Ken Shadlen June 5th, 2025

Analysing Pharmaceutical patents and researching generic drug policies — and revisiting Mexico City

Professor Ken Shadlen reflects on a recent research trip to Mexico City to study pharmaceutical patent linkage and generic drug regulation, while also revisiting places from his long personal and academic history with the city.

I spent a week in Mexico City over the April/May break. The DF (I'll always refer to Mexico City as "el DF," I can't adjust to "CDMX") is one of my favorite places on earth. It's where I conducted the research for my PhD in the 1990s, where I undertook subsequent research to convert the PhD into my first book, *Democratization Without Representation*, on the changing relationship between small industry and the state in the context of economic liberalization and democratization, and it's where I conducted a third of the research for *Coalitions and Compliance*, my book on the political economy of pharmaceutical patents in Latin America. I've been going regularly to Mexico City for more than 30 years and always love being there.

The main reasons for this year's trip were to present a paper on pharmaceutical patents at a Mexican university and to conduct research on the regulation of generic drugs. .

Pharmaceutical Patent "Linkage"

In most countries, the processes by which pharmaceutical companies receive authorization to sell their products (to private or public purchasers) and the processes by which they receive patents are separate. The agencies that grant marketing authorization don't pay attention to whether or not there's a patent on the drug, and the agencies that grant patents don't concern themselves with the specific pharmaceutical products that the invention relates to.

Mexico, along with 15 or so other countries, is different in this regard. A system called "linkage" (the English word is used universally, though sometimes this is referred to as *vinculación*) requires the patent office (IMPI) to publish a list of all the pharmaceutical patents it has granted, and prohibits

the health regulatory agency (COFEPRIS) from granting marketing authorization to a product that has a patent on IMPI's list.

At first glance there may seem to be nothing concerning about linkage in Mexico (or elsewhere). After all, if a drug has a patent, the generic firm may not be able to sell its product anyway, even if it receives the green light from the regulator to do so. But not so quick. In addition to the principle-based concern many have of public authority being used to monitor and defend private rights in this way, there are material concerns about how arrangements such as these can extend periods of patent protection and keep generic alternatives out of the market for longer periods of time, and as a result drive up the costs of medicines.

To understand the concerns, keep in mind that patents last 20 years (from the date of application), and that a given drug may have multiple patents associated with it, each filed– and therefore expiring – sequentially. Now, with these basics in mind, let's think about what happens in the absence of linkage, the "normal" situation described above, where patent offices and health regulators go about their business without regard for what the other is doing. In such a setting, where health regulators grant marketing authorization without taking into account the patent situation, it it happens that generic Company B obtains marketing authorization for a given drug that originator Company A has a patent on, Company A will typically sue Company B for infringing its patent, to which Company B will typically respond by claiming either that it's not in fact infringing A's patent or that A's patent is invalid and should never have been granted…and a judge ultimately decides if Company B can sell its product or not. Sometimes A wins in court, and sometimes B wins – it turns out that not all patents that are granted are equally strong when their validity is questioned, nor are they all equally difficult to avoid infringing even when they're valid.

When a country has a system of linkage, however, all of the granted patents on a given product may (I use conditional language because it depends on the details of the country's linkage system) be treated as being equally strong and likely to be infringed. They all end up endowed with extensive blocking power.

I wrote about the origins of Mexico's linkage system in Chapter 7 of *Coalitions and Compliance*, and, with co-authors Bhaven Sampat and Amy Kapczynski, I discussed the potential consequences of linkage generally in an article on measures that some countries have taken that go beyond their obligations under the WTO's TRIPS Agreement.

Studying Linkage and HIV/AIDS Medicines in Mexico

My seminar on 30 April was on Mexico's linkage system. With Daniel Bernal, a colleague at the Tecnológico de Monterrey's School of Government and Public Transformation (Mexico City campus), we are investigating the effects of these arrangements on the acquisition of HIV medicines. Our goal is to quantify the amount of "excess" and potentially avoidable expenditures that Mexico's HIV/AIDS agency has incurred on account of being unable to purchase less expensive

generic options, because of linkage, and in doing so shed light on how Mexico's linkage system functions in practice. Our collaboration is supported by LSE's Global Research Fund, which generously funded Daniel's visit to LSE last year and my trip in April.

We look at all of the medicines purchased from 2010-2021 by Mexico's National Center for the Prevention and Control of HIV and AIDS (CENSIDA), and for each year we have data on which drugs CENSIDA purchased from which producers, how many doses it procured, and the prices paid.

For each drug (and combination of drugs) we also have information on all of the patents granted in Mexico, including a distinction between the "primary" patents, on the molecules, and the "secondary" patents, on alternative forms of existing drugs, including for example different formulations or combinations. Because secondary patents are, in general, more likely to be invalidated if contested, and easier to evade even when their validity is upheld, we expect linkage to matter more for this type of patent, as it may inflate their power to block generic entry.

The project is not yet finished, though we see quite a few cases where CENSIDA purchased the originator products for long periods of time after all of the primary patents had expired. The table below lists the year the primary patents expired on a set of HIV/AIDS medicines and the number of years after this before CENSIDA began purchasing generic versions, and the final column provides information on the secondary patents associated with each medicine.

Ejemplos

Droga	Fecha Expiración Primaria (FEP)	Años tras FEP sin compra genérico	# de Secundarias (Fecha Expiración)
Abacavir	2008	8	3 (2016, 2018, 2019)
Abacavir/Lamivudina	2010	8	13 (2011x2, 2012x4 2016x4, 2018x2, 2019)
Atazanavir	2017	2	1 (2018)
Dolutegravir	2026	??	2 (2029, 2031)
Efavirenz	2013	4	3 (2018, 2019x2)
Emtricitabine	2012	3	6 (2011, 2012x2, 2022, 2024, 2025)
Lopinavir/ritonavir	2016	8	15 (2017x2, 2019x2, 2020x3, 2021x2, 2024x6)
Nevirapina	2010	10	2 (2018, 2028)
Tipranavir	2015	3	--

As the research is incomplete we don't know yet what to make of this. On the one hand, we observe many purchases of originators' products that are made after the expiration of primaries, for drugs that have secondary patents in force, which suggests that the linkage system may be having an effect. On the other hand, purchasing of generics usually starts before *all* of the secondaries have expired, so even if the linkage system is affecting the timing of generic entry it does not appear to

be the case that all secondary patents block entry. Dolutegravir (with the question marks) is included to illustrate the issues at stake and draw attention to the question of what might happen going forward: will CENSIDA start purchasing generics in 2026 when the primary patent expires or not until 2029 or 2031 when the secondaries expire? Figuring out precisely how and when the linkage system leads to secondary patents blocking generic entry is the task that lies ahead for us – watch this space.

Here are links to the seminar announcement and the presentation (PDF).

Generic Drugs

As interesting and important as patents are, most of the time when we need a medicine we take older drugs, where all of the patents have expired. Companies that seek to sell such products still need marketing authorization from health regulators, but, even in countries with a linkage system, they don't need to worry about patent infringement. Drugs of this sort are commonly thought of as "generics," since the knowledge is in the public domain and available, in theory, for any company to produce (the WHO refers to these as "multisource" drugs).

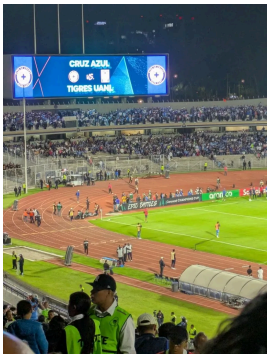
It turns out that the design and functioning of multi-source, "generic" drug markets vary from country to country. Here in the UK, for example, once patents expire most drugs become commodities: doctors prescribe a medicine using the generic molecule name, patients bring the prescription to the pharmacy (or it's sent electronically), the pharmacist dispenses whatever version of the drug they stock. No one – not the prescriber, nor the patient, nor the pharmacist – cares about the manufacturer. That's not how multi-source drug markets function in most of Latin America, however, where "generics" are not fully commodified.

To compare generic drug markets in Latin America, I consider two dimensions: what sorts of information companies must provide regulators to obtain marketing authorization, and the extent to which stakeholders (doctors, pharmacists, patients) treat different versions of the "same" drugs as being distinct or interchangeable products. The research maps variation along these dimensions and compares the cases of Argentina, Brazil, and Mexico. In each country, I identify the actors that mobilize in favor of different approaches to "commodification" and study the ensuing conflicts as countries move down different paths.

Nostalgia, Food, and Football

While in DF I took the opportunity to engage in a nostalgia tour. The first 2 photos are of the buildings of the business associations that were central to the research I conducted for my PhD and *Democratization Without Representation*. The first had been the principal representative of small- and medium-sized manufacturing firms until the 1980s and 1990s, when a rival group split off. The main association still exists, the latter, which set up shop just a few blocks away, has since dissolved and, evidently, sold the property to an Italian restaurant/cafe! The third photo is of me in front of the house where I rented a room as a PhD researcher in the 1993-94 academic year. No trip

to el DF would be worthwhile without great food, tacos al pastor and delicious tacos de maciza, and of course football. It was great to be back, hasta la próxima.



The views expressed in this post are those of the author and in no way reflect those of the International Development LSE blog or the London School of Economics and Political Science.

Featured image credit: Professor Ken Shadlen

About the author

Ken Shadlen

Ken Shadlen is Professor of Development Studies in the Department of International Development at LSE. Ken 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 Ken's research has focused largely on the global and cross-national politics of intellectual property (IP). He is interested in the implications that the new global IP regime presents for late development, and the various ways that international norms for IP affect national practices.

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