Biomedical patents: Overturning preconceptions

Everyone can agree that innovation in medicine saves lives. But how to best protect these bright ideas with patents continues to stir vigorous debate among doctors and lawyers alike. In Europe, regulators are exploring whether legal changes are necessary to reduce patent infringement litigation and bring generic drugs to market more swiftly. Meanwhile, as *Nature Medicine* went to press, US lawmakers were considering reforms such as the Patent Reform Act of 2009—which could lead to a change from a 'first to invent' to a 'first to file' system and lower penalties awarded for patent violations.

The proposed changes to US patent law have pitted the biomedical industry against the information technology industry. Drug companies have voiced concerns about the move to weaken patents, as they spend millions developing drugs each generally covered by a single patent. Software developers, in contrast, churn out products that weave together numerous bits of patented computer code, creating a difficult and costly legal maze that they say stymies innovation.

In the following pages, *Nature Medicine* explores the changing landscape of biomedical patent law. The articles in this section look at a range of topics, such as the spate of upcoming patent expirations that threaten pharmaceutical companies' profits, and go further to ask whether alternative systems to replace patents make more sense for medicine.

Sluggish generics entry prompts calls for European patent reform

This past July, the European Commission released estimates that if generic drugs were to enter markets immediately after patents expire—instead of the present average of seven months later—EU patients and national health services might save €3 billion ($4.5 billion) annually. But regulators acknowledge that costly and time-consuming patent disputes, and possible anticompetitive practices in the pharmaceutical industry, mean that such savings remain elusive.

As part of an effort to improve patient access to generic drugs, the European Competition Directorate began unannounced raids of a handful of pharmaceutical makers on 6 October to investigate suspected anticompetitive business practices. The raids followed a broader antitrust inquiry of 43 originator and 27 generic pharmaceutical firms published in July 2009 by the directorate, which functions as the European Commission's antitrust unit and is also responsible for inquiries into other commercial sectors and individual firms. The report accused originator companies, which invent new drugs, of using litigation to unfairly block competition from generic drug makers, who create their own versions of name brand drugs when the patents expire.

Pharmaceutical firms, academics and government agencies weighed in on the European Commission's November 2008 preliminary report with criticisms and suggestions on why the pharmaceutical sector has put fewer generic drugs on the market in recent years, as well as how to encourage more drug production and distribution. One provocative proposal, reported by the *Financial Times* before the release of the final July report, was that originator companies should post financial bonds, which they would pay generic drug makers should they be found guilty of pursuing 'spurious' patent infringement litigation. The European Generic Medicines Association complained that the cost of litigation could be a larger proportion of smaller generic drug makers' budgets than of a larger originator firms'.

Others questioned whether the European Commission's antitrust arm is the right tool for cutting the Gordian knot of European intellectual property law. "It's taken 30 years to try to move toward a single patent enforcement area," with help from lawyers, industry, courts and regulatory authorities, notes Michael Burdon, head of intellectual property at the law firm Olswang in London and a member of the IP Advisory Committee of the BioIndustry Association. However, he says, despite regular discussions "we're still at least a few years away."

But generic drug makers have also been accused of contributing to the delays in getting their products to market. The July report said that that some generic drug makers accepted settlements in the form of reverse payments from originators to delay generic drug sales, a practice which earns money for both businesses by forcing patients to continue buying pricier name brand drugs.

Across the pond, the Federal Trade Commission is investigating similar practices in the US. European generic drug makers also have a weaker incentive to reach the market first than in the US, where the first generic drug maker to market earns a six-month exclusivity period for producing the generic version.

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This little pill went to market: Generics are sometimes delayed

The July report did call for streamlining the generic approval process and the establishment of a European Patent Court, but the competition directorate does not have the authority to enact regulation or establish such a court. For now, patents rulings in one European country don't apply in another, Burdon says, so the cost and uncertainty of litigation often prompts legitimate out-of-court settlements. Such settlements are now under "continued monitoring," according to the competitions directorate press officer Jonathan Todd. No new rules or recommendations have emerged from the 6 October sting, he told *Nature Medicine*, but the directorate has the authority to require firms to change anticompetitive practices or pay fines.

The success of a European patent court will depend on an opinion the European Commission has requested on the authority of such a court from the European Court of Justice, Burdon says, but since there is no formal timeline for such rulings, it could be months or years away.

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