

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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

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JAZZ PHARMACEUTICALS, INC. and	)	
JAZZ PHARMACEUTICALS IRELAND	)	
LIMITED,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 21-1138 (GBW)
	)	
AVADEL CNS PHARMACEUTICALS LLC,	)	
	)	
Defendant.	)	

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JAZZ PHARMACEUTICALS, INC. and	)	
JAZZ PHARMACEUTICALS IRELAND	)	
LIMITED,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 21-1594 (GBW)
	)	
AVADEL CNS PHARMACEUTICALS LLC,	)	
	)	
Defendant.	)	

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**JOINT POST-TRIAL STATUS REPORT**

Pursuant to the Court’s request following the rendering of the jury’s verdict on March 4, 2024, Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (together, “Jazz”) and Defendant Avadel CNS Pharmaceuticals (“Avadel”) hereby submit this Post-Trial Status Report and proposed briefing schedule indicating their proposals on how the case should proceed and identifying the post-trial motions each side intends to file.

## **I. ENTRY OF JUDGMENT**

### **A. Jazz’s Proposal**

The Court stated that a trial on the parties’ equitable issues would take place “some time around June.” March 4, 2024 Tr. at 4. Jazz intends to proceed to trial on its equitable claim for injunctive relief. *See* D.I. 331 at 4, ¶ 3. Avadel, rightfully so, has elected to drop its remaining equitable claims. But Avadel is refusing to supplement discovery relevant to Jazz’s remaining claim even though Avadel has continued to publicly release relevant information as recently as Monday of this week (and undoubtedly has internal materials relevant to Jazz’s claim as well). *See generally*, Exhibit A, Tr. at 9-10, 12, 22-23, 25-26. As explained further below, Jazz seeks supplemental discovery narrowly limited in both subject matter and time period, consistent with the parties’ disclosure requirements under Federal Rule of Civil Procedure 26(e), and judgment on its equitable claim, before proceeding to entry of judgment in this matter.

Avadel requests entry of partial judgment without even addressing, let alone making a showing of satisfying, the requirement for such judgment under Federal Rule of Civil Procedure 54(b). There is no need to enter judgment at this time because Jazz’s equitable claim seeking a permanent injunction is still not resolved. Judgment should be entered after Jazz’s equitable claim for injunctive relieve has been decided by the Court. This is how the parties agreed to proceed in the similarly situated case of *Natera, Inc. v. ArcherDX, Inc.*, No. 20-125 (GBW) (D. Del.) where

the Court entered a single judgment on all issues on September 19, 2023 following both jury and bench trials (No. 20-125, D.I. 665). The fact that the defendant in *Natera* was pursuing equitable relief while Avadel has abandoned its equitable claims here does not mean that Jazz should be forced to forego a bench trial on its request for a permanent injunction as the parties and the Court intended in the Court's July 3, 2023 Scheduling Order. D.I. 331 at 4, ¶ 3 ("Any request by Jazz for a permanent injunction shall also be tried in the bench trial.") Avadel's citation to the *ArcherDX v. Qiagen*, No. 18-1019 (MN) (D. Del.) case actually supports Jazz's position. There, the parties agreed to brief the permanent injunction together with the JMOL issues (Civ. No. 18-1019, D.I. 472, attached as Exhibit B), but the Court denied plaintiffs' motion for an injunction subject to renewal after a hearing, the parties agreed that additional discovery would be necessary in advance of the hearing, and the parties provide a stipulated discovery schedule (Civ. No. 18-1019, D.I. 528, attached as Exhibit C). This is exactly the procedure that Jazz proposes here. Given the above, Jazz respectfully submits that judgment should not be entered until after Jazz's equitable claim for injunctive relief has been resolved, which is consistent with the legal precedent on when judgment can and should be entered.

Federal Rule of Civil Procedure 54(b) governs entry of partial judgment. Under that Rule, partial judgment may be entered "only if the court expressly determines that there is no just reason for delay." As the Supreme Court has explained, "partial final judgment" is used only to prevent "the hardship and denial of justice through delay if each issue must await the determination of all issues as to all parties before a final judgment can be had." *Dickinson v. Petroleum Conversion Corp.*, 338 U.S. 507, 511 (1950). Avadel has not identified any alleged "hardship and denial of justice through delay" that would take place if the Court entered a single, final judgment after the bench trial in June—a few months away—versus entry of partial judgment now. Moreover, the

term “judgment” in the Federal Rules refers to a “final decision,” *Bankers Trust Co. v. Mallis*, 435 U.S. 381, 384 n.4 (1978); Fed. R. Civ. P. 54 (“‘Judgment’ as used in these rules includes a decree and any order from which an appeal lies.”), and there is no final and appealable judgment when equitable claims remain to be decided. See *Cordance Corp. v. Amazon.com, Inc.*, 696 F.Supp.2d 445, 450 (D. Del. 2010). It would be improper to start the appeal, post-trial briefing, and execution clocks by entering “partial” judgment on nonfinal claims.

As such, Jazz respectfully submits that judgment should be entered after resolution of its remaining equitable issues, which the Court indicated would be tried as part of a bench trial around June 2024, and that no partial judgment needs to be entered at this time. But if the Court intends to enter judgment now, Jazz respectfully submits that Jazz’s form of proposed judgment attached as Exhibit D be entered because it more accurately reflects the jury’s verdict given that the jury’s verdict used incorrect sales numbers which only went through September 6, 2023. Avadel’s reliance on the judgment entered in *ArcherDX v. Qiagen*, No. 18-1019 (MN) (D. Del.) case again supports Jazz’s position. See Exhibit E. In *ArcherDX v. Qiagen*, the jury awarded Plaintiff both lost profits and reasonable royalty damages. See Exhibit F at 8. Judge Noreika included the lost profits and reasonable royalty damages awards as separate numbers in the judgment (Exhibit E at ¶¶ 5-6), but did not find it necessary to specify (a) the type of damages awarded or (b) the dates covered by the damages awards (*id.*), which Avadel attempts to include here.

Jazz’s remaining equitable issues are Jazz’s request for a permanent injunction and, in the alternative, an ongoing royalty for infringement by Avadel’s Lumryz product to the extent that the Court denies Jazz’s request for a permanent injunction in whole or in part. Jazz also intends to seek an equitable order for supplemental damages, an accounting, and pre-judgment and post-

judgment interest. Following entry of judgment, the Jazz reserves its rights to file any additional post-trial motions(s) permitted by law.

### **B. Avadel's Proposal**

Given Jazz's multiple requests for equitable relief and the parties' intent to seek judgment as a matter of law on multiple issues, Avadel believes that it will be more efficient to address the parties' issues together in consolidated briefing, rather than through successive rounds of briefing. In particular, Avadel believes it makes little sense to consider Jazz's requests regarding remedies without first ensuring that the jury's verdict on the liability and validity issues will stand, or to address Jazz's requested remedies serially, as Jazz proposes, i.e., injunction now, and then damages later. Avadel therefore proposes that the Court enter judgment on the jury verdict, after which the parties can address the various motions for judgment as a matter of law at the same time as Jazz's requests for a permanent injunction, ongoing royalty, supplemental damages, an accounting, and pre- and post-judgment interest. In light of the jury verdict, Avadel will not pursue its inequitable conduct defense at this time, but reserves its right to reassert that defense should the jury's verdict be modified, either as a result of post-trial briefing or any appeal.

Avadel's proposed approach follows the Court's July 3, 2023 Scheduling Order (D.I. 331) in this case, where the Court ordered that "[f]or the jury trial, the parties shall comply with Paragraph 18-23 of the Court's procedures as set forth in the Court's Rule 16 Scheduling Order for Patent (Non-ANDA) cases . . ." with the exception of Paragraph 19 governing pretrial submissions. Paragraph 22 of the Court's Rule 16 Scheduling Order states that "[w]ithin seven (7) days after a jury returns a verdict in any portion of a jury trial, the parties shall jointly submit a form of order to enter judgment on the verdict" along with a joint status report. The same approach outlined in the Court's order was followed by Judge Noreika in *ArcherDX v. Qiagen*,

Civ. No. 18-01019-MN, where a judgment following jury verdict was entered despite anticipated JMOL and damages-related briefing. *See* Exhibit E. Notably, in *ArcherDX*, as here, the only equitable issue to be resolved after the jury verdict was plaintiff’s request for a permanent injunction. In contrast, *Natera* presented a situation in which both parties had equitable issues to be tried, and is therefore factually distinguishable from the present case. Jazz does not explain why the parties should ignore the Court’s scheduling order with respect to entry of judgment on the jury verdict in favor of a different approach. Moreover, Jazz’s assertion that Avadel’s approach would require Jazz to “be forced to forego a bench trial on its request for a permanent injunction” is simply wrong; Avadel’s request for entry of a judgment on the jury verdict would not impact Jazz’s ability to seek a permanent injunction.

Avadel also disagrees that supplemental discovery is warranted. As discussed below, at no time prior to the submission of this joint status report did Jazz raise the need for supplemental discovery following the completion of the jury trial. Jazz has also failed to explain how additional discovery would be non-duplicative of discovery already taken in this case. Indeed, the only justification provided by Jazz for additional discovery is a citation to *publicly available* information, which does not require the supplemental discovery—including additional fact depositions—sought by Jazz.

Avadel’s form of proposed judgment is attached as Exhibit G. Jazz’s proposed form of judgment confusingly omits the date through which Jazz sought damages from the jury (January 31, 2024) and omits the form of relief that Jazz sought (reasonable royalty and not lost profits). Avadel’s proposed form of judgment (and in particular the language presented in paragraph 4 of the proposed judgment) clarifies the nature of the damages sought by Jazz during the jury trial and the relevant period of time for the jury’s damages award, both of which should be factually

uncontested. Avadel's proposed form of judgment also reflects the jury verdict form, which asked the jury to determine "the *reasonable royalty* to which Jazz is entitled." Given Jazz's stated intent to seek additional damages for sales up through the verdict and an ongoing royalty as an alternative form of forward-looking relief, the form of verdict should identify the damages period and type of relief that Jazz requested from the jury so that there will be no requests for double relief.

## **II. EQUITABLE ISSUES**

### **A. Jazz's Proposal**

Jazz believes that there should be a short supplemental discovery period which would close no later than April 19, 2024, for document and deposition discovery limited to Jazz's request for a permanent injunction, and, if such request is denied, to an ongoing royalty. Such limited discovery is relevant to the permanent injunction issue which will be heard at the bench trial scheduled for some time around June 2024. Indeed, Avadel *agrees* that certain information will need to be updated and that the parties should be permitted to submit evidentiary support—including potential fact and expert declarations—but seeks to unilaterally limit the scope of supplemental discovery and deny any deposition discovery despite the declarations. Avadel's position does not make sense. Accordingly, Jazz requests that the Court grant it the short supplemental discovery period that it seeks. The supplemental discovery Jazz seeks generally goes towards Avadel's direct competition with Jazz's oxybate products, Avadel's current and projected market share, any updated market research, Avadel's plans to expand into additional patient populations for idiopathic hypersomnia and pediatrics, and Avadel's pricing, formulary status, and formulary strategies.<sup>1</sup> With respect to depositions, Jazz is only seeking a single supplemental

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<sup>1</sup> Further, for example, with respect to Jazz's request for supplemental damages and accounting, Avadel is required to produce additional information regarding its Lumryz sales through the date of the jury verdict.

Rule 30(b)(6) deposition of Avadel and the deposition of any individual who submits a declaration in support of Avadel's opposition to Jazz's request for a permanent injunction. Jazz agrees to provide the same to Avadel with respect to depositions.

Jazz also proposes the following briefing schedule for Jazz's request for a permanent injunction:

- May 3, 2024 – Jazz files its motion along with any supporting papers;
- May 17, 2024 – Avadel files its opposition along with any supporting papers;
- May 24, 2024 – Jazz files its reply along with any supporting papers.

For the briefing described above regarding Jazz's request for a permanent injunction, Jazz proposes that it be limited to a maximum of 20 pages for its opening brief, Avadel to 20 pages for its answering brief, and Jazz to 10 pages for its reply brief. Jazz proposes that briefing on Jazz's motion for an ongoing royalty be deferred until after the Court rules on Jazz's motion for a permanent injunction.

### **B. Avadel's Proposal**

Avadel does not believe that any additional discovery is necessary or appropriate in connection with Jazz's request for a permanent injunction or ongoing royalty. From the outset of this case, Jazz requested injunctive relief, (*see* Civ. No. 21-00691, D.I. 1; Civ. No. 21-01138, D.I. 1; Civ. No. 21-01594, D.I. 1) and Jazz had ample opportunity to engage in the necessary discovery, including through its requests for documents, interrogatories, and depositions of relevant fact witnesses. This includes discovery on topics such as Avadel's market share, market research, plans to expand into additional patient populations for idiopathic hypersomnia and pediatrics, pricing, formulary status, and formulary strategies. Indeed, Avadel's CEO, Greg Divis, was questioned extensively during the jury trial on precisely these topics. Further, the parties'



Stipulation and Proposed Order Regarding Trial by Jury and Modifying Case Schedule (D.I. 327) entered by the Court on July 3, 2023 (D.I. 331), bifurcated the parties' equitable claims and defenses solely for trial (not for discovery). Prior to the negotiation of this joint status report, Jazz never identified the need for any additional discovery, and it cannot establish the requisite good cause for reopening discovery at this juncture, including additional depositions of an unspecified number of fact witnesses. Jazz's contention that Avadel agreed that fact discovery generally will need to be updated is incorrect; Avadel agreed only to updating sales figures for LUMRYZ for purposes of calculating payment under a running royalty, should the Court find a running royalty appropriate here. *ArcherDX* does not suggest a different approach; there, as Jazz acknowledges, the parties *agreed* to the need for additional discovery after the Court ordered an evidentiary hearing at defendant's request. *See* Exhibit C at 2; Civ. No. 18-1019, D.I. 521 (attached as Exhibit H) at 29-30. Here, Avadel strongly disputes the need for any additional discovery in light of the discovery that has already occurred in this case. Finally, the fact that the parties may submit declarations in support of their positions in connection with their briefing on Jazz's request for a permanent injunction does not support the broad supplemental discovery that Jazz now seeks. Indeed, the schedule Jazz proposes for the permanent injunction briefing (two weeks for opposition briefing, and one week for reply briefing), would not permit the orderly deposition of declarants.

As explained above, Avadel submits that Jazz's requests for equitable relief and for judgment as a matter of law should be briefed together, and proposes the following schedule for both parties to submit consolidated briefing on their respective requests for relief:<sup>2</sup>

- 28 days after entry of judgment: Parties file motions, proposed orders, and consolidated opening briefs along with evidentiary support for the requested

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<sup>2</sup> **Avadel's position:** Assuming entry of judgment by March 22, 2024, post-trial briefing will be completed by May 31, 2024.

relief;

- 28 days after opening briefs: Parties file their consolidated oppositions along with any evidentiary support;
- 14 days after opposition briefs: Parties file their consolidated reply briefs. No new evidence shall be submitted with the reply briefs absent leave of the Court.

This schedule will permit a trial or hearing, to the extent necessary, on Jazz's request for a permanent injunction in June 2024.

For this consolidated briefing, Avadel proposes that the parties be limited to a maximum of 40 pages for their opening briefs, 40 pages for their opposition briefs, and 20 pages for their reply briefs.

### **III. JAZZ'S POST-TRIAL MOTIONS**

Jazz intends to file the following motions based on the jury's verdict:

1. Motion for judgment as a matter of law regarding infringement of claims 7 and 11 of U.S. Patent No. 10,758,488;
2. Motion for judgment as a matter of law regarding the jury's reasonable royalty finding or, in the alternative, a new trial on the issue of damages;
3. Motion for a permanent injunction;
4. Motion for an ongoing royalty<sup>3</sup>;
5. Motion for supplemental damages including (1) an accounting of pre-verdict infringing sales not included in the jury's damages award and (2) an accounting of infringing sales that occur between the jury's verdict and the Court's decision on Jazz's motion for a permanent injunction; and

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<sup>3</sup> Jazz intends to file a motion for an ongoing royalty as a form of alternative relief, if its motion for permanent injunction is denied.

6. Motion for pre-judgment interest on all pre-judgment damages; and post-judgment interest on the total damages awarded to Jazz, including any post-verdict damages that the Court awards if it grants Jazz's motion for an ongoing royalty.

Jazz reserves the right to file any additional post-trial motion(s) permitted by law. Jazz proposes that any motions for attorneys' fees and any motion pursuant to 35 U.S.C. § 285 be deferred until 21 days following issue of a mandate following any appeal, or, if no party files an appeal, 21 days after the expiration of the time to file a notice of appeal.<sup>4</sup>

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<sup>4</sup> **Jazz's position:** In related action Civ. No. 22-941, Jazz intends to supplement its pending motion to stay proceedings regarding Avadel's antitrust counterclaims pending resolution of the parties' motions for judgment as a matter of law and appeal, if any, in view of the jury's verdict. Under Third Circuit precedent, the jury's verdict, if not overturned, is fatal to Avadel's antitrust claims as it demonstrates that Avadel cannot prove an essential element of its claims—that it was legally able to enter the market without infringing a valid patent. *In re Wellbutrin XL Antitrust Litigation Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017) (“It is not enough for the [plaintiffs] to show that [a pharmaceutical company] wanted to launch its drug; they must also show that the launch would have been legal.”). **Avadel's position:** Avadel will oppose Jazz's request for a stay if and when Jazz files the procedurally proper motion in C.A. No. 22-941-GBW. Avadel disputes Jazz's interpretation of *In re Wellbutrin XL*, and in any event, the facts of *In re Wellbutrin XL* are inapplicable here, as its applicability requires that a patent exists “prohibiting the launch,” which did not occur here. *In re Wellbutrin XL Antitrust Litigation Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017).

**Jazz's position:** In related action Civ. No. 22-487, Jazz intends to move to stay proceedings regarding Avadel's trade secrets and related claims in view of the jury's findings that Avadel failed to prove that the '488 patent or '782 patent lacked written description or enablement, failed to prove that the '488 patent was invalid for improper inventorship or derivation, and failed to prove that '782 patent was invalid for improper inventorship (i.e., Jazz inventors had full possession of the claimed inventions before Avadel). The jury's verdict, if not overturned, renders Avadel's claims in Civ. No. 22-487 unviable. **Avadel's position:** Avadel disagrees with Jazz's interpretation of the implication of the jury verdict on C.A. No. 22-487-GBW, but is potentially amenable to staying C.A. No. 22-487-GBW under appropriate circumstances, and will confer with Jazz regarding such issues.

#### **IV. AVADEL'S POST-TRIAL MOTIONS**

Avadel intends to file the following motions based on the jury's verdict:

1. Motion for judgment as a matter of law regarding invalidity of claims 7 and 11 of U.S. Patent No. 10,758,488 for lack of written description, lack of enablement, improper inventorship, and derivation; and
2. Motion for judgment as a matter of law regarding invalidity of claim 24 of U.S. Patent No. 11,147,782 for lack of written description, lack of enablement, and improper inventorship.

#### **V. POST-TRIAL BRIEFING**

##### **A. Jazz's Proposal**

Jazz proposes that opening post-trial briefs will be due 28 days after the entry of judgment, with opposition briefs due 14 days later, and reply briefs due 7 days after opposition briefs. The page limits for any additional briefing regarding the potential post-trial motions discussed above, or that the Court may request after the bench trial on equitable issues, shall be set at 20 pages per side for opening briefs, 20 pages per side for opposition briefs, and 10 pages per side for reply briefs.

##### **B. Avadel's Proposal**

As described above, Avadel proposes that the parties' consolidated post-trial briefing of no more than 40 pages will be due 28 days after entry of judgment, with opposition briefs of no more than 40 pages due 28 days later, and reply briefs of no more than 20 pages due 14 days after opposition briefs.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Jeremy A. Tigan*

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Jack B. Blumenfeld (#1014)  
Jeremy A. Tigan (#5239)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200  
jblumenfeld@morrisnichols.com  
jtigan@morrisnichols.com

OF COUNSEL:

F. Dominic Cerrito  
Eric C. Stops  
Evangeline Shih  
Andrew S. Chalson  
Gabriel P. Brier  
Frank C. Calvosa  
Nicholas A. LoCastro  
Krista M. Rycroft  
Quentin Jorgensen  
Catherine T. Mattes  
Abigail DeMasi  
Elizabeth J. Murphy  
Raymond N. Nimrod  
Ellyde R. Thompson  
Brian J. Forsatz, Ph.D.  
Shannon Prince  
Shira Bergman  
QUINN EMANUEL URQUHART  
& SULLIVAN, LLP  
51 Madison Avenue, 22nd Floor  
New York, NY 10010  
(212) 849-7000

Alexandra Kim  
QUINN EMANUEL URQUHART  
& SULLIVAN, LLP  
111 Huntington Ave., Suite 520  
Boston, MA 02199  
(617) 712-7100

McCARTER & ENGLISH, LLP

*/s/ Daniel M. Silver*

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Daniel M. Silver (#4758)  
Alexandra M. Joyce (#6423)  
Renaissance Centre  
405 N. King Street, 8th Floor  
Wilmington, DE 19801  
(302) 984-6300  
dsilver@mccarter.com  
ajoyce@mccarter.com

OF COUNSEL:

Kenneth G. Schuler  
Marc N. Zubick  
Alex Grabowski  
Sarah W. Wang  
LATHAM & WATKINS LLP  
330 North Wabash Avenue, Suite 2800  
Chicago, IL 60611  
(312) 876-7700  
kenneth.schuler@lw.com  
marc.zubick@lw.com  
alex.grabowski@lw.com  
sarah.wang@lw.com

Herman Yue  
LATHAM & WATKINS LLP  
1271 Avenue of the Americas  
New York, NY 10020  
(212) 906-1200  
Herman.Yue@lw.com

Audra M. Sawyer  
LATHAM & WATKINS LLP  
555 Eleventh Street, NW, Suite 1000  
Washington, D.C. 20004  
(202) 637-2200  
Audra.sawyer@lw.com

Christopher D. Porter  
Elizabeth M. Devaney  
QUINN EMANUEL URQUHART  
& SULLIVAN, LLP  
Pennzoil Place  
711 Louisiana Street, Suite 500  
Houston, TX 77002  
(713) 221-7000

*Attorneys for Plaintiffs  
Jazz Pharmaceuticals, Inc. and  
Jazz Pharmaceuticals Ireland Limited*

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Daralyn J. Durie  
MORRISON & FOERSTER LLP  
425 Market Street  
San Francisco, CA 94105  
(415) 268-6055  
ddurie@mofo.com

Kira A. Davis  
Katherine E. McNutt  
MORRISON & FOERSTER LLP  
707 Wilshire Boulevard  
Los Angeles, CA 90017  
(213) 892-5200  
kiradavis@mofo.com  
kmcnutt@mofo.com

*Attorneys for Defendant  
Avadel CNS Pharmaceuticals LLC*