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-CFC

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

DOCKET A L A R M Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii				
INTRODUCTION				
LEGAL STANDARD				
ARGU	MENT		6	
A.	Unless	Enjoined, Amgen's Infringement Will Irreparably Harm Genentech	6	
	1.	The Court Finding of Delay Would Require Premature and Unnecessary Filings	6	
	2.	The Evidence Presented Supports Genentech's Irreparable Harm.	10	
B.	The Re	emaining Factors Support Granting Genentech's Rule 62(d) Motion	12	
	1.	Genentech Has Made a Strong Showing That It Is Likely to Succeed on the Merits	.12	
	2.	The Balance of Hardships Favors Genentech	13	
	3.	Granting An Injunction Pending Appeal Serves The Public Interest.	13	
CONCLUSION15				

TABLE OF AUTHORITIES

Federal Cases

Abbott Labs. v. Sandoz, Inc., 500 F. Supp. 2d 807 (N.D. Ill. 2007),
Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341 (Fed. Cir. 2008)9, 10
Amgen, Inc. v. Sandoz, Inc., No. 2015-1499, D.I. 105 (Fed. Cir. May 5, 2015)4
<i>Amgen Inc. v. Sandoz Inc.</i> , No. 3:14-cv-04741-RS (N.D. Cal. Apr. 15, 2015)4
<i>Apple Inc. v. Samsung Elecs. Co.,</i> 695 F.3d 1370 (Fed. Cir. 2012) (<i>Apple I</i>)
Apple Inc. v. Samsung Elecs. Co., 735 F.3d 1352 (Fed. Cir. 2013) (Apple II)
Apple Inc. v. Samsung Elecs. Co., 809 F.3d 633 (Fed. Cir. 2015)
Astrazeneca LP v. Breath Ltd., Nos. 2013–1312, 2013–1352, 2013 WL 9853383 (Fed. Cir. May 24, 2013)5
BioTechnology Gen. Corp. v. Genentech, Inc., 80 F.3d 1553 (Fed. Cir. 1996)11
Butamax Adv. Biofuels LLC v. Gevo, Inc., 2012 WL 2675232 (D. Del. July 6, 2012)
Celsis in Vitro, Inc. v. Cellzdirect, Inc., 664 F.3d 922 (Fed. Cir. 2012)11, 13
In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 2011 WL 1980610 (D. Del. May 20, 2011)5
Douglas Dynamics, LLC v. Buyers Prods. Co., 717 F.3d 1336 (Fed Cir. 2013)11
High Tech Medical Instrumentation, Inc. v. New Image Industries, Inc., 49 F.3d 1551 (Fed. Cir. 1995)10

<i>Impax Labs., Inc. v. Aventis Pharm. Inc.,</i> 235 F. Supp. 2d 390 (D. Del. 2002)				
<i>Kos Pharms., Inc. v. Andrx Corp.,</i> 369 F.3d 700 (3d Cir. 2004)				
Noven Pharm., Inc. v. Mylan Techs. Inc., 2018 WL 4007848 (D. Del. Aug. 22, 2018)				
PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558 (Fed. Cir. 1996)12				
Pfizer, Inc. v. Teva Pharm., USA, Inc., 429 F.3d 1364 (Fed. Cir. 2005)				
Polymer Techs v. Bridwell, 103 F.3d 970 (Fed. Cir. 1996)				
Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359 (Fed. Cir. 2001)11				
<i>In re Revel AC, Inc.</i> , 802 F.3d 558 (3d Cir. 2015)				
<i>Sandoz Inc. v. Amgen Inc.</i> , 137 S. Ct. 1664 (2017)				
Standard Havens Prods., Inc. v. Gencor Indus., Inc., 897 F.2d 511 (Fed. Cir. 1990)				
<i>Trading Techs. Int'l, Inc. v. eSpeed, Inc.,</i> No. 04 C 5312, 2008 WL 4531371 (N.D. Ill. May 22, 2008), aff'd, 595 F.3d 1340 (Fed. Cir. 2010)				
Federal Statutes				
42 U.S.C. § 262(k)(4)14				
Rules				
Fed. R. App. P. 8				
Fed. R. Civ. P. 62(d)				

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

Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.