Exhibit 3 – Defendants' Statement of Issues of Fact

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and INTERMUNE, INC., Plaintiffs, v. AUROBINDO PHARMA LIMITED, et al., Defendants.	)	C.A. No. 19-78 (RGA) CONSOLIDATED

DEFENDANTS' STATEMENT OF ISSUES OF FACT
WHICH REMAIN TO BE LITIGATED

Defendants Apotex Inc., Apotex Corp., Sandoz, Inc. and Lek Pharmaceuticals d.d. (collectively, "Defendants") identify the following issues of fact which remain to be litigated. This statement is based on the arguments Defendants expect to make at trial, as well as their understanding of the arguments that Plaintiffs intend to make. Defendants reserve the right to supplement or amend this statement if Plaintiffs seek to introduce different factual arguments and in light of any further decisions and orders of the Court, any of Plaintiffs' pretrial statements, and to the extent any amendments or other events arise impacting the facts or issues for trial.

Should the Court determine that any issue identified here is more appropriately considered an issue of law, Defendants incorporate that issue into Defendants' Statement of Issues of Law Which Remain to be Litigated (Exhibit 5). Likewise, to the extent that Defendants' Statement of Issues of Law Which Remain to be Litigated set forth in Exhibit 5 contains issues of fact, those issues are incorporated herein by reference.

I. PERSON OF ORDINARY SKILL IN THE ART

1. Whether a person of ordinary skill in the art ("POSA") to whom the asserted claims are directed would be an individual with an M.D. specializing in pulmonary medicine and having several years of experience treating patients with pulmonary diseases, including idiopathic pulmonary fibrosis ("IPF"), or having several years of experience researching treatments for pulmonary diseases, including IPF, who could call upon or consult with experts in other relevant fields, including pharmacokinetics, pulmonology, drug metabolism, or clinical trial design, to make inferences from the prior art, as of the following dates:

- U.S. Patent Nos. 7,566,729 ("the '729 patent"), 7,635,707 ("the '707 patent"), 8,592,462 ("the '462 patent"), and 8,609,701 ("the '701 patent") (collectively, the "liver function test patents" or "LFT patents"): November 10, 2008
- U.S. Patent Nos. 7,816,383 ("the '383 patent") and 8,013,002 ("the '002 patent") (collectively, the "fluvoxamine CYP patents"): December 4, 2009

II. INVALIDITY OF THE ASSERTED CLAIMS OF THE LIVER FUNCTION TEST PATENTS

2. Whether, as of November 10, 2008, a POSA would have been motivated to practice each of the asserted claims of the LFT patents, and would have had a reasonable expectation of success in doing so.

3. Whether each of the asserted claims of the LFT patents is invalid as obvious under 35 U.S.C. § 103 over Azuma.

4. Whether each of the asserted claims of the LFT patents is invalid as obvious under 35 U.S.C. § 103 over Azuma in view of the Pirespa Label.

5. Whether any secondary considerations identified by Plaintiffs are supported by the evidence and are relevant to the obviousness of each asserted claim of the LFT patents under 35 U.S.C. § 103.

6. Whether any secondary considerations identified by Plaintiffs have a nexus to each of the asserted claims of the LFT patents.

7. Whether any secondary considerations identified by Plaintiffs are sufficient to overcome a showing that each of the asserted claims of the LFT patents is invalid as obvious under 35 U.S.C. § 103.

8. Whether each of the asserted claims of the LFT patents is invalid for lack of written description under 35 U.S.C. § 112 because the patents fail to adequately disclose any credible utility for the claimed methods.

III. INVALIDITY OF THE ASSERTED CLAIMS OF THE FLUVOXAMINE CYP PATENTS

9. Whether, as of December 4, 2009, a POSA would have been motivated to practice each of the asserted claims of the fluvoxamine CYP patents, and would have had a reasonable expectation of success in doing so.

10. Whether each of the asserted claims of the fluvoxamine CYP patents is invalid as obvious under 35 U.S.C. § 103 over the Pirespa Label and Pirfenidone Report 2008 in view of the Luvox Label and 2006 FDA Guidance.

11. Whether each of the asserted claims of the fluvoxamine CYP patents is invalid as obvious under 35 U.S.C. § 103 over the '644 Publication in view of the Pirespa Label, Pirfenidone Report 2008, and the Luvox Label.

12. Whether any secondary considerations identified by Plaintiffs are supported by the evidence and are relevant to the obviousness of each asserted claim of the fluvoxamine CYP patents under 35 U.S.C. § 103.

13. Whether any secondary considerations identified by Plaintiffs have a nexus to each of the asserted claims of the fluvoxamine CYP patents.

14. Whether any secondary considerations identified by Plaintiffs are sufficient to overcome a showing that each of the asserted claims of the fluvoxamine CYP patents is invalid as obvious under 35 U.S.C. § 103.

15. Whether each of the asserted claims of the fluvoxamine CYP patents is invalid for lack of written description under 35 U.S.C. § 112 because the patents fail to adequately disclose any credible utility for the claimed methods.

IV. NONINFRINGEMENT OF THE ASSERTED CLAIMS OF THE LIVER FUNCTION TEST PATENTS

16. Whether Plaintiffs have proven by a preponderance of the evidence that Defendants' ANDA products will be administered to any patients according to the claimed methods of each asserted claim of the LFT patents.

17. Whether Plaintiffs have proven by a preponderance of the evidence that the proposed labeling for Defendants' ANDA products instructs, encourages, recommends, or promotes the method of treatment of each asserted claim of the LFT patents.

18. Whether Plaintiffs have proven by a preponderance of the evidence that the proposed labeling for Defendants' ANDA products will cause Defendants' ANDA products to be administered to any patients according to the claimed methods of each asserted claim of the LFT patents.

19. Whether Plaintiffs have proven by a preponderance of the evidence that Defendants have the specific intent to induce infringement of each asserted claim of the LFT patents.

V. NONINFRINGEMENT OF THE ASSERTED CLAIMS OF THE FLUVOXAMINE CYP PATENTS

20. Whether Plaintiffs have proven by a preponderance of the evidence that Defendants' ANDA products will be administered to any patients according to the claimed methods of each asserted claim of the fluvoxamine CYP patents.

21. Whether Plaintiffs have proven by a preponderance of the evidence that the proposed labeling for Defendants' ANDA products instructs, encourages, recommends, or promotes the method of treatment of each asserted claim of the fluvoxamine CYP patents.

22. Whether Plaintiffs have proven by a preponderance of the evidence that the proposed labeling for Defendants' ANDA products will cause Defendants' ANDA products to be administered to any patients according to the claimed methods of each asserted claim of the fluvoxamine CYP patents.

23. Whether Plaintiffs have proven by a preponderance of the evidence that Defendants have the specific intent to induce infringement of each asserted claim of the fluvoxamine CYP patents.