

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CATALENT PHARMA SOLUTIONS, INC.,
Petitioner

v.

PATHEON SOFTGELS INC.,
Patent Owner

Case IPR2018-00421
U.S. Pat. No. 9,693,978

PATHEON SOFTGELS INC.'S EXHIBIT LIST

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P.O. Box 1450
Alexandria, VA 22313-1450

IPR2018-00421

Patent 9,693,978 B2

| <i>Patheon Exhibit #</i> | <i>Description</i> |
|-------------------------------------|--|
| 2001 | Declaration of Mansoor Khan, R.Ph., Ph.D. |
| 2002 | <i>Curriculum Vitae</i> for Mansoor Khan, R.Ph., Ph.D. |
| 2003 | Serajuddin, A., "Solid Dispersion of Poorly Water-Soluble Drugs: Early Promises, Subsequent Problems, and Recent Breakthroughs," <i>J. Pharm. Sci.</i> , 88:1058–1066 (1999) |
| 2004 | Patravale, V.B. <i>et al.</i> , "Nanosuspensions: a promising drug delivery strategy," <i>J. Pharm. & Pharmacol.</i> , 56:827–840 (2004) |
| 2005 | WO 95/31979 to Shelley <i>et al.</i> , "Solutions of Aryl or Heteroaryl Substituted Alkanoic Acids in Lipophilic Solvents and Soft Gelatin Capsules Containing Such Solutions" (Nov. 30, 1995) |
| 2006 | Ranucci <i>et al.</i> , "Pharmacokinetic results on naproxen prodrugs based on poly(ethyleneglycol)s," <i>J. Biomater. Sci. Polymer Edn.</i> , 6:141–147 (1994) |
| 2007 | WO 95/31194 to Shapiro, H., "Compositions for Treatment of Chronic Inflammatory Diseases" (Nov. 23, 1995) |
| 2008 | Shah <i>et al.</i> , "In Vitro Dissolution Profile of Water-Insoluble Drug Dosage Forms in the Presence of Surfactants," <i>Pharm Res.</i> 6:612-618 (1989) |
| 2009 | Crowley and Martini, "Physicochemical Approaches to Enhancing Oral Absorption," <i>Pharm. Tech. Eur.</i> , 16:18-27 (2004) |
| 2010 | Serajuddin <i>et al.</i> , "Water Migration from Soft Gelatin Capsule Shell to Fill Material and Its Effect on Drug Solubility," <i>J. Pharm. Sci.</i> , 75:62-64 (1986) |
| 2011 | Merisko-Liversidge <i>et al.</i> , "Nanosizing: a formulation approach for poorly-water-soluble compounds," <i>Eur. J. Pharm. Sci.</i> , 18:113-120 (2003) |
| 2012 | Naprosyn [®] , Physician's Desk Reference, 48 th ed., 2363–2365 (1994) |
| 2013 | Anaprox [®] , Physician's Desk Reference, 48 th ed., 2350–2352 (1994) |
| 2014 | Aleve [®] , Physician's Desk Reference, 49 th ed., 1910 (1995) |
| 2015 | Naprelan [®] , Physician's Desk Reference, 53 rd ed., 3335–3337 (1999) |

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|---------------------------------|---|
| 2016 | FDA Approved Products: Naprosyn®, available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=017581 , last accessed May 19, 2018 |
| 2017 | FDA Approved Products: Anaprox®, available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=018164 , last accessed May 19, 2018 |
| 2018 | FDA Approved Products: Naprelan®, available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020353 , last accessed May 19, 2018 |
| 2019 | FDA Approved Products: Aleve®, available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020204 , last accessed May 19, 2018 |
| 2020 | FDA Approved Products: Naproxen Sodium Soft Gelatin Capsules, available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021920 , last accessed May 19, 2018 |
| 2021 | Tabibi and Gupta, “Soft Gelatin Capsules Development,” in <i>Water Insoluble Drug Formulation</i> , Chapter 17, pp. 609–633, Interpharm Press (2000) |
| 2022 | Seager and Slabaugh, “Acids, Bases, and Salts,” in <i>Introductory Chemistry</i> , Chapter 9, Scott, Foresman and Co. (1979) |
| 2023 | Gennadios, “Soft Gelatin Capsules,” in <i>Protein-Based Films and Coatings</i> , Chapter 16, pp. 393 – 443, CRC Press LTD (2002) |
| 2024 | Recorded Assignments for U.S. Patent No. 9,693,978 and 9,693,979, Reel 043042, Frame 0619 to 0652 (recorded June 29, 2017) |
| 2025 | International Conference on Harmonisation, “Topic Q3B: ICH Harmonised Tripartite Guideline for Impurities in New Medicinal Products,” (November 6, 1996) |
| 2026 | The Merck Index, Merck & Co., Inc., 12 th Ed. (1996), pp. xii-xvii, 392-393, 641-642, 763-764, 911, 1101, 1305, 1320, and 1349 |

IPR2018-00421
Patent 9,693,978 B2

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|--------------------------|--|
| 2027 | Chang, R., "Chemistry," 6 th ed., Ch. 15, pp. 597–641, McGraw-Hill (1998) |

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

The undersigned hereby certifies that the above-captioned Patheon Softgels Inc.'s Exhibit List, along with Exhibits 2001-2027, were served in their entirety on May 22, 2018, upon the following parties via email:

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