

# **EXHIBIT 1 REDACTED IN ITS ENTIRETY**

# EXHIBIT 2

No. 2019-2156

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**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

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GENENTECH, INC.,

*Plaintiff-Appellant,*

CITY OF HOPE,

*Plaintiff,*

v.

AMGEN INC.,

*Defendant-Appellee.*

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On Appeal from the United States District Court  
for the District of Delaware, No. 1:18-cv-00924-CFC, Judge Colm F. Connolly

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**SECOND DECLARATION OF ROBERT JACOBSON IN SUPPORT OF  
AMGEN INC.'s OPPOSITION TO GENENTECH, INC.'S EMERGENCY  
MOTION FOR AN INJUNCTION PENDING APPEAL**

1. My name is Robert Jacobson. I am the Executive Director of U.S. Value and Access for Biosimilars at Amgen. I have held this role since July 2017, and I have been employed by Amgen since March 2001. I make this declaration based on my own personal knowledge.

2. In my current role as the Executive Director of U.S. Value and Access for Biosimilars, I oversee Amgen's activities in the U.S. relating to pricing, contracting, and patient support for Amgen's biosimilar programs. I also oversee Amgen's U.S. policy work related to these areas of value and access for biosimilars. In carrying out these job responsibilities, I am involved in, and knowledgeable about, Amgen's contractual relationships with group purchasing organizations, payers, distributors and healthcare providers.

3. Kanjinti® is Amgen's trastuzumab biosimilar. Kanjinti® is FDA approved to treat HER2 overexpressing early stage and metastatic breast cancer and metastatic gastric cancer. Kanjinti® is administered periodically to patients by intravenous infusion for periods of up to a year (or more). Kanjinti® can be curative in some early stage breast cancer patients. Kanjinti® can increase disease-free survival and overall survival in other patients. To obtain the benefits of Kanjinti®, patients prescribed the drug must have access to an uninterrupted supply of medicine. Kanjinti® is sold in a 420-mg multi-dose vial.

4. Amgen received FDA approval to market Kanjinti® on June 13, 2019.

5. From July 8-10, 2019, Amgen began commercial marketing of Kanjinti®.

6. Following the district court's standstill order on July 10, 2019, Amgen ceased its external commercial activities related to Kanjinti®. Amgen reinitiated its commercial launch of Kanjinti® in the United States on July 18 after the district court denied Genentech's emergency motions for a temporary restraining order and for a preliminary injunction and lifted its standstill order.

7. On July 18, 2019, Amgen initiated supply of Kanjinti® to the market.

8. Amgen has received confirmation from its customers that they have begun administering Kanjinti® to cancer patients.

9. An injunction ordering Amgen to halt sales of Kanjinti® would cause significant harm to Amgen's reputation as a reliable supplier of high quality medicines. The district court's July 10 standstill order already required Amgen to inform customers that it could not commence with sales of Kanjinti®. A second injunction prohibiting future sales would cause substantial disruption to Amgen's customers' businesses, and could cause those customers to reduce or terminate their commercial relationships with Amgen.

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