Commentary

Why data exclusivity is the new patent protection

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When it comes to health care everyone, it seems, wants to talk about patents.

Congress wants to reform them.
The WHO wants to circumvent them.
Some, such as Senator Bernie Sanders, want to eliminate them.

All concerned address the issue with passion and an interest in improving global public health.

But, even with the best intentions, they're missing the point. We need to focus beyond reforming patent law. We need to rethink the existing system to encourage pharmaceutical innovation (both incremental and discontinuous) in order to realize the potential of the Biomedical Century.

And not just in the United States – but globally.

The solution isn't exclusively patent reform – that's too narrow. We need to consider new strategies that enhance and protect intellectual property rights. What we need to seriously study – and transnationally – is the issue of data exclusivity.

Data exclusivity is the new patent protection – because what we really have to protect is innovation.

Why?

Innovation is slow. As any medical scientist will tell you, there are few '*Eureka!*' moments in health research. Progress comes step-by-step, one incremental innovation at a time. Companies more often profit by improving existing chemicals and making processes more efficient than by revolutionizing the whole field with new products.

Innovation is hard. Today it takes about 10 000 new molecules to produce one FDA-approved medicine. And if that's not frightening enough, only three out of 10 new medicines earn back their research and development costs. And here's the kicker – unlike other R&D-intensive industries, pharmaceutical investments generally must be sustained for over two decades before the few that make it can generate any profit.

Innovation is expensive. In 2003, researchers at Tufts Center for the Study of Drug Development estimated the costs to bring a new medicine to market to be US$802 million, and others suggest that the total cost is closer to $1.7 billion.

Innovation is under attack. From accusations of the 'me-too' variety, to crackpot schemes to replace pharmaceutical patents with a 'prize' system, life for innovator pharmaceutical companies is rough and tough. Israel Makov (founder of the Israeli generics giant Teva) once told me that he wasn't really in the pharmaceutical business, but rather 'in the litigation business'.

But innovation is important – and not just for pharmaceutical industry profits. Increases in life expectancy resulting from better treatment of cardiovascular disease from 1970 to 1990 have been conservatively estimated as bringing benefits worth more than $500 billion a year. In 1974, cardiovascular disease was the cause of 39 per cent of all deaths. Today it is about 25 per cent. Cerebrovascular diseases were responsible for 11 per cent of deaths back then. In 2004 they caused 6.3 per cent of deaths. Kidney diseases were linked to 10.4 per cent of deaths and now they are associated with 1.8 per cent. *And that's just for the United States*.

As Harvard University health economist (and Obama health-care advisor) David Cutler has noted, 'The average person aged 45 will live three years longer than he used to solely because medical care for cardiovascular disease has improved. Virtually every study of medical innovation suggests that changes in the nature of medical care over time are clearly worth the cost'.

When innovator drug companies decide to play more aggressively in the generic drug world – that's business, sound business. When a senior executive at the world's largest drug company says that innovation isn't the 'be-all and end-all' – that's frightening, very frightening.

To borrow an over-used adjective from the world of global climate change – we must protect 'sustainable' innovation.

Current patent life just doesn't cut it. Not in the United States. Not in the EU. And certainly not via TRIPS.

According to a recent article, '*Investments in Pharmaceuticals Before and After TRIPS: Property Rights and New Drug Development*' (Authors: Margaret Kyle, assistant professor, London Business School; and Anitha M. McGahan, Professor, Rotman School of Management, University of Toronto), while "TRIPS was central in the development of foundational pharmaceutical capabilities in least-developed and developing countries …" and "TRIPS had a strong, consistent, and major impact on general and corporate investment at every phase of research on global disease …" all is not rosy:

Kyle, *et al* also report that, 'There appears to be a gap that prevents the immediate efficacy of TRIPS in promoting the introduction of new drugs on poverty diseases'. And they conclude by saying "This research suggests an opportunity to implement policies that are complementary to TRIPS for filling this gap to promote research on poverty diseases immediately".

If we don't think seriously about moving away from patent reform and towards more robust protection of data exclusivity we are going to seriously jeopardize the potential for new medicines – at a time when science makes potential breakthroughs tantalizingly close.

Do we really want promising compounds abandoned because of awkwardly crafted and inconsistent (read 'unpredictable') patent terms? Let's not forget the wise words of that well-known intellectual property attorney, our sixteenth President – Abraham Lincoln, who commented that patents 'add the fuel of interest to the passion of genius'.

Peter J. Pitts
Center for Medicine in the Public Interest,
New York, USA