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Additional disclosure requirements regarding origin of biologic materials in patent applications (Dnr 114-1436-04)

Background:

The matter regarding additional disclosure requirements on the origin of biologic materials in patent applications has been submitted for consideration to SwedenBIO from the National Board of Trade and the Swedish Foreign Ministry. The process has been initiated by discussions within a number of international bodies¹ on the future design and implementation of the patent systems and its relation to international agreements like the Convention on Biological Diversity (CDB). SwedenBIO is the Swedish national biotechnology industry organization and represents about 80 biotechnology companies and their partners. Today the membership base comprises over 80% of the employees active in the Swedish biotechnology industry within the area of healthcare biotechnology.

The comments below focus on two separate areas. The SwedenBIO position and arguments will be explained under “comments”. Firstly, the overall topic of additional disclosure requirements will be commented upon. Secondly, given that a sanction system becomes reality, the views of the biotechnology industry are presented how such a system should be drafted.

Summary:

SwedenBIO considers that additional disclosure requirements regarding the origin of biological material should not be included in the present patent system. Possible sanctions connected to this should also be regulated outside the patent law. The objective of the patent system is to facilitate innovation – not the division of profits between stakeholders generated from successful innovation. Still, SwedenBIO have an understanding for developing countries aiming to get access and share profits from innovations originating from genetic resources present in their countries. Regulations for this have to be detailed and decided upon in systems separate from the patent system and we encourage the international community to act on this issue. It is necessary to find a solution that is acceptable by the developing countries, the industrialized countries and the industry overall.

¹ Including WTO, WIPO and CDB

Comments:**1: Additional disclosure requirements for biological material in patent applications**

Position: SwedenBIO considers that additional disclosure requirements regarding the origin of biological material should not be included in the present patent system. Instead, separate systems should be designed to handle these conflicts, but these should be organized outside the patent system.

Selected arguments:

1. The present patent system aims at increasing the welfare and development of society by regulating a balance between a granted, time-limited, exclusive right (patent) and common access to a certain innovation and technology. The patent does not regulate or give any rights regarding the use of previously known subject matter or other materials (including biological materials) as they occur in nature. To use the patent system as an instrument to regulate areas, which it was not intended to regulate, is therefore principally wrong.
2. Today, similar requirements as the proposed disclosure are already in place. The present patent system requires innovations to be described in a reproducible and operational manner. This means that the origin of biological materials is in practice almost always provided in order to comply with these disclosure requirements. The introduction of additional disclosure requirements would risk imposing “double work” and increasing an already considerable burden on patent applicants.
3. Biological matter and genetic resources do not recognize national borders and a specific biological material and species are present and used in many countries and continents. The introduction of additional disclosure requirements would risk opening up costly and complicated secondary disputes on the origin of biological material between countries, regions and ethnic groups.

Results:

Additional disclosure requirements would complicate an already complex system. Increased costs and a more complicated application process would be counterproductive in encouraging innovation and economic prosperity in both developing and industrialized countries. New conflicts will potentially appear and the patent system would be forced to settle disputes in situations it was not designed to handle.

Proposed sanctions:

Position: SwedenBIO considers that sanctions supporting the disclosure of data on the origin of biological material should lie outside the patent system. Instead, the international community should develop and finalize regulations concerning the use of biological material and the division of profits from these in general.

Selected arguments:

1. Sanctions with similar objectives are already in place and work, if the strict basic patent law requirements for patent applications are considered. This means that the introduction of sanctions would not add value, instead the efficacy of the present system would be at risk.
2. The patentability of a biological invention is connected to basic patent law requirements and not regulations on the origin of the biological material.

3. It is wrong to make the handling and granting of a patent dependent on events outside the control of the applicant. This type of events would include lack of information given earlier and actions originating from competitors seeking to protect their business interests.
4. The intention of the patent system is to encourage innovation, not to facilitate division of profits between stakeholders. The proposed sanctions within the patent system risk deter potential patent applicants and the progress of welfare and development. Therefore it is principally wrong to introduce the proposed sanctions within the present patent system. Instead regulations and sanctions regarding the division of profits from biological material should be finalized down and detailed by stakeholders in the international community.

Results:

Formal and material sanctions supporting the disclosure requirements on the origin of biological matter within the patent system risk to slow down the innovation system. More effort would be necessary to capture the full potential from future biological inventions and therapies since the costs, timeframe and business risk is likely to increase.

Process:

In the process of compiling this PM, SwedenBIO's Science working group and patent experts at leading member companies have contributed with expertise and insight. Contributors include AstraZeneca, Awapatent, Biovitrum, Advokatfirman Delphi & Co. Mr. Mats Berggren, project leader at SwedenBIO, has been responsible for compiling the final document.

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