Listing of Challenged Claims of the '307 Patent

Claim	Recited Claim Language
1[pre]	1. A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising
1[a]	administering to the subject a pharmaceutical composition comprising a clinically proven safe and clinically proven effective amount of
1[b]	an anti-IL-12/IL-23p40 antibody, wherein the antibody comprises a heavy chain variable region and a light chain variable region, the heavy chain variable region comprising: a complementarity determining region heavy chain 1 (CDRH1) amino acid sequence of SEQ ID NO:1; a CDRH2 amino acid sequence of SEQ ID NO:2; and a CDRH3 amino acid sequence of SEQ ID NO:3; and the light chain variable region comprising: a complementarity determining region light chain 1 (CDRL1) amino acid sequence of SEQ ID NO:4; a CDRL2 amino acid sequence of SEQ ID NO:5; and a CDRL3 amino acid sequence of SEQ ID NO:6,
1[c]	wherein after treating with the antibody, the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤2 points with no individual subscore >1 and the US definition of clinical remission with absolute stool number ≤3, rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) clinical response based on the Mayo endoscopy subscore, (iv) improvements from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) mucosal healing, (vi) decrease from baseline in Mayo score, and (vii) clinical response as determined by a decrease from baseline in the Mayo score by ≥30% and ≥3 points and a decrease from baseline in the rectal bleeding subscore ≥1 points or a rectal bleeding subscore of 0 or 1.
2	2. The method of claim 1, wherein the antibody comprises the heavy chain variable region of the amino acid sequence of SEQ ID NO:7 and the light chain variable region of the amino acid sequence of SEQ ID NO:8.
3	3. The method of claim 1, wherein the antibody comprises a heavy chain of the amino acid sequence of SEQ ID NO:10 and a light chain of the amino acid sequence of SEQ ID NO:11.
4	4. The method of any one of claims 1-3, wherein the antibody is in a pharmaceutical composition for intravenous administration comprising a solution comprising 10 mM L-histidine, 8.5% (w/v) sucrose, 0.04% (w/v) polysorbate 80, 0.4 mg/mL L-methionine, and 20 μg/mL EDTA disodium salt, dehydrate, at pH 6.0.

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5	5. The method of any one of claims 1-3, wherein the antibody is in a pharmaceutical composition for subcutaneous administration comprising a solution comprising 6.7 mM L-histidine, 7.6% (w/v) sucrose, 0.004% (w/v) polysorbate 80, at pH 6.0.
6	6. The method of claim 4, wherein the antibody is administered intravenously to the subject at week 0 of the treatment, at a dosage of about 6.0 mg/kg body weight of the subject or 130 mg per administration.
7	7. The method of claim 6, wherein the antibody is further administered subcutaneously to the subject at week 8 of the treatment, at a dosage of about 90 mg per administration.
8	8. The method of claim 7, wherein the subject had previously failed or was intolerant of at least one therapy selected from the group consisting of an anti-TNF, vedolizumab, corticosteroids, azathioprine (AZA), and 6 mercaptopurine (6 MP), or the subject had demonstrated corticosteroid dependence.
9	9. The method of claim 7, wherein the antibody is administered in a maintenance dose every 8 weeks after the treatment at week 8 or every 12 weeks after the treatment at week 8.
10	10. The method of claim 9, wherein the subject is identified as having a clinical remission based on at least one of the global definition and the US definition by week 16 of the treatment and the clinical remission continues at least 44 weeks after week 0.
11	11. The method of claim 9, wherein the subject is in corticosteroid-free clinical remission at least 44 weeks after week 0.
12	12. The method of claim 8, wherein the subject is identified as having an endoscopic healing continuing at least 44 weeks after week 0.
13	13. The method of claim 9, wherein the subject is identified as achieving a clinical response based on the Mayo endoscopy subscore continuing at least 44 weeks after week 0.
14	14. The method of claim 9, wherein the subject is identified as having improvements from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score continuing at least 44 weeks after week 0.
15	15. The method of claim 9, wherein the subject is identified as having a mucosal healing continuing at least 44 weeks after week 0.
16	16. The method of claim 9, wherein the subject identified as having a decrease from baseline in Mayo score continuing at least 44 weeks after week 0.

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17	17. The method of claim 9, wherein the subject is identified as having a normalization of one or more biomarkers selected from the group consisting of C-reactive protein, fecal lactoferrin and fecal calprotectin continuing at least 44 weeks after week 0.
18	18. The method of claim 9, wherein the subject is in clinical response as determined by a decrease from baseline in the Mayo score by ≥30% and ≥3 points and a decrease from baseline in the rectal bleeding subscore ≥1 points or a rectal bleeding subscore of 0 or 1 continuing at least 44 weeks after week 0.
19[pre]	19. A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising:
19[a]	a. intravenously administering to the subject an anti-IL-12/IL-23p40 antibody in a first pharmaceutical composition at a dosage of about 6.0 mg/kg body weight of the subject or 130 mg per administration at week 0 of the treatment, and b. subcutaneously administering to the subject the anti-IL-12/IL-23p40 antibody in a second pharmaceutical composition at a dosage of 90 mg per administration at week 8 of the treatment,
19[b]	wherein the antibody comprises a heavy chain variable region and a light chain variable region, the heavy chain variable region comprising: a complementarity determining region heavy chain 1 (CDRH1) amino acid sequence of SEQ ID NO:1; a CDRH2 amino acid sequence of SEQ ID NO:2; and a CDRH3 amino acid sequence of SEQ ID NO:3; and the light chain variable region comprising: a complementarity determining region light chain 1 (CDRL1) amino acid sequence of SEQ ID NO:4; a CDRL2 amino acid sequence of SEQ ID NO:5; and a CDRL3 amino acid sequence of SEQ ID NO:6; and
19[c]	wherein the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) having a clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤2 points with no individual subscore >1 and the US definition of clinical remission with absolute stool number ≤3, rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) having an endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) achieving a clinical response based on the Mayo endoscopy subscore, (iv) having improvements from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) having a mucosal healing, (vi) having a decrease from baseline in Mayo score, and (vii) in clinical response as determined by a decrease from baseline in the Mayo score by ≥30% and ≥3 points and a decrease from baseline in the rectal bleeding subscore ≥1 points or a rectal bleeding subscore of 0 or 1,

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19[d]	had previously failed or was intolerant of at least one therapy selected from the group consisting of: an anti-TNF, vedolizumab, corticosteroids, azathioprine (AZA), and 6 mercaptopurine (6 MP), or the subject had demonstrated corticosteroid dependence.
20	20. The method of claim 19, wherein the antibody comprises the heavy chain variable region of the amino acid sequence of SEQ ID NO:7 and the light chain variable region of the amino acid sequence of SEQ ID NO:8.
21	21. The method of claim 19, wherein the antibody comprises a heavy chain of the amino acid sequence of SEQ ID NO:10 and a light chain of the amino acid sequence of SEQ ID NO:11.
22	22. The method of any one of claims 19-21, wherein the pharmaceutical composition for intravenous administration further comprises a solution comprising 10 mM L-histidine, 8.5% (w/v) sucrose, 0.04% (w/v) polysorbate 80, 0.4 mg/mL L-methionine, and 20 μg/mL EDTA disodium salt, dehydrate, at pH 6.0.
23	23. The method of claim 22, wherein the pharmaceutical composition for subcutaneous administration further comprises a solution comprising 6.7 mM L-histidine, 7.6% (w/v) sucrose, 0.004% (w/v) polysorbate 80, at pH 6.0.
24	24. The method of any one of claims 19-21, wherein the subject is identified as having a clinical remission based on at least one of the global definition and the US definition by week 16 of the treatment.
25	25. The method of any one of claims 19-21, wherein the subject is identified as having an endoscopic healing by week 16 of the treatment.
26	26. The method of any one of claims 19-21, wherein the subject is identified as achieving a clinical response based on the Mayo endoscopy subscore by week 16 of the treatment.
27	27. The method of any one of claims 19-21, wherein the subject is identified as having improvements from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score by week 16 of the treatment.
28	28. The method of any one of claims 19-21, wherein the subject is identified as having a mucosal healing by week 16 of the treatment.
29	29. The method of any one of claims 19-21, wherein the subject is identified as having a decrease from baseline in Mayo score by week 16 of the treatment.
30	30. The method of any one of claims 19-21, wherein the subject is identified as having a normalization of one or more biomarkers selected from the group consisting of C-reactive protein, fecal lactoferrin and fecal calprotectin by week 16 of the treatment.

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31	31. The method of any one of claims 19-21, wherein the subject is in clinical response as determined by a decrease from baseline in the Mayo score by ≥30% and ≥3 points and a decrease from baseline in the rectal bleeding subscore ≥1 points or a rectal bleeding subscore of 0 or 1 by week 16 of the treatment.
32	32. The method of any one of claims 19-21, wherein the subject is not a responder to the treatment with the antibody by week 8 and is a responder to the treatment by week 16 of the treatment.
33[pre]	33. A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising:
33[a]	a. intravenously administering to the subject an anti-IL-12/IL-23p40 antibody in a first pharmaceutical composition at a dosage of about 6.0 mg/kg body weight of the subject or 130 mg per administration at week 0 of the treatment, and b. subcutaneously administering to the subject the anti-IL-12/IL-23p40 antibody in a second pharmaceutical composition at a dosage of 90 mg per administration at week 8 of the treatment,
33[b]	wherein the antibody comprises a heavy chain variable region and a light chain variable region, the heavy chain variable region comprising: a complementarity determining region heavy chain 1 (CDRH1) amino acid sequence of SEQ ID NO:1; a CDRH2 amino acid sequence of SEQ ID NO:2; and a CDRH3 amino acid sequence of SEQ ID NO:3; and the light chain variable region comprising: a complementarity determining region light chain 1 (CDRL1) amino acid sequence of SEQ ID NO:4; a CDRL2 amino acid sequence of SEQ ID NO:5; and a CDRL3 amino acid sequence of SEQ ID NO:6,
33[c]	followed by a maintenance therapy, wherein the maintenance therapy comprises subcutaneously administering to the subject the anti-IL-12/IL-23p40 antibody at a dosage of 90 mg per administration, once every 8 weeks or once every 12 weeks, and
33[d]	wherein the maintenance therapy is provided for 44 weeks and after treating with the antibody,

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33[e]	the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) having a clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤2 points with no individual subscore >1 and the US definition of clinical remission with absolute stool number ≤3, rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) having an endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) achieving a clinical response based on the Mayo endoscopy subscore, (iv) having improvements from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) having a mucosal healing, (vi) having a decrease from baseline in Mayo score, and (vii) in clinical response as determined by a decrease from baseline in the Mayo score by ≥30% and ≥3 points and a decrease from baseline in the rectal bleeding subscore ≥1 points or a rectal bleeding subscore of 0 or 1.
34[pre]	34. A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising:
34[a]	a. intravenously administering to the subject an anti-IL-12/IL-23p40 antibody comprising a heavy chain variable region of the amino acid sequence of SEQ ID NO:7 and a light chain variable region of the amino acid sequence of SEQ ID NO:8, in a first pharmaceutical composition at a dosage of about 6.0 mg/kg body weight of the subject or 130 mg per administration at week 0 of the treatment, and b. subcutaneously administering to the subject the anti-IL-12/IL-23p40 antibody in a second pharmaceutical composition at a dosage of 90 mg per administration at week 8 of the treatment,
34[b]	followed by a maintenance therapy, wherein the maintenance therapy comprises subcutaneously administering to the subject the anti-IL-12/IL-23p40 antibody at a dosage of 90 mg per administration, once every 8 weeks or once every 12 weeks,
34[c]	and after treating with the antibody, the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) having a clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤2 points with no individual subscore >1 and the US definition of clinical remission with absolute stool number ≤3, rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) having an endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) achieving a clinical response based on the Mayo endoscopy subscore, (iv) having improvements from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) having a mucosal healing, (vi) having a decrease from baseline in Mayo score, and (vii) in clinical response as determined by a decrease from baseline in the Mayo score by ≥30% and ≥3 points and a decrease from baseline in the rectal bleeding subscore ≥1 points or a rectal bleeding subscore of 0 or 1.