# UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD MYLAN PHARMACEUTICALS INC

MYLAN PHARMACEUTICALS INC. and PFIZER, INC, Petitioners,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH, Patent Owner.

Case IPR2018-01675 Patent No. 8,603,044

PETITONER MOTION TO EXCLUDE 37 CFR §42.64(c)



The petitioner (Mylan) seeks exclusion of patent owner (Sanofi) exhibits 2001-2023, 2100-2107, 2111-2153, 2158-2201, 2203-2212, 2214-2218, and 2223-2225, and the redirect testimony in Mylan exhibit 1054. Except as otherwise noted, the objections appear in Papers 30, 40 and 66.

#### I. ARGUMENT

Petitioner ("Mylan") submits the following objections:

#### A. EX2001-EX2003 – Press Releases (PR Newswire)

EX2001-EX2003 should be excluded under Federal Rules of Evidence (FRE) 402-403. They are offered to show Mylan's clinical development and commercialization of a follow-on insulin glargine product. Paper 23, 6. That Mylan is developing such a product is not relevant to any contested issue in this proceeding. Thus, EX2001-EX2003 lack relevance and risk confusing the issues.

### B. EX2004, EX2005, EX2007 – Sanofi Complaints, (D. Del.), (D.N.J.)

EX2004, EX2005 and EX2007 should be excluded under FRE 402-403.

EX2004 and EX2005 are offered to show Sanofi asserted the '044 patent against other competitors. Paper 13, 6. EX2007 is offered to show that Sanofi asserted the '044 patent in collateral litigation. Paper 13, 10. Whether the '044 patent has been



asserted is not relevant to any contested issue in this proceeding. Thus, these exhibits lack relevance and risk confusing the issues.

#### C. EX2006 – Stipulation and Proposed Order, (D.N.J.)

EX2006 should be excluded under FRE 402-403. EX2006 is offered to show a joint request for a trial date in collateral litigation. Paper 19, 2; Paper 23, 8. This request is not relevant to any contested issue in this proceeding. Thus, EX2005 lacks relevance and risks confusing the issues.

#### D. EX2007-EX2010 – Mylan Invalidity Contentions, (D.N.J.)

EX2007-EX2010 should be excluded under FRE 402-403. These exhibits are offered to show that Mylan has referenced overlapping prior art as a basis for invalidity in the co-pending district court case. Paper 23, 7 n.2, 10, and 11. That Mylan has referenced overlapping prior art in its invalidity contentions in the district court case is not relevant to any contested issue in this proceeding. Thus, they lack relevance and risk confusing the issues.

#### E. EX2011 – Service of Sanofi's Responses (D.N.J.)

EX2011 should be excluded under FRE 402-403. EX2011 is offered to show the date on which Sanofi served its response to Mylan's amended invalidity contentions, Paper 23, 15-16, which is not relevant to any contested issue in this proceeding. Thus, EX2011 lacks relevance and risks confusing the issues.



#### F. EX2012 – MP4 file of Sanofi's Patented Pen animation

EX2012 should be excluded under FRE 801-804. EX2012 is offered to show an animated operation of an embodiment of the injection pen described in the '486 patent. Paper 23, 19. The animation is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions.

#### G. EX2013, EX2014, EX2015 – Dictionary Excerpts

EX2013-EX2015 should be excluded under FRE 801-804. These exhibits are offered to define "helical." Paper 23, 26-28. The definition is offered for the truth of its content without satisfying any of the hearsay exceptions.

#### H. EX2016-EX2020 – Papers, (N.D. W. Va.), (D.N.J.)

EX2016-EX2020 should be excluded under FRE 402-403. These exhibits are offered to show party statements regarding the timelines of collateral litigation. Paper 19, 1-4. These statements are not relevant to the issues in this proceeding. These exhibits lack relevance and risk confusing the issues.

#### I. EX2021, EX2022 – Transcript Excerpts, (D.N.J.)

EX2021 and EX2022 should be excluded under FRE 402-403. These exhibits are offered to show comments of the district court judge and magistrate judge, respectively, in collateral litigation. Paper 19, 2-3. These comments are not



relevant to any contested issues in this proceeding. Thus, these exhibits lack relevance and risk confusing the issues.

#### J. EX2023 –Local Patent Rules, Explanatory Notes

EX2023 should be excluded under FRE 402-403. EX2023 is offered to establish the patent rules specific to the United States Court for the District of New Jersey. Paper 19, 3. These rules are irrelevant to the issues in this proceeding. Thus, EX20123 lacks relevance and risks confusing the issues.

#### K. EX1054 – Professor Slocum Redirect (pp. 391-406)

Objection preserved at page 391 of the exhibit. The redirect should be excluded under FRE 702(a). Professor Slocum may be an esteemed professor of mechanical engineering, but that does not automatically qualify him as an expert in injection pens. Indeed, he conceded that he "didn't have personal knowledge of the industry at the time of the invention, so I wanted to talk to [inventor Robert Veasey] who was clearly in the thick of it at the time." Sanofi did not offer Mr. Veasey as its expert on what a person of ordinary skill in the art would have known or done at the relevant time; instead, it relied on Professor Slocum, who bases his testimony on what Mr. Veasey told him off the record.

Triers of fact must exercise a gatekeeping function, "ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at



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