From: Storz, Ulrich
To: MDB-Patents-Consultation-Group
Cc: Albersmeyer, Uwe; hsauer@bio.org
Subject: Comment of the German Biotech industry towards Commissioner"s proposed practice for patent eligibility of Biotech Inventions
Date: Saturday, 7 November 2015 6:43:50 AM

Dear Commissioner,

The German Biotech Industry is extremely concerned about the legal uncertainty that has arisen in the aftermath of the US Supreme Court's decision "Ass'n for Molecular Pathology v. Myriad Genetics". The German Biotech Industry thus appreciates the fact that the Commissioner of IP Australia has published her proposed practice after the Australian High Court decision "D'Arcy v Myriad Genetics Inc [2015] HCA 35, and has invited interested parties to provide comments thereon.

The US Supreme Court decision has created irritations amongst examiners of the USPTO, and despite guidelines that have repeatedly issued by the office, led to a de-facto stay of the prosecution of patent applications relating to different types of biotechnology inventions. In particular, the Supreme Court refers to what it calls "the very point of patents", which exist to promote creation, while products of nature would not be created, and „manifestations of nature would be free to all men and reserved exclusively to none".

While there is a logic in this sentence, the court seems to have overlooked that new pharmaceutic products will only be developed if they can be protected by patents. The latter are indispensable to recover the tremendous investments that are being made during drug development. Thus, denying patent protection to a particular class of inventions, in an attempt to ensure that these inventions remain free for all men, may result in a situation where nobody can use them – because they have never been developed and approved for medical use.

Frankly, the implementation of the US decision counteracts efforts to harmonize patent law globally. More importantly, the broad interpretation of the US decision is also contrary to international obligations. With regard to the treaty aspects, we refer to the Paris Convention of 1883 as the beginning of harmonization efforts, and also refer to the creation of WIPO (1967), the Patent Cooperation Treaty (1970), and GATT/TRIPS (1995).

The traditional alternative to patent protection, trade secret, is not available to foreign and multinational companies because of the disjunction between U.S. patent eligibility standards the rest of the world. Such companies face the choice of filing only in the U.S. and requesting no publication, and then keeping the invention as a trade secret if unsuccessful, or filing everywhere and having patent protection globally but no protection (patent or trade secret) in the U.S. As a result the current US practice is the de facto abolition of intellectual property protection in the United States for many foreign and multinational companies who were able to procure patents abroad.

We would like to point the Commissioner's attention to the Guidelines for Examination at the European Patent Office, which under G-II, 3.1 set forth the following:

"If a new property of a known material or article is found out, that is mere discovery and unpatentable because discovery as such has no technical effect and is therefore not an invention within the meaning of Art. 52(1). If, however, that property is put to practical use, then this constitutes an invention which may be patentable. For example, the discovery that a particular known material is able to withstand mechanical shock would not be patentable, but a railway sleeper made from that material could well be patentable. To find a previously unrecognized substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable. An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect"

We believe that these guidelines provide a reasonable approach to the problem of patent eligibility of subject matter that has been taken, or derived, from nature. It provides a practicable and reproducible test to discriminate non-patent eligible discoveries from patent eligible inventions.

On this background, the German Biotech Industry appreciates the reasonable and farseeing approach IP Australia's Commissioner has recently proposed, and fully supports its enactment.
Further, the German Biotech Industry dares to hope that, once enacted, this policy may also have a beneficial effect on the situation in the United States, which is barely tolerable as it puts in question the existence of an

entire technical discipline which like no other industry depends on patent rights to protect their R&D investments, in order to ensure that new drugs and other products can and will still be developed in the future.

Mit freundlichen Grüßen,
Kind regards,

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