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LUNDAK RULING MAY EASE DEPOSIT REQUIREMENTS

WASHINGTON—A recent decision by the U.S. Court of Appeals for the Federal Circuit could relax the muddled rules for depositing biological material that is to be patented.

Robert L. Lundak's 1981 patent application, serial number 247,656 entitled "High Fusion Frequency Fusible Lymphoblastoid Cell Line," was originally rejected because Lundak did not deposit his cell line until one week after he filed for a U.S. patent. The Patent and Trademark Office (PTO) Board of Appeals later affirmed the examiner's rejection. This September, however, the U.S. Court of Appeals reversed the decision, and in so doing may have effectively done away with the requirement of depositing biological substances prior to the granting of a patent.

For a number of years, the PTO has required that inventors deposit samples of biological material at the time of filing in cases where there are uncertainties about the reproducibility of results. The PTO's reasoning seems to have been two-fold: First, the deposit requirement ensured that the PTO would have access to the substance if it so desired. Second, such a deposit was seen as "proof" that the inventor had truly produced what he claimed he had.

In answering the first justification, the Court decided that, in practice, the inventor himself would be able to supply the PTO with any non-deposited material. In answering the second rationale, the Court ruled that the deposit itself is not needed to show "constructive reduction to practice." In the Court's words, "An accession number and deposit date add nothing to the written description of the invention. They do not enlarge or limit the disclosure." Thus, conclude many patent attorneys, deposit is not required now until the date that the patent actually issues. Once the patent does issue, of course, the culture must be placed at an independent depository that ensures permanent availability of the substance.

According to Lundak's attorney, Bertram I. Rowland, "The U.S. has acted as a leader in showing that deposit is not the way to go." Rowland is a partner in the law firm of Townsend and Townsend (San Francisco, CA). He says the most important effect of the decision is that it could open worldwide discussion on what kind of deposit regulations should be enforced. He points to three examples where differences in countries'

rules currently cause complications:

- In Europe, an inventor is allowed to restrict access to the deposited substance until such time as the patent issues. West Germany, however, does not allow this kind of restriction. This means that if an inventor chooses to restrict access while the patent is being examined, any European patent he eventually receives will not be honored by Germany;

- Korea is unusual in its requirement that the inventor deposit the substance in Korea, *regardless* of where else it may be already deposited; and

- Japan only requires deposit of types of organisms that its own depository accepts—those that its depository does not handle need not be deposited.

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In the Lundak case, oversight seems to have been the major reason why the deposit was not made at the time the patent was filed. "This was a very expensive way of correcting an unfortunate error," says Rowland. Lundak reports that he deposited the cell line at the American Type Culture Collection (Rockville, MD) as soon as he was instructed to do so. He adds that he had been making the line available to colleagues prior to then.

Lundak's patent application is assigned to the University of California (Riverside), where he worked before joining Techniclone International (Santa Ana, CA) as president. Says Lundak, "The patent is extremely important because it represents a patent on a cell line that has been shown to be perhaps the best parental line for making human hybridomas at the moment." (Just because the rejection on the grounds of deposit has been reversed, however, does not mean that the patent necessarily will be granted: there could still exist other rejections that have not yet surfaced.)

According to Geoffrey M. Karny, a

patent attorney at the firm of Finnegan, Henderson, Farabow, Garrett & Dunner (Washington, D.C.), the new ruling "allows for more flexibility and removes some disincentives for filing for patents." Karny points out that the decision still leaves a gray area: how far can the deposit requirement be pushed?

"We're trying to make a thoughtful appraisal of the impact of the Lundak decision," reports Charles Van Horn, director of the PTO's Group 120, which is in charge of organic chemistry and biotechnology. He expects to issue proposed guidelines on the subject soon.

The key question brought about by the ruling is how it will affect the deposit practices of future inventors. "If I had another cell line to patent, I would make sure that it is appropriately deposited ahead of the fact," says once-burned Lundak.

Karny perceives few advantages to delaying deposit, and agrees with this conservative approach—especially until the PTO clarifies its position. "I'd probably recommend depositing," he says, "unless you could give me a business reason why you wouldn't want to deposit."

One such reason could involve the European Patent Office's practice of publishing patent applications and making deposited material publicly available 18 months after the priority filing date. This usually occurs before the patent issues, so the material becomes available whether or not the patent is eventually granted. "The advantage to delaying deposit is that I know that 18 months from filing, my competition won't have the development," says Rowland.

Another question about the ruling is how it will affect European patents, because Europe still requires deposit at the time of filing. The inventor has up to one year after he files in the U.S. to file in Europe and still receive the earlier priority filing date. Will he still be able to get this priority date on his European patent if he waits until filing the European application before making the deposit? "The Lundak decision is fine for the U.S.," Karny says, "but, as far as I know, one would probably want to have made the deposit at the time of U.S. filing to meet the European requirements."

Concludes Karny, "I think the ruling does provide some additional flexibility for companies and inventors, which I think is good."

—Arthur Klausner