IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs, v. AMGEN INC., Defendant.	C.A. No. 18-924-GMS [redacted] PUBLIC VERSION FILED: July 19, 2019

DECLARATION OF ANUPAM B. JENA, M.D., PH.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

July 10, 2019

TABLE OF CONTENTS

I. ASSIGNMENT AND SUMMARY OF KEY OPINIONS

1. I, Anupam Jena, submit this declaration on behalf of Genentech Inc. ("Genentech") in the above captioned case. I have been asked to provide an analysis of whether Genentech will be harmed if Amgen is allowed to launch Kanjinti, its biosimilar trastuzumab product, and whether it would be possible to fully and reliably quantify and remediate that harm if Kanjinti is subsequently found to infringe certain Genentech patents, U.S. Patent Nos. 6,627,196 (the "'196 patent"), 7,371,379 (the "'379 patent"), and 10,160,811 (the "'811 patent") (together the "dosing patents"). I have also been asked to address, based on my experience and training in economics and medicine, whether the dosing patents asserted by Genentech are key drivers of the demand for Herceptin by patients and providers, the balance of hardships between Genentech and Amgen related to the issuance of an injunction, and whether an injunction would serve the public interest.

2. I was asked to assess whether Amgen's launch of Kanjinti will irreparably harm Genentech if Kanjinti is subsequently found to infringe Genentech's patents. I was asked to assume that the dosing patents are valid, and that Amgen's conduct infringes one or more claims of the dosing patents. From an economic perspective, determining whether harm is irreparable requires answering two questions: (1) At the time of the patent trial, will Genentech have incurred harm between the time of the Kanjinti launch and trial that can be reliably measured and compensated with monetary damages? and (2) Can any harm that is expected to persist *after* trial be fully and accurately estimated at the time of trial? I have concluded that the answer to both questions is no.

3. If Amgen is allowed to sell Kanjinti pending trial, [redacted], and would affect both the marketplace for Herceptin and the marketplace for other oncological therapeutic agents in ways that will be difficult to document with precision and that cannot be reversed even following entry of a permanent injunction. Pharmaceutical markets are dynamic and are affected by many variables, including the reputation, pricing practices, and market strategies of specific incumbent sellers and entrants. Based on my review and analysis, I find that if Amgen is allowed to launch Kanjinti, the market will change irreversibly to Genentech's detriment. In

addition, it will be impossible to quantify to a reasonable degree of precision the full magnitude of that harm.

4. There are currently no biosimilar versions of trastuzumab on the market, [redacted] Thus, if Amgen were to launch before trial, it would fundamentally alter the marketplace for Herceptin, as well as for several of Genentech's other oncological biologic products. There are currently no biosimilar versions of trastuzumab products on the market. Amgen's entry as the first biosimilar would fundamentally change that market. Amgen's stature as a large manufacturer with biologics experience and an extensive portfolio of current and anticipated biologic and biosimilar medications would magnify these impacts. Kanjinti is likely to be accepted and adopted into the marketplace more quickly because of Amgen's reputation and Amgen has the ability to engage in unique pricing strategies that make Genentech's harm different from and likely greater than the harm it might face from a different biosimilar entrant.

5. Amgen launching first would also likely change the market in a persistent way: Even if Kanjinti were removed from the market after trial, the effects of the launch would persist. The pharmaceutical distribution chain is complex and it is unrealistic to expect Genentech to be able to reverse policies it adopted to counteract Amgen's infringing competition. Nor will it be possible to reverse the extent to which Amgen's launch accelerated the pressure payers put on Genentech to offer pricing concessions, or any concessions Genentech provided in response to that pressure, [redacted]

6. These market dynamics become even more complex in view of additional future entrants. [redacted] It will be difficult, if not impossible, to reliably disentangle the effects of Kanjinti's market entry from that of another biosimilar

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