from SAB 2022 Work Plan Topics; (8) Environmental Information Services Working Group Report Review of the NOAA Subseasonal to Seasonal (S2S) Report to Congress; (9) NOAA Response to SAB Climate Working Group Review of the Coastal Inundation at Climate Timescales White Paper. Meeting materials, including work products, will be made available on the SAB website: *https://sab.noaa.gov/index.php/current-meetings/.*

Dave Holst,

Chief Financial Officer/Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2022–16269 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC213]

Marine Mammals; File No. 26170

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Keith Ellenbogen, Blue Reef, 189 Schermerhorn Street, 8E; Brooklyn, NY 11201, in due form for a permit to conduct commercial and educational photography on marine mammals.

DATES: Written, telefaxed, or email comments must be received on or before August 29, 2022.

ADDRESSES: These documents are available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 26170 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Courtney Smith, Ph.D., or Amy Hapeman, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to observe, film, and photograph cetaceans and seals within the U.S. northeast Atlantic waters of the U.S., from the Gulf of Maine (including Cape Cod Bay and Stellwagen Bank National Marine Sanctuary) through the New York Bight (Montauk, NY to Cape May, NJ), including the Hudson Canyon. Up to 405 humpback (*Megaptera novaeangliae;* West Indies Distinct Population Segment) and long-finned pilot (*Globicephala melaena*) whales; harbor porpoise (*Phocoena phocoena*); and Atlantic white-sided (*Lagenorhyncus acutus*), bottlenose (*Tursiops truncatus*), long-beaked common (*Delphinus capensis*), Risso's (*Grampus griseus*), short-beaked common (*Delphinus delphis*), and striped (*Stenella coeruleoalba*) dolphins; and up to 675 harbor (*Phoca vitulina*) and gray (*Halichoerus grypus*) seals may be harassed annually from close approaches by marine vessels, experienced swimmers/divers, and during ground surveys for photography and filming purposes. The permit is requested for five years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: July 26, 2022.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–16277 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2021–0058]

Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice.

SUMMARY: The duty of candor and good faith in dealing with the United States Patent and Trademark Office (USPTO) includes the duty to disclose to the USPTO information material to the patentability of a claimed invention. Each party submitting a paper to the USPTO has an additional duty to perform an inquiry that is reasonable under the circumstances, including reviewing documents to identify information that is material to the patentability of a claimed invention. The USPTO relies on each individual who is subject to these duties to abide by them. The duties are imposed to assist patent examiners and administrative patent judges in evaluating patentability effectively and efficiently. The duties promote robust and reliable patents, and drive competition and economic growth. In the pharmaceutical space, the duties promote robust and reliable patents that incentivize and protect innovation that brings life-saving drugs to the American people while not unnecessarily delaying more affordable generic drugs. This notice is intended to clarify the duties, including as to materials or statements material to patentability or statements made to the USPTO that are inconsistent with statements submitted to the FDA and other governmental agencies.

FOR FURTHER INFORMATION CONTACT: Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at 571–272–0909.

SUPPLEMENTARY INFORMATION:

I. *Background:* On July 9, 2021, President Biden issued an *Executive Order on Promoting Competition in the American Economy,* 86 FR 36987 (2021). President Biden expressed concern that ''too often, patent and other laws have been misused to inhibit or delay—for years and even decades—competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs.'' The President called for action ''to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law.''

On September 9, 2021, Senator Patrick Leahy and Senator Thom Tillis sent a letter to Mr. Andrew Hirshfeld, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, requesting that the Office ''take steps to reduce patent applicants'

making inappropriate conflicting statements in submissions to the [USPTO] and other federal agencies.'' The letter provided a specific example in which ''inconsistent statements submitted to the Food and Drug Administration (FDA) to secure approval of a product—asserting that the product is the same as a prior product that is already on the market—can then be directly contradicted by statements made to the [USPTO] to secure a patent on the product.'' The letter noted that such inconsistent statements ''should be cause for rejecting the application and, when made knowingly and with bad intent, potentially other sanctions.''

This notice is part of the USPTO's efforts to put into effect the Administration's goals and address the Senators' concerns. It is also part of the USPTO's ongoing mission to issue robust and reliable patents and to make sure our intellectual property ecosystem works to bring more innovation to impact—in every technological space including the critical pharmaceutical space. This notice clarifies the ''duty of disclosure'' and ''duty of reasonable inquiry'' owed to the USPTO and American public. This notice specifically addresses these duties as they relate to information and statements material to patentability including, but not limited to, those received from or submitted to the FDA and other governmental agencies.

II. *Who Has a Duty to Disclose Material Information:* The duty to disclose applies to matters pending before the USPTO and extends broadly to ''[e]ach individual associated with the filing and prosecution of a patent application'' and ''[e]ach individual associated with the patent owner in a reexamination proceeding.'' 37 CFR 1.56(a) and 1.555(a). For patent applications, including reissue applications, these individuals include each inventor named in the application, each attorney or agent who prepares or prosecutes the application, and ''[e]very other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.'' 37 CFR 1.56(c); *see* 37 CFR 1.171. For reexamination proceedings, these individuals include ''the patent owner, each attorney or agent who represents the patent owner, and every other individual who is substantively involved on behalf of the patent owner in a reexamination proceeding.'' 37 CFR 1.555(a).

The duty to disclose also extends to parties and individuals involved in a proceeding before the Patent Trial and Appeal Board (PTAB). According to 37 CFR 42.11(a), ''Parties and individuals involved in the proceeding have a duty of candor and good faith to the Office during the course of a proceeding.'' Not only does the duty apply to each individual associated with a patent application (including a reissue application) or reexamination proceeding that is on appeal to the PTAB, but the duty to disclose also extends to patent owners presenting substitute claims in an inter partes review or post grant review proceeding. ''Under 37 CFR 42.11, all parties have a duty of candor, which includes a patent owner's duty to disclose to the Board information of which the patent owner is aware that is material to the patentability of substitute claims, if such information is not already of record in the case.'' *Lectrosonics, Inc.* v. *Zaxcom, Inc.,* IPR2018–001129, 001130, Paper 15 at 9–10 (PTAB Feb. 25, 2019) (precedential).

III. *What Material Information Must Be Disclosed:* ''[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.'' 37 CFR 1.56(b). The USPTO holds those individuals subject to this duty to the highest standards. In close cases where the materiality or consistency of the information is in question, the applicant should consider submitting this information to the USPTO. *See* Manual of Patent Examining Procedure (9th ed. Rev. 10.2019) (MPEP) § 2004, item 10.

Specifically, the duty of candor and good faith, and by extension the duty to disclose, applies to positions taken by applicants or parties involving the claimed subject matter. For instance, in PTAB proceedings, parties should not take a position about the patentability of challenged claims that is inconsistent with positions taken in submissions to other Government agencies regarding the same subject matter. *See, e.g.,* Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, Final Rule, 77 FR 48612, 48630 (Aug. 14, 2012) (''The scope of the duty [of candor and good faith] is comparable to the obligations toward the tribunal imposed by Rule 11 of the Federal Rules of Civil Procedure.'').

If a party to a USPTO proceeding discovers that an earlier position taken in a submission to the USPTO or another Government agency was incorrect or inconsistent with other statements made by the party, the party must promptly correct the record. *See, e.g., In re Tendler,* Proceeding No. D2013–17 (USPTO Jan. 1, 2014) (suspending a practitioner for four years for failure to correct the written record after learning of inaccuracies in a declaration the practitioner had filed). In the context of prosecution, an applicant must disclose to the USPTO any information that refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the Office, or (ii) asserting an argument of patentability. *See* 37 CFR 1.56(b)(2). In the context of PTAB proceedings, if the party is or becomes aware of incorrect or inconsistent positions, the party must make the PTAB panel aware of the incorrect or inconsistent positions and must submit the inconsistent information. Patent owners may bring information, including prior art and incorrect or inconsistent positions, to the attention of the USPTO through supplemental examination, *ex parte* reexamination, reissue applications, or submissions under 37 CFR 1.501. During prosecution, third parties may have an opportunity to disclose information to the USPTO through third party submissions under 37 CFR 1.290 and protests under 37 CFR 1.291. After issuance, third parties may disclose information directed to issued patents to the USPTO via submissions under 37 CFR 1.501, in *ex parte* reexamination, or in PTAB trial proceedings. A finding of ''fraud,'' ''inequitable conduct,'' or violation of duty of disclosure through bad faith or intentional misconduct with respect to any claim in an application or patent, renders all the claims thereof unpatentable or invalid. MPEP § 2016.

Patent examiners also have the ability to require submission of information that may be reasonably necessary to properly examine or treat a matter in a pending or abandoned application. 37 CFR 1.105(a)(1). The information that must be submitted to comply with a requirement for information under 37 CFR 1.105 may not be material to patentability in itself under 37 CFR 1.56, but it is necessary to obtain a complete record from which a determination of patentability may be made. MPEP § 704.12(a). Therefore, when an examiner has a reasonable

basis to conclude that an individual identified under 37 CFR 1.56(c) or any assignee has information that would aid in the examination of the application or treatment of some matter, the examiner may require submission of information that is not necessarily material to patentability. This requirement could include statements made or information submitted to other Government agencies such as the FDA. For example, when examining a claim directed to a process of manufacturing a particular drug product that was effectively filed more than one year after FDA approval of the drug product, an examiner may appropriately require an applicant to submit to the USPTO information submitted to the FDA (*e.g.,* in a New Drug Application or Biologics License Application) on how the drug product was manufactured.

IV. *What Is the Duty of Reasonable Inquiry:* ''The presentation to the Office (whether by signing, filing, submitting, or later advocating) of any paper by a party, whether a practitioner or non-practitioner, constitutes a certification under § 11.18(b).'' 37 CFR 1.4(d)(4)(i). Section 11.18(b) includes 11.18(b)(2), which calls for a duty of reasonable inquiry to ensure that the paper is not being presented for any improper purpose, the legal contentions are warranted by law, the allegations and other factual contentions have evidentiary support, and the denials of factual contentions are warranted on the evidence.[1]

Accordingly, each party presenting a paper to the USPTO, whether a practitioner or non-practitioner, has a duty to perform an inquiry that is reasonable under the circumstances. This reasonable inquiry may comprise reviewing documents that are submitted to or received from other Government agencies, including the FDA. If any reviewed document is material to the patentability of a pending matter before the Office, such as a patent application (including a reissue application), a reexamination proceeding, or an issue pending before the PTAB, the party has a duty to submit the information to the USPTO. 37 CFR 1.56, 1.555, 42.11(a); *see* 37 CFR 42.11(c), 11.18(b)(2). A duty of reasonable inquiry may exist based on circumstances known to the party presenting the paper to the USPTO. Failing to inquire when the circumstances warrant it could result in sanctions or other action under 37 CFR 11.18(c), which may include: (1) striking the offending paper; (2) referring a practitioner's conduct to the Director of Enrollment and Discipline for appropriate action; (3) precluding a party or practitioner from submitting a paper, or presenting or contesting an issue; (4) affecting the weight given to the offending paper; or (5) terminating the proceedings in the Office. *See, e.g., In re Hao,* Proceeding No. D2021–14 (USPTO Apr. 27, 2022) (involving disciplinary sanctions predicated on non-compliance with 37 CFR 11.18).

V. *When the Duties of Disclosure and Reasonable Inquiry Arise in Dealings With Other Government Agencies:* Each individual with a duty to disclose, or party with a duty of reasonable inquiry, should ensure that the statements made to the USPTO and other Government agencies, or any statements made on their behalf to other Government agencies regarding the claimed subject matter, are consistent. *See Belcher Pharms., LLC* v. *Hospira, Inc.,* 11 F.4th 1345 (Fed. Cir. 2021) (affirming a district court's determination of inequitable conduct because the patent owner's Chief Science Officer failed to provide to the USPTO submissions he made to the FDA about the prior art that were inconsistent with positions taken before the USPTO during the prosecution of a pending patent application). Furthermore, providing material information to other Government agencies, including the FDA, while simultaneously withholding the same information from the USPTO undermines both the intent and spirit of the duty of disclosure and violates those duties. For example, in *Bruno Independent Living Aids, Inc.* v. *Acorn Mobility Services, Ltd.,* 394 F.3d 1348, 1354 (Fed. Cir. 2005), the U.S. Court of Appeals for the Federal Circuit inferred intent to deceive and found inequitable conduct occurred when an official involved in both the FDA and the USPTO submissions chose to disclose material prior art to the FDA but not to the USPTO.

Activities or documents associated with market testing, marketing, or commercialization by the patent applicant can also be material to patentability, and therefore, when material, should be disclosed to the USPTO. *See GS Cleantech Corp.* v. *Adkins Energy LLC,* 951 F.3d 1310, 1330–1332 (Fed. Cir. 2020) (finding that a district court did not abuse its discretion in reaching its inequitable conduct determination where the district court concluded that the inventors and their lawyers made a deliberate decision to withhold material information from the USPTO regarding an offer for sale and reduction to practice of the claimed invention that would have implicated an on-sale bar to the granting of a patent; the lawyers filed with the USPTO a declaration containing a false statement about the timing of an offer for sale despite having in their possession materials that would call into question the veracity of the statement; and the inventors and lawyers subsequently failed to correct the false declaration). By following the guidance in this notice, it is expected that patent applicants can obtain more reliable patent protection and avoid the findings of inequitable conduct and sanctions noted above.

Similarly, each individual with a duty to disclose, or party with a duty of reasonable inquiry, should review documents it receives from other Government agencies to determine whether the information should be submitted to the USPTO. For example, when a company seeks FDA approval to market a generic drug before the expiration of patents related to the drug, the generic drug application (*e.g.,* an Abbreviated New Drug Application (ANDA)) must contain a ''paragraph IV certification'' that the patents submitted to the FDA by the brand-name drug's sponsor, listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), and related to the drug are invalid, are unenforceable, or will not be infringed by the generic product. Except in limited circumstances, notice of a paragraph IV certification must also be communicated to the owner of the patent subject to the certification and to the New Drug Application holder. Such a notice includes a detailed statement providing factual and legal bases for the paragraph IV certification. 21 CFR 314.95(c)(7). Consequently, to assist USPTO staff in evaluating patentability effectively and efficiently, the party receiving a paragraph IV certification should review such documents to determine whether they are material to the patentability of any pending matters before the USPTO, such as pending patent applications, reexamination proceedings, or issues in proceedings pending before the PTAB. If the content

[1] ''To the best of the party's knowledge, information and belief, formed after an inquiry reasonable under the circumstances, (i) The paper is not being presented for any improper purpose, such as to harass someone or to cause unnecessary delay or needless increase in the cost of any proceeding before the Office; (ii) The other legal contentions therein are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; (iii) The allegations and other factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and (iv) The denials of factual contentions are warranted on the evidence, or if specifically so identified, are reasonably based on a lack of information or belief.'' 37 CFR 11.18(b)(2).

of the detailed statement, or other information that is part of the ANDA process, is deemed material to patentability in a pending USPTO matter, then such information must be submitted to the USPTO during the pendency of the matter, to meet the duties of candor and good faith and disclosure under 37 CFR 1.56, 1.555, 42.11(a) or (c), or 11.18(b)(2).

Deliberate schemes or established practices to prevent 37 CFR 1.56(c) individuals from obtaining knowledge of material information is not acting in accordance with candor and good faith under 37 CFR 1.56(a). For example, walling off the patent prosecution practitioners from the attorneys seeking FDA approval, as a way to prevent material information from being exchanged between the practitioners and attorneys, is inappropriate. The U.S. Supreme Court has refused to enforce patents where deliberate steps were taken to suppress material information. *See, e.g., Keystone Driller Co.* v. *Gen. Excavator Co.,* 290 U.S. 240 (1933) (patent owner's suit dismissed where the patent owner paid a third party to keep a prior use secret); *Precision Instruments Mfg. Co.* v. *Auto. Maint. Mach. Co.,* 324 U.S. 806 (1945) (suit dismissed where patent owner actively suppressed evidence of perjury to the USPTO).

Though the FDA compiles paragraph IV certifications and publishes a list on its website, submitting this list to the USPTO does not satisfy the duty of disclosure for any material information submitted with the paragraph IV certification. These lists do not include patent numbers, relevant claims, or an explanation of the basis for the certification. Therefore, information and documents submitted with the paragraph IV certification that are material to patentability or to issues in proceedings pending before the USPTO, including the PTAB, must be submitted directly to the USPTO and as described above, the examiner may appropriately require submission of information concerning the certifications in certain situations.

Katherine K. Vidal,

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

[FR Doc. 2022–16299 Filed 7–28–22; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date added to and deleted from the Procurement List:* August 28, 2022.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024–3243.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404 or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 4/29/2022, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List. This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the product(s) and service(s) and impact of the additions on the current or most recent contractors, the Committee has determined that the product(s) and service(s) listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the product(s) and service(s) to the Government.

2. The action will result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service(s) are added to the Procurement List:

Service(s)

Service Type: Facility Support Services
Mandatory for: U.S. Navy, DFAS Command Building, Bratenahl, Ohio
Designated Source of Supply: VGS, Inc., Cleveland, OH
Contracting Activity: DEPT OF THE NAVY, NAVAL FAC ENGINEERING CMD MID LANT

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2022–16278 Filed 7–28–22; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete product(s) from the Procurement List that were previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: August 28, 2022.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024–3243.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404 or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following product(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
8465–00–262–5237—Lanyard, Pistol, White
8465–00–965–1705—Lanyard, Pistol, Olive Green