

Abstract

Jo Lynn Jeter is a 2004 graduate of the University of Oklahoma College of Law. She was a member of the Oklahoma Journal of Law and Technology during the 2003-2004 academic year. Ms. Jeter wrote this eBrief while working on the Project on Intellectual Property Rights in Living Matter under the direction of Professor Drew Kershen. Below, Ms. Jeter discusses the administrative regulations and policies pertaining to patents on living matter. The United States Patent and Trademark Office (USPTO) has been delegated considerable discretion by Congress to oversee the patent process. It is essential for one seeking a patent or patent-like protection in the United States to become familiar with the contents of the Manual on Patent Examining Procedure (MPEP) and various guidelines issued by USPTO. This eBrief provides helpful insight into these topics.

Edited by Brian Carter

AGRICULTURAL BIOTECHNOLOGY: U.S. POLICY REGARDING PATENT APPLICATIONS

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I. Introduction

The U.S. Constitution authorizes Congress “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹ Within the scope of this clause, Congress establishes conditions and tests for patentability through federal statutes. The conditions for patentability must be strict enough to justify the issuance of a limited monopoly that comes with a patent, but lenient enough to encourage and promote innovation. In order to create a consistent policy regarding the ease or difficulty of receiving patents under patent statutes, the United States Patent and Trademark Office issues “Guidelines” to direct its office personnel. The Guidelines establish policies for examining a patent application.

¹ U.S. CONST. art. I, § 8, cl. 8.

II. USPTO POLICY AND AGRICULTURAL BIOTECHNOLOGY

There are three means by which one may receive federal statutory intellectual property protection for living matter: The Plant Patent Act of 1930 (“PPA”),² Plant Variety Protection Act of 1970 (“PVPA”)³ or Patent Act of 1952.⁴ The Patent Act’s patentable subject matter overlaps with the protected subject matter under the PPA and the PVPA. However, the availability of one form of statutory protection does not preclude the availability of protection under another form.⁵ In order to receive protection under one of these Acts, the respective statutory requirements must be met. The PPA applies only to certain *asexually* reproduced plants.⁶ The conditions for obtaining a patent under the PPA are *distinctiveness, novelty, non-obviousness* and a *description* “as complete as is reasonably possible.”⁷ Conversely, the PVPA applies to *sexually* reproduced plants.⁸ To qualify for a PVPA certificate, the variety must be *new, distinct, uniform and stable*.⁹ The Patent Act of 1952 conveys patent protection to

² 35 U.S.C. §§ 161-164 (2000).

³ 7 U.S.C. §§ 2321-2582 (2000).

⁴ 35 U.S.C. §§ 101-318 (2000).

⁵ See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-bred Int’l., Inc.*, 534 U.S. 124, 132, 145 (2001) (holding plants patentable under the Patent Act of 1952, despite their coverage under the PPA and PVPA). Examining the text of the Acts and the legislative history, neither of the plant-specific Acts expressly excludes any plant subject matter from protection under the general patent law. *Id.* at 134-44.

⁶ See 35 U.S.C. § 161 (2000) (emphasis added).

⁷ See 35 U.S.C. §§ 161-164 (2000); see also *Yoder Bros., Inc. v. California-Florida Plant Corp.*, 537 F.2d 1347, 1377 (5th Cir. 1976) (“novelty” refers to newness in its conception); *Jacobson Bros., Inc. v. United States*, 512 F.2d 1065, 1068 (1975) (“non-obviousness” is a prerequisite of any patent and simply requires that the creation or improvement not be obvious at the time the invention was made); *Yoder*, 537 F.2d at 1379 (“We think that the most promising approach toward the obviousness requirement for plant patents is reference to the underlying constitutional standard that it codifies namely, invention”); *In re Greer*, 484 F.2d 488, 490-91 (Cust. & Pat. App. 1973) (the U.S. Court of Customs and Patent Appeals has interpreted the description provision “as complete as is reasonably possible” to mean that there is no requirement for a “how-to-make” disclosure in a plant patent application); *Ex parte Solomons*, 201 U.S.P.Q. (BNA) 42 (1978) (the less strict description requirement is due to the impossibility of producing the patented plant from a description, because it must be asexually reproduced).

⁸ 7 U.S.C. § 2402 (2000) (emphasis added).

⁹ See *id.* § 2402(a)(1) (emphasis added) (“New” if “on the date of filing the application for plant variety protection, propagating or harvested material of the variety has not been sold or otherwise disposed of to other persons, by or with the consent of the breeder, or the successor in interest of the breeder, for purposes of exploitation of the variety”); *id.* § 2402(a)(2) (“Distinct” if the “variety is clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of filing of the application”); *id.* § 2402(a)(3)

“whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof.”¹⁰ “Manufacture” and “composition of matter” include live, human-made creations, such as microorganisms and plants.¹¹ Further, the Patent Act requires patentable subject matter to be *new*, *useful*, and *non-obvious*.¹² In addition, the applicant for a utility patent must meet stringent description requirements.¹³

It is more difficult to obtain a utility patent for a plant than to obtain a Plant Patent or a PVPA certificate, due to the additional requirement of usefulness and the more stringent description requirement. However, a utility patent may be more desirable because of its greater scope of protection.¹⁴ Thus, the Patent Act may often be an applicant’s first choice of protection for plant creations if the statutory requirements can be met.

(“Uniformity” requires the variety be “describable, predictable and commercially acceptable); *id.* § 2402(a)(4) (“Stability” requires the variety “remain unchanged with regard to the essential and distinctive characteristics of the variety” upon reproduction).

¹⁰ 35 U.S.C. § 101.

¹¹ See *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (the U.S. Supreme Court, after examining the text and legislative history of the Patent Act, gave the terms “manufacture” and “composition of matter” a broad interpretation to include a live, human-made microorganism); *Id.* at 309-10 (the Court reiterated that discoveries in nature are not patentable, but stated that a non-naturally occurring manufacture or composition of matter that is a product of human ingenuity having a distinctive name, character and use is patentable subject matter under section 101 of the Act, even if it is living matter); see also *In re Hibberd*, 227 U.S.P.Q. (BNA) 443 (1985) (the broad interpretation of “manufacture” and “composition of matter” within the Act led to the U.S. Patent and Trademark Office (USPTO) issuing utility patents for plants, plant parts and seeds); *J.E.M. Ag Supply, Inc. v. Pioneer Hi-bred Int’l, Inc.*, 534 U.S. 124, 127 (2001) (the U.S. Supreme Court later affirmed the USPTO’s issuing of patents for plants, plant parts as seeds in a clear ruling that plants were patentable subject matter under the general Patent Act).

¹² See 35 U.S.C. §§ 101-103 (2000) (emphasis added). For a better understanding of what these specific requirements entail, see § 102(a) (providing that a plant is considered new if it was not known or used by others before its discovery); *Yoder*, 537 F.2d at 1378 (to be new, the plant must be “one that literally had not existed before, rather than one that had existed in nature but was newly found”); *Imperial Chem. Indus., PLC v. Henkel Corp.*, 545 F. Supp. 635, 644-45 (1982) (The “product of a patented process is useful if it may serve some identifiable purpose”); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966) (the “emphasis on non-obviousness is one of inquiry, not quality”); *Yoder*, 537 F.2d at 1378-79 (Obviousness serves as “Congress’ articulation of the constitutional standards of invention.” There must be an actual invention, and non-obviousness requires the invention entail a degree of skill and ingenuity greater than that possessed by one with an ordinary level of knowledge in the practice or trade).

¹³ See 35 U.S.C. § 112 (2000).

¹⁴ Unlike the PVPA, the Patent Act does not contain exemptions that limit the scope of protection. The PVPA contains three exemptions from infringement limiting its scope in protection: (1) Public Interest Exemption, 7

In order to determine whether a patent applicant has met the stringent statutory requirements of the Patent Act, the United States Trademark and Patent Office (“USPTO”) has issued “Guidelines” establishing the policies and procedures for evaluating patent applications. The Guidelines assist USPTO personnel in determining whether to issue a patent under the Patent Act. The Guidelines do not alter any statutory requirements and do not constitute substantive rulemaking; thus, they do not have the force of the law, but merely assist in carrying out the law.¹⁵ In 2001, the USPTO issued two separate Guidelines relating to the requirements of utility patents. The first Guidelines address the “utility” requirement; the second Guidelines address the “written description” requirement. These Guidelines provide insight into USPTO policy regarding patent applications as discussed in detail below.

A. “Utility” Examination Guidelines

The *Utility Examination Guidelines*¹⁶ establish the policies and procedures for evaluating whether a patent application complies with the utility requirements of 35 U.S.C. §§ 101 and 112.¹⁷ In determining whether the utility requirements have been met, the Guidelines instruct office personnel to do the following:

1. Read the claims and the supporting written description;
2. Review the claims and the supporting written description to determine if the applicant has asserted for the claimed

U.S.C. § 2404; (2) Research Exemption, 7 U.S.C. § 2544; and (3) the Farmer’s Exemption, 7 U.S.C. § 2543. Also, the PVPA limits protection to a single variety and the PPA limits protection to a specific plant; the Patent Act does not. Specifically, the PVPA protection falls short of a utility patent because a breeder can use a plant that is protected by a PVP certificate to “develop” a new inbred line while he cannot use a plant patented under the general Patent Act for such a purpose. *See* 7 U.S.C. § 2541(a)(4), stating that infringement includes “use of the variety in producing (as distinguished from developing) a hybrid or different variety therefrom”.

¹⁵ 66 Fed. Reg. 1092, 1097-98 (Jan. 5, 2001); 66 Fed. Reg. 1099, 1104 (Jan. 5, 2001).

¹⁶ 66 Fed. Reg. 1092 (Jan. 5, 2001). This revision supersedes the Revised Interim Utility Guidelines that were published at 64 Fed. Reg. 71,440 (Dec. 21, 1999) and correction at 65 Fed. Reg. 3425 (Jan. 21, 2000).

¹⁷ 66 Fed. Reg. at 1098. Title 35 U.S.C. § 101 states that “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.” Title 35 U.S.C. § 112 states that “the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same....”

invention any specific and substantial utility that is credible; 3. Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility... the examiner should provide documentary evidence regardless of publication date to support the factual basis of the prima facie showing of no specific and substantial credible utility... 4. A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.¹⁸

Under instruction number one, if at any time an examiner finds it “readily apparent” that a claimed invention has a “well-established utility,” the examiner should not impose a rejection based on lack of utility.¹⁹ Furthermore, “an invention has a well-established utility: 1. if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention, and 2. the utility is specific, substantial, and credible.”²⁰ Under instruction number two, an examiner cannot reject the patent application based on lack of utility if the applicant has *asserted* a “specific and substantial utility that is credible.”²¹ An applicant has asserted a “specific and substantial utility that is credible” if “the claimed invention is useful for any particular practical purpose and the assertion would be considered credible by a person of ordinary skill in the art.”²² To satisfy the utility requirement, only one credible assertion of specific and substantial utility is required for each claimed invention.²³

Accordingly, there are two means by which an examiner may find the “utility” requirement satisfied. First, if the claimed invention has a readily apparent well-established utility; or second, if the applicant asserts any specific and substantial utility for the claimed

¹⁸ 66 Fed. Reg. at 1098.

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.* The specific and substantial utility requirement “excludes ‘throw-away,’ ‘insubstantial,’ or ‘nonspecific’ utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement,” *Id.* “Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant’s assertions,” *Id.*

²³ *Id.*

invention that is credible.²⁴ If neither of these two requirements is satisfied, office personnel are instructed to reject the application.²⁵ If the application is rejected, the burden shifts to the applicant to present evidence in order to prove there is in fact a specific and substantial utility that one of ordinary skill in the art would have recognized.²⁶ An applicant may amend his or her claims rebutting the basis for the examiner's rejection, to which an examiner must fully consider and respond.²⁷

Upon rejecting an application, instruction number three requires office personnel to include a "detailed explanation" of why there is no specific and substantial credible utility.²⁸ Also, "whenever possible, the examiner should provide documentary evidence... to support the factual basis... of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions."²⁹ Finally, the Guidelines instruct office personnel to "treat as a true statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned."³⁰

Given these Guidelines, it is evident that the applicant is given wide latitude in establishing the utility of a claimed invention. An applicant may assert the claimed invention's utility or, if the invention's utility is well-established and readily apparent, the examiner must

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.* at 1099.

²⁸ *Id.* at 1098.

²⁹ *Id.*

³⁰ *Id.* at 1098-99.

accept the application as sufficiently establishing utility, even if no specific and substantial utility has been asserted. Also, if an application is rejected, the applicant may rebut the findings with any reasoning, arguments, evidence or publications in order to have the application reconsidered. The office must fully reconsider and respond to the rebuttal.³¹

Specifically, one seeking patent protection for living matter under the Patent Act must assert a specific, substantial and credible utility. The applicant need not assert commercial success, but must assert that the claimed invention serves some identifiable purpose.³² For example, an applicant may assert the claimed invention requires less pesticide or herbicide for growing crops, is useful in developing pharmaceutical drugs, is a necessary element of a laboratory experiment or study, or is more environmentally friendly than its competition. These, of course, are only a few examples of the many possible uses an applicant may assert.

B. “Written Description” Requirement Guidelines

The *Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, 1: Written Description Requirement*³³ establish the policies and procedures for evaluating whether a Patent Act application meets the written description requirements. An applicant is required to provide “a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains... to make and use the same.”³⁴ Thus, there are two distinct description requirements: 1. the “written description requirement,” the purpose of which is to confirm the inventor had possession of what is claimed and actually invented what is claimed; and 2. the

³¹ *Id.* at 1099.

³² *See* Imperial Chem. Indus., PLC v. Henkel Corp., 545 F. Supp. 635, 645 (1982).

³³ 66 Fed. Reg. 1099 (Jan 5, 2001). These Guidelines supersede the “Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, 1 ‘Written Description’ Requirement” that were published in the Federal Register at 64 Fed. Reg. 71,427 (Dec. 21, 1999).

³⁴ 35 U.S.C. § 112 (2000).

“enablement requirement,” which ensures “the inventor conveys to others how to make and use the claimed invention.”³⁵ These Guidelines address only the first aspect of the description requirement: the written description requirement.

To satisfy the written description requirement, one must “describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.”³⁶ The Guidelines provide that “whether the description requirement is met is a question of fact that must be determined on a case-by-case basis.”³⁷ With this in mind, the Guidelines issue the following instructions to USPTO personnel:

1. For each claim, determine what the claim as a whole covers; 2. Review the entire application to understand how [the] applicant provides support for the claimed invention including each element and/or step; and 3. Determine whether there is sufficient written description to inform a skilled artisan that the applicant was in possession of the claimed invention as a whole at the time the application was filed.³⁸

Under the first instruction, the examiner must analyze each claim separately, and give it the “broadest reasonable interpretation in light of and consistent with the written description.”³⁹ The examiner must determine what the claim as a whole covers, and the entire claim must satisfy the written description requirements.⁴⁰ Next, under the second instruction the examiner must “compare the scope of the claim with the scope of the description” to determine whether the description qualifications have been met from the standpoint of one skilled in the art.⁴¹ Finally, the third instruction directs the examiner to determine if the description is sufficient enough to make clear to one skilled in the art that the applicant was in possession of the claimed

³⁵ 66 Fed. Reg. at 1104-05.

³⁶ *Id.* at 1104.

³⁷ *Id.* at 1105.

³⁸ *Id.* at 1105-07.

³⁹ *Id.* at 1105.

⁴⁰ *Id.*

⁴¹ *Id.*

invention.⁴² An applicant may show possession of the claimed invention through a number of methods, such as describing an actual reduction to practice;⁴³ disclosing detailed drawings or structural chemical formulas; or describing distinguishing identifying characteristics.⁴⁴ An applicant may use words, structures, figures, diagrams or formulas.⁴⁵ The applicant's primary goal is to sufficiently describe the invention in order to show possession of the claimed invention to one skilled in the art; however, "an inventor does not need to know how or why the invention works in order to obtain a patent."⁴⁶

For an applicant seeking patent protection for a plant, a description of an actual reduction to practice may be the most practical way to show possession of the claimed invention; for example, "description of an actual reduction to practice of a biological material is shown by specifically describing a deposit" made in accordance with the federal regulations.⁴⁷ However, "[t]he description must be sufficient to permit verification that the deposited biological material is in fact that disclosed."⁴⁸ The deposit is not a substitute for the written description requirement, but rather may serve as a supplement to an applicant's disclosure for the written description requirement. Biological material includes "material that is capable of self-replication, either

⁴² Id.

⁴³ "A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. Description of an actual reduction to practice of a biological material may be shown by specifically describing a deposit made in accordance with the requirements of 37 CFR 1.801 et seq," Id.

⁴⁴ Id. at 1104, 1105.

⁴⁵ Id. at 1104.

⁴⁶ See *Newman v. Quigg*, 877 F.2d 1575, 1581 (1989).

⁴⁷ 66 Fed. Reg. at 1105; see 37 C.F.R. § 1.801-1.809 (setting forth examining procedures and conditions of deposits of biological matter). See generally MANUAL OF PATENT EXAMINING PROCEDURE ch. 2400 (Biotechnology) (providing guidance on the practices and procedures for implementation of the deposit rules), available at http://www.uspto.gov/web/offices/pac/mpep/mpep_e8_2400_508.pdf.

⁴⁸ Deposit of Biological Materials for Patent Purposes, Final Rule, 54 Fed. Reg. 34,864, 34,880 (Aug. 22, 1989).

directly or indirectly.”⁴⁹ Thus, if the applicant seeks patent protection for a claimed plant invention, he or she would more than likely deposit seed.

Overall, the Guidelines reflect a USPTO policy in favor of determining that an application satisfies the description requirements. For example, the Guidelines provide that “there is a strong presumption that an adequate written description of the claimed invention is present in the specifications as filed” and “rejection of an original claim for lack of written description should be rare.”⁵⁰ Further, the “examiner has the initial burden” of presenting reasons why the written description requirements are not met.⁵¹ The Guidelines also state that the office should “clearly communicate the findings, conclusions, and reasons which support them,” and “when possible, the office... should offer helpful suggestions on how to overcome rejections.”⁵²

An applicant must also fulfill the enablement requirement, an additional aspect of the description requirement not addressed by the Guidelines. To fulfill the enablement requirement, an applicant must provide “a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art... to make and use the same.”⁵³ The federal regulations permit a deposit of

⁴⁹ 37 C.F.R. § 1.801 (1989). “Direct Self-replication includes those situations where the biological material reproduces by itself,” 54 Fed. Reg. 34,864, 34,874 (Aug. 22, 1989). “Representative examples (of self-replicating biological material) include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds.” 37 C.F.R. 1.801. “Indirect self-replication is meant to include those situations where the biological material is only capable of replication when another self-replicating biological material is present.” 54 Fed. Reg. at 34,874. “Viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material.” 37 C.F.R. 1.801. The lists of representative examples are not intended to be mutually exclusive and whether a biological material is sufficient to comply with 35 U.S.C. § 112 must be determined on a case-by-case basis. 54 Fed. Reg. at 34,874.

⁵⁰ *Id.* at 1105.

⁵¹ *Id.*

⁵² *Id.* at 1107.

⁵³ 35 U.S.C. § 112 (2000).

biological material to be referenced in a patent application where an invention is, or relies on, biological material.⁵⁴ Thus, similar to the possession requirement addressed above, a deposit of biological material in accordance with federal regulations may be necessary for fulfilling the enablement requirement. The deposit of plant material together with the written specification must enable those skilled in the art to make and use the claimed invention.⁵⁵ The examiner has the initial burden of establishing a reasonable basis to question the enablement provided by the applicant.⁵⁶

C. “Novelty” and “Non-Obviousness” Requirements

The Guidelines comprise only two conditions for patentability under the Patent Act: the utility requirement and written description requirement. The applicant must also assert and fulfill the requirements of novelty and non-obviousness.⁵⁷ A plant is considered new if it “literally had not existed before, rather than one that had existed in nature but was newly found.”⁵⁸ A plant must also be non-obvious. Obviousness serves as “Congress’ articulation of the constitutional standards of invention.”⁵⁹ There must be an actual invention, and non-obviousness requires the invention to entail a degree of skill and ingenuity greater than that possessed by one with an ordinary level of knowledge in the practice or trade.⁶⁰ The USPTO provides that all of the aspects of a claim must be considered when weighing the differences

⁵⁴ 37 C.F.R. § 1.802 (1989).

⁵⁵ See 35 U.S.C. § 112.

⁵⁶ See *In re Wright*, 999 F.2d 1557, 1562 (1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure).

⁵⁷ 35 U.S.C. §§ 101-103 (2000).

⁵⁸ *Yoder Bros., Inc. v. California-Florida Plant Corp.*, 537 F.2d 1347, 1378 (1976).

⁵⁹ *Id.*

⁶⁰ *Id.* at 1379.

between a claimed invention and the prior art when determining the obviousness of a process or method claim.⁶¹

III. Conclusion

One seeking intellectual property protection for living matter will more than likely seek a utility patent under the Patent Act if the requirements can be met, because the Act provides a greater scope of protection. Before applying for such a patent, an applicant should consult the Guidelines provided by the USPTO in order to increase the likelihood of success in receiving a patent. While the Guidelines do not cover all the requirements under the Patent Act, they provide patent examiners with procedures and policies for analyzing the most problematic areas of patents: the utility and written description requirements. The Guidelines provide an overall policy in favor of issuing patents if the statutory requirements are met through presumptions in favor of the applicant and cooperative assistance. Also, upon applying for a patent, one should consult the Manual of Patent Examining Procedure (“MPEP”) issued by the USPTO, which contains the basic requirements and standards of obtaining a patent. The MPEP is used by USPTO office personnel and is encouraged for use by applicants. Chapter 2400 of the MPEP provides a thorough guidance on the practices and procedures for depositing biological material.⁶²

⁶¹ See Manual of Patent Examining Procedure § 2143.03.

⁶² The Manual of Patent Examining Procedure can be found at http://www.uspto.gov/web/offices/pac/mpep/mpep_e8_2004_508.pdf.