The patent system is created to encourage innovations and innovative activities on which science development, technological progress and economic growth may depend. It is also designed to compensate the inventors for their creative work and, at the same time, guarantees that new knowledge and new technologies based on that knowledge are available to society. However, it is extremely challenging to maintain an optimal equilibrium between the admissibility of the activities intended to promote innovativeness and the scope of the rights conferred by a patent. To keep that balance the patent system has developed varied mechanisms, among which a research (experimental use) exemption plays a principal role.

This exemption to patent rights, allows researchers to use patented subject matter for carrying out research and experiments without the necessity of applying for a license from the patent rights holder. The research exemption is supposed to secure progress in science and technology against difficulties and obstacles caused by a patent monopoly. The subject and scope of this exception are different for different legislative regulations, Also the views about its real impact on technological progress are various. According to some, the research exemption is very beneficial, whereas according to others it is quite the opposite – the research exemption weakens a patent, which in turn weakens incentive to invest in new techniques and technologies. Even among supporters of the research exemption there is no consensus about its optimal form, that would ensure legislative possibility of freedom in conducting scientific research and would not destroy a patent value, which is the exclusive right to benefit from commercial exploitation of the invention.

This diversity of opinions is reflected in patent acts of EU countries and in judicial decisions. On the one hand, there is a tendency to broaden the research exemption, on the other hand, to narrow it down. However, both the research exemption doctrine proponents and opponents point to the necessity of the consistent interpretation of the research exemption conception, due to its growing importance to the patent system and especially to pharma and biotech industry.

Patents and licenses for genetic inventions seem to stimulate research, knowledge transfer, and introduction of new technology into markets. The 1998 European Directive on the protection of biotechnological inventions (EC/98/44), which specifies that patents should only be granted if a specific gene function is identified, remains an important step in establishing balance in this area across Europe. Biological materials and processes have for decades been recognized by patent authorities as patentable. However, for about a decade, some countries have expressed concerns in how certain genetic inventions and patents have been licensed and exploited, particularly for diagnostic genetic services in the field of human health care.

The OECD member countries, in consultation with interested parties, stated that guidelines setting out the principles and best practices for licensing of genetic inventions used for human health care purposes would be an appropriate and measured adequate response to the identified difficulties (OECD Council of the Recommendation on the Licensing of Genetic Inventions on February 23rd, 2006). Experts, on the other hand, are debating whether to limit the claims of patents for genetic invention only to the functions disclosed in the patents.

Finally, in accordance to last years facts, Myriad Genetics and the University of Utah Research Foundation are appealing a decision rendered in March 2010 that found that the company’s BRCA gene patents are “unpatentable.” A US District Court has ruled that claims in seven patents supporting a widely used genetic test for inherited breast and ovarian cancer susceptibility are invalid. The plaintiffs called the patents illegal on the basis that they restrict both scientific research and patients’ access to medical care and that patents on human genes violate patent law because genes are “products of nature”. The decision is likely to be challenged in a legal appeal — but if upheld, it could have huge implications for the biotechnology industry. Despite their patentability, debates remain about the international harmonization of patent and licensing practices for genetic inventions and identified implementation of the European Directive.
ICGEB's policy guidelines on its rights to intellectual property

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Article 14 of the ICGEB Statutes considers issues related to inventions resulting from ICGEB scientific research: publication of results, vesting of all rights in the Centre for work produced or developed by its researchers, patents policy, access to intellectual property rights by Member States and the use by the Centre of its intellectual property rights. In particular, while stressing that the ICGEB shall publish all results of its research activities, the same article indicates that it shall be the policy of the Centre to obtain patents on results developed through projects of the ICGEB and that the latter shall use any financial or other benefits associated with its IPRs to promote the development, production and wide application of biotechnology, predominantly in the interest of developing countries.

The process of filing patent applications for inventions deriving from the scientific research of the three Components of the ICGEB (in Trieste, New Delhi and Cape Town), is presently regulated by the “Policy Guidelines on Patents, Licensing, Copyrights and other Rights to Intellectual Property”, adopted by its Board of Governors in November 2000. Within the ICGEB Directorate an internal service has been established to monitor all instances related to possible ICGEB patent applications. This includes direct contact between inventor(s) and Patent Attorneys entrusted with the filing of the applications at National and/or International Patent Offices, in compliance with the provisions of the Patent Co-operation Treaty (PCT) and the European Patent Convention (EPC). This service also oversees the finalisation of Agreements with industrial partners for the transfer of technology and for the license of ICGEB patented know-how.

The approach of the ICGEB on the use of its intellectual property is basically derived from its status and mandate in favor of its Member States. However, at this stage an overall revision of the current ICGEB policies may become necessary, resulting in a proper compromise that keeps into due consideration its statutory requirements and the overall philosophy of the Centre. In this case the effort should be directed at seeking a commitment from ICGEB licensees to commercialize/ manufacture in ICGEB Member States at fair, affordable costs, involving whenever possible local production capacities, or building those same capacities, as the case may be.