**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| GENENTECH, INC. and CITY OF HOPE,<br><br>Plaintiffs,<br><br>v.<br><br>AMGEN, INC.,<br><br>Defendant. | C.A. No. 18-924-CFC<br><br>[redacted]<br><br>PUBLIC VERSION FILED: July 25, 2019 |

**GENENTECH'S COMBINED REPLY BRIEF IN SUPPORT OF ITS EMERGENCY MOTIONS FOR A TEMPORARY RESTRAINING ORDER AND A PRELIMINARY INJUNCTION**

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The issues raised by these motions are sufficiently important that they should be decided on the merits. Once Amgen launches, Genentech cannot be put back into the place that it would have been in had its patent rights been respected. Doing so will not prejudice Amgen; [redacted] Genentech therefore requests a TRO and ultimately a preliminary injunction to maintain the status quo.

Amgen's opposition confirms that Genentech did not sit on its rights. [redacted] and, before that, made repeated representations to the Court that no launch decision had been made. Amgen never informed the Court or Genentech of its decision to launch and instead actively concealed its plans—for example, by unilaterally cancelling a key deposition of a launch decisionmaker. Genentech filed these motions as soon as it obtained market intelligence indicating that Amgen had in fact decided to launch imminently.

[redacted], and it has not raised a substantial question of invalidity. Amgen merely offers attorney argument unsupported by any expert testimony that Genentech's patents are invalid as obvious—a position recently rejected under a lower burden of proof after full IPR trials. The fact that Genentech's settlements of other lawsuits allowed those defendants to launch in the future does not diminish the irreparable harm of Amgen launching now. Nor does disruption to Amgen's recent efforts to launch at risk support Amgen in the balance of hardships. And Amgen cannot rely on the non-infringing indications in its product label to argue that its launch is in the public interest, where Amgen could have but has refused to remove the infringing indications, [redacted].

## I. GENENTECH'S MOTIONS ARE TIMELY.

Delay in bringing a preliminary injunction motion does not accrue "until the infringer actually started to (or was about to) commit [the] particular infringing act." *Integra Lifesciences Corp. v. Hyperbranch Med. Tech., Inc.*, 2016 WL 4770244, at *9 (D. Del. Aug. 12, 2016). There

was no such delay here. Genentech filed its motions within weeks of FDA approval of Kanjinti and just two days after Amgen's launch decision—notwithstanding that Amgen made every effort to conceal its actual launch plans from the Court and Genentech.[1]

It made no sense for Genentech to seek injunctive relief earlier. Kanjinti was not FDA-approved until June 13, 2019, and until last week Amgen consistently represented that it had not decided whether or when to launch. For example, just a few weeks ago, Amgen's counsel flatly told the Court that no launch decision had been made:

> Part of the problem is ***we have not made that ultimate decision yet*** because we have not launched yet. We have not launched yet. That's what I'm saying. ***Those decisions are ongoing.***

June 18, 2019 Hr'g Tr. 78:22-25; *id.* at 31:4-11 ("***So it may not be ripe***. It's all future activity."). Amgen then reiterated the following week that its launch decision was "***something that has not occurred***." D.I. 266 at 1. On June 26-27, 2019, [redacted]—Amgen's Rule 30(b)(6) witness on Amgen's "anticipated launch date"—[redacted]. Amgen's other witnesses testified similarly. [redacted]

To be sure, Amgen provided Genentech with discovery indicating that Amgen intended to be "ready" to launch by July 2019. But Amgen's counsel made clear at the June 18, 2019 hearing that planning to be ready to launch is very different from a decision to launch:

[redacted],

[1] For example, Amgen unilaterally cancelled (for the second time) the June 19, 2019 deposition of [redacted]—the decisionmaker to whom Amgen's opinion letters are addressed—and refused to make her available until after Amgen intended to launch. *See* Ex. 233.

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