IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

AMGEN INC. and AMGEN MANUFACTURING LIMITED, Plaintiffs, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., MYLAN GMBH and MYLAN N.V., Defendants.	)	Civil Action No. 2:17-cv-01235-MRH Judge Mark R. Hornak ***Electronically Filed***

JOINT MOTION FOR A STATUS CONFERENCE
TO RESOLVE THE PARTIES' DISPUTES REGARDING
DAMAGES AND OTHER REMEDIES DISCOVERY

Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, "Amgen") and Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. (collectively, "Mylan") respectfully request a status conference with the Court to resolve the parties' disputes as to:

(1) whether discovery as to Amgen's damages and remedies should proceed in this action such that Mylan is required to produce such information responsive to Amgen's discovery requests (Amgen's position); or

(2) whether damages and remedies issues should be bifurcated from liability both for discovery and for trial (Mylan's position).

The parties have a fundamental dispute on these issues which they have not been able to resolve despite multiple teleconferences to meet and confer including between lead counsel for Amgen and lead counsel for Mylan.

A. Factual Background

This case was filed on September 22, 2017, pursuant to 42 U.S.C. § 262(*l*)(6), before Mylan had received FDA approval to market its accused biosimilar pegfilgrastim product, Fulphila™. On June 4, 2018, Mylan received FDA approval, and stated in a press release the same day that Mylan anticipated launching its biosimilar product in "the coming weeks."[1] Amgen is seeking discovery related to its remedies claims in discovery served March 23, 2018 and April 11, 2018. The parties now dispute whether Mylan is required to produce the discovery requested in Amgen's Requests for Product ("RFP") Nos. 5, 12, 13, 16, 18, 21, 22, 30-37, and 45. In its April 23, 2018 and May 11, 2018 responses, Mylan objected to the requested discovery on the grounds that: (1) the discovery was "premature and speculative, as Mylan has not received approval from the FDA" for the accused biosimilar product and "therefore cannot commercially launch its product" (RFP Nos. 18, 21, 22, 30, 32, 33, 35); (2) "damages discovery should be bifurcated from discovery regarding liability" (RFP Nos. 18, 21, 22, 30-33, 36, 37). In addition, it is Amgen's position that RFP Nos. 5, 12, 13, 16, 34, and 45 are the subject of this discovery dispute, but Mylan did not object to those requests on the basis of prematurity or bifurcation; Mylan did object to those requests on other grounds.

To the best of Amgen's knowledge, Mylan has now launched Fulphila™ commercially and is actively marketing the product. For example, FDA's National Drug Code Directory website[2] confirms that Mylan started to market Fulphila™ on July 9, 2018. Mylan has also announced its wholesale price for Fulphila™ of $4175 per syringe, more than 30% below the

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[1] *Available at*, http://newsroom.mylan.com/2018-06-04-U-S-FDA-Approves-Mylan-and-Biocons-Fulphila-TM-pegfilgrastim-jmdb-the-First-Biosimilar-to-Neulasta-R.

[2] *Available at*, https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm).

price of Amgen's Neulasta®.[3] As of July 10, 2018, the last meet and confer between counsel, Mylan's counsel was not able to confirm to Amgen whether or not Mylan has launched Fulphila™.

Mylan also recently confirmed that it intends to ask that damages should be bifurcated from liability in this action, given that Amgen will not agree to bifurcation. It is Mylan's position that its commercial launch does not change the fact that damages discovery should be bifurcated.

B. Amgen's Position

Mylan's decision to launch Fulphila™ before the resolution of Amgen's patent infringement claims has a significant impact on this case because it means that damages and other remedies are central disputed factual issues, and that a jury that will be asked to decide the disputed facts for both liability and remedies. Therefore, Amgen requests that Mylan be compelled to produce damages and remedies discovery. and that Mylan's request that damages should be bifurcated from liability both for discovery and trial be denied. *See Copper Innovations Grp., LLC v. Nintendo Co.*, No. CV 07-1752, 2008 WL 11341318, at *1-2 (W.D. Pa. Sept. 12, 2008) (bifurcation is granted only in "extenuating circumstances" and is the "exception, not the rule").

First, the issue of damages will be tried before a jury, and it is more efficient to have a single jury decide both liability and damages, rather than impaneling two juries to hear evidence from the same witnesses. ***Second,*** it is more efficient to have liability and damages discovery

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[3] *See* FiercePharma, "Can Mylan dodge Pfizer's Remicade woes with a low-priced Neulasta copy?" (July 12, 2018), *available at*, https://www.fiercepharma.com/pharma/can-mylan-dodge-pfizer-s-remicade-woes-a-low-priced-neulasta-copy.

proceed together given the overlap in fact witnesses and document production. Indeed, bifurcation could lead to more discovery disputes between the parties as to whether specific items of discovery relate to liability, damages, or both. ***Third,*** Amgen also seeks and will have to prove entitlement to an injunction; it would be unfair to delay that process by requiring an entire new discovery phase after Amgen prevails on liability. ***Fourth,*** the prejudice to Amgen in having to wait to get its remedies adjudicated after a separate discovery period and trial, outweighs any prejudice to Mylan. The incremental cost of Mylan conducting the discovery now is small relative to Mylan's revenue from selling its accused biosimilar product. ***Lastly,*** bifurcation of damages will handicap any further settlement discussions as any settlement will need to take into account Amgen's claims for damages; absent disclosure of the relevant facts and theories on damages, it is difficult to see how there could be meaningful discussions.

C. Mylan's Position

Damages and injunctive relief should be bifurcated from liability under Federal Rule of Civil Procedure 42(b); or in the alternative, discovery related solely to damages and injunctive relief should be stayed until after resolution of Mylan's motion for judgment on the pleadings and anticipated motion for summary judgment.[4] Mylan is not suggesting, as Amgen implies, that damages discovery necessarily be postponed until after a trial decision on liability, but such discovery could easily be stayed at least until a decision is reached on Mylan's outstanding and

[4] Indeed, bifurcation is routinely granted in pharmaceutical/complex science patent litigations. *See, e.g.*, *AstraZeneca AB v. Apotex Corp*., Nos. 01 Civ. 9351, M-21-81(BSJ), 2010 WL 2541180, at *1 (S.D.N.Y. June 9, 2010); *Pfizer Inc. v. Novopharm Ltd*., No. 00 C 1475, 2000 WL 1847604, at *3-4 (N.D. Ill. Dec. 14, 2000); *Princeton Biochemicals, Inc. v. Beckman Instruments, Inc*., 180 F.R.D. 254, 256-62 (D.N.J. 1997); *Amgen, Inc. v. Chugai Pharm. Co*., No. CIV.A . 87-2617-Y, 1989 WL 169006, at *5 (D. Mass. Dec. 11, 1989), *aff'd in part, vacated in part*, 927 F.2d 1200 (Fed. Cir. 1991).

upcoming motions. Bifurcation is proper and should be granted for at least the following reasons.[5] ***First***, damages and liability are separate issues that will not require overlapping discovery or witnesses; Amgen has admitted that the discovery it requests is relevant only to damages and fails to identify any overlap between the issues, particularly as Amgen admits it does not practice the alleged inventions. *In re Maxim Integrated Products, Inc.*, MDL No. 2354, 2013 WL 12197610, at *3 (W.D. Pa. Apr. 3, 2013); *Smith v. Alyeska Pipeline*, 538 F. Supp. 977, 983 (D. Del. 1982). ***Second***, bifurcation would promote judicial economy and conservation of resources, particularly as damages discovery is complex, requiring Mylan to produce thousands of pages of additional discovery and requiring additional fact witness testimony and costly expert discovery regarding complex models for computing damages, which include multiple products. Further, Mylan disputes that Amgen is entitled to lost profits, given that it does not practice the alleged inventions and substantial non-infringing alternatives exist. *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978). Mylan also submits there is a high probability Mylan will prevail on its non-infringement claims given non-infringement rulings in related litigations on the same (or substantially the same) patents. ***Third***, presenting liability and damages in a single trial would prejudice Mylan, including presenting to the jury additional complex legal issues that are irrelevant to liability and may cause jury confusion, particularly given the complex technology at issue and the extensive fact and expert discovery that will likely significantly extend the length of trial. ***Fourth***, there is no prejudice to Amgen. Amgen readily admits that the issues are separate enough not to require the same jury. Further, given the

[5] Mylan requests that briefing be permitted on the issue of bifurcation.

complexity of the liability issues, bifurcation reduces complexity and will promote resolution of liability issues, which can also lead to settlement.

Respectfully submitted,

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Dated: July 23, 2018

CERTIFICATE OF SERVICE

I hereby certify that on the 23rd day of July, 2018, I electronically filed the foregoing **JOINT MOTION FOR A STATUS CONFERENCE TO RESOLVE THE PARTIES' DISPUTES REGARDING DAMAGES AND OTHER REMEDIES DISCOVERY** with the Clerk of Court using the CM/ECF system which sent notification to all counsel of record.

THE WEBB LAW FIRM

s/ *Kent E. Baldauf, Jr.*
Kent E. Baldauf, Jr.

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	)	No. 2:17-cv-01235-MRH
Plaintiffs,	)	
	)	Judge Mark R. Hornak
v.	)	
	)	
MYLAN INC., MYLAN PHARMACEUTICALS INC., MYLAN GMBH and MYLAN N.V.,	)	***Electronically Filed***
	)	
	)	
Defendants.	)	

ORDER OF COURT

AND NOW, this _____ day of _____, 2018, based upon the parties' **JOINT MOTION FOR A STATUS CONFERENCE TO RESOLVE THE PARTIES' DISPUTES REGARDING DAMAGES AND OTHER REMEDIES DISCOVERY**, it is hereby ORDERED, ADJUDGED and DECREED that said Motion is GRANTED. A Status Conference is scheduled for _____, 2018 at _____ a.m./p.m.

BY THE COURT,

_____J.