# Policy Guidelines on Patents, Licensing, Copyrights and other Rights to Intellectual Property of the International Centre for Genetic Engineering and Biotechnology (ICGEB)

Adopted by the Board of Governors under Article 6(2)(e), (8) of the Statutes, at its seventh session (New Delhi, 13-14 November 2000)



## I. ICGEB Statutes and Intellectual Property

1. One of the basic objectives of the ICGEB is "to promote international co-operation in developing and applying peaceful uses of genetic engineering and biotechnology in particular for developing countries", "to develop and promote the application of genetic engineering and biotechnology for solving problems of development, particularly in developing countries", and "to assist developing countries in strengthening their scientific and technological capabilities in the field of genetic engineering and biotechnology" (Article 2(a), (d), (c) of the Statutes).

2. Towards the fulfilment of its objectives, the ICGEB shall in particular "carry out research and development including pilot-plant activities in the field of genetic engineering and biotechnology", "carry out a programme of bio-informatics to support in particular research and development and application for the benefit of developing countries", and "maintain close contacts with industry" (Article 3(a), (h), (j) of the Statutes).

3. The means for the practical achievement of the objectives of ICGEB are twofold: on the one hand the publication of all results of its research activities is mandatory, "provided such publication does not contravene its general policy regarding rights to intellectual property approved by the Board", on the other hand "patent and other rights, and any financial or other benefits associated herewith" shall be used (Article 14(1), (5) of the Statutes).

4. Patent and other intellectual property rights are thus assigned a key role to play for the successful achievement of the objectives of ICGEB. Even the mandatory publication of all results of its research activities is subordinated to the general policy regarding intellectual property as laid down by ICGEB's Board of Governors.

5. The legal basis for an effective utilization of rights to intellectual property is secured by the ownership of ICGEB in "all rights, including title, copyright and patent rights, relating to any work produced or developed by the Centre" (Article 14(2)of the Statutes). As far as results of genetic engineering and biotechnology developed through projects of the Centre with third

parties are concerned, the ICGEB is obliged to follow the policy "to obtain patents or interests in patents" thereon (Article 14(3) of the Statutes).

6. ICGEB's Board of Governors under Article 6(2)(e) of the Statutes is, in principle, free to adopt in its general intellectual property policy, its own rules on the exploitation of the research results of the Centre, as well as on access to intellectual property rights therein, provided that those rules are in accordance with Article 14 of the Statutes. Thereunder, Member States and developing countries that are not Members of the Centre, shall be granted access to such intellectual property rights "in accordance with applicable international conventions" (Article 14(4) of the Statutes). Moreover, ICGEB rules regulating access to intellectual property shall not establish criteria prejudicial to any Member or group of Members.

7. Thus, under the Statutes, the intended objective for patents and other intellectual property rights owned by the Centre and for the financial or other benefits associated herewith, is to promote the development, production and wide application of biotechnology, predominantly in the interest of developing countries. Patents are expected to offer at the same time effective incentives for ICGEB's own research and development activities and the utilization of the results of those activities must aim at providing additional funds for the Centre's research work, and at backing up the transfer of the results of research and development into developing countries. They will be particularly needed in the latter respect when substantial investments in developing countries will be necessary for the introduction and application of the biotechnology at hand.

## II. General Intellectual Property Policy Considerations

1. Intellectual property rights in general and patents in particular have played and continue to play an important role in the rise, the development and the application of the modern biotechnology. More recently it has also been generally accepted that the patent system is well suited to be utilized as the primary mechanism for transferring inventions from publicly funded institutions to the private sector. The successful U.S. Federal Technology Transfer legislation adopted in 1986, for instance, is based on this idea. Licensing of patents held on publicly funded research thus enhances wide application of the protected technology in industry and commerce and at the same time secures additional financial means for the technology-generating institutions.

2. The effects of patents and other intellectual property rights are limited to the territory of the state(s) for which they are issued, registered or acquired. In countries where no protection is sought or no patents issued, inventions can be freely utilized. Whereas copyright protection, for instance of computer programmes, does not depend on the fulfilment of any formalities, nor on the payment of any fees, but only upon the fact of creation of the work and its eligibility for copyright protection, patents are issued in a formal patent granting proceedings, which requires the filing of a patent application nationally or by using existing international conventions, such as the Patent Co-operation Treaty (PCT) or the European Patent Convention (EPC), the payment of all sorts of fees (e.g. for filing, search, examination and maintenance) and eventually depends upon the fulfilment of the highly sophisticated patentability requirements.

3. Costs related to acquiring, maintaining, licensing and defending patents and other intellectual property rights are substantial. Statistics published for U.S. universities, which successfully license their technologies, reveal that in 1992 for example, Stanford University spent 1.8 Mio US $, the Massachusetts Institute of Technology (MIT) 2.88 Mio. US $ and Harvard University 0,91 Mio US $ for the respective legal fees. ICGEB's decision whether and where to file patent applications for a specific research result, quite apart from the patentability requirements, shall consider, *inter alia* the following aspects: The potential general commercial value of the invention at hand; the potential specific commercial value of the invention at hand for all or a Member State and/or any specific developing country not Member.

The potential general commercial value is decisive under the aspect of the generation of additional income of the Centre, which shall be achieved by protecting the technology and its subsequent licensing in developed countries; a specific commercial value of a technology for a Member State and/or a developing country not Member is to be assumed in particular when the introduction and application of the technology at hand is of particular importance for that country and requires substantial investments of the private sector, which will not be effected if no proprietary rights will subsist in that technology.

4. For inventions, the potential general commercial value of which is affirmed by the ICGEB Director, patent applications shall be filed in all countries in which the respective inventions could potentially be successfully exploited and where ICGEB could potentially find commercial partners (licensees). ICGEB shall use all possibilities offered by international conventions, such as the Paris Convention for the protection of industrial property, as regards the priority right of 12 months and the PCT, for subsequent international filing and designation of as many PCT contracting states as advisable. All cost saving possibilities shall be used. Also, the time between the priority filing and the final decision on the subsequent designations shall be utilized for further evaluation of the commercial potentials of the invention at stake and for the search for suitable commercial partners.

5. When, for an invention with an affirmed potential general commercial value, a priority patent application is filed, the ICGEB shall inform of that filing, without delay, all Member States. Within four months from the receipt of the information on the patent filing, however, not later than eight months from the priority date, Member States shall notify the ICGEB of their specific interest in the invention and its utilization and whether or not a subsequent filing should be effected for their country. Such notification shall be effected by interested Member States through a written procedure to be established by the Director, specifying all the commitments that they are undertaking. The ICGEB shall follow the respective requests of the Member States. However, the ICGEB shall be free to file subsequent patent applications also in those Member or non Member States, which did not so request, if it deems such subsequent filings appropriate either for purposes of successful commercialization or for wide application of the respective biotechnology in that particular country. In the latter case, the ICGEB shall inform the respective Member State accordingly. The access to patented technology in that Member State as guaranteed under Article 14(4) of the Statutes shall be negotiated between the ICGEB and the respective Member State, if the latter so requires.

6. On inventions without affirmed potential general commercial value, which seem to meet the patentability requirements, the ICGEB shall without delay and confidentially inform Member States. Member States shall inform the ICGEB within three months from the receipt of the respective information of their specific interest in the invention and whether and in which countries patent applications for that invention should be filed. The interest of a Member State will be notified through a written procedure as per paragraph 5 above. The ICGEB shall follow the respective requests of the Member States and file a priority application no later than two months from the date of the receipt of request. Member States which requested the patent filing shall remain responsible for all the subsequent policies related to the respective rights.

7. It is understood that, whenever the ICGEB will acquire intellectual property rights, the rules of applicable national or regional law and international conventions, as the case may be, will be strictly observed. In particular, the provisions of the Convention on Biological Diversity (CBD) and national and regional laws implementing that Convention, relating, inter alia, to prior informed consent, benefit sharing, transfer of technology, etc., as well as the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, will be paid full tribute.

## III. Ownership of Intellectual Property Rights

1. Staff Rules and Regulations of ICGEB shall provide that staff members of the Centre have to vest in the Centre all rights including title, copyright and patent rights, in any work performed by them as part of their official duties.

2. Visiting fellows temporarily integrated in the research work of the Centre shall be subjected to the same treatment as staff members for any work result performed by them in the framework of a research project of the Centre.

3. Collaborative research activities of the Centre with Affiliated Centres and Networks should be seen, essentially, as part of the national R&D programmes implemented by the Member States; as such, the results emanating from this research, should, in all objectivity, belong to the Institute and to the scientists who have actually carried it out. However, since the Centre, and through the latter all its Member States, has contributed to the research and to the possible patentable results of the concerned Affiliated Centre, the latter will make those results available to other Member States under conditions (if any) which are more favourable than those normally implemented on the market.

4. In the case of collaborative research activities of the Centre with industry, the ICGEB shall secure in respective contracts its rights in the results of collaborative research activities commensurate to its intellectual and financial contributions. Such rights may be title in patents or other intellectual property rights, but may also be title in down payments and/or royalties for the utilization of such work by the industrial partner as trade secret.

5. In case of inventions protected upon the request and at the expenses of a Member State or Member States due to its potential specific commercial value for the respective Member State (countries), the patent will be co-owned by the ICGEB and by the respective Member State.

## IV. Transfer of Technology

1. Under the direct supervision of the Director, the ICGEB Administration shall be responsible for facilitating the transfer of ICGEB technology to the public use and benefit in particular for developing countries. ICGEB evaluates, obtains proprietary protection and assists in the distribution of technology, for research purposes; it also assists in the commercial development of selected technologies by identifying potential markets and negotiating license agreements as set forth in these Guidelines.

2. The Director, assisted by the Heads of Component and by the Programme and Administrative Co-ordinator, shall in particular, evaluate the protection requirements and the general commercial potential of the notified inventions; decide on the filing of patent applications or starting legal actions against potential infringers, as well as on the concluding of licensing agreements related to patents and other intellectual property rights vested in the Centre. The Administration shall also negotiate agreements under Article 14(4) of the Statutes with Member States and developing countries not Members.

3. In the fulfilment of these responsibilities the Director may seek assistance from external advisors, such as patent attorneys, attorneys at law, firms specialized in commercializing intellectual property rights, etc., as the case may be.

4. Costs for protecting, commercializing and defending patent and other intellectual property rights of affirmed general commercial value in which the Centre has vested rights, shall be borne by the regular budget of the Centre. As a rule, and on a yearly basis, they should not exceed 0.5% of the annual budget of the Centre.

5. Costs for protecting, commercializing and defending patent and other intellectual property rights upon the request of Member States shall be borne by the respective requestor(s).

6. Should the proceeds from the successful commercialization of patent and other intellectual property rights vested in the Centre, or in which the Centre holds title respectively, allow so, the Director may decide to set-up an Office of Technology Transfer; the costs involved in the operation of the Office would be covered by these proceeds.

## V. Rules of Procedure

These Rules of procedure shall be applied to patents and all other intellectual property rights and be mandatory for all staff members of the Centre, as well as for visiting fellows temporarily integrated in research projects of the Centre.

### (i) Intellectual Property Rights

1.1 A patent is a grant issued by a state authority (patent office) of a given country conferring on the inventor or his (her) successor in title the right to exclude all others from making, using, offering for sale, selling or importing the invention in the territory for which the patent is issued, for a period of 20 years from the filing date. In some countries (e.g. the United States, Spain and other countries of the European Union) and in the case of pharmaceutical and agro-chemical inventions, this period can be extended up to five years, through the obtention of a Supplementary Protection Certificate.

1.2 Following the adoption of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) in 1994, Members of the World Trade Organization (WTO) are obliged to make patents available for any inventions whether products or processes, in all fields of technology provided that they are new, involve an inventive step (are "non-obvious"), are capable of industrial application ("useful") and are disclosed in a manner sufficiently clear and complete to enable a person skilled in the art to reproduce them (Articles 27(1) and 29(1) TRIPs). Transitory periods of 5-10 years have been introduced for WTO Members developing or least developed countries.

1.3 However, WTO Members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals, as well as plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than micro-biological processes. However, plant varieties have to be protected in all Member States either by patents or by an effective *sui generis* system or by any combination thereof (Article 27(3) (b) TRIPs).

1.4 The Centre may wish to exploit an invention which cannot be exploited without infringing a previous patent and which involves an important technical advance of considerable economic significance (a dependent invention); in this case, the Centre should seek dependency compulsory license from the authorities of the countries of interest and under the laws in force in those countries (Article 31(l) TRIPs).

1.5 Although discoveries as such are not eligible for patent protection in all countries, naturally occurring substances including biological material such as genomic DNA sequences, plasmids, viruses, tissues, or cell lines of microbial, plant, animal or human origin and monoclonal antibodies respectively, can be patented in most countries, provided they were not known before the filing date. Moreover, the inventor must disclose a teaching as to how those products can be put at the disposal of the public at will and for which purpose (function) they can be used. The same is true for methods for the production of such products by selection,

cultivation, biochemical synthesis and the like. Patents are in particular available also in case such methods are used for the production of intermediates and/or end products, e.g. drugs to be employed in, for instance, somatic gene or somatic cell therapy.

1.6 Apart from the United States of America and Slovenia, where a grace period of 12 months from the first written or oral public disclosure of an invention by the inventor is available, and Japan with a more limited 6 month grace period, an invention is unpatentable in all countries unless the application is filed before public disclosure, whether written or oral: e.g.: contributions to the ICGEB annual Activity Report, scientific manuscripts, posters and presentations at open meetings or conferences, etc.

1.7 Under the first to file principle, applied in all countries but in the United States, the inventor or his (her) successor in title who first files a patent application for a specific invention, is entitled to the patent. He retains this right when subsequently filing applications in other countries by claiming the priority right of the first filing under the Paris Convention for the Protection of Industrial Property. In the United States of America, however, the right to the patent is with the person who has first made the invention. Since the changes of the US law of 1996, this principle is applicable without any discrimination also to inventions made outside the United States. Thus, the Centre can acquire patent rights in an invention in the United States and prevail over other US or third country inventors if the invention at hand was first made by the ICGEB researchers and provided this fact can be proven by laboratory protocols (notebooks), witnesses, and the like, even in case the Centre was the second of even third applicant.

2.1 Certificates for new varieties of plants are issued at present in more that 30 countries, but will have to be made available according to the new TRIPs rules in all those WTO Members which will not offer patent protection for inventions of plant varieties. The basic principles of national laws regulating protection of new varieties of plants follow the lines set forth in the International Convention for the Protection of New Varieties of Plants (UPOV Convention) adopted in 1961 and subsequently revised in 1972, 1978 and 1991.

2.2 Under the UPOV type of protection plant varieties are eligible for protection if they are new e.g. not yet commercially exploited, distinct, uniform and stable. Under the 1978 UPOV Act, the scope of protection is restricted primarily to the commercial marketing of the reproductive material of the variety. Therefore, the end product, the fruits, leaves, etc., is not covered_ and the Contracting States are allowed to limit protection to plant varieties the genus or species of which is contained in an official list of protected taxa attached to the national legislation. Moreover, breeders enjoy the so-called "breeder's privilege" or "research exemption" which gives them the freedom to use protected plant varieties in their breeding programmes to generate other (derived) varieties. Farmers, on the other hand, are allowed to save part of the seed from the first crop of plants of the protected variety for sowing on their own farms to produce a second and subsequent crops ("farmer's privilege"). Under the 1991 UPOV Act the "breeder's privilege" _with_regard to essentially derived varieties as well as the "farmer's privilege" have experienced substantial limitations and the scope of protections has been broadened so as to cover, under certain circumstances, also the end product. However, this revision of the UPOV Convention entered into force only for those States Parties that had ratified it, while other States continue referring to the 1978 Act.

3. A copyright confers on the owner the exclusive right to reproduce the work, prepare derivative works, distribute by sale or otherwise, and display or perform the work publicly. Copyright subsists in "original works of authorship". In some countries, such as for instance the United States, copyright depends on the fixation of the work in any tangible medium of expression from which they can be perceived, reproduced of otherwise communicated, either directly or with the help of a machine or device. Copyright protection extends to expression and not to ideas, procedures, methods of operation or mathematical concepts as such. Under Article 10 TRIPs WTO Members are obliged to protect by copyright computer programmes as well as

compilations of data or other material, whether in machine-readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations. However, such protection does not extend to the data or material itself.

4. A trade or service mark is any sign or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings. They may facilitate the commercialization of the technologies of the Centre.

5. Under the laws of all WTO Members natural and legal persons are offered the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information is secret in the sense that it is not as a body or in the precise configurations and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question, has commercial value because it is secret, and has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret ("trade secrets").

6. Biological materials and computer software, regardless of their possible patent or copyright protection, shall be treated as Tangible Research Property (TRP) of the Centre and shall be subject to these Guidelines.

### (ii) Notification and Clearance for Publications

1. Group Leaders shall notify to the Director the presence of any invention, computer software or any other kind of technology developed by staff Members of the Centre and visiting fellows temporarily integrated in research projects of the Centre, as a part of their employment duties.

2. The ICGEB Administration, in co-operation with the Group Leader concerned, shall investigate the protection requirements of the notified technology and evaluate its potential general commercial value. It will subsequently act as provided for under II.4.-6. above of these Guidelines.

3. Group Leaders shall ascertain, prior to their submission to scientific journals, organizers of scientific conferences and the like, that any scientific manuscript, poster, slide, transparency, etc., does not constitute a disclosure of a technology which would or could be patentable; similarly, Group Leaders should be satisfied that no disclosure (such as a detailed description to be included in the ICGEB Annual Activity Report) is made on technologies for which a patent is in the process of being filed.

4. The Director, in co-operation with the Heads of Components, may be requested to examine the content of documents intended to be used for scientific presentations or articles in order to investigate whether they contain patentable inventions or other information eligible for protection by other intellectual property rights and to evaluate their potential general commercial value. In case the documents contain patentable inventions of potential general commercial value, the ICGEB shall take all steps necessary for filing a patent application securing the priority right within 60 days.

## VI. Commercial Development

1. It is acknowledged by the Statutes that the primary objectives of ICGEB in many cases can be sufficiently achieved by the mere publication of research results. In other cases, however, it is necessary to encourage industry, by the granting of license rights, to invest its resources to develop products and processes for use by the public, particularly in developing countries.

2. The ICGEB will pursue the licensing of technology owned by the Centre by researching the market for the technology, identifying third parties to commercialize it, entering into discussions with potential licensees, developing a business plan, negotiating appropriate licenses or other agreements, monitoring progress, and distributing royalties to the inventors/authors in accordance with the distribution scheme set forth in these Guidelines.

3.1 In case of inventions of potential general commercial value, the Director will negotiate with potential partners from developed as well as from developing countries non-exclusive or exclusive licensing agreements, depending on the market conditions and in particular depending on the amount of investments necessary for the successful exploitation of the technology at stake. Although preference shall be given to non-exclusive licenses, exclusive licensing agreements can be justified. Such agreements can relate to the use of patents, certificates for the protection of new varieties of plants, secret know-how (trade secrets), copyrights as well as TRP.

3.2 In negotiating a license agreement with an industrial partner, the Director shall take into consideration established precedents and will follow, in as much as the negotiating strategy will allow, the model of agreement attached as enclosure I. Moreover, in establishing a fair price (down-payment) for the release of the license, due attention shall be given by the Director to the costs incurred by the Centre for the research activities that lead to the patented invention, the administrative expenditures related to the filing and the maintenance of the patent and, whenever applicable, the costs for the development of the invention. The total or partial recovery of these expenditures through the license agreement will depend on the type of agreement (exclusivity/non exclusivity), the country in which the industrial partner operates (Member State/ non-Member State) and the economic situation of the latter (developing/industrialized country).

3.3 In case of inventions protected upon the request and at the expenses of a Member State or Member States due to its potential specific commercial value for the respective Member State (countries), the Director or the respective Member State shall negotiate the conditions of the licensing agreements with third parties in co-ordination with the respective country (countries) or with the Director, as the case may be. Prior to concluding such agreements, the Director or the respective Member State shall get the approval of the respective Member State, which has acted as requestor, if they so require, or of the Director, as the case may be.

4. It shall be the policy of ICGEB not to commit future inventions to licensees even where improvements to technology are anticipated. Some very narrowly drawn exceptions may occasionally be appropriate to handle subordinate patents and well-defined derivative works for licensed software.

5. Any dispute arising from the licensing of intellectual property rights owned by ICGEB shall be settled in accordance with the arbitration rules established by the United Nations Commission on International Trade Law (UNCITRAL) as at present in force.

## VII. Tangible Research Property

1. Biological TRP owned by the Centre, may usually be distributed for research purposes only, with minimal conditions attached. Any such distribution is subject to an agreement by the recipient that commercial development or commercial use or further transfer of the biological material is not to be undertaken. The Administration shall provide the Group Leader responsible for such material at the Centre with the necessary forms. In addition, the Group Leader may wish to control subsequent use of the material, for example, by requiring recipient to follow a specific research protocol in the use of the biological materials.

2. If there is a possibility of biohazard or other risk associated with the transport, storage, or use of a particular biological TRP, or if the recipient is likely to use the TRP for clinical research, ICGEB should be covered by appropriate disclaimers of liability and indemnities.

3. TRP may have potential commercial value as well as scientific value, and the Group Leader who may wish to make TRP available for scientific use in a manner which does not diminish its value or inhibit its commercial development should seek guidance from the Director.

## VIII. Trade and Service Marks

Trade and Services Marks owned by ICGEB are to be licensed through the Centre. Any exceptions to this procedure must be approved in advanced by the Director or his appointed representative.

## IX. Royalty Distribution

Royalty income received during the preceding ICGEB fiscal year for a technology license shall be distributed in accordance with the following scheme:

1. In case of inventions of potential general commercial value (as per paragraph VI-3.1 above), for which the Centre has covered all the costs of filing and maintaining the relevant patent:

- From the Gross Royalty Income, deduct 15% for Administrative Expenditures as well as all the costs sustained. The resulting amount will be the Net Royalty Income which shall be divided as follows:
- 1/3 to the inventor(s), with a ceiling of US$ 200,000 per year and 5% of any sum in excess to that ceiling;
- 1/3 to the research budget of the Group in which the inventor(s) operate(s), with a ceiling of US$ 200,000 per year and 5% of any sum in excess to that ceiling;
- 1/3 to the ICGEB General Fund, plus 90% of the sums in excess of the ceilings of US$ 200,000 described above.

2. In case of inventions protected upon the request and at the expenses of a Member State or Member States (as per paragraph VI-3.2 above):

- From the Gross Royalty Income, 15% for Administrative Expenditures will be deducted and retained by the ICGEB, while the costs sustained for filing and maintaining the patent by the Member State(s) that has/have requested the protection will be reimbursed to that/those Member State(s). The resulting amount will be the Net Royalty Income which shall be divided as follows:

- 1/3 to the inventor(s), with a ceiling of US$ 200,000 per year and 5% of any sum in excess to that ceiling;
- 1/3 to the research budget of Group in which the inventor(s) operate(s), with a ceiling of US$ 200,000 per year and 5% of any sum in excess to that ceiling;
- 1/6 to the ICGEB General Fund, plus 45% of the sums in excess of the ceilings of US$ 200,000 described above.
- 1/6 to the Member State(s) that has/have requested the protection, plus 45% of the sums in excess of the ceilings of US$ 200,000 described above (in case of several Member States being involved, this amount will be shared on an equal basis among them).