

## Patterson Belknap Webb & Tyler LLP

1133 Avenue of the Americas New York, NY 10036-6710 212.336.2000 fax 212.336.2222 www.pbwt.com

April 12, 2016

Gregory L. Diskant  
Partner  
(212) 336-2710  
Direct Fax: (212) 336-2947  
gldiskant@pbwt.com

**By ECF**

The Honorable Mark L. Wolf  
U.S. District Court, District of Massachusetts  
1 Courthouse Way  
Boston, MA 02210

**Re: *Janssen Biotech Inc. et al. v. Celltrion, Inc. et al.*, 15-cv-10698 (MLW)**

Dear Judge Wolf:

We write to advise the Court that the FDA approved defendants' biosimilar product one week ago, on April 5, 2016, and that defendants' commercial launch is imminent. Defendants notified us that they intend to begin commercial sales of their biosimilar in no later than 180 days (on October 2, 2016), subject to certain reservations.

We also write to comply with our promise to advise the Court, within seven days of approval, whether plaintiffs will seek a preliminary injunction on U.S. Patent No. 7,598,083 (the "'083 patent") to block defendants' commercial launch. At the conference on February 9, 2016, when plaintiffs raised the issue of a preliminary injunction, the Court stated its general reluctance to issue a preliminary injunction and then issue a final decision on the merits at a later time, and expressed a preference for consolidating preliminary injunction proceedings with trial on the merits. Feb. 9, 2016 Tr. (Ex. A) at 44-45. In light of the Court's comments, plaintiffs have decided not to seek a preliminary injunction. Instead, plaintiffs request that the Court hold an expedited trial on the merits of the '083 patent dispute so that plaintiffs' request for a permanent injunction can be adjudicated by October 2, 2016. This would avoid the irreparable harm that would be caused by defendants' commercial launch. *See, e.g., Gillette Co. v. RB Partners*, 693 F. Supp. 1266, 1295 (D. Mass. 1988) (Wolf, J.) (ordering expedited trial on limited issues where "the passage of time may involve a measure of irreparable harm if the [counterclaim plaintiff's] claims are meritorious").

Since the February 9 hearing, plaintiffs have compiled powerful evidence that the defendants' cell culture media infringe the '083 patent under the doctrine of equivalents ("DOE"). Defendants admit that their cell culture media contain *every single one* of the 52 required ingredients and 7 of the 9 optional ingredients required by the '083 patent. They also admit that the amounts of these ingredients fall within the range of concentration claimed by the '083 patent for 49 of the 61 ingredients. The only infringement dispute relates to the relevance of the 12 differences in concentration ranges – a limited number of differences given the

Hon. Mark L. Wolf  
April 12, 2016  
Page 2

overwhelming overlap between the patent and the defendants' media. We now have scientific evidence that these few differences in concentration are insubstantial.

This evidence is in the form of sophisticated scientific experiments recently completed on plaintiffs' behalf by ExcellGene SA, a Swiss biotechnological research firm. The ExcellGene experiments, which took months to execute due to the complexity of the technology involved, closely track the experiments disclosed in the specification of the '083 patent. The ExcellGene scientists created precise copies of defendants' cell culture media, and then modified the concentration of each of the 12 ingredients that fall outside the ranges claimed in the '083 patent, one after the other, so that they fall literally within the claimed range. For each modification, the scientists then tested whether there was any impact on the relevant performance variables. The data show (and the ExcellGene scientists conclude) that the differences are *not* substantial: "[N]one of the variant media tested . . . showed a significant difference in performance" compared to the defendants' cell culture media. The defendants' cell culture media infringe the '083 patent under the DOE. *See AquaTex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320, 1326 (Fed. Cir. 2007).

Plaintiffs seek an expedited trial on the merits and an injunction barring defendants from selling their biosimilar product, which is manufactured through infringement of the '083 patent, and thereby causing irreparable harm to plaintiffs' business. An expedited trial on the merits is especially reasonable and practical here, as it would advance the Court-ordered schedule by only five months. Plaintiffs filed this action more than a year ago and discovery on the '083 patent is already well underway. The parties have already agreed to a schedule under which a trial on plaintiffs' claims under the '083 patent would be held in February 2017, less than one year from now (D.E. # 97). Plaintiffs believe it is readily possible to move the trial date up from February 2017 to September 2016 in order to have their claim for a permanent injunction on the '083 patent resolved before defendants' threatened launch date.

Because defendants' product was only approved last week and plaintiffs' DOE experiments were only recently completed, we have not yet had the opportunity to consult with defendants on this request for an expedited trial. We intend to meet and confer with defendants shortly on this proposal. In the event that defendants oppose, plaintiffs will submit a formal motion in support of this request.

Respectfully submitted,

/s/ Gregory L. Diskant

Gregory L. Diskant  
*Counsel for Plaintiffs*

cc: All counsel

# **EXHIBIT A**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

	)	
JANSSEN BIOTECH, INC.,	)	
and NEW YORK UNIVERSITY,	)	
	)	
Plaintiffs,	)	
	)	Civil Action
v.	)	No. 15-CV-10698-MLW
	)	
CELLTRION HEALTHCARE CO.,	)	
LTD, CELLTRION, INC., and	)	
HOSPIRA, INC.,	)	
	)	
Defendants.	)	
	)	

BEFORE THE HONORABLE MARK L. WOLF  
UNITED STATES DISTRICT JUDGE

STATUS CONFERENCE

February 9, 2016  
4:27 p.m.

John J. Moakley United States Courthouse  
Courtroom No. 10  
One Courthouse Way  
Boston, Massachusetts 02210

Kelly Mortellite, RMR, CRR  
Official Court Reporter  
John J. Moakley United States Courthouse  
One Courthouse Way, Room 5200  
Boston, Massachusetts 02210  
mortellite@gmail.com

1 you briefly in the jury room. And I'm ordering that you order  
2 the transcript of this proceeding because it will help me  
3 prepare.

4 MR. DISKANT: Your Honor, could I raise one other  
5 issue before we go?

6 THE COURT: Yes.

7 MR. DISKANT: Which is, it's in what we submitted, but  
8 I don't think it's been mentioned orally today, and counsel of  
9 course knows what I'm about to say. We're giving very serious  
05:30 10 consideration and we may well bring a preliminary injunction on  
11 the '083 patent. As counsel says, there are differences  
12 between their cell media and our patent claims. We are  
13 studying them extremely closely. We are gathering evidence  
14 that would support a preliminary injunction. We will not file  
15 it unless we have that evidence. We're not in a position to  
16 say that today.

17 THE COURT: Let me ask you this. I haven't done a  
18 patent case in a long time. Do the ordinary requirements for a  
19 preliminary injunction apply, and do you have to show an  
05:30 20 imminent threat of irreparable harm, something that couldn't be  
21 adequately -- there's no adequate remedy at law?

22 MR. DISKANT: That's correct. And irreparable harm is  
23 invariably found in these cases where generics or lower-price  
24 competitors enter the market against a branded competitor  
25 because it results in price diminution, destroys the market,

1 destroys relationships. And there's an unbroken string of  
2 Federal Circuit cases to that effect. I think that where the  
3 rubber will meet the road on the preliminary injunction will be  
4 on likelihood of the success on the merits. And as I said, we  
5 will not file it unless we think we can win it, but we may well  
6 and we hope to be able to --

7 THE COURT: That would be on the doctrine of  
8 equivalents?

9 MR. DISKANT: Yes. And it's in the proposed  
05:31 10 statement, we've committed to advising counsel no later than  
11 one week after FDA approval of our decision, and the 180 days  
12 we're arguing about is in the statute --

13 THE COURT: So you would be a seeking preliminary  
14 injunction that requires that they wait 180 days?

15 MR. DISKANT: There are two issues there. We've  
16 already filed that motion.

17 THE COURT: Right. So you'd want a preliminary  
18 injunction that would indefinitely until the conclusion of the  
19 case?

05:32 20 MR. DISKANT: Yes.

21 THE COURT: Then I would say to you what's necessary  
22 to try this case on the merits? Because under Rule 65, I have  
23 the authority to consolidate the hearing or the motion for  
24 preliminary injunction with a trial on the merits. And I may,  
25 again, I think certainty -- you know, you're confirming my

1 understanding, but certainty is important to everybody here.  
2 So if I grant a preliminary injunction saying you're reasonably  
3 likely to win and then two years from now you lose, you know,  
4 that's injured the market. So I don't know -- would you need a  
5 lot of discovery on this?

6 MR. DISKANT: No. I completely agree with you. Right  
7 now we've agreed to a trial one year from today. In our view,  
8 assuming the 180 days goes our way, which again I think is  
9 likely, they're not going to be able to launch until October 4,  
05:33 10 and that six-month period under the law is for the purpose of  
11 bringing that PI. I think you could advance trial on the  
12 merits to October 4, and we'd be done with it.

13 We haven't filed that motion yet, so I don't want to  
14 jump the gun, but that's very much on my mind.

15 THE COURT: And I commend you for telling me, and I  
16 believe you, that you're going to think very carefully before  
17 you file that motion. Because, you know, proliferation of  
18 motions diffuses the focus. You each think you have  
19 meritorious arguments. You want to keep me focused. All  
05:33 20 right.

21 MR. HURST: Just, if you're wondering, on the motion  
22 for a preliminary injunction on the '083 soup patent, this is  
23 not an issue for today. Our suspicion is that motion won't be  
24 coming because of the not one difference but 12 differences.  
25 I've not seen a case like that proceed forward, and there's

1 other problems with their case as well. But I think that we'll  
2 cross that bridge if we ever arrive to it.

3 THE COURT: All right. I'd like to see you briefly in  
4 the jury room. You're welcome to join them.

5 Court is in recess.

6 (Adjourned, 5:33 p.m.)

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25



**CERTIFICATE OF SERVICE**

I hereby certify that, on April 12, 2016, a copy of the foregoing document was filed through the electronic filing system and served electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Alison C. Casey