

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

BTG INTERNATIONAL LIMITED, et al.,)	
)	Hon. Kevin McNulty, U.S.D.J
Plaintiffs,)	
)	Civil Action No.:
v.)	2:15-cv-05909-KM-JBC
AMNEAL PHARMACEUTICALS LLC, et al.,)	
)	
Defendants.)	
BTG INTERNATIONAL LIMITED, et al.,)	
)	Hon. Kevin McNulty
Plaintiffs,)	Civil Action No.:
)	2:16-cv-02449-KM-JBC
v.)	
AMERIGEN PHARMACEUTICALS, INC., et al.,)	
)	
Defendants.)	
BTG INTERNATIONAL LIMITED, et al.,)	Hon. Kevin McNulty
)	
Plaintiffs,)	Civil Action No.:
)	2:17-cv-06435-KM-JBC
v.)	
TEVA PHARMACEUTICALS USA, INC.,)	
)	
Defendant.)	

~~[PROPOSED]~~ FINAL JUDGMENT UNDER RULE 54(b)

This matter was raised to the Court by way of Plaintiffs’¹ unopposed letter motion requesting entry of judgment pursuant to Federal Rule of Civil Procedure 54(b) (“Motion”).

From July 23 to August 2, 2018, the Court held a bench trial in the above-captioned matters. On October 26, 2018, the Court issued its Opinion^{*} and Order (Dkt. 560, 561) determining that the asserted claims (4, 8, 11, 19, and 20) of Plaintiffs’ U.S. Patent No. 8,882,438 (“the ’438 patent”) are invalid for obviousness, but are supported by an adequate written description. The Court also determined that if the asserted ’438 patent claims were valid,

¹ “Plaintiffs” refers to Janssen Biotech, Inc. (“Janssen Biotech”), Janssen Oncology, Inc. (“Janssen Oncology”), Janssen Research & Development, LLC (“Janssen R&D”) (collectively, “Janssen”), and BTG International Limited (“BTG”).

the Participating Defendants'² activities upon approval of their ANDAs would constitute induced and contributory infringement, and thus the filing of each of Defendants' ANDAs would have been an act of infringement under 35 U.S.C. § 271(e)(2)(A). The '438 patent is the only patent asserted in these actions.

To facilitate an appeal of the Court's Opinion^{*} and Order, Plaintiffs request entry of judgment under Rule 54(b) consistent with the Opinion^{*} and Order as to their claims for infringement of the '438 patent against the Participating Defendants, as well as the Participating Defendants' counterclaims for declaratory judgments of non-infringement and invalidity of the '438 patent in the -5909 and -2449 actions. In addition, Plaintiffs request entry of judgment under Rule 54(b) consistent with the Opinion^{*} and Order as to their claims for infringement against Teva under the '438 patent and Teva's counterclaim for declaratory judgment of non-infringement and invalidity in the -6435 action pursuant to Plaintiffs' and Teva's stipulation that the Court's judgment as to Teva in the -5909 action would apply to the -6435 action as well. Dkt. No. 381 at 5.

Accordingly, it is ORDERED, ADJUDGED and DECREED:

1. The balance of the equities and interests of judicial administration favor entry of final judgment under Rule 54(b) as requested by Plaintiffs' Motion.

2. There is no just reason for delaying entry of final judgment under Rule 54(b) as requested by Plaintiffs' Motion.

3. For the reasons stated in the Court's October 26, 2018 Opinion^{*}, the asserted claims (4, 8, 11, 19, and 20) of the '438 patent are invalid for obviousness.

4. For the reasons stated in the Court's October 26, 2018 Opinion^{*}, the asserted claims of the '438 patent satisfy the written description requirement of 35 U.S.C. § 112.

5. In the alternative, if the '438 patent were valid, for the reasons stated in the Court's October 26, 2018 Opinion^{*}, each of the Participating Defendants would engage in induced and contributory infringement of the asserted '438 patent claims if its ANDA were approved, and therefore the filing of each of the ANDAs constituted an act of infringement of the asserted claims of the '438 patent under 35 U.S.C. § 271(e)(2):

- For Amerigen, ANDA No. 208027;
- For Amneal, ANDA No. 208327;

² "Participating Defendants" refers to Amerigen Pharmaceuticals Limited, Amerigen Pharmaceuticals, Inc. ("Amerigen"); Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC ("Amneal"); Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories Ltd. ("DRL"); Mylan Pharmaceuticals Inc., Mylan Inc. ("Mylan"); Teva Pharmaceuticals USA, Inc. ("Teva"); West-Ward Pharmaceuticals Corp. (n/k/a Hikma Pharmaceuticals USA Inc.) and Hikma Pharmaceuticals, LLC ("West-Ward"), Wockhardt Bio AG, Wockhardt USA, LLC, and Wockhardt Ltd. ("Wockhardt").

- For DRL, ANDA No. 208416;
- For Mylan, ANDA No. 208446;
- For Teva, ANDA Nos. 208432 and 210726;
- For West-Ward, ANDA No. 208339; and
- For Wockhardt, ANDA No. 208380.

6. For the reasons stated in the Court's October 26, 2018 Opinion,^{*} FINAL JUDGMENT is hereby entered under Rule 54(b) of the Federal Rules of Civil Procedure in favor of Amneal, DRL, Mylan, Teva, West-Ward, and Wockhardt as to Plaintiffs' claims for infringement of the '438 patent, and the counterclaims of Amneal, DRL, Mylan, Teva, West-Ward, and Wockhardt for declaratory judgment of invalidity of the '438 patent, in the -5909 action.

7. In the alternative, if the '438 patent were valid, for the reasons stated in the Court's October 26, 2018 Opinion,^{*} FINAL JUDGMENT is hereby entered under Rule 54(b) of the Federal Rules of Civil Procedure in favor of Plaintiffs as to the counterclaims of Amneal, DRL, Mylan, Teva, West-Ward, and Wockhardt for declaratory judgment of non-infringement of the '438 patent, in the -5909 action.

8. For the reasons stated in the Court's October 26, 2018 Opinion,^{*} FINAL JUDGMENT is hereby entered under Rule 54(b) of the Federal Rules of Civil Procedure in favor of Amerigen as to Plaintiffs' claims for infringement of the '438 patent, and the counterclaim of Amerigen for declaratory judgment of invalidity of the '438 patent, in the -2449 action.

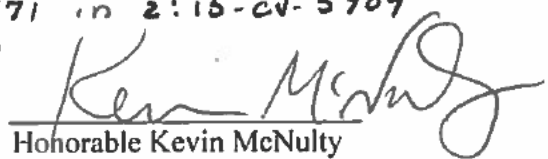
9. In the alternative, if the '438 patent were valid, for the reasons stated in the Court's October 26, 2018 Opinion,^{*} FINAL JUDGMENT is hereby entered under Rule 54(b) of the Federal Rules of Civil Procedure in favor of Plaintiffs as to the counterclaim of Amerigen for declaratory judgment of non-infringement of the '438 patent, in the -2449 action.

10. For the reasons stated in the Court's October 26, 2018 Opinion,^{*} FINAL JUDGMENT is hereby entered under Rule 54(b) of the Federal Rules of Civil Procedure in favor of Teva as to Plaintiffs' claim for infringement of the '438 patent, and the counterclaim of Teva for declaratory judgment of invalidity of the '438 patent, in the -6435 action.

11. In the alternative, if the '438 patent were valid, for the reasons stated in the Court's October 26, 2018 Opinion,^{*} FINAL JUDGMENT is hereby entered under Rule 54(b) of the Federal Rules of Civil Procedure in favor of Plaintiffs as to the counterclaim of Teva for declaratory judgment of non-infringement of the '438 patent, in the -6435 action.

** Amended October 31, 2018. (Dkt. 571 in 2:15-cv-5909 and Dkt. 43 in 2:16-cv-2449)*

DATED: 10/31/2018


Honorable Kevin McNulty
United States District Judge