

Exhibit 10
Kashiv's 42 U.S.C. § 262(l)(3)(B) Disclosure for U.S. Patent No. 12,030,959

The following is a detailed statement that describes, on a claim-by-claim basis, the current factual and legal bases for Kashiv's opinion that the claims of U.S. Patent No. 12,030,959 ("the '959 patent") would not be infringed by the commercial manufacture, importation, use, or sale of Kashiv's aBLA products, are unenforceable, and/or are invalid.

Kashiv has provided this detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) for the sole and exclusive purpose of assisting Genentech in determining whether a claim of patent infringement could reasonably be asserted against Kashiv for the patents Genentech has listed pursuant to 42 U.S.C. § 262(l)(3)(A). This detailed statement shall not limit Kashiv's ability to present any and all defenses to any claim of patent infringement brought against it concerning the '959 patent. Kashiv may raise additional non-infringement and invalidity defenses to such a claim, including those that it becomes aware of through fact discovery, expert review or discovery, court or administrative proceedings, and/or continued analysis of the relevant factual and legal issues. *See Minnesota Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 782 (Fed. Cir. 2002); *Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 CIV. 8928 (BSJ), 2000 WL 257125, at *1 (S.D.N.Y. Mar. 8, 2000). Kashiv may also modify, supplement and/or amend the factual and legal bases for the defenses set forth in this detailed statement, including in response to allegations or evidence presented by Genentech or others. Because Kashiv does not have access to the patentees' internal, technical, and/or patent application files, or to those individuals who were involved in patent prosecution, discovery may be required to identify other potential defenses including, without limitation, a defense based on inequitable conduct before the U.S. Patent and Trademark Office ("PTO").

I. U.S. Patent No. 12,030,959

The '959 patent, titled "ANTI-IgE ANTIBODY THERAPY FOR MULTIPLE FOOD ALLERGIES," issued on July 9, 2024, naming Ryan Patrick Owen, Ahmar Iqbal, and Robert A. Wood as inventors. The '959 patent issued from U.S. Appl. No. 18/486,053, filed on October 12, 2023, as a continuation of Appl. No. PCT/US2023/070639, filed on July 20, 2023, which claims the benefit of U.S. Prov. Appl. No. 63/512,051, filed on July 5, 2023. Kashiv reserves the right to contest the earliest priority date to which the '959 patent is entitled.

The '959 patent contains 29 claims. The claims are reproduced below.

1. A method of treating a human subject having an allergy to a food allergen, the method comprising:
administering to the subject by subcutaneous injection a pharmaceutical composition comprising a dose of omalizumab,
wherein the pharmaceutical composition is administered once about every two weeks and the dose of omalizumab is from 150 mg to 225 mg, or the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is from 75 mg to 150 mg, and
wherein body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 1850 IU/ml.

Exhibit 10

Kashiv's 42 U.S.C. § 262(D)(3)(B) Disclosure for U.S. Patent No. 12,030,959

2. The method of claim 1, wherein the pharmaceutical composition is administered once about every two weeks and the dose of omalizumab is:
150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml; or
150 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or
225 mg when the body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml; and
wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.
3. The method of claim 1, wherein the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is:
75 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml;
and wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.
4. The method of claim 1, wherein the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is:
150 mg when the body weight of the subject is equal to or greater than or equal to 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; and
Wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.
5. The method of claim 1, wherein the pharmaceutical composition is administered to a subject having a body weight of greater than 12 kg and less than or equal to 15 kg at a dose of:
75 mg once about every four weeks if the total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml; or
150 mg once about every four weeks if the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; or
150 mg once about every two weeks if the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or
225 mg once about every two weeks if the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml; and
wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

Exhibit 10
Kashiv's 42 U.S.C. § 262(D)(3)(B) Disclosure for U.S. Patent No. 12,030,959

6. The method of claim 2, wherein the body weight of the subject is determined prior to administration of a first dose of omalizumab.
7. The method of claim 2, wherein the subject is not receiving concurrent oral immunotherapy with the food allergen.
8. The method of claim 2, wherein treating comprises reducing an allergic reaction following accidental exposure of the subject to the food allergen.
9. The method of claim 2, wherein treating comprises reducing a moderate-to-severe allergic reaction following exposure of the subject to the food allergen.
10. The method of claim 1, wherein the pharmaceutical composition is administered once about every two weeks and the dose of omalizumab is:
150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or
150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and the total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1500 IU/ml; and
wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.
11. The method of claim 1, wherein the pharmaceutical composition is administered once about every four weeks and the dose of omalizumab is:
75 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml; or
150 mg when the body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and the total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; and
wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.
12. A method of treating a human subject having an allergy to a food allergen, the method comprising:
 - (i) administering to the subject by subcutaneous injection once about every four weeks a pharmaceutical composition comprising a dose of omalizumab of:
150 mg when body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; or
 - (ii) administering to the subject by subcutaneous injection once about every

Exhibit 10

Kashiv's 42 U.S.C. § 262(l)(3)(B) Disclosure for U.S. Patent No. 12,030,959

two weeks a pharmaceutical composition comprising a dose of omalizumab of:

- 150 mg when body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml; or
 - 150 mg when body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or
 - 225 mg when body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml; and
- wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.

13. The method of claim 12, wherein the body weight of the subject is determined prior to administration of a first dose of omalizumab.
14. The method of claim 12, wherein treating comprises reducing a moderate-to-severe allergic reaction following exposure of the subject to the food allergen.
15. The method of claim 12, wherein treating comprises reducing an allergic reaction following accidental exposure of the subject to the food allergen.
16. The method of claim 12, wherein the subject is not receiving concurrent oral immunotherapy with the food allergen.
17. A method of treating a human subject having an allergy to a food allergen, the method comprising:
 - (i) administering to the subject by subcutaneous injection once about every four weeks a pharmaceutical composition comprising a dose of omalizumab of:
 - 75 mg when body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml; or
 - 150 mg when body weight of the subject is equal to or greater than 10 kg and less than or equal to 15 kg, and total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; or
 - (ii) administering to the subject by subcutaneous injection once about every two weeks a pharmaceutical composition comprising a dose of omalizumab of:
 - 150 mg when body weight of the subject is equal to or greater than 10 kg and less than or equal to 12 kg, and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml; or
 - 150 mg when body weight of the subject is greater than 12 kg and less than or

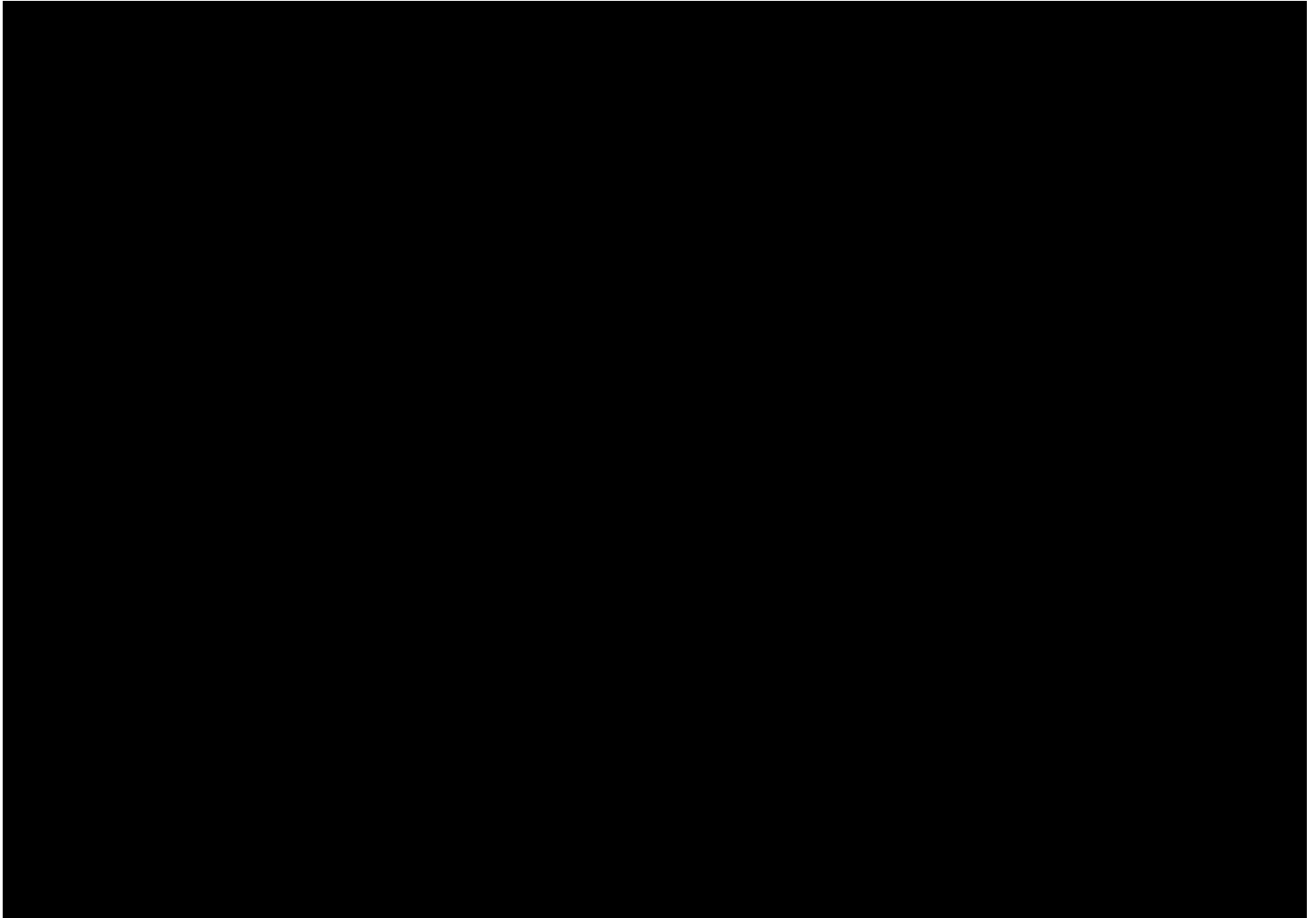
Exhibit 10

Kashiv's 42 U.S.C. § 262(D)(3)(B) Disclosure for U.S. Patent No. 12,030,959

- equal to 15 kg, and total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1200 IU/ml; or
225 mg when body weight of the subject is greater than 12 kg and less than or equal to 15 kg, and total serum IgE level of the subject is greater than 1200 IU/ml and less than or equal to 1850 IU/ml; and
wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.
18. The method of claim 17, wherein the body weight of the subject is determined prior to administration of a first dose of omalizumab.
19. The method of claim 17, wherein the subject is not receiving concurrent oral immunotherapy with the food allergen.
20. The method of claim 17, wherein the subject is from 1 year to 5 years of age.
21. The method of claim 17, wherein the subject has an allergy to peanut and to one or more of milk, egg, and cashew.
22. The method of claim 17, wherein treating comprises reducing an allergic reaction following exposure of the subject to the food allergen.
23. The method of claim 22, wherein the exposure to the food allergen is accidental.
24. The method of claim 22, wherein the allergic reaction is a moderate-to-severe allergic reaction.
25. A method of treating a human subject having an allergy to a food allergen, the method comprising:
administering to the subject having a body weight equal to or greater than 10 kg and less than or equal to 12 kg by subcutaneous injection a pharmaceutical composition comprising a dose of omalizumab of:
75 mg once about every four weeks if total serum IgE level of the subject is equal to or greater than 30 IU/ml and less than or equal to 300 IU/ml; or
150 mg once about every four weeks if total serum IgE level of the subject is greater than 300 IU/ml and less than or equal to 600 IU/ml; or
150 mg once about every two weeks if total serum IgE level of the subject is greater than 600 IU/ml and less than or equal to 1500 IU/ml; and
wherein the total serum IgE level of the subject is determined prior to administration of a first dose of omalizumab.
26. The method of claim 25, wherein the body weight of the subject is determined prior to administration of a first dose of omalizumab.

Exhibit 10
Kashiv's 42 U.S.C. § 262(l)(3)(B) Disclosure for U.S. Patent No. 12,030,959

27. The method of claim 25, wherein treating comprises reducing a moderate-to-severe allergic reaction following exposure of the subject to the food allergen.
28. The method of claim 25, wherein treating comprises reducing an allergic reaction following accidental exposure of the subject to the food allergen.
29. The method of claim 25, wherein the subject is not receiving concurrent oral immunotherapy with the food allergen.



III. Claims 1-29 of the '959 Patent Are Invalid As Anticipated and/or Obvious

As explained below, [REDACTED]
[REDACTED] all claims of the '959 patent are invalid as anticipated and/or obvious.

On May 26, 2026, Amneal Pharmaceuticals, Inc. and Kashiv Biosciences filed a petition for *inter partes* review of the '959 patent (the "IPR Petition"; IPR2026-00260, Paper 1), supported by the

Exhibit 10
Kashiv's 42 U.S.C. § 262(l)(3)(B) Disclosure for U.S. Patent No. 12,030,959

Declaration of Dr. Asif Rafi ("Rafi Declaration; IPR EX1002). The IPR Petition and supporting Rafi Declaration and exhibits, all of which are incorporated herein by reference, provide detailed bases for why at least claims 1, 3, 5, 17-18, and 20-24 of the '959 patent are anticipated, and all claims of the '959 patent are obvious.

Ground	Claims	35 U.S.C.	References
1	1, 3, 5, 17-18, 22-24	§102	<i>MacGinnitie</i> (EX1008)
2	1, 3, 5, 17-18, 22-24	§103	<i>MacGinnitie</i>
3	1, 3, 5, 17-18, 20-23	§102	<i>Bégin</i> (EX1009)
4	1, 3, 5, 17-18, 20-23	§103	<i>Bégin</i>
5	1-29	§103	<i>OUtMATCH-V26</i> (EX1005), <i>PI2021</i> (EX1007), and <i>Arasi</i> (EX1006)

Thus, for the same reasons as set forth in the IPR Petition (IPR2026-00260, Paper 1), all claims of the '959 patent are invalid as anticipated and/or obvious.