Debating Patents and Drug Prices: Trade Agreements and the Trans-Pacific Partnership

Professor Ken Shadlen and co-authors challenge a recent article in Foreign Affairs that claimed to show that trade agreements with the USA have not affected the price of patented drugs in developing countries.

One of the most contentious issues in the debate surrounding the Trans-Pacific Partnership (TPP) relates to the agreement's implications for drug prices, particularly in developing countries. The TPP, signed earlier in 2016 by twelve countries (though awaiting ratification), includes stronger protections for drug companies than any agreement before it, and is expected to become the new gold standard in trade agreements.

The TPP comes two decades after drug companies achieved the largest single expansion in drug patent protection in history through the World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). TRIPS made pharmaceutical patent protection obligatory for all WTO members. Regional and bilateral trade agreements negotiated after TRIPS further extend the level of patent or patent-like protection that countries must offer to drug companies, increasing their leverage to exclude generic competitors in national markets. Because the TPP, in turn, builds on these previous agreements, it has thus raised concerns about drug prices and access to medicines in developing countries.

A recent paper in *Foreign Affairs* by Thomas J. Bollyky from the Council on Foreign Relations argues that these concerns are misplaced. While conceding that patents *can* increase the prices of medicines, he brings new data to the debate, and argues that recent trade agreements have not in fact raised prices in affected countries. He concludes that "the current evidence suggests that it may be time to move beyond the large pricing and spending claims made for and against the pharmaceutical provisions in U.S. trade deals and to focus the trade and medicines debate elsewhere." The analysis (and a *Washington Post* editorial that followed and publicized it) have been influential, and likely will be again as the TPP debate continues.

Foreign Affairs printed a rebuttal of this article that I wrote with Amy Kapczynski (Yale Law School) and Bhaven Sampat (Columbia University's School of Public Health). We point to a number of flaws in Bollyky's analysis, flaws that, we maintain, are misleading in terms of what they claim about the effects of previous trade agreements on drug prices, and in terms of what they imply about the TPP's possible consequences. In our piece we argue that the measure he uses to assess the effects is problematic, for example, that the comparison of this measure in countries with and without trade agreements with the U.S. is faulty, and that the claim that these agreements have had little effects on prices fails to appreciate important temporal dimensions of the introduction of drug patents and additional protections in developing countries (i.e. it's too early to tell). We also argue that, even if one were to accept the finding that trade agreements with the US have not raised prices in developing countries (yet), the mechanisms to which this is attributed are unconvincing – and even if one were to accept the findings and the explanation, these same mechanisms would be greatly curtailed by the TPP anyhow.

It is essential to point out that we do not claim to know that regional and bilateral trade agreements with the US have raised drug prices; it's too early to tell means just that — it's too early to tell. Rather, we are making a largely methodological critique of Bollyky's analysis, calling into question how he went about reaching his conclusions and rejecting the claim that, because we allegedly now know that prices have not been affected, the issue is now resolved and it is time to "move beyond" the debate over the patent provisions in U.S. trade agreements and drug prices. To the contrary, this should be the beginning of the debate. As suggested by the sub-title of our piece, the relationship between trade agreements and drug prices is "Not a Settled Matter."

Foreign Affairs allowed Bollyky a chance to respond to our piece, which he did, claiming that we misrepresented his analysis and that we over-state the ways that the TPP differs from current trade agreements. We don't agree (not surprisingly): Bollyky fails to engage with our main points, demonstrates yet more confusion on the temporal dimensions of when the effects of the patent provisions in trade agreements might kick in, and, by criticizing us for not demonstrating an effect on prices, fundamentally distorts the nature of our critique. A reply is in the works and we will update this post accordingly. For now, you can read the original article, our response, and Bollyky's reply on the Foreign Affairs website (registration required) and reach your own conclusions.

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Ken Shadlen is a political scientist in the Department of International Development, and works on the comparative and international political economy of development, with a focus on understanding variation in national policy responses to changing global rules. In recent years his research has focused on the global and cross-national politics of intellectual property (IP). Ken is particularly interested in the implications that the new global IP regime presents for late development, and the various ways that the international norms and rules for IP are adopted at the national level and affect national practices.

In his forthcoming book (*Coalitions and Compliance: The Political Economy of Pharmaceutical Patents in Latin America*) he examines the different ways that countries introduced pharmaceutical patents in the 1990s, and then subsequently revised their new pharmaceutical patent systems in the 2000s. In an ESRC-funded project with Bhaven Sampat ("TRIPS Implementation and Secondary Pharmaceutical Patenting: An Empirical Analysis"), they considered how pharmaceutical patent systems function, in practice. They analysed the extent to which differences in national pharmaceutical patent systems, particularly different approaches toward applications for secondary patents, affect overall patenting patterns, and seeked to understand the factors that account for differential effectiveness of national policies toward secondary patents.

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