kim *Avadel Pharmaceuticals plc - Chief Commercial Officer*

Thomas S. McHugh *Avadel Pharmaceuticals plc - Senior VP & CFO*

CONFERENCE CALL PARTICIPANTS

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Ami Fadia *Needham & Company, LLC, Research Division - Senior Analyst*

Chase Richard Knickerbocker *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

Christopher Lawrence Howerton *Jefferies LLC, Research Division - Equity Analyst*

François Daniel Brisebois *Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst*

Marc Harold Goodman *SVB Securities LLC, Research Division - Senior MD of Neuroscience & Senior Research Analyst*

Matthew Lee Kaplan *Ladenburg Thalmann & Co. Inc., Research Division - MD & Head of Healthcare Equity Research*

PRESENTATION

Operator

Good morning. My name is Rob, and I will be your conference operator today. At this time, I would like to welcome everyone to the Avadel Pharmaceuticals Third Quarter 2022 Earnings Conference Call. After the speakers' remarks, there will be a question-and-answer session. (Operator Instructions) Austin Murta from Avadel Investor Relations, you may begin your conference.

Unidentified Company Representative

Good morning, and thank you for joining us on our conference call to discuss third quarter 2022 earnings. As a reminder, before we begin, the following presentation includes several matters that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to risks and uncertainties that could cause the actual results to differ materially from those contemplated in such forward-looking statements. These risks include risks that products in the development stage may not achieve scientific objectives or milestones or meet stringent regulatory requirements, uncertainties regarding market entry and acceptance of products and the impact of competitive products and pricing.

These and other risks are described more fully in Avadel's public filings under the Exchange Act included in the Form 10-K for the year ended December 31, 2021, and which was filed on March 16, 2022 and subsequent SEC filings. Except as required by law, Avadel undertakes no obligation to update or revise any forward-looking statements contained in this presentation to reflect new information, future events or otherwise.

On the call today are Greg Divis, Chief Executive Officer; Jennifer Gudeman, Vice President of Medical and Clinical Affairs; Richard Kim, Chief Commercial Officer; and Tom McHugh, Chief Financial Officer. At this time, I'll turn the call over to Greg.

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Thank you, Austin. Good morning, everyone, and thank you for joining us this morning to discuss Avadel's third quarter 2022 results. Q3 was another important quarter for Avadel and our pursuit to bring LUMRYZ to people with narcolepsy.

Most importantly, LUMRYZ are investigational once-in-bedtime oxybate therapy for the treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy was granted tentative approval by the FDA in July. The FDA's formal decision of granting technical approval results in 3 very important developments for Avadel.

First, it validates LUMRYZ safety profile and clinical efficacy and as such, has confirmed that LUMRYZ is approvable as a once at bedtime therapy. We view this as a major regulatory derisking event for Avadel.

Second, it enables us to complete work on key launch-related activities, including the build-out of the REMS program and the manufacture of commercial launch supply. We made significant progress in these activities in Q3 and are on track to have both completed before the end of the year. Lastly, it confirms that the potential latest date we should receive a final approval decision is after expiry of the REMS patent, which will occur on June 17, 2023, approximately 7 months from now. A final approval will then be followed by a launch that is expected no later than Q3 of 2023 into what we believe is a $3 billion-plus market opportunity. We will continue to take the necessary actions to bring LUMRYZ to final approval and more importantly, to provide access to people with narcolepsy who are desperately seeking new treatment options.

Very recent comprehensive market research that Richard will highlight shortly, continues to confirm the significant interest in LUMRYZ across all patient and physician segments, all of which is supported further by what we see in the real-world data coming from our RESTORE study, where 94% of twice-nightly switch patients prefer the once at bedtime dosing of LUMRYZ.

The combination of the real-world data of RESTORE along with our extensive market research and data analytics confirms our belief that LUMRYZ is well positioned to capture a meaningful share of the projected $3 billion-plus once at bedtime oxybate market. Although our base case assumption is to receive a final approval decision following expiration of the REMS patent in June of 2023, we continue to pursue efforts that could potentially lead to a final approval decision sooner.

More specifically, the Delaware court has granted our expedited request and has scheduled a hearing on our renewed motion to delist the REMS patent from the Orange Book for next week on Tuesday, November 15 at 10 a.m. Eastern Time. We look forward to the Delaware Court's decision and the opportunity to potentially accelerate the time line to a final approval and subsequent launch for LUMRYZ.

With that, I'll turn the call over to Jennifer to provide details on our recent data presentations. Jennifer?

Jennifer Gudeman

Thanks, Greg, and good morning. As Greg said, this was an important quarter of progress for Avadel. We continue to add to the robust body of evidence supporting LUMRYZ. These extensive and positive data will support the launch following potential final FDA approval.

Let's start with the Test Congress held a few weeks ago, where we had 3 posters presented with updated data from our open-label study RESTORE. First, we provided further confirmation of long-term safety and tolerability with Bloom rise among the 180 participants who received at least 1 dose.

Second, for patients not previously taking an oxybate, most have been efficiently titrated to a stable dose within 1 month. The majority of switch patients, they remain at once nightly dose of LUMRYZ equivalent to their previous total nightly intake of a media release oxybate. These more real-world data will be instructive for clinicians to consider when we launch commercially, Understanding the patient perspective and experience is critical to Avital. After 3 months on therapy of LUMRYZ, which patients are asked which dosing regimen may prefer. As we have seen consistently, there is an overwhelming preference for dosing that only LUMRYZ will offer with 94% stating they preferred the once-nightly dosing regimen over twice nightly. Let's look at some of the reasons for that preference by understanding the challenges with twice-nightly oxybate.

For those switching from either of the twice-nightly oxybate, we asked at baseline about their experience with the second dose, which revealed several key points.

First, about 2/3 of participants had accident only missed their second dose in the past 3 months. Of these, 80% reported feeling worse the next day. These data align with what we hear directly from patients as having a negative impact to them, frequently missing a dose and feeling worse the next day.

Next, 61% reported taking their second dose more than 4 hours after the first dose. Of these, 88% confirmed that they experienced next day grogginess. These data also align with what we hear anecdotally from patients. Lastly, approximately 25% of participants reported the need for someone else to wake them for the second dose.

Now turning towards the ANA meeting. We were very pleased to debut data in partnership with the Mayo Clinic that examined more than 2,000 patients with narcolepsy seen at Mayo in the past 20 years. These were compared to an equivalent number of a matched cohort of patients without narcolepsy to identify the top 20 comorbidities increased in the narcolepsy cohort.

Among the top 20 comorbidities increased, 3 were sleep conditions, 3 were psychiatric conditions, both are well recognized to be increased in people with narcolepsy. What generated considerable interest were 2 additional findings.

First, 5 gain-related disorders were significantly increased in the narcolepsy cohort. Second, the top 20 comorbidities did not include hypertension or other types of cardiac disease, such as myocardial infarction or stroke. We have additional real-world data from the collaboration with the Mayo Clinic that we will be submitting for 2023 medical congresses specifically focused on the cohort that has been treated with sodium oxybate.

What we and the narcolepsy community are most excited about is when LUMRYZ is available and real-world evidence can be generated to further validate the transformational impact of LUMRYZ for people with narcolepsy.

I will now turn the call over to Richard to provide details on the commercial opportunity and are advancing preparations for launch. Richard?

Richard Kim - *Avadel Pharmaceuticals plc - Chief Commercial Officer*

Thanks, Jennifer, and good morning, everyone. I'll provide updates on our growing market insights and our overall launch readiness. But today, I'd like to start with a reminder of why we do what we do.

This fall, our team attended a lot of meetings with seed specialists and people with narcolepsy to continue to demonstrate Avadel's commitment to the narcolepsy community. At each conference, we were asked several times unsolicited, when our product will be approved and made available. These people are well aware of LUMRYZ and have told us they are waiting for it.

Now to take the step further, I want to share a patient family story that is really stuck with me. A couple of weeks ago, 1 father told us that every single night, he wakes up at 3 a.m. to call his son in college so that he does not miss taking the second dose of oxybate and that he just can't wait for the day where both he and his son don't have to wake up at 3:00 a.m. in the middle of the night for his son to attend classes the next day.

As much as we focus on people with narcolepsy, we sometimes overlook the impact on family members and caregivers. This is just 1 of the many personal stories that we often hear and continues to remind us why we cannot relent in our pursuit of bringing once at bedtime limited to people with narcolepsy and their families.

Let me now transition to our continued focus on advancing our deep understanding of the arts market, which continues to inform our launch of planning. We conducted a new quantitative market research project from over 130 narcolepsy treaters that once again validated our key market assumptions and offer some important new insights about current non-oxrate prescribers.

While we ask several questions, 1 key takeaway is that oxybate use will increase once gloominess available across oxybate prescribers and even current non-oxybate prescribers. Here are a few key points from this market research.

First, all prescribers can identify patients who are eligible for oxybate therapy. However, many eligible patients are still not treated. High-volume oxybate prescribers state using oxybate in about 45% of their narcolepsy patients with another 20% eligible, but not being treated with an oxybate. By comparison, low-volume oxybate prescribers stay using oxybate in under 10% of all narcolepsy patients with an additional 20% eligible, but not being treated with an oxybate.

Second, when shown the LUMRYZ product profile, current oxybate prescribers predict that oxybate market utilization as measured by market share will grow by at least 50%. Third, for narcolepsy prescribers who do not use oxybates, these HCPs state that 1 in 4 of their narcolepsy patients are oxybate eligible despite not currently prescribing the twice-nightly formulations.

Now the top reasons for not using oxybate are similar with other groups in that the prescribers are concerned with reimbursement challenges and the inability of their patients to comply with twice-only dosing.

However, when shown the LUMRYZ product profile, almost half of these current non-prescribing oxybate HCPs stated they would use LUMRYZ in the future and that they can already identify eligible patients they would treat. We also see awareness about Avadel, LUMRYZ and once-nightly sodium oxybate increasing compared to last year with the greatest awareness increase in high oxybate prescribers.

What this all translates into is that when LUMRYZ is available across all oxybate prescribing segments. These HCPs intend to give LUMRYZ to highest share of scripts in a growing future oxybate market.

Now when we look at the oxybate market from a patient claims perspective, our analytics suggest that the market potential for LUMRYZ could be roughly double that of the current twice-nightly oxybate market, with more than 30,000 potential eligible patients.

Recall, the estimated total patient position consists of 3 key segments. First, approximately 16,000 actively treated 290 patients; second, an estimated 10,000 to 15,000 potential patients previously treated with an oxybate who have discontinued twice therapy within the last 3 years. And third, roughly 3,000 new oxybate patient starts and in this segment, we expect robust yet growth of 25% to 50% per year in the future. All 3 patient segments have expressed high levels of interest in LUMRYZ and along with HCPs are also aligned in the belief that once at bedtime dosing is the most important engine for an oxybate therapy when comparing different formulations, thus demonstrating our preference for aluminide over the current standard of care.

Now turning to our launches efforts. Q3 was a busy quarter for our team. We made significant progress building our commercial launch supply for LUMRYZ and all the programs that will enable the fulfillment of a prescription after approval, mainly the detailed build-out of the REMS, our ongoing patient support services development and finalization of the contracts for our specialty pharmacy network. The progress we have made will enable us to shorten the time from a final approval decision in June to full launch of LUMRYZ in the third quarter of 2023.

As Jennifer mentioned, we had a strong showing at the chest and ANA congresses as well as attending and presenting at some of the first live patient organization meetings in a couple of years. On the payer front, our team had several key meetings with the decision makers at the GPOs and PBM that manage over 85% of the commercially insured lives.

We continue to advance our conversations with them around contracts and coverage for LUMRYZ and the feedback continues to be positive. One more key update on loss readiness. We just began to build out our launch team knowing that we are now only about 7 months away at the latest from a final approval decision.

This first portion of our build-out plan paired with what remains, balances are need to be launched-ready while continuing to be thoughtful about how and when we invest our resources. We look forward to providing more updates on future calls.

With that, I will now turn the call over to Tom for an update on the company's financials. Tom?

Thomas S. McHugh - *Avadel Pharmaceuticals plc - Senior VP & CFO*

Thank you, Richard. I'll provide a few highlights for the quarter and also note that full financial results are available in the press release and the 10-Q. I'll start with the balance sheet where we reported $106.5 million of cash, cash equivalents and marketable securities as of September 30, 2022.

The company also had $143.8 million convertible notes, which includes $117.4 million maturing in October of 2023. Subsequent to September 30, we completed an open market repurchase at a discount to par of $8.9 million of the $26.4 million of notes that mature in February of 2023. As a result, the amount that matures in February was reduced to $17.5 million. Excluding restructuring charges, Total operating expenses in the quarter ended September 30, 2022, were $17 million compared to $25.7 million in the same period in 2021 and $26.3 million in the quarter ended June 30, 2022.

The decrease in operating expenses in the current quarter resulted primarily from cost optimization actions taken by the company, and we are on track to reduce quarterly cash operating expenses, excluding inventory purchases, to our target range of $12 million to $14 million.

R&D expenses were $2.9 million in the quarter ended September 30, 2022, compared to $4.4 million for the same period in 2021. The $1.5 million decrease is due to lower costs related to the manufacturer of LUMRYZ and lower compensation costs.

SG&A expenses were $14.1 million in the quarter ended September 30, 2022, compared to $21.3 million for the same period in 2021. The decrease is a result of a number of factors, including lower cost of marketing, compensation, medical affairs and consulting fees.

Net loss for the third quarter 2022 was approximately $20.1 million or $0.33 per diluted share compared to net loss of approximately $22 million or $0.38 per diluted share in the same period in 2021. I will now turn the call back to Greg for closing remarks.

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Thank you, Tom. To wrap up, being approximately 7 months away from the backstop date on which we expect to receive a final approval decision for LUMRYZ and a potential launch shortly thereafter, we are focused on executing the most important priorities that offer us the opportunities to both accelerate a final approval decision and shorten the time between approval and launch.

Receiving tentative approval for LUMRYZ is a significant derisking element to our mission and our overall value proposition as a company, which is further supported by all of our customer insights and stakeholder feedback, which continue to demonstrate the significant opportunity for LUMRYZ to command a meaningful share of the $3 billion plus 1 at bedtime oxybate market. We will remain relentless in our efforts to fully realize the value of LUMRYZ for all stakeholders, including patients, prescribers and investors.

We thank you for your support, and we look forward to providing future updates on our progress. With that, we will open the call for questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And your first question comes from the line of Francois Brisebois from Oppenheimer.

François Daniel Brisebois - *Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst*

Congrats on the progress here. So just a quick couple of ones here. In terms of building out the REMS, can you just maybe help us understand what challenges can come up when you build out REMS? Why it might be straightforward, why it might not be. Just a little more color around that.

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes, Frank, it's Greg. Thanks. I would describe it really in 2 steps. There's a technology component to this and an infrastructure required to actually execute and do the necessary work to ensure safe use, that the REMS program is designed from an IT infrastructure, programming and whatnot.

And then there becomes a second piece of that, which is staffing it as you get -- fully staffing it as you head toward a final approval and a subsequent launch. So again, we partnered with a leading very experienced REMS provider who has great experience with controlled substances. And so from that standpoint, the execution of our build-out to date which again is expected to be completed from an operational standpoint before the end of this calendar year is on track.

We'll clearly, as we head toward a final approval, begin to staff up the necessary resources to operationalize it. But the underlying, if you will, components of it, will be done well in advance.

François Daniel Brisebois - *Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst*

Okay. Great. And then in terms of the store data, you guys keep showing some good data on it. Is there -- is that data useful or important for the payers from the payer's perspective in terms of reimbursement?

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Well, maybe I'll let Richard comment on that.

Richard Kim - *Avadel Pharmaceuticals plc - Chief Commercial Officer*

Frank, thanks for the question. Yes. The great thing is we're really blessed with a bank of full range of clinical data that Jennifer and her team have actually produced from both -- from Reston and now the posters from the store. So I would say everything has been very useful with the conversations with payers and as we get into more in-depth conversations, the fact that 94% of patients, when previously being on a twice nightly prefer to be on the once nightly formulation, I think, bodes well. So in short, the answer is yes, Frank, we'll absolutely leverage that in the appropriate payer settings going forward as well.

François Daniel Brisebois - *Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst*

Okay. Great. And then I just -- sorry, last question. I feel like I have to just ask about it here. The -- in terms of the Delaware hearing on the 15th here, so next week. Can you just kind of maybe walk us through the potential, although it's hard to say, but the potential outcomes in terms of time lines? Or is a decision made do you expect it to be made on the bench? And if not, if the decision is in your favor what does that mean in terms of next steps here? Just to get a better feel for what can happen on the timeline?

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. I think to describe that situation kind of at large and how we view it is we're not going to speak obviously to the specifics of the litigation, just not -- it's not what we do.

But from a process standpoint, we were pleased that after the claim construction hearing that the Delaware Court decided to grant our request for an expedited hearing on this motion to the list, which as we noted, is next Tuesday. And what will be argued by both sides will be -- should this patent be listed in the orange book. That will be a major part of that hearing.

And for reference purposes, all of the documentation, all the briefings from both parties work on this specific matter were completed by the end of August. So it's been a brief fully for quite some time. So on Tuesday, will be the chance for both sides to issue their -- argue their size, respectively. The outcome of that, we would expect to be 1 of 2 things.

The court will either agree with us that, that patent is not Orange Book listable because of the nature of that patent or won't agree with us. If he agrees with us, that the court agrees with us, then we would certainly go down the path of -- expect it to go down the path of a request to have that patent delisted, and we would immediately begin our work to transition from a tentative approval to a final approval decision. So in this case, there will be 2 steps.

It will be a delisting required and then subsequent to that will be the FDA's final approval decision in terms of timing and how and when that will occur, will the judge rule from the bench or not? We have no insight from that perspective. We're just pleased that he's granted our expedited request for the hearing and look forward to Tuesday's meeting.

Operator

Your next question comes from the line of Ami Fadia from Needham.

Ami Fadia - *Needham & Company, LLC, Research Division - Senior Analyst*

Firstly, I wanted to understand how you're thinking about sort of coverage of FT218 in the context of the possible entry of generic Xyrem early next year as well as how you're thinking about contracting with payers. Can you give us some color around some of that dynamic there? And how are payers thinking about or what feedback have you received from peers with regards to the potential of patients from Xyrem or Xyway switching on to FT218 in the future? And I have more questions later.

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Richard, do you want to take that?

Richard Kim - *Avadel Pharmaceuticals plc - Chief Commercial Officer*

Yes, sure. No, great questions. Thank you. First, it's been just great for the team to be out in front of the payers again, one-on-one meetings also this fall, the PCMA and AMCP meetings.

Overall, our basic strategy, as we've stated several times, has been to really seek parity coverage compared to the branded oxybate as well. And when we think about our conversations with the payers. Well, first and foremost, we've always assumed generics and authorized generic will be in the market by the time we launch. And the general feedback that we sort of hear from the payers is they're really treating the -- at least the authorized generic is really more of a brand extension.

Most people are predicting that it will be priced similar to other authorized generic potentially in about a 15% price discount range. compared to the branded. But also keep in mind that Z Rem is currently priced about 8.5% more expensive than Xywav.

So our overall strategy, once again, is really more parity. So when we think about our sort of contracting sort of philosophy, first and foremost, we're going to be going through what others haven't, which is contracting directly with the 3 GPOs before we launch. So we're well under our way with our conversations across the 3 major GPOs. And what I can sort of say is I think the feedback has been really positive.

They've sort of had -- oxybate have had really no competition for 20 years. So the fact that there's another branded compound coming to marketplace, I think the payers have really enjoyed the conversation. I mean we're not naive. We know that they want to leverage us in their conversations. But

the 1 thing I'll say the team has done an excellent job of -- it's also really conveying our clinical value proposition across the board as well. So we feel like we're in the right place where we need to be with the payers right now.

And we're really sort of impressed with the progress that we've made so far with the GPOs and also the PBMs around the downstream coverage decisions is later. So we really think we're sort of right in the right sweet spot right now with where we should be with the payers today.

Ami Fadia - *Needham & Company, LLC, Research Division - Senior Analyst*

Great. And my second question is can you help us sort of set expectations for how to think about the ramp next year? Let's just assume for that purpose, but it will be some time after June. So in that context, 2 things I wanted to understand better. How long would it take to really get the rents up and running? -- given that you have to wait until approval to start to seek sort of physicians to sign up and get familiarized with the new processes. And adopt us coming from? Would it be a be or (inaudible).

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. So I think on the first question, we don't view the actual REMS build out to be a rate limiter in terms of impacting our time line post an approval. We certainly will be actively engaging with physicians post and approve.

We certainly can engage with physicians on REMS to register them, so on and so forth until after a final approval for sure. But we don't view that as a significant rate limiter relative to our timing from an approval to a launch. What at 1 point previously was going to be upwards of 6 months, we've significantly condensed that down given the work that's been done to date and will continue to be done prior to a final approval decision. And Ami, I'm sorry, your second question regarding REMS that you had the question on, could you just restate?

Ami Fadia - *Needham & Company, LLC, Research Division - Senior Analyst*

The second part on REMS was how long do you think it would take for physicians to familiarize themselves with the new processes or sort of the form that needs to be filled to send a patient to your sort of patient support hub.

The other question I had was just around where do you see early adopters coming from, whether it would be from Xyrem or (inaudible)?

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. Richard, do you want to take that question?

Richard Kim - *Avadel Pharmaceuticals plc - Chief Commercial Officer*

Yes. So maybe first, as far as sort of the timing for the physicians. Obviously, rent certification is really a critical component to make sure that we have the right and appropriate use of our products. But it's not a really laborious process.

People in essence, really familiarize themselves to the PI and some training on board. So it shouldn't take very long. And it's not dissimilar to what has been done in the past, but clearly, we have our own unique label. So we don't see that as really a long process on me. And as far as sort of where do we see the sources business coming from. From our market research that we've just done this latest wave, the candid answer is pretty much all segments of of prescribers and types of patients.

Clearly, there's a lot more familiarity with current high oxybate prescribers, but we see from our research that both Xywav and Xyrem patients are very interested in learning more about LUMRYZ as well. And we've also sort of seen a bit of a tapering of Xywav uptake in the marketplace as well. So we see great opportunities as lowa patients tend to be more motivated for earlier doctors as we've done seen from our market research.

And for the Xyrem patients, our value proposition is probably even more -- is very clear for them as well. So we're going to be focusing our initial efforts really on the high users within the marketplace will clearly support all users. But at the end of the day, when our research continues to sort of show is we have great opportunities within the current oxybate prescribers. There are high volume, the low volume ones.

And what was really interesting for us to sort of see in this latest wave of market research is for current narcolepsy prescribers who don't use oxybate, almost half of them said they would want to prescribe Bloom rise when it becomes available as well. So we'll sort of time those out over the first stages of launch. But we're just really delighted to sort of see that the LUMRYZ value proposition comes across very clearly to all of our segments that we're trying to speak to.

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. The only thing I would add to Richard's comment, Ami, is that these 30,000 to 35,000 patients that we've described in these 3 segments, they really predominantly fall within that highly concentrated source of business, the 1,600 physicians that make up 80% of that volume. It's all within that same group from that standpoint. So as Richard referenced is kind of the high oxybate users, it is a very concentrated opportunity for us where the lion's share of our opportunity exists. So thank you.

Operator

And your next question comes from the line of Chris Howerton from Jefferies.

Christopher Lawrence Howerton - *Jefferies LLC, Research Division - Equity Analyst*

I guess 2 for me would be with respect to the ongoing RESTORE study, could you give us a sense of the durability that you're seeing of patients on LUMRYZ and just how that might translate to persistency on the commercial market. And then I appreciate all the kind of discussion with respect to launch readiness. Could you give us a little more understanding in terms of what specifically you expect your commercial team to look like? And maybe a little bit more about the distribution and timing of hiring for that team.

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. Thanks, Chris. Jen, do you want to start on RESTORE?

Ami Fadia - *Needham & Company, LLC, Research Division - Senior Analyst*

Yes, absolutely. Chris, thank you for the question. So just to level set, the RESTORE study began in March of 2020, obviously, coinciding with when the pandemic started.

What we put out this October is that we've had about 27% of participants discontinue in this study. So being open label and the fact that these participants are having to travel to the clinical trial site once a month to pick up their medication because it is a Schedule 1 until the point of approval, we're not surprised by that rate of discontinuation.

In fact, I could have understood if it were higher with the requirement to travel to those sites on a monthly basis. I think what we're most pleased about is that there's a very low rate of discontinuation due to adverse reactions. In October presentations, we had noted that it's about 5% of participants who have discontinued due to adverse events. And we know that tolerability can be one of the biggest challenges with taking any oxybate formulation.

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Thanks, Jen. Richard, maybe you can just kind of frame up kind of the commercial team we'll be building toward?

Richard Kim - *Avadel Pharmaceuticals plc - Chief Commercial Officer*

Yes, super. No, thanks for the question, Chris. So first, as we've mentioned previously, we retained some of our key skill sets so that we could obviously keep our momentum going for our launch readiness here.

Overall, what we've sort of stated is our goals to have somewhere around 50 sales representatives out there. As Greg had mentioned, there's 5,000 prescribers, 1,600 make up 80% of the volume. So we know that we can cover all of those prescribers with that sales team.

We also will have other key field members such as our field reimbursement team that we will have out there as well. We have -- as mentioned, we have just begun hiring some folks back into the mix here as well. And what we'll be building backwards from is sort of that backstop of that June approval date. But obviously, we're trying to remain flexible depending on where some of the hearing outcomes become as well.

So the buildup has begun in a very targeted way. but we're going to make sure that we're ready to peak at the latest for a June approval of next year.

Christopher Lawrence Howerton - *Jefferies LLC, Research Division - Equity Analyst*

Awesome. And Greg, do you mind if I maybe sneak in 1 more follow-up?

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Go ahead, Chris.

Christopher Lawrence Howerton - *Jefferies LLC, Research Division - Equity Analyst*

Okay. Great. And Tom, I'm really happy to see that you purchased some of the notes that were due in February, I guess. Is that still kind of the plan to be potentially opportunistic for those notes that are still outstanding? Or any additional comments you want to make around the strategy there?

Thomas S. McHugh - *Avadel Pharmaceuticals plc - Senior VP & CFO*

Yes. No, it is opportunistic in nature, Chris, and we had a good opportunity to buy some dose back at a discount. Our commentary in the last couple of months is that our assumption with regards to cash runway is that the notes that come due in February need to be settled in cash anyway. So we were able to just accelerate the purchase a little bit and save some money along the way.

Operator

Our next question comes from the line of Adam Evertts from LifeSci Capital.

Adam Gerald Evertts - *LifeSci Capital, LLC, Research Division - Senior Research Analyst*

Great. One sort of clarification for me. On the survey data mentioned by Richard on this call, is that a new survey or additional details from prior surveys? And I guess either way, do you expect to present those data at a medical meeting or other format in 2023?

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. It's new research. We're constantly updating and refreshing our understanding of the market. So this is some data from a very, very recent large quant study that Richard referenced. And I don't know if we'll present that specific data in a scientific congress, but we'll certainly continue to provide some of these insights and learnings as we go forward. both in these sorts of events and then potentially at a future kind of prelaunch commercial day.

Operator

Your next question comes from the line of Marc Goodman from SVP.

Marc Harold Goodman - *SVB Securities LLC, Research Division - Senior MD of Neuroscience & Senior Research Analyst*

Greg, first, just on the legal stuff. If the Delaware Court next week gives you a negative outcome, right, the patent should be listed, then is there anything left? I'm trying to remember if there are any other issues that you could do? Or is that it we're waiting until June?

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. I think that's the primary -- depending on the ruling next -- whenever it occurs after next Tuesday, the base case assumption is June 17 expiry in an approval decision post that. .

Otherwise, whatever happens next week will either give us an opportunity to bring that up a little earlier potentially depending upon timing. And otherwise, as Richard described, we're operating toward the base case of June.

Marc Harold Goodman - *SVB Securities LLC, Research Division - Senior MD of Neuroscience & Senior Research Analyst*

Right. I'm just saying like the administrative process that got thrown out, this is the result of the Markman hearing. So basically, like this is it, right? I mean if it goes negative, Okay. We'll just go to that scenario where it's June, right? There's nothing else that you're going to do legally.

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. There's no other legal matters, if you will, pending that could react or result in something sooner. Correct.

Marc Harold Goodman - *SVB Securities LLC, Research Division - Senior MD of Neuroscience & Senior Research Analyst*

Right. Okay. Good. And then just to be clear, on the positive outcome, it's unclear if we figure out right then and there next week if it's a positive view or if it takes what do you think it could be a couple of weeks. It could take a month? How long do you think this judge is going to take? .

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

It's really too difficult to predict, I would say. It would be inappropriate from that standpoint. We're pleased that after the claim construction hearing on October 25, it was only 3 days later that he decided to grant us our request for this expedited hearing.

So again, we believe the court understands the matter quite well and the urgency that we've expressed accordingly and are glad the hearing is less than 7 days away from now.

Marc Harold Goodman - *SVB Securities LLC, Research Division - Senior MD of Neuroscience & Senior Research Analyst*

Got it. Okay. And then, Tom, just on managing through with the finances, I guess, number one, have you tapped the ATM at all? Don't you have that ability?

Thomas S. McHugh - *Avadel Pharmaceuticals plc - Senior VP & CFO*

Yes, that's right, Marc. And what we -- it's in our 10-Q, we raised about a little over $10 million during the third quarter from sales off the ATM. But if we -- that is a no. That's right.

Marc Harold Goodman - *SVB Securities LLC, Research Division - Senior MD of Neuroscience & Senior Research Analyst*

Right. And so is that included in the 106.5?

Christopher Lawrence Howerton - *Jefferies LLC, Research Division - Equity Analyst*

It is, yes. .

Marc Harold Goodman - *SVB Securities LLC, Research Division - Senior MD of Neuroscience & Senior Research Analyst*

Okay. And then I'm sorry, I just I didn't catch the date. When did you buy the $9 million in the open market for the convert?

Thomas S. McHugh - *Avadel Pharmaceuticals plc - Senior VP & CFO*

It was over the course of the third quarter. So there was no single purchase was...

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

The convert was a recent purchase.

Thomas S. McHugh - *Avadel Pharmaceuticals plc - Senior VP & CFO*

No, the note. My apologies, Marc. No, we repurchased the notes in the open market just earlier this month actually, it was just about a week ago.

Marc Harold Goodman - *SVB Securities LLC, Research Division - Senior MD of Neuroscience & Senior Research Analyst*

I see. Okay. And how have discussions been with the convert holders in general? I mean I would -- I guess rates have really backed up pretty darn quickly. So what's been the discussions like?

Thomas S. McHugh - *Avadel Pharmaceuticals plc - Senior VP & CFO*

Listen, I think I would characterize them as constructive. We haven't done any formal engagement with the convertible note holders. I think they, like us, are being deliberate in our approach. We want to see how this next legal proceeding plays out for the hearing next week before making decisions on what to do. But I would generally characterize our discussions as constructive.

Marc Harold Goodman - *SVB Securities LLC, Research Division - Senior MD of Neuroscience & Senior Research Analyst*

And have you, as a management team, also been in discussions potentially with doing some type of royalty deal? Have those discussions started as well? And is everything kind of hinging on waiting to next week before anything moves forward? .

Thomas S. McHugh - *Avadel Pharmaceuticals plc - Senior VP & CFO*

Yes, fair question, Marc. And over the last several months, we've been really consistent in our thinking and our communications that we do want to see how these -- the legal things played out. Of course, we know how the DC 1 played out and we have Delaware coming up next week. We're looking at all options. And the time to execute and the form of finance we may pursue. It's -- I wouldn't necessarily say that the legal proceeding is a gating item to us, but we do want to see how it turns out because a favorable outcome, of course, just puts us in a better position.

And as Greg noted earlier, a decision that's not in our favor puts us to a base case and a planning time line of June of next year towards an approval decision.

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. And I would add, Marc, that -- just I would just add, Marc. We've been quite -- I would say a couple of things.

One, we've been very prescriptive in our thinking about financing the company and the launch. And this -- and the notion and the consideration of a form of committed capital that comes upon the approval and upon the launch for us with over $100 million of cash on hand is every bit as valuable as cash in the balance sheet today. So we've had extensive discussions with a number of parties who do think -- could potentially be sources of that sort of committed capital in the future upon the advancement in progress of the NDA to a final approval.

So again, I don't want to send the message that we're just waiting for after the hearing. Like we've done a lot of work to put ourselves in a position to begin to execute coming out of next week or whenever that ruling is and recognizing that the time lines between an approval decision after next week, if it goes in our favor or in June of next year, have become compressed a little bit and have begun to converge on themselves.

So we're actively involved in solving how we fund the company at launch and through the lens of what's in the best interest of our shareholders for sure.

Operator

And your next question comes from the line of Matt Kaplan from Ladenburg Thalmann.

Matthew Lee Kaplan - *Ladenburg Thalmann & Co. Inc., Research Division - MD & Head of Healthcare Equity Research*

I just wanted to zero in on the kind of the sodium oxybate narcolepsy, cataplexy market dynamics that you're seeing and hearing out there after attending these meetings recently in discussions with payers, PBMs.

What's your sense in terms of the impacts of and what's going on with the low salt, twice-nightly product out in the marketplace? And I guess, secondly, you mentioned kind of the 3 components of the 30,000 patients. What's your sense in terms of being able to expand the sodium oxybate market after full approval and a launch?

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Thanks, Matt. Richard, do you want to take that?

Richard Kim - *Avadel Pharmaceuticals plc - Chief Commercial Officer*

Yes, sure. Thanks, Matt. So first, as far as the payers are concerned, they're very on top of what's been going on in the marketplace. And as I mentioned before, we've had really great conversations with them.

Maybe 1 sort of thing I can add that I didn't mention before is when payers are thinking about sort of switches, how to look at AGs, one of the benefits that we have coming to this marketplace of that sort of more than 30,000 patients that have been treated, the vast majority have already been exposed to an oxybate.

So we're very confident that payers will acknowledge that they've already experienced an oxybate before, which bodes very well for us even in light of an AG or anything coming to the marketplace.

So overall, as far as the payers are concerned, we think we're very well positioned. And as we think about where the market will expand, what we've learned from this market research that we did most recently is there's still quite a few patients that are viewed to be oxybate eligible who are not receiving oxybate, probably greatest within low oxybate users currently and non oxybate users, clearly.

So we a see opportunities there for them to just prescribe to patients they've already identified and clearing the opportunity longer term is to get more de novo patients into the mix here as well.

What we sort of see from our research is from this latest round is that the market should grow by at least 50% with the introduction of LUMRYZ in the marketplace with once again, the largest percentage growth coming from lower users who probably have really struggled with the proposition of twice-nightly oxybate in the past.

So the good news is we see growth opportunities within the high oxybate users still but maybe even a higher percentage of growth opportunity from lower and clearly getting some nonprescribers into the mix as well.

Operator

(Operator Instructions) Your next question comes from the line of Chase Knickerbocker from Craig Hallum.

Chase Richard Knickerbocker - *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

I just want to put a finer point on some of the questions Chris asked around the ramp of your commercial capabilities, what specifically has been added in this first tranche of hiring, I guess, you mentioned on the call, some key field personnel on the MSL side. Is it some of the management around sales capabilities?

And I guess, assuming base case of June approval, how should we think about the ramp of sales personnel hiring? Richard, what kind of time frame do you want most of the reps on board to be able to really get them trained up in preparation for launch?

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Thanks, Chase. Richard, do you want to start?

Richard Kim - *Avadel Pharmaceuticals plc - Chief Commercial Officer*

Yes, sure. So yes, we -- just a couple of areas that we have focused in on the initial wave is we have hired a new head of sales so that we can get the framework for the sales force going -- and we've also selectively added some more of our payer resources as well with where we are in our conversations with the GPOs and the PBMs as well.

So we'll be sort of selectively adding to a few places, clearly balancing sort of the financial sort of situation with our need to grow. But once if you think backwards to June, our goal is to really peak at the right time. And with the fact that we've now compressed the time from a final approval potential decision in June, to a 3Q launch, our goal is to bring on a lot of our field force before that approval time line as well because we want to make sure that they are familiar with the territory, with their customers and everything as well. So we continue to sort of balance the need we're sort of in a position to be able to pull that off.

But as Greg and Tom have mentioned, also still balancing sort of where we may wind up with some of the proceedings from both legal in the financial raises as well. So I feel right now we're in a really good spot. The great news is there's been a lot of interest in people wanting to come join Avadel.

So with the folks that we've retained and kept here, and our plans around building out once again, our goal is to really peak at the right time to sort of be ready for that June backstop date.

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. I think, Chase, I would just add to that, that we've got a really kind of disciplined approach and a detailed plan of how we build toward a June decision and then a launch thereafter. And then how do you pull that up if you have any -- in the event there's good news and that decision come sooner, right, from that standpoint.

So again, I think it's all mapped out. We know where kind of things that got -- that are longer kind of poles in the tent that require more work leading up into those days, and those are the roles that Richard noted that we'll bring on board. So I appreciate the question.

Chase Richard Knickerbocker - *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

Yes. Helpful color. And then just 1 last for me, if I could. Around a potential positive outcome if we make that assumption, being at its -- we're sitting in November now. I mean what does it accelerate your kind of thinking on potential approval with those extra regulatory matters and getting the patent deal less that needs to happen in your thoughts, what is it kind of due to accelerate approval now that we're in November.

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. Again, I think there's 2 steps to that process. The first is getting a decision from the court and then that results in the delisting and then the FDA making a final approval decision that we obviously would be working to want to have done as soon as possible from that standpoint.

But any sort of positive momentum that create -- that moves us in that direction earlier than June is just upside from our standpoint, recognizing that we're only 7 months away. So I think that we've noted that the time lines have converged a little bit from that standpoint as the cases in Delaware have slipped a little bit, but we're certainly pleased that this important hearing is taking place next week from that standpoint.

I think ultimately, it really is a function of the difference between launching, as we've said kind of in Q3, if we go to June and launching before that. If we if a decision and approval comes sooner. And any launch earlier, quite frankly, is better, simply put from that standpoint.

Operator

Your next question comes from the line of Paul Matteis from Stifel.

Unidentified Analyst

This is James on for Paul. Maybe just a quick clarifying 1 on DEA scheduling. I guess, can you remind us the latest there? And is there anything that needs to happen there post full approval? And would that be kind of gating to any other kind of prelaunch activities that need to recur?

Gregory J. Divis - *Avadel Pharmaceuticals plc - CEO & Director*

Yes. Thanks. There's -- first of all, Congress has already determined what the scheduling requirement of sodium oxybate or oxybate product is a Schedule III. So anything that has to happen administratively whether it be from DEA related or whatnot, isn't a rate limiter relative to us coming to market from that standpoint.

It's not -- it's all contemplated in our consideration of timing. If we had an approval after June 17 and an expectation that we would launch therefore in Q3, we'll be -- certainly be ready to launch in Q3, that contemplates any of those sorts of matters.

Operator

And there are no further questions at this time. This does conclude today's conference call. We thank you for your participation, and you may now disconnect.

EXHIBIT H

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