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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

GENENTECH, INC. AND CITY OF HOPE,
Patent Owners

Case IPR2016-00710
Patent 6,331,415

PATENT OWNERS' OPPOSITION TO MOTION FOR JOINDER

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Patent Owners Genentech Inc. ("Genentech") and City of Hope (collectively, "Patent Owners") submit this Opposition to Petitioner Mylan Pharmaceuticals Inc.'s ("Mylan") Motion for Joinder Pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. §§ 42.22 and 42.122(b) ("Motion for Joinder") (Paper 3).

Mylan seeks to join this *inter partes* review with IPR2015-01624 ("Sanofi IPR"), filed by Sanofi-Aventis U.S. LLC ("Sanofi") and Regeneron Pharmaceuticals, Inc. ("Regeneron") and relating to the same patent at issue here, U.S. Patent No. 6,331,415 ("the Cabilly '415 patent"). Sanofi and Regeneron oppose Mylan's Motion for Joinder on the ground that it unilaterally seeks to require them to cooperate with Mylan. Mylan's attempt to force itself into the Sanofi IPR and to require Sanofi and Regeneron's cooperation will be disruptive to the proceedings, and Patent Owners object to joinder on that basis.

Mylan asserts that if the Board grants the Motion for Joinder, Mylan, Sanofi, and Regeneron *together* will (1) submit "consolidated filings for all substantive papers in the proceeding (*e.g.*, Reply to the Patent Owner's Response, Opposition to Motion to Amend, Motion for Observation on Cross Examination Testimony of a Reply Witness, Motion to Exclude Evidence, Opposition to Motion to Exclude Evidence and Reply)" (*Id.*at 6); (2) submit the same arguments in order to "avoid lengthy and duplicative briefing" (*Id.*); and (3) designate a single "attorney to conduct the cross-examination of any given witness produced by Genentech and

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City of Hope, and the redirect of any given witness produced by Mylan, Sanofi, and Regeneron within the timeframe normally allotted by the rules for one party." (*Id.* at 6-7.)

Far from such cooperation, however, Patent Owners understand that Sanofi and Regeneron oppose joinder. Given this lack of agreement, Patent Owners are concerned that joinder will interfere with the efficient administration of the Sanofi IPR. Indeed, the Sanofi IPR is already at an advanced stage – the Board issued its Institution Decision on February 5, 2016; the parties have scheduled the deposition of Sanofi-Aventis/Regeneron's expert declarant, Dr. Foote, for April 21, 2016; and Patent Owners' Response is due May 13, 2016. In addition, Mylan's effort to join the Sanofi IPR may well interfere with settlement efforts between Sanofi/Regeneron and Patent Owners.

While Patent Owners believe that Mylan's motion should be denied, in the event that the Board decides to allow joinder, Mylan should be required to abide by the conditions set forth in its Motion for Joinder. These conditions are as follows:

1. Mylan agrees to "consolidated filings for all substantive papers in the proceeding (*e.g.*, Reply to the Patent Owner's Response, Opposition to Motion to Amend, Motion for Observation on Cross Examination Testimony of a Reply Witness, Motion to Exclude Evidence, Opposition to Motion to Exclude Evidence and Reply). Specifically,

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Mylan will agree to incorporate its filings with those of Sanofi and Regeneron into a consolidated filing in the Sanofi IPR, including being subject to the ordinary rules for one party on page limits." (Paper 3 at 6.) Mylan further agrees that "Sanofi, Regeneron and Mylan will be jointly responsible for the consolidated filings." (*Id.* at 6, 8.)

2. Mylan agrees "not to be permitted any arguments separate from those advanced by Sanofi and Regeneron in the consolidated filings" in order to "avoid lengthy and duplicative briefing." (*Id.* at 6.)
3. Mylan agrees that "[c]onsolidated discovery is also appropriate given that Mylan, Sanofi, and Regeneron are using the same expert declaration in the two proceedings." (*Id.* at 6.) Specifically, "Mylan, Sanofi, and Regeneron will designate an attorney to conduct the cross-examination of any given witness produced by Genentech and City of Hope, and the redirect of any given witness produced by Mylan, Sanofi, and Regeneron within the timeframe normally allotted by the rules for one party. Mylan will not receive any separate cross-examination or redirect time from that of Sanofi and Regeneron." (*Id.* at 6-7.)

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4. Mylan agrees to "rely solely on the testimony of Sanofi's expert, Dr. Foote, unless the Sanofi IPR is settled prior to a final written decision" and that "no additional discovery would be needed" as long as the Sanofi IPR remains pending following joinder. (*Id.* at 7.) In the event that the Sanofi IPR is settled prior to a final written decision, Mylan identifies Dr. Kathryn Calame as its expert. (*Id.*; *see also* Declaration of Kathryn Calame, Ph.D. (Ex. 1059).)
5. Mylan agrees that "[t]he Mylan IPR [2016-00710] contains the same grounds of unpatentability instituted in the Sanofi IPR," and that "the Mylan IPR raises no new grounds of unpatentability from those of the Sanofi IPR." (Paper 3 at 7-8.)
6. Mylan agrees that joinder will have "[n]o impact on [the] IPR trial schedule" and that "[t]he trial schedule for the Sanofi IPR would not need to be delayed to effect joinder . . . ." (*Id.* at 8.)

In addition to the foregoing, because Mylan introduces the declaration of Dr. Calame in support of its petition and contingently relies on the testimony in the Foote declaration, Patent Owners seek clarity regarding the use of Dr. Foote's deposition testimony if the Sanofi IPR terminates. Specifically, as a condition to any joinder, Patent Owner's request the Panel direct that (1) any deposition testimony of Dr. Foote taken in this proceeding may be entered into the record and

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