Deposit of Biological Materials in Support of a U.S. Patent Application

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ABSTRACT

The deposit of biological material in support of a U.S. patent application is a mechanism by which an applicant can cure what might otherwise be potentially fatal defects in a patent application and even an issued patent. A biological deposit can, in some cases, satisfy the requirements of enablement, written description, and best mode, and potentially broaden the scope of claims in the event of litigation. This chapter briefly explores the relationship between biological deposits and patentability requirements, what can be deposited, where and when a deposit can be made, and who has access to the deposit.

1. WHAT DOES A DEPOSIT ACCOMPLISH?

Referencing deposited biological material in the specification of a U.S. patent application provides the advantage of the deposited material being incorporated into that patent's disclosure.[3] As part of the disclosure, the deposited material may be employed to augment or correct deficiencies in the specification of the application, specifically, as to enablement, written description, and best mode requirements.

1.1 Deposit and the enablement requirement

While not always required, a deposit of biological material is one way to satisfy the *enablement requirement* of 35 U.S.C. § 112. The specification of a patent must enable a person *skilled in the art* to make and use the invention claimed, aided only by his or her ordinary skill and the state of the art.[4] The enablement requirement is typically accomplished through a written description of the invention within the specification. But inventions not easily or reasonably described by the written word alone may be "*described in surrogate form by a deposit that is incorporated by reference into the specification.*"[5] By providing access to biological material that is difficult to describe, an applicant enables the public to make and use the claimed invention.

A deposit of biological material also can reduce the amount of disclosure required in the application to enable the claimed invention. For example, in *In Ex parte C*, by describing the parental varieties and the selection process in conjunction with a seed deposit, applicants successfully enabled a novel variety of soybean plant, seeds from the plant, and a method of producing seeds by self-pollination.[6] Notably, the Board of Patent Appeals and Interferences (BPAI) did not require an exacting description of breeding, selection, and testing since the invention, a disease-resistant soybean plant, was placed in deposit.

A deposit of biological material may enable more than just the species so deposited. For example, in *Ajinomoto v. Archer-Daniels-Midland*, the Federal Circuit held that a method for producing an amino acid from a genetically engineered bacterium was enabled, despite the fact that only one altered strain of bacteria that produced threonine

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was disclosed and deposited.[7] However, the BPAI was not quite so generous in several previous cases. For example, in *Ex parte Hata*, the BPAI affirmed the rejection of claims directed to treatment of infectious disease by administering specific strains of *Lactobacillus* on the grounds that the select strains deposited were narrower than the broader class of all strains and that undue experimentation would be required to locate new microorganisms covered by the claim.[8]

1.2 *Deposit and the written description requirement*

While not always required, a deposit of biological material is one way of satisfying the written description requirement of 35 U.S.C. § 112. This requirement is met if the specification describes the claimed invention in sufficient detail, such that one skilled in the art would reasonably conclude that the applicant was in *possession* of the claimed invention at the time of filing. This can be achieved by describing the invention with all its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.[9] Put simply, the specification must describe the invention such that it is distinguishable.

Until 2002, it was somewhat uncertain whether a deposit of a biological sample could satisfy the written description requirement. But in that year, the Federal Circuit, in *Enzo v. Gen-Probe*, held that deposit of a biological sample in a public repository could fulfill the requirement.[10] The specification of the Enzo patent provided a functional description (hybridization characteristics) and referenced a biological deposit, but disclosed no sequences or structural descriptions of any of the claimed nucleic acids. Thus, under *Enzo*, a reference to a deposit coupled with a functional description meets the written description requirement so long as a known correlation exists between the described function and a deposited or described structure. The generic scope of claims supported would be that which a person of skill would deem the patentee to possess based upon the disclosure, which includes information obtainable from the deposits.[11]

The information obtainable from deposits in support of a patent can potentially broaden interpretation of the claims. For example, in *Schering v. Amgen*, the patent owner could have used deposited biological material to show that the claims to leukocyte interferon encompassed the subtype IFN-alpha14, despite that the specification disclosed only two other subtypes.[12] In *Schering*, the patent owner provided evidence that the deposit coded for IFN-alpha14, but only to the appellate court and not to the trial court. The court held that, although a deposit could satisfy the enablement requirement, the deposit must be part of the record before it is used to provide support for a particular claim construction. Because the patent owners in *Schering* presented the evidence too late, the deposit could not influence claim construction. However, the lesson remains that deposited biological material incorporated into the disclosure may be used to support a claim interpretation more broadly than that explicitly disclosed in the specification.

1.3 *Deposit and the best mode requirement*

A deposit of biological material may also satisfy the *best mode requirement* under 35 U.S.C. § 112, ¶ 1,[13] but a deposit is not strictly necessary.[14] The best mode of carrying out an invention must be disclosed in sufficient detail at the time of filing the application to allow one of ordinary skill to practice it. To satisfy the best mode requirement, there must be no concealment of a mode of practice known by the inventor at the time of filing to be better than that disclosed.[15]

In *Amgen v. Chugai Pharmaceutical*, the defendants argued that, in the field of living materials, a biological deposit should be required so that the public has access to exactly what the patent applicant contemplates as the best mode.[16] The Federal Circuit held that a deposit was not necessary where the best mode of preparing a cell line necessary to practice the invention was disclosed and enabled in the specification.[17]

Similarly, in *Scripps v. Genetech*, where a patent specification described the process for producing, screening, and evaluating monoclonal antibodies, the Federal Circuit held that applicants had not concealed the best mode for

practicing the invention of protein purification using antibodies, despite not having deposited successfully isolated antibodies.[18] In *Scripps*, the court specifically rejected the argument that the "*laborious nature of the process of screening the monoclonal antibodies*" required deposit of the antibodies representing the best mode.

2. WHAT CAN BE DEPOSITED?

Biological material eligible for deposit are those materials capable of direct or indirect self-replication.[19] Representative examples include bacteria, fungi, yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens, and seeds. Furthermore, the deposit rules provide that viruses, vectors, cell organelles, and other nonliving material existing in, and reproducible from, a living cell may be deposited by means of a deposit of the host cell capable of reproducing the nonliving material.

Generally, for each deposit, the specification of the patent must contain the accession number for the deposit, the date of the deposit, a description of the deposited biological material sufficient to specifically identify it and to permit examination, and the name and address of the depository.[20]

3. IS A DEPOSIT REQUIRED?

The biological deposit "requirement" is not a requirement per se. Rather, the deposit rules provide a mechanism by which an applicant can overcome what would otherwise be a deficiency in the patent application. It is important to note that a biological deposit may be referenced in a specification even when not required. Moreover, referencing a biological deposit in the specification does not give rise to a presumption that the deposit was necessary under 35 U.S.C. § 112.

A biological deposit may be necessary where biological material is required to practice an invention and "*words alone cannot sufficiently describe how to make and use the invention in a reproducible manner.*"[21] For example, a deposit could be required where an invention cannot be practiced without access to an organism only obtainable from nature.[22] In the words of the Federal Circuit:

> *When an invention relates to new biological material, the material may not be reproducible even when detailed procedures and complete taxonomic description are included in the specification. It is then a condition of the patent grant that physical samples of such materials be deposited and made available to the public, under procedures established by the [U.S. Patent and Trademark Office] and international treaty.*[23]

Even so, if "*words alone cannot sufficiently describe*" the invention such that a biological deposit would normally be required, such a deposit would still not be necessary if the biological material necessary to the invention is (1) known and readily available to the public or (2) derived from readily available starting materials through routine screening that does not require undue experimentation.[24]

3.1 *Known and readily available*

Biological material need not be deposited unless access to the material is required under 35 U.S.C. § 112 and the material is not otherwise known *and* not readily available to the public. Indications that biological material is known and available include:

- commercial availability
- references to biological material in printed publications
- declarations of accessibility by those working in the field
- evidence of predictable isolation techniques
- an existing deposit

Thus a patentee may forgo a deposit in favor of assuming an obligation to make the necessary biological material publicly available.

While the U.S. Patent and Trademark Office (PTO) will accept a showing of current availability, the patentee takes the risk that the biological material will cease to be known and readily available.[25] The rules do not provide for post-issuance original deposits. But the PTO will accept a replacement deposit when a patent owner has diligently provided the replacement deposit after receiving notification that the depository can no

longer furnish samples of the original deposit, or that the deposit has become contaminated or lost its capability to function.[26] Failure to diligently make a replacement deposit will preclude grant of a certificate of correction.[27] A replacement deposit subsequently made will not be recognized by the PTO, and a request for a certificate of correction, even if made promptly thereafter, will not be granted.[28] Furthermore, the failure to make a replacement deposit where a deposit is considered to be necessary to satisfy the requirements of 35 U.S.C. § 112, will cause a patent involved in a reissue or reexamination proceeding to be treated by the PTO as if no deposit had been made.[29]

As such, unavailability of biological material necessary to practice the invention is a defect that cannot be cured after the grant of a patent and can result in unenforceability. This risk is reflected in advice from the PTO:

[Where] an applicant for patent has any doubt as to whether access to a biological material specifically identified in the specification is necessary to satisfy 35 U.S.C. § 112 or whether such a material, while currently freely available, may become unavailable in the future, the applicant would be well-advised to make a deposit thereof before any patent issues.[30]

3.2 *Derived without undue experimentation*

If only starting materials are readily available, the specification must provide sufficient guidance on making or isolating the biological material necessary to the invention without undue experimentation, or else a deposit of the material will be required.[31] Undue experimentation is decided under a standard of reasonableness; it is not merely a quantitative determination. Generally, there is no undue experimentation where time-consuming experiments are merely routine, such as a reliable screening test performed on a large number of samples.[32]

4. WHEN CAN BIOLOGICAL MATERIAL BE DEPOSITED?

Under current U.S. patent laws and practice, biological material may be deposited at any time prior to the issue of the patent the deposit supports. This includes deposits made during the pendency of the application. But deposit after application can seriously compromise international rights.

In the United States, biological material specifically identified in the patent application may be deposited during the pendency of the application (*i.e.*, before issuance of the application as a patent).[33] A reference to a deposit in the specification provides a basis for making a deposit after the filing date of the application. The applicant must merely provide a corroborating statement that the deposited biological material is that specifically identified in the application as filed. If the requirements are met, the post-filing addition to the application of a deposit date and accession number at an independent depository will not be considered new matter prohibited by 35 U.S.C. § 132.[34]

As such, a U.S. patent applicant could privately deposit a biological sample on or before the patent application date, identify the deposited material in the disclosure, and then later transfer the sample to a recognized public depository and add the depository data at any time prior to the issuance of the patent. Such a private deposit may be in the inventor's own laboratory or in the laboratory of a colleague, so long as the PTO has access to the samples during pendency and the samples are transferred to a public depository before the patent issues.

For example, in *In re Lundak*, the inventor deposited a biological sample necessary to his invention in the laboratory of a colleague.[35] After filing a patent application that identified the privately held sample, the inventor transferred the sample to the American Type Culture Collection (ATCC) and amended his application with the accession number and deposit date. The Federal Circuit held that for the purposes of 35 U.S.C. § 112, it was "*not material whether a [biological] sample … resided in the [inventor's] hands or the hands of an independent depository as of filing date.*" [36]

As another example, in *In re Argoudelis*, Argoudelis deposited biological material with a depository prior to filing the patent application but restricted access to the deposit during the pendency to persons authorized by the patent

applicant.[37] The court found the deposit met the requirements of 35 U.S.C. § 112 despite the restriction on public access, because access would be unrestricted after patent issuance.[38] Similarly, in *Feldman v. Aunstrup*, Aunstrup deposited biological samples at a recognized depository in the Netherlands before his filing date, but restricted deposit availability to his designees.[39] These restrictions were removed before the patent issued. The court found the deposit sufficient because the PTO could access the deposit through Aunstrup during application pendency, and the public was assured access upon issuance.[40]

To the contrary, many foreign jurisdictions require a deposit to be made before the filing date of the priority application to obtain foreign priority rights. For example, an applicant who deposits biological material after filing a U.S. provisional application but before filing a PCT application will be unable to benefit from the U.S. provisional application priority date to the extent it is dependent on the deposit. As such, to fully preserve foreign rights, an applicant should make any deposit of biological samples before the priority application is filed.[41]

Examples of jurisdictions that require deposits to be made before the filing date of the priority application include Australia, Canada, China, and the European countries that are members of the European Patent Organization (as established by the European Patent Convention). While certain of these jurisdictions provide means of correcting for a late deposit, such remedies often require that (1) the failure to deposit be the result of an error in judgment or an omission that led to the failure to deposit (such error not being the failure to deposit itself and not including intentional delay, for example, for strategic or financial reasons) or (2) the applicant be able to declare that, although a deposit was not made, the biological sample was nevertheless available to the public on the filing date of the application. Because the successful use of such remedies is not a foregone conclusion, it is highly encouraged that any deposit be made prior to the filing of an application that may be called to serve as a priority document for an international application.

Again, while a post-filing, pre-issuance deposit is sufficient for the purposes of a U.S. patent application, this approach may not fully preserve foreign patent rights.

5. WHERE IS BIOLOGICAL MATERIAL DEPOSITED?

A U.S. applicant may deposit biological materials in any of the 35 International Depositary Authorities (IDA) recognized by the World Intellectual Property Organization (WIPO) under the Budapest Treaty.[42] Signatory countries (64, as of 2006),[43] including the United States, are required to recognize a biological deposit made in any depository institution approved by WIPO, no matter the location. Under the Budapest Treaty, storage time is required to be at least 30 years, and after the applicant has made the deposit, it cannot be reclaimed. Furthermore, the depository has a duty of secrecy concerning the fact of a deposit and the nature of the deposited material.

Only two of the 37 IDAs recognized by WIPO are in the United States—the American Type Culture Collection (ATCC) in Manassas, Virginia, and the Agricultural Research Service Culture Collection (NRRL, acronym based on former name) in Peoria, Illinois. But as of 1999, these two U.S. depositories held 51.6% (or 20,461 deposits) of the world's total patent-related biological deposits.[44] As an example of applicable fees, the ATCC charges US$2,500 for a patent-related deposit. This fee includes viability testing, a deposit certificate, 30 years of storage, release of samples according to deposit rules, quarterly informing report of distribution of released materials, and regulatory compliance reviews.[45]

A recent report from the U.S. Government Accounting Office (GAO) compiled empirical data regarding the deposit practice in the United States.[46] The GAO reported that about 0.6% of U.S. patents (308 out of 52,841) granted during the final three months of 1999 were supported by biological deposits in the two IDAs in the United States. Of these, only 53 patents (about 0.1%) were supported by biological deposits of seeds. The ATCC, one of only four IDAs accepting seed

deposits, estimated that less than 8% of its total deposits were for seeds.

An applicant should also maintain his or her own samples of the biological material during the term of deposit. As discussed above, unavailability of biological material necessary to practicing the invention is a defect that cannot be cured after the grant of a patent and can result in unenforceability. The applicant's practice of maintaining his or her own samples for the duration of the patent protects against any circumstances wherein samples would no longer be available from the depository.

6. WHO IS ENTITLED TO SAMPLES OF DEPOSITED BIOLOGICAL MATERIAL?

During pendency of an application, a deposit incorporated into a patent application specification need not be available to the public, but must be available to the PTO.[47]

After issuance of a patent, deposited biological material that is incorporated into the specification by accession number must be freely available to the public.[48] That is to say, all restrictions on availability of the deposit to the public must be irrevocably removed upon granting of the patent, unless the request is not made according to proper procedures. As a small measure of protection, a depositor can contract with the depository to require that samples of a deposited biological material will only be furnished if the request is in a dated writing that contains the name and address of the requesting party and the accession number of the deposit, and the depositor is notified in writing of such a request.[49]

The deposit of biological material in a recognized depository is not a grant of a license, either express or implied, to infringe the patent. Furthermore, the release of deposited material from the depository to others does not grant them a license, either express or implied, to infringe the patent. The ATCC, for example, provides a standard disclaimer in its catalogs, reference guides, and to recipients of cultures: "*This material is cited in a United States and/or other Patent and may not be used to infringe the patent claims.*" [50] Regardless, a depositor should supplement this disclaimer with a letter tailored to each notification of request for samples, making it clear there is no implied or express license covering the biological materials received from the depository.

The number of samples estimated to have been released worldwide to legally entitled parties in 1999 was estimated at 7,400. In that year, the ATCC released about 7,000 samples, or 95% of the worldwide total. In comparison, NRRL (the other recognized U.S. depository) released 123 samples, European IDAs released 190 samples, and a Japanese IDA released 63 samples.

In its recent report to Congress, the GAO was unable to identify a single documented case in which a person or organization had gained access to a biological deposit and then used it to infringe the underlying patent.[51] This lack of findings was based on court cases, representatives from the biotechnology industry, and officials from PTO, ATCC, NRRL, and WIPO.

7. CONCLUSION

The rules governing biological deposits in support of a patent application provide a means of curing potentially fatal patent defects, as well as flexibility in the preparation of the application. As discussed above, a biological deposit can in some cases satisfy the requirements of enablement, written description, and best mode, and potentially broaden the scope of claims in the event of litigation. A deposit will usually be necessary only when words fail to explain how to make and use the invention, but an applicant may reference a deposit even when not required. While a deposit can be made at any time during pendency of a U.S. application, those seeking foreign rights are advised to deposit before the filing of any priority application. A U.S. applicant can deposit in any of the 35 IDAs recognized by WIPO, with two of these in the United States The public will have free access to biological materials deposited in support of an issued patent, but the patent owner is somewhat protected by receiving information regarding who receives such deposits. ■

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1 The views expressed in this article are those of the authors alone, and should not otherwise be attributed to the firm or its clients. The author's law practice is concentrated in biotechnology, biochemical, and pharmaceutical patent preparation and prosecution, as well as validity/invalidity and infringement opinions and counseling related to patentability and freedom to operate.

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3 *Ex parte Maizel*, 27 USPQ2d 1662 (BPAI 1992).

4 35 U.S.C. § 112, ¶ 1.

5 *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 1326 (Fed. Cir. 2002); See *In re Wands*, 858 F.2d 731; 8 USPQ2d 1400, 1403 (Fed. Cir. 1998).

6 27 USPQ2d 1492 (BPAI 1993).

7 228 F.3d 1338 (BPAI 1987), 56 USPQ2d 1332 (Fed. Cir. 2000), *cert. denied*, 121 S. Ct. 1957 (2001).

8 6 USPQ2d 1652 (BPAI 1987). See *Ex parte Jackson*, 217 USPQ 804 (BPAI 1982); *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) (limiting enablement of generic claims covering bacterial vaccine of hybrid *S. typhi* bacterial species to the extent of deposited species where there were no working examples outside of deposited species and unpredictability in the hyperconjugation procedure used to produce the strains).

9 MPEP § 2163 (2003) (citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565 (Fed. Cir. 1997)).

10 See *supra* note 5, at 1325.

11 See *supra* note 5, at 1327.

12 222 F.3d 1347, 55 USPQ2d 1650 (Fed. Cir. 2000).

13 *Wands*, 858 F.2d, at 736.

14 *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 856, 112 S.Ct. 169, 116 L.Ed.2d 132 (1991).

15 *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 US 947 (1987).

16 *Amgen*, 927 F.2d 1200.

17 See *supra* note 16.

18 *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

19 37 C.F.R. § 1.801.

20 37 C.F.R. § 1.809(d).

21 MPEP § 2402.

22 See *Amgen*, 927 F.2d, at 1211.

23 *Ajinomoto*, 228 F.3d, at 1345, 56 USPQ2d at 1337–1338.

24 *Wands*, 858 F.2d, at 735–736.

25 Compare *In re Metcalfe*, 410 F.2d 1378, 161 USPQ 789 (CCPA 1969).

26 37 C.F.R. § 1.805(a). During a PTO proceeding (such as, for example, the prosecution of a patent application, the reissue or reexamination of a patent, or an interferences proceeding), the PTO will not recognize a replacement deposit by the patent owner if the depository could still provide samples of the original deposit. MPEP § 2407.06.

27 MPEP § 2411.04. A replacement deposit made in connection with a reissue or reexamination shall not be accepted unless a certificate of correction is requested. MPEP § 2407.02.

28 MPEP § 2411.04.

29 MPEP § 2407.03.

30 MPEP § 2411.04.

31 See 37 C.F.R. § 1.802; *Hybritech, Inc. v. Abbott Laboratories*, 849 F.2d 1446, 7 USPQ2d 1191 (Fed. Cir. 1988); *Amgen*, 927 F.2d, at 1211; *Wands*, 858 F.2d, at 735.

32 Compare *Jackson*, 217 USPQ 804 (isolation procedure required undue experimentation so deposit was required) *with Hata*, 6 USPQ2d 1652 (biological materials obtainable through routine experimentation and a reliable screening test did not require deposit).

33 37 C.F.R. 1.804; MPEP § 2406.

34 *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985).

35 See *supra* note 36.

36 *Lundak*, 227 USPQ, at 93–94.

37 434 F.2d 1390, 168 USPQ 99 (CCPA 1970).

38 *Id.*, at 1393 ("It is not necessary that the general public have access to the culture prior to the issuance of the patent").

39 517 F.2d 1351, 186 USPQ 108 (CCPA 1975).

40 See *supra* note 39, at 1355.

41 See MPEP § 2406.03.

42 *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*, 32 U.S.T. 1241 (April 28, 1977) www.wipo.int/treaties/en/registration/budapest/trtdocs_w0002.html. A listing of the IDAs as of May 17, 2006 www.wipo.int/treaties/en/registration/budapest/pdf/idalist.pdf.

43 WIPO, Budapest Treaty Contracting Parties, Status as of May 17, 2006 www.wipo.int/treaties/en/documents/pdf/budapest.pdf.

44 U.S. General Accounting Office, Report to Congressional Committees GAO-01-49, *Intellectual Property: Deposits of Biological Materials in Support of Certain Patent Applications*, at 9 (Oct. 2000) www.gao.gov/new.items/d0149.pdf.

45 ATCC. 2004. *Patent Depository Expanded Services and Fee Changes for 2004* www.atcc.org/Services/PatentFees.cfm.

46 See *supra* note 44, at 9.

47 *Lundak*, 227 USPQ at 93–94.

48 37 C.F.R. § 1.808 (a)(2).

49 37 C.F.R. § 1.808.

50 ATCC. 2004. *Use of Patent Cultures*, www.atcc.org/Services/PatentMore.cfm.

51 See *supra* note 44.