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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN
MANUFACTURING, LIMITED,

Plaintiffs,

v.

SANDOZ INC., SANDOZ INTERNATIONAL
GMBH, and SANDOZ GMBH,

Defendants.

Case No. 3:14-cv-04741-RS

~~PROPOSED~~ FINAL JUDGMENT
UNDER RULE 54(B) AND ORDER
ESTABLISHING SCHEDULE FOR RULE
62(C) PROCEEDINGS AND STAYING
ALL OTHER PROCEEDINGS

The Honorable Richard Seeborg

On March 19, 2015, the Court issued its Order on Cross Motions for Judgment on the Pleadings and Denying Motion for Preliminary Injunction. (ECF No. 105.) The Court’s Order dismissed with prejudice the first and second causes of action brought by Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, “Amgen”) and entered judgment in favor of Defendant Sandoz Inc. (“Sandoz”) on Sandoz’s first, second, third, fourth, and fifth counterclaims insofar as those counterclaims are consistent with the Court’s interpretation of the Biologics Price Competition and Innovation Act (“BPCIA”). The Order also denied Amgen’s motion for a preliminary injunction, as well as Amgen’s motion for judgment on the pleadings (or alternatively for partial summary judgment) on Sandoz’s sixth and seventh counterclaims, allowing those counterclaims to proceed.

1 Following the Court’s March 19, 2015, Order, the only claims remaining before the Court
2 relate to Amgen’s ’427 patent: Amgen’s claim of infringement, and Sandoz’s counterclaims of
3 noninfringement and invalidity. These remaining patent claims are distinct and separable from
4 the two claims and five counterclaims that were adjudicated in the March 19, 2015, Order.

5 Pursuant to the parties’ agreement that, should either party appeal the decision of this
6 Court, the parties would jointly seek expedited review in the Federal Circuit, the parties have
7 jointly moved for entry of final judgment under Rule 54(b) of the Federal Rules of Civil
8 Procedure so as to facilitate an immediate appeal of the BPCIA-related claims, all of which were
9 resolved by the Court’s March 19, 2015, Order.

10 Rule 54(b) certification is not available as of right. Rather, it requires that the judgment to
11 be entered be final as to the claims it addresses, and that there be no just reason for delay. *See*
12 *e.g., W.L. Gore & Associates, Inc. v. International Medical Prosthetics Research Associates, Inc.*,
13 975 F.2d 858, 862 (Fed. Cir. 1991). A judgment is final for Rule 54(b) purposes where it is “an
14 ultimate disposition of an individual claim entered in the course of a multiple claims action.” *Id.*
15 at 861-62 (emphasis omitted) (citing *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 436 (1956)).
16 In determining whether there is just reason for delay, the Court considers “such factors as whether
17 the claims under review [are] separable from the others remaining to be adjudicated and whether
18 the nature of the claims already determined [are] such that no appellate court would have to
19 decide the same issue more than once even if there were subsequent appeals.” *Id.* at 862 (quoting
20 *Curtiss-Wright Corp. v. General Elec. Co.*, 446 U.S. 1, 8 (1980)).

21 Having considered the standard for entry of judgment under Rule 54(b), the Court finds
22 that it is appropriate to enter judgment under Rule 54(b) as to Amgen’s first and second causes of
23 action and as to Sandoz’s first through fifth counterclaims. There is no just reason to delay entry
24 of final judgment on these adjudicated claims and counterclaims. They all relate to the correct
25 interpretation of the BPCIA and do not address the sole subject of the remaining claims and
26 counterclaims (Amgen’s third cause of action and Sandoz’s sixth and seventh counterclaims),
27 which relate to enforceability, infringement, and validity of the ’427 patent. Moreover, the claims
28 and counterclaims decided by the Court’s March 19, 2015, Order raise important legal issues that

1 are time-sensitive not only to the emerging biosimilar industry but also to the parties here: the
2 Food and Drug Administration has now approved Sandoz's application for its biosimilar product
3 (the first biosimilar that the FDA has approved), implicating concerns about prejudice to the
4 parties that could result from a delayed appeal on the BPCIA-related claims and counterclaims.
5 Finally, entry of a Rule 54(b) judgment is especially appropriate here, where Amgen intends to
6 appeal now the denial of the preliminary injunction under 28 U.S.C. § 1292(a), because entry of
7 such judgment will allow the entire March 19, 2015, Order to be appealed together.

8 The parties have also jointly requested entry of a scheduling order for Amgen's
9 contemplated motion for an injunction under Rule 62(c). Additionally, the parties jointly have
10 requested entry of an order staying all remaining proceedings in this Court (apart from those on
11 the contemplated Rule 62(c) motion) until issuance of the Federal Circuit's mandate in the appeal
12 from this Rule 54(b) judgment and this Court's March 19, 2015, Order.

13 Accordingly, it is ORDERED and ADJUDGED:

14 1. FINAL JUDGMENT is hereby entered under Rule 54(b) of the Federal Rules of
15 Civil Procedure in favor of Sandoz and against Amgen on Amgen's first and second causes of
16 action, as well as on Sandoz's first, second, third, fourth, and fifth counterclaims in accordance
17 with the Court's March 19, 2015, Order.

18 2. Amgen will make any motion for an injunction under Rule 62(c) no later than
19 Tuesday, March 24, 2015. Sandoz will file its response to any such motion by March 31, 2015.
20 Amgen will file its optional reply by April 2, 2015.

21 3. All other proceedings in this Court related to this matter, except for the entry of the
22 jointly requested Rule 54(b) judgment and Amgen's contemplated Rule 62(c) motion, are
23 STAYED until issuance of the Federal Circuit's mandate in the appeal from this Rule 54(b)
24 judgment and this Court's March 19, 2015, Order. During the period of the stay imposed by this
25 paragraph, Amgen may continue efforts to effect service on Sandoz International GmbH and
26 Sandoz GmbH, provided, however, that the time to move, answer, or otherwise respond to the
27 complaint for either entity so served is tolled until twenty days after the expiration of the stay
28 imposed by this paragraph.

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Dated: 3/25, 2015



THE HONORABLE RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE