

PGRs Filed in TC 1600 – 2014 – 2018

| | PGR number | Petitioner | Patent Owner /Respondent | Patent Number | Orange Book? ² | Transitional Appln ³ | Status | | | | | Grounds alleged in Petition ¹ | | | | | | |
|---|---------------|-------------------------------|---|---------------|----------------------------------|---------------------------------|----------------|--------------------|------------------|------------------------|--------------------------------|--|------------|----------|---------|---------|-----|------------------|
| | | | | | | | Terminated | Institution Denied | Trial Instituted | Final Written Decision | Pending | 101 (SM) | 101 (MISC) | 112 (WD) | 112 (E) | 112 (I) | 102 | 103 |
| 1 | PGR2014-00010 | Accord Healthcare, Inc. | Helsinn Healthcare S.A. | 8,598,219 | X Aloxi [®] | X | X ⁴ | | | | NA | | | X | X | X | | |
| 2 | PGR2015-00011 | Altaire Pharmaceuticals, Inc. | Paragon BioTeck, Inc. | 8,859,623 | X Phenylephrine hydrochloride | | | | | | X (Fed. Circ.) ⁵ | | | | | X | X | X |
| 3 | PGR2016-00002 | PeroxyChem LLC | Innovative Environmental Technologies, Inc. | 9,126,245 | | | X | | | | NA | X | | X | X | | | |
| 4 | PGR2016-00007 | Dr. Reddy's Laboratories, Ltd | Helsinn Healthcare S.A. | 9,173,942 | X Aloxi [®] | X | | X | | | NA | | | | | | | X |
| 5 | PGR2016-00008 | Dr. Reddy's Laboratories, Ltd | Helsinn Healthcare S.A. | 9,173,942 | X Aloxi [®] | X | | X | | | NA | | | X | | | | X (ON - SALE) |

¹ Abbreviations: SM – Subject Matter Eligibility; WD – Written Description; E – Enablement; I – Indefiniteness; 102 – Novelty; 103 – Obviousness.

² Is the patent listed in the Electronic Orange Book? (<https://www.accessdata.fda.gov/scripts/cder/ob/>)

³ A transitional application is any nonprovisional application that is filed on or after March 16, 2013, that claims the benefit of the filing date of a pre-AIA (filed prior to March 16, 2013) provisional, foreign, nonprovisional, or PCT application that designates the United States.

⁴ The PTAB E2E website indicates the status for this PGR as “Institution Denied”. However, a review of the record indicates that this PGR was terminated on November 24, 2014, based on a Joint Motion to Terminate the Proceeding based on a settlement between the parties filed on November 20, 2014.

⁵ PTAB decision (November 14, 2016): Altaire failed to prove that claims 1-13 were unpatentable for obviousness over two production lots of Altaire’s phenylephrine hydrochloride ophthalmic solution products (Lots #11578 and #11581). Appealed to Federal Circuit (2017-1482). In a decision dated May 2, 2018, the Federal Circuit (Judges O’Malley, Schall and Wallach), reversed-in-part, vacated-in-part, and remanded to PTAB. As of September 28, 2018, no further updates regarding the remand.

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|----|---------------|------------------------------|---|---------------|----------------|--------------------|------------|-----------------------------|------------------|------------------------|---------|----------|------------|----------|---------|---------|-----|-----|
| 6 | PGR2016-00010 | Mylan Pharmaceuticals Inc. | Yeda Research and Development Co. Ltd. | 9,155,776 | X Copaxone® | X | | X (NOT ELIGIBLE FOR PGR) | | NA | | | | X | | | X | X |
| 7 | PGR2016-00018 | B.R.A.H.M.S. GmbH | Becton, Dickinson and Company | 9,091,698 | | | X | | | NA | | | | X | X | X | X | X |
| 8 | PGR2016-00028 | Amneal Pharmaceuticals LLC | Yeda Research & Development Co., Ltd. | 9,155,776 | X Copaxone® | X | X | | | NA | | | | X | | | X | X |
| 9 | PGR2016-00042 | Corvus Pharmaceuticals, Inc. | The Government of The United States of America as represented by the Secretary of The Department of Health and Human Services | 9,415,105 | | X | | X | | NA | | | | X | X | | X | X |
| 10 | PGR2017-00008 | Grünenthal GmbH | Antecip Bioventures II LLC | 9,283,239 | | X | | | | X ⁶ | | | | X | X | | X | X |
| 11 | PGR2017-00011 | L'Oréal USA, Inc. | Liqwd, Inc. | 9,498,419 | | | | X | | NA | | | | X | X | X | | |

⁶ PTAB decision (June 22, 2018): Grünenthal demonstrated by a preponderance of the evidence that claims 1-17 were unpatentable for a lack of written description. No appeal to the Federal Circuit appears to have been filed.

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|----|---------------|-------------------------------|----------------------------------|---------------|---------------|--------------------|------------|-----------------------------|------------------|------------------------|---------|----------|------------|----------|---------|---------|-----|-----|
| 12 | PGR2017-00012 | L'Oréal USA, Inc. | Liqwd, Inc. | 9,498,419 | | | | | | X ⁷ | | | | | | | X | X |
| 13 | PGR2017-00016 | Merck Sharp & Dohme Corp. | Wyeth LLC | 9,399,060 | | X | | X | | NA | | | | | X | X | | X |
| 14 | PGR2017-00017 | Merck Sharp & Dohme Corp. | Wyeth LLC | 9,399,060 | | X | | X | | NA | | | | | | | X | X |
| 15 | PGR2017-00020 | Crescendo Bioscience, Inc | Graham, L. Douglas | 9,387,246 | | | | X | | NA | | | | X | X | | | |
| 16 | PGR2017-00021 | Aradigm Corporation | Insmmed, Inc. | 9,402,845 | | X | | X (NOT ELIGIBLE FOR PGR) | | NA | | | | X | X | | | X |
| 17 | PGR2017-00022 | Grünenthal GmbH | Antecip Bioventures II LLC | 9,408,862 | | | | | X | | | | | | X | X | X | X |
| 18 | PGR2017-00033 | Nippon Suisan Kaisha Ltd. | Pronova Biopharma Norge AS | 9,447,360 | | X | | | X | | | | | X | | X | X | X |
| 19 | PGR2017-00034 | Concert Pharmaceuticals, Inc. | Incyte Corporation | 9,662,335 | X Jakafi® | X | | X (NOT ELIGIBLE FOR PGR) | | NA | | | | X | X | | X | |
| 20 | PGR2017-00039 | KVK-Tech, Inc. | Silvergate Pharmaceuticals, Inc. | 9,463,183 | X Qbrelis® | | | | | X ⁸ | | | | X | X | | | X |
| 21 | PGR2018-00001 | Grünenthal GmbH | Antecip Bioventures II LLC | 9,539,268 | | | | | X | | | | | X | X | X | X | X |

⁷ PTAB decision (June 27, 2018): L'Oréal demonstrated by a preponderance of the evidence that claims 1-8 and 10 were obvious over the combination of Kitabata (US 2002/0189034), Berkemer (German Patent Application Publication No. 1,220,969) and KR '564 (Korean Patent Application No. 10-2006-0059564). Liqwd appealed to the Federal Circuit on July 10, 2018.

⁸ PTAB decision (May 7, 2018): Adverse judgment entered against KVK-Tech based on Joint Motion for Adverse Judgment against Petitioner filed by the parties on April 16, 2018.

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|----|---------------|-----------------------------------|-----------------------------|---------------|--------------|--------------------|------------|-----------------------------|------------------|------------------------|---------|----------|----------------|----------|---------|---------|-----|-----|
| 22 | PGR2018-00006 | CathWorks Ltd. | HeartFlow, Inc. | 9,613,186 | | | X | | | | NA | | | | | | | X |
| 23 | PGR2018-00023 | L'Oréal USA, Inc. | Liqwd, Inc. | 9,668,954 | | | | X | | | NA | | | | | X | X | X |
| 24 | PGR2018-00024 | L'Oréal USA, Inc. | Liqwd, Inc. | 9,668,954 | | | | X | | | NA | | | X | | | X | X |
| 25 | PGR2018-00025 | L'Oréal USA, Inc. | Liqwd, Inc. | 9,668,954 | | | | | X | | NA | | | | | | | X |
| 26 | PGR2018-00033 | Rimfrost AS | Aker Biomarine Antarctic AS | 9,644,170 | | X | | X (NOT ELIGIBLE FOR PGR) | | | NA | X | X ⁹ | X | X | | X | X |
| 27 | PGR2018-00048 | Collegium Pharmaceutical, Inc. | Purdue Pharma L.P. | 9,693,961 | | X | | | | | X | | | X | X | X | X | |
| 28 | PGR2018-00057 | Personal Genome Diagnostics, Inc. | Guardant Health, Inc. | 9,840,743 | | X | X | | | | | X | | X | | X | X | X |
| 29 | PGR2018-00058 | Personal Genome Diagnostics, Inc. | Guardant Health, Inc. | 9,834,822 | | | X | | | | | X | | | | X | X | X |
| 30 | PGR2018-00059 | Anylam Pharmaceuticals, Inc. | Silence Therapeutics GMBH | 9,695,423 | | X | | | | | X | | | X | X | | X | X |
| 31 | PGR2018-00062 | Grünenthal GmbH | Antecip Bioventures II LLC | 9,707,245 | | X | | | | | X | | | X | X | | X | X |
| 32 | PGR2018-00067 | Anylam Pharmaceuticals, Inc. | Silence Therapeutics GmbH | 9,758,784 | | X | | | | | X | | | X | X | | X | |

⁹ Lack of inventorship.

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| 33 | PGR2018-00069 | Novartis Pharmaceuticals Corporation | Plexxikon, Inc. | 9,844,539 ¹⁰ | | X | | | | | X | | | X | X | | X | |
| 34 | PGR2018-00072 | Benson Hill Biosystems, Inc. | The Broad Institute, MIT, Harvard | 9,790,490 (CRISPR) | | | | | | | X | | X ¹¹ | X | X | X | | X |
| 35 | PGR2018-00075 | Alnylam Pharmaceuticals, Inc. | Silence Therapeutics GmbH | 9,783,802 | | X | | | | | X | | | X | X | X | X | |
| 36 | PGR2018-00088 | Alnylam Pharmaceuticals, Inc. | Silence Therapeutics GmbH | 9,790,505 | | X | | | | | X | | | X | X | X | X | |
| 37 | PGR2018-00089 | Alnylam Pharmaceuticals, Inc. | Silence Therapeutics GmbH | 9,790,501 | | X | | | | | X | | | X | X | | X | |
| 38 | PGR2018-00092 | Grunenthal GmbH | Antecip Bioventures II LLC | 9,820,999 | | X ¹² | | | | | X | | | | X | | X | X |
| 39 | PGR-2018-00098 | Hybrigenic SA | Forma Therapeutics, Inc. | 9,840,491 | | | | | | | X | | | X | X | | | X |
| | Total out of 39 | | | | 5 different drugs | 23 | 7 | 13 | 4 | 4 | 11 | 4 | 2 | 28 | 25 | 15 | 27 | 27 |

¹⁰ Plexxikon, Inc. has asserted this patent against Novartis in litigation in *Plexxikon Inc. v. Novartis, Pharmaceutical Corporation*, Civil Action No. 4:17-cv-04405-HSG (EDL) as covering Tafinlar®.

¹¹ Lack of practical utility.

¹² While technically a transitional application with provisional applications claiming priority back to May 2012, several continuation-in-part applications appear in the priority chain which were filed after March 16, 2013.