# CARLSON, GASKEY & OLDS

A PROFESSIONAL CORPORATION

David L. Atallah Todd W. Barrett Timothy C. Bradley Stephen A. Burch Karin H. Butchko John E. Carlson Anthony P. Cho Benjamin J. Coon Jessica Fleetham David J. Gaskey William S. Gottschalk 400 WEST MAPLE ROAD SUITE 350 BIRMINGHAM, MI 48009 Telephone 248.988.8360 Facsimile 248.988.8363 Quincy J. Harrison Matthew L. Koziarz Kerrie A. Laba Timothy J. Murphy Theodore W. Olds, III Laura E. Parker Stephen A. Sequin John M. Siragusa Steven Susser Alex Szypa Brian S. Tobin

**February 3, 2022** 

Direct Dial: (248) 283-0687 Email: acho@cgolaw.com

Peter R. Marksteiner Clerk of Court U.S. Court of Appeals for the Federal Circuit 717 Madison Place, N.W., Suite 401 Washington, D.C. 20439 (202) 275-8000

#### BY ECF

Re: Arthrex, Inc. v. Smith & Nephew, Inc., No. 2018-2140

Dear Mr. Marksteiner:

Appellant Arthrex, Inc., respectfully submits this letter pursuant to Federal Rule of Appellate Procedure 28(j) to identify a pertinent and significant authority that came to Arthrex's attention after the filing of its supplemental brief on January 11, 2022.

Arthrex's brief refers to the Patent and Trademark Office's Agency Organization Order 45-1, by which the PTO delegated the Director's authority to the Commissioner for Patents. Arthrex's brief cites (at page 8) and attaches (as Exhibit C) a version of the order dated June 24, 2002, which was formerly available on the PTO's website. On February 2, 2022, however, the PTO filed in another case a more recent version of the order dated November 7, 2016, which to our knowledge was not publicly available until the PTO furnished a copy to a third party in response to a FOIA request late last year. *See* U.S. Inventor, *PTAB FOIA & Procedures*, https://usinventor.org/ptab-foia-documents. The 2016 version of the order states that it supersedes the 2002 version.

The relevant language in Section II.D of the orders is identical, except that the 2002 version states that, "[i]f both the Under Secretary and the Deputy Under Secretary positions are vacant, the Commissioner for Patents and the Commissioner for Trademarks, in that order, will perform the functions and duties of the Under Secretary," whereas the 2016 version states that, "[i]f both the Under Secretary and the Deputy Under Secretary positions are vacant, the Commissioner for Patents and the Commissioner for Trademarks, in that order, will perform the *non-exclusive* functions and duties of the Under Secretary." (Emphasis added.)

Arthrex submits that the change in wording has no impact on its arguments. The relevant point remains that the Director's unilateral power to review Board decisions is a non-delegable function for purposes of the Federal Vacancies Reform Act. *See* Arthrex Supp. Br. 20-23. Nonetheless, Arthrex is submitting the current version of the order as an exhibit to this letter so the Court has that version before it.

Case: 18-2140 Document: 161-1 Page: 2 Filed: 02/03/2022

February 3, 2022 Page 2

Respectfully submitted,

**CARLSON, GASKEY & OLDS** 

Anthony P. Cho

cc: Counsel of Record (via ECF) encl.: Exhibit 1

# **CERTIFICATE OF SERVICE**

I hereby certify that on February 3, 2022, I electronically filed the foregoing document using the Court's CM/ECF system, which sent notification of such filing to all counsel of record as follows:

Charles T. Steenburg
Michael N. Rader
Nathan R. Speed
Richard F. Giunta
Turhan F. Sarwar
Wolf Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210

Mark A. Perry Gibson, Dunn & Crutcher LLC 1050 Connecticut Avenue, NW Washington, DC 20036

Mark J. Gorman Smith & Nephew, Inc. 7135 Goodlett Farms Parkway Cordova, TN 38013

Joshua M. Salzman
Katherine Twomey Allen
Scott R. McIntosh
Courtney Dixon
Joseph H. Hunt
Department of Justice, Civil Division

Thomas W. Krause, Solicitor
Farheena Y. Rasheed, Deputy Solicitor
Sarah E. Craven, Associate Solicitor
Molly R. Silfen, Associate Solicitor
Daniel Kazhdan
United States Patent and Trademark Office

Charles R. Macedo David P. Goldberg Amster Rothstein & Ebenstein LLP 90 Park Avenue New York, NY 10016

Robert Joseph Rando, Esq. The Rando Law Firm P.C. 6800 Jericho Turnpike, Suite 120W Syosset, NY 11791

Ksenia Takhistova Hunton Andrews Kurth LLP 200 Park Avenue New York, NY 10166

Matthew S. Hellman Yusuf Esat Jenner & Block LLP 353 North Clark Street Chicago, IL 60654

Jeffrey Francer The Association for Accessible Medicines Suite 850 601 New Jersey Avenue, NW Washington, DC 20001

Dated: February 3, 2022 /s/ Jessica Fleetham

Jessica Fleetham

# **EXHIBIT 1**

Case: 18-2140 Document: 161-2 Page: 2 Filed: 02/03/2022

AOO 45-1

### UNITED STATES PATENT AND TRADEMARK OFFICE

# **AGENCY ORGANIZATION ORDER 45-1 Agency Organization Order Series**

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

Date of Issuance: 11/07/2016 **Effective Date: 11/07/2016** 

### TABLE OF CONTENTS

# Section

I., Purpose Appointment and General Authority of Under Secretary and Commissioners П. Specific Authorities III, IV. **Functions** 

Effect on Other Orders V.

AOO 45-1

# UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

### I. <u>PURPOSE</u>

This Agency Organization Order (AOO) sets forth the authority and functions of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (Under Secretary), and provides for the organizational structure of the United States Patent and Trademark Office (USPTO).

# II. <u>APPOINTMENT AND GENERAL AUTHORITY OF UNDER SECRETARY AND COMMISSIONERS</u>

A. On November 29, 1999, the President signed into law the Patent and Trademark Office Efficiency Act (PTOEA), which establishes the USPTO as an agency of the United States, within the Department of Commerce (DOC).

### **Under Secretary and Deputy Under Secretary**

- B. The Under Secretary is appointed by the President, by and with the advice and consent of the Senate, and reports to the Secretary of Commerce (Secretary) with respect to policy matters. The Under Secretary, as established by 35 U.S.C. § 3, is responsible for providing policy direction and management supervision for the USPTO and the issuance of patents and registration of trademarks, and for consulting with the Patent Public Advisory Committee and the Trademark Public Advisory Committee.
- C. The Under Secretary will be assisted by the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office (Deputy Under Secretary) who will act in the capacity of the Under Secretary in the event of the absence or incapacity of the Under Secretary. The Deputy Under Secretary is appointed by the Secretary upon consideration of individuals nominated by the Under Secretary.
- D. The Deputy Under Secretary shall serve as Acting Under Secretary during any period in which the Under Secretary has died, resigned, or otherwise become unable to perform the functions and duties of the office, subject to the limitations set forth in the Federal Vacancies Reform Act of 1998, as amended, 5 U.S.C. § 3345 et seq. The Deputy Under Secretary shall perform the non-exclusive functions and duties of the Under Secretary when the Under Secretary dies, resigns, or is otherwise unable to perform the functions and duties of the Under Secretary, and when there is no Acting Under Secretary. If both the Under Secretary and the Deputy Under Secretary positions are vacant, the Commissioner for Patents and the Commissioner for Trademarks, in that order, will perform the non-exclusive functions and duties of the Under Secretary. In the event there is no Commissioner appointed under 35 U.S.C. § 3(b)(2), the Chief Policy Officer and

AOO 45-1

Director for International Affairs, the Chief Financial Officer, the Chief Administrative Officer, or the General Counsel of the USPTO, in order of length of service in those positions, shall perform the non-exclusive functions and duties of the Under Secretary.

- E. In the event of the absence or incapacity of the Under Secretary and Deputy Under Secretary, the following officials may be designated by the Under Secretary or Deputy Under Secretary, as appropriate, to perform the non-exclusive functions and duties of the Under Secretary: the Commissioner for Patents, the Commissioner for Trademarks, the Chief Policy Officer and Director for International Affairs, the Chief Financial Officer, the Chief Administrative Officer, or the General Counsel for USPTO.
- F. A Commissioner performing the functions and duties of the Under Secretary will not assist the Secretary in evaluating the performance of the Commissioners.

#### **Commissioners**

- G. The Secretary will appoint a Commissioner for Patents and a Commissioner for Trademarks, each of whom will serve for a five-year term. The Secretary may reappoint a Commissioner to subsequent five-year terms in accordance with PTOEA.
- H. The Under Secretary will appoint such other officers, employees and agents of the Office as deemed necessary to carry out the functions of USPTO, consistent with Tile 35, U.S.C.
- In accordance with PTOEA and Title 35, U.S.C., in carrying out its functions, USPTO will be subject to the policy direction of the Secretary, but otherwise will retain responsibility for decisions regarding the management and administration of its operations and will exercise independent control of its budget allocations and expenditures, personnel decisions and processes, procurements, and other administrative and management functions, in accordance with applicable provisions of the law.

### **Public Advisory Committees**

- J. USPTO will have a Patent Public Advisory Committee and a Trademark Public Advisory Committee. The Secretary will appoint nine members to each committee who will serve at the pleasure of the Secretary. The Secretary will designate a chair of each Advisory Committee, each of whom will serve for a three-year term. In addition to the voting members, each Advisory Committee will include a representative of each labor organization recognized by USPTO.
- K. The Under Secretary will consult with the Patent Public Advisory Committee on a regular basis on matters relating to the patent operations of USPTO, will consult with the Trademark Public Advisory Committee on a regular basis on matters relating to the trademark operations of USPTO, and will consult with the respective Public Advisory Committee before submitting budgetary proposals to the Office of Management and Budget (OMB) or changing or proposing to change patent or trademark user fees or

AOO 45-1

patent or trademark regulations that are subject to the requirement to provide notice and opportunity for public comment under Title 5, U.S.C. § 553, as the case may be.

### Administrative Patent Judges and Administrative Trademark Judges

- L. The Patent Trial and Appeal Board shall include the Under Secretary, the Deputy Under Secretary, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative patent judges.
- M. The Trademark Trial and Appeal Board shall include the Under Secretary, the Deputy Under Secretary, the Commissioner for Patents, the Commissioner for Trademarks, and the administrative trademark judges.
- N. Administrative patent judges and administrative trademark judges are appointed by the Secretary, in consultation with the Under Secretary.

### III. SPECIFIC AUTHORITIES

- A. Pursuant to the authority vested in the Secretary and the Under Secretary by law, and in recognition of USPTO's responsibility for decisions regarding management and administration of its operations and its independent control of its budget allocations and expenditures, personnel decisions and processes, procurements, and other administrative and management functions in accordance with the PTOEA and applicable provisions of law, the Under Secretary will exercise the responsibilities relating to USPTO operations and functions including:
  - 1. The functions prescribed by 17 U.S.C. § 914 regarding the privilege of foreign national, domiciliaries, and sovereign authorities to make interim registrations for mask works pursuant to Chapter 9 of Title 17 and by Executive Order (E.O.) 12504 regarding regulations for the presentation to the President of requests for issuance of proclamations described in such Chapter;
  - 2. The functions, other than the appointment of Commissioners, prescribed for the Secretary by 35 U.S.C. § 3(b)(2), including recommendation of Commissioners for the Secretary to appoint, formulation of the annual performance plans for the Commissioners, supervision of the Commissioners, and evaluation of the Commissioners with prompt notice to the Secretary of the evaluations;
  - 3. The functions, other than appointment of members and designation of chairs, prescribed for the Secretary by 35 U.S.C. § 5, including recommendation of public advisory committee members for the Secretary to appoint, recommendation of public advisory committee chairs for the Secretary to designate, and provision of such support to the public advisory committees as required by statute or otherwise as the Under Secretary deems appropriate;

AOO 45-1

4. The functions prescribed for the Secretary by Chapter 17 of Title 35, U.S.C., except for the appellate function under 35 U.S.C. § 181 (see DOO 10-6, "Office of the General Counsel," § 4.01i);

- 5. Except as otherwise specified herein, the Under Secretary will exercise the following administrative and management responsibilities:
  - a. Performing the responsibilities of agency head pertaining to USPTO, including the following examples:
    - i. 31 U.S.C. § 3325(a) regarding the certification of vouchers for disbursement of government funds;
    - ii. Any procurement-related authority;
    - iii. Title 5, U.S.C. (Government Organization and Employees);
    - iv. Title 40, U.S.C. (Public Buildings, Property, and Works);
    - v. Title 41, U.S.C. (Public Contracts); and
    - vi. Title 44, U.S.C. (Public Printing and Documents);
  - b. Carrying out responsibilities under Title VII of the Civil Rights Act of 1964, the Equal Employment Opportunity Act of 1972 and all applicable statutes, E.O.s, and regulatory provisions;
  - c. Carrying out responsibilities under:
    - i. The Federal Advisory Committee Act (5 U.S.C. Appendix 2);
    - ii. The Privacy Act (5 U.S.C. § 552a) and implementing directives of the General Services Administration and OMB;
    - iii. The Budget and Accounting Procedures Act of 1950 (P.L. 81-784), subject to III.A.6, below;
    - iv. The Chief Financial Officers Act of 1990 (P.L. 101-576);
    - v. The Government Management Reform Act of 1994 (P.L. 103-356);
    - vi. The Government Performance and Results Act of 1993 (P.L. 103-62);
    - vii. The Federal Records Act (P.L. 81-754);

AOO 45-1

- viii. The Government Paperwork Elimination Act (P.L. 105-277, Title XVII);
- ix. The Paperwork Reduction Act of 1995 (P.L. 104-13);
- x. OMB Circular A-130, "Management of Federal Information Resources;" and Sections 5 and 6 of the Computer Security Act of 1987 (P.L. 100-235) regarding Federal computer systems security training, identification of systems containing sensitive information, and a plan for computer system security and privacy;
- xi. The Freedom of Information Act (5 U.S.C. § 552);
- xii. 30 U.S.C. §§ 351-359 and 40 U.S.C. §§ 1314, regarding granting easements and other rights of access to real property, or consenting to the lease of mineral rights;
- xiii. The Competition in Contracting Act (P.L. 98-369, Title VII);
- xiv. E.O. 12088 regarding compliance with pollution control standards at USPTO facilities;
- xv. The Inspector General Act of 1978 (5 U.S.C. Appendix 3);
- d. Exercising responsibilities regarding finance, accounting, fiscal management, budgeting, and planning, subject to section III.A.6, below;
- e. Procuring real or personal property or goods and services of any kind by USPTO under any Federal law, regulation, directive or order;
- f. Performing the responsibilities for managing any real property USPTO may acquire, lease, purchase, or acquire responsibility in, including environmental compliance reports;
- g. Developing and issuing agency administrative orders, policies, standards and procedures for administrative functions in USPTO;
- h. Providing publications and printing (e.g. micropublishing, design, graphics, editorial, promotional, distribution, and publishing control), library, mail, messenger, and distribution services for USPTO;
- i. Managing USPTO computer services and electronic mail systems and coordinating with DOC to ensure interoperability;

AOO 45-1

 Monitoring, overseeing, reviewing, managing, maintaining, procuring, or evaluating of USPTO Information Technology (IT) programs, performance, risks, acquisitions, initiatives, resources, personnel, training, or management;

- k. Setting goals for improving the efficiency or effectiveness of USPTO IT operations;
- Approving strategic and operational information technology plans and developing information technology policies and procedures, including security;
- m. Managing and maintaining USPTO IT systems for administrative and program management including property and procurement management systems;
- n. Protecting USPTO's assets, operations and personnel;
- o. Managing USPTO's programs for safeguarding national security information (E.O. 12958), personnel security (E.O.s 10450 and 12968), national industrial security (E.O.s 10865 and 12829), physical facility security, and other programs for protecting USPTO's assets, operations, and personnel;
- p. Carrying out responsibilities regarding special studies, reports, technical information, and other related functions under 15 U.S.C. §§ 1525-1527 (P.L. 91-412);
- q. Ensuring USPTO compliance with:
  - The provisions of the Federal Managers Financial Integrity Act of 1982 (P.L. 97-255) and acting as the designated senior official for the implementation of OMB Circular A-123, "Management's Responsibility for Enterprise Risk Management and Internal Control," and OMB Circular A-127, "Financial Management Systems;"
  - ii. The Drug-Free Workplace Act (P.L. 111-350, Chapter 81) and the procurement integrity provisions of the Office of Federal Procurement Policy Act Amendments of 1988 (P.L. 100-679);
- r. Establishing policies and procedures for the development and operation of financial management, financial information, and internal control systems;
- s. Providing direction, formulation, analysis, coordination, and

AOO 45-1

implementation of USPTO's financial management policies and procedures;

- t. Developing and issuing policies, standards, measures, and procedures for the issuance of patents and the registration of trademarks, and provide functional appraisal and supervision in the conduct of its functions;
- u. Developing and administering the personnel management policies and programs of USPTO, including the direction, administration, and processing of all matters involving personnel, payroll, and occupational safety and health;
- v. Executing all functions relating to all elements of all USPTO officers' and employees' annual performance plans, rewards and promotions, except for the plans, bonuses, and agreements of the Under Secretary, the Deputy Under Secretary, the Commissioner for Patents, and the Commissioner for Trademarks;
- w. Developing, implementing, and improving management structures, systems, tools, and practices to achieve the highest degree of management efficiency, operational effectiveness, and economy, and to limit the opportunity for fraud and mismanagement;
- x. Coordinating preparation of national emergency plans and the development of preparedness programs required by E.O. 12656 and Federal Preparedness Circular No. 10; and serving as the USPTO's Emergency Coordinator, as required by E.O. 12656;
- The Under Secretary shall have the authority to provide appropriate 6. communication and coordination, when appropriate, with all other agencies and offices of the Federal Government directly on applicable USPTO matters, including as examples, OMB, subject to the provisions in section III.D of this AOO and the proviso in this paragraph, the Department of the Treasury, the Office of Personnel Management, the Government Accountability Office, the General Services Administration, and other Executive Branch or independent agencies; the House Government Operations Committee, the Budget Committees, Appropriations Committees, and Judiciary Committees of the Congress, the Joint Committee on Printing, the Government Printing Office, and other Legislative Branch committees, offices, and agencies. The Under Secretary shall transmit the USPTO budget directly to OMB, provided, however, that the Under Secretary shall first timely provide the Secretary in advance with the proposed USPTO budget in order to receive the Secretary's policy review and direction before USPTO transmits the budget to OMB; and
- 7. Such functions under other authorities as are applicable to administration and

AOO 45-1

### management of the USPTO.

- B. Exercise of the authorities described in paragraph A of this section shall be subject to the policy direction, and such functions, powers, duties and responsibilities as are retained by the Secretary, as are set forth in paragraph D, below.
- C. The Under Secretary may, except as precluded by law or regulation, redelegate the authorities in this section to officers and employees of USPTO, subject to such conditions in the exercise of the delegated authorities as the Secretary or Under Secretary may prescribe.
- D. Functions, powers, duties, and responsibilities retained by the Secretary, as policy direction or incidental thereto, include:
  - 1. Policy direction as provided in 35 USC § 1;
  - 2. The power to accept gifts and bequests on behalf of the USPTO valued at greater than \$35,000;
  - 3. USPTO shall remain subject to the oversight responsibilities of the Inspector General;
  - 4. Legal services related to the following:
    - a. Legislation and matters related thereto, as provided in Departmental Organizational Order 10-6;
    - b. Review of regulations subject to the following procedures:
      - i. USPTO shall notify the DOC Office of the General Counsel of all planned rulemaking activity in a timely manner,
      - ii. The DOC Office of the General Counsel may review any rulemaking that it, the USPTO, or OMB determines to be significant or to implicate policy matters, and
      - iii. The USPTO may otherwise promulgate rules relating to agency management or personnel, agency organization, agency procedures or practices, or public property, benefits, or contracts without further review;
    - c. Authorities of the Secretary provided in Chapter 40 of title 15, U.S.C., except with regard to:
      - i. The use of undesignated general gift funds;

AOO 45-1

ii. The conduct of studies, reports, technical information, and other related functions under 15 U.S.C. § 1525 (first paragraph) et seq.; and

- iii. Review of joint projects under the 15 U.S.C. § 1525 (second paragraph) et seq.;
- d. Appellate liaison with the Civil Appellate Section of the United States
  Department of Justice regarding all appeals of court litigation including
  litigation for which USPTO otherwise is responsible;
- e. All functions of the DOC's Designated Agency Ethics Official (DAEO) and agency-head review of all ethics-related collective bargaining agreements or portions thereof, and any ensuing litigation due to the agency-head review, except as USPTO is authorized by statute or other authority to have its own DAEO;
- f. DOC-wide and other litigation which may affect USPTO as an operating unit of DOC as well as other operating units of DOC;
- g. Gifts, other than the use of undesignated gift funds;
- h. Review of Department Organization Orders and Department Administrative Orders;
- i. Restrictions on expenditures intended or designed to influence Congress on legislation;
- j. Qui tam actions;
- k. Advice on grand jury and Congressional investigations.

# E. Payment for Services

- 1. USPTO shall make reimbursements for services provided by DOC into the Working Capital Fund, the Advances and Reimbursements Fund, or other Departmental funds as may be necessary to support the Secretary's policy direction of USPTO and other functions, powers, duties, and responsibilities retained by the Secretary.
- 2. Except as provided in section III.E.1, USPTO shall receive services from DOC on the basis of mutual agreements entered into under authority of 35 U.S.C. § 2(b)(5), and shall reimburse DOC for services received according to the terms of such agreements.

AOO 45-1

3. USPTO may enter into agreements under authority of 35 U.S.C. § 2(b)(5) to use services, equipment, personnel, and facilities of other departments, agencies, and instrumentalities of the Federal Government, on a reimbursable basis.

### IV. <u>FUNCTIONS</u>

The Under Secretary performs the following functions:

- Administers the laws relating to the granting and issuing of patents;
- Administers the laws relating to the registration of trademarks;
- Administers the laws relating to the dissemination to the public of information with respect to patents and trademarks;
- Advises the Secretary on intellectual property policy. Subject to the policy direction of
  the Secretary, also advises Federal departments and agencies on matters of intellectual
  property policy in the United States and intellectual property protection in other countries.
  Advises the President, through the Secretary, on national and certain international
  intellectual property policy issues.
- Conducts programs, studies, and exchanges of items and services regarding intellectual property;
- Conducts cooperative programs with nongovernmental organizations, foreign intellectual property offices and international intergovernmental organizations;
- Serves as focal point within DOC and is prepared, when requested by appropriate
  authority and subject to the policy direction of the Secretary, to serve as spokesperson for
  the Executive Branch on the broad range of domestic and international intellectual
  property issues confronting the Nation; and
- Performs other functions required or deemed necessary and proper by the Under Secretary in exercising the authority described herein.

## V. <u>EFFECT ON OTHER ORDERS</u>

This AOO supersedes AOO 45-1, dated June 24, 2002, and replaces its content in its entirety.

Michelle To Lee

11/7/2016 Date

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office