

Basel, 8 November 1996

European Patent for Key PCR Enzymes to be Awarded to Roche

Scientific Innovation Recognized

The European Patent Office (EPO) will grant F. Hoffmann-La Roche Ltd., Basel, Switzerland, a European patent which broadly covers enzymes with wide utility in an extensive range of scientific and medical applications. This decision is an important success for members of the worldwide scientific community who depend on the patent system for recognition of their innovations.

Covered by the patent will be thermostable enzymes having DNA polymerase activity from any species of bacteria such as Taq DNA polymerase from *Thermus aquaticus*. These enzymes are of particular importance in the Polymerase Chain Reaction (PCR), a major scientific innovation that enables virtually unlimited replication of genetic material. At a hearing on November 6, the Examining Division of the EPO accepted the claims covering *native* and *recombinant* thermostable DNA polymerases, without limitation to a particular species or genus, submitted by Roche. The European patent is expected to be issued within the next six months.

Roche's Patent Portfolio Strengthened

This imminent patent grant reinforces the protection afforded by the European patent system of innovative scientific research. It is a key element in further strengthening the large patent portfolio owned by Roche in the area of nucleic acid amplification technology. Roche has previously been granted patents for thermostable enzymes, as well as for the use of these enzymes in the amplification process, in all major territories of the world.

"The approval of this patent, especially by the expert scientific examiners of the EPO, is an important recognition of the biochemical facts that clearly distinguish the invention of our scientists from prior work and the contributions of our company to making PCR available to basic researchers," said Dr. Thomas White, Vice President of Research and Development at Roche Molecular Systems.

Impact on Ongoing Litigation in the United States

Roche is now in a position to actively protect its own interests in the area of nucleic acid amplification technology as well as those of its licensees. This decision is also important in regard to patent litigation in the United States. Roche is in protracted litigation with the Promega Corporation, which produces and sells Taq in violation of U.S. patent law. "Promega has engaged in a self-serving public relations campaign to misrepresent the clear scientific and patent law facts surrounding this case," said Dr. White. "The EPO decision proves the commitment of European authorities for a strong patent system to protect scientific research. It also represents a solid victory for innovative scientists worldwide who rely on the patent system to protect their inventions," he added.

PCR technology

PCR technology allows very minute amounts of genetic material to be amplified into billions of copies in just a few hours, thereby facilitating the detection of the DNA or RNA of pathogenic organisms, even before antibodies against these organisms can be formed. PCR has a broad range of scientific applicability and is widely used in the medical field for the diagnosis of infectious agents, genetic disease, cancer and other conditions.

The Roche Commitment to PCR

Roche is a leading international research-based health care company. Since acquiring rights to nucleic acid amplification technology less than five years ago, Roche's commitment to this area has made PCR the leading DNA probe technology in the world in a wide range of applications. By simplifying the PCR process, Roche has made PCR accessible to the routine diagnostic laboratory through the introduction of a broad menu of pre-packaged and standardized PCR-based test kits under the trade name AMPLICOR.

Roche's most recent achievements in the PCR area are the introduction in 1995 of the COBAS AMPLICOR, the first system to automate the PCR process, and the U.S. launch in 1996 of the AMPLICOR HIV-1 MONITOR Test, the first test approved by the U.S. Food and Drug Administration to accurately and precisely measure the quantities of HIV-1 RNA in the blood (viral load). Roche's commitment to advancing the PCR technology is further demonstrated by its widespread licensing of this technology, including granting licenses to more than 400 diagnostic laboratories around the world.

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