#### UNITED STATES PATENT AND TRADEMARK OFFICE

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#### BEFORE THE PATENT TRIAL AND APPEAL BOARD

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## REGENERON PHARMACEUTICALS, INC., Petitioner

V.

### NOVARTIS PHARMA AG, NOVARTIS TECHNOLOGY LLC, NOVARTIS PHARMACEUTICALS CORPORATION,

Patent Owner

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**Case IPR2020-01317** 

Patent 9,220,631

NOVARTIS PHARMA AG, NOVARTIS TECHNOLOGY LLC, AND NOVARTIS PHARMACEUTICALS CORPORATION'S PATENT OWNER PRELIMINARY RESPONSE



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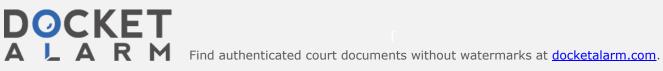
## **TABLE OF AUTHORITIES**

Page(s)

Cases
Advanced Bionics, LLC. V. Med-El Elektromedizinishce Gerate GMBH, No. IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020)
Apple Inc. v. Fintiv Inc., IPR2020-00019, Paper 11 (PTAB, March 20, 2020)passim
Apple Inc. v. Fintiv Inc., IPR2020-00019, Paper 15 (PTAB, May 13, 2020)
Apple Inc. v. Maxell, Ltd., IPR2020-00203, Paper 12 (PTAB July 6, 2020)10
Becton, Dickinson and Co. v. B. Braun Melsungen AG, No. IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017)passim
Cisco Sys., Inc. v. Ramot at Tel Aviv University Ltd., IPR2020-00122, Paper 15 (PTAB May 15, 2020)
Crocs, Inc. v. Int'l Trade Comm., 598 F.3d 1294 (Fed. Cir. 2010)
Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131 (2016)
In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1062 (Fed. Cir. 2012)44
Ecolochem, Inc. v. S. California Edison Co., 227 F.3d 1361 (Fed. Cir. 2000)39
Fitbit, Inc. v. Koninklijke Philips N.V., IPR2020-00772, Paper 14 (P.T.A.B. Oct. 19, 2020)passim
<i>In re Fritch</i> , 972 F.2d 1260 (Fed. Cir. 1992)29



Harmonic Inc. v. Avid Tech., Inc., 815 F.3d 1356 (Fed. Cir. 2016)	5
Impax Labs. Inc. v. Lannett Holdings Inc., 893 F.3d 1372 (Fed. Cir. 2018)	44
Intel Corp. v. VLSI Tech. LLC, IPR2020-00106, Paper 17 (PTAB May 5, 2020)	10
Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359 (Fed. Cir. 2016)	39
KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007)	35, 36
Mylan Pharm. Inc. v. Research Corp. Techs., Inc., 914 F.3d 1366 (Fed. Cir. 2019)	46
NHK Spring Co. v. Intri-Plex Techs., Inc., IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018)	6, 10
Novartis Pharma AG, et al. v. Regeneron Pharmaceuticals, Inc., 1:20-cv-690 (S.D.N.Y. July 30, 2020)	xi
Novartis Pharma AG v. Regeneron Pharm. Inc., 1:20-cv-00690 (N.D.N.Y.)	8
Polaris Indus., Inc. v. Arctic Cat, Inc., 882 F.3d 1056 (Fed. Cir. 2018)	38
Regents of Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286 (Fed. Cir. 2018)	
Samsung Electronics America, Inc. v. Uniloc 2017 LLC, IPR2019-01218, Paper 7 (PTAB Jan. 7, 2020)	10
Stryker Corp. v. KFX Medical, LLC, IPR2019-00817, Paper 10 (PTAB Sept. 16, 2019)	43
Supercell Oy v. Gree, Inc., IPR2020-00310, Paper 13 (PTAB June 18, 2020)	10



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