Biosimilars legislation awakens data exclusivity debate

These days, drug developers use more than just a assortment of chemicals to make new medications: about a quarter of all new drugs are what's known as biologics—complex proteins derived from genetically engineered living cells. This relatively new class of drugs has yielded important new treatments for diseases such as cancer, arthritis and multiple sclerosis. But because biologic drugs are not produced in the same way as small-molecule drugs, there is uncertainty about how long generic drug makers should have to wait before they can produce their own versions.

According to the US Food and Drug Administration (FDA), there is no such thing as a true 'generic' biologic drug. Whereas generic small-molecule drugs have very similar chemical compositions to the originals, no two biologic drug–producing organisms could ever be identical. The resulting biologic drug copies, dubbed biosimilars or follow-on biologics, should be considered 'similar to' but not the same as the original compound, according to 2007 congressional testimony about the FDA's position on these drugs by Janet Woodcock, the director of the FDA's Center for Drug Evaluation and Research.

The FDA holds that, without legislative action, it doesn't have the ability to approve biosimilars without putting these drugs though the same lengthy approval process as is necessary for the original biologic versions.

As *Nature Medicine* went to press, legislation that would create such an approval process was pending as part of the health care reform bills in both houses of the US Congress. One sticking point, though, is the length of data exclusivity that a drug developer should be able to hold. Issued by the FDA at the time of a drug's approval, data exclusivity offers broader protection than a patent, which may not prevent the manufacture of biologic compounds that are only 'similar to' the original. The current version of the legislation would give companies that design biologic drugs 12 years of data exclusivity, even though most new small-molecule drugs only receive five years of such exclusivity.

Agencies such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the National Venture Capital Association support this 12-year exclusivity period. They cite Henry Grabowski, director of the Program in Pharmaceuticals and Health Economics at Duke University, who published data that projected 12 to 16 years to recoup the costs of biologic development (*Nat. Rev. Drug Discov.* doi:10.1038/nrd2532; 2009).

The question of exclusivity has been answered in Europe since 2004, when the European Agency for the Evaluation of Medicinal Products opened the door for biosimilars by establishing an exclusivity period of ten years.

Back in the US, the AARP, along with organizations such as the American Medical Student Association and the National Women's Health Network, supports an exclusivity period of only five years so that cheaper drugs can reach patients on the same scale of time as regular generic drugs. This could be a relief for the government's budget, they say. According to the Medicare Payment Advisory Commission, 43% of the Medicare part B budget is spent on the top six biologic drugs.

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Online resource aims to smooth the biomed patent search

A new online resource project aims to provide a free and multilayered global database of patented intellectual property in the life sciences.

Supported by $3 million from the Bill & Melinda Gates Foundation, the Initiative for Open Innovation (IOI) is the brainchild of Australia-based Richard Jefferson, who in 1991 founded the Cambia organization to give developing countries access to the tools of molecular biology.

"The IOI is really not about patents, it's about innovation, transparency and decision support—patents are the entry point," Jefferson says."Patents are a brilliant resource, but only when there is clarity and transparency in the system, which are now lacking," he adds.

Launched in July at a UN conference in Geneva, the IOI is also supported by the Oregon-based Lemenson Foundation and Brisbane's Queensland University of Technology.

Further backing has come from the World Intellectual Property Organisation (WIPO), whose director, Australian Francis Gurry, is a member of the IOI's International Advisory Council, which met for the first time in August. "This initiative is very timely, as the international policy community is undertaking an active process of review and examination of innovation structures and strategies in a range of key technology domains," Gurry says.

Other advisory council members include David Lipman, director of the US National Center for Biotechnology Information at the National Institutes of Health, Tan Tieniu, deputy secretary general of the Chinese Academy of Sciences, and Malebona Matsoso, director of Public Health, Innovation and Intellectual Property at the World Health Organization. *Nature*'s editor-in-chief, Philip Campbell, is also a member.

The IOI will build on Cambia's Patent Lens project, which now provides a free database of more than 77 million DNA and protein sequences disclosed in patents. Patent Lens (www.patentlens.net), which turns up more than 9,000 search results for the breast cancer gene *BRCA1*, will be integrated into the IOI as its core informatics platform.

Initially focused on the life sciences with priority given to influenza, malaria and tuberculosis, the IOI will provide a searchable patent database across sectors, disciplines and jurisdictions in all major languages. It will include the full text of patents and applications, associated DNA, protein sequences and chemical structures, with dynamic links to associated business and regulatory data, and scientific and technical literature.

This cross-referenced online facility will be a key point of differentiation from existing free and proprietary patent search services, which, apart from the WIPO, are also generally country-specific and single language. "Public sector scientists rarely read the patent literature and even more rarely have the technical facility to understand the meaning of patents in their context and in the innovation trajectory to which their work contributes," Jefferson says.

A strategic plan is due for endorsement by the IOI's advisory panel by the end of this year, and features of the project supported by the Gates Foundation grant will begin to appear in the middle of next year.

Simon Grose, Canberra