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▼ Swiss patent proposal prompts criticism

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Members of the drug industry debate the effects of a proposed law in Switzerland that would limit the patent protection of gene sequences.

The Swiss government has put together a second revision of its proposed patent law, and is asking for public consultation until the end of October. The government will surely have many comments to sift through, because representatives of the biotech and pharma industries disagree as to whether the law's utility requirements will hinder or foster innovative biotech research.

Although Switzerland is not a member of the European Union, it aims to put into place a law that is in line with the EU biotech patent directive (98/44/EC). The new draft legislation requires that a patent application describing a sequence (or a partial sequence) of a gene must also include the industrial application, or utility, of that sequence—in line with the EU directive remains silent on the scope of protection to be granted to gene sequences, whereas the Swiss patent law proposes restricting a patent on a gene sequence to a specific, credible and nonspeculative function.



Swiss Federal Institute of Intellectual Property

The Federal Institute of Intellectual Property administers patents, copyrights and trademarks in Switzerland.

For example, the scope of a patent for a gene sequence that codes for a protein and is described as being used only to determine a predisposition for breast cancer would be limited to that sole function. So, other researchers who subsequently discover that the gene sequence has a second use (e.g., encodes an alternately spliced protein that can diagnose bone cancer) would be able to file for a new, independent patent. The US allows a single patent to cover such multiple utilities, and an expert committee set up by the European Commission (EC) is expected to conclude its report on which strategy to follow, among other things, by the end of November.

Representatives of the Swiss government say the new patent legislation is a balanced package that takes into account the various and competing interests of society. Lukas Buehler, co-head of legal services, patents and design law at the Swiss Federal Institute of Intellectual Property, says the proposal provides adequate patent protection that would stimulate research and protect the country's vibrant biotech industry. "The proposed scope of protection for patents on genes corresponds to the contribution that the patent holder has made to the advancement of technology," he says. Buehler says the utility limitations will stimulate researchers' interest in exploring all the possible functions of a gene sequence, whereas overly broad patents can restrict the commercial exploitation of research.

Ian Metcalfe, head of scientific writing at vaccine developer Berna Biotech in Berne, says the Swiss biotech community is more or less split on the new patent proposal, with smaller companies in favor of more specific patents whereas the larger ones are against them. "Biotech companies with either large academic bases or very specific core competencies welcome the need for more specific patent claims," he says. "Specific patents will be more likely to drive innovation by helping minimize monopolistic positions. Also, smaller companies can defend specific patents more easily."

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However, members of the larger firms want broader patents because they

give the licensee more opportunities for commercialization. Vincenza Trivigno, senior adviser of economic affairs for Interpharma, a Swiss pharma trade organization in Basel, says, "Strong patent protection is vital for biotech companies involved in R&D, and the Swiss biotech industry is very R&D intensive." She believes the legislation sends out the "wrong" signal, namely that Switzerland is not committed to encouraging biotech innovation by giving broad patent protection.

Not all Swiss biotech company executives are worried that this law would affect their business models, because patent protection would be limited only in Switzerland, which is a relatively small market. Dominik Escher, CEO of ESBATech AG, a developer of antibody therapeutics in Zurich, says, "The important markets for us are the international ones. We apply for patents in the US and Japan and the European Patent Office in Munich." Escher adds that most Swiss biotech companies also submit patent applications in these three markets, which, according to IMS Health in London, account for over 80% of all biotech sales.

But the Swiss proposal could influence the outcome of the current discussion on the scope of protection granted to gene sequences under the EU biotech patent directive. If the EC follows Switzerland's lead in the coming months, then this debate will surely expand because of the increased market that will be affected.

Web links

US Patent and Trademark Office

→ http://www.uspto.gov/

Swiss Federal Institute of Intellectual Property

 \rightarrow http://www.ige.ch/

European Patent Office

→ http://www.european-patent-office.org/

Japan Patent Office

 \rightarrow http://www.jpo.go.jp/

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