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BIO expresses concerns regarding new patent reform legislation

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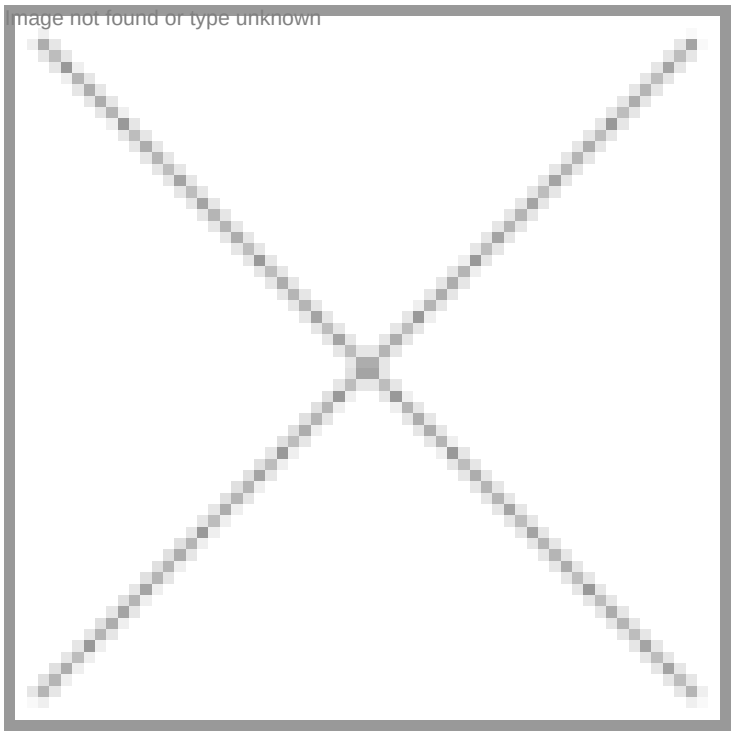


BIO expresses concerns regarding new patent reform legislation

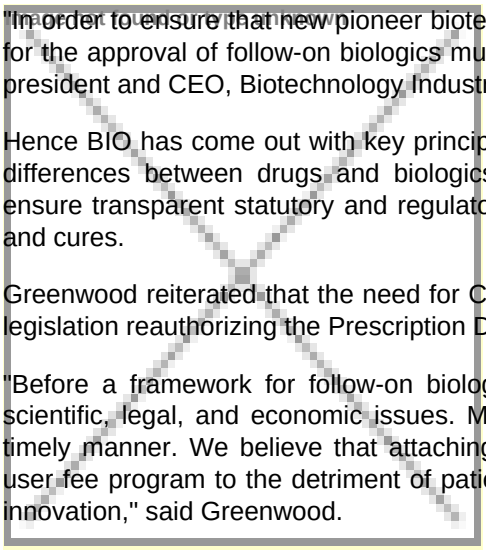
Biotechnology Industry Organization (BIO) welcoming the efforts by Senators Leahy and Hatch and Congressmen Berman and Smith to make improvements to the US patent system noted, " Unfortunately, the 'Patent Reform Act of 2007,' as introduced on April 18, 2007, also contains provisions that will weaken the enforceability of validly issued patents, and fails to include necessary reforms to make the patent system more objective and efficient. "

In a statement, Jim Greenwood, president, BIO said, "The Bill threatens the ability of biotechnology companies and researchers to find and develop innovative treatments for some of the world's most deadly diseases, such as cancer, heart disease, Alzheimer's, Parkinson's and HIV/AIDS, as well as new solutions to address critical agricultural and environmental challenges facing the global community.

He further said, "The Patent Reform Act of 2007 would create a new post-grant opposition system, under which a patent is given no presumption of validity and could be broadly challenged administratively throughout its term -even years after the patentee and the public have come to rely on it, and years after biotech companies have invested hundreds of millions of dollars to bring a patented invention through clinical trials and regulatory approval. Under such a scheme, patents will have less value and investment predicated upon them will diminish."

Source: www.bio.org

BIO's key principles on follow-on biologics



Jim Greenwood

Source: www.bio.org

"In order to ensure that new pioneer biotechnology products continue to reach patients and physicians, any statutory pathway for the approval of follow-on biologics must protect patient safety and preserve incentives to innovate," said Jim Greenwood, president and CEO, Biotechnology Industry Organization (BIO).

Hence BIO has come out with key principles for legislators. The principles include: ensure patient safety, recognize scientific differences between drugs and biologics, maintain the physician-patient relationship, preserve incentives for innovation, ensure transparent statutory and regulatory processes and continue to prioritize FDA review and approval of new therapies and cures.

Greenwood reiterated that the need for Congress to consider a pathway for approving follow-on biologics independent of the legislation reauthorizing the Prescription Drug User Fee Act (PDUFA).

"Before a framework for follow-on biologics can be established, Congress must carefully consider and resolve complex scientific, legal, and economic issues. Meanwhile, it is important that Congress complete the PDUFA reauthorization in a timely manner. We believe that attaching follow-on biologics legislation to PDUFA would jeopardize reauthorization of the user fee program to the detriment of patients waiting for new therapies, FDA's internal scientific capabilities, and biomedical innovation," said Greenwood.

Innovative therapies will have minimal impact on healthcare costs: study

The widening use of new, innovative biopharmaceutical treatments for diseases such as cancer, multiple sclerosis and heart disease, will have a limited impact on healthcare costs for private healthcare payers over the next several years, according to an independent study released by the Biotechnology Industry Organization (BIO).

The study, prepared by the international actuarial firm Milliman, Inc. and titled Realizing the Value of FDA-Approved Therapies, found new innovative therapies, including both new drugs and biologics, will add one percent to the healthcare costs covered by private commercial payers such as insurance companies and employer-sponsored health plans. This increase translates to an additional claims cost to private payers of about $5 per member per month.

Moreover, the study found that private payers can make minor changes in their benefit plans to assure the affordability of innovative therapies for their members.

The Milliman study reports that the costs of innovative therapies will generally not create a large cost burden relative to other costs for private healthcare payers by 2011. The total cost for all innovative therapies (existing and new) approved by the US Food and Drug Administration (FDA) is estimated to be about 6 percent of total private commercial payer costs by 2011. This compares to about five percent for 2006.

The study points out that innovative therapies may actually bring down healthcare costs in some cases. The report notes that new and improved medical treatment does not necessarily cost more than traditional
treatment

"The largest healthcare expense borne by payers is not prescription drug and biologic costs but hospital and other non-drug costs," stated Bruce Pyenson, principal and consulting actuary, Milliman, and author of the report. "While prescription drug costs account for about 14 percent, non-drug costs account for 86 percent of expense borne by payers, according to Milliman's 2006 Group Health Insurance Survey of HMOs."

Source: www.bio.org

Europe loses as trialogue talks fail on proposed Advanced Therapies Regulation

EuropaBio, the European Association for Bioindustries, has expressed its disappointment over the breakdown in the informal talks between the Parliament, Council and Commission which were looking to reach an early agreement on badly needed advanced therapies regulation, but instead ended without any concrete outcome.

The informal trialogue meeting talks broke down when the Rapporteur insisted on including two amendments in the agreement package that would exclude certain advanced therapy medicinal products from the scope of the regulation. To include these amendments would cause certain products and technologies to remain unregulated, posing potential health hazards to European patients and disadvantaging Europe's emerging Advanced Therapies sector. EuropaBio calls upon the Rapporteur to continue with the approach that had been originally agreed.

Insisting on a short-term push to include these amendments into the compromise package creates the risk of losing out on the long awaited objective to have advanced therapies regulated at European level for Europe's patients, clinicians, researchers and industry. Holding up the adoption of the Regulation in this way is not serving Europe's science base and the progress in medicines for the benefit of European citizens and patients.

Following the rejection of the rapporteurs' report on the Advanced Therapies Regulation by the ENVI committee in September of 2006 for this very reason, the European Commission and the Council had proposed, instead, to let Member States take decisions on this sensitive issue based on the principle of subsidiarity rather than compromise on safety standards.

Europe has been waiting for this legislation for a long time. This delay will cause serious problems for innovative companies and could affect the future of the life science sector. Ultimately though, it is the patients who lose out as they wait in vain for treatments that could make their lives better.

Source: www.europabio.org

BioImpact.org relaunched

On the occasion of Biovision, the World Life Sciences Forum in Lyon, France Biotech, (the French Biotechnology Industry Association), BIA (the UK BioIndustry Association), EuropaBio (the European Bioindustry Federation), Leem (Les Entreprises du MÃ©dicament- the French Pharmaceutical Industry Association), and LIR (Laboratoires Internationaux de Recherche) launched the new version of www.bioimpact.org and new findings about the impact of biotechnology on the treatment of diseases heavily affecting millions of patients: breast cancer, cardio-vascular diseases, inflammatory bowel diseases and chronic inflammatory joint diseases in particular.

With a renewed website, BioImpact.org provides the visitor with patient testimonials and science based information, presented in simple and accessible fact sheets, videos and detailed reports including all scientific references, for those who are willing to learn more about the pathologies, the biotechnology treatments and how they save lives, help patients and serve our society. With more than 250 medicines and vaccines already available and more than 400 therapeutic products under development in 2006, the socio-economic impact of biotechnology is highly significant.

The earlier edition of BioImpact.org showed the value of medicines discovered and developed by biotechnology and pharmaceutical companies; improved product safety, reduced side effects, new therapeutic strategies addressing unmet medical needs, or technologies improving public health coverage.

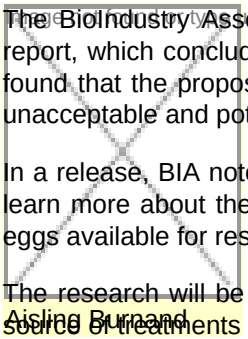
The latest 2007 version of BioImpact.org includes additional information such as extensive European epidemiologic data (incidence, prevalence and mortality), quality of life data and economic data (economic costs of the disease, cost of biotherapy, cost/efficiency, target populations). It helps to understand how biotechnology is contributing to therapeutic progress and to public health and what is its real added value for our society, in terms of public health and in economic terms.

Source: www.europabio.org

BIA hails S&T Committee Report on regulation of hybrid, chimera embryos

The BioIndustry Association (BIA) of the UK has welcomed the House of Commons Science and Technology Committee report, which concluded that the creation of hybrid embryos should be permitted for research purposes. The committee also found that the proposals in a current government White Paper to prohibit the creation of hybrid embryos for research to be unacceptable and potentially harmful to the UK science.

In a release, BIA noted that it believes the research using hybrid embryos could be a powerful tool that will help scientists to learn more about the differences between diseased and normal cells. Currently this work is stifled by a shortage of human eggs available for research.



The research will be used to develop the techniques required for the production of stem cells, which could prove to be the source of treatments for diseases such as muscular dystrophy, Parkinson's and motor neurone disease.

Aisling Burnand, chief executive of the BIA, said, "It is essential that this research is permitted so that many thousands of patients can benefit from new therapies in the future. It is important to safeguard the UK's position as a world-leading environment for cutting-edge research in bioscience as recognized in the committee's report. We look forward to contributing to the HFEA consultation on this issue later this year and hope it will take into account the views of the Science and Technology Committee."

Source: www.bioindustry.org