IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD	:	
v.	:	CIVIL NO. 17-cv-01065-MSG-RL
BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM FREMONT, INC.	:	

ORDER

AND NOW, this 8th day of June, 2018, upon consideration of Boehringer's May 30 Letter to the Court regarding Boehringer's RFP Nos. 19-20 and AbbVie's June 4 Letter in response, it is hereby

O R D E R E D

as follows:

1) To the extent not already produced, AbbVie will produce the following portions of BLA No. 125057 to the extent they concern manufacturing of adalimumab, formulation of adalimumab, and/or treating rheumatoid arthritis or ankylosing spondylitis, and the following portions of IND submissions for the treatment of rheumatoid arthritis, ankylosing spondylitis, or total spinal ankylosis:

   a. Table of contents, including supplements;

   b. Summary information of proposed labeling text, scientific rationale, intended use and potential clinical benefits, foreign marketing history,

chemistry, manufacturing and control information, and nonclinical pharmacology and toxicology, clinical documentation summary, including any supplements thereof;

c. Chemistry, Manufacturing and Control Information ("CMC"), including any supplements thereof (*i.e.*, sections related to the manufacture of adalimumab), and excluding cross reference authorization letters, raw material certificates of analysis; and

d. Clinical Documentation, including the summary of clinical safety and benefit risk analysis, and documents related to rheumatoid arthritis or ankylosing spondylitis, and excluding protected individual patient data.

2) Boehringer will identify by June 7 what it identifies as the relevant sections from BLA No. 125057 as well as the subset of those sections Boehringer believes are missing from what AbbVie has already produced.

3) AbbVie shall provide the table of contents for all BLA Supplements and for all ankylosing spondylitis – related supplements until November 10, 2018.

4) Boehringer will identify any specific documents that it purports are missing from the production of BLA supplements and IND submissions and that Boehringer contends are relevant to a claim or defense in the case following a reasonable opportunity to review these materials.

5) AbbVie will promptly work with Boehringer to address any reasonable request by

Boehringer pursuant to paragraphs 2 or 4.

BY THE COURT:

s/Richard A. Lloret
RICHARD A. LLORET
U.S. MAGISTRATE JUDGE