Anahita Razmi

GENERICS

PROJECT INFO ARTIST PAGE → ALLIANCE MEMBER →

GENERICS links to the project **Darookhaneh Apotheke Pharmacy**, an Iranian pharmacy in Berlin, Germany.
Run by **Anahita Razmi** and **Sohrab Kashani** in spring 2022, its display consisted of a large selection of boxes of Iranian generic drugs.

Connecting to questions that arose in this exhibition space, the conversation with **Tahir Amin, Co-founder and Co-Executive Director of Intellectual Property at the Initiative for Medicines, Access & Knowledge (I-MAK)**, provides further info on the complex role of generic drugs in the current global pharmaceutical market. It furthermore speculates on the potential of the 'generic' as a cultural construct, countering

"A **generic** drug is a pharmaceutical drug that contains the same chemical substance as a drug that was originally protected by chemical patents. Generic drugs are allowed for sale after the patents on the original drugs expire. Because the active chemical substance is the same, the medical profile of generics is believed to be equivalent in performance. A generic drug has the same active pharmaceutical ingredient (API) as the original, but it may differ in some characteristics such as the manufacturing process, formulation, excipients, color, taste, and packaging."

- Wikipedia – Generic Drug

"The **generic** is capable of supporting a multiplicity of heterogeneous acts or predicates, among other things the thoughts of science and philosophy: the generic is endowed with extension but without totality or singularity, thus under-determined, non-absolute."

- François Laruelle – 'The Generic Orientation of Non-Standard Aesthetics"

Anahita:

Thank you for the opportunity to have this conversation, Tahir, which sort of is a continuation of a conversation that linked to Darookhaneh

Apotheke Pharmacy (www.darookhaneh.de), an Iranian pharmacy in Berlin, and an artistic project by Sohrab Kashani and myself. Lots of topics came up through the project that needed a follow-up conversation – linking cultural questions to legal and medical ones. One of these topics is a more in-depth look at generic drugs in the global pharmaceutical market – and subsequently the potential of the 'generic' as a cultural construct. To get some basics of this discussion right, can you tell me what a generic drug actually is?

Tahir:

Regulatory agencies have definitions for what a generic is, and these are pretty much established. We have to be clear that the generics you are talking about are drugs that are made from small chemical molecules. In the chemical space you can have an exact copy – I mean, even though some people, usually the branded pharmaceutical companies, will say generics are not really an exact copy – but you can test them to be identical in terms of bioequivalence so that they will trigger the same responses and have the same therapeutic effect.
And then in the biologic space, the 'generic equivalent' is called a biosimilar. Biologics and biosimilars are never identical. They can never be identical, it's just the nature of the living organisms and the nature of biologics. So, what you do is you have a biosimilar that is as close as it can be to the originally approved product.

But the thing that then often gets pushed around in the discussion about generics, at least in the Western hemisphere, is: Oh, well, are generics that are bioequivalent actually of good quality? And then that becomes the discussion. When we talk about generics, the branded pharmaceutical companies talk about counterfeits and often the two terms get confused – and this is done deliberately. Big pharmaceutical companies are often very, very adept at making generic sound like counterfeit. They try to push the boundaries even though there's a legal definition of a generic, even by regulatory standards like the U.S. FDA (Food and Drug administration) or EMA (the European Medical Association), which approves these kinds of drugs.
Still the industry is always trying to grey that line between generic and counterfeit, saying some generics don't have the full active ingredient or 'well, they're not *really* the same'. It will make people go back to the branded drug, because they imagine it is more reliable, safer, and better.

Anahita:

How do intellectual property regulations and patents play into this question? Do current global laws support the emergence of generics? In Iran, for example, pharmaceuticals and generics are not regulated through international intellectual property laws but through a 'National Generic Medicine Policy', which was implemented after the Islamic Revolution in 1979. Which means companies simply produce what they can produce, and products on the market are changing fast.
The project *Darookhaneh Apotheke Pharmacy* was basically filled with copies of Iranian generic drugs produced by a long list of Iranian pharmaceutical brands unfamiliar to the Western eye. A strange display that immediately also links to the question of what pharmaceuticals are not available in an Iranian 'darookhaneh' in 2022 – and why they are not available on a market that is less defined by monopolies than by other difficulties, such as sanctions and import/export difficulties.

Tahir:

This is a particular situation and very different compared to the U.S., Europe and countries that are part of the World Trade Organization's TRIPS Agreement. When India was implementing the TRIPS Agreement into its national patent law in order to be compliant, people were worried that Indian generics would be prevented from manufacturing and supplying HIV medicines, particularly as they were responsible for supplying around 80% of HIV drugs to countries in Africa. Today, for the HIV and hepatitis C drugs space especially, many Indian generic companies say it is really not a worthwhile business option because the margins are really, really low. You have to compete with so many other generics. and so it becomes a very saturated marketplace. It also does not help that because of the TRIPS Agreement and more countries now having patent laws, Indian generic companies' ability to supply these markets are now barred unless they have a license from the patent holder and permission to seek in those markets.

And I imagine that would be the same in Iran because it's not as though any one company has an exclusivity. They're all making whatever medicine they are capable of making. Now, of course, the question then might be: how does the Iranian regulatory authority decide who gets approval and who doesn't? And that might be more behind-the-scenes politics, the bigger and more powerful companies getting approved, or it's a case of having lots of suppliers. Yet, if you think about it – in this way, there is going to be what is really a free market? I mean, that really is the definition of a free market and competition: everybody's just competing with everybody else. That's the absurdity of the United States and Europe: those who claim they are free markets when really, it's all about monopolies and protection.

Anahita:

Thinking further about these protections and the TRIPS Agreement from 1994, about who was interested in implementing it and who's joined it since, I wonder where it right now stands in relation to pharmaceuticals – and beyond?

Tahir:

The TRIPS Agreement's stated objective is to ensure that there is adequate (a minimum level) protection for intellectual property rights (IP) and that enforcing such rights is not considered a barrier to legitimate trade. Alongside this stated objective, there is the popular narrative that IP drives 'innovation' and economic growth/development. However, the counter-narrative is that TRIPS was the master plan of corporations in the Global North (the pharmaceutical and copyright industries) to globalise the IP regime in order to curb those countries that were essentially 'imitators', – or as the Western corporations would say in the 1980s about South Korea and Japan's ability to imitate in the electronics space: 'pirates' – in order to play technology catch-up. Technically, IP is the antithesis of a free market because you give monopoly power to one or a few people and then you don't really have a competitive market in the true sense. IP advocates have done a clever job of saying, oh, you know, there's still competition, because everybody then is incentivised to 'innovate' and needs to come up with something different, and that drives progress, and that's freedom in itself.

In the pharmaceutical market, the TRIPS Agreement really showed that the pharmaceutical industry from the Global North was worried that countries emerging out of colonialism were going to start competing. These countries didn't have IP laws like in the United States or in Europe. And so, they could pretty much copy everything and have free space to develop their infant industry and technology capabilities. The Global North needed to defend themselves from these other countries that were going to become competitors. Most countries in the Global South at the time TRIPS came about, were importers of technology. They weren't exporting technology, and they weren't going to become inventors of technology overnight. So, who did TRIPS really serve?

I think, in a way, we've gone back to feudalism, or a new version of feudalism – where a few people hold all the knowledge. It is all about those with power defining those who are trying to work around rules that were enforced on them.

Anahita:

Taking Iran as an example of a country not being part of the World Trade Organisation (WTO) and the TRIPS Agreement, we can see weird, muddled examples of dealings with intellectual property. There is that interesting case of Razak Pharma, for example. The company was founded in 1964 as an international subsidiary of Pfizer and went into production in 1967. After the Islamic Revolution in 1979, it was nationalised, and the name changed to Razak laboratories. Razak still uses a logo that very much resembles the Pfizer logo (https://razakpharma.com/) without having any current ties to it. Iran's economy is most heavily affected by Western sanctions; it currently does not seem to gain much from adhering to international copyright and patent laws. And it is necessarily a country of pirate versions and black markets – be it software, commodities, medicine. Without naïvely idealising the disruptive potentials of such markets, is there anything to learn from them?

Tahir:

When we look at the history of all countries, including those in the Global North, over the 19th and 20th centuries, every country has had to imitate – or be a 'pirate' – in order to develop. The push to globalise IP happened when the West and its industries had reached technological ascendancy, the economy was switching to a knowledge economy, and they were worried that the Global South 'imitators' of technology would catch up. Technically there is a difference between an 'imitator' and a 'pirate' (the latter often used by those in power to evoke a more sinister meaning that could also include counterfeiters), but in the 1980s, 'pirate' was a term used by the Global North corporations to get the U.S. and EU governments attention to put IP at the heart of trade policy.
Even the Indian generic companies were labelled pirates before agreeing to join TRIPS. China is often tagged a pirate economy, even though they are a member of the WTO.
In some ways, without being bound by the rules of IP, Iran has the space to imitate – but it does depend on national economic policies and their ability to invest in developing their technologies. The difficult part with the sanctions is even if Iran started developing its own versions/imitations of existing technologies, its ability to sell beyond its borders is restricted by sanctions – which did not impede other imitator countries that developed technological capability.

Anahita:
I am also wondering about the role of the EU, and specifically Germany, in the TRIPS agreement. The EU – and Germany in particular – were the crucial entities blocking a TRIPS waiver in the pandemic. Robert Habeck, co-leader of the German Green Party, explicitly advocated for a TRIPS waiver in 2021. After becoming the Minister for Economic Affairs and after speaking to BioNTech in early 2022, he changed his position and then opposed it.

Tahir:
Based on my experience, I think the U.S. is the most fanatical about IP today. And so, I'm curious where Germany sits on that right now, as they used to patent a lot – countries like the U.S. were behind on those types of things, especially when it came to chemicals.
For the discussions about the TRIPS waiver though, I felt this was a bit of good cop bad cop game. And the Europeans were going to play bad cop this time. Also, saying that you want to support a waiver and what you put down onto paper are two different things.

As the recent WTO decision on allowing "developing countries" to bypass only patents on vaccines (but not diagnostics or therapeutic drugs) shows, after 18 months of prevarication and delay, the U.S., the EU, and their pharmaceutical companies essentially got what they wanted. The decision significantly watered down what India and South Africa had requested in their original TRIPS waiver proposal and essentially re-confirmed the already existing legal flexibilities to override patents already allowed in TRIPS. These are the same legal flexibilities that the U.S. and the EU have pressured countries in the Global South from using for the last 27 years of TRIPS. By agreeing to the WTO Decision, the Global South countries have set themselves back and accepted an outcome that reflects the power dynamics of the last 27 years of TRIPS where the Global North countries dictated at the WTO. So much for the WTO being a multilateral forum. No deal would have been better than any deal in this case.

And I think, when you have the German Green Party member who all of a sudden has flipped and is now in government, this might be because the question becomes a question of national security interests. The thinking goes: If we take the protection of IP away, or, you know, if we waive it – even in the crucial emergency case of a pandemic – then other countries are going to catch up. They're scared it is going to kill industry in Germany. I think, in more ways than just IP, it's a security interest. It's about economics. It's about power.

Anahita:
So, does the recent WTO decision mean the end of any discussion about a true waiver?
What about the example of the South African biotechnology company Afrigen, which is currently developing a copy, a generic, of Moderna's mRNA vaccine without waiting for any waiver. Does a trajectory like this propose a more promising way forward?

Tahir:

In terms of a ‘true waiver’ or broad IP Waiver, the recent WTO decision does say that the WTO will continue discussions as to whether the decision should be extended to diagnostics and therapeutic treatments. Based on what I have read and people I have spoken to, the Global North countries will not agree to this though, so I do think a broad waiver is unlikely to happen. It’s why I believe the Global South countries should have called the EU and the U.S.’s bluff and rejected the so-called ‘compromise’ deal they were offering.

Meanwhile, I think these hub-type things, like the technology transfer hub at Afrigen, are great. I think, ultimately, that’s where a lot of the countries of the Global South have to go. They must start becoming self-sufficient. They cannot rely on the Global North. Now, of course, there are going to be problems in terms of how far they can get. But the fact that they have reverse-engineered Moderna’s vaccine – I think they did it within six months – is great. The question now is, how can they scale it up? And the question is, are IP barriers going to get in the way. If you think about this model on a bigger scale and repeat it on another continent and decentralise production, it probably could be a really good step forward.

The current director-general of the World Health Organization, Dr. Tedros, comes from Ethiopia. He has seen the effects of this pandemic on the Global South. It is probably the first time in the 20 years that I’ve been in this field that somebody from the World Health Organization has spoken the way he has. The hub might not have happened had it been a different director-general. So, I think change is happening, even if it’s not necessarily as smooth as we would like to see it. I also don’t think the hub idea is the entire solution because some of these legal frameworks that are going to become a problem down the road still need to be removed.

`Anahita:`

Does that question also come down to whether a company like Moderna would actually sue them? Thinking about how these companies roll, are there differences? Or can one say one company is more ethical or supportive than another?

`Tahir:`

In the end of the nineties/early 2000s, 40 pharmaceutical companies sued Nelson Mandela’s government for trying to import generic HIV medicines. That was the biggest pharma PR disaster that ever happened. And I think the industry is still very wary of doing anything like that ever again. At the same time, it does it all the time – but you know, it does it very quietly. They’re always suing somebody. I’m sure there will be a lot of pressure that will be put on the South African government if there’s any infringement of IP. Ironically, Moderna is infringing other people’s IP rights at this moment. They’re in lawsuits themselves, including suing Pfizer. All the while they are making the argument that any legal action against them should be against the U.S. Government as they were contracted by them to make the vaccine. So, while they lobbied against a TRIPS waiver, they gave themselves one and are now asking the U.S. Government to protect them from these lawsuits.

`Anahita:`

Are there any less corrupted examples of global collaboration in the pharmaceutical space?
As someone who depends on public information on these topics, I also find it interesting to have a closer look at them in terms of PR, media and communication. Which links to how the public views them, and what the public thinks about who and what needs to be supported when it comes to health access.

`Tahir:`

The biggest thing that these companies have done is to give away voluntary licenses. Usually, it’s to low-income countries. They won’t allow those countries to sell in the bigger markets though, because that’s where they themselves make that profit. So, that is also a way of controlling the marketplace. We saw that with HIV and HCV drugs, where in many of the countries they allow these generic companies to make and sell a product, they didn’t have any patents or IP rights. So, in a way they are kind of getting IP in, because all they do is to make sure that they have the patents and the license agreements with key manufacturer countries like India, Argentina, Brazil, China. Through that they can also stop alternative sources of production. It would be interesting to see if Global South countries would infringe IP rights if they can’t get closer to the TRIPS waiver they need. The current climate and events at the WTO show that the rules are stacked in favour of the

Global North, and it may require some assertive action to break some of this power. It would then be interesting to see how that looks from a PR point of view if these actions save lives.

Anahita:

That’s a striking thought. In relation to PR and the public opinion, I am also curious about how cultural differences play into these questions? And I am sometimes wondering how much of our reasoning in this is actually tied to cultural history and cultural conventions and how much is tied to current capitalist logics.

Tahir:

You know, that’s an area that I’m trying to look into more. I’m curious about Eastern philosophies, for example, and how they speak about the idea of property and ownership of knowledge. Because in the West, property is such a huge thing, and the question of IP is part of that idea, that everyone’s entitled to property. In the United States private property is sacrosanct, entire bodies of law have been written on private property. And then the same property laws are applied to knowledge. In my opinion, the age of enlightenment thinking in Europe has a lot to do with the creation of the idea that knowledge could become property and was the birth of modern global capitalism and IP. The clash of traditional knowledge, culture, and capitalism is currently playing out in the psychedelics space, where traditional healers are fighting to ensure years old medicinal practices are not privatised by IP. Whereas investors in the West see an opportunity to profit, communities of traditional healers and others are seeking an alternative model to bringing medicines to the market but without property rights like patents.

The unfortunate part is that the neoliberal agenda and globalisation of IP has been forced on the Global South countries (through agreements like TRIPS) and continues to spread. Reversing this trend may only happen in a global crisis. While it seems this pandemic has not been enough to reverse this trend, some of the future crises around climate change may require to break from the old thinking of property that the West hangs onto.

Anahita:

As an art worker, I also wonder how art plays into this thinking. In the arts and under the promise of ‘artistic freedom’, we do not usually focus on patents or copyright too much. At the same time, there is an ever-recurring focus on artistic originality, genius, newness – and ownership, at least in the commercial market, where values are speculative, fluid and not tied to any transparent, decipherable rules. And then it’s interesting to think about how this links to the logic of other commercial markets. Does art’s cultish mystery when it comes to value, creativity, and originality possibly perpetuate how we think about progress and innovation in other fields?

And does the concept of the ‘generic’ maybe propose an alternative here?

It comes along as wonderfully boring: it is not original or novel, nor a pirate or radical, but instead, it does enable access and further development.

Tahir:

The author Anand Giridharadas recently wrote a bestselling book, and in an interview about it, he referred to Thomas Piketty’s book, Capital in the 21st Century. He said there were so many breadcrumbs in that book that allowed him to write his book. It is a nice example of acknowledging that knowledge is always built off someone else’s shoulders. All knowledge is built off previous knowledge, and is refusing this thought maybe just handy for making ‘newness’ and ‘innovation’ into a commodity that one can capitalise on? The term ‘innovation’ has become conflated with ‘invention’ in both the IP world and in everyday language. Separating innovation and invention, and changing the culture around how people understand these terms, could have a significant shift on how we view ‘progress’.

In pharmaceuticals, we see that there are so many patents in the same space, and they’re all very close. It’s a collaborative system, but it’s really dressed up as this mythical, ‘innovative’ space where one person, one player, one ‘innovation’, gets the glory.

And in some ways the patent system is no different to awards like fellowship prizes or Nobel prizes for science or some other discipline. They are given to a few individuals despite that it’s very often more than one person’s effort and work in that field that helped to make things possible. It seems we can’t escape ourselves the way we’ve set it up: we need our stories, we live in the cult of individual winners; it’s part of our individualistic society.

Capitalism breeds on individualism. It doesn’t breed on a collective.
It is interesting to think about where the idea of the generic sits on that – as there’s nothing individualistic about it.
I believe we need to reform our legal systems, but as this is a cultural battle, it starts with rethinking our language and knowledge systems.

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