

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Taro Pharmaceuticals U.S.A., Inc.

Petitioner,

v.

Apotex Technologies, Inc.

Patent Owner

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Patent No. 7,049,328 B2

Title: USE FOR DEFERIPRONE

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*Inter Partes* Review No. IPR2017-01446

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PETITIONER'S UPDATED EXHIBIT LIST

**List of Exhibits for U.S. Patent No. 7,049,328 Petition for *Inter Partes* Review**

| <b>Exhibit No.</b> | <b>Description</b>  |
|--------------------|---|
| 1001               | U.S. Patent No. 7,049,328, Spino et al., <i>Use for Deferiprone</i> , Issued on May 23, 2006, ('328 Patent)   |
| 1002               | Declaration of Jayesh Mehta, M.D.   |
| 1003               | Curriculum Vitae of Jayesh Mehta, M.D.  |
| 1004               | Prosecution History of U.S. Patent No. 7,049,328  |
| 1005               | Olivieri et al., <i>Reduction of Tissue Iron Stores and Normalization of Serum Ferritin During Treatment with the Oral Iron Chelator L1 in Thalassemia Intermedia</i> , BLOOD, 79(10):2741–48, 1992 (“Olivieri 1992”)   |
| 1006               | Hoffbrand & Wonke, <i>Iron Chelation Therapy</i> , JOURNAL OF INTERNAL MEDICINE, 242 (Supplement 740): 37–41, 1997 (“Hoffbrand 1997”)   |
| 1007               | Hoffbrand et al., <i>Long-Term Trial of Deferiprone in 51 Transfusion-Dependent Iron Overloaded Patients</i> , BLOOD, 91(1):295–300, 1998 (“Hoffbrand 1998”)  |
| 1008               | U.S. Patent No. 5, 922,761, Lai, <i>Methods for In Vivo Reduction of Iron Levels and Compositions Useful Therefor</i> , Issued on July 13, 1999 (“Lai '761”)  |
| 1009               | Current Index of Medical Specialities, Vol. 21, No. 2, Apr-Jun 1998, CIMS 61 (“CIMS 1998”)  |
| 1010               | Olivieri et al., <i>First Prospective Randomized Trial of the Iron Chelators Deferiprone (L1) And Deferoxamine</i> , Abstract 983: Hemoglobinopathies and Thalassemias II, 249a, PROGRAM OF THE 37 <sup>TH</sup> ANNUAL MEETING OF THE AMERICAN SOCIETY OF HEMATOLOGY, December 1995 (“Olivieri Abstract 1995”) |

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| 1011 | Agarwal, <i>Deferiprone (Kelfer): A Report of 22 Patients Who Have Taken it For Over a Decade</i> , 10 <sup>TH</sup> INTERNATIONAL CONFERENCE ON ORAL CHELATORS IN THE TREATMENT OF THALASSEMIA AND OTHER DISEASES AND BIOMED MEETING, March 2000 (“Agarwal 2000”) |
| 1012 | Olivieri et al., <i>Iron-Chelation Therapy with Oral Deferiprone in Patients with Thalassemia Major</i> , N. ENGL. J. MED., 332:918–22, 1995 (“Olivieri 1995”)   |
| 1013 | Nathan, <i>Prospective on Thalassemia, Pediatrics</i> , 102(1):281–89, 1998 (“Nathan 1998”)  |
| 1014 | Olivieri et al., <i>Survival in Medically Treated Patients with Homozygous <math>\beta</math>-Thalassemia</i> , N. ENGL. J. MED., 331:547–78, 1994 (“Olivieri 1994”)   |
| 1015 | Nathan & Gunn, <i>Thalassemia: The Consequences of Unbalanced Hemoglobin Synthesis</i> , AMERICAN JOURNAL OF MEDICINE, 41:815–30, 1966 (“Nathan 1966”)   |
| 1016 | Bannerman et al., <i>Thalassemia Intermedia, with Iron Overload, Cardiac Failure, Diabetes Mellitus, Hypopituitarism and Porphyrinuria</i> , AMERICAN JOURNAL OF MEDICINE, 476–86, 1967 (“Bannerman 1967”)   |
| 1017 | Barman Balfour & Foster, <i>Deferiprone: A Review of its Clinical Potential in Iron Overload in <math>\beta</math>-Thalassemia Major and Other Transfusion-Dependent Diseases</i> , DRUGS 58(3):553–78, 1999 (“Barman Balfour 1999”)                               |
| 1018 | Barry et al., <i>Long-term Chelation Therapy in Thalassemia Major: Effect on Liver Iron Concentration, Liver Histology, and Clinical Progress</i> , BMJ, 2:16–20, 1974 (“Barry 1974”)  |
| 1019 | Kontoghiorghes, <i>Oral Iron Chelation is Here</i> , BMJ, 303:1279–80, 1991 (“Kontoghiorghes 1991”)  |
| 1020 | Nathan, <i>An Orally Active Iron Chelator</i> , N. ENGL. J. MED., 332(14):953–54, 1995 (“Nathan 1995”)   |

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| 1021 | GB 2 118 176, <i>Pharmaceutically Active 3-Hydroxypyrid-2-and-4-ones</i> , Published on October 1983 (“Hider Patent”)   |
| 1022 | Diav-Citrin & Koren, <i>Oral Iron Chelation with Deferiprone</i> , NEW FRONTIERS IN PEDIATRIC DRUG THERAPY, 44(1):235–47, 1997 (“Diav-Citrin 1997”)   |
| 1023 | Prescribing Information for Ferriprox® (deferiprone) tablets, for oral use (Revised 10/2011) (“Deferiprone Label 2011”)   |
| 1024 | Olson et al., <i>Endomyocardial Biopsy in Hemochromatosis: Clinicopathologic Correlates in Six Cases</i> , JACC, 13(1):116–20, 1989 (“Olson 1989”)  |
| 1025 | Kontoghiorghes et al., <i>L1-Deferiprone Worldwide Update and New Strategies for Improving its Therapeutic Efficiency</i> , 10 <sup>TH</sup> INTERNATIONAL CONFERENCE ON ORAL CHELATORS IN THE TREATMENT OF THALASSEMIA AND OTHER DISEASES AND BIOMED MEETING, March 2000 (“Kontoghiorghes 2000”) |
| 1026 | Faa & Crisponi, <i>Iron Chelating Agents in Clinical Practice</i> , COORDINATION CHEMISTRY REVIEWS, 184:291–310, 1999 (“Faa 1999”)  |
| 1027 | Borgna-Pignatti, <i>Survival and Disease Complications in Thalassaemia Major</i> , ANNALS NEW YORK ACADEMY OF SCIENCES, 227–31, 1998 (“Borgna-Pignatti 1998”)   |
| 1028 | McDonald, <i>Deferoxamine and Diethylenetriaminepentaacetic Acid (DTPA) in Thalassaemia</i> , THE JOURNAL OF PEDIATRICS 69(4):563–71, 1966 (“McDonald 1966”)  |
| 1029 | Cerami, “ <i>Propper</i> ” <i>Use of Desferrioxamine</i> , N. ENGL. J. MED, 294(26): 1456-57, 1976 (“Cerami 1976”)  |
| 1030 | European Patent Register Opposition to EP1294379, A New Use for Deferiprone, Application published on January 10, 2002  |
| 1031 | Morrison, <i>Diagnosis and Management of Hereditary Hemochromatosis</i> , JOURNAL OF CLIN. OUTCOMES MANAGEMENT, Vol 6, No. 5, (1999). (“Morrison”)  |

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| 1032 | Kratz, <i>Normal Reference Laboratory Values</i> , NEW ENGLAND JOURNAL OF MEDICINE, Vol. 339, No. 15 (1998) (“Kratz”). |
| 1033 | Mehta et al., <i>Deaths in Patients Receiving Oral Iron Chelator LI</i> , BR. J. HAEMATOL., 85:430–31, 1993            |
| 1034 | Mehta et al., <i>Deferiprone in Iron Overload</i> , N. ENGL. J. MED., 333:597–99, 1995                                 |
| 1035 | Mehta et al., <i>Oral Iron Chelator LI and Autoimmunity</i> , BLOOD, 81:1970–71, 1993                                  |
| 1036 | March 23, 2018 Telephonic Hearing Transcript<br>PROTECTIVE ORDER MATERIAL  |
| 1037 | October 8, 2009 Letter from ApoPharma to FDA<br>PROTECTIVE ORDER MATERIAL  |
| 1038 | October 7, 1999 Email from M. Spino to F. Tricta with attachments<br>PROTECTIVE ORDER MATERIAL                         |
| 1039 | October 8, 1999 Email from F. Tricta to M. Spino with attachment<br>PROTECTIVE ORDER MATERIAL                          |
| 1040 | April 3, 2000 Email from M. Spino to J. Furedy, copying F. Tricta with attachment<br>PROTECTIVE ORDER MATERIAL         |
| 1041 | January 1, 2000 Email from M. Spino to S. Mandell with attachments<br>PROTECTIVE ORDER MATERIAL                        |
| 1042 | November 8, 2017 Deposition Transcript of Michael Spino<br>PROTECTIVE ORDER MATERIAL                                   |
| 1043 | November 7, 2017 Deposition Transcript of Fernando Tricta, M.D.<br>PROTECTIVE ORDER MATERIAL                           |
| 1044 | Opening Expert Report of Thomas D. Coates, M.D.<br>PROTECTIVE ORDER MATERIAL   |
| 1045 | Opening Expert Report of Dudley J. Pennell, M.D.<br>PROTECTIVE ORDER MATERIAL  |
| 1046 | Intentionally Left Blank   |
| 1047 | MODULE 2, SECTION 2.7.3, SUMMARY OF CLINICAL EFFICACY FOR FERRIPROX® (deferiprone)<br>PROTECTIVE ORDER MATERIAL        |
| 1048 | MODULE 2, SECTION 2.7.5, LITERATURE REFERENCES FOR FERRIPROX® (deferiprone)<br>PROTECTIVE ORDER MATERIAL               |

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