UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF DOCKETING

17-2636 - Salix Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.

Date of docketing: September 29, 2017

Appeal from: United States District Court for the Northern District of West Virginia case no. 1:15-cv-00109-IMK

Appellant(s): Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc.

Critical dates include:

- Date of docketing. See Fed. Cir. R. 12.
- Entry of appearance. (*Due within 14 days of the date of docketing*.) See Fed. Cir. R. 47.3.
- Certificate of interest. (*Due within 14 days of the date of docketing*.) See Fed. Cir. R. 47.4.
- Docketing Statement. (*Due within 14 days of the date of docketing or within 30 days if the United States or its officer or agency is a party in the appeal*.) [Only in cases where all parties are represented by counsel. See Fed. Cir. R. 33.1 and the mediation guidelines available at www.cafc.uscourts.gov.]
- Requests for extensions of time. See Fed. Cir. R. 26 and 27. **N.B. Delayed requests are not favored by the court**.
- Briefs. See Fed. Cir. R. 31. **N.B. You will not receive a separate briefing schedule from the Clerk's Office**. However, in a case involving an appellant, a cross-appellant, and an appellee, a special briefing schedule is used. The appellant's opening brief is due within 60 days of the date of docketing. The cross-appellant's opening brief is due within 40 days of filing of the appellant's opening brief. The appellee's brief is due within 40 days of filing of the cross-appellant's brief. The appellant's response/reply brief is due within 40 days of filing of the appellee's brief. The cross-appellant's reply brief is due within 14 days of filing of the appellant's response/reply brief. The joint appendix is due within 10 days of filing of the cross-appellant's reply brief.
- Settlement discussions. See Fed. Cir. R. 33.
- **ORAL ARGUMENT SCHEDULE CONFLICTS:** Counsel should advise the clerk in writing within 30 days once briefing is completed of potential scheduling conflicts or as soon as they are known and should not wait until an actual conflict arises. Once scheduled, a case will not be postponed except on motion showing **compelling reasons**. See Practice Note following Fed. Cir. R. 34.

The official caption is reflected on the electronic docket under the listing of the parties and counsel. The Rules of Practice and required forms are available at www.cafc.uscourts.gov.

Peter R. Marksteiner
Clerk of Court

cc: United States District Court for the Northern District of West Virginia
Dana Kathryn Severance
Christopher Thomas

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

SALIX PHARMACEUTICALS, INC. and DR. FALK PHARMA GmbH, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., and MYLAN INC., Defendants.	C. A. No. 1:15-CV-00109-IMK

PLAINTIFFS' NOTICE OF APPEAL

NOTICE IS HEREBY GIVEN that Salix Pharmaceuticals, Inc. and Dr. Falk Pharma GmbH, Plaintiffs in the above-captioned action, hereby appeal to the United States Court of Appeals for the Federal Circuit from the District Court's Judgment in a Civil Action (Dkt. No. 256) entered on September 12, 2017, and all findings, rulings, determinations, conclusions, orders, opinions, proceedings, and decisions leading thereto, underlying, or incorporated therein, including the Findings of Fact and Conclusions of Law Granting Judgment in Favor of the Defendants (Dkt. No. 255) entered on September 12, 2017.

Date: September 27, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 27th day of September, 2017, a true and correct copy of the aforesaid document was filed with the Clerk of the Court using the CM/ECF system, which will send notification of the filing to the following counsel of record:

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FORM 7. Appeal Information Sheet

FEDERAL CIRCUIT APPEAL INFORMATION SHEET

- [X] United States District Court for the Northern District of West Virginia
- [ ] United States Court of International Trade
- [ ] United States Court of Federal Claims
- [ ] United States Court of Appeals for Veterans Claims

Type of case: Patent Infringement

Salix Pharmaceuticals, Inc v. Mylan Pharmaceuticals, Inc.

(List all parties. Use an asterisk to indicate dismissed or withdrawn parties. Use a separate sheet if needed. Explain any discrepancy with the caption used on the judgment, order, or opinion.)

Docket No. 1:15cv109 Date of Judgment or Order 9/12/2017

Cross or related appeal? _____ Date of Notice of Appeal 9/27/2017

Appellant is: [✓] Plaintiff [ ] Defendant [ ] Other (explain)_____

FEES: Court of Appeals docket fee paid? [✓] Yes [ ] No

U.S. Appeal? [ ] Yes [ ] No

In forma pauperis? [ ] Yes [ ] No

Is this matter under seal? [ ] Yes [✓] No

COUNSEL: (List name, firm, address, and telephone of lead counsel for each party. Indicate party represented. Use separate sheet if needed.)

See Attached Docket Sheet

COURT REPORTER: (Name and telephone): Linda Bachman (304) 623-7154

IMPORTANT: Attach a copy of the judgment or order appealed from and any supporting opinion or memorandum. Forward together with a copy of the notice of appeal and certified docket entries.

Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, NW
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LC1

U.S. District Court
Northern District of West Virginia (Clarksburg)
CIVIL DOCKET FOR CASE #: 1:15-cv-00109-IMK

Salix Pharmaceuticals, Inc et al v. Mylan Pharmaceuticals, Inc. et al
Assigned to: District Judge Irene M. Keeley
Cause: 35:271 Patent Infringement

Date Filed: 06/26/2015
Date Terminated: 09/12/2017
Jury Demand: None
Nature of Suit: 830 Patent
Jurisdiction: Federal Question

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LEAD ATTORNEY
PRO HAC VICE
ATTORNEY TO BE NOTICED

Deepro Mukerjee
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Lance Soderstrom
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Micheal L. Binns
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ATTORNEY TO BE NOTICED

Robert L. Florence
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Anil H. Patel

(See above for address)
TERMINATED: 01/15/2016

Cedric C.Y. Tan
(See above for address)
TERMINATED: 01/15/2016

Christine I. Nam
(See above for address)
TERMINATED: 01/15/2016
PRO HAC VICE

George J Barry , III
(See above for address)
TERMINATED: 01/15/2016
PRO HAC VICE

Jessica M. Hauth
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TERMINATED: 10/15/2015

Timothy H. Kratz
(See above for address)
TERMINATED: 01/15/2016

William J O'Brien
(See above for address)
ATTORNEY TO BE NOTICED

Counter Claimant

Mylan, Inc.
TERMINATED: 05/04/2017

represented by **Anil H. Patel**
(See above for address)
TERMINATED: 01/15/2016
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Catherine R.L. Lawson
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Jessica M. Hauth
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TERMINATED: 10/15/2015

William J O'Brien
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V.

Counter Defendant

Dr. Falk Pharma GmbH represented by **Dana K. Severance**

TERMINATED: 05/04/2017

(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Daniel M. Attaway
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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

James F. Companion
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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

John W. Cox
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Kristen H. Cramer
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LEAD ATTORNEY
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Mary W Bourke
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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Tryn T. Stimart
(See above for address)
TERMINATED: 11/29/2016

Yolonda G. Lambert
(See above for address)
TERMINATED: 06/06/2017

Counter Defendant

Salix Pharmaceuticals, Inc
TERMINATED: 05/04/2017

represented by **Dana K. Severance**
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Tryn T. Stimart
(See above for address)
TERMINATED: 11/29/2016

Yolonda G. Lambert
(See above for address)
TERMINATED: 06/06/2017

Date Filed	#	Docket Text
06/26/2015	1	COMPLAINT for Patent Infringement against Mylan Pharmaceuticals, Inc., Mylan, Inc., filed by Salix Pharmaceuticals, Inc, Dr. Falk Pharma GmbH. (Attachments: # 1 Exhibit A - US Patent, # 2 Exhibit B - US Patent, # 3 Exhibit C - US Patent, # 4 Exhibit D - US Patent, # 5 Supplemental Information, # 6 Civil Cover Sheet)(cnd) (Entered: 06/26/2015)
06/26/2015	2	Filing fee: $ 400.00, receipt number WVNW001184. (cnd) (Entered: 06/26/2015)
06/26/2015	3	REPORT to USPTO on the filing or determination of an action regarding re 1 Complaint. (cnd) (Entered: 06/26/2015)
06/26/2015	5	Corporate Disclosure Statement by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc identifying Corporate Parent Salix Pharmaceuticals, Ltd., Corporate Parent Valeant Pharmaceuticals International, Corporate Parent Valeant Pharmaceuticals International, Inc. for Salix Pharmaceuticals, Inc.. (cnd) (Entered: 06/26/2015)

07/01/2015	6	VERIFICATION OF ATTORNEY ADMISSION as to Dana Severance, Daniel Attaway, Kristen Cramer, Mary Bourke, and Tryn Stimart re 1 Complaint. (cnd) (Entered: 07/01/2015)
07/09/2015	7	MOTION for Leave to Appear Pro Hac Vice *of Daniel Marcus Attaway* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order)(Companion, James) (Entered: 07/09/2015)
07/09/2015	8	MOTION for Leave to Appear Pro Hac Vice *of Dana K. Severance* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order)(Companion, James) (Entered: 07/09/2015)
07/09/2015	9	MOTION for Leave to Appear Pro Hac Vice *of Tryn T. Stimart* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order)(Companion, James) (Entered: 07/09/2015)
07/09/2015	10	MOTION for Leave to Appear Pro Hac Vice *of Kristen Healey Cramer* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order)(Companion, James) (Entered: 07/09/2015)
07/09/2015	11	MOTION for Leave to Appear Pro Hac Vice *of Mary W. Bourke* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order)(Companion, James) (Entered: 07/09/2015)
07/09/2015	12	SUMMONS Returned Executed as to Mylan Pharmaceuticals, Inc. - Secretary of service accepted service on 7/2/2015. (jss) (Entered: 07/09/2015)
07/09/2015	13	SUMMONS Returned Executed as to Mylan, Inc. - Secretary of State accepted service on 7/2/2015. (jss) (Entered: 07/09/2015)
07/09/2015	14	Pro Hac Vice Filing fee: $ 1,000.00, receipt number WVNW001197, for Attorneys Daniel Marcus Attaway, Dana K. Severance, Tryn T. Stimart, Kristen Healey Cramer and Mary W. Bourke. (jmm) (Entered: 07/09/2015)
07/09/2015	15	ORDER granting Kristin Cramer's 10 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 7/9/15. (jss) (Entered: 07/09/2015)
07/09/2015	16	ORDER granting Tryn Stimart's 9 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 7/9/15. (jss) (Entered: 07/09/2015)
07/09/2015	17	ORDER granting Dana Severance's 8 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 7/9/15. (jss) (Entered: 07/09/2015)
07/09/2015	18	ORDER granting Daniel Attaway's 7 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 7/9/15. (jss) (Entered: 07/09/2015)
07/09/2015	19	ORDER granting Mary Bourke's 11 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 7/9/15. (jss) (Entered:

		07/09/2015)
07/13/2015	20	ANSWER to 1 Complaint, , COUNTERCLAIM against Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc by Mylan, Inc., Mylan Pharmaceuticals, Inc.. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C)(O'Brien, William) (Entered: 07/13/2015)
07/13/2015	21	NOTICE /Verification of Attorney Admission. (jss) (Main Document 21 replaced on 7/13/2015) (jss). Modified on 7/13/2015 replaced form and regenerated NEF (jss). (Entered: 07/13/2015)
07/14/2015	22	Corporate Disclosure Statement by Mylan Pharmaceuticals, Inc., Mylan, Inc. identifying Corporate Parent Abbott Laboratories, Corporate Parent Mylan N.V. for Mylan Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., Mylan, Inc., Mylan, Inc... (O'Brien, William) (Entered: 07/14/2015)
07/21/2015	23	MOTION for Leave to Appear Pro Hac Vice *(George J. Barry III)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Attachment, # 2 Text of Proposed Order)(O'Brien, William) (Entered: 07/21/2015)
07/21/2015	24	MOTION for Leave to Appear Pro Hac Vice *(Micheal L. Binns)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Attachment, # 2 Text of Proposed Order)(O'Brien, William) (Entered: 07/21/2015)
07/21/2015	25	MOTION for Leave to Appear Pro Hac Vice *(Jessica M. Hauth)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Attachment, # 2 Text of Proposed Order)(O'Brien, William) (Entered: 07/21/2015)
07/21/2015	26	MOTION for Leave to Appear Pro Hac Vice *(Timothy H. Kratz)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Attachment, # 2 Text of Proposed Order)(O'Brien, William) (Entered: 07/21/2015)
07/21/2015	27	MOTION for Leave to Appear Pro Hac Vice *(Anil H. Patel)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Attachment, # 2 Text of Proposed Order)(O'Brien, William) (Entered: 07/21/2015)
07/22/2015	28	PHV fee for Timothy Kratz, George Barry, III, Jessica Hauth, Anil Patel, and Michael Binns: $ 1000.00, receipt number WVNC001373. (cnd) (Entered: 07/22/2015)
07/23/2015	29	ORDER granting George J. Barry III's 23 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 7/23/15. (jss) (Entered: 07/23/2015)
07/23/2015	30	ORDER granting Michael L. Binns' 24 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 7/23/15. (jss) (Entered: 07/23/2015)
07/23/2015	31	ORDER granting Jessica M. Hauth's 25 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 7/23/15. (jss) (Entered: 07/23/2015)
07/23/2015	32	ORDER granting Timothy H. Kratz's 26 Motion for Leave to Appear pro

		hac vice. Signed by District Judge Irene M. Keeley on 7/23/15. (jss) (Entered: 07/23/2015)
07/23/2015	33	ORDER granting Anil Patel's 27 Motion for Leave to Appear Pro Hac Vice. Signed by District Judge Irene M. Keeley on 7/23/15. (cnd) (Entered: 07/23/2015)
08/03/2015	34	REPLY by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc to 20 Answer to Complaint, Counterclaim,,. (Companion, James) (Entered: 08/03/2015)
08/03/2015	35	AMENDED ANSWER to 1 Complaint, , Amended COUNTERCLAIM against Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C)(Copland, Gordon) (Entered: 08/03/2015)
08/10/2015	36	FIRST ORDER AND NOTICE REGARDING DISCOVERY AND SCHEDULING: ******NOTICE TO ATTORNEYS*** : Pursuant to Rule 7.1 of the Federal Rules of Civil Procedure, ALL Non-governmental CORPORATE parties must file a DISCLOSURE STATEMENT with the Court. Forms are available on the Court's Web Site at http://www.wvnd.uscourts.gov/forms.htm*** Rule 26 Meeting to be held by 8/26/2015. Rule 26 Meeting Report due by 9/9/2015. Scheduling Conference set for 9/23/2015 01:30 PM in Clarksburg District Judge Courtroom, 2nd Floor before District Judge Irene M. Keeley. Discovery due by 9/28/2015. Signed by District Judge Irene M. Keeley on 8/10/15. (cnd) (Entered: 08/10/2015)
08/12/2015	37	MOTION for Leave to Appear Pro Hac Vice *(Cedric C.Y. Tan)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Attachment, # 2 Text of Proposed Order)(O'Brien, William) (Entered: 08/12/2015)
08/13/2015	38	PHV Filing fee: C. Tan, $ 200.00, receipt number WVNC001391 (mh) (Entered: 08/13/2015)
08/13/2015	39	ORDER: It is ORDERED that C. Y. Tan's 37 Motion for Leave to Appear Pro Hac Vice is hereby GRANTED. Signed by District Judge Irene M. Keeley on 8/13/15. (cnd) (Entered: 08/13/2015)
08/18/2015	40	REPLY by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc to 35 Amended Answer to Complaint,, Counterclaim,. (Companion, James) (Entered: 08/18/2015)
08/21/2015	41	MOTION for Leave to Appear Pro Hac Vice *(Christine I. Nam)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Attachment, # 2 Text of Proposed Order)(O'Brien, William) (Attachment 2 replaced, modified docket text on 8/21/2015 - Filed in wrong case) (cnd). (Entered: 08/21/2015)

08/21/2015	42	Pro Hac Vice fee for Christine Nam: $ 200.00, receipt number WVNC001399. (cnd) (Entered: 08/21/2015)
08/21/2015	43	Proposed Order re 41 MOTION for Leave to Appear Pro Hac Vice *(Christine I. Nam)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (O'Brien, William) (Entered: 08/21/2015)
08/24/2015	44	ORDER: It is ORDERED that Christine Nam's 41 Motion for Leave to Appear Pro Hac Vice is hereby GRANTED. Attorney Christine Nam is added for Mylan Pharmaceuticals, Inc. and Mylan, Inc. Signed by District Judge Irene M. Keeley on 8/24/15. (cnd) (Entered: 08/24/2015)
08/25/2015	45	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *(First Interrogatories to Plaintiffs)*. (O'Brien, William) (Entered: 08/25/2015)
08/25/2015	46	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *(Request for Production of Documents and Things to Plaintiffs)*. (O'Brien, William) (Entered: 08/25/2015)
09/09/2015	47	REPORT of Rule 26(f) Planning Meeting. (Copland, Gordon) (Entered: 09/09/2015)
09/15/2015	48	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs' First Set of Interrogatories to Mylan Pharmaceuticals, Inc. and Mylan, Inc. (Nos. 1-7)* (Companion, James) (Entered: 09/15/2015)
09/15/2015	49	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs' First Set of Requests to Mylan Pharmaceuticals, Inc. and Mylan, Inc. For the Production of Documents and Things (Nos. 1-63)* (Companion, James) (Entered: 09/15/2015)
09/23/2015	50	MINUTE ENTRY: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.*** Proceedings held before District Judge Irene M. Keeley: Scheduling Conference held on 9/23/2015. (Court Reporter L Bachman.) (mh) (Entered: 09/23/2015)
09/28/2015	51	SCHEDULING ORDER: Discovery due by 4/1/2016. Dispositive Motions due by 10/7/2016. Proposed Pretrial Order/Memoranda due by 2/15/2017. Claim Construction hearing set for 3/9/2016 at 10:00 AM in Clarksburg District Judge Courtroom, 2nd Floor before District Judge Irene M. Keeley Final Pretrial Conference and Settlement Conference set for 2/24/2017 at 10:30 AM in Clarksburg District Judge Courtroom, 2nd Floor before District Judge Irene M. Keeley. Bench Trial set for 3/6/2017at 09:30 AM in Clarksburg District Judge Courtroom, 2nd Floor before District Judge Irene M. Keeley. Signed by District Judge Irene M. Keeley on 9/28/15. (jss)

		Modified on 9/30/2015 - added Claim Construction Hearing (jss). (Entered: 09/28/2015)
09/28/2015	52	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs' Objections and Responses to Defendants First Interrogatories to Plaintiffs* (Companion, James) (Entered: 09/28/2015)
09/28/2015	53	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs' Objections and Responses to Defendants' Request for Production of Documents and Things to Plaintiffs* (Companion, James) (Entered: 09/28/2015)
09/28/2015		Set/Reset Hearings: Discovery Hearing /Claim Construction hearing set for 3/9/2016 at 10:00 AM in Clarksburg District Judge Courtroom, 2nd Floor before District Judge Irene M. Keeley - per 51 Scheduling Order (jss) (Entered: 09/30/2015)
09/30/2015	54	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs Rule 26(a)(1)(A) Disclosures* (Companion, James) (Entered: 09/30/2015)
09/30/2015	55	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Initial Disclosures*. (O'Brien, William) (Entered: 09/30/2015)
10/15/2015	56	MOTION to Withdraw *(Jessica M. Hauth)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(O'Brien, William) (Entered: 10/15/2015)
10/15/2015	57	ORDER: It is ORDERED that Defendants' 56 Motion for Leave to Withdraw as Counsel is hereby GRANTED. Attorney Jessica M. Hauth terminated. Signed by District Judge Irene M. Keeley on 10/15/15. (cnd) (Entered: 10/15/2015)
10/19/2015	58	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Responses and Objections to Plaintiffs' First Set of Interrogatories to Mylan Pharmaceuticals Inc. and Mylan Inc. (Nos. 107)*. (O'Brien, William) (Entered: 10/19/2015)
10/19/2015	59	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Responses and Objections to Plaintiffs' First Set of Requests to Mylan Pharmaceuticals Inc. and Mylan Inc. for the Production of Documents and Things (Nos. 1-63)*. (O'Brien, William) (Entered: 10/19/2015)
10/23/2015	60	STIPULATION *on Discovery of Documents (Joint)* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 10/23/2015)
10/23/2015	61	Proposed *Stipulated Protective* Order by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Exhibit A - Declaration of Acknowledgement and Agreement to be Bound by Protective Order, # 2 Exhibit B - Declaration of Acknowledgement and Agreement to be Bound

		by Protective Order)(Companion, James) (Entered: 10/23/2015)
10/23/2015	62	STIPULATED PROTECTIVE ORDER. Signed by District Judge Irene M. Keeley on 10/23/15. (jss) (Entered: 10/23/2015)
12/03/2015	63	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *for Mylan's Proposed Claim Terms for Construction*. (Copland, Gordon) (Entered: 12/03/2015)
12/04/2015	64	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re asserted claims pursuant to Paragraph 4 of Scheduling Order* (Companion, James) (Entered: 12/04/2015)
12/04/2015	65	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re claim terms pursuant to Paragraph 6 of Scheduling Order* (Companion, James) (Entered: 12/04/2015)
12/17/2015	66	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *regarding Mylan's proposed claim terms and claim construction*. (Copland, Gordon) (Entered: 12/17/2015)
12/18/2015	67	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs' Proposed Claim Constructions and Preliminary Identification of Intrinsic and Extrinsic Evidence* (Companion, James) (Entered: 12/18/2015)
12/18/2015	68	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *of Defendants' amended Proposed List of Identified Claim Terms and Proposed Construction*. (O'Brien, William) (Entered: 12/18/2015)
01/11/2016	69	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs' Notice of Deposition of Defendants Mylan Pharmaceuticals, Inc. and Mylan, Inc. Pursuant to Rule 30(b)(6)* (Companion, James) (Entered: 01/11/2016)
01/14/2016	70	NOTICE of Change of Address by Gordon H. Copland (Copland, Gordon) (Entered: 01/14/2016)
01/14/2016	71	MOTION for Leave to Appear Pro Hac Vice *(Robert L. Florence)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(Copland, Gordon) (Entered: 01/14/2016)
01/14/2016	72	MOTION for Leave to Appear Pro Hac Vice *(Melanie Black Dubis)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(Copland, Gordon) (Entered: 01/14/2016)
01/14/2016	73	MOTION to Withdraw *(Patel, Tan, Nam, Barry, and Kratz)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(Copland, Gordon) (Entered: 01/14/2016)
01/14/2016	74	*Defendants' Opening Claim Construction Brief* Other Document filed by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Attachment, # 2 Exhibit A, # 3 Exhibit B, # 4 Exhibit C, # 5 Exhibit D, # 6 Exhibit E, # 7

		Exhibit F, # 8 Exhibit G, # 9 Exhibit H, # 10 Exhibit I, # 11 Exhibit J, # 12 Exhibit K, # 13 Exhibit L, # 14 Exhibit M, # 15 Exhibit N, # 16 Exhibit O, # 17 Exhibit P, # 18 Exhibit Q, # 19 Exhibit R, # 20 Exhibit S, # 21 Exhibit T)(O'Brien, William) (Entered: 01/14/2016)
01/14/2016	75	*Plaintiffs' Opening Brief on Claim Construction* Other Document filed by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Appendix A, # 2 Appendix B, # 3 Appendix C)(Companion, James) (Entered: 01/14/2016)
01/14/2016	76	*Declaration of Tryn T. Stimart, Esquire, in Support of Plaintiffs' Opening Brief on Claim Construction* Other Document re 75 Other Document filed by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Exhibit 6, # 7 Exhibit 7, # 8 Exhibit 8, # 9 Exhibit 9, # 10 Exhibit 10, # 11 Exhibit 11, # 12 Exhibit 12, # 13 Exhibit 13, # 14 Exhibit 14, # 15 Exhibit 15, # 16 Exhibit 16, # 17 Exhibit 17, # 18 Exhibit 18, # 19 Exhibit 19, # 20 Exhibit 20)(Companion, James) (Entered: 01/14/2016)
01/14/2016	77	*Declaration of Alan Victor Safdi, M.D., F.A.C.G.* Other Document re 75 Other Document filed by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Exhibit 1)(Companion, James) (Entered: 01/14/2016)
01/15/2016	78	ORDER: Order granting 73 Motion to Withdraw. Attorney Christine I. Nam; Anil H. Patel; Cedric C.Y. Tan; George J Barry, III and Timothy H. Kratz terminated. Signed by District Judge Irene M. Keeley on 1/15/16. (jss) (Entered: 01/15/2016)
01/15/2016	79	Pro hac vice Filing fee for M. Dubis and R. Florence: $ 400.00, receipt number WVNC001539 (jss) (Entered: 01/15/2016)
01/15/2016	80	ORDER granting Melanie Black Dubis' 72 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 1/15/16. (jss) (Entered: 01/15/2016)
01/15/2016	81	ORDER granting Robert L. Florence's 71 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 1/15/16. (jss) (Entered: 01/15/2016)
01/27/2016	82	MOTION for Leave to Appear Pro Hac Vice *(Karen L. Carroll)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(Copland, Gordon) (Entered: 01/27/2016)
01/28/2016	83	Pro Hac Vice Filing fee for K. Carroll: $ 200.00, receipt number WVNC001558 (jss) (Entered: 01/28/2016)
01/29/2016	84	ORDER granting Karen L. Carroll's 82 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 1/29/16. (jss) (Entered: 01/29/2016)
02/04/2016	85	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc.

		for Defendants' Notice of Deposition of Peter Gruber. (O'Brien, William) (Entered: 02/04/2016)
02/04/2016	86	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *for Defendants' Notice of Deposition of WIlliam Forbes*. (O'Brien, William) (Entered: 02/04/2016)
02/04/2016	87	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *for Defendants' Notice of Deposition of Norbert Otterbeck*. (O'Brien, William) (Entered: 02/04/2016)
02/04/2016	88	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *for Notice of Deposition of Platiniffs Salix Pharmaceuticals, Inc. and Dr. Falk Pharma GmbH Pursuant to Fed. R. Civ. P. 30(b)(6)*. (O'Brien, William) (Entered: 02/04/2016)
02/04/2016	89	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Notice of Deposition of David A. Mitchell* (Companion, James) (Entered: 02/04/2016)
02/04/2016	90	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Notice of Deposition of Joseph Sobecki* (Companion, James) (Entered: 02/04/2016)
02/04/2016	91	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Notice of Deposition of Abhijit Deshmukh* (Companion, James) (Entered: 02/04/2016)
02/04/2016	92	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Notice of Deposition of Ramakrishna Bangaru* (Companion, James) (Entered: 02/04/2016)
02/04/2016	93	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Notice of Deposition of Santanu Chakraborty* (Companion, James) (Entered: 02/04/2016)
02/04/2016	94	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Notice of Deposition of Ritish Kakaria* (Companion, James) (Entered: 02/04/2016)
02/08/2016	95	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *for Mylan Pharmaceuticals Inc.s and Mylan Inc.s Supplemental Responses and Objections To Plaintiffs First Set Of Interrogatories To Mylan Pharmaceuticals Inc. and Mylan Inc. (Nos. 1-7)*. (O'Brien, William) (Entered: 02/08/2016)
02/08/2016	96	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *for Mylan Pharmaceuticals Inc.s and Mylan Inc.s Responses and Objections To Plaintiffs Notice of Deposition of Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. Pursuant To Rule 30(b)(6)*. (O'Brien, William) (Entered: 02/08/2016)
02/10/2016	97	Joint MOTION for Extension of Time to File *Responsive Claim*

		Construction Briefs by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 02/10/2016)
02/10/2016	98	ORDER granting Joint 97 Motion for Extension of Time: The Court GRANTS the motion and ORDERS the parties to file responsive claim construction briefsby February 12, 2016. Signed by District Judge Irene M. Keeley on 2/10/16. (jss) (Entered: 02/10/2016)
02/12/2016	99	RESPONSE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 02/12/2016)
02/12/2016	100	Other Document re 99 Response *Declaration of Tryn T. Stimart, Esquire in Support of Plaintiff's Responsive Brief on Claim Construction* filed by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Exhibit Exhibit 1, # 2 Exhibit Exhibit 2, # 3 Exhibit Exhibit 3, # 4 Exhibit Exhibit 4, # 5 Exhibit Exhibit 5, # 6 Exhibit Exhibit 6)(Companion, James) (Entered: 02/12/2016)
02/12/2016	101	MEMORANDUM *of law* by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Responsive Brief on Claim Construction*. (Copland, Gordon) (Entered: 02/12/2016)
03/02/2016	102	MOTION To Permit Local Counsel to Attend Depositions by Telephone *and Proposed Order Regarding Same* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order) (Companion, James) (Entered: 03/02/2016)
03/02/2016	103	ORDER DIRECTING DEFENDANTS TO RESPOND: The Court ORDERS the defendants to respond to the plaintiffs 102 Motion To Permit Local Counsel to Attend Depositions by Telephone no later than Monday, March 7, 2016 Signed by District Judge Irene M. Keeley on 3/2/16. (jss) (Entered: 03/02/2016)
03/02/2016	104	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs' First Set of Requests for Admission to Defendants (Nos. 1-60), Second Set of Interrogatories (No. 8), Second Notice of Deposition of Defendants Pursuant to Rule 30(b)(6) and Notice of Deposition of Shane C. Shupe* (Companion, James) (Entered: 03/02/2016)
03/03/2016		Set/Reset Hearings: Markman Hearing set for 3/9/2016 10:00 AM in Clarksburg District Judge Courtroom, 2nd Floor before District Judge Irene M. Keeley set per 51 order. (jss) Modified on 3/3/2016 - corrected date and regenerated nef (jss). (Entered: 03/03/2016)
03/07/2016	105	RESPONSE to Motion re 102 MOTION To Permit Local Counsel to Attend Depositions by Telephone *and Proposed Order Regarding Same* filed by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Copland, Gordon) (Entered: 03/07/2016)
03/07/2016	106	ORDER GRANTING PLAINTIFFS MOTION TO PERMIT LOCAL COUNSEL TO ATTEND DEPOSITIONS BY TELEPHONE 102 . Signed by District Judge Irene M. Keeley on 3/7/16. (jss) (Entered: 03/07/2016)

03/09/2016	107	MINUTE ENTRY: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.*** Proceedings held before District Judge Irene M. Keeley. Markman Hearing held on 3/9/2016. (Court Reporter Linda Bachman) (dk) (Entered: 03/09/2016)
03/15/2016	108	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs' Objections and Responses to Defendants' Notice of Deposition of Plaintiffs Pursuant to Fed. R. Civ. P. 30(b)(6)* (Companion, James) (Entered: 03/15/2016)
03/15/2016	109	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *regarding Responses and Objections to Plaintiffs Second Notice of Deposition of Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. Pursuant to Rule 30(b)(6)*. (O'Brien, William) (Entered: 03/15/2016)
04/01/2016	110	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs' Supplemental Objections and Responses to Defendants' First Interrogatories (Nos. 1-4, 11-14) to Plaintiffs* (Companion, James) (Entered: 04/01/2016)
04/01/2016	111	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Responses to Plaintiffs' Second Set of Interrogatories*. (Copland, Gordon) (Entered: 04/01/2016)
04/01/2016	112	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Responses to Plaintiffs' First Requests for Admission*. (Copland, Gordon) (Entered: 04/01/2016)
04/01/2016	113	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Second Supp. Response to Plaintiffs' First Interrogatories*. (Copland, Gordon) (Entered: 04/01/2016)
04/11/2016	114	TRANSCRIPT of Markman Hearing Proceedings held on March 9, 2016, before Judge Irene M. Keeley. Court Reporter/Transcriber Linda Bachman, Telephone number (304) 282-0395; Linda_Bachman@wvnd.uscourts.gov. Parties have five business days to file a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript will become available via PACER to the public without redaction after 90 calendar days.. Redaction Request due 5/2/2016. Redacted Transcript Deadline set for 5/12/2016. Release of Transcript Restriction set for 7/11/2016. (llb) (Entered: 04/11/2016)
04/11/2016	115	TRANSCRIPT PURCHASE ORDER by Mylan Pharmaceuticals, Inc., Mylan, Inc. for proceedings held on March 9, 2016 before Judge Irene M. Keeley. (llb) (Entered: 04/11/2016)
04/11/2016	116	TRANSCRIPT PURCHASE ORDER by Salix Pharmaceuticals, Inc for

		proceedings held on March 9, 2016 before Judge Irene M. Keeley. (llb) (Entered: 04/11/2016)
04/12/2016	117	MEMORANDUM OPINION AND ORDER CONSTRUING PATENT CLAIMS. Signed by District Judge Irene M. Keeley on 4/12/16. (jss) (Entered: 04/12/2016)
04/18/2016	118	Joint MOTION Modifying Scheduling Order by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order) (Companion, James) (Entered: 04/18/2016)
04/19/2016	119	ORDER granting 118 Joint MOTION Modifying Scheduling Order. It is hereby ORDERED that the deadlines indicated from the Court's September 28, 2015 Scheduling Order DE 51 shall be extended pursuant to L.R. Civ. P. 16.01(F). Signed by District Judge Irene M. Keeley on 4/19/2016. copy counsel of record)(jmm) Modified on 4/19/2016 linked DE 51 to docket text (jmm). (Entered: 04/19/2016)
04/28/2016	120	STIPULATION re 119 Order on Motion for Miscellaneous Relief,,, *Extending Deadlines for Exchange of Expert Reports* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (O'Brien, William) (Entered: 04/28/2016)
05/27/2016	121	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs' Opening Expert Reports* (Companion, James) (Entered: 05/27/2016)
05/27/2016	122	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *re Defendants' Opening Expert Reports*. (O'Brien, William) (Entered: 05/27/2016)
06/28/2016	123	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Responsive Expert Report of Alan Victor Safdi, M.D., F.A.C.G.* (Companion, James) (Entered: 06/28/2016)
06/28/2016	124	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Expert Report of Dr. Stanley S. ("Bob") Davis* (Companion, James) (Entered: 06/28/2016)
06/28/2016	125	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *for Rebuttal Report of David Auslander*. (Copland, Gordon) (Entered: 06/28/2016)
07/12/2016	126	Other Document *Notice of Change of address - Micheal Binns, Robert Florence and Karen Carroll* filed by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Copland, Gordon) (Entered: 07/12/2016)
08/02/2016	127	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Reply Expert Report of Martyn C. Davis, Ph.D. and Reply Expert Report of Alan Victor Safdi, M.D., F.A.C.G.* (Companion, James) (Entered: 08/02/2016)
08/02/2016	128	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc.

		for Expert Reply report of Dr. Korelitz. (Copland, Gordon) (Entered: 08/02/2016)
08/08/2016	129	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Notice of Deposition of David E. Auslander, Ph.D.* (Companion, James) (Entered: 08/08/2016)
08/08/2016	130	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Notice of Deposition of Dr. Burton I. Korelitz, M.D.* (Companion, James) (Entered: 08/08/2016)
08/08/2016	131	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Notice of Deposition of Steven H. Neau, Ph.D.* (Companion, James) (Entered: 08/08/2016)
08/19/2016	132	NOTICE of Appearance by Adam S Ennis on behalf of All Defendants (Ennis, Adam) (Entered: 08/19/2016)
08/22/2016	133	NOTICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Notice of Deposition of Dr. Stanley "Bob" Davis* (Lauderman, Christopher) (Entered: 08/22/2016)
08/22/2016	134	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Notice of Deposition of Dr. Alan Safdi*. (Lauderman, Christopher) (Entered: 08/22/2016)
08/22/2016	135	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Notice of Deposition of Dr. Pamela Golden*. (Lauderman, Christopher) (Entered: 08/22/2016)
08/22/2016	136	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Notice of Deposition of Dr. Martyn Davies*. (Lauderman, Christopher) (Entered: 08/22/2016)
08/23/2016	137	CERTIFICATE OF SERVICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *Sur-Reply Expert Report of David E. Auslander, Ph.D.*. (Lauderman, Christopher) (Entered: 08/23/2016)
10/05/2016	138	MOTION Joint Motion to Amend Dispostive Motion Schedule by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(Copland, Gordon) (Entered: 10/05/2016)
10/07/2016	139	PAPERLESS ORDER (Status Conference re 138 set for 10/7/2016 at 5:00 PM before District Judge Irene M. Keeley. The status conference will be conducted by telephone.). Signed by District Judge Irene M. Keeley on 10/7/2016. (dk) (Entered: 10/07/2016)
10/07/2016	140	MINUTE ENTRY: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.***

		Proceedings held before District Judge Irene M. Keeley. Status Conference held on 10/7/2016. (Court Reporter Linda Bachman) (dk) (Entered: 10/07/2016)
10/11/2016	141	ORDER FOLLOWING STATUS CONFERENCE: Order granting in part and denying in part the Joint Motion to Amend Scheduling Order 138 . Dispositive Motions are due by October 28, 2016 and Responses to Dispositive Motions are dye by November 18, 2016. Signed by District Judge Irene M. Keeley on 10/11/16. (jss) (Entered: 10/11/2016)
11/28/2016	142	MOTION to Withdraw as Attorney *re Tryn T. Stimart* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order)(Companion, James) (Entered: 11/28/2016)
11/29/2016	143	ORDER: Order granting 142 Motion to Withdraw as Attorney. Attorney Tryn T. Stimart is hereby withdrawn as counsel for Plaintiffs Salix Pharmaceuticals, Inc. and Dr. Falk Pharma GmbH. Signed by District Judge Irene M. Keeley on 11/29/16. (jss) (Entered: 11/29/2016)
02/03/2017	144	NOTICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *PURSUANT TO 35 U.S.C. § 282* (O'Brien, William) (Entered: 02/03/2017)
02/09/2017	145	MOTION for Leave to Appear Pro Hac Vice *of John Cox* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order)(Companion, James) (Entered: 02/09/2017)
02/09/2017	146	MOTION for Leave to Appear Pro Hac Vice *for Catherine Lawson* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(Copland, Gordon) (Entered: 02/09/2017)
02/09/2017	147	MOTION for Leave to Appear Pro Hac Vice *of Christopher Thomas* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(Copland, Gordon) (Entered: 02/09/2017)
02/09/2017	148	Pro Hac Vice Filing fee for John Cox: $ 200.00, receipt number WVNW001617 (jss) (Entered: 02/09/2017)
02/10/2017	149	ORDER granting 145 Motion for John Cox to Appear Pro Hac Vice. Signed by District Judge Irene M. Keeley on 2/10/17. (mh) (Entered: 02/10/2017)
02/10/2017	150	Exhibit List by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 02/10/2017)
02/10/2017	151	Witness List by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 02/10/2017)
02/10/2017	152	Exhibit List by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 02/10/2017)
02/10/2017	153	Other Document *Plaintiffs' Designation of Deposition Testimony and Written Discovery* filed by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 02/10/2017)

02/10/2017	154	Witness List by Mylan Pharmaceuticals, Inc., Mylan, Inc..(Copland, Gordon) (Entered: 02/10/2017)
02/10/2017	155	*Designation of Deposition and Discovery of Defendants* Other Document filed by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Copland, Gordon) (Entered: 02/10/2017)
02/13/2017	158	PHV Filing fee for Catherine Lawson and Christopher Thomas. $ 400.00, receipt number WVNC001814 (mh) (Entered: 02/13/2017)
02/14/2017	159	ORDER granting 147 Motion for Christopher M. Thomas to Appear Pro Hac Vice on behalf of Mylan Defendants. Signed by District Judge Irene M. Keeley on 2/14/17. (mh) (Entered: 02/14/2017)
02/14/2017	160	ORDER granting 146 Motion for Catherine R. L. Lawson to Appear Pro Hac Vice on behalf of Mylan Defendants. Signed by District Judge Irene M. Keeley on 2/14/17. (mh) (Entered: 02/14/2017)
02/17/2017	169	*Expert Witness Biographical Sketches* Other Document filed by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D)(Companion, James) (Entered: 02/17/2017)
02/17/2017	171	*Defendants' Expert Biographical Sketches* Other Document filed by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Exhibit A - Dr. Auslander's CV, # 2 Exhibit B - Dr. Korelitz's CV, # 3 Exhibit C - Dr. Neau's CV)(O'Brien, William) (Entered: 02/17/2017)
02/24/2017	173	MINUTE ENTRY: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.*** Proceedings held before District Judge Irene M. Keeley. Pretrial Conference held on 2/24/2017. (Court Reporter Linda Bachman) (dk) (Entered: 02/24/2017)
02/24/2017	174	PAPERLESS ORDER (For the reasons set forth on the record, the Bench Trial previously set to begin on 3/6/2017 at 9:30 AM is RESCHEDULED to begin on 3/7/2017 at 9:30 AM in Clarksburg District Judge Courtroom, 2nd Floor before District Judge Irene M. Keeley.). Signed by District Judge Irene M. Keeley on 2/24/2017. (dk) (Entered: 02/24/2017)
03/02/2017	175	TRANSCRIPT of Final Pretrial Conference Proceedings held on February 24, 2017, before Judge Irene M. Keeley. Court Reporter/Transcriber Linda Bachman, Telephone number (304) 282-0395; Linda_Bachman@wvnd.uscourts.gov. Parties have five business days to file a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript will become available via PACER to the public without redaction after 90 calendar days.. Redaction Request due 3/23/2017. Redacted Transcript Deadline set for 4/3/2017. Release of

		Transcript Restriction set for 5/31/2017. (llb) (Entered: 03/02/2017)
03/02/2017	176	TRANSCRIPT PURCHASE ORDER by Mylan Pharmaceuticals, Inc., Mylan, Inc. for proceedings held on February 24, 2017 before Judge Irene M. Keeley. (llb) (Entered: 03/02/2017)
03/02/2017	177	TRANSCRIPT PURCHASE ORDER by Salix Pharmaceuticals, Inc. for proceedings held on February 24, 2017 before Judge Irene M. Keeley. (llb) (Entered: 03/02/2017)
03/06/2017	178	MOTION Joint Request for Status Conference in Advance of Trial by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 03/06/2017)
03/06/2017	179	Joint MOTION TO PERMIT ENTRY TO THE COURTHOUSE WITH ELECTRONIC EQUIPMENT by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(O'Brien, William) (Entered: 03/06/2017)
03/06/2017	181	PAPERLESS ORDER (Telephonic Status Conference re 178 Joint Request for Status Conference in Advance of Trial set for 3/6/2017 at 1:00 PM, before District Judge Irene M. Keeley. Counsel for the Plaintiffs is directed to provide call-in information to all parties and the Court. Call-in information to the Court is to be sent by email to Candace_Levitsky@wvnd.uscourts.gov, no later than 12:30 p.m.). Signed by District Judge Irene M. Keeley on 3/6/2017. (dk) (Entered: 03/06/2017)
03/06/2017	182	ORDER GRANTING JOINT 179 MOTION TO PERMIT ENTRY TO THE COURTHOUSE WITH ELECTRONIC EQUIPMENT. Signed by District Judge Irene M. Keeley on 3/6/17. (jss) (Entered: 03/06/2017)
03/06/2017	183	MINUTE ENTRY: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.*** Proceedings held before District Judge Irene M. Keeley. Status Conference held on 3/6/2017. (Court Reporter Linda Bachman) (dk) (Entered: 03/06/2017)
03/06/2017	184	ORDER *****SEALED*****; *****SEALED*****. (copies counsel and Court reporter) Signed by District Judge Irene M. Keeley on 3/6/17. (jss) (Entered: 03/06/2017)
03/07/2017	185	Disclaimer for Realtime Unedited Transcript. (jss) Modified on 3/9/2017 Signed by District Judge Irene M. Keeley on 3/7/17. (jss). (Entered: 03/07/2017)
03/07/2017	186	MINUTE ENTRY: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.***

		Proceedings held before District Judge Irene M. Keeley. Bench Trial Day One held on 3/7/2017. (Court Reporter Jennifer Kirkbride) (dk) (Entered: 03/07/2017)
03/08/2017	187	TRANSCRIPT of Proceedings held on March 7, 2017, before Judge Irene M. Keeley. Court Reporter/Transcriber Linda Bachman; Jennifer Kirkbride, Telephone number (304) 282-0395; Linda_Bachman@wvnd.uscourts.gov. Parties have five business days to file a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript will become available via PACER to the public without redaction after 90 calendar days.. Redaction Request due 3/29/2017. Redacted Transcript Deadline set for 4/10/2017. Release of Transcript Restriction set for 6/6/2017. (llb) (Main Document 187 replaced on 4/11/2017) (jss). (Additional attachment(s) added on 4/11/2017: # 1 Errata Sheet for Trial Day 1, March 7, 2017) (jss). (Entered: 03/08/2017)
03/08/2017	188	MINUTE ENTRY: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.*** Proceedings held before District Judge Irene M. Keeley. Bench Trial held on 3/8/2017. (Court Reporter Jennifer Kirkbride) (dk) (Entered: 03/08/2017)
03/09/2017	189	*SEALED* TRANSCRIPT of Sealed Hearing held on March 8, 2017, before Judge Irene M. Keeley. Court Reporter/Transcriber Linda Bachman; Jennifer Kirkbride, Telephone number (304) 282-0395; Linda_Bachman@wvnd.uscourts.gov.. (llb) (Main Document 189 replaced on 4/11/2017) (jss). (Entered: 03/09/2017)
03/09/2017	190	TRANSCRIPT of Proceedings held on March 8, 2017, before Judge Irene M. Keeley. Court Reporter/Transcriber Linda Bachman; Jennifer Kirkbride, Telephone number (304) 282-0395; Linda_Bachman@wvnd.uscourts.gov. Parties have five business days to file a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript will become available via PACER to the public without redaction after 90 calendar days.. Redaction Request due 3/30/2017. Redacted Transcript Deadline set for 4/10/2017. Release of Transcript Restriction set for 6/7/2017. (llb) (Main Document 190 replaced on 4/11/2017) (jss). (Additional attachment(s) added on 4/11/2017: # 1 Errata Sheet for Trial Day 2, March 8, 2017) (jss). (Entered: 03/09/2017)
03/09/2017	191	MINUTE ENTRY: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.*** Proceedings held before District Judge Irene M. Keeley. Bench Trial Day 3 held on 3/9/2017. (Court Reporter Jennifer Kirkbride) (dk) (Entered:

		03/09/2017)
03/09/2017	192	Clerk's Exhibit and Witness List for Trial held 3/7/17 - 3/9/17. (dk) (Main Document 192 replaced on 3/23/2017 to correct typographical error) (dk). (Entered: 03/09/2017)
03/09/2017	193	TRANSCRIPT of Proceedings held on March 9, 2017, before Judge Irene M. Keeley. Court Reporter/Transcriber Linda Bachman; Jennifer Kirkbride, Telephone number (304) 282-0395; Linda_Bachman@wvnd.uscourts.gov. Parties have five business days to file a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript will become available via PACER to the public without redaction after 90 calendar days.. Redaction Request due 3/30/2017. Redacted Transcript Deadline set for 4/10/2017. Release of Transcript Restriction set for 6/7/2017. (llb) (Main Document 193 replaced on 4/11/2017) (jss). (Additional attachment(s) added on 4/11/2017: # 1 Errata Sheet for Trial Day 3, March 9, 2017) (jss). (Entered: 03/09/2017)
03/09/2017	194	TRANSCRIPT PURCHASE ORDER by Salix Pharmaceuticals, Inc for proceedings held on March 7-9, 2017 before Judge Irene M. Keeley. (llb) (Entered: 03/09/2017)
03/09/2017	195	TRANSCRIPT PURCHASE ORDER by Mylan Pharmaceuticals, Inc., Mylan, Inc. for proceedings held on March 7-9, 2017 before Judge Irene M. Keeley. (llb) (Entered: 03/09/2017)
03/15/2017	196	Redaction of 175 Transcript,,. hearing held February 24, 2017 (llb) (Entered: 03/15/2017)
03/17/2017	197	ORDER SCHEDULING CONCLUSION OF BENCH TRIAL: On or before Friday, March 31, 2017, the parties are to file a stipulation scheduling these dates, and also to include three dates on which they are available for an interim status conference prior to the resumption of trial. Signed by District Judge Irene M. Keeley on 3/17/17. (jss) (Entered: 03/17/2017)
03/17/2017	198	ORDER SETTING BRIEFING SCHEDULE: The parties opening briefs are due Monday, April 10, 2017. The parties responsive briefs are due Wednesday, May 10,2017. Signed by District Judge Irene M. Keeley on 3/17/17. (jss) (Entered: 03/17/2017)
03/20/2017		Set/Reset Hearings: Continued Bench Trial set for 5/31/2017 and 6/1/2017, at 9:30 AM, each day, in Clarksburg District Judge Courtroom, 2nd Floor before District Judge Irene M. Keeley. (dk) (Entered: 03/20/2017)
03/22/2017	199	Joint MOTION Joint request for status conference by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Copland, Gordon) (Entered: 03/22/2017)
03/24/2017	200	ORDER SCHEDULING STATUS CONFERENCE: Finding good cause, the Court SCHEDULES a telephonic status conference for Tuesday, March 28, 2017, at 4:30 P.M. Signed by District Judge Irene M. Keeley on

		3/24/17. (jss) (Entered: 03/24/2017)
03/28/2017	201	PAPERLESS ORDER CANCELING STATUS CONFERENCE. For reasons appearing to the Court, the Status Conference set for 3/28/2017 at 4:30 P.M., is CANCELED. Signed by District Judge Irene M. Keeley on 3/28/2017. (dk) (Entered: 03/28/2017)
03/29/2017	202	Joint MOTION to establish schedule for supplemental expert discovery by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Copland, Gordon) (Entered: 03/29/2017)
03/30/2017	203	ORDER GRANTING JOINT MOTION REGARDING SUPPLEMENTAL EXPERT DISCOVERY: It is ORDERED that the parties' 202 Joint Motion to Establish Schedule for Supplemental Expert Discovery is hereby GRANTED. The Interim Status Conference is set for 4/27/2017 02:30 PM in Judge Keeley Chambers before District Judge Irene M. Keeley, via telephone. Signed by District Judge Irene M. Keeley on 3/30/17. (cnd) (Entered: 03/30/2017)
04/03/2017	204	MOTION For Leave to Expand Page Limit *(Unopposed)* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order)(Companion, James) (Entered: 04/03/2017)
04/03/2017	205	ORDER: Order granting 204 Plaintiffs' Unopposed Motion to Expand Page Limit and ORDERS that Plaintiffs opening post-trial brief is expanded from a 30-page limit to a 35-page limit. Signed by District Judge Irene M. Keeley on 4/3/17. (jss) (Entered: 04/03/2017)
04/03/2017	206	MOTION Enlargement of Page Limit for initial brief by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(Copland, Gordon) (Entered: 04/03/2017)
04/04/2017	207	ORDER ENLARGING PAGE LIMIT: Order granting 206 Motion to Enlarge Page Limit and ORDERS that the page limit on Defendants opening post-trial brief is expanded from a 30-page limit to a 35-page limit. Signed by District Judge Irene M. Keeley on 4/4/17. (jss) (Entered: 04/04/2017)
04/10/2017	208	MEMORANDUM *Plaintiffs' Opening Brief Regarding Infringement of United States Patent Number 8,865,688* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc . (Companion, James) (Entered: 04/10/2017)
04/10/2017	209	Other Document *Proposed Findings of Fact and Conclusions of Laaw* filed by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Copland, Gordon) (Entered: 04/10/2017)
04/12/2017	210	MOTION for Leave to Appear Pro Hac Vice *(Joseph M. Janusz, Esq.)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(O'Brien, William) (Entered: 04/12/2017)
04/12/2017	211	MOTION for Leave to Appear Pro Hac Vice *(Deepro Mukerjee, Esq.)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of

		Proposed Order)(O'Brien, William) (Entered: 04/12/2017)
04/12/2017	212	MOTION for Leave to Appear Pro Hac Vice *(Lance Soderstrom, Esq.)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(O'Brien, William) (Entered: 04/12/2017)
04/12/2017	213	MOTION for Leave to Appear Pro Hac Vice *(James C. Grant, Esq.)* by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Attachments: # 1 Text of Proposed Order)(O'Brien, William) (Entered: 04/12/2017)
04/13/2017	214	Joint MOTION Regarding Expert Discovery by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order) (Companion, James) (Entered: 04/13/2017)
04/14/2017	215	ORDER: It is ORDERED that the parties' 214 Joint Motion Regarding Supplemental Expert Discovery is hereby GRANTED and the deposition date of Dr. Bloomfeld be extended through and including 4/23/17. Signed by District Judge Irene M. Keeley on 4/14/17. (cnd) (Entered: 04/14/2017)
04/19/2017	216	CERTIFICATE OF SERVICE by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc *re Plaintiffs' Notice of Deposition of Richard S. Bloomfeld, M.D.* (Companion, James) (Entered: 04/19/2017)
04/27/2017	217	MINUTE ENTRY: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.*** Proceedings held before District Judge Irene M. Keeley. Status Conference held on 4/27/2017. (Court Reporter Cindy Knecht) (dk) (Entered: 04/27/2017)
04/28/2017	218	PHV Filing fee, J. Janusz, D. Mukerjee, L. Soderstrom, J. Grant: $ 800.00, receipt number WVNC001871 (mh) (Entered: 04/28/2017)
05/01/2017	219	ORDER granting James C. Grant's 213 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 5/1/17. (jss) (Entered: 05/01/2017)
05/01/2017	220	ORDER granting Joseph M. Janusz's 210 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 5/1/17. (jss) (Entered: 05/01/2017)
05/01/2017	221	ORDER granting Deepro Mukerjee's 211 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 5/1/17. (jss) (Entered: 05/01/2017)
05/01/2017	222	ORDER granting Lance Soderstrom's 212 Motion for Leave to Appear pro hac vice. Signed by District Judge Irene M. Keeley on 5/1/17. (jss) (Entered: 05/01/2017)
05/04/2017	223	STIPULATION *(Joint)* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals,

		Inc. (Attachments: # 1 Text of Proposed Order)(Companion, James) (Entered: 05/04/2017)
05/04/2017	224	ORDER: The Court Orders that all claims, affirmative defenses and counterclaims in this action as they relate to the Otterbeck patents and Counterclaim patents are hereby dismissed with prejudice. Signed by District Judge Irene M. Keeley on 5/4/17. (jss) (Entered: 05/04/2017)
05/05/2017	225	Other Document *Defendants' Corrected Proposed Findings of Fact and Conclusions of Law* filed by Mylan Pharmaceuticals, Inc., Mylan, Inc.. (Copland, Gordon) (Entered: 05/05/2017)
05/05/2017	226	Other Document *Plaintiffs' Corrected Opening Post-Trial Brief Regarding Infringement of United States Patent Number 8,865,688* filed by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 05/05/2017)
05/09/2017	227	MOTION to Expand Page Limit *(Unopposed)* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order) (Companion, James) (Entered: 05/09/2017)
05/09/2017	228	ORDER granting 227 Unopposed Motion to Expand Page Limit and ORDERS that the parties' closing post-trial briefs are expanded from a 20-page limit to a 25-page limit. Signed by District Judge Irene M. Keeley on 5/9/2017. (kac) (Entered: 05/09/2017)
05/10/2017	229	RESPONSE by Mylan Pharmaceuticals, Inc., Mylan, Inc. to 208 MEMORANDUM, 226 Other Document. (Copland, Gordon) (Entered: 05/10/2017)
05/10/2017	230	*Plaintiffs' Answering Post-Trial Brief Regarding Infringement of U.S. Patent No. 8,865,688* Other Document filed by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Exhibit A)(Companion, James) (Entered: 05/10/2017)
05/19/2017	231	*Letter to Judge Irene M. Keeley re hyperlinked briefs* Other Document filed by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 05/19/2017)
05/19/2017	232	NOTICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. *of Final PTAB Written Decision* (Attachments: # 1 Attachment Final Decision of PTAB) (Copland, Gordon) (Entered: 05/19/2017)
05/24/2017	233	ORDER SCHEDULING STATUS CONFERENCE: The Court SCHEDULES a telephonic status conference for Tuesday, May 30, 2017, at 9:00 A.M. Signed by District Judge Irene M. Keeley on 5/24/17. (jss) (Entered: 05/24/2017)
05/30/2017	234	MINUTE ENTRY: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.***

		Proceedings held before District Judge Irene M. Keeley. Status Conference held on 5/30/2017. (Court Reporter Linda Bachman) (dk) (Entered: 05/30/2017)
05/30/2017	235	PAPERLESS ORDER: For reasons appearing to the Court, the continued bench trial scheduled for 5/31/2017, and 6/1/2017, is CANCELED. Signed by District Judge Irene M. Keeley on 5/30/2017. (dk) (Entered: 05/30/2017)
06/06/2017	236	MOTION to Withdraw *as counsel by Yolonda G. Lambert* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Attachments: # 1 Text of Proposed Order)(Companion, James) (Entered: 06/06/2017)
06/06/2017	237	ORDER: Order granting 236 Motion to For Leave to Withdraw as Counsel and Orders Yolonda G. Lambert is hereby withdrawn as counsel. Signed by District Judge Irene M. Keeley on 6/6/17. (jss) (Entered: 06/06/2017)
06/07/2017	238	STIPULATION *(Joint)* by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 06/07/2017)
06/08/2017	239	TRANSCRIPT of Status Conference Proceedings held on May 30, 2017, before Judge Irene M. Keeley. Court Reporter/Transcriber Linda Bachman, Telephone number (304) 282-0395; Linda_Bachman@wvnd.uscourts.gov. Parties have five business days to file a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript will become available via PACER to the public without redaction after 90 calendar days.. Redaction Request due 6/29/2017. Redacted Transcript Deadline set for 7/10/2017. Release of Transcript Restriction set for 9/6/2017. (llb) (Entered: 06/08/2017)
06/08/2017	240	TRANSCRIPT PURCHASE ORDER by IPD Analytics for proceedings held on May 30, 2017 before Judge Irene M. Keeley. (llb) (Entered: 06/08/2017)
06/08/2017	241	TRANSCRIPT PURCHASE ORDER by Salix Pharmaceuticals, Inc for proceedings held on May 30, 2017 before Judge Irene M. Keeley. (llb) (Entered: 06/08/2017)
06/09/2017	242	TRANSCRIPT PURCHASE ORDER by Mylan Pharmaceuticals, Inc., Mylan, Inc. for proceedings held on May 30, 2017 before Judge Irene M. Keeley. (llb) (Entered: 06/09/2017)
06/22/2017	243	Proposed Order by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 06/22/2017)
06/22/2017	244	NOTICE by Mylan Pharmaceuticals, Inc., Mylan, Inc. re 238 Stipulation - *filing of proposed order implementing stipulation* (Attachments: # 1 Text of Proposed Order (proposed order by Mylan))(Copland, Gordon) (Entered: 06/22/2017)
06/23/2017	245	*Plaintiffs' Response to Mylan's Notice of Submission of Proposed Order* Other Document filed by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. (Companion, James) (Entered: 06/23/2017)

06/27/2017	246	ORDER SCHEDULING STATUS CONFERENCE: It is ORDERED that the Court SCHEDULES a Status Conference by telephone for 6/30/2017 at 03:00 PM. Signed by District Judge Irene M. Keeley on 6/27/17. (cnd) (Entered: 06/27/2017)
06/30/2017	247	NOTICE of Appearance by Shawn A. Morgan on behalf of All Defendants (Morgan, Shawn) (Entered: 06/30/2017)
06/30/2017	248	MINUTE ENTRY: ******NOTICE*** THE ATTACHED DOCUMENT IS NOT ACCESSIBLE. IT IS FOR STATISTICAL PURPOSES ONLY.*** Proceedings held before District Judge Irene M. Keeley. Status Conference held on 6/30/2017. (Court Reporter FTR Gold cbg keeley salix v mylan 1 15 cv 109 6 30 2017.) (dk) (Entered: 06/30/2017)
07/10/2017	249	ORDER IMPLEMENTING JOINT STIPULATION: The Court ORDERS as follows: With respect to the product described in the MPI Apriso ANDA, any and all claims by Plaintiffs alleging infringement of claim 2 of the 688 patent are DISMISSED WITH PREJUDICE; Except for the limited purpose of maintaining jurisdictionover MPIs invalidity counterclaims in order to enter a consent judgment based on the PTABs Determination respecting the invalidity of claim 1 of the 688 patent, and consistent with the provisions of paragraph 3 below, Mylans affirmative defenses and counterclaims of invalidity with respect to the688 patent are DISMISSED WITH PREJUDICE; Should the United States Court of Appeals for the Federal Circuit affirm the PTABs Determination regarding claim 1 of the 688 patent, or in the event there is no appeal from the PTABs Determination, the Court will enter a final consent judgment in this action in Mylans favor as to the invalidity of claim 1 of the 688 patent; and Each party shall bear its own attorneys fees and costs relating to these issues. Signed by District Judge Irene M. Keeley on 7/10/17. (jss) (Entered: 07/10/2017)
07/19/2017	250	Corporate Disclosure Statement by Mylan Pharmaceuticals, Inc., Mylan, Inc. identifying Corporate Parent Mylan N.V. for Mylan Pharmaceuticals, Inc., Mylan, Inc... (O'Brien, William) (Entered: 07/19/2017)
07/31/2017	251	TRANSCRIPT of Status Hearing Proceedings held on June 30, 2017, before Judge Irene M. Keeley. Court Reporter/Transcriber Linda Bachman, Telephone number (304) 282-0395; Linda_Bachman@wvnd.uscourts.gov. Tape Number: FTR Gold. Parties have five business days to file a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript will become available via PACER to the public without redaction after 90 calendar days.. Redaction Request due 8/21/2017. Redacted Transcript Deadline set for 8/31/2017. Release of Transcript Restriction set for 10/30/2017. (llb) (Entered: 07/31/2017)
07/31/2017	252	TRANSCRIPT PURCHASE ORDER for proceedings held on June 30, 2017 before Judge Irene M. Keeley. (llb) (Entered: 07/31/2017)

07/31/2017	253	TRANSCRIPT PURCHASE ORDER by Mylan Pharmaceuticals, Inc., Mylan, Inc. for proceedings held on June 30, 2017 before Judge Irene M. Keeley. (llb) (Entered: 07/31/2017)
07/31/2017	254	TRANSCRIPT PURCHASE ORDER by Salix Pharmaceuticals, Inc for proceedings held on June 30, 2017 before Judge Irene M. Keeley. (llb) (Entered: 07/31/2017)
09/12/2017	255	FINDINGS OF FACT AND CONCLUSIONS OF LAW GRANTING JUDGMENT IN FAVOR OF THE DEFENDANTS. The plaintiffs have not carried their burden to prove by a preponderance of the evidence that Mylans ANDA product will infringe each element of claim 1 of the 688 Patent either directly or indirectly. The Court DIRECTS the Clerk to transmit copies of this Order to counsel of record, to enter a separate judgment order, and to terminate as moot the pending motions (Dkt. Nos. 163 ; 166). Signed by District Judge Irene M. Keeley on 9/12/17. (jss) (Entered: 09/12/2017)
09/12/2017	256	JUDGMENT in favor of Mylan Pharmaceuticals, Inc. and Mylan, Inc. against Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. Signed by Clerk of Court on 9/12/17. (jss) Modified on 9/13/2017 to correct signature (jss). (Entered: 09/12/2017)
09/12/2017	257	REPORT to USPTO on the filing or determination of an action regarding a Patent or Trademark. (jss) (Entered: 09/12/2017)
09/27/2017	258	NOTICE OF APPEAL as to 256 Judgment, 255 Sealed Motion,, Findings of Fact & Conclusions of Law, Order Dismissing Case,,,,,,,, by Dr. Falk Pharma GmbH, Salix Pharmaceuticals, Inc. Filing fee $; 505, receipt number 0424-2435022. (Companion, James) (Entered: 09/27/2017)
09/27/2017	259	Transmission of Notice of Appeal and Docket Sheet to US Court of Appeals re 258 Notice of Appeal. (jss) (Entered: 09/27/2017)
09/28/2017	260	NOTICE OF DOCKET CORRECTION re 258 Notice of Appeal. This notice of appeal was to be filed in the United States Court of Appeals for the Federal Circuit. Attorney was advised to filed Appeal directly with the United States Court of Appeals for the Federal Circuit. (jss) (Entered: 09/28/2017)

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

SALIX PHARMACEUTICALS, INC.;
and DR. FALK PHARMA GmbH,

Plaintiffs,

v. **CIVIL ACTION NO. 1:15CV109**
(Judge Keeley)

MYLAN PHARMACEUTICALS, INC.;
and MYLAN, INC.,

Defendants.

FINDINGS OF FACT AND CONCLUSIONS OF LAW GRANTING JUDGMENT IN FAVOR OF THE DEFENDANTS

I. INTRODUCTION

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 ("Hatch-Waxman Act"), seeks to encourage "pioneering research and development of new drugs," as well as the "production of low-cost, generic copies of those drugs." To that end, a manufacturer may obtain Food and Drug Administration ("FDA") approval to market a generic drug by establishing through an Abbreviated New Drug Application ("ANDA") that its proposed drug is bioequivalent[1] to a pioneering drug approved by the FDA for marketing under a New Drug Application

[1] "Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 314.3(b).

("NDA"). Eli Lilly & Co. v. Teva Pharms. USA, Inc., 557 F.3d 1346, 1348 (Fed. Cir. 2009) (citing 21 U.S.C. § 355(j)(2)(A)).

Before receiving approval, an ANDA applicant must make a certification regarding patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") as covering the NDA drug, and it may certify that they are "invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted" ("paragraph IV certification"). Id. (citing § 355(j)(2)(A)(IV)). Upon receiving a paragraph IV certification, a patentee may sue the applicant for patent infringement within 45 days, thus delaying FDA approval of the ANDA. Id. (citing § 355(j)(5)(B)(iii)).

In this Hatch-Waxman patent-infringement action, the plaintiffs, Salix Pharmaceuticals, Inc. ("Salix"), and Dr. Falk Pharma GmbH ("Dr. Falk"), allege infringement by the defendants, Mylan Pharmaceuticals, Inc. ("MPI"), and Mylan, Inc. (collectively, "Mylan"), of U.S. Patent No. 8,865,688 ("the '688 Patent"), which is associated with the NDA product Apriso®.[2] The Court held a

[2] Initially, seven patents associated with Apriso® were at issue in this case. The parties have since stipulated to the dismissal of all claims, defenses, and counterclaims regarding Patent No. 6,551,620 ("the '620 Patent"), Patent No. 8,337,886 ("the '886 Patent"), Patent No. 8,496,965 ("the '965 Patent") (collectively, "the Otterbeck patents"), Patent No. 8,911,778

three-day bench trial in this matter between March 7 and March 9, 2017 (Dkt. Nos. 186; 188; 191). Now pending are the parties' post-trial proposed findings of fact and conclusions of law regarding the infringement of the '688 Patent (Dkt. Nos. 225; 226).

Pursuant to Fed. R. Civ. P. 52(a), after considering the record and applicable law, the Court makes the following findings of fact and conclusions of law, concluding that the plaintiffs have not met their burden to prove that Mylan has infringed the asserted claim of the '688 Patent.

II. FINDINGS OF FACT[3]

A. The Parties

1. Salix is a corporation organized under the laws of California, having its principal place of business at 8510 Colonnade Center Drive, Raleigh, North Carolina 27615.

("the '778 Patent"), Patent No. 8,940,328 ("the '328 Patent"), and Patent No. 8,956,647 ("the '647 Patent") (collectively, "the Counterclaim patents") (Dkt. No. 224). They have also stipulated to the dismissal of all claims alleging infringement of claim 2 of the '688 Patent, as well as Mylan's affirmative defenses and counterclaims of invalidity with respect to claims 1 and 2 of the '688 Patent (Dkt. No. 249).

[3] Unless otherwise noted, these findings of fact are taken from the parties' joint stipulation of facts (Dkt. No. 172). Findings of fact regarding matters in dispute are contained in Part III (Discussion and Conclusions of Law), and are preceded by phrases such as "the Court finds" or "the Court concludes."

2. Salix is a wholly-owned subsidiary of Salix Pharmaceuticals, Ltd., which was acquired by Valeant Pharmaceuticals International, an indirect, wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc., on April 1, 2015.

3. Dr. Falk is a German corporation having its principal place of business at Leinenweberstr. 5, 79108 Freiburg im Breisgau, Germany.

4. MPI is a corporation organized under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

5. Mylan Inc. is a corporation organized under the laws of Pennsylvania, having a place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania.

6. The Court has subject matter and personal jurisdiction over each of the parties.

B. Background

7. On October 31, 2008, the FDA approved NDA 22-301 for the manufacture, marketing, and sale of Apriso® in a 375 mg dosage strength, with a single indication for the maintenance of remission of ulcerative colitis in adults.

8. Salix holds NDA 22-301 and has sold Apriso® under NDA 22-301 since its approval by the FDA.

9. By letter dated May 14, 2015, in accordance with 21 U.S.C. § 355(j)(2)(B), MPI notified the plaintiffs that it had filed ANDA 20-7271 seeking FDA approval under the Federal Food, Drug, and Cosmetic Act of the product that is the subject of MPI's ANDA 20-7271 ("Mylan's ANDA product") prior to the expiration of the '688 Patent.

10. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv), MPI's ANDA certifies that the '688 Patent is invalid, unenforceable, and/or not infringed by Mylan's ANDA product.

11. The plaintiffs received MPI's paragraph IV certification letter no earlier than May 15, 2015.

12. Pursuant to 35 U.S.C. § 271, the plaintiffs filed this lawsuit on June 26, 2015, alleging, among other things, that the manufacture, use, sale, offer for sale, or importation of Mylan's ANDA product will infringe the '688 Patent (Dkt. No. 1).

C. The Patent-in-Suit

13. On October 21, 2014, the United States Patent and Trademark Office ("PTO") issued the '688 Patent, which bears the title "Compositions and Methods for Treatment of Bowel Diseases with Granulated Mesalamine."

14. On its face, the '688 Patent lists William Forbes as the inventor. On May 9, 2017, the PTO granted Salix's July 31, 2015,

petition to correct inventorship, adding Lorin Johnson as a co-inventor (Dkt. Nos. 172 at 5; 230-1).

15. Dr. Falk is the owner by assignment of the ‘688 Patent, and Salix is an exclusive licensee of the ‘688 Patent.

16. Salix listed the ‘688 Patent in the Orange Book as covering Apriso®.

17. The Orange Book states that the ‘688 Patent expires on May 1, 2030.

18. The plaintiffs assert that, by filing its ANDA, Mylan has infringed claim 1 of the ‘688 patent:

i. A method of maintaining remission of ulcerative colitis in a subject comprising

ii. administering to the subject a granulated mesalamine formulation comprising four capsules each comprising .375 g of granulated mesalamine once per day in the morning, without food, wherein:

iii. said method maintains remission of ulcerative colitis in a subject for a period of at least 6 months of treatment;

iv. remission is defined as a DAI score of 0 or 1;

v. the granulated mesalamine formulation is not administered with antacids; and

vi. wherein 85% to 90% of the mesalamine reaches the terminal ileum and colon.[4]

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[4] Although not subdivided as such in the ‘688 Patent, the parties agree that claim 1 should be divided into these elements.

FINDINGS OF FACT AND CONCLUSIONS OF LAW GRANTING JUDGMENT IN FAVOR OF THE DEFENDANTS

19. The ‘688 Patent specification describes ulcerative colitis as “an idiopathic, chronic relapsing and remitting, non-specific inflammatory disease of the colonic mucosa” (JTX0006-0009 at 1:15-17; Day 1 Tr. 55:18-56:2).

20. It further states that “[t]he mechanism of action of [mesalamine] is unknown, and without wishing to be bound by any particular scientific theory, it appears to be local to the intestinal mucosa rather than systemic” (JTX0006-0014 at 11:49-52).

D. Claim Construction

21. On April 12, 2016, following extensive briefing and a claim construction hearing, the Court issued a Memorandum Opinion and Order Construing Patent Claims (Dkt. No. 117).

22. The Court construed the following claim terms contained within the ‘688 Patent:

- “Remission is defined as a DAI score of 0 or 1" means “remission is defined as a rectal bleeding subscore of 0 and a mucosal subscore of less than 2”;
- “Without food” has its plain and ordinary meaning;
- “Wherein: said method maintains remission of ulcerative colitis in a subject for a period of at least 6 months of treatment” has its plain and ordinary meaning; and

- "Wherein 85% to 90% of the mesalamine reaches the terminal ileum and colon" has its plain and ordinary meaning.

23. The parties did not ask the Court to construe the claim term "granulated mesalamine formulation," nor did they stipulate to its plain and ordinary meaning.

III. DISCUSSION AND CONCLUSIONS OF LAW

A. Legal Standard

"[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). "The patentee bears the burden of proving infringement by a preponderance of the evidence." Creative Compounds, LLC v. Starmark Labs., 651 F.3d 1303, 1314 (Fed. Cir. 2011) (quoting SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1123 (Fed. Cir. 1985)). "An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc) (internal citation omitted). The first step is a question of law,

id. at 979, while the second step is a question of fact. Spectrum Pharms., Inc. v. Sandoz Inc., 802 F.3d 1326, 1337 (Fed. Cir. 2015).

1. Claim Construction

When interpreting the meaning of a claim, a court may consider the claim, the specification, and the prosecution history as intrinsic evidence. Markman, 52 F.3d at 979 (quoting Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). An invention itself, and the scope of a patentee's right of exclusion, will be defined by the patent's claims. See Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)); see also Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention.").

"In construing a claim term, we look at the term's plain and ordinary meaning as understood by a person of ordinary skill in the art." Stryker Corp. v. Zimmer, Inc., 837 F.3d 1268, 1272 (Fed. Cir. 2016) (citing Phillips, 415 F.3d at 1313). "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed

term appears, but in the context of the entire patent, including the specification." Phillips, 415 F.3d at 1312.

Aside from the claims themselves, the specification in the patent often provides the "best source for understanding a technical term." Id. at 1315 (quoting Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998)). "The claims of a patent are always to be read or interpreted in the light of its specifications." Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 217 (1940). A patentee may deviate from the plain and ordinary meaning of a term if she "sets out a definition and acts as her own lexicographer." Stryker Corp., 837 F.3d at 1272. Thus, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Phillips, 415 F.3d at 1316. Nevertheless, the Federal Circuit has "repeatedly warned" against limiting claims to the embodiments specifically described in the specification. Id. at 1323 (citing Gemstar-TV Guide Int'l Inc. v. Int'l Trade Comm'n, 383 F.3d 1352, 1366 (Fed. Cir. 2004)).

In addition, "[l]ike the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." Id. at 1317. Importantly, the inventor's limitation of the invention during the patent's prosecution may

suggest that a claim has a narrower scope than it otherwise might have. Id. Finally, although a court must be cautious when considering extrinsic evidence, such as expert testimony, dictionaries, and learned treatises, such sources may be reliable if they were publicly available and establish "what a person of skill in the art would have understood disputed claim language to mean." Id. at 1314 (quoting Innova, 381 F.3d at 1116).

2. Infringement

Under 35 U.S.C. § 271(e)(2), it is an act of infringement to submit an ANDA "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1354 (Fed. Cir. 2003) (quoting § 271(e)(2)). This creates "a highly artificial act of infringement that consists of submitting an ANDA . . . containing" a paragraph IV certification that erroneously claims a generic drug will not infringe a patent covering the pioneer drug. See Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990).

If a patentee files suit on the basis of such a certification, "the district court determines . . . whether the drug sought to be marketed infringes the claims of that patent." Bristol-Myers Squibb

Co. v. Royce Labs., Inc., 69 F.3d 1130, 1135 (Fed. Cir. 1995). In essence, the patentee is seeking a court determination of whether "if a particular drug were put on the market, it would infringe the relevant patent." Id. "[T]he infringement inquiry focuses on a comparison of the asserted patent claims against the ANDA product that is likely to be sold following FDA approval." Spectrum Pharms., 802 F.3d at 1336 (citing Warner-Lambert Co., 316 F.3d at 1365-66).

B. Person of Ordinary Skill

Determining who constitutes a person of ordinary skill in the art ("POSITA") is a question of fact, see ALZA Corp. v. Andrx Pharms., LLC, 603 F.3d 935, 940 (Fed. Cir. 2010), which has been said to involve a two-step inquiry: "The first part is determining what exactly is that 'relevant art' at issue, the second is determining who qualifies as a 'person of ordinary skill' in that art." Seed Research Equip. Solutions, LLC v. Gary W. Clem, Inc., No. 09-01282-EFM-KGG, 2011 WL 5024351, at *3 (D. Kan. Oct. 20, 2011) (citing Arachnid, Inc. v. Merit Indus., Inc., 201 F. Supp. 2d 883, 888 (N.D. Ill. 2002)).

"Art" is defined simply as "[a] field of useful endeavor." "Relevant art" is the "[a]rt to which one can reasonably be expected to look for a solution to the problem that a patented

device tries to solve." *Art*, Black's Law Dictionary (10th ed. 2014). "The relevant art is defined by the nature of the problem confronting the would-be inventor." Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 716 (Fed. Cir. 1991) (internal quotation omitted). "Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." Daiichi Sankyo Co., Ltd. v. Apotex, Inc., 501 F.3d 1254, 1256 (Fed. Cir. 2007). These factors are exemplary, not exhaustive. Id.

1. The Parties' Contentions

The parties agree that the definition of a POSITA for the '688 Patent includes appropriately experienced physicians (Day 1 Tr. 63:9-64:2; Day 2 Tr. 119:13-18). Indeed, the methods of the '688 Patent will most often be practiced by physicians prescribing medication to their ulcerative colitis patients. The parties dispute, however, whether a POSITA should also include individuals with more specialized training in the development and testing of pharmaceutical formulations, even those without practical experience treating gastrointestinal diseases.

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FINDINGS OF FACT AND CONCLUSIONS OF LAW GRANTING JUDGMENT IN FAVOR OF THE DEFENDANTS

The plaintiffs' expert clinician, Dr. Alan V. Safdi, expressed the following opinion:

> My opinion is you need a physician or a clinician with a medical degree, and they have to have significant experience treating or prescribing to treat patients suffering from ulcerative colitis, whether in the acute phases or when they are in remission, as well as all of the other implications, because it is not just a colon disease. It can involve joints, eyes, skin, a variety of different areas. So, it is so important for the person to have experience in that field.
>
> It may include, in addition - and would have to be in addition - somebody with a pharmacy background if the doctor needs somebody to explain the pharmacokinetic studies.

(Day 1 Tr. 63:14-24). Dr. Safdi envisioned a team approach, in which a "pharmacist or a PhD. in pharmacy" with "practical experience" may need to help physicians conceptualize treatment of the disease (Day 1 Tr. 64:6-24). He also testified that a pharmaceutical formulator would "almost invariably" fall outside the definition "[u]nless they have experience in regards to treating and monitoring patients with ulcerative colitis" (Day 1 Tr. 65:7-14).

With these qualifications, the plaintiffs ask that the Court find a POSITA to be:

> A clinician with a medical degree with experience diagnosing, treating, and/or prescribing medication to treat patients suffering from ulcerative colitis, and similar diseases and conditions at the time of the

> invention. The [POSITA] may also include individuals who have an advanced degree in medicine, pharmacy, pharmaceutics, or a related field [(]e.g., chemistry, biochemistry, pharmacokinetics/pharmacodynamics) with practical experience associated with ulcerative colitis.

(Dkt. No. 226 at 11).

Mylan disagrees that non-clinicians may only complement the knowledge of a physician; it argues that clinicians are not knowledgeable concerning how to make the granulated mesalamine formulations disclosed in the '688 Patent (Dkt. No. 225 at 22). Mylan thus proposes the following POSITA definition regarding the granulated mesalamine formulation:

> [P]ersons of ordinary skill in the art would include individuals with at least three to five years of experience in pharmaceutics and related sciences, and be knowledgeable about, and have experience in, physical chemistry or analytical chemistry techniques as they relate to pharmaceutical formulations.

Id. This definition was originally proposed by one of Mylan's experts with regard to the '620 Patent, an Apriso® Orange Book patent disclosing a pellet formulation for treatment of the intestinal tract, which was incorporated by reference into the '688 Patent (Day 2 Tr. 120:19-121:22).

2. The Court's Definition

The invention disclosed in claim 1 of the '688 Patent encompasses a method of maintaining the remission of ulcerative

colitis by administering a particular formulation - a granulated mesalamine formulation - in a particular manner (JTX0006-0025 at 34:10-22). That physicians are the envisioned practitioners of this method does not necessarily lead to the conclusion urged by the plaintiffs that the relevant art should be confined to medicine and the primary POSITA must be a medical doctor (Dkt. No. 226 at 11). A review of the inventors, other active workers in the field, the type of problems encountered in the art, and the subject matter of the '688 Patent itself demonstrates that the relevant art includes both medicine and the pharmaceutical sciences, and thus that a POSITA necessarily includes both experienced physicians and those with training in pharmaceutical formulations.

Tellingly, neither of the inventors credited with devising the methods of the '688 Patent is a physician. See Daiichi Sankyo, 501 F.3d at 1256. Co-inventor William Forbes, Ph.D., received his doctorate in pharmacy from Creighton University and, for a number of years, conducted development activities related to cardiology. In 2005, after he had some experience in gastroenterology, Salix hired Dr. Forbes as its vice president of research and development. The company's work on Apriso® was ongoing at that time, and Dr. Forbes's role included designing studies, enrolling studies, and working with the FDA (Day 2 Tr. 79:23-82:22). Co-inventor Lorin

Johnson, Ph.D., received his doctorate in molecular biology from the University of Southern California in 1976 and began his career in academia (Day 3 Tr. 6:1-2). In 1983, Dr. Johnson entered the biotechnical industry, and co-founded Salix in November 1989 (Day 3 Tr. 6:3-7:4).

Further, it is clear that other professionals conducting work related to the '688 Patent and its subject matter were not physicians. At trial, the plaintiffs offered the testimony of Dr. Roland Greinwald, the head of research and development at Dr. Falk since 2000 (Day 2 Tr. 177:5-18). Dr. Greinwald holds a doctorate in pharmaceutical biology and began working for Dr. Falk in 1993 as a clinical project manager (Day 2 Tr. 178:6-17). He is not a physician and has never treated patients (Day 2 Tr. 209:16-210:6). Nonetheless, Dr. Greinwald has coauthored several studies comparing the transit and release of mesalamine pellets and mesalamine tablets in healthy male volunteers, as well as the dosage forms' efficacy to treat active ulcerative colitis (PTX0096; PTX0214).[5]

[5] Moreover, Dr. Forbes is the signatory for a number of Salix's clinical studies related to Apriso® and the '688 Patent (PTX0224; PTX0226; PTX0227). The investigator for one of these studies was also a doctor of pharmacy rather than medicine (PTX0224-0002).

The type of problems encountered in the art also indicates the necessity of a non-physician POSITA. The '688 Patent identifies a specific objective: in order to effectively maintain remission of ulcerative colitis, orally administered meslamine compounds must deliver "the intact molecule to the colonic mucosa without breakdown during digestion" (JTX0006-0009 at 1:60-62). According to the patent, other existing oral mesalamine treatments exhibit shortcomings with regard to this goal, "including premature release, the possibility of dose dumping, and sensitivity to conditions that increase gastric pH and cause premature release of mesalamine (e.g., ingestion of a meal)" (JTX0006-0009 at 1:62-2:8). The challenges associated with delivery of mesalamine to the colon, while undoubtedly of concern to physicians practicing the method of the '688 Patent, are most effectively addressed by professionals with training in pharmaceutical formulations.

This reality is illustrated not only by the inventors' experience, but also by the fact that the '688 Patent itself encompasses "compositions" and incorporates several drug-formulation patents, the contents of which would not be familiar to clinicians.[6] Under the description heading "Granulated Mesalamine

[6] Although plaintiffs' expert Dr. Martin C. Davies opined that the '688 Patent is not directed to a formulator because the patent

Formulation," the '688 Patent states that "[m]esalamine formulations are described in U.S. Pat. No. 6,277,412; 6,551,620 and US Publication 2003/0133983 to Dr. Falk Pharma GmbH. The entire contents of U.S. Pat. No. 6,277,412; 6,551,620 and US Publication 2003/0133983 are expressly incorporated by reference herein" (JTX0006-0013 at 10:47-52). The '620 Patent is entitled "Pellet Formulation for the Treatment of the Intestinal Tract" and describes various manufacturing techniques (JTX0002).

Dr. Safdi, the plaintiffs' physician expert, did not review these specification references in formulating his opinion. He further testified that he is not aware of the differences among various multi-particulate manufacturing techniques (Day 1 Tr. 126:19-25, 128:19-23). Given that a POSITA is presumed to review claim terms in light of the specification, Phillips, 415 F.3d at 1312, the plaintiffs have not demonstrated that Dr. Safdi, although an accomplished gastrointestinal clinician, qualifies as a POSITA with regard to the pharmaceutical formulation at issue.

After considering the parties' arguments and the factors discussed, the Court concludes that the relevant art includes both

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itself does not contain process information or describe how to make a granulated mesalamine formulation (Day 1 Tr. 158:24-159:25), a full understanding of the '688 Patent requires an understanding of the formulation patents incorporated by reference.

the medical treatment of ulcerative colitis, as well as the development of pharmaceutical formulations for that treatment. Thus, a POSITA with respect to the '688 Patent is 1) a medical doctor with specialized experience treating patients with ulcerative colitis or similar gastrointestinal diseases, 2) an individual with an advanced degree in medicine, pharmacy, pharmaceutics, chemistry, biochemistry, pharmacokinetics, or a related field with practical experience associated with ulcerative colitis or similar gastrointestinal diseases, or 3) with regard to formulation aspects of the patent, an individual with an advanced degree in pharmaceutics or related sciences and experience developing or testing pharmaceutical formulations.

3. Expert Witnesses

Under the Court's definition, each of the parties' four expert witnesses is a POSITA qualified to opine on the '688 Patent. See Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1363 (Fed. Cir. 2008) ("[I]t is an abuse of discretion to permit a witness to testify as an expert on the issues of noninfringement . . . unless that witness is qualified as an expert in the pertinent art."); Flex-Rest, LLC v. Steelcase, Inc., 455 F.3d 1351, 1360-61 (Fed. Cir. 2006).

FINDINGS OF FACT AND CONCLUSIONS OF LAW GRANTING JUDGMENT IN FAVOR OF THE DEFENDANTS

Plaintiffs' expert witness Dr. Safdi is a practicing gastroenterologist from Cincinnati, Ohio (Day 1 Tr. 40:12-17). Most of his working hours are dedicated to caring for patients with inflammatory bowel diseases, including ulcerative colitis (Day 1 Tr. 43:9-14). Since 1981, however, he also has been heavily involved in clinical research (Day 1 Tr. 40:15-27; 43:15-16). "Quite a few" of the clinical research and clinical projects with which he has been associated have involved mesalamine (Day 1 Tr. 47:7-15). At trial, the Court accepted Dr. Safdi as a clinical expert in gastroenterology and in the treatment of ulcerative colitis and Crohn's disease (Day 1 Tr. 49:16-50:2). Due to his extensive clinical experience with ulcerative colitis, the Court finds that Dr. Safdi is a POSITA.

Plaintiffs' expert witness Dr. Pamela Golden received her Ph.D. in pharmaceutics with an emphasis in pharmacokinetics (Day 1 Tr. 187:23-188:4). She has participated in clinical rotations focused on gastrointestinal diseases, and while she was employed at Salix, she worked with practitioners specializing in ulcerative colitis to design protocols and interpret studies (Day 1 Tr. 188:20-189:9). More particularly, she has "worked on a protocol to assess mesalamine in pediatrics, and also worked on balsalazide, which is the pro-drug of mesalamine," and she "dispensed mesalamine

products during [her] time as a practicing pharmacist" (Day 1 Tr. 188:15-19). At trial, the Court accepted Dr. Golden as an expert in pharmacokinetics with practical experience in the treatment of ulcerative colitis (Day 1 Tr. 189:15-18). Due to her advanced degree in pharmaceutics and experience testing pharmaceutical formulations for the treatment of gastrointestinal diseases, the Court finds that Dr. Golden is a POSITA.

Plaintiffs' expert witness Dr. Martin C. Davies holds a Ph.D. in pharmacy and is a drug formulator focused on the design and characterization of pharmaceutical dosage forms (Day 1 Tr. 145:10-11, 146:14-147:20). Dr. Davies splits his time between private pharmaceutical consultation and his position as a professor at the University of Nottingham in the United Kingdom (Day 1 Tr. 146:8-13). At trial, the Court accepted Dr. Davies as an expert in pharmaceutical formulations and the testing of pharmaceutical dosage forms (Day 1 Tr. 149:3-11). Given his advanced degree in pharmacy and his extensive experience with pharmaceutical formulations, the Court finds that Dr. Davies is a POSITA.

Mylan's expert witness Dr. David Auslander holds a masters degree in pharmaceutics and a Ph.D. in pharmaceutical sciences (Day 2 Tr. 103:14-18). He has extensive experience in the pharmaceutical industry, but limited experience with oral intestinal delivery

systems and no experience with those involving mesalamine (Day 2 Tr. 111:2-112:4). In fact, his experience with oral intestinal delivery systems is limited to the formulation of sulfa drugs in the early 1980s (Day 2 Tr. 148:14-18). The Court accepted Dr. Auslander as an expert in pharmaceutical formulations and drug delivery systems generally, but not as an expert in oral intestinal delivery systems (Day 2 Tr. 113:1-5). Nonetheless, due to his expertise in pharmaceutical formulations, the Court finds that Dr. Auslander is a POSITA.

C. Direct Infringement of the ‘688 Patent

“To establish liability for direct infringement of a claimed method or process . . . a patentee must prove that each and every step of the method or process was performed.” Aristocrat Techs. Australia Pty Ltd. v. Int’l Game Tech., 709 F.3d 1348, 1362 (Fed. Cir. 2013) (citing BMC Res., Inc. v. Paymentech, L.P., 498 F.3d 1373, 1378 (Fed. Cir. 2007)). Direct infringement occurs when “every limitation of the claim is literally met” by the accused product. See Enercon GmbH v. Int’l Trade Comm’n, 151 F.3d 1376, 1384 (Fed. Cir. 1998).

There is no real dispute that the administration of Mylan’s ANDA product in accordance with its package insert will meet most of the elements of claim 1 of the ‘688 Patent (Dkt. No. 226 at 25-

28). Mylan avers that the only “two claim limitations at issue in this action are: (i) ‘wherein 85% to 90% of the mesalamine reaches the terminal ileum and colon;’ and (ii) ‘granulated mesalamine’” (Dkt. No. 225 at 8). For the reasons that follow, the Court concludes that Mylan’s ANDA product meets neither of these limitations when they are properly construed.

1. Disputed Element (ii): “administering to the subject a granulated mesalamine formulation comprising four capsules each comprising 0.375 g of granulated mesalamine once per day in the morning, without food, wherein:”

The parties dispute whether Mylan’s ANDA product meets the “granulated mesalamine formulation” limitation (“GMF limitation”) because they disagree concerning its construction. Although neither party sought a construction of the term before the bench trial in this case, that fact does not foreclose the Court from sua sponte construing the limitation prior to comparing Mylan’s ANDA product to claim 1 of the ‘688 Patent. See Conoco, Inc. v. Energy & Envtl. Int’l, L.C., 460 F.3d 1349, 1359 (Fed. Cir. 2006).[7] The Court concludes that the GMF limitation requires a granulation process

[7] Neither party waived the right to claim construction, as it was clear during expert discovery and prior to trial that the meaning of the GMF limitation was in dispute. See Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1360 (Fed. Cir. 2004).

and that, because Mylan's ANDA product is never granulated, it cannot infringe the '688 Patent.

a. Claim Construction

Although sometimes easily ascertained from "the widely accepted meaning of commonly understood words," many claim terms carry a meaning in the relevant art that "is often not immediately apparent" to lay judges. Phillips, 415 F.3d at 1314. The first place to which a court should look for guidance is the claims themselves, which in some cases "provide substantial guidance as to the meaning of particular claim terms" through context and usage. Id. at 1314-15. The claims of the '688 Patent, however, provide no such help regarding the technical meaning of the GMF limitation.

Nonetheless, the claims stand as part of "a fully integrated written instrument" and "must be read in view of the specification, of which they are a part." Id. at 1315 (emphasis added). The '688 Patent specification itself is somewhat inconsistent with its usage of the GMF limitation. Throughout the examples, the patent equates "mesalamine granules" with a "granulated mesalamine formulation" and often uses the terms interchangeably (JTX0006-0015 at 14:58-61; JTX0006-0021). Elsewhere, it refers to "pellets of the granulated mesalamine formulation" (JTX0006-0013 at 9:52). One thing is clear, however: a "granulated" formulation of mesalamine is distinct from

a "non-granulated" formulation. One express purpose of administering a granulated formulation is to address instances where treatment with a "non-granulated . . . mesalamine formulation" has failed (JTX0006-0010 at 3:3-8).

Under the heading "Granulated Mesalamine Formulation," the '688 Patent explains:

> Mesalamine formulations are described in U.S. Pat. No. 6,277,412; 6,551,620 and US Publication 2003/0133983 to Dr. Falk Pharma GmbH. The entire contents of U.S. Pat. No. 6,277,412; 6,551,620 and US Publication 2003/0133983 are expressly incorporated by reference herein.

(JTX0006-00013 at 10:48-52). The '620 Patent discloses "[a]n orally administerable pharmaceutical pellet formulation for the treatment of the intestinal tract" (JTX0002-0001). The pellet formulation, which includes mesalamine in a polymer matrix, "can be prepared according conventional processes known to the person skilled in the art" (JTX0002-0006 to 0007 at 4:66-5:1). By way of example, the '620 patent describes a pellet core made by mixing, moistening, kneading, extruding, and spheronizing the necessary ingredients (JTX0002-0007 at 5:40-65).

After incorporating the '620 Patent, the '688 Patent goes on to describe several embodiments of the GMF limitation:

> In one embodiment, each granulated mesalamine formulation capsule contains, for example, granules composed of

> mesalamine in a polymer matrix with an enteric coating that dissolves at pH 6 and above.
>
> . . .
>
> Formulations of granulated mesalamine useful in the methods disclosed herein comprise, for example, granulated mesalmine with a pH dependant coating that dissolves at pH 6 or greater, reached in the terminal ileum and colon, and a polymer matrix core which distributes the mesalamine uniformly throughout the lumen of the terminal ileum and colon.

(JTX0006-0013 to 0014 at 10:63-67, 11:26-32).

At trial, the parties utilized expert testimony to elucidate the particular meaning of the GMF limitation and these passages. Dr. Safdi opined that, to a physician, the plain and ordinary meaning of "granulated mesalamine formulation" is merely "small particles, beads, pellets, granules of a mesalamine formulation," to the exclusion of solid tablets (Day 1 Tr. 87:21-25, 89:8-11). According to him, a physician thus would not distinguish between terms such as "granule" or "pellet," nor would one understand the term "granulated mesalamine formulation" to require a particular manufacturing process (Day 1 Tr. 89:21-25).

The interchangeable nature of words such as "granulated" and "granule" and "pellet" in Dr. Safdi's professional vocabulary sheds some light on the '688 Patent's oscillation between "mesalamine granules" and "granulated mesalamine formulation." It does not,

however, clarify the specification's reference to "pellets of the granulated mesalamine formulation." Under Dr. Safdi's interpretation, this phrase might also redundantly read "granules of the granulated mesalamine formulation."

Critically, however, Dr. Safdi did not review the incorporated patents and publications that describe "mesalamine formulations." He did not ask to see the manufacturing process described in Mylan's ANDA, in part because he cannot distinguish how pellets, beads, or granules are manufactured (Day 1 Tr. 126:19-25, 127:6-17, 128:19-23). In other words, the plain and ordinary meaning that Dr. Safdi assigns to "granulated mesalamine formulation" is based almost entirely on the claim term and fails to consider the specification's description of mesalamine formulations.

Given "the importance of the specification in claim construction" and that "[t]he best source for understanding a technical term is the specification from which it arose," Phillips, 415 F.3d at 1312 (alteration in original), the Court finds that Dr. Safdi's testimony in this regard is entitled to little weight.[8]

[8] In addition, the Court gives little weight to co-inventor Dr. Johnson's similar testimony that he uses the terms pellets, granules, and beads interchangeably (Day 3 Tr. 19:4-10). See Howmedica Osteonics Corp. v. Wright Med. Tech., Inc., 540 F.3d 1337, 1346 (Fed. Cir. 2008) (quoting Markman, 52 F.3d at 985) ("[W]e have explained that '[t]he subjective intent of the inventor

Therefore, it is necessary to consider the conflicting positions of the parties' pharmaceutical experts, Dr. Davies and Dr. Auslander.

Dr. Auslander opined that the claim term "granulated" carries a plain meaning to one skilled in the art of pharmaceutical formulations. It is a verb modifier that requires the mesalamine formulation to be granulated, or to undergo granulation, a specific process in pharmaceutical manufacturing (Day 2 Tr. 116:22-117:2). Granulation is "the agglomeration of smaller particles into larger ones, then those larger particles usually are size reduced to bring it back to a proper particle size distribution so that one could accomplish content uniformity, dissolution behavior and . . . compatibility with very high-speed machinery in the pharmaceutical world" (Day 2 Tr. 122:3-9). According to Dr. Auslander, one cannot know whether a mesalamine formulation is granulated without examining the manufacturing process (Day 2 Tr. 169:14-17).[9] He

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when he used a particular term is of little or no probative weight in determining the scope of a claim.'").

[9] The plaintiffs protest that the manufacturing process is irrelevant because physicians practicing the method of the '688 Patent would not have access to such information (Dkt. No. 226 at 15). The only relevant knowledge requirement in this case, however, is whether Mylan knew that it would induce infringement by those administering its ANDA product, not whether physicians know that they are directly infringing. See Commil USA, LLC v. Cisco Sys., Inc., 135 S.Ct. 1920, 1926 (2015).

further explained that this construction is consistent with the disclosures of the '620 Patent, describing mesalamine formulations, because it contains examples of how to make mesalamine pellets using granulation (Day 2 Tr. 127:10-128:12; JTX0002-0007).

Dr. Davies, on the other hand, testified that the plain and ordinary meaning of "granulated mesalamine formulation" is dictated solely by those patents and publications, including the '620 Patent, that are incorporated by reference in the '688 Patent to describe mesalamine formulations (Day 1 Tr. 163:17-21, 179:12-180:2). According to Dr. Davies, because the '620 Patent does not limit the manner by which its polymer-matrix pellet formulations are manufactured, processes such as suspension layering and granulation both meet the GMF limitation (Day 1 Tr. 164:25-166:2). In essence, Dr. Davies believes that any pellet formulation with mesalamine in a polymer matrix described in the '620 Patent is a "granulated mesalamine formulation" encompassed by claim 1 of the '688 Patent (Day 1 Tr. 182:16-183:8).

Although both formulation experts posit reasonable meanings for the GMF limitation that are supported by their reading of the '620 Patent, the Court is ultimately convinced by Dr. Auslander's testimony because it accounts for the fact that the language of the limitation requires the "mesalamine formulation" to be

"granulated." The patentee could have claimed "granules of mesalamine formulation" or "pellets of mesalamine formulation," thus encompassing all manner of multi-particulate mesalamine formulations, but he did not do so. Instead, he elected to describe the subject formulation as "granulated," a term with special meaning to those in the relevant art.[10]

Moreover, although the plaintiffs argue that Dr. Auslander's interpretation improperly constrains the GMF limitation by using the specification (Dkt. No. 226 at 32), his technical reading of the term is fully supported by the patent's detailed description. In a specification rife with reference to the "granulated mesalamine formulation," the '688 Patent incorporates the '620 Patent only to generally describe "mesalamine formulations" (JTX0006-0013 at 10:48). The plaintiffs argue as if it were so, but the patentee simply did not equate the GMF limitation with all formulations described in the '620 Patent, as his lexicographic license would have allowed. See Stryker Corp., 837 F.3d at 1272 (describing an exception to assigning plain and ordinary meaning

[10] The plaintiffs' repeated assertion that some products such as "granulated sugar" do not undergo a granulation process is of little moment (Dkt. No. 226 at 32). The '688 Patent claims the administration of a pharmaceutical formulation; the relevant question is whether "granulated" has a plain and ordinary meaning in pharmaceutical manufacturing, to the exclusion of other fields.

when "a patentee sets out her own definition"). Indeed, that "mesalamine formulations" are described separately supports the conclusion that "granulated" has a particular plain and ordinary meaning, as Dr. Auslander testified.

Under Dr. Auslander's interpretation, the interchangeable use of "granule" and "pellet," as well as "mesalamine granules" and "granulated mesalamine formulation," remains reasonable. Neither party disputes that multi-particulate systems include pellets, beads, and granules (Day 2 Tr. 160:15-24, 166:21-167:22), or that granulation processes can yield pellets (Day 2 Tr. 166:12-14). In fact, that granulation processes can yield pellets gives the most natural reading to the phrase "pellets of a granulated mesalamine formulation" as used in the '688 Patent specification (JTX0006-0013 at 9:52). Therefore, after a thorough review of the claims, specification, and expert testimony,[11] the Court concludes that the GMF limitation requires a mesalamine formulation that has undergone a granulation process.

b. Mylan's ANDA Product

The undisputed evidence of record establishes that Mylan's ANDA product does not undergo a granulation process and thus cannot

[11] Neither party directed the Court to any substantive discussion of the GMF limitation in the prosecution history.

meet the GMF limitation. Mylan's corporate designee on this issue was Dr. Abhijut Deshmukh, its global head of scientific affairs for the oral solid dosage form business (Day 2 Tr. 30:18-23). Dr. Deshmukh testified that, when Mylan began its development work for a generic version of Apriso® in 2011 (Day 2 Tr. 31:13-17), it experimented with three manufacturing processes: extrusion-spheronization, minitablets, and Würster coating (Day 2 Tr. 32:18-23). Mylan rejected extrusion-spheronization because of the unit operations, equipment, and process control associated with granulating, extruding, spheronizing, drying, and coating (Day 2 Tr. 41:7-16). It rejected a minitablet technique for similar reasons (Day 2 Tr. 42:8-19). Ultimately, Mylan settled on a Würster coating process, by which it sprays "mesalamine, ethyl celluslose, hypromellose dissolved in IPA water" onto sugar spheres, making what Dr. Deshmukh referred to as "drug loaded beads" (Day 2 Tr. 44:19-23).

Both parties' formulation experts corroborated this testimony. Based on information in Mylan's ANDA, Dr. Davies testified that Mylan uses a suspension layering process; it sprays sugar spheres with a solution of mesalamine and polymers, resulting in sugar spheres coated with a polymer matrix (Day 1 Tr. 166:8-13, 168-170). He confirmed this hypothesis by placing Mylan's ANDA product in

various fluids that mimic the pH of the gastrointestinal tract to demonstrate that the pellets are composed of mesalamine in a polymer matrix over sugar spheres, with an enteric coating (Day 1 Tr. 175:17-177:14). Dr. Auslander likewise concluded that the process described in Mylan's ANDA is a Würster coating process - not a granulation process - by which Mylan coats sugar seeds (Day 2 Tr. 129:4-10, 136:9-13, 139:8-14, 140:12-18).[12]

Therefore, the plaintiffs have not proven by a preponderance of the evidence that Mylan's ANDA product undergoes a granulation process. Because the GMF limitation requires such a process, Mylan's ANDA product cannot infringe claim 1 of the '688 Patent.

2. Disputed Element (vi): "wherein 85% to 90% of the mesalamine reaches the terminal ileum and colon."

Claim 1 of the '688 Patent also requires that its method result in "85% to 90% of the mesalamine reach[ing] the terminal ileum and colon" ("the 85% to 90% limitation") (JTX0006-0025 at

[12] Dr. Davies testified that the description of a polymer matrix formulation in the '688 Patent encompasses Mylan's ANDA product because it contains a polymer matrix (Day 1 Tr. 177:19-178:5, 180:15-18), and the plaintiffs extensively cross-examined Dr. Auslander on his contrary conclusion that Mylan's ANDA product is a "reservoir device" (Day 2 Tr. 154:4-157:11; Dkt. No. 226 at 18). Whether Mylan's ANDA product contains a polymer matrix is secondary, however, to whether the product has been granulated as required by the GMF limitation. As Dr. Auslander explained, the polymer-matrix formulations disclosed in the '688 Patent can be prepared using a granulation process (Day 2 Tr. 166:12-20).

34:21-22). The threshold inquiry concerns whether the plaintiffs' uncontroverted POSITA testimony that "85% to 90%" is meant as a lower limit can overcome the fact that the claim is written as an express range. Concluding that the 85% to 90% limitation is not subject to such a construction, the Court further concludes that the plaintiffs have failed to prove by a preponderance of the evidence that Mylan's ANDA product delivers mesalamine within the claimed range, and that they have also failed to prove infringement of the 85% to 90% limitation under the doctrine of equivalents.

a. Claim Construction

In its Memorandum Opinion and Order Construing Patent Claims, the Court adopted the parties' agreed construction of the 85% to 90% limitation and held that the limitation should be given its plain and ordinary meaning (Dkt. No. 117 at 31-32). Nonetheless, the Court is free to revisit this construction, as "district courts may engage in rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves." Conoco, 460 F.3d at 1359. The plaintiffs ask the Court to construe the limitation to mean "85% to 90% is the lower limit of mesalamine delivered to the terminal ileum and colon" (Dkt. No. 230 at 13). Mylan asks the Court to construe it as an exact range (Dkt. No. 225 at 29).

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FINDINGS OF FACT AND CONCLUSIONS OF LAW GRANTING JUDGMENT IN FAVOR OF THE DEFENDANTS

The Court begins, as it must, with the language of the claims themselves. Phillips, 415 F.3d at 1314. On its face, the 85% to 90% limitation plainly provides that an express range of mesalamine in the formulation be delivered to the terminal ileum and colon (JTX0006-0025 at 34:21-22). Although ranges expressed in a claim do not necessarily function as "a strict numerical boundary," avoiding such a "specified parameter" is usually accomplished by the addition of a modifier to the range limitation. See, e.g., Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1310-11 (Fed. Cir. 2003) ("[W]ords of approximation, such as 'generally' and 'substantially,' are descriptive terms commonly used in patent claims to avoid a strict numerical boundary to a specified parameter." (internal quotation omitted)); Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1581 (Fed. Cir. 1995) ("The addition of 'approximately' which means 'reasonably close to,' eliminates the precise lower limit of that range, and, in so doing extends the scope of the range."). On the other hand, "[w]ithout broadening words that ordinarily receive some leeway," a precise range usually cannot avoid being interpreted as a "strict numerical boundary." Jeneric/Pentron, Inc. v. Dillon Co., Inc., 205 F.3d 1377, 1381 (Fed. Cir. 2000). "This . . . is particularly appropriate when

other variables in the same claims explicitly use qualifying language." Id.

Here, although the 85% to 90% limitation contains no qualifying language, claim 1 also discloses that the method of treatment will maintain remission "for a period of at least 6 months of treatment" (JTX0006-0025 at 34:16-17) (emphasis added). The patentee thus used qualifying language in claim 1, but chose not to do so with regard to the 85% to 90% limitation. This drafting decision weighs heavily in favor of construing the 85% to 90% limitation as a closed range of mesalamine delivery. See Jeneric/Pentron, 205 F.3d at 1381.

Moreover, the specification never discusses the 85% to 90% limitation as a threshold of mesalamine delivery. Phillips, 415 F.3d at 1315. For instance, the detailed description states, without qualification, that "[t]he release profile and additional pharmacokinetic data show that the pellets of the granulated mesalamine formulation have a relatively low rate and extent of systemic absorption, and that 85% to 90% of drug reaches the diseased area," the terminal ileum and colon (JTX0006-0013 at 9:50-54). Likewise, excluding the amount of mesalamine released in the terminal ileum (Day 3 Tr. 38:9-15), Example 4 states that "[a]pproximately 80% of an administered oral dose of mesalamine is

estimated to be available in the colon, sigmoid, and rectum when dosed as mesalamine granules" (JTX0006-0016 at 16:65-67). By the plaintiffs own account, "approximately 80%" is meant to account for the "approximately 5%" absorbed in the terminal ileum (Dkt. No. 230 at 8). "Approximately 80%" thus does not lend uncertainty to the 85% to 90% limitation itself, and it certainly does not indicate that the limitation is meant as a threshold.

Nor does the '688 Patent ever suggest that the claimed method's objective is to deliver as much mesalamine to the terminal ileum and colon as possible. Indeed, the problem in the relevant art, "delivery of the intact molecule to the colonic mucosa," appears to involve the proportion of mesalamine that reaches the colon intact, not the total (JTX0006-0009 at 1:60-62). The '688 Patent discloses that the effective daily amount of granulated mesalamine formulation, depending on the embodiment, may be .5 to 4 grams, 1.5 grams, or 3 grams (JTX0006-0009 at 2:40-48; JTX0006-0014 at 12:8-19), and it ultimately leaves the selection of a therapeutically effective dosage to health care professionals (JTX0006-0014 at 12:30-50). The method claimed in the '688 Patent is of a decidedly different character than simply getting as much mesalamine to the terminal ileum and colon as possible.

At trial, however, the plaintiffs offered testimony regarding a much broader meaning for the 85% to 90% limitation than seemingly disclosed by the claims and specification. Dr. Safdi testified that, based on the known variation of gastrointestinal pH, the 85% to 90% limitation is "a lower limit of delivery to the terminal ileum and colon" that accounts for "the normal variability of pH" (Day 1 Tr. 94:21-95:1). He further opined that there would never be an upper limit on mesalamine delivery. A clinician practicing the method of the '688 Patent merely wants to know "that it is a good delivery system" with "the vast majority of drug being available to the terminal ileum, being available to the colon to treat the affected areas" (Day 1 Tr. 97:22-98:4).

Dr. Golden also opined that the plain and ordinary meaning of the 85% to 90% limitation is that at least that much mesalamine reaches the terminal ileum and colon (Day 1 Tr. 190:5-14). According to Dr. Golden, the limitation is expressed as a narrow range that represents only a minimum target of delivery; it is better if more mesalamine reaches the inflamed areas (Day 1 Tr. 191:7-14). Likewise, co-inventor Dr. Johnson testified that the limitation is "a lower limit of what would be expected of this formulation. . . . We would never set an upper limit on a formulation to treat this disease" (Day 3 Tr. 35:2-6). Hoechst

Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1580 (Fed. Cir. 1996) ("[W]e have treated [the inventor's] testimony as cumulative to the other evidence, and as enlarging our understanding of the technology and the usage of the disputed terms."). He further testified that the range was selected after using pharmacokinetic data from Salix's fasted clinical studies with Apriso® to calculate that, on average, 95% of the mesalamine reached the terminal ileum and colon (Day 3 Tr. 38:16-39:8).

Finally, although Mylan relies heavily on its contents to argue prosecution disclaimer, the prosecution history of the '688 Patent provides little support for either parties' interpretation. "[F]or prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakeable." Avid Tech., Inc. v. Harmonic, Inc., 812 F.3d 1040, 1045 (Fed. Cir. 2016) (quoting Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1325-26 (Fed. Cir. 2003)). During prosecution, the examiner rejected what eventually became claim 1 of the '688 Patent for allegedly being anticipated by an article contained in the prior art (JTX0017-0271). In order to overcome the rejection, the patentee added, among other things, the 85% to 90% limitation:

> [T]he Salix article does not teach the additional recited feature that 85% to 90% of mesalamine reaches the terminal ileum and colon. Rather, the Salix article discloses that the administered formulation is a delayed and extended release formulation. The Salix article provides no information for how the drug is distributed throughout the targeted therapeutic region, nor is there any teaching that the drug would specifically be distributed in this manner.

(JTX0017-0301).

The patentee did not include the 85% to 90% limitation in an attempt to distinguish the claim from a specific range in the prior art, as the Salix article did not include such a range. Rather, the alleged disavowal is subject to the "reasonable interpretation[]" that the patentee was only describing the manner in which mesalamine is distributed in the terminal ileum and colon. This description simply does not meet the "exacting standard" for Mylan to establish that there was a "clear and unmistakable disclaimer." Avid Technology, 812 F.3d at 1046; see also Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 978-79 (Fed. Cir. 1999) (finding disavowal of two feed tubes in a beverage dispenser patent because the patentee had distinguished the prior art as involving separate feed tubes). Inclusion of the 85% to 90% limitation alone would not "lead a competitor to believe that the applicant had disavowed coverage" for quantities of mesalamine outside or above that range.

Schwing GmbH v. Putzmeister Aktiengesellschaft, 305 F.3d 1318, 1324 (Fed. Cir. 2002).

Mylan offered no testimony regarding the 85% to 90% limitation, but argues that the Court must disregard the plaintiffs' extrinsic expert evidence as inconsistent with the meaning given to the 85% to 90% limitation by the intrinsic evidence of the claim, specification, and prosecution history (Dkt. No. 229 at 7-9). Indeed, it is black-letter law that, when a construing a disputed claim, courts should focus on such intrinsic evidence. Elkay Mfg., 192 F.3d at 976-77. Informative extrinsic evidence may be used only to the extent that it is not "clearly at odds with the construction mandated by the intrinsic evidence." Id. at 977.

The Court agrees with Mylan that, although a POSITA might understand the 85% to 90% limitation to represent a minimum threshold of mesalamine delivery, the limitation is expressed as a closed range in claim 1 and, at best, an approximation in the specification. Given this inconsistency, the present case is comparable to the circumstances of Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371 (Fed. Cir. 2004). There, the patentee claimed a process that included "heating the resulting batter-coated dough to a temperature in the range of about 400° F. to 850°

F." Id. at 1371. In litigation, the patentee argued that the district court should construe the claim to mean that the dough be heated in an oven at the specified temperature, rather than actually heated to the specified temperature, which would result in the dough being "burned to a crisp." Id. at 1373-74. Both the district court and the Federal Circuit declined to do so, instead finding that the limitation unambiguously required that the dough itself be heated to such high temperatures. Id. at 1374. The Federal Circuit noted that it would "construe the claim as written, not as the patentees wish they had written it." Id.

In doing so, the court disregarded testimony of the patentee's POSITA, who opined that he would read the heating limitation to apply to the oven temperature rather than the dough itself. His opinion was based, in part, on the fact that "[i]t was well known in 1987, and still is well known, that raising the temperature of a dough product itself to such high temperatures would result in an unusable product." Id. at 1375. But he did not explain why a POSITA would view the otherwise unambiguous claim language as having such a "special meaning." The Federal Circuit viewed this testimony as a mere extension of the patentee's argument that the claim essentially should be rewritten so that the process could perform its intended function. Id. at 1375-76.

Similarly, the contentions of Dr. Safdi, Dr. Golden, and Dr. Johnson must be rejected as inconsistent with the plain language of the limitation, as well as the disclosures in the specification. As discussed, each testified that no POSITA would place an upper limit on the amount of mesalamine delivered to the target area, and Dr. Golden further testified that targeting such a small range would be impractical (Day 1 Tr. 191:7-14). It may be true that, in some cases, more mesalamine being delivered to the diseased area will better effectuate maintenance of remission. But none of the POSITA testimony established that closed ranges such as the 85% to 90% limitation are regularly used as lower limits in the relevant art, or that they have that special meaning. Rather, the testimony is but an extension of the plaintiffs' argument that the 85% to 90% limitation should be construed to mean "at least 85%" or "85% to 100%," rather than the plain language of the claim itself. See Chef America, 358 F.3d at 1374.

The unambiguous language of the '688 Patent calls for the conclusion that the 85% to 90% limitation means exactly what it says, regardless of how the plaintiffs wish they had drafted it. See id.; see also Ecolab, Inc. v. FMC Corp., 569 F.3d 1335, 1345 (Fed. Cir. 2009) (distinguishing Chef America in a case that involved ambiguous language susceptible to more than one reasonable

construction). The Court will "not replace [a] claim term with a different term, but instead interprets the claimed" range in light of the claims and specification. Wellman, Inc. v. Eastman Chem. Co., 642 F.3d 1355, 1367 (Fed. Cir. 2011). Therefore, it concludes that the 85% to 90% limitation is an express range of mesalamine delivery, not a minimum threshold as the plaintiffs contend.

b. Mylan's ANDA Product

The plaintiffs have failed to prove by a preponderance of the evidence that Mylan's ANDA product meets the 85% to 90% limitation when properly construed as a closed range. Indeed, both of the plaintiffs' experts testified that more than 90% of the mesalmine in Mylan's ANDA product will reach the terminal ileum and colon. Dr. Safdi opined that, because small bowel transit ranges from 84 to 180 minutes, the fact that Mylan's pharmacokinetic studies resulted in a maximum plasma concentration of mesalamine after five hours means that "at least 85 to 90 percent of [the mesalamine] is going to be within the colon" (Day 1 Tr. 107:13-108:25). In fact, Dr. Safdi testified that the amount of mesalamine in the colon would "probably exceed[]" 85% to 90% (Day 1 Tr. 109:4-5). Likewise, using mean plasma concentration data from Mylan's ANDA, Dr. Golden

calculated that 94% of the mesalamine in Mylan's ANDA product reaches the terminal ileum and colon (Day 1 Tr. 202:22-25).[13]

Both Dr. Safdi's and Dr. Golden's testimony establish that the amount of mesalamine delivered by Mylan's ANDA product falls well outside the narrowly claimed range. Mylan's ANDA product thus cannot literally infringe the 85% to 90% limitation.

c. Doctrine of Equivalents

In the alternative, the plaintiffs argue that they have met their burden of proof under the doctrine of equivalents (Dkt. No. 226 at 38). "Even when an accused product does not meet each and every claim element literally, it may nevertheless be found to infringe the claim if there is equivalence between the elements of the accused product or process and the claimed elements of the patented invention." Intendis GMBH v. Glenmark Pharms., Inc., USA, 822 F.3d 1355, 1360 (Fed. Cir. 2016) (quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997) (internal quotation omitted). "A finding of infringement under the doctrine of equivalents requires a showing that the difference between the claimed invention and the accused product was insubstantial." Crown

[13] As the plaintiffs do not argue that the 85% to 90% limitation is approximate, they do not argue that this calculation falls within the possible meaning of "approximately 80%" of the mesalamine being available to the colon.

Packaging Tech., Inc. v. Rexam Beverage Can Co., 559 F.3d 1308, 1312 (Fed. Cir. 2009) (citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950)).

"One way of doing so is by showing on a limitation by limitation basis that the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product," often referred to as the "function-way-result test." Id. Notably, "the doctrine . . . must be applied to individual elements of the claim, not to the invention as a whole." Warner-Jenkinson Co., 520 U.S. at 29.

That the 85% to 90% limitation is a specific numeric range does not foreclose the plaintiffs' reliance on the doctrine of equivalents. Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283, 1291-92 (Fed. Cir. 2010) (citing Abbott Labs. v. Dey, L.P., 287 F.3d 1097, 1107-08 (Fed. Cir. 2002)) (collecting cases). Moreover, ranges need not be associated with "words of approximation . . to enable application of the doctrine of equivalents." Id. at 1293. The proper inquiry is a question of fact: "whether the accused value is insubstantially different from the claimed value." Id. ("[A] reasonable factfinder could conclude

that an AUC value of 3493.38 hr*ng/mL is insubstantially different from . . . 3500 hr*ng/mL.").

Numeric range limitations may be met by an equivalent outside the claimed range if the equivalent accomplishes the same purpose as the claimed range. In Abbott Labs., the patents at issue "relate[d] to a lung surfactant composition for treating respiratory distress syndrome in premature babies," including "a surfactant having the desirable properties of rapid spreading in the lungs and of reducing ultra-alveolar surface tension." 287 F.3d at 1099. The Federal Circuit allowed the doctrine of equivalents to be applied to a claim requiring 68.8% to 94.5% of the composition to be a phospholipid because expert testimony demonstrated that quantities of phospholipid above 94.5% but below 100% "would be exactly the same." Critically, the court noted that the expansion did not entirely eliminate the upper limit. Id. at 1107-08.

Here, the plaintiffs argue that the difference between the 85% to 90% limitation and Dr. Golden's 94% calculation is insubstantial because "enough mesalamine reaches the terminal ileum and colon to achieve the intended purpose of maintaining remission of ulcerative colitis" (Dkt. No. 226 at 39). But according to the plaintiffs' expert testimony, the delivery of between 90% and 100% of mesalamine to the target area is by no means "insubstantially

different" from the claimed range of 85% to 90%. Dr. Safdi testified that "[i]n clinical practice, you would never have a ceiling on delivery. If it is 92 percent, it is better. We have more drug available to the mucosa to treat the disease" (Day 1 Tr. 95:2-10). He merely wants to see "the vast majority of drug being available" (Day 1 Tr. 97:22-98:4). Dr. Golden and Dr. Johnson similarly testified that the range represents a lower limit because more mesalamine delivery is better (Day 1 Tr. 191:5-14; Day 3 Tr. 35:2-6).

The Court finds that 94% is substantially different from the 85% to 90% limitation because the plaintiffs' proposition that more mesalamine is better simply does not demonstrate an "insubstantial difference." Rather, it actually establishes that amounts of mesalamine outside the claimed range have a different and "better" character. Had the patentee wished to encompass meslamine delivery between 85% and 100%, he could have done so. To extend the range as the plaintiffs suggest would render the upper limit meaningless and vitiate the claimed range entirely.[14] See Akzo Nobel Coatings, Inc. v. Dow Chem. Co., 811 F.3d 1334, 1342 (Fed. Cir. 2016) (quoting

[14] Indeed, under the plaintiffs' logic, any five-percent range that qualifies as a "vast majority" could have been claimed in the patent and met by an actual delivery amount up to 100%.

Brilliant Instruments, Inc. v. GuideTech, LLC, 707 F.3d 1342, 1347 (Fed. Cir. 2013)) ("[S]aying that a claim element would be vitiated is akin to saying that there is no equivalent to the claim element in the accused devise based on the well-established . . . 'insubstantial differences' test[]."); Carnegie Mellon Univ. v. Hoffmann-La Roche Inc., 541 F.3d 1115, 1129 (Fed. Cir. 2008) (finding that a bacterial source was not equivalent because substituting that source for the specifically claimed source would render the claim's selection meaningless). Therefore, Mylan's ANDA product does not infringe the '688 Patent under the doctrine of equivalents.[15]

d. The Preferred Embodiment

The plaintiffs argue that such a result demonstrates the Court's claim construction is erroneous, as it excludes the preferred embodiment. Using data from Apriso® clinical studies, Dr. Golden calculated that, on average, 97% of its mesalamine reaches the terminal ileum and colon when administered using the method of the '688 Patent (Dkt. No. 230 at 15). Setting aside Mylan's challenge to the validity of Dr. Golden's methods (Dkt. No. 225 at

[15] Given its conclusion under the "insubstantial differences" test, the Court need not reach Mylan's alternative argument that prosecution history estoppel forecloses application of the doctrine of equivalents (Dkt. No. 229 at 13).

33-36), her 97% calculation obviously places Apriso® well above the 85% to 90% limitation.

Indeed, "[a] claim construction that excludes the preferred embodiment 'is rarely, if ever, correct and would require highly persuasive evidentiary support.'" Adams Respiratory, 616 F.3d at 1290 (quoting Vitronics Corp. v. Conceptronic Inc., 90 F.3d 1576, 1583-84 (Fed. Cir. 1996)). But the Federal Circuit's warning in this regard is confined to the specification's description of a preferred embodiment, not a commercial manifestation. See, e.g., Kaneka Corp. v. Xiamen Kingdomway Grp. Co., 790 F.3d 1298, 1304 (Fed. Cir. 2015); Nellcor Puritan Bennett, Inc. v. Masimo Corp., 402 F.3d 1364, 1368 (Fed. Cir. 2005) ("[C]onstruing the term 'filtered' to require removal of the aperiodic noise would have the effect of excluding all the embodiments described in the specification."); Pfizer, Inc. v. Teva Pharms., USA, Inc., 429 F.3d 1364, 1374 (Fed. Cir. 2005); Vitronics Corp., 90 F.3d at 1583.

The plaintiffs do not argue that the Court's construction is inconsistent with the '688 Patent's description of the preferred embodiment, and the Court has taken into account matters contained within the specification regarding the 85% to 90% limitation. Therefore, Dr. Golden's extrinsic calculations regarding Apriso® are simply irrelevant to the Court's claim construction.

D. Indirect Infringement of the '688 Patent

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). A necessary prerequisite for induced infringement is the existence of direct infringement. Limelight Networks, Inc. V. Akamai Techs., Inc., 134 S.Ct. 2111, 2117 (2014). "[T]he sale of a product specifically labeled for use in a patented method constitutes inducement to infringe that patent." Eli Lilly & Co. v. Actavis Elizabeth LLC, 435 F. App'x 917, 926 (Fed. Cir. 2011) (unpublished decision) (citing AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1060 (Fed. Cir. 2010); DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1305-06 (Fed. Cir. 2006)). Because the plaintiffs have not proven that the administration of Mylan's ANDA product will directly infringe the GMF or 85% to 90% limitations, they likewise cannot prove that Mylan will induce infringement of the '688 Patent.

E. Costs

Mylan argues that this is an exceptional case for which it should be awarded costs under 35 U.S.C. § 285 (Dkt. No. 225 at 39-40). Indeed, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. The Supreme Court has held "that an 'exceptional' case is simply one that stands out from others with respect to the substantive

strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S.Ct. 1749, 1756 (2014). Awarding attorney fees is within the discretion district courts after "considering the totality of the circumstances" in a case. Id.

Having reviewed the totality of the circumstances in this case, the Court concludes that the plaintiffs' position is not so weak, nor their litigation strategy so unreasonable, that it stands out from others. See id. Mylan's main contention is that, had the plaintiffs reviewed its ANDA prior to filing suit, they would have discovered that Mylan's ANDA product meets neither the GMF nor 85% to 90% limitations (Dkt. No. 225 at 40). Although the Court was not convinced by the plaintiffs' arguments in this litigation, their positions certainly have not been "exceptionally meritless." Octane Fitness, 134 S.Ct. at 1757. Therefore, the Court denies Mylan's request for an award under 35 U.S.C. § 285.

IV. CONCLUSION

For the reasons discussed, the plaintiffs have not carried their burden to prove by a preponderance of the evidence that Mylan's ANDA product will infringe each element of claim 1 of the '688 Patent either directly or indirectly. Creative Compounds, LLC,

651 F.3d at 1314. Therefore, the paragraph IV certification regarding the '688 Patent in Mylan's ANDA is correct, and there is no impediment under 21 U.S.C. § 355(j)(5)(B)(iii) to FDA approval.

It is so **ORDERED**.

The Court **DIRECTS** the Clerk to transmit copies of this Order to counsel of record, to enter a separate judgment order, and to terminate as moot the pending motions (Dkt. Nos. 163; 166).

DATED: September 12, 2017.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT

for the

Northern District of West Virginia

SALIX PHARMACEUTICALS, INC., et al

Plaintiff(s)

v.

MYLAND PHARMACEUTICALS, INC., et al

Civil Action No. 1:15CV109

Defendant(s)

JUDGMENT IN A CIVIL ACTION

The court has ordered that:

☐ Judgment award ☐ Judgment costs ☐ Other

This action was:

☐ tried by jury ☐ tried by judge ☒ decided by judge

decided by Judge Irene M. Keeley

The plaintiffs have not carried their burden to prove by a preponderance of the evidence that Mylan's ANDA product will infringe each element of claim 1 of the '688 Patent either directly or indirectly. Creative Compounds, LLC, 651 F.3d at 1314. Therefore, the paragraph IV certification regarding the '688 Patent in Mylan's ANDA is correct, and there is no impediment under 21 U.S.C. § 355(j)(5)(B)(iii) to FDA approval.

Date: September 12, 2017

CLERK OF COURT

Cheryl Dean Riley

by: Julie Schoonover, Deputy Clerk

Signature of Clerk or Deputy Clerk