

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner

v.

**NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,**
Patent Owners

Case IPR2020-1318
Patent 9,220,631

**DECLARATION OF JEFFREY SALLING IN SUPPORT OF NOVARTIS'S
PATENT OWNER PRELIMINARY RESPONSE**

I. INTRODUCTION

1. I, Jeffrey Salling, have personal knowledge of the facts set forth in this Declaration and am competent to testify concerning the same.

2. I am employed by Novartis Services Inc. in East Hanover, N.J. I have been Global Director of eDiscovery & Senior Legal Counsel at Novartis since April 2019. In this position, I oversee Novartis's global discovery operations, to ensure compliance with discovery obligations consistent with applicable rules.

3. BACKGROUND

4. Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, "Novartis") were previously involved in litigation concerning U.S. Patent 9,220,631 in ITC Investigation No. 337-TA-1207 ("ITC Investigation"). Novartis file systems maintain Novartis electronic files created and stored by Novartis employees.

5. File systems are maintained by Novartis Information Technology (IT) which is the infrastructure upon which the metadata is supported.

6. Based on my understanding and experience, metadata is data about the data (for example, creation date, modified date, etc.). Metadata is generated contemporaneously with the creation, modification, or movement of the electronic files with which they are associated.

7. Metadata includes information such as the file name and modified

date for an electronic document. The modified date reflects the date on which the document was last modified or changed, such as by changing the file name or altering its contents.

8. The metadata associated with each electronic file is created and stored in the ordinary course of business at Novartis.

9. Novartis documents were collected from Novartis file systems for production in the ITC Investigation. This collection of data was inclusive of the associated metadata. A number of these documents (and metadata) were produced to Regeneron Pharmaceuticals Inc. (“Regeneron”) in the ITC Investigation.

10. Each page of each document produced to Regeneron in the ITC Investigation was stamped with a unique identifier referred to as a Bates number. The Bates number appears in the lower right corner of each page of each produced document. For Novartis’ production to Regeneron in the ITC Investigation, Novartis employed Bates numbers beginning with the Bates prefix “NOVITC(CH)” or “NOVITC(US).”

II. Documents Produced by Novartis in the ITC

11. **Exhibit 2126** is a document bearing Bates number NOVITC(CH)00054063, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2126, and aside from the redactions, which

were applied at the direction of Novartis' outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file "20120320 Novartis Pre-Filled Syringes (NVS).pdf." I have personal knowledge of the metadata associated with the native file "20120320 Novartis Pre-Filled Syringes (NVS).pdf," which reflects that it has a "Modified Date" of March 27, 2012. These metadata were generated and maintained by Novartis in the ordinary course of business.

12. **Exhibit 2128** is a document bearing Bates number NOVITC(CH)00167663, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2128, and aside from the redactions, which were applied at the direction of Novartis' outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file "RP01098A Development Report.pdf." I have personal knowledge of the metadata associated with the native file "RP01098A Development Report.pdf," which reflects that it has a "Modified Date" of March 26, 2013. These metadata were generated and maintained by Novartis in the ordinary course of business.

13. **Exhibit 2129** is a document bearing Bates number NOVITC(CH)00168961, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC

Investigation. I have examined Exhibit 2129, and aside from the redactions, which were applied at the direction of Novartis' outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file "Comparison Vetter Puurs syringes rap ID.pdf." I have personal knowledge of the metadata associated with the native file "Comparison Vetter Puurs syringes rap ID.pdf," which reflects that it has a "Modified Date" of December 20, 2019. These metadata were generated and maintained by Novartis in the ordinary course of business.

14. **Exhibit 2130** is a document bearing Bates number NOVITC(CH)00169036, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2130, and aside from the redactions, which were applied at the direction of Novartis' outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file "Lucentis_PFS_Design_Review_Section_6_10aug06xl.ppt." I have personal knowledge of the metadata associated with the native file "Lucentis_PFS_Design_Review_Section_6_10aug06xl.ppt," which reflects that it has a "Modified Date" of August 10, 2006. These metadata were generated and maintained by Novartis in the ordinary course of business.

15. **Exhibit 2131** is a document bearing Bates number

NOVITC(CH)00170304, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2131, and aside from the redactions, which were applied at the direction of Novartis' outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file "090095a985da60fc_7008027_P35_M_966_1.doc." I have personal knowledge of the metadata associated with the native file "090095a985da60fc_7008027_P35_M_966_1.doc," which reflects that it has a "Modified Date" of January 28, 2019. These metadata were generated and maintained by Novartis in the ordinary course of business.

16. **Exhibit 2136** is a document bearing Bates number NOVITC(CH)00217349, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2136, and aside from the redactions, which were applied at the direction of Novartis' outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file "Lucentis GNE PFS – Tech. Eval. final Sept. 2006.doc." I have personal knowledge of the metadata associated with the native file "Lucentis GNE PFS – Tech. Eval. final Sept. 2006.doc," which reflect that it has a "Modified Date" of January 9, 2009. These metadata were generated and maintained by Novartis in

the ordinary course of business.

17. **Exhibit 2137** is a document bearing Bates number NOVITC(CH)00217646, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2137, and aside from the redactions, which were applied at the direction of Novartis' outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file "[Unnamed Presentation]." I have personal knowledge of the metadata associated with the native file "[Unnamed Presentation]," which reflects that it has a "Modified Date" of December 4, 2008. These metadata were generated and maintained by Novartis in the ordinary course of business.

18. **Exhibit 2138** is a document bearing Bates number NOVITC(CH)00217650, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2138, and aside from the redactions, which were applied at the direction of Novartis' outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file "[Unnamed Presentation]." I have personal knowledge of the metadata associated with the native file "[Unnamed Presentation]," which reflects that it has a "Modified Date" of December 4, 2008. These metadata were generated and

maintained by Novartis in the ordinary course of business.

19. **Exhibit 2139** is a document bearing Bates number NOVITC(CH)00810847, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2139, and aside from the redactions, which were applied at the direction of Novartis' outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file "QOS_drug-product-syringe.pdf." I have personal knowledge of the metadata associated with the native file "QOS_drug-product-syringe.pdf," which reflects that it has a "Modified Date" of May 13, 2013. These metadata were generated and maintained by Novartis in the ordinary course of business.

20. **Exhibit 2140** is a document bearing Bates number NOVITC(CH)00874056, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2140, and aside from the redactions, which were applied at the direction of Novartis' outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file "Lucentis PFS update – NSO IFB – June 16_2011-final-revised2.ppt." I have personal knowledge of the metadata associated with the native file "Lucentis PFS update – NSO IFB – June 16_2011-final-revised2.ppt," which reflect that it has a

“Modified Date” of June 15, 2011. These metadata were generated and maintained by Novartis in the ordinary course of business.

21. **Exhibit 2144** is a document bearing Bates number NOVITC(CH)01498292, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2144, and aside from the redactions, which were applied at the direction of Novartis’ outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file “Lucentis PFS Project Review – GPT November 15_2011 – Main deck.ppt.” I have personal knowledge of the metadata associated with the native file “Lucentis PFS Project Review – GPT November 15_2011 – Main deck.ppt,” which reflects that it has a “Modified Date” of November 11, 2011. These metadata were generated and maintained by Novartis in the ordinary course of business.

22. **Exhibit 2145** is a document bearing Bates number NOVITC(CH)01863737, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2145, and aside from the redactions, which were applied at the direction of Novartis’ outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file “Lucentis PFS – IPT meeting – March 19th 2007_CS.ppt.” I have personal

knowledge of the metadata associated with the native file “Lucentis PFS – IPT meeting – March 19th 2007_CS.ppt,” which reflect that it has a “Modified Date” of March 15, 2007. These metadata were generated and maintained by Novartis in the ordinary course of business.

23. **Exhibit 2146** is a document bearing Bates number NOVITC(CH)01863785, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2146, and aside from the redactions, which were applied at the direction of Novartis’ outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file “Novartis Vetter Disclosure to Bayer Healthcare 01 April~.pdf.” I have personal knowledge of the metadata associated with the native file “Novartis Vetter Disclosure to Bayer Healthcare 01 April~.pdf,” which reflects that it has a “Modified Date” of April 1, 2014. These metadata were generated and maintained by Novartis in the ordinary course of business.

24. **Exhibit 2147** is a document bearing Bates number NOVITC(CH)01906307, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2147, and aside from the redactions, which were applied at the direction of Novartis’ outside Swiss counsel to comply with

Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file “ASP CDA.pdf.” I have personal knowledge of the metadata associated with the native file “ASP CDA.pdf,” which reflects that it has a “Modified Date” of March 19, 2009. These metadata were generated and maintained by Novartis in the ordinary course of business.

25. **Exhibit 2150** is a document bearing Bates number NOVITC(CH)02929814, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2150, and aside from the redactions, which were applied at the direction of Novartis’ outside Swiss counsel to comply with Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file “7008027_P83_MB_967_17.pdf.” I have personal knowledge of the metadata associated with the native file “7008027_P83_MB_967_17.pdf,” which reflect that it has a “Modified Date” of September 3, 2019. These metadata were generated and maintained by Novartis in the ordinary course of business.

26. **Exhibit 2254** is a document bearing Bates number NOVITC(CH)00885630, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2254, and aside from the redactions, which were applied at the direction of Novartis’ outside Swiss counsel to comply with

Swiss data protection law, I have confirmed that this Exhibit is a PDF of the native file “Lucentis PFS_Technical Review_2012_02_16.” I have personal knowledge of the metadata associated with the native file “Lucentis PFS_Technical Review_2012_02_16,” which reflects that it has a “Modified Date” of February 16, 2012. These metadata were generated and maintained by Novartis in the ordinary course of business.

27. **Exhibit 2166** is a document bearing Bates number NOVITC(US)00389194, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2166 and I have confirmed that this Exhibit is a PDF of the native file “Brolucizumab Global Forecast incl PFS analysis - October 18th 2016.pptx.” I have personal knowledge of the metadata associated with the native file “Brolucizumab Global Forecast incl PFS analysis - October 18th 2016.pptx,” which reflects that it has a “Modified Date” of October 18, 2016. These metadata were generated and maintained by Novartis in the ordinary course of business.

28. **Exhibit 2167** is a document bearing Bates number NOVITC(US)00394737, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2167 and I have confirmed that this

Exhibit is a PDF of the native file

“Ophthalmology.zip?Ophthalmology\RTH258\Competitive Landscape\Retina CI Review - Feb19.pdf.” I have personal knowledge of the metadata associated with the native file “Ophthalmology.zip?Ophthalmology\RTH258\Competitive Landscape\Retina CI Review - Feb19.pdf,” which reflects that it has a “Modified Date” of February 25, 2019. These metadata were generated and maintained by Novartis in the ordinary course of business.

29. **Exhibit 2168** is a document bearing Bates number NOVITC(US)00395564, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2168 and I have confirmed that this Exhibit is a PDF of the native excel file

“Ophthalmology.zip?Ophthalmology\RTH258\Forecast\workspace\rth forecast scenario scratch\20171204_Brolucizumab_nAMD_US_Yr6-8 zerod out for namd.xlsm.” I have personal knowledge of the metadata associated with the native file “Ophthalmology.zip?Ophthalmology\RTH258\Forecast\workspace\rth forecast scenario scratch\20171204_Brolucizumab_nAMD_US_Yr6-8 zerod out for namd.xlsm,” which reflects that it has a “Modified Date” of December 6, 2017.

30. **Exhibit 2169** is a document bearing Bates number NOVITC(US)00395565, which was among the documents collected from the

Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2169 and I have confirmed that this Exhibit is a PDF of the native excel file

“Ophthalmology.zip?Ophthalmology\RTH258\Forecast\workspace\rth forecast scenario scratch\20171205_Brolucizumab_nAMD_US.XLSM.” I have personal knowledge of the metadata associated with the native file

“Ophthalmology.zip?Ophthalmology\RTH258\Forecast\workspace\rth forecast scenario scratch\20171205_Brolucizumab_nAMD_US.XLSM,” which reflects that it has a “Modified Date” of December 6, 2017.

31. **Exhibit 2170** is a document bearing Bates number NOVITC(US)00507243, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2170 and I have confirmed that this Exhibit is a PDF of the native file “Lucentis PFS 0.5mg Impact.pptx.” I have personal knowledge of the metadata associated with the native file “Lucentis PFS 0.5mg Impact.pptx,” which reflects that it has a “Modified Date” of November 17, 2019.

32. **Exhibit 2171** is a document bearing Bates number NOVITC(US)00697489, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC

Investigation. I have examined Exhibit 2171 and I have confirmed that this Exhibit is a PDF of the native file “PFS Research_US RS Panel May 2020.pptx.” I have personal knowledge of the metadata associated with the native file “PFS Research_US RS Panel May 2020.pptx,” which reflects that it has a “Modified Date” of May 13, 2020.

33. **Exhibit 2172** is a document bearing Bates number NOVITC(US)00718202, which was among the documents collected from the Novartis file system and produced to Regeneron in connection with the ITC Investigation. I have examined Exhibit 2172 and I have confirmed that this Exhibit is a PDF of the native file “Situation Assessment 2019 02 24 CW.pptx.” I have personal knowledge of the metadata associated with the native file “Situation Assessment 2019 02 24 CW.pptx,” which reflects that it has a “Modified Date” of February 25, 2019.

III. DECLARATION

34. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that all of my statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: 1/18/2022

**Salling
Jeffrey**
By: Jeffrey Salling

Digitally signed by Salling Jeffrey
DN: dc=com, dc=novartis,
ou=people, ou=GR,
serialNumber=2157089, cn=Salling
Jeffrey
Date: 2022.01.18 17:09:08 -05'00'