UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

SANDOZ INC.,
Petitioner

v.

ABBVIE BIOTECHNOLOGY LTD.,
Patent Owner

_____

U.S. Patent No.: 9,512,216
Issue Date: December 6, 2016
Title: Use of TNFα Inhibitor

_____

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,512,216 PURSUANT TO 35 U.S.C. §§311-319 AND 37 C.F.R. §42

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

EXHIBIT LIST

Ex. No.[1]	Description	Referred To As	Reference Type[2]
1001	United States Patent No. 9,512,216, filed June 3, 2016, issued Dec. 6, 2016	"'216 patent"	n/a
1002	Declaration of Simon M. Helfgott, M.D.	"Helfgott Decl."	n/a
1003	THERAPY OF MODERATE-TO-SEVERE-PSORIASIS (Gerald D. Weinstein & Alice B. Gottlieb eds., 2nd ed. Mar. 19, 2003)[3]	"Weinstein"	102(b)
1004*	Letter from Jay P. Siegel, Center for Biologics Evaluation and Research, to Abbott Laboratories, Approval Letter(s) Application Number 125057/0 (Dec. 31, 2002)	"HUMIRA® approval letter"	102(b)
1005	WOLFGANG A. RITSCHEL & GREGORY L. KEARNS, HANDBOOK OF BASIC PHARMACOKINETICS . . . INCLUDING CLINICAL APPLICATIONS (5th ed. 1999)	"Ritschel & Kearns"	102(b)
1006	Enbrel® (etanercept) Label (Immunex Corp. issued Jan. 2002)	"Enbrel® 2002 Label"	102(b)
1007*	B. A. van de Putte et al., *Efficacy of the Fully Human Anti-TNF Antibody D2E7 in Rheumatoid Arthritis*, 42 ARTHRITIS & RHEUMATISM (1999) (ACR	"van de Putte"	102(b)

[1] Pincites in the Petition and Declarations to exhibits marked with an asterisk (*) refer to stamped-on page numbers. All other pincites in the Petition and Declarations are to original page numbers.

[2] This column indicates whether an exhibit is prior art under 35 U.S.C. §§102(a), (b) or (e). "n/a" indicates the exhibit is not being relied upon as prior art.

[3] Weinstein was published on March 19, 2003. *See* ex.1065.

Ex. No.[1]	Description	Referred To As	Reference Type[2]
	Abstract Concurrent Session, RA: TNF-Blockade, Wednesday, Nov. 17, 1999 S400)		
1008	TEXTBOOK OF PSORIASIS (Paul D. Mier & Peter C. M. van de Kerkhof eds., 1986)	"Mier"	102(b)
1009	P. J. Mease, *Tumour Necrosis Factor (TNF) in Psoriatic Arthritis: Pathophysiology and Treatment with TNF Inhibitors*, 61 ANNALS RHEUMATIC DISEASES 298 (2002)	"Mease 2002"	102(b)
1010	Marjorie Ridley & Margaret Safranek, *Common Skin Conditions*, 58 *OCCASIONAL PAPER ROYAL C. GEN. PRACTITIONERS* 50 (1992)[4]	"Ridley"	102(b)
1011	Alan J. Lewis & Anthony M. Manning, *New Targets for Anti-Inflammatory Drugs*, 3 CURRENT OPINION CHEMICAL BIOLOGY 489 (1999)	"Lewis"	102(b)
1012*	Luke Timmerman, *Abbott's Humira, the 3rd-in-Class Drug That Toppled Lipitor as No. 1*, XCONOMY (Apr. 16, 2012), *available at* http://www.xconomy.com/national/2012/04/16/abbotts-humira-the-3rd-in-class-drug-that-toppled-lipitor-as-no-1/#	"Timmerman"	n/a
1013	P. Ettehadi et al., *Elevated Tumour Necrosis Factor-Alpha (TNF-α) Biological Activity in*	"Ettehadi"	102(b)

[4] Ridley was published in 1992. Ex.1066.

Ex. No.[1]	Description	Referred To As	Reference Type[2]
	Psoriatic Skin Lesions, 96 CLINICAL & EXPERIMENTAL IMMUNOLOGY 146 (1994)		
1014	George Spencer-Green, *Etanercept (Enbrel): Update on Therapeutic Use*, 59 ANNALS RHEUMATIC DISEASES i46 (2000)	"Spencer-Green"	102(b)
1015	Petra D. Cravens & Peter E. Lipsky, *Dendritic Cells, Chemokine Receptors and Autoimmune Inflammatory Diseases*, 80 IMMUNOLOGY & CELL BIOLOGY 497 (2002)	"Cravens"	102(b)
1016	D. E. Furst et al., *Building Towards A Consensus for the Use of Tumour Necrosis Factor Blocking Agents*, 58 ANNALS RHEUMATIC DISEASES 725 (1999)	"Furst"	102(b)
1017	Philip J. Mease et al., *Etanercept in the Treatment of Psoriatic Arthritis and Psoriasis: A Randomised Trial*, 356 LANCET 385 (2000)	"Mease 2000"	102(b)
1018	P. J. Mease, *Cytokine Blockers in Psoriatic Arthritis*, 60 ANNALS RHEUMATIC DISEASES iii37 (2001)	"Mease 2001"	102(b)
1019	Joachim R. Kalden, *Emerging Role of Anti-Tumor Necrosis Factor Therapy in Rheumatic Diseases*, 4 ARTHRITIS RES. S34 (2002)	"Kalden"	102(b)
1020	B. Everts et al., *Morphine Use and Pharmacokinetics in Patients with Chest Pain Due to Suspected or Definite Acute Myocardial Infarction*, 2 EUR. J. PAIN 115 (1998)	"Everts"	102(b)

Ex. No.[1]	Description	Referred To As	Reference Type[2]
1021*	WO 99/65867, filed June 17, 1999, published Dec. 23, 1999	"WO '867"	102(b)
1022	*Amgen Inc. v. AbbVie Biotech. Ltd.*, No. IPR2015-01517 (Patent Owner's Preliminary Response, Oct. 19, 2015)	"Prelim. Response in '158 IPR"	n/a
1023	United States Patent No. 6,306,900, filed Oct. 23, 2000, issued Oct. 23, 2001	"'900 patent"	102(b)
1024*	Trexall Tablets (Methotrexate Tablets USP) Approval Package for Application Number: ANDA 40-385 (approved Mar. 21, 2001)	"Trexall® Label"	102(b)
1025	KELLEY'S TEXTBOOK OF RHEUMATOLOGY vol. 2 (Shaun Ruddy et al. eds., 6th ed. 2001)[5]	"Kelley's Textbook"	102(b)
1026*	Humira™ (adalimumab) Label (Abbott Laboratories revised Jan. 2003)	"Humira® 2003 Label"	102(b)
1027*	Remicade® (infliximab) Label (Centocor, Inc. revised June 2002)	"Remicade® 2002 Label"	102(b)
1028	Hanns-Martin Lorenz & Joachim R. Kalden, *Perspectives for TNF-α-Targeting Therapies*, 4 ARTHRITIS RES. S17 (2002)	"Lorenz"	102(b)
1029	Claudia Dechant et al., *One Year Outcome of Patients with Severe Psoriatic Arthritis Treated with Infliximab*, 43 ARTHRITIS & RHEUMATISM [212] (2000)	"Dechant"	102(b)
1030	K. Eberhardt & E. Fex, *Clinical Course and Remission Rate in Patients with Early Rheumatoid Arthritis: Relationship to Outcome After 5 Years*, 37 BRIT.	"Eberhardt"	102(b)

[5] Kelley's Textbook was published in June 2001. *See* ex.1073.

Ex. No.[1]	Description	Referred To As	Reference Type[2]
	J. RHEUMATOLOGY 1324 (1998)		
1031	HARRY L. ARNOLD JR. ET AL., ANDREWS' DISEASES OF THE SKIN: CLINICAL DERMATOLOGY (8th ed. 1990)	"Diseases of the Skin"	102(b)
1032	*Coherus BioSciences Inc. v. AbbVie Biotech. Ltd.*, No. IPR2016-00172 (Patent Owner's Response, Paper No. 37, Sept. 13, 2016)	"Patent Owner's Response in '135 IPR"	n/a
1033	A. L. J. Ogilvie et al., *Treatment of Psoriatic Arthritis with Antitumour Necrosis Factor-α Antibody Clears Skin Lesions of Psoriasis Resistant to Treatment with Methotrexate*, 144 BRIT. J. DERMATOLOGY 587 (2001)	"Ogilvie"	102(b)
1034	Humira® (adalimumab) Label (AbbVie Inc. revised April 2017), 2017 Physician's Desk Reference	"2017 Humira® Label"	n/a
1035	2001 Physician's Desk Reference (55th ed. published Nov. 2000[6]) excerpts	"2001 PDR"	102(b)
1036	U. Chaudhari et al., *Efficacy and Safety of Infliximab Monotherapy for Plaque-Type Psoriasis: A Randomised Trial*, 357 LANCET 1842 (2001)	"Chaudhari"	102(b)
1037	Filip Van den Bosch et al., *Effects of a Loading Dose Regimen of Three Infusions of Chimeric Monoclonal Antibody to Tumour Necrosis Factor α (Infliximab) in Spondyloarthropathy: An Open*	"Van den Bosch"	102(b)

[6] According to Amazon, the 2001 PDR was published in November 2000. *See* ex.1074.

Ex. No.[1]	Description	Referred To As	Reference Type[2]
	Pilot Study, 59 ANNALS RHEUMATIC DISEASES 428 (2000)		
1038*	U.S. Environmental Protection Agency, Office of Research and Development, EXPOSURE FACTORS HANDBOOK (Aug. 1997)	"EPA Handbook"	102(b)
1039*	WO 98/05357, filed Aug. 1, 1997, published Feb. 12, 1998	"Feldmann"	102(b)
1040	Douglas J. Perkins et al., *Reduction of NOS2 Overexpression in Rheumatoid Arthritis Patients Treated with Anti-Tumor Necrosis Factor α Monoclonal Antibody (cA2)*, 41 ARTHRITIS & RHEUMATISM 2205 (1998)	"Perkins"	102(b)
1041	Chaity Chaudhury et al., *The Major Histocompatibility Complex-Related Fc Receptor for IgG (FcRn) Binds Albumin and Prolongs Its Lifespan*, 197 J. EXPERIMENTAL MED. 315 (Feb. 2003)	"Chaudhury"	102(b)
1042	Frank M. Balis et al., *Pharmacokinetics of Subcutaneous Methotrexate*, 6 J. CLINICAL ONCOLOGY 1882 (1988)	"Balis"	102(b)
1043	Roelien H. Enting et al., *A Prospective Study Evaluating the Response of Patients with Unrelieved Cancer Pain to Parenteral Opioids*, 94 CANCER 3049 (2002)	"Enting"	102(b)
1044*	Application No. 11/104,117, Declaration of Diane R. Mould (dated Mar. 17, 2014)	"Mould Decl."	n/a
1045*	Application No. 11/104,117,	"Collett	n/a

Ex. No.[1]	Description	Referred To As	Reference Type[2]
	Declaration of John Collett (dated Mar. 17, 2014)	Decl."	
1046*	Alfons den Broeder et al., *A Single Dose, Placebo Controlled Study of the Fully Human Anti-Tumor Necrosis Factor-α Antibody Adalimumab (D2E7) in Patients with Rheumatoid Arthritis*, 29 J. RHEUMATOLOGY 2288 (2002)	"den Broeder"	102(b)
1047*	Center for Drug Evaluation and Research, Medical Review(s) for Application No. sBLA 125057/110 (Mar. 2007)	"FDA Medical Doc"	n/a
1048*	Enbrel® (etanercept) Label (Immunex Corp. revised November 2016), 2016 Physician's Desk Reference	"Enbrel® 2016 Label"	n/a
1049*	Center for Drug Evaluation and Research, Clinical Pharmacology and Biopharmaceutics Review(s) for Application No. sBLA 125057/110 (Mar. 2007)	"FDA Pharmacology Doc."	n/a
1050	Declaration of John Posner, Ph.D.	"Posner Decl."	n/a
1051	PHARMACEUTICS: THE SCIENCE OF DOSAGE FORM DESIGN (M. E. Aulton ed., 2nd ed. 2002)	"Aulton"	102(b)
1052*	Press Release, Abbott Laboratories, Abbott Laboratories Initiates Clinical Trials to Explore Use of Humira(™) (Adalimumab) in Psoriasis and Psoriatic Arthritis (Mar. 3, 2003), *available at* https://web.archive.org/web/20030701072200/https:/www.immunetolerance.org/artman/publish/articl	"AbbVie Press Release"	102(b)

Ex. No.[1]	Description	Referred To As	Reference Type[2]
	e_148.html		
1053	Madhulika A. Gupta & Aditya K. Gupta, *Age and Gender Differences in the Impact of Psoriasis on Quality of Life*, 34 INT'L J. DERMATOLOGY 700 (1995)	"Gupta"	102(b)
1054	DEREK WALLER & ANDREW RENWICK, PRINCIPLES OF MEDICAL PHARMACOLOGY (1994)	"Waller"	102(b)
1055*	M. Schattenkirchner et al. *Long-Term Use of the Fully Human Anti-TNF Antibody D2E7 in Combination with Methotrexate in Active Rheumatoid Arthritis*, 43 ARTHRITIS & RHEUMATISM S228 [968] (2000)	"Schattenkirchener"	102(b)
1056	GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS (Joel G. Hardman & Lee E. Limbird eds., 10th ed. 2001)	"Goodman & Gilman's"	102(b)
1057	United States Patent No. 8,889,136, filed April 11, 2005, issued Nov. 18, 2014	"'136 patent"	n/a
1058	*TNF-Alpha Inhibitor Projected to Offer Huge Market by 2010*, JAPAN CHEMICAL WEEK (Sept. 2001)	"Japan Chemical Week"	102(b)
1059	Humira® (adalimumab) Label (Abbott Laboratories July 30, 2004)	"Humira® 2004 Label"	n/a
1060*	H. Marzo-Ortega et al., *Infliximab is Effective in the Treatment of Resistant Psoriatic Arthritis and Skin Psoriasis: A Clinical and MRI Study*, 41 RHEUMATOLOGY	"Marzo-Ortega"	102(b)

Ex. No.[1]	Description	Referred To As	Reference Type[2]
	[OP11] (2002)		
1061	U. Wollina & H. Konrad, *Treatment of Recalcitrant Psoriatic Arthritis with Anti-Tumor Necrosis Factor-α Antibody*, 16 J. EURO. ACAD. DERMATOLOGY &VENEREOLOGY 127 (2002)	"Wollina"	102(b)
1062	Joachim Kempeni, *Update on D2E7: A Fully Human Anti-Tumour Necrosis Factor α Monoclonal Antibody*, 59 ANNALS RHEUMATIC DISEASES i44 (2000)	"Kempeni"	102(b)
1063	SN 11/104,117, Applicant Amendment and Response to December 16, 2013 Non-Final Office Action and accompanying Declarations (Mar. 18, 2014)	"Applicant Amendment and Response"	n/a
1064	Ronald D. Schoenwald, Basic Principles, *in* PHARMACOKINETICS IN DRUG DISCOVERY AND DEVELOPMENT (Ronald D. Schoenwald ed., 2002)	"Schoenwald"	102(b)
1065	United States Copyright Office, Public Catalog Record *for* THERAPY OF MODERATE-TO-SEVERE-PSORIASIS (Gerald D. Weinstein & Alice B. Gottlieb eds., 2nd ed., *available at*, http://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=1&ti=1,1&Search_Arg=therapy%20of%20moderate%20to%20severe%20psoriasis&Search_Code=TALL&CNT=25&PID=ZV3R2SmxeDyQlVUt7yxTFJL0c4QuM&SEQ=20170925084001&SID=1	"Weinstein Copyright"	n/a

Ex. No.[1]	Description	Referred To As	Reference Type[2]
1066	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2560222/	"Ridley Copyright"	n/a
1067	https://academic.oup.com/rheumatology/article/41/suppl_2/3/1788099/Paediatrics-and-Other-Inflammatory-Arthopathies	"Marzo-Ortega publication information"	n/a
1068	Declaration of Victoria Reines	"Reines Decl."	n/a
1069	Cover of Arthritis Research vol. 4, supplement 3 (2002) supplied by the British Library	n/a	n/a
1070	H. Marzo-Ortega et al., *Infliximab is Effective in the Treatment of Resistant Psoriatic Arthritis and Skin Psoriasis: A Clinical and MRI Study*, 41 RHEUMATOLOGY [OP11] (2002)[7]	n/a	102(b)
1071	Screenshot of https://web.archive.org/web/20030308015249/http://www.remicade.com:80/pdf/prescribing.pdf from the Way Back Machine	n/a	n/a
1072	Screenshot of https://web.archive.org/web/20030331010007/https://www.fda.gov/ohrms/dockets/ac/03/briefing/3930B1_02_B-Abbott-Humira%20Prescribing%20Info.pdf from the Way Back Machine	n/a	n/a
1073	United States Copyright Office, Public Catalog for Kelley's Textbook of Rheumatology	n/a	n/a
1074	https://www.amazon.com/Physicians-Desk-Reference-2001-	n/a	n/a

[7] See ex.1067 for publication information.

Ex. No.[1]	Description	Referred To As	Reference Type[2]
	Pdr/dp/1563633752		
1075	Humira™ (adalimumab) Label (Abbott Laboratories Dec. 2002)	"Humira® 2002 Label"	102(b)
1076	Affidavit of Christopher Butler	"Butler Affidavit"	n/a

I. INTRODUCTION

Pursuant to 35 U.S.C. §§311-319 and 37 C.F.R. §42, Sandoz Inc. ("Sandoz" or "Petitioner") respectfully requests *Inter Partes* Review ("IPR") of claims 1-16 of U.S. Patent No. 9,512,216 (the "'216 patent," ex.1001[8]), which is currently assigned to AbbVie Biotechnology Ltd. ("AbbVie" or "Patent Owner").

The '216 patent claims a subcutaneously administered dosing regimen for the anti-TNF-α antibody adalimumab, the active ingredient in AbbVie's Humira® product, to treat moderate to severe chronic plaque psoriasis ("PsO"). The patient is administered an initial dose of 80mg, followed by 40mg every other week ("eow") starting one week after the initial 80mg dose, wherein the treated patient achieves a Psoriasis Area and Severity Index ("PASI") 75 response after 12 weeks of treatment. The '216 patent explains that the 40mg eow dose is a "treatment" dose and the initial, one-time 80mg dose is an "induction" dose.

The prior art rendered the claimed PsO dosing regimen obvious to a person of ordinary skill in the art ("POSA"). It taught all of these elements and provided the motivation to combine them with a reasonable expectation of success.

First, the PsO treatment dose of 40mg adalimumab subcutaneously administered eow was obvious because the prior art taught that (i) the FDA had

[8] Pincites in the Petition and Declarations to exhibits marked with an asterisk (*) refer to stamped-on page numbers. All other pincites in the Petition and Declarations are to original page numbers.

already approved this exact same dosing regimen to treat rheumatoid arthritis ("RA"); (ii) adalimumab would be useful in treating PsO, and (iii) RA and PsO are closely related conditions, mediated by TNF-α, that could be treated with the same drugs using the same dosing regimens.

Second, it was obvious to administer an 80mg induction dose of adalimumab one week before beginning the PsO adalimumab treatment dose because a POSA would have known that (i) an induction dose would provide more rapid relief to patients suffering severe physical and psychological symptoms associated with diseases like PsO; (ii) the first-in-class TNF-α inhibitor infliximab was administered with an induction dose to treat PsO; (iii) an appropriate induction dose for a drug like adalimumab, which has linear (*i.e.*, "first order") pharmacokinetics and is dosed approximately on its two-week half-life, would be double the 40mg treatment dose; (iv) an 80mg dose was shown to be effective in treating RA when dosed weekly; (v) an interval of either one week or two weeks between administering an induction dose and beginning treatment dosing would have achieved the goal of more rapid relief; and (vi) it would be most convenient to use an induction dose (such as 80mg) that was a multiple of AbbVie's already approved 40mg pre-filled syringe.

Given the clear teachings of the prior art, the claimed induction dosing regimen was one of a finite number of obvious options that a POSA would have considered.

Under well-established Federal Circuit authority, the recited PASI 75 response score is not entitled to patentable weight since it simply expresses an intended result of the claimed method. Even if the recited PASI 75 response is considered a claim limitation, the ’216 patent specification makes plain that it is simply a natural result for a certain percentage of patients from receiving adalimumab according to an obvious dosing regimen.

As explained below, a POSA would have been motivated by the prior art to treat PsO patients with an induction dose of 80mg of adalimumab followed one week later by the same 40mg adalimumab subcutaneously administered eow dosing regimen already proven in the prior art to be effective in treating RA, and would have had a reasonable expectation that the dosing regimen would be successful in treating PsO.

II. MANDATORY NOTICES UNDER 37 C.F.R. §42.8(a)(1)

A. Real Party-In-Interest (37 C.F.R. §42.8(b)(1))

Sandoz is the real party-in-interest.

B. Related Matters (37 C.F.R. §42.8(b)(2))

1. Related Board Proceedings

In IPR2017-01824, Petitioner asserted invalidity of the '216 patent over a combination of prior art references that differs from the combination asserted herein. The proposed Ground for unpatentability of the challenged claims set forth herein are not redundant with the Ground in the prior Petition. *See Liberty Mutual Ins. Co. v. Progressive Casualty Ins. Co.*, CBM 2012-00003, Paper 7 (P.T.A.B. Oct. 25, 2012).

Petitioner in IPR2017-01824 asserted the Humira® 2002 Package Insert, the AbbVie Press Release, Aulton and Weinstein, in view of Marzo-Ortega, whereas here, Petitioner asserts invalidity over the combination of the Humira® 2003 Label or the Humira® 2002 Label[9], the AbbVie Press Release, Aulton and Weinstein, in view of Mease 2002. Whereas Marzo-Ortega only discussed using the TNF-α inhibitor infliximab to treat PsO at the same dosing regimen used to treat RA, Mease 2002 discussed using both etanercept and infliximab to treat PsO at the same dosing regimens used to treat RA. Nevertheless, both Petitions contain numerous references describing the background art (summarized in Tables 3 and 4 below) showing it was well known that both TNF-α inhibitors and other drugs

[9] The Humira® 2003 Label and the Humira® 2002 Label are substantively similar and provide the same information pertinent to this Petition.

could be used to treat RA and PsO/psoriatic arthritis ("PsA") using the same or similar dosing regimens.

AbbVie owns the patents that are the subjects of the following administrative matters: (1) *Coherus BioSciences Inc. v. AbbVie Biotech. Ltd.*, Case No. IPR2016-00172 (P.T.A.B.), Petition for *Inter Partes* Review of U.S. Patent No. 8,889,135 ("the '135 patent"), dated November 9, 2015; (2) *Boehringer Ingelheim GmbH v. AbbVie Biotech. Ltd.*, Case No. IPR2016-00408 (P.T.A.B), Petition for *Inter Partes* Review of U.S. Patent No. 8,889,135, dated December 29, 2015; (3) *Boehringer Ingelheim GmbH v. AbbVie Biotech. Ltd.*, Case No. IPR2016-00409 (P.T.A.B), Petition for *Inter Partes* Review of U.S. Patent No. 8,889,135, dated December 29, 2015; (4) *Coherus BioSciences Inc. v. AbbVie Biotech. Ltd.*, Case No. IPR2016-00188 (P.T.A.B.), Petition for *Inter Partes* Review of U.S. Patent No. 9,017,680, dated December 7, 2015; (5) *Coherus BioSciences Inc. v. AbbVie Biotech. Ltd.*, Case No. IPR2016-00189 (P.T.A.B.), Petition for *Inter Partes* Review of U.S. Patent No. 9,073,987, dated December 7, 2015. On May 17, 2016, the Board issued a decision instituting *inter partes* review for Case No. IPR2016-00172. On June 13, 2016, the Board issued decisions instituting *inter partes* review for Case Nos. IPR2016-00188 and IPR2016-00189. On July 7, 2016, the Board issued decisions instituting *inter partes* review for Case Nos. IPR2016-00408 and IPR2016-00409.

On May 16, 2017, the Board issued a Final Written Decision in IPR No. 2016-00172 on the ’135 patent. On June 9, 2017, the Board issued Final Written Decisions in IPR Nos. 2016-00188 and 2016-00189 on the ’680 and ’987 patents, respectively. All three patents were directed to a method of treating RA by administering 40mg D2E7 subcutaneously eow. *Coherus BioSciences, Inc. v. AbbVie Biotech. Ltd.*, IPR Nos. 2016-00172, 2016-00408, 2016-00409 (P.T.A.B). In its decisions, the Board found the claims of all three patents invalid over van de Putte (ex.1007* at 3) and Kempeni 1999. *Id.* The patents that are the subjects in the identified administrative matters and the ’216 patent however do not claim priority to any of the same applications. On July 6, 2017, the Board issued Final Written Decisions in Nos. IPR2016-00408 and IPR2016-00409. In IPR2016-00408, the Board found the claims of the ’135 patent unpatentable over van de Putte 2000 and Rau 2000. In IPR2016-00409, the Board found the claims of the ’135 patent unpatentable over van de Putte 1999 and Kempeni 1999, and alternatively over Rau 1998, Schattenkirchner 1998, and van de Putte 1999.

The following list includes U.S. applications and patents that claim the benefit of the priority of the filing of the ’216 patent or that the ’216 patent claims priority from: U.S. Patent Nos. 9,067,992; 8,906,373; 8,808,700; 8,715,664; 8,889,136; 9,090,689; 9,187,559; 9,061,005; 9,499,615; 9,085,620; 8,961,973; 8,961,974; 8,986,693 and U.S. Application Nos. 60/681,645; 60/569,100;

60/561,710; 60/561,139; 14/809,828; 11/804,587; 12/008,064; 14/229,703; 14/229,709; 14/326,061; 14/745,092; 14/229,602 and 15/288,750.

In addition to IPR2017-01824, Petitioner has filed the following petitions for IPR: IPR2017-01823 (U.S. Patent No. 8,802,100); IPR2017-01987 (U.S Patent No. 8,911,737), IPR2017-01988 (U.S Patent No. 8,974,790), IPR2017-02105 (U.S. Patent No. 9,090,689) and IPR2017-02106 (U.S. Patent No. 9,067,992). AbbVie is the patent owner of these patents, however only U.S. Patent Nos. 9,090,689, 9,067,992 and the '216 patent claim priority to the same applications, the earliest of which is SN 60/561,139 filed on April 9, 2004.

2. Related Litigations

The '216 patent is related to two of the patents at issue[10] in the following judicial matter in which Petitioner was not and is not a party, which may affect, or be affected by a decision in this proceeding: *AbbVie Inc. et al. v. Amgen Inc. et. Al.*, No. 1:16-cv-00666-MSG (D. Del. Filed Aug. 4, 2016). The '216 patent is not related to any of the patents that have been asserted in the following litigation in which Petitioner was not and is not a party: *AbbVie Inc. et al. v. Boehringer Ingelheim Int'l GMBH et al.*, 1:17-cv-01065-MSG (D. Del. filed Aug. 2, 2017).

[10] U.S. Patent Nos. 8,961,973; 8,986,693 and the '216 patent claim priority to the same application, SN 60/561,139 filed April 9, 2004.

Petitioner is not aware of any reexamination certificates or pending prosecution concerning the '216 patent.

C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))

Lead Counsel	Back-up Counsel
David K. Barr (Reg. No. 31,940) David.Barr-PTAB@apks.com Arnold & Porter Kaye Scholer LLP 250 W. 55th Street New York, NY 10019 T: 212-836-7560 F: 212-836-6560	Daniel L. Reisner (*pro hac vice* motion to be filed) Daniel.Reisner@apks.com Arnold & Porter Kaye Scholer LLP 250 West 55th Street New York, NY 10019 T: 212-836-8132 F: 212-836-6432

D. Service Information (37 C.F.R. §42.8(b)(4))

Please address all correspondence to the lead and backup counsel at the contact information above. Petitioner also consents to service by email to:

David.Barr-PTAB@apks.com
Daniel.Reisner@apks.com

E. Fee Payment Authorization (37 C.F.R. §42.103(a))

The Petitioner authorizes the Patent and Trademark Office to charge Deposit Account No. 502387 for the fees set in 37 C.F.R. §42.15(a) for this Petition for IPR, and further authorizes payment of any additional fees to be charged to this Deposit Account.

III. GROUNDS FOR STANDING (37 C.F.R. §42.104(a))

As required by 37 C.F.R. §42.104(a), Petitioner certifies that the '216 patent is eligible for IPR and that Petitioner is not barred or estopped from requesting IPR on the Ground identified herein.

IV. IDENTIFICATION OF CHALLENGE AND STATEMENT OF THE PRECISE RELIEF REQUESTED (37 C.F.R. §42.104(b))

A. Effective Filing Date of the '216 Patent

For purposes of this Petition only, the effective filing date of the challenged claims is assumed to be the filing date of the earliest application to which the '216 patent claims priority, April 9, 2004. Sandoz reserves the right to challenge the effective filing date of the '216 patent in any other proceeding.

B. The Prior Art and Statutory Grounds of the Challenge (37 C.F.R. §42.104(b)(2))

Petitioner requests *inter partes* review and cancellation of claims 1-16 of the '216 patent on one Ground pursuant to 35 U.S.C. §103 as set forth herein. Petitioner's detailed statement of the reasons for the relief requested is set forth below in Section VI. In accordance with 37 C.F.R. §42.6(c), copies of the exhibits are filed herewith. In addition, the Petition is accompanied by the declaration of Simon Helfgott, M.D. (ex.1002) and John Posner, Ph.D. (ex.1050).

The Ground for invalidating the claims of the '216 patent includes the following publications that are pre-AIA §102(b) prior art based on the assumed April 9, 2004 priority date:

Table 1. Prior Art Publications Relied Upon by Petitioner

Reference	Publication Date	Type of Prior Art
Humira® 2003 Label (ex.1026)	January 2003	102(b)
Humira® 2002 Label (ex.1075)	December 2002	102(b)
AbbVie Press Release (ex.1052)	March 3, 2003	102(b)
Aulton (ex.1051)	2002	102(b)
Weinstein (ex.1003)	March 19, 2003	102(b)
Mease 2002 (ex.1009)	April 2002	102(b)

These prior art references and the knowledge of a POSA are supported and informed by the wider body of prior art concerning the treatment of PsO and related diseases. *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013) (explaining that *KSR* "required an analysis that reads the prior art in context, taking account of 'demands known to the design community,' 'the background knowledge possessed by a person having ordinary skill in the art,' and 'the inferences and creative steps that a person of ordinary skill in the art would

employ.'"). The Exhibit List indicates the prior art status of the publications discussed in Section VI, which illustrate this wider body of prior art.[11]

The challenged claims are unpatentable based upon the following Ground:

Table 2. Ground for Inter Partes Review

Claims	Priority Date	Statutory Basis and Prior Art
1-16	April 9, 2004	Obvious under 35 U.S.C. §103(a) over the Humira® 2003 Label or the Humira® 2002 Label (collectively "the Humira® 2003/2002 Label"), the AbbVie Press Release, Aulton and Weinstein, in view of Mease 2002.

Section VI and the Declarations of Simon Helfgott, M.D. (ex.1002) and John Posner, Ph. D. (ex.1050) further describe the grounds for the invalidation of the '216 patent. Ex.1002 at ¶¶107-116; Ex.1050 at ¶¶86-90.

[11] Although AbbVie disclosed to the Patent Office most of the above-listed references and the background prior art discussed herein, they were included along with several hundred other references. With the exception of Aulton, which was considered in an earlier application (SN 11/104,117) in the chain that lead to the '216 patent that claims a different dosing regimen for a different disease, there is no evidence the Examiner ever considered the specific portions of the prior art described in this Petition. *See* ex.1063; *see Microsoft Corp. v. Parallel Networks Licensing, LLC*, No. IPR2015-00486, Paper No. 10, Decision Institution of *Inter Partes* Review, at 14-15 (P.T.A.B. July 15, 2015) (rejecting the argument that the PTAB should not institute an IPR because the Petition relied on a reference that "was previously presented to the [PTO]"; explaining that the reference was "not applied against the claims and there is no evidence that the Examiner considered the particular disclosures cited by [the Petitioner] in the Petition."). Moreover, the Examiner did not have the benefit of the expert declarations submitted here by Sandoz which places the teachings of the prior art in context. Accordingly, the instant petition presents a Ground of invalidity that was not considered during the original prosecution.

Dr. Helfgott is an expert in the field of rheumatology. Ex.1002 at ¶¶3-15. He is an Associate Professor of Medicine in the Division of Rheumatology, Immunology and Allergy at Harvard Medical School. *Id.* at ¶3, Appx. A. He has been treating patients with psoriasis for over 20 years, using a variety of therapeutics, including monoclonal antibodies. *Id.* at ¶14.

Dr. Posner is an expert in the field of pharmacology. Ex.1050 at¶¶3-15. He has over 30 years of experience in clinical pharmacology. *Id.* He has considerable experience devising and executing plans for evaluating the human pharmacology of many novel compounds, including developing dosing regimens. *Id.* at ¶3.

Drs. Helfgott and Posner are qualified to provide opinions as to what a POSA would have understood, known, or concluded as of April 9, 2004 and are therefore competent to testify in this proceeding. Many of the prior art references cited herein are articles and abstracts that were published in medical journals. As Dr. Helfgott explains, over the course of his career he has subscribed to many such journals and/or has accessed them in libraries or from online databases. Ex.1002 at ¶15. In his experience, journal issues are available to the public (either through the mail to subscribers, including libraries, or online when published over the internet), as of approximately the date printed on the face of the reference, if not slightly earlier. *Id.* Accordingly, Dr. Helfgott states that references with a printed