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Biological Deposits Necessary for Patent Protection: An Expansion of Permissible Procedure—In re Lundak, 773 F.2d 1216, 227 U.S.P.Q (BNA) 90 (Fed. Cir. 1985)

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BIOLOGICAL DEPOSITS NECESSARY FOR PATENT PROTECTION: AN EXPANSION OF PERMISSIBLE PROCEDURE—*In re Lundak*, 773 F.2d 1216, 227 U.S.P.Q. (BNA) 90 (Fed. Cir. 1985).

I. INTRODUCTION

The standard for biological deposits necessary for compliance with the enablement provisions of the Patent Act of 1952 (codified at Title 35 U.S.C.) has been altered by the Federal Circuit Court of Appeals in *In re Lundak*.[1] Before *Lundak*, patent applications dependent on the use of biological materials[2] called for the deposit of a biological sample in an independent depository, out of the inventor's control, on or before the filing date.[3] The *Lundak* decision now permits an inventor to retain control of the deposit during prosecution of the patent application, so long as the public is guaranteed access to the invention upon issuance of a patent grant.

At first impression this modification of the deposit procedure appears to be relatively innocuous. However, the decision inserts uncertainty and potential for abuse into the protocol for biological deposits. The attractiveness of post-filing deposits is outweighed in most cases by the risk of losing foreign patent protection through failure to deposit on or before filing. In addition, the practical need to provide adequate corroborating evidence of the chain of custody of the deposit from private hands to an independent depository acts as a further disincentive to depositing after the filing date.[4] Thus, pre-filing deposit of the biological material remains the safest route to sufficient disclosure of the patentable subject matter required for attainment of both foreign and domestic protection of proprietary rights.

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1. 773 F.2d 1216, 227 U.S.P.Q. (BNA) 90 (Fed. Cir. 1985). Lundak's patent has since issued under the designation U.S. Patent No. 4,594,325.

2. UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 608.01(p) (5th ed. 1983) [hereinafter MPEP] requires a deposit "[w]hen the invention depends on the use of a microorganism which is not . . . known and readily available." *See infra* note 17. In practice, the deposit requirement has been extended to cover biological materials other than microorganisms. *See infra* note 3. This Note focuses on biological inventions that require a deposit, while recognizing that some biotechnological products and processes (i.e., those that utilize biological materials that are known or currently available to the public) do not require deposit. *See infra* note 7.

3. Biological materials requiring deposit include: strains of microorganisms newly isolated from the environment; plasmids, expression vectors, viruses, microorganisms, and more complex living cells containing recombinant DNA; mutated microorganisms or cells; and hybridomas and monoclonal antibodies. Lundak's patent application involved an immortal mouse cell line and hybridomas. *See infra* note 35.

4. *See infra* Part IV.A.1.b.

II. THE DEPOSIT REQUIREMENT AND BIOLOGICAL PATENTS

A. Rationale and Purposes of a Deposit Requirement

A patent grants an inventor "the right to exclude others from making, using, and selling the invention throughout the United States."[5] In exchange, the public receives an "enabling" disclosure of the invention that allows a person who is technically familiar with the field of the invention to "make and use the same" without undue experimentation.[6] For some classes of biological patent applications, patent law requires deposit of a sample of the biological material,[7] in addition to submission of a written application. The deposit requirement ensures a quid pro quo of public access to a biological material necessary for enablement in return for the patent monopoly. The rationale for the deposit requirement is that patents covering biological materials cannot be described by words alone.[8] Scientific knowledge has not yet progressed to the point where living cells can be recreated from a written description (the specification), absent necessary starting materials. Therefore, a deposit is required to complement and render enabling a written disclosure of a patentable microorganism or cell line.[9]

5. 35 U.S.C. § 154 (1982). A patentee receives exclusive rights to the invention for a 17-year period.

6. 35 U.S.C. § 112, para. 1 (1982) states:

> 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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The public should not be required to reisolate or recreate the particular biological material that is the subject matter of the patent application; therefore, with many biotechnological inventions a deposit is required. However, if all necessary starting materials are known and readily available, a deposit may not be required. *See* MPEP § 608.01(p). In addition, a deposit demonstrates that the invention was completed at the time of filing.

The deposit requirement is thought to be supported in law by 35 U.S.C. § 114, para. 2 (1982), which addresses models and specimens: "When the invention relates to a composition of matter, the Commissioner may require the applicant to furnish specimens or ingredients for the purpose of inspection or experiment." The Patent Office does not maintain depositories of its own, but rather prescribes standards to be met by recognized, independent depositories, such as the American Type Culture Collection or the Northern Regional Research Laboratory. The American Type Culture Collection will be used as the prototype independent depository throughout this Note; however, other independent depositories are recognized as sufficient to fulfill the enablement requirement of 35 U.S.C. § 112, para. 1 (1982).

8. *Lundak*, 773 F.2d at 1220, 227 U.S.P.Q. (BNA) at 93.

9. For a review of the deposit requirement generally, see Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. PAT. OFF. SOC'Y 569 (1985); Meyer, *Problems and Issues in Depositing Microorganisms for Patent Purposes*, 65 J. PAT. OFF. SOC'Y 455 (1983). The Patent and Trademark Office (PTO) relies on 35 U.S.C. § 112, para. 1 (1982) to support the deposit requirement. *See* MPEP § 608.01(p). Deposits have also been analogized to an "incorporation-by-reference," a device frequently used for including outside material in the specification by reference only. *Ex parte* Schmidt-Kastner, 153 U.S.P.Q. (BNA) 473, 474 (PTO Bd. App. 1963).

A deposit verifies that the invention has been reduced to practice,[10] and eliminates any need for the public to do significant experimentation to obtain a starting material or the patentable invention itself. Upon deposit, a sample of the invention, or of a biological element required to make and use the invention, is then available to the Patent and Trademark Office (PTO) for inspection, if necessary.[11]

Under the enablement requirement of 35 U.S.C. § 112, para. 1,[12] the deposit of a biological specimen in conjunction with a written specification fulfills two purposes : (1) it provides the public and the PTO with access to the deposit, and (2) it creates prima facie evidence that the date of invention is the filing date of the application.[13] The procedure by which these purposes are fulfilled has evolved over time.[14]

B. Public Access to a Deposit

Originally, the deposit procedure required unrestricted public access to all deposited material as of the filing date.[15] *In re Argoudelis* redefined public accessibility in 1970.[16] In *Argoudelis,* the inventors had deposited on or before the filing date of the application, but had restricted public access to the deposit during pendency of the application.

The Court of Customs and Patent Appeals held that the statutory requirements of section 112 were met by deposit in an independent depository that restricted public access until after issuance of the patent.[17] The court

10. Actual reduction to practice demonstrates that an invention is operable, i.e., *has* been reduced to practice. *See infra* notes 29–30 and accompanying text. Constructive reduction to practice means that there is essentially no question, *at filing,* that the invention is capable of being reduced to practice; it further demonstrates that no technical problems remain to be solved, and no undue experimentation will be required, before one skilled in the art is able to make and use the invention. *See In re* Argoudelis, 434 F.2d 1390, 1395, 168 U.S.P.Q. (BNA) 99, 104 (C.C.P.A. 1970) (Baldwin, J., concurring); *infra* notes 23–30 and accompanying text; *cf.* note 33.

11. Inspection may be necessary, for example, if a question arises during prosecution regarding enablement on the filing date. Access to the deposit during pendency is determined by the Commissioner of the PTO in accordance with 35 U.S.C. § 122 (1982) or 37 C.F.R. § 1.14(e) (1985). However, in practice the PTO rarely, if ever, requests a sample of a deposit for inspection.

12. *See supra* note 6.

13. *See Argoudelis,* 434 F.2d at 1394–95, 168 U.S.P.Q. (BNA) at 103–04 (Baldwin, J., concurring).

14. *See generally* Note, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That Is the Question,* 52 FORDHAM L. REV. 592 (1984); Note, *Patent Protection for Microbiological Processes: Has* In re Argoudelis *Been Mutated?,* 1984 WIS. L. REV. 1679 (1984).

15. *See Argoudelis,* 434 F.2d at 1392, 168 U.S.P.Q. (BNA) at 101 (quoting *Ex parte* Argoudelis, 157 U.S.P.Q. (BNA) 437, 443 (PTO Bd. App. 1966, 1967)).

16. 434 F.2d 1390, 168 U.S.P.Q. (BNA) 99 (C.C.P.A. 1970).

17. The court noted four factors relating to permanent availability of the deposited microorganism: (1) the deposit was made in a public depository; (2) the depository was operated by a department of the U.S. Government; (3) the depository had a contractual obligation to place the deposit in a permanent

reasoned that for examination purposes, the PTO could gain access to the deposit, if necessary, through the inventor during pendency. Approval of restricted access during pendency is only reasonable; written descriptions of all patents are kept secret during pendency.[18] By restricting access to a deposit before issuance, an inventor avoids giving competitors access to a deposit during prosecution of the application. The depositor thus retains a significant head start on deriving any patentable improvements on the biological material. Further, restricted access prevents public disclosure until the depositor is assured of patent protection for the invention. After *Argoudelis*, an application requiring a deposit would not receive a section 112 rejection for lack of public access upon issuance unless the examiner believed that the written disclosure plus deposit would not be enabling when the patent issues.[19] The *Argoudelis* decision was subsequently incorporated into Patent Office guidelines for microbiological inventions.[20]

The depositing procedure accepted in *Argoudelis* was broadened in 1975 by *Feldman v. Aunstrup*,[21] which held that Aunstrup's restricted access deposit of a specimen in a foreign depository met the requirements of section 112.[22] Since the restrictions on access in *Feldman* had been lifted at

collection, and to supply samples to persons entitled to receive them; and (4) there was no suggestion that the deposit would change or become unusable. *Id.* at 1394, 168 U.S.P.Q. (BNA) at 103.

18. 35 U.S.C. § 122 (1982) states that "[a]pplications for patents shall be kept in confidence . . . and no information concerning the same given without authority of the applicant or owner unless necessary to carry out the provisions of any Act of Congress or in such special circumstances as may be determined by the Commissioner." *See also* 3 D. CHISUM, PATENTS § 11.02[4] (rev. 1986).

19. *See supra* notes 5–9 and accompanying text.

20. MPEP § 608.01(p) contains guidelines, issued by the PTO, that set forth minimum standards for a sufficient, enabling deposit:

> (1) [T]he applicant, no later than the effective U.S. filing date of the application, has made a deposit of a culture of the microorganism in a depository affording permanence of the deposit and ready accesibility [sic] thereto by the public if a patent is granted, under conditions which assure (a) that access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122, and (b) that all restrictions on the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent;
>
> (2) such deposit is referred to in the body of the specification as filed and is identified by deposit number, name and address of the depository, and the taxonomic description to the extent available is included in the specification; and
>
> (3) the applicant or his assigns has provided assurance of permanent availability of the culture to the public through a depository meeting the requirements of (1). Such assurance may be in the form of an averment under oath or by declaration by the applicant to this effect.

21. 517 F.2d 1351, 186 U.S.P.Q. (BNA) 108 (C.C.P.A. 1975), *cert. denied*, 424 U.S. 912, 188 U.S.P.Q. (BNA) 720 (1976).

22. The four factors enumerated in *Argoudelis* were interpreted to be sufficient, but not mandatory, for an enabling deposit. *See Feldman*, 517 F.2d at 1355, 186 U.S.P.Q. (BNA) at 112. In particular, the *Feldman* court held that use of a private depository not operated by the United States Government, and not operated within the United States was enabling. *See id.* at 1356, 186 U.S.P.Q. (BNA) at 113; *see also supra* note 17.

the time of decision, public access upon issuance was assured. As in *Argoudelis,* the PTO could obtain access during pendency through the inventor, and deposit at the time of filing was held to constitute reduction to practice.[23] Thus, after *Feldman,* use of either foreign or domestic independent depositories adequately fulfilled the enablement requirement of section 112.

C. *The Doctrine of Constructive Reduction to Practice*

The second aspect of the enablement requirement of 35 U.S.C. § 112, para. 1 establishes the filing date of a patent application as the prima facie date of invention.[24] The doctrine of constructive reduction to practice applies to inventions that have not been successfully made or carried out on or before the filing date, but that could be reduced to practice on the filing date.[25]

If two or more inventors develop similar inventions very close in time, the inventor that first reduces the invention to practice is entitled to priority.[26] In determining priority of invention, three elements are considered: (1) date of conception (mental discovery of the means and ends of the invention); (2) date of reduction to practice; and (3) reasonable diligence by the inventor, from the date of conception to the date of reduction to practice, in perfecting the invention and pursuing a patent.[27] The date of reduction to practice becomes significant if an inventor needs to prove priority of invention.[28]

Demonstration of reduction to practice of an invention verifies that a product or process has been, or could be, made or performed successfully

23. *Feldman,* 517 F.2d at 1354–55, 186 U.S.P.Q. (BNA) at 112–13. On the filing date, Aunstrup's invention was "fully capable of being reduced to practice . . . [and] the second function of § 112, first paragraph—that of establishing the application filing date as the prima facie date of invention—was satisfied by Aunstrup's specification." *Id.* at 1355, 168 U.S.P.Q. (BNA) at 113.

24. *See supra* notes 13, 23 and accompanying text.

25. *See infra* notes 26–32 and accompanying text.

26. *See* 3 D. CHISUM, PATENTS § 10.01 (rev. 1986). Two exceptions to this general rule should be noted: (1) an inventor who is the first to conceive the invention, but the last to reduce it to practice, may get priority upon a demonstration of reasonable diligence in reducing the invention to practice that began before the first reduction to practice; and (2) the first to reduce to practice cannot get priority if the invention is abandoned, suppressed, or concealed. *Id.*

27. *See* 35 U.S.C. § 102(g) (codifying prior decisional law). *See generally* 3 D. CHISUM, PATENTS § 10.03[1] (rev. 1986).

28. Priority rules focus on conception, actual reduction to practice, and constructive reduction to practice, in that order. In contrast, proof of priority emphasizes the same elements in reverse order (constructive reduction to practice, actual reduction to practice, conception). *See* 3 D. CHISUM, PATENTS § 10.03[1][c] (rev. 1986). For example, an inventor might have to prove an earlier date of actual reduction to practice or an earlier date of conception to establish priority over another inventor. *See also infra* notes 29–32 and accompanying text.

on or before the filing date of the application.[29] The doctrine of constructive reduction to practice is based on two premises: (1) actual reduction to practice is unnecessary to issuance of a valid patent (i.e., while the invention is still just an idea, it is perfectly capable of working and so is no less an invention); and (2) as a matter of law, the date of filing should be taken as the date of reduction to practice.[30]

If the disclosure of the patent application meets the requirements of 35 U.S.C. § 112, para. 1, for every type of patent the filing date constitutes a constructive reduction to practice.[31] The inventor is entitled to use the filing date as the date of reduction to practice for priority and patentability purposes, even though the invention may not be actually reduced to practice, because the application as filed allows another to practice the invention. In contrast, an applicant demonstrates actual reduction to practice of the invention when a described process is performed or a product is synthesized; the invention is thus proven operable.[32]

In the context of patent applications covering biological compositions of matter, deposits are tangible evidence of an invention (a product) actually reduced to practice. By requiring a deposit upon application, the filing date represents the latest date of actual reduction to practice of the biological material,[33] as well as the date of constructive reduction to practice imposed by patent law.

In summary, before *Lundak* and for applications requiring a deposit, disclosures were considered enabling under 35 U.S.C. § 112, para. 1 if: (1) the PTO or authorized third parties[34] could gain access to the deposit during pendency of the patent application (restricted public access permitted); (2) the public was assured of access to the deposit upon issuance of the patent; and (3) the deposit was placed in an independent depository, out of the inventor's hands, on or before the filing date, to fulfill the reduction to practice requirement. *Lundak* represents a clear departure from the requirement for transfer to an independent depository by the filing date in order to satisfy the enablement requirement of 35 U.S.C. § 112, para. 1.

29. Under 35 U.S.C. § 101 (1982), patentable inventions include "any new and useful process, machine, manufacture, or composition of matter." However, this Note deals exclusively with products and processes, the types of inventions most commonly arising in biotechnology patent applications.

30. *See* 3 D. CHISUM, PATENTS § 10.05[2] (rev. 1986). The second premise avoids the difficulty of demonstrating an earlier reduction to practice in most cases. However, where junior and senior applicants are claiming priority, either applicant may establish an earlier date of invention by demonstrating earliest reduction to practice through proper supporting evidence.

31. *See* 3 D. CHISUM, PATENTS § 10.05[1] (rev. 1986).

32. *See id.* § 10.06.

33. The possibility that a deposited sample may not be actually reduced to practice cannot be ruled out, since actual reduction to practice requires not only making the invention, but also testing it for its desired results.

34. *See supra* note 11.

III. THE *LUNDAK* DECISION

A. Facts

Lundak sought patent protection for a cell line useful for the production of monoclonal antibodies.[35] This claim was unquestionably of a type requiring a deposit.[36] Through inadvertence, Lundak's application was filed approximately one week before the cell line was deposited with the American Type Culture Collection (ATCC), a recognized PTO depository.[37] Prior to and after filing, Lundak maintained his cell line in his own laboratory at the University of California, and in the laboratories of colleagues at that university and elsewhere.[38] Lundak subsequently deposited the cell line with ATCC approximately one week after filing. The examiner rejected Lundak's claims under section 112 for non-enablement, due to the late deposit. In response, Lundak embarked on a series of legal challenges, culminating in a Court of Appeals for the Federal Circuit (Federal Circuit)[39] opinion that modified the deposit requirements under 35 U.S.C. § 112, para. 1.

B. Board Decision

Following the Patent Office examiner's final rejection of the claims, Lundak petitioned the Commissioner of Patents, requesting a post-dating of his application to the date of deposit. The Commissioner denied the petition, in the belief that the application was complete for purposes of assigning a filing date.[40]

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35. Lundak's claims encompassed (1) an immortal human B-cell line and (2) a hybridoma produced from the fusion of an immune lymphocyte and such immortal B-cell. The immortal cell line was obtained through a process of mutagenesis and selection. For a general description of hybridoma techniques and monoclonal antibodies, see Milstein, *Monoclonal Antibodies*, 243 SCI. AM. 66 (1980).

36. The entire series of *Lundak* opinions refer only to deposit of the immortal cell line of the first claim, but do not refer to the hybridoma of the second claim, which results from "the fusion of an immunized lymphocyte and a cell line according to Claim 1." *Lundak*, 773 F.2d at 1218, 227 U.S.P.Q. (BNA) at 91. Immunized lymphocytes are well-known, and since the cell line of claim 1 required deposit, all necessary starting materials for constructing a hybridoma according to the second claim were known and readily available. *See supra* note 2. Thus, no additional deposit was needed for enablement of claim 2.

37. *See supra* note 7.

38. *Lundak*, 773 F.2d at 1219, 227 U.S.P.Q. (BNA) at 92.

39. The Federal Circuit was created by a 1982 Act of Congress, so that all patent cases would be adjudicated by one court of appeals. Congress intended to provide uniformity and stability to appellate patent decisions. The Federal Circuit came into existence on October 1, 1982, and is bound by the precedent of the Court of Customs and Patent Appeals.

40. After denial of his petition by the Commissioner, Lundak brought a mandamus action in the Federal Circuit regarding the Commissioner's refusal to post-date his application. The mandamus action was consolidated into the instant appeal of the examiner's section 112 rejection for non-

Lundak then appealed the examiner's 35 U.S.C. § 112, para. 1 final rejection to the PTO Board of Appeals,[41] arguing that deposit after filing, but before issuance, met the requirements for enablement. The Board of Appeals en banc held the deposit inadequate for enablement at filing.[42] *Argoudelis* and *Feldman* were distinguished by the Board, because both involved deposits made before or on the filing date.[43]

Although Lundak's cell line was in both his own and his colleagues' hands on the filing date, the Board held that this manner of "deposit" did not guarantee the reliability of maintenance, permanence, or accessibility, as would be provided by a "recognized" depository.[44] The Board further stated that the later deposit was prohibited by the "new matter" provision of 35 U.S.C. § 132,[45] which precludes addition of new matter to the specification after filing of the application.[46] However, six of the eighteen Board members would have allowed Lundak to supplement the record to prove chain of custody from his laboratory to ATCC deposit.[47]

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enablement, since both actions arose from a common factual situation. *See Lundak*, 773 F.2d at 1220, 227 U.S.P.Q. (BNA) at 93.

41. *Ex parte* Lundak, No. 588-11 (PTO Bd. App. Aug. 21, 1984).

42. The en banc panel is indicative of the perceived importance of the case within the PTO. Twelve members believed that Lundak had filed an inadequate disclosure; that is, that someone skilled in the art could not make and use the invention. In addition, Lundak did not provide evidence that the cell line was generally known or available through any reasonable source. *Ex parte* Lundak, slip op. at 9. Two members found evidentiary deficiencies in Lundak's chain of custody from his laboratory to the ATCC, but would have permitted Lundak to prove chain of custody by either (1) filing a continuation application and supplementing the record, or (2) petitioning the Commissioner to reopen the prosecution and then supplementing. A continuation is a second application for the same invention, and may be used to establish a right to further examination by the primary examiner. *See* 35 U.S.C. § 120 (1982); 37 C.F.R. §§ 1.60, 1.78 (1985); *see also Ex parte* Lundak, slip op. at 16–17 (McKelvey, concurring). Four members considered their concurrence to constitute a new ground of rejection; under 37 C.F.R. § 1.196(b) (1985), Lundak could have introduced proper declarations or affidavits to prove sufficient maintenance and chain of custody to overcome the § 112 rejection. *See Ex parte* Lundak, slip op. at 24 (Rzucidlo, concurring).

43. *See Ex parte* Lundak, slip op. at 7–8.

44. *See id.* at 6 n.*, 7.

45. According to 35 U.S.C. § 132 (1982), "[n]o amendment shall introduce new matter into the disclosure of the invention."

46. The present practice of many inventors is to deposit at the time of filing, fulfilling the pre-*Lundak* guidelines for deposit. An application requiring a deposit often contains reference to a timely ATCC deposit (for example, "ATCC Accession No. ————"), and the specific accession number assigned by the ATCC after receipt of the deposit is added later by amendment.

The Board believed that Lundak's 20-year contractual arrangement with ATCC left open the real possibility that the deposit could become non-enabling before termination of the patent monopoly. At the time of reconsideration by the Board, Lundak had extended the ATCC contract. However, to overcome non-enablement Lundak needed to show more than being *in position* to provide an enabling disclosure (i.e., deposit) at some time in the future.

47. *See supra* note 42.

C. *Federal Circuit Opinion*

Lundak appealed to the Federal Circuit, which reversed the section 112 rejection of Lundak's application for non-enablement due to deposit after filing.[48] The court found no controlling distinction between PTO access to Argoudelis' restricted domestic deposit, Aunstrup's restricted foreign deposit in *Feldman,* and Lundak's private deposit at the University of California.[49] The *Lundak* decision thus eliminated the prior mandatory transfer of a physical specimen of the invention to an independent depository on or before the filing date.[50] Although the *Lundak* court did not explicitly have to address the question of timing of transfer to an independent depository, because it had been mooted,[51] the opinion suggested that such transfer must be made *some* time prior to issuance of the patent.[52]

In response to the PTO's argument that a post-filing deposit should be barred as new matter, the court analogized Lundak's deposit one week after filing to material incorporated-by-reference in *In re Hawkins.*[53] In *Hawkins,* the inventor had inserted textual material from cross-referenced, co-pending British patent applications into his United States application after the initial filing date. The *Hawkins* court held that this did not constitute addition of new matter.[54] The *Lundak* court relied directly on *Hawkins,* and distinguished *White Consolidated Industries, Inc. v. Vega Servo-Control, Inc.,*[55] wherein an applicant did not disclose an essential trade secret[56] either during pendency or after issuance.[57]

48. *See supra* note 40.

49. *See Lundak,* 773 F.2d at 1222, 227 U.S.P.Q. (BNA) at 94.

50. In Lundak's case, public access after issuance was no longer in doubt, because he had deposited with the ATCC during pendency and before PTO prosecution.

51. *See supra* note 50.

52. At present, prosecution of a biotechnology patent application may take as long as two to three years, suggesting that the applicant would have this extended period of time in which to deposit.

53. 486 F.2d 569, 179 U.S.P.Q. (BNA) 157 (C.C.P.A. 1973).

54. *Hawkins,* 486 F.2d at 575, 179 U.S.P.Q. (BNA) at 162.

55. 713 F.2d 788, 218 U.S.P.Q. (BNA) 961 (Fed. Cir. 1983).

56. A trade secret may require elaborate precautions to keep an invention from becoming public knowledge. Once the secret is revealed to an unauthorized person, the invention may become accessible to the public, with no return for the inventor or owner of the trade secret. In contrast to patent protection, which is based on a policy of public disclosure of an invention, for trade secret protection an inventor must maintain absolute control of the secret, keeping it from those not entitled to receive the information. Further, enforcement of trade secrets is expensive and difficult. *See generally* WASH. REV. CODE ch. 19.108 (1985) (Uniform Trade Secrets Act); RESTATEMENT (FIRST) OF TORTS § 757 (1939).

57. In *White Consolidated,* the application containing the trade secret was non-enabling as filed. Since no attempt was made to insert the trade secret information, the question of new matter was not addressed. In contrast to Hawkins' previously filed foreign patent applications, Lundak made reference in his specification to an *intended* ATCC deposit. On its facts, *Lundak* appears to be distinguishable from

The Federal Circuit concluded that it was immaterial whether Lundak's cell line was in his hands, the hands of colleagues, or in the hands of an independent depository as of filing. The court believed that an accession number[58] and deposit date would not enlarge or limit the disclosure of the invention. Further, this was not the type of new matter that 35 U.S.C. § 132 was designed to guard against.[59] The court believed that the disclosure as filed satisfied the requirement for reduction to practice as of filing, since the PTO had conceded that the cell line was in Lundak's possession at the time of filing.[60]

The court then addressed the PTO's argument that the deposit procedure approved in *Lundak* would facilitate filing of sham applications. In a brief dismissal of that possibility, the Federal Circuit stated that any post-*Lundak* procedural change should not alter the risk or frequency of sham applications.[61] The court asserted that the examiner has always relied on the inventor's documentation,[62] thereby implying that the pre-*Lundak* protocol was just as uncontrolled and subject to abuse as a procedure permitting deposit after the filing date.

In what may have been an apparent effort to avoid working a perceived injustice against Lundak, the Federal Circuit reversed the PTO Board of Appeals.[63] The court thus eliminated the former bright line rule requiring a

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Hawkins, because unlike Hawkins' British applications on file with an independent agency, Lundak's cell line was not already "on file" in an independent depository. Thus, deposit in university laboratories at filing more closely resembles the trade secret of *White Consolidated*. The court nevertheless concluded that Lundak's reference to intended ATCC deposit was sufficient to avoid a new matter prohibition.

58. A unique accession number is assigned to a deposit upon receipt by an independent depository. The accession number identifies the deposit for the depository and for individuals who wish to order samples of the deposit once it becomes publicly available.

59. *Lundak*, 773 F.2d at 1223, 227 U.S.P.Q. (BNA) at 96.

60. *See Ex parte* Lundak, No. 588-11, slip op. at 15 (PTO Bd. App. Aug. 21, 1984) (McKelvey, concurring).

61. *See Lundak*, 773 F.2d at 1223–24, 227 U.S.P.Q. (BNA) at 96.

62. *Id.* at 1224, 227 U.S.P.Q. (BNA) at 96.

63. In retrospect, several alternatives were available to Lundak or the Federal Circuit which might have provided relief for Lundak's predicament. Prompt filing of a continuation-in-part (CIP) application would have allowed Lundak to add a reference to the late deposit in the specification. Ordinarily, a CIP filed anytime during pendency may use material in the parent application to overcome a reference, or to support priority in an interference action. However, Lundak would have received no benefit from the filing date of the parent application, because the parent was non-enabling as filed. Since Lundak did not promptly file a CIP, thereby securing a filing date that was only days or weeks after the original erroneous filing, the apparent harsh result that would have resulted from denying Lundak's appeal could have been attributed to his own failure to mitigate potential damages by CIP submission.

The court might also have attempted to narrow the *Lundak* decision by permitting a deposit one week after the filing date, when supported by sufficient corroboration of a chain of custody, but only in cases where an applicant demonstrates reasonable diligence in transferring a sample to an independent

deposit that is out of the inventor's hands and in an independent depository as of the filing date to satisfy the enablement requirement of section 112.

IV. ANALYSIS

A. *Consequences Stemming from Elimination of the Pre-*Lundak *Bright Line Deposit Rule*

After the *Lundak* decision, applications encompassing biotechnological inventions no longer need to be accompanied by deposit on or before the filing date. Elimination of this requirement fosters uncertainty in the patent application process, because corroborating evidence offered as proof of reduction to practice as of the filing date must now be evaluated on a case by case basis. In addition, the decision increases the potential for filing of sham applications, and is incompatible with foreign patent requirements.

1. Uncertainty in the Application Procedure

a. Surrender of Objectivity with Approval of Post-Filing Deposit

The *Lundak* decision has injected uncertainty into the deposit procedure, where before there was certainty.[64] The Federal Circuit has receded from the pre-*Lundak* "bright line," objective determination of constructive/actual reduction to practice for biotechnological inventions. Instead, the PTO has been launched onto a "slippery slope" determination of whether the filing date in each case of late deposit in fact represents the date of

depository. Although a determination of reasonable diligence would not be as finite as the "bright line" in existence before *Lundak,* at least the necessary transfer would be made sometime early in the pendency period, rather than allowing transfer immediately prior to issuance of a biological patent.

The Federal Circuit might have elected to post-date Lundak's application to the date of deposit, as Lundak originally requested. However, the Federal Circuit may have been reluctant to directly post-date when a mechanism for indirectly post-dating applications, filing of a CIP, was already in place. Further, post-dating could place an administrative burden on the PTO. By withholding assignment of a filing date until both the written application *and* the deposit have been submitted, the court could have given an inventor significant impetus to deposit as quickly as possible after the written materials had been submitted, in order to obtain the earliest possible filing date. (A later filing date might preclude avoidance of a prior art reference or be fatal to a favorable interference decision.) In contrast, the course chosen by the Federal Circuit encourages postponement of ATCC deposit for as long as possible.

64. Although the expanded Board of Appeals differed as to which of the dual purposes of 35 U.S.C. § 112, para. 1 (1982) (public access on issuance or constructive reduction to practice as of filing) was not met by Lundak's late deposit, the Federal Circuit considered the question of public access to be mooted by Lundak's ATCC deposit one week after filing. The court's opinion therefore focused on the aspect of constructive reduction to practice. *See supra* notes 26–32 and accompanying text.

invention. While the *Lundak* decision does offer certain benefits to inventors,[65] any benefits derived from case by case adjudication are outweighed by the sacrifice of certainty.[66]

Before *Lundak,* the biotechnological applicant had to make an objective showing of reduction to practice (possession of the biological material) by means of a written disclosure *with deposit* on or before the filing date, in cases where a deposit was required. By permitting post-filing deposits, any showing of reduction to practice by a late depositor must now be subjectively reviewed on an individual basis by the PTO. The late depositor will need to present adequate corroborating evidence that, as of the filing date, the biological material was in the inventor's hands, and that the same biological material has been deposited with an independent depository, in order to obtain the benefit of the filing date.[67] If the PTO determines that deposit of a biological material is necessary for enablement, and that the invention was not reduced to practice as of the filing date, the patent will be denied on the grounds of non-enablement. While it is unclear what type and amount of corroborating evidence will suffice to prove enablement as of the filing date, the practical importance of the standard for corroborating evidence is immense.

b. Corroborating Evidence

The *Lundak* decision permits an applicant to submit a necessary deposit after the filing date of the written application. In order to guarantee actual/constructive reduction to practice on or before the filing date, late deposits will require corroborating evidence of the chain of custody from private depositories to the ATCC. The PTO has not yet established the standard for such corroborating evidence.[68] The PTO Board of Appeals recently applied

65. *See infra* note 71 and accompanying text.

66. Bright lines in patent law assist competitors and courts in objectively determining the bounds of patent protection, and indicate to applicants the proper conduct necessary to obtain the broadest scope of protection. Prior to *Lundak,* determination of whether a deposit evidenced reduction to practice as of the filing date was straightforward. If the biological material was placed in an independent depository on or before the filing date, the deposit was presumed to demonstrate actual and constructive reduction to practice, and to be sufficient for an enabling disclosure. After *Lundak,* a late depositor will continue to receive a presumption of actual and constructive reduction to practice as of the filing date, but enablement on the filing date must be affirmatively established by adequate corroborating evidence of the chain of custody of the deposit.

67. For biological patents, this will require a showing of actual reduction to practice of the deposited material as of the filing date. *See supra* notes 26–34 and accompanying text (Part II.C.).

68. The PTO has recently issued draft policy guidelines for deposit of biological materials. Pat. Trademark & Copyright J. (BNA) No. 32, at 90 (May 22, 1986) [hereinafter *Draft Guidelines*]. These guidelines require a corroborating statement, but do not detail how much or what kind of evidence will be sufficient.

By analogy to case law on adequacy of corroboration in patent interferences, certain elements may

Lundak in *Ex parte Old,*[69] a case involving private deposit in a research institute. However, in *Old,* the Board did not have to address the standard for corroborating evidence required to prove chain of custody, because the deposit had not been transferred from the Sloan-Kettering Institute for Cancer Research to an independent depository.[70] Corroborating evidence was not reviewed in *Old,* so a biotechnological inventor still faces reasonable uncertainty as to what standard of corroborating evidence might be applied in instances of post-filing deposit of biological materials.

Case by case evaluation of corroborating evidence will also significantly affect the PTO itself. Federal Circuit approval of deposition after filing will lead, in practice, to an increased amount of paperwork and time for reviewing corroborating evidence on a case by case basis. In turn, the workload of examiners will be increased, and longer time periods from filing to issuance will likely result. Logically, for post-filing depositors, more extensive corroborating evidence may be required with increasing time periods from filing date to ATCC deposit date.

An advantage gained by inventors by postponing deposit is elimination of the cost and effort of depositing with an independent depository before receiving assurance that a patent will issue.[71] However, inventors who

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not be required: (1) that the corroboration be present in a single affidavit; (2) that one of the affiants saw the inventor prepare the new microorganism or cell line; and (3) that the affiant understood the significance of the experiment. *See* Berges v. Gottstein, 618 F.2d 771, 205 U.S.P.Q. (BNA) 691 (C.C.P.A. 1980). Factors favorable to a finding of sufficient corroboration include: a highly organized and routinely practiced procedure for identifying, preserving, and testing new strains or cell lines; results of independent testing; absence of contradiction and internal conflict in the evidence; and difficulty in fabricating results. *Id.* at 774–75, 205 U.S.P.Q. (BNA) at 694–95. While it is no longer necessary to prove in detail an unbroken chain of custody in patent interference actions, the requirement for some evidence of independent corroboration, beyond the inventor's testimony, has not been omitted. Since it is uncertain how strict the standard for corroboration of deposits will be, the safest approach would be to document and witness every transfer and storage step leading to actual reduction to practice.

69. 229 U.S.P.Q. (BNA) 196 (PTO Bd. App. 1985).

70. As in *Lundak, Old* resulted in reversal of a section 112 rejection for non-enablement. The applicants in *Old* filed declarations that several hybridoma cell lines had been deposited prior to the filing date at Sloan-Kettering Institute for Cancer Research, asserting that the maintenance practiced at Sloan-Kettering is substantially the same as that practiced by the ATCC. However, in contrast to *Lundak,* the applicants stated that they had no intent to transfer the deposits to the ATCC until *after* receipt of a notice of allowance.

The Board interpreted *Old* in light of *Lundak,* and was similarly convinced that the applicants had demonstrated reduction to practice prior to filing. In addition, public access to the invention was believed assured by the "renown and integrity" of Sloan-Kettering and its professed maintenance procedures. *Old,* 229 U.S.P.Q. (BNA) at 199. The PTO Board of Appeals apparently read *Lundak* as approving private deposit until notice of allowance was sent. The difficulty presented by this reading is that the type and quantity of corroborating evidence required to support storage in private depositories remains an unknown parameter.

71. At the time this Note was prepared, the costs for depositing with ATCC in compliance with international requirements, for example, include: $570 for storage and maintenance for 30 years plus 5 years after the most recent request for a sample of the deposit; $100 for viability testing (optional); $300

choose to exercise the option to deposit after filing are exchanging the ease and certainty that was provided by a pre-filing enabling deposit for the unpredictability of case by case analysis that accompanies post-filing deposits.[72] If a late depositor's corroborating evidence is found to be insufficient, the section 112 rejection for non-enablement will stand and no patent will issue.

2. *Potential for Sham*

The Federal Circuit discounted any increased potential for sham applications in the wake of *Lundak*.[73] A distinct possibility, however, is that *Lundak* might open the door for deposit of improved or switched samples during pendency, rather than deposit of the sample in the inventor's hands at filing. This consequence may arise after *Lundak* because the deposit can remain solely in the applicant's hands up to the time the patent issues.[74]

If a new or improved biological sample is deposited after the filing date, the deposit adds new information to the specification and would be barred as new matter under 35 U.S.C. § 132.[75] Deposit in independent domestic or foreign depositories as of the filing date circumvented any temptation to stretch the definition of what was "in the inventor's hands at filing" because compliance with the pre-*Lundak* procedure meant that the deposit was *out*

for notification to depositors of recipients of a deposit for 30 years (optional); and $10 for immediate notification of the assigned ATCC accession number (optional). *See* ATCC Form 34, *reprinted in* Patent Practitioner's Guide to Deposition and Depositories Worldwide, AIPLA Chemical Practice Comm., Biotechnology Subcomm., Statistics Section (Jan., 1985). In addition, before *Lundak* the inventor may have made multiple deposits to cover all possible PTO enablement requirements; i.e., starting materials, end products, and expression vectors. Thus, for institutional applicants who file numerous biological patent applications each year, depositing can become very costly, particularly because payment is made in advance, before receipt of assurance that the patent will issue.

72. The eventual result of extended time for deposit and uncertainty arising from case by case adjudication might lead to pursuit of trade secret protection instead of patent protection for biotechnology inventions, in a manner analogous to computer software protection.

73 *See supra* notes 61–62 and accompanying text.

74. Pre-*Lundak* procedures entailed a matching of the strain or cell line described in the specification to a specific deposit; improved strains or cell lines could not be added because they would be barred as new matter under 35 U.S.C. § 132 (1982). However, it should be noted that, before *Lundak*, independent depositories did not examine or characterize materials deposited with them, either for viability or content. After *Lundak*, the inventor conceivably could later deposit a biological material that was not in the inventor's hands on the filing date, if the biological material was adequately described in the written specification. The *Lundak* decision might encourage filing of applications for inventions conceived, but not actually or constructively reduced to practice, in order to obtain a United States priority date. In actuality, however, any material reduced to practice after the filing date may be difficult, if not impossible, to identify as the biological material that was in the inventor's hands on the filing date. Further, most inventors would not risk potential loss of patent rights due to insufficient evidence of reduction to practice on the filing date.

75. New matter may include the addition of inherent characteristics, such as chemical or physical properties, a new structural formula, or a new use. MPEP § 608.04(a) (relying on 37 C.F.R. § 1.118 (1985)).

of the inventor's hands at filing. A procedure that opens the door to fraud on the PTO may lead to abuse, especially in light of increasing commercial and financial pressures placed on biological inventors and enterprises to obtain patent protection for technology developed in the laboratory.[76]

3. International Implications/Complications

Foreign patent protection for an invention dependent on a new or unavailable biological material may be precluded by the depositing procedure accepted in *Lundak*.[77] The Federal Circuit decision provides a liberal deposit procedure sufficient for receipt of United States patent protection, but the court did not address potential problems in obtaining foreign patent protection.

Although independent deposit by an inventor after the filing date, when accompanied by sufficient corroboration of the chain of custody, will now allow enablement of domestic patent applications, foreign filing procedures that require the pre-*Lundak* protocol of deposit on or before the filing date will not be met by post-filing deposits.[78] Accordingly, if an applicant for a domestic patent perceives any possibility that foreign patent protection might be sought, the required domestic biological deposit should still be made according to the pre-*Lundak* procedure. Inventors might not elect to follow the more liberal deposit procedures permitted by *Lundak,* in the realization that by taking advantage of such procedures they may be sacrificing potential world-wide patent protection. Commercial realities may therefore limit the practical impact of the *Lundak* decision.

Additionally, the door has been opened for some foreign applicants to obtain domestic patent protection for inventions where foreign patents were

76. Sanctions resulting from fraud on the PTO are discussed at 4 D. CHISUM, PATENTS § 19.03[6] (rev. 1986). Proof of fraud may result in removal of a patent application from PTO files, or in invalidity or unenforceability of a patent.

77. Issuance of a domestic patent only grants patent rights enforceable in the United States. To exclude others from making, using, and selling the invention outside the United States, foreign patent protection must be obtained.

78. Although international policy supports uniformity in patent laws, international deposit requirements are determined by national laws. The European Patent Convention (EPC), consisting of 11 countries, requires a deposit on or before the filing date of the application. *See* EPC Rule 28, *reprinted in* R. CRESPI, PATENTING IN THE BIOLOGICAL SCIENCES, 203–06 app. (1982). *See generally* Comment, *Patenting Microorganisms: Working the Bugs Out of the International Depositary Authority,* 14 CAL. W. INT'L L.J. 49 (1984). The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, T.I.A.S. No. 9768, *reprinted in* 6 D. CHISUM, PATENTS app. 22 (rev. 1986) [hereinafter Budapest Treaty], recognizes deposits made with any International Depositary Authority. According to article 3, no party to the treaty can impose requirements additional to or different from those provided by the Budapest Treaty. Budapest Treaty signatories include: the Federal Republic of Germany, France, Japan, the Soviet Union, the United Kingdom, the United States, and 13 other countries.

not available because of deposit after filing. A foreign inventor who inadvertently or intentionally deposited after filing might now use a foreign filing date for domestic priority, if the domestic application is filed within a year of foreign filing.[79]

Finally, the *Lundak* decision makes the determination of international priority dates of filing much less clear. After *Lundak,* a late deposit is not barred as new matter, and therefore the filing date of the application is the domestic priority date. Although at present a domestic patent application accompanied by a post-filing deposit would preclude use of a United States filing date as a priority date for foreign patent applications, several options might arise. Under one option, in cases of post-filing deposit, foreign filing procedures might assign a priority date of the date of deposit, rather than of the domestic filing date. Second, foreign patent authorities might defer to the domestic patent priority date, and grant that date priority for foreign purposes.[80] Third, foreign filing procedures might be amended to conform with the *Lundak* decision, for achievement of deposit uniformity throughout the world. At present it remains unknown which, if any, of these results will follow from *Lundak.*

B. Future of the Deposit Requirement

Although *Lundak* permits a liberalized deposit procedure, an applicant can avoid submission of corroborating evidence documenting the chain of custody of the deposit by continuing to satisfy the pre-*Lundak* requirements. Fulfilling pre-*Lundak* requirements eliminates the uncertainty and the associated risk of insufficient corroboration. In addition, the temptation to assert in the future that later improvements were known at the time of filing would thereby be avoided. Finally, compliance with foreign patenting requirements may be ensured by depositing on or before the filing date. Therefore, the potential hazards associated with post-filing deposits would appear to outweigh the monetary and practical benefits that may be derived by postponing deposit with an independent depository.

By depositing after the filing date of the application, an applicant loses a presumption of enablement that accrued under the pre-*Lundak* depositing procedure. After *Lundak,* an applicant who chooses to deposit after the filing date must take active steps to establish enablement as of the filing date. In contrast, a deposit on or before the filing date gives rise to a

79. 35 U.S.C. § 119 (1982) describes in more detail the effect of an earlier foreign filing date on a U.S. patent application filed within 12 months from the earliest such foreign application.

80. However, in the reverse circumstance, the United States will not give an applicant benefit from foreign priority documents unless the foreign application complies with the requirements of United States patent law. *See* 3 D. CHISUM, PATENTS § 14.03[3] n.19 (rev. 1986).

presumption of enablement, which may be overcome only by a prima facie showing to the contrary.

The *Lundak* court granted the late depositor benefit of the filing date only after concluding that Lundak's written specification, plus corroborating evidence of *actual* reduction to practice, sufficed to meet the section 112 requirement for enablement.[81] Lundak thus received a presumption (and the benefit) of a priority date as of filing, because he was able to demonstrate that he had actually reduced the invention to practice as of the filing date. The possibility of mere constructive reduction to practice as of the filing date for any biotechnological patent application that currently requires an accompanying deposit apparently continues to be foreclosed after the *Lundak* decision.

The deposit requirement assures that a *particular* end product may be reproducibly obtained. However, in light of rapid advances in biotechnology, commentators currently debate whether a deposit is indeed necessary in every case of biotechnological invention.[82] If certain types of patentable subject matter are relieved of the deposit requirement, constructive reduction to practice of biotechnological inventions could conceivably occur.[83] At present the deposit procedure for biological materials has been modified, and in the future deposits may even be eliminated for

81. Although Lundak did not deposit in an independent depository on or before the filing date, Lundak's 10 pages of written description were held to be more than adequate to demonstrate reduction to practice (possession of the invention), even in the absence of a prefiling deposit. Reduction to practice was further supported with declarations by the inventor and his colleagues, filed during the period between the Board decision and argument before the Federal Circuit, that the cell line was in their hands at filing and was the same as the sample deposited one week later with ATCC.

Although a hybridoma, according to Lundak's second claim, may not have been actually reduced to practice on the filing date, the hybridoma is a type of biological material that did not require deposit, and thus might be constructively reduced to practice. *See supra* note 36. However, the PTO Board of Appeals discussion in *Old,* directed to hybridomas and obviousness, suggests that hybridomas may not be amenable to constructive reduction to practice. *See Old,* 229 U.S.P.Q. (BNA) at 200.

82. The argument hinges as much on technical as on legal issues. *See* Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement,* 67 J. PAT. OFF. SOC'Y 569 (1985); Comment, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That Is the Question,* 52 FORDHAM L. REV. 592 (1984); Note, *Patent Protection for Microbiological Processes: Has* In re Argoudelis *Been Mutated?,* 1984 WIS. L. REV. 1679 (1984).

83. For example, a hybridoma according to Lundak's second claim did not require a separate deposit, because the necessary starting materials were known and readily available. *See supra* note 36. A hybridoma useful for production of a *specific* monoclonal antibody would likely require a deposit, however, since the hybridoma would not be known or readily available. With the sophisticated and reproducible techniques utilized in molecular biology today, a strong argument can be made for the superfluousness of a deposit for selected inventions (for example, plasmids and peptides encoded by a known DNA sequence), where one skilled in the art could reproduce the invention from a written description only. In the future, an inventor might successfully file a biotechnical patent application that does not require a deposit on the basis of constructive, rather than actual, reduction to practice. *See generally* note 82.

certain types of biological inventions. *Lundak,* however, has not yet obviated the legal necessity, arising out of 35 U.S.C. § 112, para. 1, for actual, rather than constructive, reduction to practice for biological inventions that require a deposit for enablement.[84] Therefore, *Lundak* will continue to have a significant impact on procedures necessary to obtain patent protection for certain classes of biological material, because proof of actual reduction to practice, either through a pre-filing deposit or a post-filing deposit with proper corroborating evidence of chain of custody, will still be required.

C. *PTO Draft Policy Guidelines*

The *Lundak* decision has prompted the PTO to draft new policy guidelines covering all biological deposits.[85] As with the previous guidelines,[86] an enabling disclosure under 35 U.S.C. § 112, para. 1 may now be satisfied either by a demonstration that a necessary biological material is "known and readily available" to the public, or by a deposit according to the PTO draft guidelines.[87] Reflecting *Lundak,* the draft guidelines require deposit in a recognized or permanent depository "not under the control of the depositor or patent owner,"[88] prior to or at the time of payment of the

84. Inventors might benefit from the requirement for corroborating evidence that the patentable biological material was in the inventor's hands as of the filing date. In the future the PTO could conceivably derive essentially pre-*Lundak* results (deposit on or before filing) by utilizing tension between 35 U.S.C. §§ 112 and 103 (1982). Section 103 requires that an invention be non-obvious: "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made."

If *Lundak* had permitted constructive reduction to practice of biological materials, reduction to practice through a written disclosure alone by one skilled in the art might be predictable in light of prior art. This level of predictability, in light of knowledge at the time of constructive reduction to practice, might in turn make the invention obvious. In this context, sections 112 and 103 might be pictured as opposite points on a continuum—the more vigorously a biological inventor argues that a deposit is not required to provide an enabling disclosure, the more the specification will be drawn toward a section 103 rejection for obviousness.

85. Draft rules for deposit of biological materials after *Lundak* were released on May 2, 1986. *See Draft Guidelines, supra* note 68.

86. *See supra* notes 2, 20.

87. *Draft Guidelines, supra* note 68, at 90. To provide an enabling disclosure without an accompanying deposit, any necessary biological material must be known and readily available to the public, with no question of continued availability beyond the life of the patent monopoly. *See id.* Factors supporting a demonstration of public accessibility, either alone or in combination, include: (1) commercial availability of the biological material through suppliers that are not controlled by a party/parties with an interest in the patent; (2) reference to the biological material in printed publications; (3) declarations of accessibility to the biological material by disinterested persons in the field of the invention; (4) abundance of the biological material in nature, either in useful form or coupled with a reliable screening procedure; and (5) previous deposit of the biological material according to these guidelines. *See id.* at 91 (I.1-5).

88. Without this limitation, it would be foreseeable that large and then small biotechnology

issue fee.[89] The PTO apparently is not ready to accept continued deposit after issuance in individual inventors' laboratories, even though certain standards for permanence and access are met.[90] By foreclosing the possibility of fulfilling the enablement requirement of section 112 through in-house deposits after issuance, the PTO has at least avoided case by case subjective determination of enablement, and, to the extent possible, minimized the opportunity for abuse and sham.

Other proposed changes from the pre-*Lundak* PTO guidelines include: (1) requirement for a viability statement;[91] (2) assurance of public accessibility to the deposit for at least five years after the most recent request for a sample, or for thirty years, whichever period is longer;[92] and (3) if a deposit is made after the filing date, a requirement for corroboration that the biological material described in the application is the same as that deposited in a recognized depository.[93]

The procedural guidelines for biological deposits drafted by the PTO after the *Lundak* decision are somewhat confusing.[94] If an inventor elects to deposit in a recognized depository on or before the filing date, much of the confusion may be avoided.

In instances of independent deposit after the filing date, the following steps have been envisioned by the PTO. An applicant who has not placed a necessary biological material in a recognized depository on or before the filing date would first receive a rejection under 35 U.S.C. § 112, para. 1 for non-enablement. The applicant could avoid the rejection either (1) by showing that the biological material is "known and available," or (2) by making a deposit and showing a corroborating chain of custody.[95] If the applicant takes neither of these steps, the applicant must assure the PTO that deposit and corroboration will be provided prior to or concurrent with payment of the issue fee. In all instances, and as required before *Lundak*, an applicant must provide the PTO access to the deposit during pendency. If

companies would develop institutional depositories which meet PTO standards. These companies could then file for and receive patent protection strictly on the basis of in-house deposits fully within their control.

89. The depository must be an International Depositary Authority, recognized by the Budapest Treaty, *see supra* note 78, or the sample must be placed in a permanent depository that meets the requirements of a Budapest Depository and is not controlled by the depositor or patent owner.

90. Private deposition could result in denial of public access to the patented subject matter, which would not support the quid pro quo of the patent monopoly system.

91. *Draft Guidelines, supra* note 68, at 91–92 (II.3). A viability statement was previously required for deposits made under the Budapest Treaty. *See supra* note 78.

92. *Draft Guidelines, supra* note 68, at 92 (II.4).

93. *Id.* at 92 (II.5).

94. The *Draft Guidelines* do not expressly state what biological materials are covered. For each biotechnical application requiring a deposit, the PTO will likely request a deposit. Before *Lundak*, the PTO had the burden of making a prima facie showing of non-enablement before requiring a deposit.

95. *Draft Guidelines, supra* note 68, at 92.

either assurance of deposit or deposit itself supported by corroboration is provided, and the subject matter of the application is determined to be patentable, the PTO will mail a notice of allowance of the patent and the rejection for non-enablement will be withdrawn.[96] If the applicant has neither deposited nor provided assurance of deposit before issuance, a request for appropriate deposit under 35 U.S.C. § 132 will be issued by the PTO.[97] The applicant then has a three-month, nonextendable period in which to deposit; otherwise the section 112 rejection will be maintained.[98]

Although procedurally the PTO has accepted declarations of inventors in the past, to ensure prompt public access to the invention, a notice of allowability would be sent. The official notice of allowance could then be reserved until the PTO has received two items: (1) documentation of an ATCC deposit, and (2) sufficient corroborating evidence that the cell line(s) deposited with the ATCC are identical to those in the hands of private depositories or laboratories at the time of filing.[99] The applicant could be given three months to document independent deposit, and failure to do so would result in final 35 U.S.C. § 112, para. 1 rejection for non-enablement. Demanding independent deposit before mailing of a notice of allowance would institute an objective deadline for all post-filing deposits analogous to the pre-*Lundak* requirements for deposit on or before the filing date, and would circumvent the need to subjectively review applicant's

96. *Id.*

97. Under section 132, if omitted requirements are found by the PTO during prosecution, the Commissioner must notify the applicant of the requirement.

98. Reliance on personal assurances might lead to a type of "worst-possible scenario." For instance, assume that after receipt of the PTO notice of allowance, the applicant gives assurance of deposit and pays the required issuance fee. The patent then issues "in regular course." A deposit is now inadvertantly made after issuance, in a situation analogous to Lundak's late filing. The courts might have to invalidate the newly-issued claims, after the time, expense, and effort of a complete PTO examination, because the disclosure would not be enabling upon issuance. If the PTO permitted deposit after issuance when supported by an abundance of corroborating evidence, relying on an applicant being in a position to deposit as of issuance, this would signal entrance to an even more dangerous "slippery slope." Another "bright line" will be exchanged for a "slippery slope" case by case analysis, but this time at a very real and great risk of loss to the public of benefits to be derived from the patented invention.

Alternatively, an applicant might request a deferral of issuance under 37 C.F.R. § 1.314 (1985) upon a showing of necessity, or might extend the three month period for independent deposit through a process of abandonment and revival of the application under 37 C.F.R. § 1.137 (1985) or 35 U.S.C. §§ 133, 151 (1982). The PTO would be likely to freely permit deferrals to allow deposit before issuance, guaranteeing public access to an enabling disclosure, but at the same time pushing back in time the 17-year grant of a patent monopoly. The buffer zone of pendency available in *Lundak* would be diminished or extinguished.

99. Deferring receipt of official PTO notice of allowance may have tax consequences for the inventor. Prior to receipt of a notice of allowance, patent applications are assignable and nondepreciable. Upon receipt of a notice of allowance, patent applications are treated as patents, *i.e.*, as depreciable property under I.R.C. § 1239 (CCH 1985). *See* Myers v. United States, 613 F.2d 230, 205 U.S.P.Q. (BNA) 591 (9th Cir.), *cert. denied*, 449 U.S. 826 (1980).

assurances to the PTO. For many biotechnology inventors, cost/benefit analysis and a desire for preservation of possible foreign patent rights will limit the use of the procedure approved in *Lundak,* at least until both United States and foreign responses to *Lundak* offer more certainty to biological inventors.

V. CONCLUSION

Prior to *Lundak,* the PTO required evidence of deposit in an independent depository on or before the filing date of the patent application, but the inventor could restrict access to the deposit until assured of patent issuance. In *Lundak,* the Federal Circuit placed a stamp of approval on biological deposits placed in recognized independent depositories after the filing date of written patent application materials. In the wake of *Lundak,* an inventor may retain control of a biological material necessary for enablement during prosecution of the patent application. The *Lundak* court may have underestimated the possibility that inventors might abuse this retention of control over deposits. Rather, the court viewed post-filing deposits as part of a rational progression from restricted access to domestic and foreign independent prefiling deposits approved in *Argoudelis* and *Feldman.* Moreover, the *Lundak* court did not address the apparent conflict between post-filing deposits and foreign filing requirements.[100]

The PTO has responded to the *Lundak* decision with new depositing guidelines that permit an inventor to satisfy the section 112 enablement requirement without an independent deposit on or before the filing date. However, the procedure described by the new PTO guidelines may insert uncertainty into procedures for biological deposits. The danger associated with this uncertainty is the possible loss of patent protection in instances of post-filing deposit, due to insufficient evidence to overcome a section 112 rejection for non-enablement. The risk of sacrificing potential patent rights, both domestic and foreign, outweighs any potential benefit derived from depositing in an independent depository upon receipt of PTO assurance that patent protection is forthcoming. Therefore, the safest and most certain course to assured enablement and subsequent issuance of a patent is to disregard the expanded permissible deposit procedure approved by the Federal Circuit in *Lundak,* and to continue to follow the depositing procedures instituted before the *Lundak* decision.

Debra K. Leith

100. Perhaps the court realized that foreign patent requirements would act to moderate the practice of depositing after the filing date, thus reducing reliance on the liberal post-*Lundak* procedure.