

Declaration of Martyn Christopher Davies in Support of
Patent Owner's Preliminary Response
IPR2025-00056

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. FALK PHARMA GMBH,
Petitioner,

v.

ELLODI PHARMACEUTICALS, L.P.,
Patent Owner.

IPR2025-00056
U.S. Patent No. 11,260,061 B2
Issue Date: March 1, 2022

Title: CORTICOSTEROID CONTAINING ORALLY DISINTEGRATING TABLET
COMPOSITIONS FOR EOSINOPHILIC ESOPHAGITIS

DECLARATION OF MARTYN CHRISTOPHER DAVIES

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I, Martyn Christopher Davies declare as follows:

I. INTRODUCTION

1. I submit this declaration in connection with Patent Owner's Preliminary Response in the *Inter Partes* Review IPR2025-00056 (the "IPR") of claims 1-30 ("challenged claims") of U.S. Patent No. 11,260,061 (the "'061 patent"; Ex. 1001). I have been retained by Cooley LLP, counsel for Patent Owner Ellodi Pharmaceuticals, L. P. in this matter.

A. Qualifications and Experience

2. I am an Emeritus Professor and a Pharmaceutical Consultant. I have over 35 years of experience in the field of pharmaceutical and biologic therapeutics and drug delivery fields.

3. I retired in 2017 as the Professor of Biomedical Surface Chemistry at the University of Nottingham, School of Pharmacy of Nottingham, Nottinghamshire, United Kingdom. I had held this position since 1996. I also provide consulting services for the pharmaceutical industry worldwide.

4. In 1980, I received my B.Sc. in Pharmacy from Brighton Polytechnic in the United Kingdom. I graduated first in my class with First Class Honours.

5. I was awarded a Ph.D. from the Chelsea School of Pharmacy, University of London (now Kings College, University of London) in 1985. My doctoral thesis focused on the surface energetics of hydroxypropylmethylcellulose

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and was titled "Properties of aqueous film coatings." My thesis research was under the supervision of Professor J.M. Newton.

6. In 2018, I was awarded a D.Sc. from the University of Nottingham and an Honourary Doctorate in Sciences from the University of Brighton.

7. In 1984, I was appointed as a temporary lecturer in the Department of Pharmacy at the University of Manchester, where my responsibilities included teaching physical chemistry and pharmaceuticals. The following year, I was appointed to a lectureship in drug delivery in the Department of Pharmaceutical Sciences at the University of Nottingham. I was appointed as a Reader in 1991 and as a full Professor in 1996, both in Biomedical Surface Chemistry.

8. Over the course of my academic career, I have taught a range of classes, including classes in physical chemistry, pharmaceutical technology, analysis, and drug delivery, to both graduate and undergraduate students. I have trained over one hundred (100) postdoctoral and post graduate students, over twenty (20) of whom have been appointed to positions at leading international universities and many obtained important positions in the pharmaceutical industry.

9. I was Head of the Life, Health and Agricultural Sciences Division, of the Graduate School from 1995 until 1997, the Deputy Head of the School of Pharmaceutical Sciences from 1999 to 2000, and the Head of the School of

Pharmaceutical Sciences and Pharmacy School from 2000 until 2003, all at the University of Nottingham.

10. I have extensive practical experience in developing and characterizing pharmaceutical formulations. This experience comes from various sources, including conducting laboratory work with doctoral students that I have supervised, in my teaching and work at the University of Nottingham, through various industry and business partnerships and consulting roles whilst working at the Laboratory of Biophysics and Surface Analysis ("LBSA"), a research division of the University of Nottingham's School of Pharmacy that I co-founded, and in the course of performing various consulting projects through my work at Molecular Profiles Ltd. (which became Juniper Pharma Services). I have extensive experience with the formulation of tablets, capsules, and advanced drug delivery and controlled release systems that include the use and study of polymeric excipients. I have also been extensively involved in the making and characterization of many pharmaceutical preparations from 1985 to date.

11. In my career I have been active in various national and international societies, including the Royal Pharmaceutical Society of Great Britain (where I was elected a Fellow), the Royal Society of Chemistry (where I was elected a Fellow), and the Controlled Release Society (where I was elected a Fellow). I have served

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as President (2011 and 2012), Vice-President (2009), and Scientific Secretary (2001) of the Controlled Release Society, the premier international society in drug delivery and controlled release.

12. I was a member of the Engineering and Physical Sciences Research Council Peer Review College, the Research Assessment Exercise 2008 Pharmacy Panel, and was a participant in the European Science Foundation Forward Look on Nanomedicine. I also was elected as a Fellow of the Academy of Pharmaceutical Sciences in the United Kingdom.

13. Over the course of my career, I have authored over 380 peer-reviewed papers, reviews, and book chapters. My work has been published in various nationally and internationally recognized journals, including the Journal of Controlled Release, the International Journal of Pharmaceutics, The Journal of Pharmaceutical Sciences, Pharmaceutical Research, Molecular Pharmaceutics, The European Journal of Pharmaceutics and Biopharmaceutics, Expert Opinion of Drug Delivery, Gastroenterology, Langmuir, the Journal of Physical Chemistry, Analytical Chemistry, PNAS and Nature Materials. I am also a named inventor on various patents and patent applications.

14. I have presented at various national and international conferences and learned societies, including the Swedish Academy of Sciences, the Royal Society

of Chemistry, the American Chemistry Society, the Controlled Release Society, and the Association of Pharmaceutical Scientists. I have presented invited seminars at various universities and research institutes including Kings College, Cambridge University, the University of Utah, and the National University of Ireland. I have also presented lectures to research groups in the pharmaceutical and chemistry industries.

15. I have sat on the editorial boards of leading international scientific journals focusing on formulation science, including the Journal of Pharmaceutical Sciences, Advanced Drug Delivery Reviews, the European Journal of Pharmaceutical Sciences, the Journal of Controlled Release, and the Journal of Biopharmaceutics and Biotechnology.

16. As mentioned earlier, I was one of the co-founders of the LBSA, which I led until 2008. The LBSA had a leading international reputation in the application of advanced analytical tools to understand the structure and function of pharmaceutical formulations such as controlled release systems, polymeric excipients, and biomedical systems. In 2003, the LBSA was awarded the GlaxoSmithKline International Achievement Award for its internationally recognized work on the commercial exploitation of nanotechnology in pharmaceutical formulations. This was the first time that this award was given to

such a group.

17. In 1997, I co-founded the private sector company Molecular Profiles Ltd. and served as the founding chairman until 2013, when the company was acquired by Columbia Laboratories and became Juniper Pharma Services, which in turn was acquired by Catalent Inc in 2018. At that time, I was appointed as an Advisor to the Board of Directors of Juniper Pharmaceuticals and Chaired and served on the Scientific Advisory Board of Juniper Pharmaceuticals. Molecular Profiles Ltd. (and then Juniper) provided customized formulation, characterization, and development across a broad range of therapies, mainly focused on small molecule Active Pharmaceutical Ingredients ("APIs"). We also provided pharmaceutical development, clinical trial manufacturing, advanced analysis, and consulting services. Molecular Profiles Ltd and then Juniper also developed, manufactured and packaged formulations for use by pharmaceutical companies in Phase I and Phase II clinical trials.

18. In 2007 and 2011, Molecular Profiles Ltd. was awarded a Queen's Award for Enterprise in recognition of its commitment to bringing high quality, innovative science to the pharmaceutical industry.

19. In January 2018, I was appointed a Commander of the Order of the British Empire ("CBE") in Her Majesty's 2018 New Year's Honours List in

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recognition of my contribution to science and achievements in pharmacy and pharmaceutical research.

20. My credentials are set forth in full detail in my Curriculum Vitae which is submitted as Exhibit 2003, and incorporated here by reference.

21. I am being compensated for the time I spend working on this matter at my standard rate. My compensation does not depend in any way upon the outcome of this proceeding, and I hold no financial interest in either Dr. Falk Pharma GmbH ("Petitioner") or Ellodi Pharmaceuticals, L.P. ("Patent Owner").

22. In formulating my opinions, I have relied upon my training, knowledge, and experience in the relevant art.

B. Materials Considered

23. The analysis that I provide in this Declaration is based on my education, research, and experience, as well as the documents I have considered. In forming my opinions, I have read and considered the claims, specification, and prosecution history of U.S. Patent No. 11,260,061 ("'061 patent"). I have reviewed the Petition for *Inter Partes* Review (and exhibits, including the Declaration of Alan F. Parr) filed by Petitioner Dr. Falk Pharma GmbH on October 21, 2024. I have also cited to or considered the following documents in my analysis below:

Exhibit No.	Description of Document
2002	Merriam-Webster's Collegiate Dictionary, 11th ed. (2006) – definitions of “adsorption” and “disposition”

II. LEGAL STANDARDS

24. In formulating my opinions and conclusions in this proceeding, I have been provided with an understanding of the prevailing principles of U.S. patent law that govern the issues of patent validity.

A. Claim Construction

25. I understand that the purpose of claim construction is to determine what a person of ordinary skill in the art would have understood the claim terms to mean. Claim terms are generally given their ordinary and customary meaning, which is the meaning that the term would have to a person of ordinary skill in the art in question as of the effective filing date.

26. I understand that the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. I understand that the patent specification, under the legal principles, has been described as the single best guide to the meaning of a claim term, and is thus highly relevant to the interpretation of claim terms. And I understand for terms that do not

have a customary meaning within the art, the specification usually supplies the best context of understanding the meaning of those terms.

27. I further understand that other claims of the patent in question, both asserted and unasserted, can be valuable sources of information as to the meaning of a claim term. Because the claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.

28. I understand that the prosecution history can further inform the meaning of the claim language by demonstrating how the inventors understood the invention and whether the inventors limited the invention in the course of prosecution, making the claim scope narrower than it otherwise would be. Extrinsic evidence, such as dictionaries, may also be consulted in construing the claim terms.

29. I understand that, in *Inter Partes* Review (IPR) proceedings, a claim of a patent shall be construed using the same claim construction standard that would be used to construe the claim in a civil action filed in a U.S. district court (which I understand is called the “*Phillips*” claim construction standard), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history

pertaining to the patent.

30. I have been instructed by counsel to apply the “*Phillips*” claim construction standard for purposes of interpreting the claims in this proceeding, to the extent they require an explicit construction. The description of the legal principles set forth above thus provides my understanding of the “*Phillips*” standard as provided to me by counsel.

31. Where claim construction issues arise, I have noted them in my analysis below.

B. Obviousness

32. I am also informed and understand that a claim may be rendered obvious to a person of ordinary skill in the art if the differences between the subject matter set forth in the patent claim and the prior art are such that the subject matter as a whole of the claim would have been obvious at the time the claimed invention was made.

33. I am informed and understand that obviousness is a determination of law based on various underlying determinations of fact. In particular, these underlying factual determinations include (1) the scope and content of the prior art; (2) the level of ordinary skill in the art at the time the claimed invention was made; (3) the differences between the claimed invention and the prior art; and (4) the extent

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of any proffered objective *indicia* of nonobviousness. I understand that the objective *indicia* which may be considered in such an analysis include commercial success of the patented invention (including evidence of industry recognition or awards), whether the invention fills a long-felt but unsolved need in the field, the failure of others to arrive at the invention, industry acquiescence and recognition, initial skepticism of others in the field, whether the inventors proceeded in a direction contrary to the accepted wisdom of those of ordinary skill in the art, and the taking of licenses under the patent by others, among other factors.

34. I am informed and understand that to ascertain the scope and content of the prior art, it is necessary to first examine the field of the inventor's endeavor and the particular problem for which the invention was made. The relevant prior art includes prior art in the field of the invention, and also prior art from other fields that a person of ordinary skill in the art would look to when attempting to solve the problem.

35. I am informed and understand that a determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. Instead, it is my understanding that to render a patent claim invalid as being obvious from a combination of references, there must be some evidence within the prior art as a

whole to suggest the desirability, and thus the obviousness, of making the combination in a way that would produce the patented invention.

36. I understand that there is a high standard before a party can rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis. Even if a certain thing may result from a given set of circumstances, I understand that is not enough to render the result inherent. I also understand that an element can only be inherently disclosed if it is necessarily present in the prior art, not just probably or possibly present. Yet, even if an element is inherent, I understand that it is not necessarily obvious.

37. I am further informed and understand that in an obviousness analysis, neither the motivation nor the purpose of the patentee dictates. What is important is whether there existed at the time of the invention a known problem for which there was an obvious solution encompassed by the patent's claims.

38. In addition, it is my understanding that to find a patent claim invalid for obviousness, there must be a finding that each element in each limitation of the patent claim is disclosed, taught, or suggested by the asserted combination of prior-art references or elsewhere in the relevant prior art. I understand, however, that a patent claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

But multiple prior-art references or elements may, in some circumstances, be combined to render a patent claim obvious. I understand that I should consider whether there is an “apparent reason” or motivation to combine the prior-art references or elements in the way the patent claims. To determine whether such an “apparent reason” or motivation exists to combine the prior-art references or elements in the way a patent claims, it will often be necessary to look to the interrelated teaching of multiple prior-art references, to the effects of demands known to the design community or present in the marketplace, and to the background knowledge possessed by a person of ordinary skill in the art.

39. I also understand that when the prior art “teaches away” from combining prior-art references or certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. A prior-art reference may be said to “teach away” from a patent when a person of ordinary skill in the art, upon reading the reference, would be discouraged from following the path set out in the patent or would be led in a direction divergent from the path that was taken by the patent. Additionally, a prior-art reference may “teach away” from a claimed invention when substituting an element within that prior-art reference for a claim element would render the claimed invention inoperable.

40. I am informed and understand that a patent for a combination which

only recites old elements with no change in their respective functions withdraws what is already known into the field of its monopoly and diminishes the resources available to person of ordinary skill in the field. When a patent claims a structure already known in the prior art that is altered by mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. I am informed and understand that the corollary to this principle is that when the prior art teaches away from combining known elements, discovery of a successful means of combining them is more likely to be nonobvious. Thus, the question to be answered is whether someone reading the prior art would be discouraged from following the path taken by the inventor.

41. I am further informed and understand that when an element is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill in the art can implement a predictable variation of that available element, Section 103 likely renders the invention obvious. For the same reason, I am informed and understand that if a technique has been used to improve one device or process, and a person of ordinary skill in the art would recognize that such technique would improve similar devices or processes in the same way, using the technique is obvious unless its actual application is beyond his or her skill. Following these

principles often requires one to look to interrelated teachings of multiple patents; the effects of demands known to the design community present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art to determine whether there was an apparent reason to combine the known element in the manner claimed by the patent at issue. I am further informed and understand that the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, because one can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

42. I am further informed and understand that although the use of the “teaching, suggestion or motivation” test for combining references has not been completely rejected, the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent can provide a reason for combining the elements in the manner claimed. Finally, I am informed and understand that common sense teaches that familiar items may have obvious uses beyond their primary purposes and, in many cases, a person of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle.

III. OVERVIEW OF THE '061 PATENT

43. The '061 patent, titled "Corticosteroid Containing Orally Disintegrating Tablet Compositions for Eosinophilic Esophagitis," was filed on March 24, 2021 and has a priority date of September 6, 2013. It has three named inventors: Michael A. Gosselin, Jin-Wang Lai, and Gopi M. Venkatesh.

44. The claims of the '061 patent are directed to an orally disintegrating tablet (ODT) comprising a topically acting corticosteroid adsorbed onto a pharmaceutically acceptable carrier. Topically acting corticosteroids are not systemically active – meaning the topically acting corticosteroid exerts its therapeutic effect only through topical contact of the corticosteroid with inflamed esophageal tissue. Thus, formulating the corticosteroid such that it is readily exposed to the inflamed tissue is essential to efficacy. The '061 patent specification describes that low-dose corticosteroid compositions may suffer from non-uniform blends and the active corticosteroid particles may become embedded within large agglomerates composed of excipients which prevents the corticosteroid from being readily exposed to inflamed EoE tissues. Ex. 1001, 2:30-3:33. In other words, when the corticosteroid is not adsorbed to a carrier, the ODT may be poorly efficacious. Ex. 1001, 10:56-59.

45. The '061 patent cites to WO2011041509 (Ex. 1063) as disclosing a

preparation of an ODT containing a low dose of corticosteroid using a granulation method, and that the method is likely used for the purposes of achieving blend uniformity. Ex. 1001, 3:5-23. Dr. Parr acknowledges that WO2011041509 contains the same disclosures as U.S. Publication No. 2011/0081411 to Perrett et al. Ex. 1070, 72 n.7, 79 n.8.

46. The '061 patent specification explains that Patent Owner first recognized that agglomeration of drug particles and excipients is an issue during production of ODTs according to the method disclosed in WO2011041509, and agglomeration prevents the corticosteroid from being readily exposed to inflamed esophageal tissues and also results in blend non-uniformity that Perrett's processing was thought to resolve in the first place. Ex. 1001, 2:30-44. The '061 patent solves the problem of agglomeration by adsorbing the topically active corticosteroid onto a pharmaceutically acceptable carrier prior to blending with other excipients, preventing the agglomeration of particles during manufacturing. Ex. 1001, 3:24-39; 3:61-4:3.

47. The '061 patent specification describes the process for "adsorbing a topically acting corticosteroid...onto at least one pharmaceutically acceptable carrier...by blending for a sufficiently long time[.]" Ex. 1001, 3:61-66. The specification also explains that blending the corticosteroid with the pharmaceutically

acceptable carrier “avoid[s] segregation-agglomeration of the drug particles in the blend...to achieve and maintain desired high blend uniformity/homogeneity and/or to achieve high content uniformity of the finished dosage units[.]” Ex. 1001, 4:4-15. The exemplary processes further teach blending micronized corticosteroid with the pharmaceutically acceptable carrier for at least ten minutes, followed by additional blending with additional excipients for at least 30 to 40 minutes. Ex. 1001, 13:3-61 (disclosing methods for manufacturing compressible blends with acceptable content uniformity); *id.*, Examples 2, 3. The adsorption of the corticosteroid onto the carrier is therefore accomplished by the sufficiently long blending process disclosed in the '061 patent specification. This process and “adsorbing micronized topically acting corticosteroid drug particles onto the pharmaceutically acceptable carrier (such as silicified microcrystalline cellulose) prior to blending with rapidly dispersing granules and other excipients” not only achieves “desired content uniformity but also enhance[s] the probability of largely keeping the corticosteroid drug particles exposed to the inflamed mucosa[.]” Ex. 1001, 10:59-67; *see also id.* at 3:24-39; 3:61-4:3.

48. The '061 patent has 30 claims. Claims 1 and 19 are independent.

Claim 1 recites:

1. An orally disintegrating tablet comprising:
 - a. a topically acting corticosteroid or pharmaceutically

acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier; and

b. at least one disintegrant;

wherein the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, is present in an amount ranging from about 0.5 mg to about 10 mg, and the topically acting corticosteroid, or pharmaceutically acceptable salt or ester thereof, has a mean particle size of ranging from about 100 nm to about 100 μ m; and

wherein the orally disintegrating tablet disintegrates within 60 seconds when tested using the USP <701>method for disintegration time.

49. Claims 2-18 and 29-30 depend on claim 1.

Claim 19 recites:

19. An orally disintegrating tablet comprising:

a. fluticasone propionate adsorbed onto microcrystalline cellulose, silicified microcrystalline cellulose, pregelatinized starch, corn starch, colloidal silica, amorphous magnesium aluminum silicate, or combinations thereof; and

b. at least one disintegrant,

wherein:

the fluticasone propionate is present in an amount ranging from about 0.5 mg to about 6 mg, and

the fluticasone propionate has a mean particle size ranging from about 100 nm to about 10 μ m; and

wherein the orally disintegrating tablet disintegrates within 30 seconds when tested using the USP <701>Disintegration test.

50. Claims 20-28 depend on claim 19.

51. Both independent claims are directed towards a low-dose orally disintegrating tablet comprising a topically acting corticosteroid that is adsorbed

onto a pharmaceutically acceptable carrier. Dependent claims 29 and 30 are method claims. Dependent claim 29 is directed to a method for treating eosinophilic esophagitis using the orally disintegrating tablet of claim 1. Dependent claim 30 is directed to a method of preparing the orally disintegrating tablet of claim 1.

A. Prosecution History

52. I understand that Petitioner acknowledges that Perrett, Dohil2009, and Venkatesh “were submitted to the USPTO during prosecution of the ’061 patent.” Pet., 74. This is true.

53. Petitioner fails to acknowledge that Perrett was considered during the prosecution of the ’061 patent. The claims were initially rejected over Ramalho et al. (US 20060051414) (“Ramalho”) in view of Perrett et al. (US 20110081411) (“Perrett”) and Milburn et al. (US 20060292099), as well as Ramalho, Perrett, and Milburn in further view of Platteeuw et al. (US 2004/0265375). Ex. 1056, 158-164.

54. The Examiner considered many prior art references cited in the Petition and Dr. Parr’s declaration, during prosecution. More specifically, each of the following documents was marked as expressly considered by the Examiner during prosecution:

- Ex. 1002 – U.S. Publication No. 2007/0111978 to Dohil et al. (“Dohil”) (see Ex. 1056 at 54);

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- Ex. 1014 –Aceves et al., “Topical viscous budesonide suspension for treatment of eosinophilic esophagitis,” *Journal of Allergy and Clinical Immunology*, 116(3):705-706 (2005) (*see* Ex. 1056 at 72);
- Ex. 1015 –Aceves et al., “Oral Viscous Budesonide: A potential new therapy for eosinophilic esophagitis in children,” *American Journal of Gastroenterology*, 102(10):1-9 (2007) (*see* Ex. 1056 at 72);
- Ex. 1020 – U.S. Publication No. 2005/0232988 to Venkatesh et al. (*see* Ex. 1056 at 540);
- Ex. 1054 – Wen, “Adsorption at solid surfaces: pharmaceutical applications,” *Encyclopedia of Pharmaceutical Technology*, Third Edition Vol. 1, ed. Swarbrick, pages 34-45 (2007) (*see* Ex. 1056 at 64 (citing pages 34-38));
- Ex. 1057 – U.S. Publication No. 2011/0081411 to Perrett et al. (*see* Ex. 1056 at 158-1640);
- Ex. 1058 – U.S. Publication No. 2009/0191275 to Dohil et al. (“Dohil2009”) (*see* Ex. 1056 at 540);
- Ex. 1063 – International Publication No. WO 2011/041509 (*see* Ex. 1056 at 58); and
- Ex. 1065 – Remedios et al., “Eosinophilic esophagitis in adults:

clinical, endoscopic, histologic findings, and response to treatment with fluticasone propionate,” *Gastrointestinal Endoscopy*, 63(1):3-12 (2006) (see Ex. 1056 at 65).

55. Petitioner also cites to the EPO proceeding for EP3041476B1. Ex. 1062. The Examiner considered various filings from this proceeding during prosecution of the '061 patent. Ex. 1056 at 24, 63-64.

56. Dr. Parr does not cite to the prosecution history of the '061 patent, or the Information Disclosure Statements submitted during prosecution disclosing the prior art references and EPO proceeding, in his declaration. As such, Dr. Parr does not acknowledge that the Examiner previously considered much of the prior art that he cites.

57. Patent Owner filed the application for the '061 patent on March 24, 2021. Ex. 1001, cover. During prosecution, the Examiner made an obviousness rejection over Ramalho in view of Perrett and Milburn, as well as Platteeuw. Ex. 1056, 158-164. Specifically, the Examiner asserted that Ramalho discloses ODTs with an excipient, and the intimate contacts between them “results in the active agent adsorbed onto the disintegrating agent.” Ex. 1056 at 160. With respect to Perrett, the Examiner argued that Perrett teaches an ODT containing a corticosteroid for treating inflammation of the esophagus, and that a POSA would have had a

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reasonable expectation of success of producing an ODT that was effective in treating said inflammation along with the teachings in Milburn and Platteeuw. Ex. 1056, 160-164. The Examiner also made a nonstatutory double patenting rejection over U.S. Patent No. 10,471,071 (the "'071 patent"). Ex. 1056, 164-166.

58. Patent Owner filed a terminal disclaimer. Ex. 1056, 95-97. Patent Owner also responded to the obviousness rejection, explaining that the claims are directed to an ODT comprising a topically acting corticosteroid that is adsorbed onto a pharmaceutically acceptable carrier, instead of being agglomerated and not exposed to inflamed tissue. Ex. 1056, 111. The adsorption leads to an increased likelihood that the drug is exposed to the inflamed esophageal tissue. Ex. 1056, 111. Ramalho is directed to systemically active, not topically active drugs. Ex. 1056, 111-112. Further, Patent Owner explained that neither Perrett, Milburn or Platteeuw disclose formulating an ODT in order to enhance exposure of a topically active drug to inflamed esophageal tissue. Ex. 1056, 112. The Examiner subsequently withdrew the rejections in view of Patent Owner's remarks and allowed the '061 patent. Ex. 1056, 46.

59. Dr. Parr repeats arguments already raised and resolved during prosecution. For example, the Examiner argued that it would have been obvious to modify Ramalho with Perrett and Milburn to obtain an ODT with micronized

corticosteroid particles for enhanced and uniform absorption of the drug. Ex. 1056 at 160-161. Patent Owner was able to overcome this rejection and neither the Petitioner, nor Dr. Parr present any different arguments than the ones asserted by the Examiner.

60. I understand that Petitioner acknowledges that Perrett was considered during the prosecution of the grandparent patent of the '061 patent, the '071 patent. Pet., 75. This is true.

61. During prosecution of the '071 patent, the Examiner relied on Perrett for the disclosure of an ODT comprising a corticosteroid blended with an excipient which also allegedly serves as a carrier. Ex. 1068, 85. Patent Owner then amended claim 1 to “clarify that the corticosteroid is adsorbed onto the pharmaceutically acceptable carrier[.]” Ex. 1068, 73. As explained by Patent Owner during the prosecution of the '071 patent, however, solid dosage forms such as those taught by Perrett:

suffer from non-uniform blends which result in inhomogeneous drug content within a batch – at drug content levels ≤ 5 wt%, drug particles tend to aggregate and form larger particles...As a result, the ODT disclosed in Perrett will consist of agglomerated corticosteroid granules that are not uniformly dispersed in the ODT and are not readily exposed to the inflamed tissue to the esophagus...

Perret did not recognize any advantage of adsorbing a corticosteroid onto a pharmaceutically acceptable carrier, much less improving drug content uniformity and exposure of the corticosteroid to the inflamed tissue to the

esophagus to treat eosinophilic esophagitis.

Ex. 1068, 75.

62. The Examiner withdrew the rejection over Perrett, and after some additional back and forth, allowed the claims. Ex. 1068, 24, 38, 57.

IV. CLAIM CONSTRUCTION

63. In his declaration, Dr. Parr opines on the construction of a number of terms in the '061 patent. I address the construction of each term below.

A. Terms Defined in the '061 Patent Specification

64. Dr. Parr states that the '061 patent defines “orally disintegrating tablet”, “orally dispersing tablet,” or “ODT” as “to a solid dosage form of the present invention, which disintegrates rapidly in the oral cavity of a patient after administration, without chewing.” Ex. 1070, ¶107 (citing Ex. 1001, 5:12-15). I agree with this definition.

65. Dr. Parr states that the '061 patent defines “sugar alcohols” as “hydrogenated forms of carbohydrates in which the carbonyl group (i.e., aldehyde or ketone) has been reduced to a primary or secondary hydroxyl group.” Ex. 1070, ¶108 (citing Ex. 1001, 9:29-31). I agree with this definition.

66. Dr. Parr states that '061 patent states that “[t]he term ‘saccharide’ is synonymous with the term ‘sugars’ includes monosaccharides such as glucose, fructose, the lactose, and ribose and disaccharides such as sucrose, lactose, maltose,

trehalose, and cellobiose.” Ex. 1070, ¶109 (citing Ex. 1001, 9:36-40). I agree with this definition.

67. Dr. Parr states that the '061 patent states that “[t]he term ‘about’, as used herein to refer to a numerical quantity, includes ‘exactly.’ For example, ‘about 30 seconds’ includes 30 seconds, exactly, as well as values close to 30 seconds (e.g., 25 seconds, 29 seconds, 31 seconds, 35 seconds, etc.). When the term ‘about’ is used in reference to a range of values, the term ‘about’ refers to both the minimum and maximum value of the range (e.g., ‘about 1-50 μm ’ means ‘about 1 μm to about 50 μm ’).” Ex. 1070, ¶110 (citing Ex. 1001, 5:21-27). I agree with this definition.

68. I apply these definitions.

B. “Rapidly Dispersing Microgranule”

69. Dr. Parr states that “rapidly dispersing microgranule” should be accorded its plain and ordinary meaning. Ex. 1070, ¶113. I do not disagree.

70. To the extent Dr. Parr or Petitioner provide any definition as to the plain and ordinary meaning of “rapidly dispersing microgranule,” I reserve the right to provide additional opinions on the meaning of the term.

C. “Adsorbed Onto A Pharmaceutically Acceptable Carrier”

1. Patent Owner's Construction of “Adsorbed Onto A Pharmaceutically Acceptable Carrier”

71. It is my opinion that, in view of the claims of the '061 patent and its

specification, a POSA would understand the plain and ordinary meaning of the claim term “adsorbed onto a pharmaceutically acceptable carrier” to mean “the adhesion of the corticosteroid onto the surface of a pharmaceutically acceptable carrier.”

72. A POSA who reviewed the specification and claims of the '061 patent would understand the term “adsorbed” to have its plain and ordinary meaning. The specification describes the “corticosteroid particles having been adsorbed largely *on* the surface of the carrier” (Ex. 1001, 3:36-37), “adsorbing a topically acting corticosteroid...*onto* [the] pharmaceutically acceptable carrier” (Ex. 1001, 3:61-65), and “[t]he corticosteroid particles are typically adsorbed *onto* the carrier” (Ex. 1001, 10:5-8) (emphases added). Thus, a POSA would understand this adsorption to refer to the adhesion or retention of the corticosteroid particle onto the surface of the carrier.

73. The specification describes the process for “adsorbing a topically acting corticosteroid optionally micronized onto at least one pharmaceutically acceptable carrier such as silicified microcrystalline cellulose by blending for a sufficiently long time[.]” Ex. 1001, 3:61-66; *see also id.*, 4:4-15 (“The present invention discloses a method of preparing pharmaceutical compositions comprising especially poorly water soluble, low-dose, micronized drugs and at least one pharmaceutically acceptable carrier which must be blended for a sufficiently long time using a suitable

blender-comminuting mill combination, thereby avoiding segregation-agglomeration of the drug particles in the blend not only during powder blending but also until processed into finished dosage forms, capsules or tablets, to achieve and maintain desired high blend uniformity/homogeneity and/or to achieve high content uniformity of the finished dosage units and also to avoid high dissolution variability.”) In embodiments, the ’061 patent specification discusses blending the micronized corticosteroid with the pharmaceutically acceptable carrier for at least ten minutes, followed by additional blending with additional excipients for at least 30 to 40 minutes, to adsorb the corticosteroid to the pharmaceutically acceptable carrier. Ex. 1001, 13:3-61 (disclosing methods for manufacturing compressible blends with acceptable content uniformity); *id.*, Examples 2, 3. A POSA would understand that the adsorption of the corticosteroid onto the carrier is accomplished by the sufficiently long blending process disclosed in the ’061 patent specification.

74. Adsorption in the context of the ’061 patent refers to the physical adsorption of the corticosteroid drug particle onto the surface of a pharmaceutically acceptable carrier. Physical adsorption involves interparticle forces including van der Waals force, hydrogen bonding, or electrostatic force. Ex. 1054, 34 (“Forces involved in adsorption include van der Waals force, hydrogen bonding or electrostatic force in physical adsorption...”); Ex. 1055, 380 (“Physical adsorption

[is] associated with van der Waals' forces). The McGraw-Hill Dictionary of Scientific and Technical Terms defines "adsorption" as "[t]he surface retention of solid, liquid, or gas molecules, atoms, or ions by a solid or liquid[.]" Ex. 1060, 41. Similarly, Merriam-Webster has defined "adsorption" as "the adhesion in an extremely thin layer of molecules (as of gases, solutes, or liquids) to the surfaces of solid bodies or liquids with which they are in contact" from 1807 to today. Ex. 2002, 18.

75. Thus, in my opinion, a POSA reading the claims of the '061 patent would understand the term "adsorbed onto a pharmaceutically acceptable carrier" to have its plain and ordinary meaning, which is "the adhesion of the corticosteroid onto the surface of a pharmaceutically acceptable carrier." I apply this construction in my analysis.

2. Petitioner's Construction of "Adsorbed Onto A Pharmaceutically Acceptable Carrier"

76. Dr. Parr opines that "adsorbed onto a pharmaceutically acceptable carrier" should be accorded its plain and ordinary definition. Ex. 1070, ¶118. I do not disagree.

77. However, I disagree with Dr. Parr's definition of the plain and ordinary meaning of the term, which he defines as "includes at least 'the reversible disposition of a corticosteroid particle on the surface of a pharmaceutically acceptable carrier.'"

Ex. 1070, ¶122.

78. It is unclear what Dr. Parr or Petitioner means by “includes at least.” Further, Dr. Parr does not cite to any intrinsic or extrinsic evidence to support the construction of “adsorption” to mean “the reversible disposition of a corticosteroid particle on the surface of a pharmaceutically acceptable carrier.” This definition is incorrect.

79. A POSA would not understand the plain and ordinary meaning of “adsorbed” to mean the “reversible disposition” of a corticosteroid particle onto a carrier. A “disposition” means an arrangement or placement of objects. Ex. 2002, 361. Thus, a POSA would understand “disposition” to refer to the physical arrangement of the corticosteroid, not “adsorption,” which, as explained above, is the adhesion or retention of particles onto a surface. Dr. Parr does not cite to any evidence in the '061 patent specification or the prosecution history to support his construction that the plain and ordinary meaning of “adsorbed” is “reversible disposition” or that a POSA would understand it as such.

80. There is also no extrinsic evidence that supports Dr. Parr's construction. None of the prior art references Dr. Parr cites to describe adsorption as a “reversible disposition.” On the contrary, Dr. Parr cites to the McGraw-Hill Dictionary which describes adsorption as having “surface retention.” Ex. 1070, ¶119. A POSA would

not understand “disposition” of a corticosteroid particle onto a carrier to necessarily mean that corticosteroid is retained on or adhered to the carrier. Retain or adhere imply an attachment of the corticosteroid to the carrier, disposition does not. Dr. Parr also relies on Martin et al. (Ex. 1055) to import “reversible” into the construction, which states “[p]hysical adsorption, associated with van der Waals’ forces, is reversible, the removal of the adsorbate from the adsorbent being known as desorption.” Ex. 1070, ¶120 (citing Ex. 1055, 380). But this disclosure clearly discusses “desorption,” the reversion of adsorption. Dr. Parr does not explain why a POSA would understand the plain meaning of “adsorption” to be the “reversible disposition.”

81. Further, a POSA would understand from the '061 patent that the corticosteroid is adsorbed onto a carrier to prevent agglomeration. Reversing the adsorption would cause re-agglomeration of the drug particles, resulting in decreased efficacy. A POSA would therefore would not understand the plain meaning of “adsorption” to be a “reversible disposition.”

82. Dr. Parr also cites to the EPO interpretation of adsorption, but this extrinsic evidence does not support his construction either. Ex. 1070, ¶124. The EPO stated that “is adsorbed” is a broad term that includes “intense contact between the carrier powder and the drug”. Ex. 1062, 15-16. The EPO further described that

“intense contact between the carrier powder and the drug...implies at least some adsorption of drug on the carrier.” Ex. 1062, 15-16. The EPO's interpretation requires “intense contact” for adsorption, which indicates something more than the mere “reversible disposition” of the drug particle on the surface of the carrier.

83. It appears that Dr. Parr is basing his construction on the disclosure in Perrett where “the corticosteroid is disposed over the surface of an excipient[.]” Ex. 1057, Claim 19 (“The pharmaceutical composition of claim 16, wherein the corticosteroid is disposed over the surface of an excipient, the rapidly dispersing granules have an average particle size of less than about 300 μm , and the disintegrant and sugar alcohol and/or saccharide have an average particle size of less than about 30 μm .”), Claim 22 (“The pharmaceutical composition of claim 20, wherein the corticosteroid is disposed on the surface of said adhesive agent.”). The only disclosure in Perrett regarding disposal of corticosteroids is in the context of an adhesive agent, which Perrett defines as an agent that promotes “adhesion of the corticosteroid to biological surfaces[.]” Ex. 1057, [0017], [0063]. This, however, is a different application of combining the corticosteroid with an excipient. A POSA would not understand this disclosure in Perrett to indicate any adsorption or adhesion of the corticosteroid onto the *carrier*. Rather, the corticosteroid is dispersed on the excipient to promote adhesion to *biological surfaces*. Further, nothing in Perrett

indicates that the disposal of corticosteroids is reversible. Neither Dr. Parr, Petitioner, or the EPO findings which are merely reproduced in Dr. Parr's declaration, explain how this disclosure disposing a corticosteroid over the surface of an excipient relates to adsorption of a corticosteroid onto a pharmaceutically acceptable carrier.

84. While I do not agree that a POSA would understand "adsorbed onto a pharmaceutically acceptable carrier" to have the meaning Dr. Parr ascribes to it, I have nevertheless also considered and addressed his construction in my analysis.

V. DR. PARR'S GROUNDS LACK CREDIBLE BASES, IGNORE CLAIM LIMITATIONS, AND MISCONSTRUE THE ASSERTED ART

85. Dr. Parr opines that the challenged claims are obvious based on three grounds: (1) claims 1-30 over Perrett (ground 1); (2) claims 1-2, 4-11, 17-20, 22, and 29-30 over Dohil 2009 (ground 2); and (3) claims 1-30 over Dohil 2009 and Venkatesh (ground 3). I disagree with Dr. Parr that the challenged claims would have been obvious to a POSA over any of his asserted prior art grounds. I discuss some of the errors for each ground, below.

A. Irrelevant Focus on ODTs in the Prior Art

86. The '061 patent is directed to ODTs comprising low doses of micronized corticosteroids that have issues with drug particle agglomeration, which leads to issues with drug exposure to inflamed esophageal tissue and efficacy.

87. Nearly 30 pages Dr. Parr's analysis on the scope of the prior art is irrelevant and does not address the claims of the '061 patent or problems solved by the '061 patent. Dr. Parr spends much of his analysis regarding the scope of the prior art on the availability of and desirability for ODTs to treat eosinophilic esophagitis (EoE). Ex. 1070, Section VII.

88. For example, Dr. Parr describes the desirability of using budesonide and fluticasone as anti-inflammatory topical corticosteroid treatments. Ex. 1070, ¶¶45-65. It is my understanding that there is no dispute that budesonide and fluticasone could be used to treat inflammation of the upper gastrointestinal tract. In fact, the '061 patent describes both being used to treat EoE in the background of the invention section. Ex. 1001, 1:54-2:29.

89. Regarding ODTs, Dr. Parr focuses on the desirability and commercial availability of ODTs. Ex. 1070, ¶¶66-95. Dr. Parr opines that ODTs were desirable because they help with patient compliance and many types of drugs would benefit from being formulated into an ODT. Ex. 1070, ¶89. Again, while the '061 patent claims an ODT, that is only a portion of the full scope of the invention.

90. Dr. Parr then touches very briefly on the adsorption of drug particles onto a carrier. Ex. 1070, ¶¶96-99. At most, Dr. Parr opines that adsorption of drug particles onto the surface of pharmaceutical carriers was known in the art as a means

of achieving content uniformity. Ex. 1070, ¶96. Dr. Parr opines that adsorption is accomplished generally from mixing or blending. Ex. 1070, ¶97.

91. Dr. Parr, however, does not contend with, or even acknowledge, the fact that there was an issue with agglomeration in the low-dose corticosteroid containing ODTs described in Perrett as discussed in the background section of the '061 patent specification. Ex. 1001, 3:5-23. This unrecognized problem of agglomeration reduced or prevented exposure of topically active corticosteroids to inflamed esophageal tissue, which reduced efficacy and resulted in blend nonuniformity.

92. Dr. Parr does not discuss the problem of agglomeration anywhere in his declaration. It is not surprising that none of the prior art references Dr. Parr cites to discuss these issues either. The issue of agglomeration in ODTs that shielded topically active corticosteroid from contacting inflamed esophageal tissue and reduced efficacy was unknown prior to the '061 patent. Therefore, a POSA would not have been motivated to modify existing prior art formulations to arrive at the claimed invention, because the POSA would have thought that Parrett's ODT was suitable for use.

B. Lack of Support for Conclusions

93. Consistent throughout Dr. Parr's declaration is a lack of support for his

conclusions. In addition to the insufficiency of evidence cited to the prior art disclosures, Dr. Parr's testimony fails to offer anything more than conclusory opinions on a POSA's motivation to modify the prior art to arrive at the claimed invention.

1. Perrett Does Not Render Obvious Claims 1-30 of the '061 Patent (Ground 1)

94. Dr. Parr asserts that Perrett renders obvious claims 1-30 of the '061 patent. However, nowhere in his declaration does Dr. Parr address the fact that Perrett is disclosed as WO 2011/041509 (Ex. 1063) and distinguished in the specification of the '061 patent. Ex. 1001, 3:5-22. As explained above, the '061 patent specification addresses Perrett's preparation of an ODT using a granulation method, and explicitly states that Perrett's process embeds the corticosteroid within agglomerated granules, reducing exposure of the corticosteroid to the inflamed tissue and resulting in poor efficacy. Ex. 1001, 3:5-23, 10:56-59. More importantly, Perrett does not recognize the issue of agglomeration in low-dose corticosteroid compositions that results from Perrett's process.

95. Dr. Parr does acknowledge that WO 2011/041509 contains the same disclosures as Perrett. Ex. 1070, 72 n.7, 79 n.8.

96. However, Dr. Parr fails to acknowledge that the '061 patent is explicitly directed to solving an unrecognized problem in Perrett, namely that Perrett's process

results in agglomeration, which reduces or prevents exposure of topically active corticosteroids to inflamed esophageal tissue.

(a) The Claims Require A Topically Acting Corticosteroid That is “adsorbed onto a pharmaceutically acceptable carrier.” Perrett Does Not Disclose This Limitation.

97. Perrett does not disclose a topically acting corticosteroid that is adsorbed onto a pharmaceutically acceptable carrier, as is required by independent claims 1 and 19. Dr. Parr relies on the EPO proceedings and general knowledge of a POSA to allege that mixing of the corticosteroid with the excipients necessarily results in at least some adsorption of the drug onto a carrier. Ex. 1070, ¶¶137-139; *see also id.*, ¶¶144-147. First, Dr. Parr fails to provide evidence that a corticosteroid was adsorbed onto a pharmaceutically acceptable carrier in Perrett. Second, I would not expect Perrett's process to result in adsorption of the corticosteroid as was described in the '061 specification to overcome the unknown issue of agglomeration and to ensure efficacy of the corticosteroid. Importantly, a POSA, based on Perrett and the common knowledge at the time, would have believed that Perrett's granulation process achieved content uniformity, and therefore would have had no reason to modify Perrett. Nothing in Dr. Parr's declaration or the petition recognize the problem of agglomeration, which remained unrecognized and unresolved until the '061 patent. Dr. Parr fails to explain how Perrett and the knowledge of a POSA

teaches the claimed invention. Instead, Dr. Parr begins from a hindsight driven conclusion that because mixing in the '061 patent results in adsorption, so too must the mixing in Perrett. But the '061 patent is evidence that this is not true.

**(i) No Evidence of Adsorption in Perrett or
Dr. Parr's Declaration**

98. Dr. Parr does not point to any evidence in Perrett to support his opinion that Perrett discloses adsorption of a drug onto a carrier. Instead, Dr. Parr relies on the EPO proceedings to opine that Perrett discloses adsorption onto a carrier during the granulation process based on Dr. Parr's unreasonably broad construction of the term "adsorption". Ex. 1070, ¶136. The EPO, and Dr. Parr, cite to Example 1 in Perrett as disclosing at least some adsorption. Ex. 1070, ¶¶135-136. In Example 1 of Perrett, the method for preparing the ODT is focused on granulating all components in the ODT (the corticosteroid, mannitol (sugar alcohol) and crospovidone (disintegrant)) and then blending the granules for only 3-5 minutes. Ex. 1057, [0091]. As discussed in the '061 patent, Perrett's process does not result in the claimed invention. Ex. 1001, 3:5-39.

99. In contrast, to achieve adsorption, the '061 patent specification describes mixing the pharmaceutically acceptable carrier with the corticosteroid for at least ten minutes before blending with additional excipients for at least 30 to 40 minutes. Ex. 1001, 13:3-61 (disclosing methods for manufacturing compressible

blends with acceptable content uniformity); *id.*, Examples 2, 3. This extended blending time, first of the corticosteroid with the carrier, and then the remaining excipients, is what achieves adsorption and keeps the corticosteroid particles from agglomerating during the manufacturing process. Ex. 1001, 4:4-15 (“The present invention discloses a method of preparing pharmaceutical compositions comprising especially poorly water soluble, low-dose, micronized drugs and at least one pharmaceutically acceptable carrier which must be blended for a sufficiently long time using a suitable blender-comminuting mill combination, thereby avoiding segregation-agglomeration of the drug particles in the blend not only during powder blending but also until processed into finished dosage forms, capsules or tablets, to achieve and maintain desired high blend uniformity/homogeneity and/or to achieve high content uniformity of the finished dosage units and also to avoid high dissolution variability.”) A POSA would therefore understand that the process described in Example 1 of Perrett does not achieve the adsorption claimed in the ’061 patent.

100. Example 1 of Perrett also does not disclose the particle size of the corticosteroid, which is required to determine whether adsorption occurred. Dr. Parr relies on Perrett’s disclosure from an unrelated part of the specification that describes an embodiment in which the average particle size of the corticosteroid crystals

ranges from 1 to 400 μ m. Ex. 1070, ¶138. Dr. Parr also relies on the prior art to argue that adsorption generally plays a role when mixing particle sizes of 400 μ m or less. Ex. 1070, ¶137. Contrary to Dr. Parr's assertion, Perrett does not disclose the particle size in Example 1, and a POSA could not know if any adsorption occurred. Ex. 1070, ¶139.

101. Even if Perrett disclosed particle size in Example 1, a POSA could not know conclusively that adsorption occurred using Perrett's process, because Perrett mixes all components of the ODT together at once for a short amount of time. The '061 patent teaches that such a process does not result in adsorption. Ex. 1001, 3:5-23. The '061 patent teaches a completely different process in which the carrier must first be mixed with the corticosteroid in the absence of other excipients for at least ten minutes and further blended with additional excipients for at least 30 to 40 minutes. Ex. 1001, 13:3-61.

102. Dr. Parr also cites to Venkatesh, which is incorporated by reference into Perrett, for its disclosure on rapidly dispersing microgranules where the drug is milled and blended with various excipients. Ex. 1070, ¶¶141-143. Dr. Parr then conclusively asserts that the granulating, milling, and blending disclosed in Perrett and Venkatesh together results in "at least some adsorption of the corticosteroid on the surface of the carrier." Ex. 1070, ¶145. Dr. Parr needed to explain how the

processes in Venkatesh and Perrett disclose adsorption of the corticosteroid onto the carrier, but he did not. As described above, adsorption occurs through the extended blending process taught in the '061 patent, which requires first mixing the corticosteroid with the pharmaceutically acceptable carrier in the absence of other excipients, and then mixing in other excipients for a sufficiently long time. Neither Perrett nor Venkatesh discloses or suggests a similar process and thus cannot disclose a corticosteroid adsorbed onto a pharmaceutically acceptable carrier as claimed in the '061 patent.

**(ii) The General Knowledge of a POSA does
Cure Deficiencies in Perrett or Dr. Parr's
Declaration**

103. Instead of explaining how Perrett's process results in adsorption of a corticosteroid to a carrier, Dr. Parr points to general prior art references that do not address the issue of agglomeration and decreased efficacy in ODTs containing a low dose of topically active corticosteroid. What's more, Dr. Parr mischaracterizes the teachings of these prior art references. For example, Dr. Parr misconstrues Wen (Ex. 1054). Dr. Parr states that "adsorption generally plays a role when mixing occurs with a mixture of particle sizes at or below approximately 400 μm [,]” for the argument that adsorption necessarily or inherently occurs during mixing. Ex. 1070, ¶137. However, Wen does not say that particles of $\leq 400 \mu\text{m}$ necessarily adsorb to

other particles during any mixing process. Wen actually says that, to achieve content uniformity, small particles need to be adsorbed to a carrier, not that adsorption inherently results due to mixing. Ex.1054, 35 (“During mixing, there are many factors that can affect the content uniformity of mixtures, and adsorption generally plays a role when the average particle size is $\leq 400\ \mu\text{m}$.”). Thus, a POSA would understand that the particle size of the corticosteroid is a relevant factor in achieving content uniformity, not that particles of $\leq 400\ \mu\text{m}$ necessarily adsorb to other particles during mixing, as Dr. Parr alleges. As discussed herein, a POSA would not combine Wen with Perrett because a POSA believed that Perrett’s granulation process achieved content uniformity.

**(iii) No Adsorption Even Applying Dr. Parr’s
Unreasonably Broad Construction of the
Term**

104. Even under Dr. Parr’s flawed construction of “the reversible disposition of a corticosteroid particle on the surface of a pharmaceutically acceptable carrier,” Perrett’s disclosure does not teach adsorption of a corticosteroid onto a pharmaceutically acceptable carrier. Dr. Parr points to a disclosure in Perrett describing the corticosteroid as disposed over the surface of the excipient. Ex. 1070, ¶145. Dr. Parr does not describe how this disposal results in any adsorption. Rather, Perrett’s disclosure for the disposal of corticosteroid over the surface of an excipient

is related to an adhesive agent, which could be irreversible. Ex. 1057, [0063], Claim 22. Dr. Parr does not opine that adhesive agents, as defined in Perrett, are pharmaceutically acceptable carriers. Ex. 1070, ¶¶133-134 (listing allegedly acceptable carriers). As discussed above, a POSA would not understand this disclosure in Perrett to indicate any adsorption of the corticosteroid onto the *carrier*. Rather, the corticosteroid is dispersed on the excipient to promote adhesion to *biological surfaces*. Further, nothing in Perrett indicates the disposition of the corticosteroid particles is reversible. Venkatesh contains no disclosure of corticosteroids, much less a disposition of a corticosteroid on the surface of an excipient. Nor does Venkatesh teach the adsorption of any drug onto the surface of an excipient.

105. Dr. Parr assumes that which he needed to prove – that adsorption occurs through the process disclosed in Perrett. But Perrett does not offer any disclosure, evidence, or data that adsorption occurs as a result of its process. Venkatesh also does not offer any insight into whether any adsorption occurs, and neither do the unasserted prior art references Dr. Parr cites to.

106. In my opinion, the granulation processes described in Perrett and Venkatesh does not establish that Perrett's ODT inherently contain a corticosteroid adsorbed to a carrier. It is my understanding that an inherent element must

necessarily be present in the teachings. The fact a certain outcome may result is not enough to show inherency. In any event, neither Dr. Parr nor Petitioner argue inherency, and neither points to any evidence to show that any adsorption necessarily occurs. As described above, the processes described in Perrett would not result in adsorption of the corticosteroid onto a carrier, because Perrett's process would result in agglomerated particles due to mixing all ingredients together at once and the shorter mixing time.

107. For these reasons, Perrett does not teach the limitation of a topically acting corticosteroid that is "adsorbed onto a pharmaceutically acceptable carrier" and thus fails to teach each limitation of claims 1-30.

108. Accordingly, it is my opinion that one of ordinary skill in the art would understand that Perrett does not render obvious claims 1-30.

**(b) Dr. Parr Does Not Explain Why a POSA
Would Have Been Motivated to Formulate an
ODT Where the Corticosteroid is Adsorbed
Onto A Pharmaceutically Acceptable Carrier**

109. Dr. Parr opines that a "person of ordinary skill in the art would have been motivated to adsorb Perrett's corticosteroid onto a carrier" because "[i]t was known that such adsorption 'can be very beneficial in several ways...' and '[s]urface adsorption of drugs on pharmaceutical carriers is advantageous for ODTs[.]'" Ex. 1070, ¶¶146-147. I disagree for the following reasons.

110. Dr. Parr does not explain why a person of ordinary skill in the art would be motivated modify Perrett's ODT by adsorbing the corticosteroid onto a carrier. Nothing in the prior art or Dr. Parr's declaration identifies an actual problem with Perrett's ODT. Instead of referencing anything specific in Perrett for content uniformity, the issue of agglomeration or the necessity of adsorption, Dr. Parr cites to generalities in other, unasserted references for support that a POSA would have been motivated to modify Perrett. Ex. 1070, ¶¶146-147. Dr. Parr provides a generalized conclusion that "[i]t was known that such adsorption 'can be very beneficial in several ways...' and '[s]urface adsorption of drugs on pharmaceutical carriers is advantageous for ODTs[.]'" Ex. 1070, ¶¶146-147.

111. Indeed, Dr. Parr ignores that the '061 patent cites to Perrett and explicitly states that Perrett does not recognize the problem of agglomeration of drug particles and reduced efficacy. As discussed in the '061 patent, the problem with Perrett's preparation is that the "topically acting corticosteroids particles may be present in the agglomerated granules and as such may not be readily exposed to the inflamed EoE tissues upon oral administration." Ex. 1001, 3:19-22. The '061 patent describes a solution to this otherwise unrecognized problem in Perrett, and the prior art, by blending the corticosteroid with the pharmaceutically acceptable carrier for a sufficiently long time, thereby adsorbing the drug onto the carrier.

112. The process of sufficiently long blending where the corticosteroid is blending with the pharmaceutically acceptable carrier first, followed by further blending taught in the '061 patent specification results in the claimed adsorption of corticosteroid onto the carrier, which solves the previously unrecognized issue of agglomeration. Dr. Parr does not explain why a POSA would have been motivated to modify Perrett by adding more process steps to (1) first blend the corticosteroid with the pharmaceutically acceptable carrier in the absence of the mannitol and crospovidone used in Perrett's Example 1 and then (2) significantly increase the blending time.

113. Dr. Parr also does not describe how a POSA would modify Perrett to achieve the claimed invention. Dr. Parr only says that a "person of ordinary skill in the art would have been motivated to adsorb Perrett's corticosteroid onto a carrier" with no further explanation of how to achieve the adsorption. Ex. 1070, ¶146. The '061 patent specification states that processes in Perrett, and by extension Venkatesh, do not result in the adsorption of the drug particles to prevent agglomeration and thereby reduces exposure of the drug to the inflamed esophageal tissue. Ex. 1001, 3:5-23. Dr. Parr does not offer any opinions as to how the processes would be modified to achieve the claimed invention.

**2. Dohil2009 Does Not Render Obvious Claims 1-2, 4-11,
17-20, 22, and 29-30 of the '061 Patent (Ground 2)**

114. Dr. Parr asserts that Dohil2009 renders obvious claims 1-2, 4-11, 17-20, 22, and 29-30 of the '061 patent. Dr. Parr relies on Dohil2009's disclosure of a lozenge or tablet comprising a corticosteroid and an optional grinding method to opine that the '061 patent is rendered obvious. Ex. 1070, ¶248. Dr. Parr mischaracterizes Dohil2009's disclosures.

115. Dohil2009 is directed primarily to liquid compositions, not ODTs. Dohil2009 is aimed at solving the problem of increasing contact of a corticosteroid with the esophagus, and teaches formulating liquid dosage forms with viscosity enhancing agents, that deliver an effective dose for the treatment of inflamed esophageal tissues. Of 177 paragraphs in Dohil2009, only 10 mention a solid dosage form. Dohil2009 makes only one reference to preparing a tablet form by "optionally grinding" a mixture of drug and excipients. Ex. 1058, [0070].

116. No lozenge or tablet is exemplified in Dohil2009 and the compositions exemplified in the Examples are liquid forms. Dr. Parr relies on Dohil2009's disclosure for a "dissolving tablet" that references dosing quantities in general for a broad range of dosage forms, with quantities ranging between 0.01 mg to 20 mg. Ex. 1070, ¶267. First, a "dissolving tablet" is not an ODT that dissolves within 60 seconds as measured with the USP <701> method as required by the claims. Second,

Dohil2009 does not provide any specific guidance on formulating an ODT. Instead, Dohil2009 simply mentions a dissolving tablet in a laundry list of formulations (“a nebulized composition, an aerosolized composition, an emulsion, a solution, a suspension, a syrup, a slurry, a dispersion, a colloid, a dissolving tablet, a dissolving wafer, a capsule, a gel capsule, a semi-solid, a solid form gel, a gel matrix, a cream, a paste, or the like.”) Ex. 1058, [0042]. A POSA would understand that each different dosage form would have different considerations for dosing quantities and manufacturing processes. As such, I would not even consider Dohil2009 to be relevant to the claims of the '061 patent.

117. Dr. Parr also mischaracterizes the examples of Dohil2009. Dr. Parr opines that Dohil2009's patients were dosed with budesonide at 0.5, 1, and 2 mg/day as evidence of dosing quantities for a tablet. Ex. 1070, ¶268. All the examples in Dohil2009 are directed to liquid compositions, not tablets or lozenges. No patients in Dohil2009 were dosed with tablets containing the claimed dosage amounts.

118. Dohil2009 is therefore directed to a liquid, not solid, composition comprising a topical corticosteroid and thus cannot teach an ODT comprising a topically acting corticosteroid that is adsorbed onto a pharmaceutically acceptable carrier.

**(a) The Claims Require A Topically Acting
Corticosteroid That is “adsorbed onto a
pharmaceutically acceptable carrier.”
Dohil2009 Does Not Disclose This Limitation.**

119. Dr. Parr further fails to establish that Dohil2009 discloses a topically acting corticosteroid that is “adsorbed onto a pharmaceutically acceptable carrier.”

120. Dohil2009 does not disclose adsorbing a corticosteroid to a carrier, address or recognize the advantage of doing so, recognize the problem of agglomeration in ODTs containing low dose corticosteroids, or discuss improving drug content uniformity and exposure of a corticosteroid to the EoE tissue when using an ODT. In fact, Dohil2009 does not address blend or content uniformity for ODTs anywhere in its disclosure. Dr. Parr does not cite to any evidence indicating that Dohil2009 recognized or acknowledged this problem with ODTs that was first recognized and solved by the inventors of the '061 patent.

121. Dr. Parr cites to Dohil2009's process of formulating the tablets by “combining the corticosteroids with solid excipients,” “*optionally* grinding the resulting mixture,” and “processing the mixture of granules” which Dr. Parr opines results in at least some of the corticosteroid being adsorbed onto the excipients. Ex. 1070, ¶¶254, 259 (emphasis added). Dr. Parr does not cite to any evidence in Dohil2009 or otherwise describing or achieving adsorption of the corticosteroid to the carrier. Dohil2009 does not and cannot disclose the limitation of a topically

acting corticosteroid adsorbed onto a pharmaceutically acceptable carrier.

122. First, Dr. Parr ignores the fact that Dohil2009 is directed towards liquid compositions and therefore would not be concerned with blend uniformity in solid dosage forms.

123. Second, Dr. Parr concludes that the optional grinding step in Dohil2009 is equivalent to repeatedly mixing and results in adsorption of the corticosteroid onto the carrier. "Optionally grinding" is not the same as repeatedly mixing. Further, even under Dr. Parr's logic that simply repeated mixing results in adsorption, a POSA would understand that the fact that one of the mixing steps is optional indicates that Dohil2009 did not consider or disclose the adsorption of the corticosteroid onto a carrier. Indeed, Dohil2009's disclosure for process of combining the corticosteroids with excipients is very sparse and limited to the one sentence discussed above. The most Dohil2009 teaches about the process is that the ingredients can be combined. Ex. 1058, [0070], [0092], [0126].

124. The '061 patent, on the other hand, describes a repeated blending, mixing, and milling process to achieve adsorption. The '061 patent teaches that the pharmaceutical composition "must be blended for a sufficiently long time...thereby avoiding segregation-agglomeration of the drug particles in the blend not only during powder blending but also until processed into finished dosage forms, capsules

or tablets...” Ex. 1001, 4:4-15. The '061 patent specification describes the pharmaceutically acceptable carrier mixed with the corticosteroid for at least ten minutes and before further blending occurs for at least 30 to 40 minutes. Ex. 1001, 13:3-61 (disclosing methods for manufacturing compressible blends with acceptable content uniformity); *id.*, Examples 2, 3.

125. Third, Dr. Parr again points to general prior art references that do not address the issue of agglomeration or unequal distribution of the corticosteroid in the ODT and decreased efficacy of the drug. Dr. Parr once more mischaracterizes the prior art. For example, Dr. Parr misconstrues Wen (Ex. 1054). Dr. Parr states that “adsorption generally plays a role when mixing occurs with a mixture of particle sizes at or below approximately 400 μm [.]” for the argument that adsorption necessarily or inherently occurs during mixing. Ex. 1070, ¶257. However, as stated above, Wen actually says that, to achieve content uniformity, small particles need to be adsorbed to a carrier, not that adsorption inherently results due to mixing. Ex. 1054, 35.

126. Nor does Dohil2009 teach adsorption under Dr. Parr's flawed construction of “the reversible disposition of a corticosteroid particle on the surface of a pharmaceutically acceptable carrier.” The one sentence in Dohil2009's disclosure only describes combining the corticosteroid with excipients. Nothing in

Dohil2009 teaches or suggests that the corticosteroid is disposed on the surface of a carrier. Instead of pointing to any evidence or explaining how a POSA would understand that the corticosteroid in Dohil2009 is disposed onto a carrier, Dr. Parr conclusively asserts that Dohil2009's process results in adsorption.

127. For these reasons, Dohil2009 does not teach the limitation of a topically acting corticosteroid that is “adsorbed onto a pharmaceutically acceptable carrier” and thus fails to teach each limitation of claims 1-2, 4-11, 17-20, 22, and 29-30.

128. Accordingly, it is my opinion that one of ordinary skill in the art would understand that Dohil2009 does not render obvious claims 1-2, 4-11, 17-20, 22, and 29-30.

**(b) Dr. Parr Does Not Explain Why a POSA
Would Have Been Motivated to Formulate an
ODT Where the Corticosteroid is Adsorbed
Onto A Pharmaceutically Acceptable Carrier**

129. Dr. Parr cites to generalities in other, unasserted references for support that a POSA would have been motivated to modify Dohil2009. Ex. 1070, ¶¶261-262. Rather than providing any support or evidence based on the disclosure of the preparation of ODTs in Perrett, Dr. Parr provides a generalized conclusion that “[i]t was known that such adsorption ‘can be very beneficial in several ways...’” and “[s]urface adsorption of drugs on pharmaceutical carriers is advantageous for ODTs[.]” Ex. 1070, ¶¶261-262.

130. Dr. Parr does not explain why a person of ordinary skill in the art would be motivated to modify Dohil2009 to adsorb the corticosteroid in the ODT to a carrier. Nothing in Dohil2009 or the prior art indicated to a POSA that agglomeration of drug particles was an issue for solid corticosteroid formulations. Dohil2009 does not discuss any issues with drug particle agglomeration or problems with blend uniformity, and only discusses efficacy and safety of liquid/viscous corticosteroid compositions. *See, e.g.,* Ex. 1058, [0105]. Dr. Parr's conclusory statements on a POSA's motivation are not commensurate with a POSA's understanding of Dohil2009 and the prior art at the time. While it may have been generally known that adsorption can be beneficial, Dr. Parr points to no evidence that there was a problem with Dohil2009's process for preparing solid compositions or indicating that a POSA would need to seek the benefits of adsorbing the corticosteroid onto a carrier in Dohil2009.

131. Dr. Parr also does not describe how a POSA would modify Dohil2009 to achieve the claimed invention. Dr. Parr only says that a "person of ordinary skill in the art would have been motivated to adsorb Dohil2009's corticosteroid onto a carrier" with no further explanation of how to achieve the adsorption. Ex. 1070, ¶261. Dohil2009 includes an optional grinding step whereas the '061 patent discloses that mixing must occur for a sufficiently long period of time to achieve the

requisite adsorption. Dr. Parr does not offer any opinions as to how the processes in Dohil2009 would be modified to achieve the claimed invention. Dr. Parr also does not explain why a POSA would have been motivated to modify Dohil2009 by adding more process steps to (1) first blend the corticosteroid with the pharmaceutically acceptable carrier in the absence of other excipients and then (2) blend for a significantly long period of time.

**3. Venkatesh and Dohil2009 Do Not Render Obvious
Claims 1-30 of the '061 Patent (Ground 3)**

132. Dr. Parr further relies on Venkatesh to opine that Dohil2009 in view of Venkatesh renders obvious claims 1-30 of the '061 patent.

133. Dr. Parr does not acknowledge that the '061 patent specification incorporates Venkatesh by reference for its disclosure on rapidly dispersing granules. Ex. 1001, 10:29-45. Venkatesh is primarily directed to the manufacture of ODTs in general using rapidly dispersing microgranules and taste-masked microcapsules. Ex. 1020, [0001].

134. Dr. Parr relies on Venkatesh's teaching of making ODTs using milled or micronized drug particles that are blended with excipients and that its ODT formulations require no "special pharmaceutical production technique and can be simply and easily produced by a normal equipment." Ex. 1070, ¶¶343-345, 359 (citing Ex. 1020, [0018]). Dr. Parr opines that the processes disclosed in Dohil2009

and Venkatesh render obvious adsorbing corticosteroid drug particles onto a carrier.

Ex. 1070, ¶345. I disagree.

135. Venkatesh is not directed to the delivery of corticosteroids, much less the topical delivery of drugs. Venkatesh is more generally directed to ODTs and taste-masking of bitter drug particles. As such, I would not even consider Venkatesh to be relevant to the claims of the '061 patent.

136. The '061 patent specification describes the issue it seeks to solve as the preparation of topically acting corticosteroids resulting in the agglomeration of the drug particles using methods described in the prior art. Ex. 1001, 3:5-23. Specifically, the '061 patent employs a particular process which requires micronized drug particles of a specific size to be mixed with one excipient for a sufficiently long amount of time, and then further blended for at least 30 to 40 minutes. Ex. 1001, 13:3-61 (disclosing methods for manufacturing compressible blends with acceptable content uniformity); *id.*, Examples 2, 3. This unique process is not disclosed in Venkatesh because Venkatesh is directed to a process for making rapidly dispersing microgranules for use with systemic drugs, and does not recognize the problem of agglomeration and shielding of topically active drugs which is solved by this extended blending process and results in adsorption of the active drug onto a pharmaceutically acceptable carrier. Venkatesh therefore does not disclose

adsorption of a topically acting corticosteroid onto a carrier.

137. As explained above, Dohil2009 is primarily directed to liquid compositions and does not recognize the issue of agglomeration of drug particles in solid corticosteroid compositions. Venkatesh does not fill this gap in Dohil2009's disclosure, but is rather focused on taste-masking of bitter drug particles in ODTs in general and providing a smooth mouthfeel. Ex. 1020, [0002], [0009], [0013]-[0015], [0018]. Taste-masking consists of coating the topically active corticosteroid with a water-insoluble polymer like ethylcellulose to prevent the drug from contacting the oral cavity. Ex. 1020, [0009] and [0018]. A POSA would understand that this would prevent the corticosteroid from topically contacting the inflamed esophageal tissue.

138. Nor does Dohil2009 in combination with Venkatesh satisfy "adsorbed onto a pharmaceutically acceptable carrier" under Dr. Parr's construction of the term. Dr. Parr does not cite to any disclosure in Dohil2009 or Venkatesh that teach "the reversible disposition of a corticosteroid particle on the surface of a pharmaceutically acceptable carrier." Dohil2009 contains only one generic statement on preparing ODTs (Ex. 1058, [0070]) and Venkatesh is directed to rapidly dispersing microgranules and taste-masking (Ex. 1020, [0001]). Neither teaches nor suggests disposing the corticosteroid onto the surface of a carrier.

139. Dohil2009 in combination with Venkatesh therefore cannot disclose "a

topically acting corticosteroid or pharmaceutically acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier.”

(a) Dr. Parr Does Not Explain Why a POSA Would Have Been Motivated to Combine Dohil2009 and Venkatesh to Arrive at the Claimed Invention

140. Dr. Parr opines that a person of ordinary skill in the art would have been motivated to modify Dohil2009 in view of Venkatesh in order to achieve an ODT with improved mouthfeel with no grittiness. Ex. 1070, ¶359. Neither “smooth creamy mouthfeel” nor “no grittiness” are limitations of the claims of the ’061 patent or problems with Dohil2009’s solid composition. Dr. Parr does not explain how either “smooth creamy mouthfeel” or “no grittiness” are related to the claims in the ’061 patent.

141. Dr. Parr does not explain why or how a POSA would be motivated to combine Dohil2009 with Venkatesh to arrive at the claimed invention, including “a topically acting corticosteroid or pharmaceutically acceptable salt or ester thereof, adsorbed onto a pharmaceutically acceptable carrier.”

142. As explained above, nothing in Dohil2009, Venkatesh, or the prior art indicated to a person of ordinary skill in the art that agglomeration of drug particles was an issue for ODTs containing low doses of corticosteroids. Dr. Parr cites to no evidence and makes no argument about why a POSA would be motivated to combine

Dohil2009 with Venkatesh to arrive at the claimed invention, let alone that such a combination would result in a corticosteroid adsorbed onto a carrier as claimed in the '061 patent.

143. Dr. Parr also does not address how a POSA would combine Dohil2009 and Venkatesh to render the claims of the '061 patent obvious.

VI. RESERVATION OF RIGHTS

144. The opinions and analyses in this report are based on currently available documents and information. Accordingly, I reserve my right to supplement and amend my opinions if additional information becomes available. Similarly, this report may be supplemented by testimony.

145. I also reserve the right to adjust or supplement my analyses in light of any rebuttal or alternative opinion advanced by the Petitioner.

VII. CONCLUSION

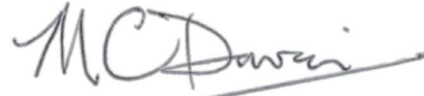
146. In my opinion, claims 1-30 of the '061 patent are not invalid in light of the prior art grounds asserted by Dr. Parr.

147. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

Declaration of Martyn Christopher Davies in Support of
Patent Owner's Preliminary Response
IPR2025-00056

Dated: March 12, 2025

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "MCDavies", written over a horizontal line.

Martyn Christopher Davies