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

GENENTECH, INC. and HOFFMANN-LA ROCHE INC. Plaintiffs, v. SANDOZ, INC. and LEK PHARMACEUTICALS d.d., Defendants.	C.A. No. _____ **JURY TRIAL REQUESTED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Genentech, Inc. ("Genentech") and Hoffmann-La Roche Inc. ("HLR," and collectively with Genentech, "Plaintiffs") hereby allege, for their Complaint against Defendants Sandoz, Inc. ("Sandoz") and Lek Pharmaceuticals d.d. ("Lek," and collectively with Sandoz, "Defendants"), on personal knowledge as to Plaintiffs' own actions and on information and belief as to the actions of others, as follows:

OVERVIEW OF THE ACTION

1. This is a patent infringement action brought under 35 U.S.C. § 271 to remedy Defendants' ongoing and willful infringement of United States Patent No. 10,188,637 (the "'637 patent"). The '637 patent is directed to a novel tablet formulation of pirfenidone, one of the very

first drugs approved for the treatment of idiopathic pulmonary fibrosis ("IPF"). In May 2022, Defendants launched generic versions of pirfenidone tablets, 267 mg and 801 mg, that infringe the '637 patent ("Accused Products"). Defendants did so despite being well aware of the '637 patent, which had been listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for Esbriet® tablets. Defendants do not have, and since their launch of the Accused Products have not sought, a license to the '637 patent. Their infringement of the '637 patent is and has been knowing, reckless, and willful, and has resulted in significant damage to Plaintiffs. Plaintiffs bring this action to hold Defendants fully accountable for their disregard of Plaintiffs' patent rights and seek monetary damages, including (without limitation) hundreds of millions—if not billions—of dollars in lost profits for pirfenidone tablet sales that, but for Defendants' infringement of the '637 patent, would have been made by Genentech. Plaintiffs do not seek an injunction and are not requesting that any generic pirfenidone product be removed from the market.

BACKGROUND OF THE INVENTION

2. IPF is a rare, fatal lung disease that results in scarring of the lungs, which makes breathing difficult and prevents the heart, muscles, and vital organs from receiving enough oxygen to work properly. The disease can advance quickly or slowly, but eventually the lungs will harden and stop working altogether. The prognosis for IPF patients is extremely poor, with patients experiencing significant progressive worsening of disease, and median survival of two-to-five years after diagnosis. IPF is irreversible. The cause is unknown, and there is no cure.

3. Genentech holds approved New Drug Application ("NDA") No. 022535 for pirfenidone capsules, 267 mg and approved NDA No. 208780 for pirfenidone tablets, 267 mg and 801 mg, which are prescribed and sold in the United States under the trademark Esbriet®. Esbriet®

has been used to treat thousands of patients suffering from IPF. Esbriet® tablets are covered by the '637 patent.

4. The FDA approved the NDA for Esbriet® capsules on October 15, 2014. During clinical development, the FDA granted Esbriet® Breakthrough Therapy designation, which allows for expedited development and review of drugs that are intended to treat serious conditions and for which preliminary clinical evidence indicates the drug may demonstrate a substantial improvement over available therapy. The FDA also awarded Esbriet® Orphan Drug designation, which provides market exclusivity for drugs used to treat rare diseases that affect fewer than 200,000 people in the United States. Although IPF has no cure, Esbriet® finally offered patients an FDA-approved drug that could slow the rate of decline in lung function, thus slowing the worsening of the disease and allowing patients to enjoy longer and more productive lives.

5. The FDA-recommended dosage for Esbriet® capsules involved dosage titration where the full daily dosage was 3 capsules (267 mg each) taken 3 times every day for a total of 2403 mg per day.

Table 1. Dosage Titration for ESBRIET in Patients with IPF

Treatment days	Dosage
Days 1 through 7	1 capsule three times a day with food
Days 8 through 14	2 capsules three times a day with food
Days 15 onward	3 capsules three times a day with food

See 2014 Esbriet Prescribing Information §2.2 (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022535s000lbl.pdf).

6. Accordingly, while Esbriet® capsules finally offered patients an FDA-approved treatment option for IPF, it required patients to take up to nine capsules per day. A dosage regimen that requires a patient to administer nine capsules daily may lead to issues with patient compliance.

For example, patients may forget or be unwilling to take nine capsules per day over a long time period. But compliance with medication dosing instructions is important to reach the full benefits of the medication. There was therefore a need to develop a formulation that could lead to increased patient compliance. However, adding more than 267 mg of pirfenidone to Esbriet® capsules was not practical because doing so would have required use of a larger capsule that would have been difficult or impossible to swallow and may have led to further compliance issues.

ESBRIET® TABLETS AND THE PATENT-IN-SUIT

7. For some patients, tablet formulations can be part of a more patient-friendly dosage regimen. However, in view of the daily dosage requirements for IPF treatment, pirfenidone tablet formulations require very high concentrations of active ingredient in order to provide a tablet size that is manageable for oral administration.

8. In addition, pirfenidone has poor powder flowability characteristics. Poor flowability can cause ingredient powders to stick to equipment during manufacturing, which can impact the accuracy and precision of formulation processing. Pharmaceutical formulations that do not consistently contain FDA-approved ingredient amounts cannot be sold in the United States and potentially could be harmful to patients.

9. To address poor flowability of an active ingredient, formulation scientists would typically utilize higher concentrations of excipients. An excipient is a substance formulated alongside the active ingredient of a medication that can confer desired properties such as flowability. But in view of the high concentration of pirfenidone needed in the oral dosage form, there was little room remaining for higher concentrations of excipients to aid in improving the flowability and processability of pirfenidone powder.

10. The inventor of the '637 patent solved this problem with his novel granulate formulation of pirfenidone, which at least includes granules of pirfenidone and a glidant and may optionally include one or more additional excipients.

11. The granulate pirfenidone formulation described in the '637 patent exhibits good flow properties (*e.g.*, reduced sticking) during the granulation process despite the extremely high percentage of active ingredient in the formulation. This granulate formulation is capable of being compressed into tablets under standard compression conditions and results in stable tablets that resist cracking, yet maintain the desired drug release properties.

12. The '637 patent generally discloses and claims a granulate formulation of pirfenidone that includes both an intragranular glidant and an extragranular glidant. Although typically glidants had only been used extragranularly to improve the flow of the as-formed granules in tableting machines, it was advantageously and surprisingly discovered that the additional use of an intragranular glidant in the pirfenidone formulations can, among other things, improve the flow of the intragranular components in powder form, improve processing and flow of the granules, and improve flow of the granules during compression, such as in a tableting process.

13. As a result of this breakthrough formulation, on January 11, 2017, the FDA approved Genentech's NDA No. 208780 for Esbriet® tablets, 267 mg, 534 mg[1], and 801 mg. Since the approval of Esbriet® tablets, patients have been able to take a single dosage form (*i.e.*, tablets) for the entirety of their treatment regimen. Moreover, after the dosage titration period, patients

[1] The 534 mg dosage strength of Esbriet® was later discontinued, not for reasons having to do with safety or effectiveness.

could take three 801 mg tablets—a more patient-friendly and compliant regimen. Esbriet® tablets are now the most commonly taken dosage form of Esbriet® by patients.

14. Esbriet® has been a highly successful product, with U.S. sales of Esbriet® tablets exceeding approximately $740 million in 2021 alone.

15. The ’637 patent, entitled “Granulate Formulation of 5-Methyl-1-Phenyl-2-(1H)-Pyridone and Method of Making the Same,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on January 29, 2019, and does not expire until March 28, 2037. A true and correct copy of the ’637 patent is attached hereto as Exhibit 1.

16. The ’637 patent has been in full force and effect since its issuance. HLR is the owner of the ’637 patent. Genentech is the exclusive licensee of the ’637 patent and holds all substantial rights to the ’637 patent, including the rights to enforce the ’637 patent and to seek damages for past, current, and future infringement thereof.

PRIOR PIRFENIDONE ANDA LITIGATION

17. On or around 2019, Sandoz, acting in concert with Lek, submitted Abbreviated New Drug Application (“ANDA”) No. 212560, which sought approval from the FDA to market a generic copy of Esbriet® (pirfenidone) 267 and 801 mg tablets and submitted ANDA No. 212600, which sought approval to market a generic copy of Esbriet® (pirfenidone) 267 mg capsules. Numerous other pharmaceutical companies also submitted ANDAs for generic pirfenidone. Genentech sued those companies, including Sandoz and Lek, in the District of Delaware for infringement of several unrelated and materially different patents, seeking remedies provided under the Hatch-Waxman Act. The District of Delaware consolidated those actions into *Genentech, Inc. v. Laurus Labs, Ltd. et al.*, 1:19-cv-00078 (D. Del. Jan. 14, 2019) (the “Pirfenidone ANDA Litigation”).

18. During the pendency of the Pirfenidone ANDA Litigation, the '637 patent issued and was listed in the Orange Book in connection with Genentech's NDA for Esbriet® tablets. The '637 patent is unrelated to the patents at issue in the Pirfenidone ANDA Litigation and its claims are materially different and patentably distinct from the claims asserted in that case. At no time was the '637 patent asserted in the prior litigation, nor has it been subject to any other litigation or adverse proceeding.

19. On December 17, 2020—eighteen months after issuance of the '637 patent—Sandoz notified Genentech by letter that it had amended its ANDA to contain a certification pursuant to 21 U.S.C. § 505(j)(2)(B)(iv), commonly referred to as a Paragraph IV Certification, with respect to the '637 patent. Sandoz's letter did not include a noninfringement position except to say that the claims of the '637 patent are not infringed because they are allegedly invalid. Defendants could have filed, but did not file, a declaratory judgment action with respect to the '637 patent.

DEFENDANTS' COMMERCIAL LAUNCH AND HARM RESULTING THEREFROM

20. Between 2019 and 2021, the lawsuits filed against each of the other companies in the Pirfenidone ANDA Litigation were consensually dismissed. None of these companies began sales of generic pirfenidone upon dismissal of the lawsuits. Defendants, however, chose a different path. Despite having knowledge of the '637 patent and lacking any argument that the Accused Products did not infringe the '637 patent, Defendants nonetheless began sales of the Accused Products on or around May 12, 2022, after Sandoz and Lek prevailed at the district court in the Pirfenidone ANDA Litigation. Since the launch of the Accused Products, Defendants have not requested a license to the '637 patent.

21. Defendants knew or should have known that their launch of the Accused Products would result in the launches of other generic pirfenidone products over the following several months from the companies that had consensually dismissed their lawsuits. Until Defendants' launch of Accused Products, no generic pirfenidone product was available in the United States. Esbriet® had generated substantial sales for Genentech and had experienced steady and substantial growth over time. The entry of multiple generic pirfenidone products eviscerated Genentech's share of the pirfenidone market several years before that otherwise might have happened. Had Defendants' not begun selling the Accused Products, thus infringing the '637 patent, Genentech would have made all pirfenidone sales.

22. The displacement of Esbriet® product from the market by generic competition has already caused Genentech substantial financial harm. Genentech has suffered lost profits and will continue to suffer lost profits for several years as a result of Defendants' infringement.

23. Plaintiffs bring this action to remedy Defendants' ongoing and willful infringement. In doing so, Plaintiffs seek monetary damages, including without limitation lost profits and in no event less than a reasonable royalty, and an accounting and/or ongoing royalty for any post-judgment infringement, and any further relief as this Court may deem just and proper such as a trebling of damages.

PARTIES

24. Genentech, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1 DNA Way, South San Francisco, California 94080. Genentech develops and commercializes pharmaceutical products throughout the United States, including within this judicial district. Genentech holds NDAs in the United States for (i) Esbriet® (pirfenidone) capsules, 267 mg and (ii) Esbriet® (pirfenidone) tablets, 267 mg and 801 mg, and is

the exclusive licensee of the '637 patent, with the right to seek damages for past, current, and future infringement.

25. Genentech was founded in 1976 and for nearly five decades has been at the forefront of innovation in the field of therapeutic biotechnology. Today, Genentech employs a large number of researchers, scientists, and post-doctoral staff members who routinely publish in top peer-reviewed journals and are among the leaders in total citations to their work by researchers. Genentech currently markets numerous approved pharmaceutical and biologic drugs for a range of serious or life-threatening medical conditions, including various forms of cancer, multiple sclerosis, hemophilia, ophthalmic diseases, rheumatoid arthritis, and respiratory diseases.

26. HLR is a corporation organized under the laws of the State of New Jersey, with its principal place of business at 150 Clove Road, Little Falls, New Jersey, 07424. HLR owns the '637 patent.

27. On information and belief, Sandoz is a corporation organized and existing under the laws of Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

28. On information and belief, Lek is a corporation organized and existing under the laws of Slovenia, having a principal place of business at Verovškova ulica 57, 1526 Ljubljana, Slovenia. On information and belief, Lek is a wholly owned subsidiary of Novartis. *See* 2022 Novartis Annual Report (https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2022.pdf) at F-76; *see also* Lek's Sustainability Report 2022 (https://lek.si/media/dropbox/porocila/Lek_Sustainability_report_2022.pdf) at 20 ("Lek Pharmaceuticals d.d. (hereinafter; Lek) is a joint-stock company, 100% owned by Novartis Pharma AG.").

29. On information and belief, Lek holds itself out as a subsidiary of both Sandoz and Novartis. For example, Lek maintains a public website where it identifies itself as "a Sandoz company" and also as "Novartis in Slovenia." *See* https://lek.si/en/about-us/company-presentation/ (last visited July 31, 2023). Lek further promotes that it plays an important role for Sandoz—"[w]e are the leading, largest and best-equipped Sandoz Development Center that carries out half of all Sandoz development projects…we are proud to be leading the introduction of Sandoz products into global markets." *Id*. And Lek explains that it is "integrated in Novartis' organizational structure, primarily in Global Drug Development, Novartis Technical Operations, Customer & Technology Solutions and generic division Sandoz." *Id*.

30. On information and belief, Sandoz and Lek are related corporate entities that act as agents of one another and/or act in concert.

31. On information and belief, Sandoz, acting in concert with Lek, is in the business of, among other things, developing, manufacturing, distributing, and seeking regulatory approval for pharmaceutical products, including generic drug products, for marketing, sale, and/or use throughout the United States, including within the State of New Jersey, through its own actions and through the actions of its agents.

32. On information and belief, Sandoz, acting in concert with Lek, has developed, manufactured, imported, marketed, distributed, used, offered for sale, and/or sold in New Jersey and across the United States, the Accused Products, and continues to do so, improperly exploiting Plaintiffs' intellectual property surrounding this important medicine.

JURISDICTION AND VENUE

33. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

A. Sandoz

34. This Court has personal jurisdiction over Sandoz because, *inter alia*, Sandoz's principal place of business is in New Jersey and its contacts with the state are so continuous and systematic as to render it essentially at home in New Jersey.

35. This Court also has personal jurisdiction over Sandoz because Sandoz, acting in concert with Lek, took the significant step of launching the Accused Products. On information and belief, Sandoz manufactures, uses, offers for sale, and/or sells the Accused Products in New Jersey and throughout the United States, which directly gives rise to Plaintiffs' patent infringement claim.

36. Sandoz is also subject to personal jurisdiction in New Jersey because, on information and belief, Sandoz has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Sandoz develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs, including the Accused Products, throughout the United States, including in New Jersey, and therefore transacts or intends to transact business within New Jersey related to Plaintiffs' claim, and/or has engaged in systematic and continuous business contacts within New Jersey. Each of these activities has a substantial effect within New Jersey and constitutes infringement of the '637 patent.

37. Sandoz has consented to or did not contest personal jurisdiction and has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in this District,

for example, in at least the following cases: *see, e.g., Astellas Pharm. Inc. et al. v. Sandoz Inc.*, No. 23-cv-01214, D.I. 17 (D.N.J. May 1, 2023); *Aragon Pharm., Inc. et al. v. Sandoz Inc.*, No. 22-cv-03044, D.I. 23 (D.N.J Aug. 1, 2022); *Vifor (Int'l) AG et al. v. Sandoz Inc.,* No. 19-16305, D.I. 11 (D.N.J. Sept. 11, 2019); *Allergan Sales, LLC et al. v. Sandoz, Inc. et al.*, No. 17-cv-10129, D.I. 18 (D.N.J. Dec. 19, 2017); *Sandoz Inc. v. Daiichi Sankyo, Inc.*, No. 16-00994, D.I. 1 (D.N.J. Deb. 22, 2016).

38. On information and belief, Sandoz is registered as a "Manufacturer and Wholesaler" within New Jersey's Department of Health under Registration No. 5003732.

39. Venue is proper in this Court with respect to Sandoz pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Sandoz committed acts of infringement, and has a regular and established place of business, in this judicial district. On information and belief, Sandoz has systematic and continuous contacts with New Jersey, and a regular and established, physical place of business in New Jersey at 100 College Road West, Princeton, New Jersey 08540.

B. Lek

40. Lek is subject to personal jurisdiction in New Jersey because, *inter alia*, on information and belief, Lek itself, and through Sandoz, purposely availed itself of the benefits and protections of New Jersey laws such that it should reasonably anticipate being sued in this Court. On information and belief, Lek collaborates with Sandoz to develop, manufacture, seek approval for, and sell generic drugs approved by the FDA, including the Accused Products, which are being marketed, distributed, and sold in New Jersey and throughout the United States.

41. On information and belief, Lek was and is actively involved with planning Sandoz's generic products, including the Accused Products. On information and belief, Lek participates in

the manufacturing and supplying of the Accused Products for sale in New Jersey and throughout the United States.

42. Additionally, and in the alternative, this Court has personal jurisdiction over Lek under Federal Rule of Civil Procedure 4(k)(2) because Plaintiffs' claim arises under federal law, Lek is a foreign defendant that is not subject to general personal jurisdiction in any state, and Lek has sufficient contacts with the United States as a whole, including but not limited to, collaborating with Sandoz and Lek in concert to manufacture, offer to sell, and sell the Accused Products through its U.S. affiliates and agents that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Lek satisfies due process.

43. Venue is proper in this Court with respect to Lek because it is a foreign entity who may be sued in any judicial district, including in the District of New Jersey. 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

COUNT I

Infringement of U.S. Patent No. 10,188,637

44. Plaintiffs incorporate herein by reference paragraphs 1 through 43 above as if fully set forth herein.

45. Defendants have infringed, and continue to infringe, the '637 patent, including at least claim 1, under 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by, making, using, offering to sell, and/or selling within the United States, and/or importing into the United States, without authority or license, the Accused Products.

46. Defendants have infringed, and continue to infringe, the '637 patent, including at least claim 1, under 35 U.S.C. § 271(b), by, *inter alia*, actively aiding and abetting infringement by each other, as well as by physicians and their patients. On information and belief, Defendants

were aware of the '637 patent at least as of December 20, 2020, the date of Sandoz's Notice Letter. On information and belief, Defendants were aware of the '637 patent at least prior to the launch of the Accused Products by virtue of their involvement in the Pirfenidone ANDA Litigation. Notwithstanding their knowledge of the '637 patent, and their knowing incorporation of the patented formulation into the Accused Products, Defendants have made, used, imported into the United States, offered for sale, and sold, and continue to make, use, import into the United States, offer to sell and sell, the Accused Products with the knowledge and specific intent to encourage and facilitate infringing uses of the Accused Products by each other, as well as by physicians and their patients. On information and belief, Sandoz has induced, and continues to induce, direct infringement by others through its control of and direction to Lek and its affirmative acts of importing, offering to sell, selling, and distributing the Accused Products. On information and belief, Lek has induced, and continues to induce direct infringement by Sandoz through its affirmative acts of manufacturing and/or importing the Accused Products.

47. Lek has infringed, and continues to infringe, the '637 patent, including at least claim 1, under 35 U.S.C. § 271(c), by, *inter alia*, contributing to direct infringement committed by Sandoz. On information and belief, Lek's affirmative acts of manufacturing and/or importing the Accused Products into the United States contribute to Sandoz's infringing sales and uses of the Accused Products. The Accused Products are a material part of the invention of the '637 patent, are not staple articles or commodities of commerce, have no substantial non-infringing use, and are known by Lek to be especially made or adapted for use in the infringement of the '637 patent. On information and belief, Lek was aware of the '637 patent at least prior to the launch of the Accused Products by virtue of its involvement in the Pirfenidone ANDA Litigation. Despite this knowledge of the '637 patent and that the Accused Products infringe the '637 patent, Lek has

performed and continues to perform these affirmative acts with the specific intent to cause the direct infringement of the '637 patent.

48. Claim 1 of the '637 patent is reproduced below with the addition of labels [a] and [b] corresponding to limitations of the claim:

> 1. A granulate formulation of 5-methyl-1-phenyl-2-(1H)-pyridone, comprising:
>
> [a] granules comprising 5-methyl-1-phenyl-2-(1H)-pyridone and a glidant; and,
>
> [b] one or more extragranular excipients comprising an extragranular glidant.

49. The Accused Products embody each and every limitation of claims of the '637 patent, literally or under the doctrine of equivalents, as described in the non-limiting examples set forth below. These examples are preliminary and are not intended to limit Plaintiffs' right to modify these non-limiting examples or allege that other aspects of the Accused Products infringe other claims of the '637 patent.

1. A granulate formulation of 5-methyl-1-phenyl-2-(1H)-pyridone, comprising:

50. To the extent the preamble is limiting, the Accused Products include a granulate formulation of pirfenidone (5-methyl-1phenyl-2-(1H)-pyridone).

51. The 2022 Sandoz Pirfenidone Tablet Prescribing Information states "[p]irfenidone tablet contains pirfenidone and the following inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, pregelatinized starch, and silicon dioxide." *See 2022* Sandoz Pirfenidone Tablet Prescribing Information § 11; *see also id.* ("[p]irfenidone . . . has been referred to as . . . 5 methyl-1-phenyl-2-(1H)-pyridone.").

[a] Granules comprising 5-methyl-1-phenyl-2-(1H)-pyridone and a glidant,

52. The Accused Products include granules comprising pirfenidone (5-methyl-1phenyl-2-(1H)-pyridone) and a glidant. For example, the Accused Products include granules comprising pirfenidone and silicon dioxide, a glidant.

[b] One or more extragranular excipients comprising an extragranular glidant

53. The Accused Products include an extragranular glidant. For example, the Accused Products include silicon dioxide as an extragranular glidant.

54. As a result of Defendants' infringement of the '637 patent, Plaintiffs have been damaged. Plaintiffs are entitled to recover for damages, including without limitation lost profits and in no event less than a reasonable royalty, sustained as a result of Defendants' acts of infringement in an amount subject to proof at trial.

55. Defendants' infringement of the '637 patent has been and continues to be willful. For example, as set forth in paragraphs 17-23, Defendants were aware of the '637 patent at least as of December 17, 2020, the date of Sandoz's Notice Letter or at least prior to the launch of the Accused Products by virtue of their involvement in the Pirfenidone ANDA Litigation. Defendants also knew that the lawsuits filed against each of the other pharmaceutical companies involved in the Pirfenidone ANDA Litigation were dismissed. Defendants could have filed a declaratory judgment action with respect to the '637 patent, but instead chose to launch the Accused Products at risk in May 2022 despite having knowledge of the '637 patent and lacking any noninfringement position. At no time since the launch of the Accused Products have Defendants requested or attempted to negotiate a license to the '637 patent. Defendants have deliberately continued to infringe in a wanton, malicious, and egregious manner, with reckless disregard for Plaintiffs'

patent rights. Thus, Defendants' infringing actions have been and continue to be consciously wrongful.

56. Defendants' inexcusable usurpation of Plaintiffs' invention, and infringement of the '637 patent, make this an exceptional case that warrants an award of attorneys' fees to Plaintiffs pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendants and grant the following relief:

A. a judgement that Defendants have directly infringed and continue to infringe the '637 patent under 35 U.S.C. § 271(a) by their manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Accused Products before the expiration of the '637 patent;

B. a judgement that Defendants have induced infringement and continue to induce infringement of the '637 patent under 35 U.S.C. § 271(b) by their manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Accused Products before the expiration of the '637 patent;

C. a judgement that Lek has contributed to infringement and continues to contribute to infringement of the '637 patent under 35 U.S.C. § 271(c) by manufacturing and/or importing the Accused Products into the United States before the expiration of the '637 patent;

D. monetary damages adequate to compensate for Defendants' infringement of the '637 patent in accordance with 35 U.S.C. § 284 in an amount to be determined at

trial, including without limitation lost profits and/or a reasonable royalty, and an accounting and/or ongoing royalty for any post-judgment infringement;

E. a judgment that Defendants' infringement was willful and enhancement of any monetary damages pursuant to 35 U.S.C. § 284;

F. a declaration that this is an exceptional case under 35 U.S.C. § 285 and an award of attorneys' fees, costs, and expenses to Plaintiffs;

G. such other relief that the Court deems just and proper under the circumstances.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs respectfully demands a jury trial as to all issues so triable.

Dated: July 31, 2023

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RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Plaintiffs Genentech, Inc. and Hoffmann-La Roche Inc. hereby certify that this matter in controversy is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding. In addition, I recognize a continuing obligation during the course of this litigation to file and serve on all other parties and with the Court an amended certification if there is a change in the facts stated herein.

Dated: July 31, 2023

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