

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

PFIZER INC.,
Patent Owner.

Inter Partes Review No.: IPR2021-01132

U.S. Patent No. 6,890,927 to Bogle *et al.*
Issued: May 10, 2005

Title: TARTRATE SALTS OF 5,8, 14-
TRIAZATERACYCLO[10.3.1.02,11.04.9]-
HEXADECA-2(11),3,5,7,9-PENTAENE AND
PHARMACEUTICAL COMPOSITIONS THEREOF

**EXPERT DECLARATION OF DR. PHILIP GOULD
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 6,890,927**

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LIST OF EXHIBITS AND ABBREVIATIONS

Exhibit	Abbreviation	Description
1001	'927 patent	U.S. Patent No. 6,890,927 B2
1003	Gould CV	Dr. Philip Gould <i>Curriculum Vitae</i>
1004	'927 patent PH	File History for U.S. Patent Application No. 10/139,730, issued as the '927 patent
1005	Coe	International Patent Application No. WO 1999/035131, to Coe <i>et al.</i>
1006	US '550	U.S. Patent No. 6,410,550
1007	US '550 PH	File History for U.S. Patent Application No. 09/402,010, issued as US '550
1008	CA '490	Canadian Patent Application No. 2,467,490
1009	Berge	Stephen M. Berge et al., <i>Pharmaceutical Salts</i> , 66 J. PHARM. SCIS. 1 (1977)
1010	Gould	Philip L. Gould, <i>Salt Selection for Basic Drugs</i> , 33 INT'L J. PHARM. 201 (1986)
1011	Wells	James I. Wells, <i>Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances</i> 21 (1988)
1012	Bighley	Lyle D. Bighley et al., <i>Salt Forms of Drugs and Absorption</i> , in 13 ENCYCLOPEDIA OF PHARMACEUTICAL TECHNOLOGY 453 (James Swarbrick & James C. Boylan eds., 1996)
1013	Paulekuhn	G. Steffen Paulekuhn et al., <i>Trends in Active Pharmaceutical Ingredient Salt Selection Based on Analysis of the Orange Book Database</i> , 50 J. MEDICINAL CHEMISTRY 6665 (2007)

1014	Morris	Kenneth R. Morris et al., <i>An Integrated Approach to the Selection of Optimal Salt Form for a New Drug Candidate</i> , 105 INT'L J. PHARM. 209 (1994)
1015	Bastin	Richard J. Bastin et al., <i>Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities</i> , 4 ORGANIC PROCESS RSCH. & DEV. 427 (2000)
1016	Nyqvist	International Patent Application No. WO 1998/054166, to Nyqvist <i>et al.</i>
1017	Jessen	International Patent Application No. WO 2000/055131, to Jessen <i>et al.</i>
1018	US '495	U.S. Patent No. 5,834,495
1019	US '376	U.S. Patent No. 5,073,376
1020	US '198	U.S. Patent No. 2,870,198
1021	US '388	U.S. Patent No. 6,794,388
1022	Stahl	HANDBOOK OF PHARMACEUTICAL SALTS 329 (P. Heinrich Stahl & Camille G. Wermuth eds., 1st ed. 2002)
1023	Pharmeuropa 2000	European Directorate for the Quality of Medicines and Healthcare, <i>Enquiry: Alkyl Mesilate (Methanesulphonate) Impurities in Mesilate Salts</i> , 12 PHARMEUROPA 27 (2000)
1024	Aakeroy	Christer B. Aakeroy & Peter B. Hitchcock; <i>Hydrogen-bonded Layers of Hydrogentartrate Anions: Two-dimensional Building Blocks for Crystal Engineering</i> , 3 J. MATERIAL CHEMISTRY 1129 (1993).

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