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Ask: NUS economists

TPP raises spectre of higher drug prices

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For The Straits Times

Q *How will the Trans-Pacific Partnership (TPP) affect Singaporeans?*

A The Trans-Pacific Partnership (TPP) is a multilateral free-trade agreement currently being negotiated among 12 countries. They include the United States, Japan, Canada, Australia and Singapore. Ministers met last month in Hawaii to conclude negotiations, but they failed to do so.

Reportedly, one of the stumbling blocks is intellectual property (IP) rights. The US is pushing new rules that it claims "will protect and promote US exports of IP-intensive products and services throughout the Asia-Pacific region for the benefit of producers and consumers of those goods and services in all TPP countries". Currently, the worldwide standard for IP rights is the Agreement on Trade-Related Aspects of Intellectual Property Rights (Trips), agreed in 1994.

The TPP is being negotiated in secret. However, the US Congressional Research Service analysed possible changes to IP rights. Worryingly, some of the proposals might not necessarily benefit producers and consumers in TPP countries, or even increase innovation.

Let me focus on patents. the Trips agreement allows patents for "any invention, whether product or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application". My research with National University of Singapore colleague Albert Hu shows that stronger patent rights do not necessarily raise the growth of industry. If they do, it is in the more advanced economies.

Trips explicitly permits national governments not to allow patents for diagnostic, therapeutic and surgical methods, or plants and animals (other than micro-organisms). Historically, European countries and the US did not grant patents for methods of medical treatment. Research shows that this policy stimulated innovation by doctors. The doctors improved on the methods of others and benefited patients.

The US reportedly wants to expand the scope of patent protection by allowing patents for methods of medical treatment. Would such patents stimulate more research and development (R&D) and new invention? To the extent that physicians are already well motivated by peer approval and the desire to improve patient care, patenting might well not increase invention. But, actually, there is no evidence of the effect of patents on invention. However, we do know that patents would be associated with higher fees for treatment and that higher fees would reduce patient welfare.

The US reportedly also wants to expand the scope of patent protection by allowing patents on plants and animals.

Unlike new drugs and semiconductors, biological "inventions" require only the recombination of existing genetic material and, to that extent, the "invention" is smaller (Trips stipulates the inventive step to be a basic requirement for a patent).

What would be the effect of patents on plants and animals? The closest evidence comes from patents on genes, which Trips specifically allows. Research shows that patenting of genes did not reduce follow-on innovation. To that extent, patenting of biological material might be innocuous.

But did the patents on genes stimulate more R&D and new invention? We do not know.

Again, we do know that patents are associated with higher prices and that higher prices would reduce consumer welfare.

Finally, the US reportedly wants to extend the period of data exclusivity for biological drugs.

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Manufacturers of generics typically rely on clinical test data from the original inventor. Without access to this data, generics manufacturers would incur much higher costs and might be deterred from entry.

Biotechnology producers claim that the process of development and approval for biological products is complex and requires a long period of exclusivity to be commercially viable. The US Biologics Price Competition and Innovation Act of 2009 increased the period of data exclusivity for biologics from five to 12 years.

Trips does not specify any term of data exclusivity, but rather requires the government to protect against unfair commercial use or disclosure of test and other information submitted to regulators.

The US reportedly wants the TPP to stipulate 12 years of data exclusivity for biologics.

What was the effect of the US extension of data exclusivity by seven years? Here, I'm beginning to sound like a broken record. To date, there has been no empirical evidence that the extension increased the invention of biological drugs, or even increased investment in R&D.

However, what is certain is that any increase in the period of data exclusivity would retard the entry of generic competition in biological drugs that have already been invented. Generic competition drives down the prices of pharmaceuticals by as much as 90 per cent. More affordable drugs obviously help sick people, particularly those with lower incomes.

It is difficult to see how higher prices would benefit them (as opposed to US drug manufacturers).

Overall, the possible changes of IP rights in the TPP would clearly benefit particular US industries. But at what cost to consumers and businesses in the other TPP countries? At the minimum, Singapore should insist that any changes to IP rights apply only prospectively – to new inventions and creations. That would focus the changes on stimulating new innovation. There is no reason to enrich US vested interests at our expense.

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