



## Patents And Drug Pricing

### Relevancy

- ✓ G.S. Paper 2, 3
- ✓ Relations between patents and drug pricing
- ✓ About secondary patents and issue of humira case
- ✓ Indian patent law

### Recently:

- ❖ India's rejection of secondary patents has kept blockbuster medicines affordable for many.

### How are patents and drug pricing related?

- Patents offer their owners market exclusivity for a limited period of time.
- For medicines, this exclusivity should last as long as the primary patent is in effect, typically 20 years.
- Primary patent relates to the active pharmaceutical ingredient (API) of the medicine.
- The end of patent exclusivity is referred to as a patent cliff.
- This is because drug prices fall steeply by as much as 80% after the end of patent exclusivity.
- The price fall is driven by the generic competition that sets in.
- Resultantly, pharmaceutical companies witness fall in profits.

### What are secondary patents?

- Secondary patents are claimed for derivatives and variants of the API.
- This may include a physical variant of the API, a new formulation, a dosage regimen, or a new method of administering the medicine.
- The pharmaceutical companies, who face losses, attempt to postpone their patent exclusivity by filing secondary patents.
- The secondary patents prop up before the expiry of a primary patent.
- It thereby stretches the patent exclusivity beyond 20 years.
- This practice of extension of patent exclusivity is called "ever greening".
- The strategy is most lucrative when employed in the context of so-called blockbuster medicines.
- These are medicines that reap annual revenues exceeding \$1 billion.

### What is the issue Humira case?

- Humira is one of the world's best-selling prescription drug.
- Its main ingredient is adalimumab which is a biologic used for the treatment of arthritis.
- In 2015, Humira faced imminent expiry of patent of its main ingredient.
- AbbVie Inc, makers of Humira, reassured its investors by citing the option of filing secondary patents which is allowed in the US.
- Humira thus continues to grow even after the expiry of the patent over its main ingredient.
- Over the years, AbbVie has increased the price of Humira in the U.S. by 100%, by steadily filing secondary patents.

### What is the case with secondary patents in India?

- The U.S. recognizes and encourages secondary patents.
- India, however, does not encourage and has limitations in securing secondary patents.
- Humira - Indian Patent Office (IPO) had rejected Humira's secondary patents.
- Consequently, cheaper versions of the drug were introduced in India.
- Evidently, Humira costs Rs.85,000 in the U.S., and the same treatment costs only Rs.13,500 in India.

### What are the other similar cases?

- Another patent case worth mentioning is the Novartis' Glivec, a crucial leukaemia cure.
- The Supreme Court of India in 2013 upheld the rejection of a secondary patent for Novartis' Glivec.
- Likewise, Spiriva, a medicine for asthma, enjoys patent protection until 2021 in the U.S., largely due to secondary patents; rejected in India.



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## What makes Indian patent law unique?

- As per the Indian Patents Act, the product in question must feature a technical advance over what came before.
- Secondary patents for pharmaceuticals are often sought for trivial variants.
- They typically fail to qualify as an invention as prescribed in the Act.
- Further, when a medicine is merely a variant of a known substance, the Patents Act necessitates a demonstration.
- This is mandated in terms of showing the improvement in its therapeutic efficacy.
- The provision also bars patents for new uses and new properties of known substances.
- This additional requirement is unique to Indian law.
- Thus, to be deemed patentable, applications for secondary patents have to clear significant hurdles.
- The patent approval procedure ensures that bad patents stay out of the system.
- Indian patent law is thus commendable in preventing the ever greening practices by pharmaceutical companies.
- This is supportive in making affordable the blockbuster medicines which are crucial to the success of public health.



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## Maldivian Polity

### Relevancy

- ✓ G.S. Paper 2,3
- ✓ Current status of Maldivian polity
- ✓ Violations made by the government and the international reactions to it.

### Recently:

- ❖ The Maldivian Supreme Court has cancelled the imprisonment of the deposed former president and 8 other opposition leaders.
- ❖ While this opens up the avenue for them to contest the upcoming elections, the government has been resorting to repressive tactics.

### What is the current status of Maldivian Polity?

- In the 2013 election, the incumbent President Abdulla Yameen defeated Mohammad Nasheed who was deposed from presidency in 2012 by a coup.
- While the results of the election are still contested, Yameen has ruled the island since then with an authoritarian streak.
- Meanwhile, Nasheed was sentenced in 2015 to 13 years in prison for charges of terrorism, and has remained in exile all these years to avoid arrest.



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- Recently, the Supreme Court cancelled his imprisonment and that of eight other political leaders, which the current ruling dispensation hasn't liked.
- The order also reinstated 12 parliamentarians who were disqualified last year also asked the government to convene the parliament (Majlis).
- As Yameen hasn't complied with the order thus far, this pits his government directly against the judiciary, polity and sections of the bureaucracy.

### **What were the violations made by the government?**

- The government has openly refused to cancel the imprisonment of the nine leaders, most of whom formed the core of the previous Nasheed Government.
- The President has also refused to allow the Majlis to meet, which has led to the resignation of its Secretary General.
- Contrarily, the government sent in the army to stop lawmakers from entering the premises, besides arresting two parliamentarians at the airport.
- Several officials, including two police chiefs and the prison chief have resigned or been sacked, as they've tended to comply with the court directives.
- The Attorney General has now termed the court directives as "illegal orders" which can't be adhered to by the executive.
- Maldives is clearly in the midst of a constitutional crisis due to stifling of the opposition, with less than a year away for the next general election.

### **What have been the international reactions?**

- India has joined the U.S., the European Union and several other countries in calling for Mr. Yameen to carry out the Supreme Court's order.
- But notably, India's clout over the ruling Maldivian dispensation has been on the wane ever since Nasheed was deposed.
- Compounding this is the reality that SAARC has become dysfunctional and Maldives has quit the "British Commonwealth".
- It will require concerted action from the international community to persuade President Yameen to steer the Maldives out of this crisis amicably without coercion.
- Ensuring the fairness of the upcoming elections, with an equal playing field for the opposition and other dissenting parties is the only way out.

### **What are the doubts about India's foreign policy in the Maldives crisis?**

- The unfolding crisis in Maldives draws attention to the perennial question about whether and when India should intervene in the internal politics of its neighbouring countries.
- Before we discuss the current context in Maldives, where President Abdulla Yameen is defying the nation's Supreme Court and the international community by refusing to release jailed members of Parliament and restore their rights, it is important to put away some misconceptions about India's approach to sovereignty and intervention.
- One popular political myth about Indian foreign policy is that New Delhi has unflinching commitment to the principle of "non-intervention".
- India certainly is opposed to other powers interfering in its domestic politics.
- It used to criticize Western powers for their frequent interventions in the developing world. But that general principle had a big exception in India's neighbourhood policy.
- India has often intervened in the internal affairs of other countries. For example liberation of Bangladesh from Pakistan in 1971, the intervention in the Sri Lankan civil war in the late 1980s or its more recent involvement in the making of Nepal's constitution.
- Second, there is also the other tendency to see India's role in every twist and turn in the domestic politics of neighbors.



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- This over-determination of an Indian role is akin to past Indian debates about the “foreign hand”, especially that of the US.
- India certainly intervenes, but not always.
- Delhi’s decision-makers are not perpetually plotting to shape the domestic politics of its neighbors.

### What constitutes the real story?

- The real story is about the simultaneous demand for and resentment against Indian intervention.
- Different political formations in the neighboring countries seek India’s intervention on their behalf in their internal disputes; and yet they criticize India if it acts in favor of their opponents.
- The problem for India has always been making sensible judgments on when it is worth intervening rather than whether.
- The third myth is that China, unlike India, believes in sovereign equality with countries big or small.
- Since most countries in the Subcontinent seek a bit of autonomy from India, they find China’s interventionism often quite useful but only up to a point.
- Geography and interdependence with India caution them against drawing too close to Beijing, and provoking Delhi into intervention and regime change.

### What has been India’s recent foreign policy regarding Maldives?

- President Yameen of Maldives has been testing the limits of his maneuverability between India and China.
- There was much criticism of Delhi, at home and abroad, in recent years that it has been too passive in relation to Yameen and has allowed China to rapidly gain ground in the Maldives.
- Delhi was torn between two very different options. For one, the logic of dealing with whoever is in power nudges India towards the negotiation of a reasonable relationship with Maldives in which Yameen respects India’s core interests.
- Last month, Delhi hosted the foreign minister of Maldives as part of an effort to normalize relations with Yameen. Delhi had to stay engaged with opposition leaders seeking a restoration of democracy.
- Many of them would like India to step in to oust Yameen. The fear of such an intervention has been openly articulated by Yameen’s propaganda machine in recent weeks.
- The intensification of the crisis in the last few days, triggered by the Maldivian Supreme Court’s decision to release all political prisoners has put Delhi in a spot. Especially after Yameen rejected India’s appeal to respect the Supreme Court’s decision and is now trying to bully the apex court into submission.
- He has probably bet that he can ride out the internal storm and count on support from China.
- The international community, including the Western powers and the United Nations, are all with India in urging Yameen to roll back his authoritarian rule.
- “Doing nothing” is surely an option for Delhi; that in effect means India chooses Yameen’s side.
- “Doing something” would involve political mediation between the government and Opposition, the use of coercive diplomacy, and ultimately force, to restore order in Maldives.
- Such an intervention is likely to get considerable international support and some Chinese criticism.
- The moment, then, may indeed be ripe for a decisive Indian intervention in the Maldives.
- But Delhi surely knows one thing from its past interventions. The task of fixing other people’s problems is never easy. And not all consequences of intervention can really be predicted or managed.
- Maldives might be tiny state with less than half a million people. With a deeply fractured political elite that has become acutely conscious of its strategic location, it will take a lot of Indian energy to repair the state of affairs in Maldives. But then that is the burden of all major powers, especially in their own regions.





## A Crisis, An Opportunity

### Relevancy

- ✓ G.S. Paper 3
- ✓ Incidents due to excessive use of pesticides and measures taken
- ✓ Regulation of pesticide usage issues
- ✓ Use of technology to regulate pesticide usage

### Recently:

- ❖ The 50th year of the Insecticides Act has coincided with distressing news from the countryside.
- ❖ In Yavatmal district of Maharashtra, more than 30 farmers and farm labourers have died due to pesticide poisoning.
- ❖ In India there have been many reported cases of deaths due to excessive usage of pesticides.

### How many incidents of deaths due to pesticide usage have been reported?

- In 2013, Bihar, more than 20 school children lost their lives after consuming mid-day meal contaminated with a highly toxic pesticide.
- Recently in Yavatmal district of Maharashtra, more than 30 farmers and farm labourers have died due to pesticide poisoning.
- In India, the consumption of pesticides has shown an upward trend from approximately 14,000 metric tonnes in 1965 to close to 56,000 metric tonnes in 2014-15.

### What were the measures taken to regulate pesticides usage?

- Government of India enacted the Insecticides Act, 1968, which regulates the import, manufacture, sale, transport and distribution and use of pesticides.
- The Insecticides Rules of 1971, made the pesticide containers mandatory to carry a specific colour mark which is associated with the toxic nature of the pesticide.
- The Pesticide Management Bill, 2008 was also proposed and pending in Parliament.
- Crop Pest Surveillance and Advisory Project has been initiated by the Maharashtra government in 2008.
- Regulations regarding basic educational qualifications of pesticide dealers were introduced in 2015.

### Why is it difficult to regulate pesticide usage?

- Farmers are not aware about the hazardous nature of the pesticide, they are often unaware of the implication of the color codes or instructions in the pesticide containers.
- For the selection and application of pesticides, farmers rely heavily on the dealer for advice, such advice is driven by their economic interest rather than knowledge of pest control.
- In 2016 government exempted existing licensees who are more than 45 years old and who have pesticide dealership experience of more than 10 years, from educational qualification on pesticides.
- Non-genuine pesticides flood the market and sales of such products account for approximately 30 per cent of the volume of the domestic pesticide industry.

### How can technology be used to regulate the usage of pesticides?

- Use of technology will help the government to regulate the usage of pesticides.
- Mobile technology can be used to develop a multi-purpose Pesticide Prescription and Transaction System (PPTS).
- The mobile number of the farmers should be registered with the proposed PPTS and a prescription in the form of a unique reference number (URN) will be sent to the farmer by SMS.
- The URN will also serve as the prescription tracking number, the URN will be shared with the dealer who will validate the URN with the PPTS.
- The system will then generate a receipt along with details of prescription including the URN.

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- For each transaction, the PPTS will also provide information about hazards and suggest safety measures to the farmer.
- The inbuilt traceability feature will also help to limit the selling of illegal and non-genuine pesticides.



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