



The Unfurling of Indian Pharma Industry

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The Unleashing of a Caged Giant

Imagine yourself being a highly skilled pharmacologist with a team of researchers back in the 1930s and staying in India. You have your own plant and machinery to work on target Identification, hit Identification, etc. The plant is extremely efficient, and the researchers working in the plant are fully enthusiastic - brimming with energy, and highly talented.

You and your team come up with an efficient drug for malaria, you believe you can produce this drug efficiently and at scale using less cost of capital. Thus, you can sell the drug at a low price - at least within India, given, that you do not have to bear any cost of export. Your team of researchers and volunteers are all geared up - when you come to know, you cannot even embark on this journey. Reason? - The Indian Patents and Design Act of 1911.

The Indian Patents and Design Act of 1911 offered both process and product patent protection to the innovators for 16 years, with an additional 7 years of extension if required.

You may be thinking - what if I provided the medicine for the same therapeutic area (in this example - malaria) but used a different manufacturing process - in my own style. That too is not permitted, because eventually, you were creating a product for malaria - which was not allowed.

This was a serious impediment for Indian pharma innovators. Imagine, you are a pharma innovator company, you are living in the 1950s in India, and painfully witnessing the malaria epidemic. But you are not allowed to create a cheaper version of the medicine, because a patent already exists for quinine (a key anti-malarial drug). Seriously Frustrating, right?

This pent-up frustration of the Indian Pharma companies was let free through the Indian Patents Act of 1970. In simple terms, the Indian Patents Act of 1970 did a smart amendment to the Indian Patents and Design Act of 1911.

It basically said (the below is expressed in simple and candid terms from an Indian Pharma company's perspective)-

The one who has innovated the drug should and rightfully so, keep its laurels to itself. But why can't I solve the same problem in my own way? To put things into perspective using the referred example - the way the innovator created anti-malarial drug remains sacrosanct and thus protected through patent. But I should be allowed to make antimalarial drugs in my own way.

In essence, the Indian Patent Act of 1970, allowed process patents for innovators. But discontinued product patent.

The Indian Patent Act of 1970 unleashed the tied-up giant - Indian Generic Pharma Industry.

A Generic medicine is produced by reverse engineering and slightly tweaking an indigenous drug.

For example, if the innovator drug company had produced the original drug using the below formula:

$$8+7-5 = 10$$

Then, the generic version, would still reach the same result: 10, but probably in the following way:

$$8+8-6 = 10$$

Thus, as you can see the objective of the generic drug manufacturer is to create the same product using slightly different technique (as the process patent still needed to be respected).

Indian Pharma Companies began to produce a plethora of generics between 1970 and 1995. This resulted in price drop of patented drugs in India and treatment of life-threatening diseases like malaria, viral fever, bacterial infections etc. affordable for Indians.

The whip of WTO - TRIPS

Getting an opportunity is one step, but making the most of that opportunity is the key, and the Indian pharmaceutical industry demonstrated just that. The abolition of product patents as part of the Indian Patent Act of 1970 allowed the Indian Generic Pharma Industry to thrive. As per Deloitte's paper - "The Indian pharmaceutical industry: The 'pharmacy of the world'?", during 1970-1995, the number of Indian domestic pharma companies rose from 2000 in 1970 to 24000 in 1995.

This meant two things - one is obvious; India became self-reliant in treating its people and providing affordable medicine as needed; The second part is - that India's efficiency in terms of skilled labor and well-equipped plants grew multi-fold during this period.

But, as they say, real life has a more interesting climax than fiction. All went well until 1995, when the World Trade Organization (WTO) was established, replacing the General Agreement on Tariffs and Trade (GATT). The intention of setting up WTO was primarily to facilitate trade negotiations, handle trade disputes between member nations, and administer trade agreements between member countries. To participate in global trade, a country must be a member of the WTO.

Everything seemed hunky Doorey so far until WTO introduces the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement). Under TRIPS, member countries were required to provide patent protection to both Product and Process for pharmaceutical products for 20 years from the filing date of application.

It meant - that section 5 of the Indian Patent Act of 1970 - which provided only process patents for pharma drugs, was no longer valid. India had to walk backward and provide product patents too. Thus, all the effort that Indian pharma companies undertook to ramp up their generic drug manufacturing capability, meant nothing.

But wait, TRIPs did not really take away everything from Indian Pharmaceutical companies all at once. It gave them time to align. And time is all that Indian Pharma companies needed to recalibrate. India had time till 2005 to align itself with TRIPs.

HIV AIDs Pandemic and Yusuf Hamied

There is an old saying - Honest and serious effort never goes in vain. All the efforts that Indian Pharmaceutical Industry undertook from 1970 to 1995, could not have gone in vain.

The opportunity presented itself through a rather unfortunate incident - the HIV/AIDS crisis in Africa. By late 1999, and 2000s Africa had turned into the epicenter of the HIV/AIDS pandemic.

Now, here is the tragedy - during the pandemic, antiretroviral treatment (treatment against retroviruses, primarily HIV) was available, but under the umbrella of a patent. As a result, even though the drug was affordable for people in the West (US and Europe), it was not affordable for people in Africa. As a matter of fact, the cost of patented antiretroviral drugs during this time was above \$10000 per year for a patient.

India had already faced the HIV/AIDS problem in the mid-1980s and solved it using its homegrown and low-cost generic version of ARV drugs.

Thus, a deadlock as below occurred during the late 1990s:

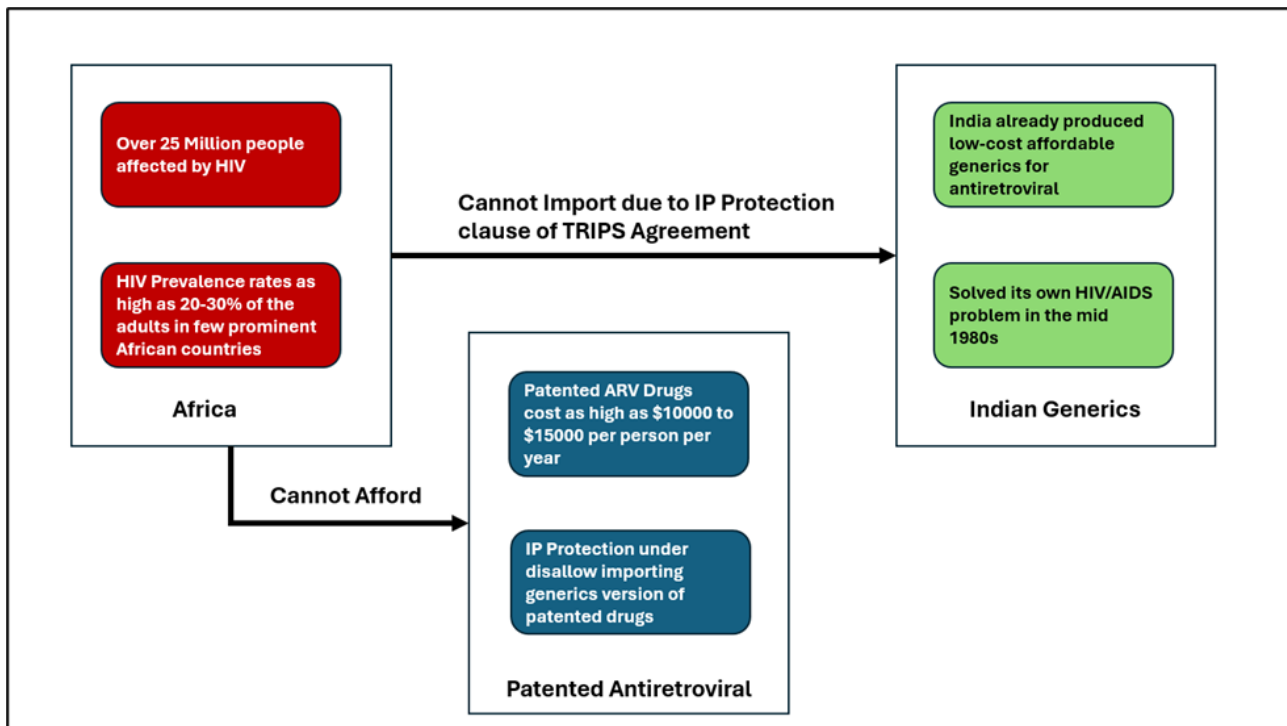


Figure: HIV/AIDS deadlock context

In comes Dr. Yusuf Khwaja Hamied, who was the chairman of Cipla during this time. He made a ridiculous offer in 2001 - he said Cipla could offer the generic version ARV drug cocktail to Africa for just \$350 a year, which is less than \$1 per day. A ridiculous offer, through which Cipla was merely breaking even, or probably losing money, made the world pause and listen. And forever changed the dynamics of the global pharmaceutical market - paving the way for Indian generic pharma manufacturers.

Doha Declaration: Compulsory Licensing and Parallel Import

The culmination of the multiple compelling factors - HIV/AIDS pandemic deadlock (presented above), Cipla's outrageous offer to provide ARV drug cocktail generic version to Africa at less than \$1 per day and the fact that the same generic helped India contain the spread of similar disease in the past resulted in the DOHA Declaration on the TRIPS agreement and public health in November 2001.

The Doha declaration led to two most significant reforms to the TRIPS agreement, which shaped the future structure of the global pharmaceutical industry:

Compulsory Licensing

WTO Members were now allowed under the TRIPS agreement to grant compulsory licenses under their domestic laws. This meant the government could now authorize the production of patented medicines within their country without the consent of the patent holder, under conditions deemed as public health crisis.

Furthermore, individual countries under WTO were provided the freedom to determine which situation classifies as a public health crisis.

It is a no-brainer, who are the biggest beneficiaries of this move (and well deserved too) - a country like India, who scaled up its pharmaceutical manufacturing capacity and skillset like no one else from 1970 to 1995, facilitated by the Indian Patents Act of 1970.

Parallel Import

Even after compulsory licensing, one more problem remains - right? What about the other low-income countries that do not have the infrastructure, skill, and know-how to scale their domestic pharma? Let us think about the HIV/AIDS scenario - India already had the generic version of the antiretroviral drug in its kitty, willing to help African people by supplying these drugs, and the price they were offering was affordable for African countries.

Should the African countries still be suffering as long they do not build and scale their domestic infrastructure and capabilities to mass produce the generic drug? The obvious answer is - No.

Thus, parallel import allows right to the WTO member countries to import patented drugs sold more cheaply in any other country without the patent holder's consent. This opened the international markets for generic drug import and export, and not only that - import and export of less-priced versions of patented drugs during a public health crisis.

Thus, the importance of process efficiency along with product efficiency in pharma stepped in. The market began to move from product monopoly players to process, scale and product efficient players.

Resulting Shape of the Industry

The series of events described above, combined with the industry's focus on such a critical subject as public health, has made the overall business structure of the pharmaceutical industry increasingly complex over time. The following is an oversimplified overview of the industry landscape:

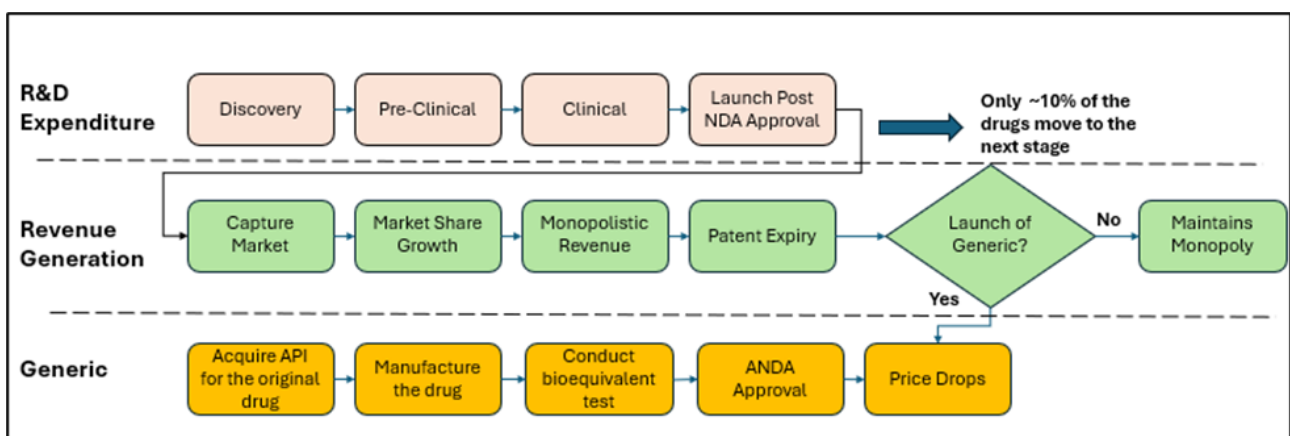


Figure: Oversimplified overview of the industry landscape

As the above picture depicts, the amount of R&D; expenditure baked into the revenue for an Innovator Company is very high - which includes expenses starting from Lead Identification, Hit Generation spanning across Clinical Trials till Regulatory approval and finally market creation for the drug.

And unfortunately (for the innovator drug companies), only about 10% of the drugs make it through to the market and generate revenue (Source of the information: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9293739/>).

In comparison, the operating expenses of a Generic Drug manufacturer are not high. The only tricky part they need to solve is sourcing the API for the patent drug as cheaply as possible, otherwise, they are not required to repeat the extensive clinical trial program required as per NDA.

However, this interplay between Branded and Generic space offers a lot of interesting scenarios that are outside the scope of this article. But I can make a one liner mention about them:

- There can be various types of generics, such as branded generics, generic generics, specialty generics, etc. It is worth knowing them in detail.
- Complex Generics are generic drugs that involve complex active drug ingredients, which require expertise to formulate and create a final delivery route. Thus, if a generic drug manufacturer is more inclined towards producing complex generics, it is possible to create at least an oligopolistic kind of moat, if not a duopoly.
- ANDA Para IV, allows generic manufacturers to challenge existing patents of brand-name drugs. If successful, the generic drug manufacturer gets 180 days of market exclusivity - during these 180 days, no other generic versions of the same drug can enter the market.