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

GENENTECH, INC. and CITY OF HOPE,	)
Plaintiffs,	) ) C.A. No. 18-924-CFC
v.	<u> </u>
AMGEN, INC.,	
Defendant.	) PUBLIC VERSION FILED: ) JULY 29, 2019

GENENTECH'S OPENING BRIEF IN SUPPORT OF ITS FED. R. CIV. P. 62(d) MOTION FOR AN INJUNCTION PENDING APPEAL, OR, IN THE ALTERNATIVE, A 14-DAY INJUNCTION TO ENABLE GENENTECH TO PURSUE AN EXPEDITED MOTION FOR AN INJUNCTION PENDING APPEAL BEFORE THE FEDERAL CIRCUIT PURSUANT TO FED. R. APP. P. 8



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#### INTRODUCTION

Genentech respectfully brings this motion pursuant to Fed. R. Civ. P. 62(d) for an injunction pending appeal, or, in the alternative, a 14-day injunction to enable Genentech to pursue an expedited motion for an injunction pending appeal before the Federal Circuit pursuant to Fed. R. App. P. 8, as it is required to do prior to filing its motion with the Federal Circuit. Fed. R. App. P. 8(a). Genentech asked Amgen to stipulate to this relief, which it has declined to do.

On July 10, 2019, Genentech filed an emergency motion in which it asked the Court to temporarily restrain and preliminarily enjoin Amgen from launching its trastuzumab biosimilar Kanjinti. In its supporting papers, Genentech contended that: (1) without an injunction, Genentech would suffer loss of market share, price erosion, and reputational injury resulting directly from Amgen's infringement that cannot be addressed with money damages; (2) Genentech is likely to prevail on the merits inasmuch as Amgen effectively concedes infringement, and Amgen's defense hinges on essentially the same invalidity arguments that the Patent Office recently rejected in multiple IPRs; (3) unlike the significant and permanent harm facing Genentech, Amgen will lose no customers or market share if forced to wait until the issues are resolved in the December trial; and (4) patient access would not be affected because Genentech ensures that patients can obtain Herceptin regardless of ability to pay. The Court did not resolve any of those issues adversely to Genentech.

Instead, the Court concluded that Genentech had failed to establish irreparable harm in two other respects—both of which establish new criteria that present substantial appellate issues.

*First*, the Court found that any harm alleged by Genentech could not be "irreparable" because Genentech delayed in filing its motions. While the Court's opinion does not specify when the period of delay started, it suggests that the clock started ticking on Genentech's



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