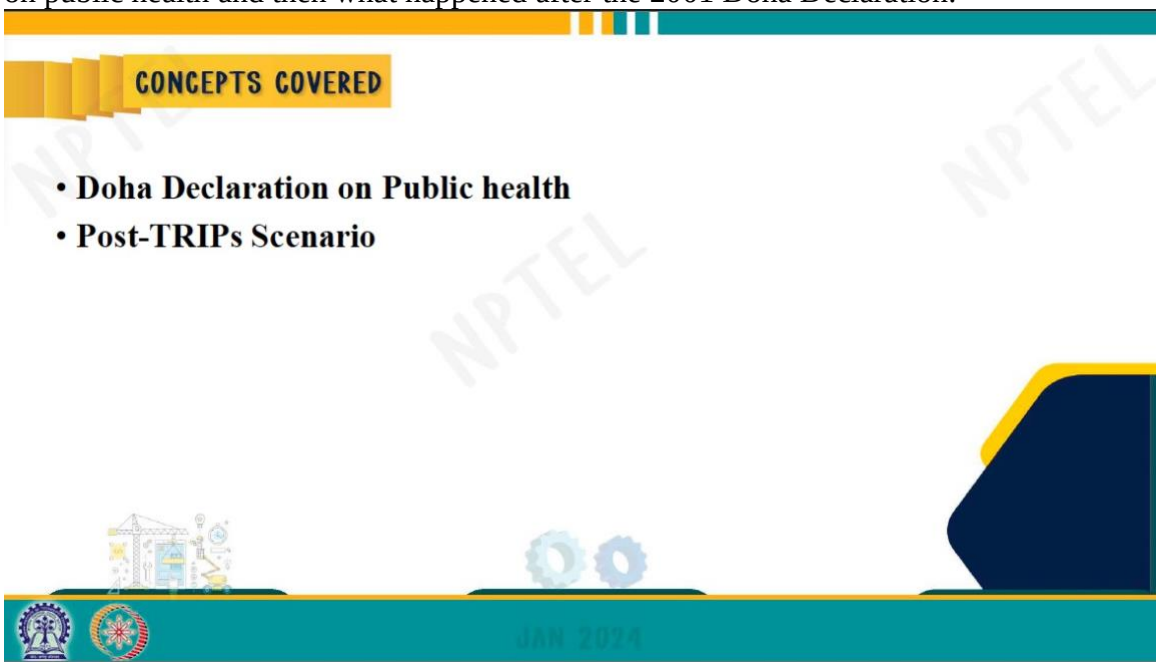
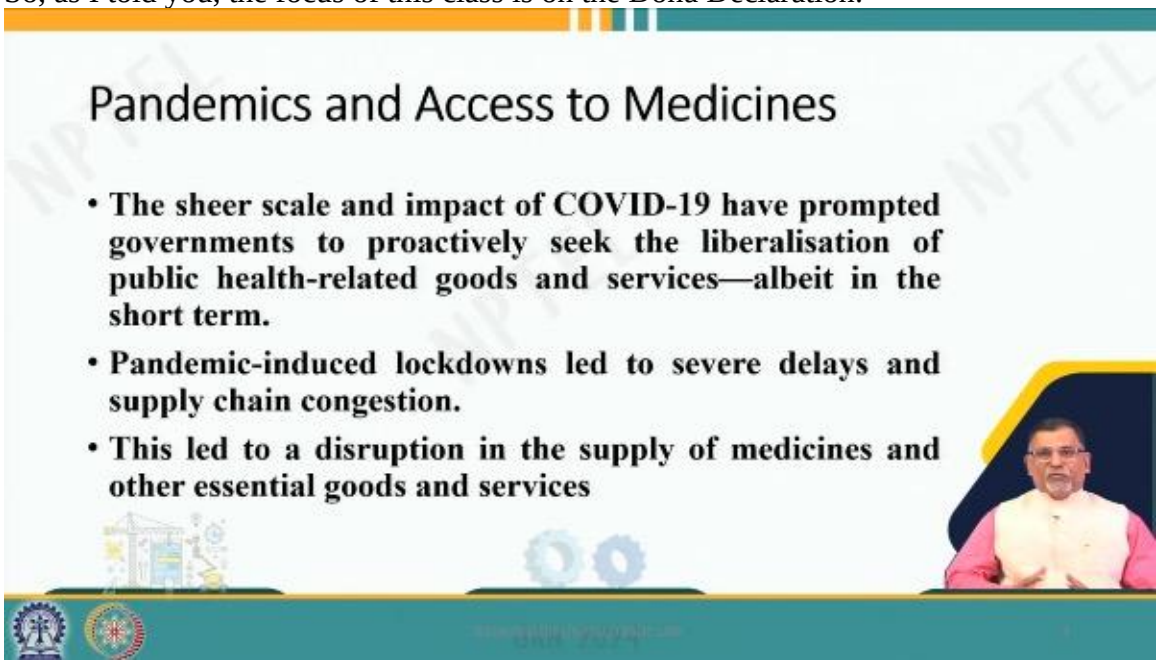
Lecture 26: Doha Declaration and Post-TRIPs Scenario

Dear students, today we are going to discuss about the TRIPS Agreement and Doha Declaration on Public Health, specifically. And this is the last lecture in the series of TRIPS Agreement. And, what is this Doha Declaration and why it is important and what it provides for, what are the provisions and what are the leeways or what are the concessions which are granted to the WTO members by the WTO General Council and what was the decision? We are going to discuss the implications of the Doha Declaration on public health and then what happened after the 2001 Doha Declaration.

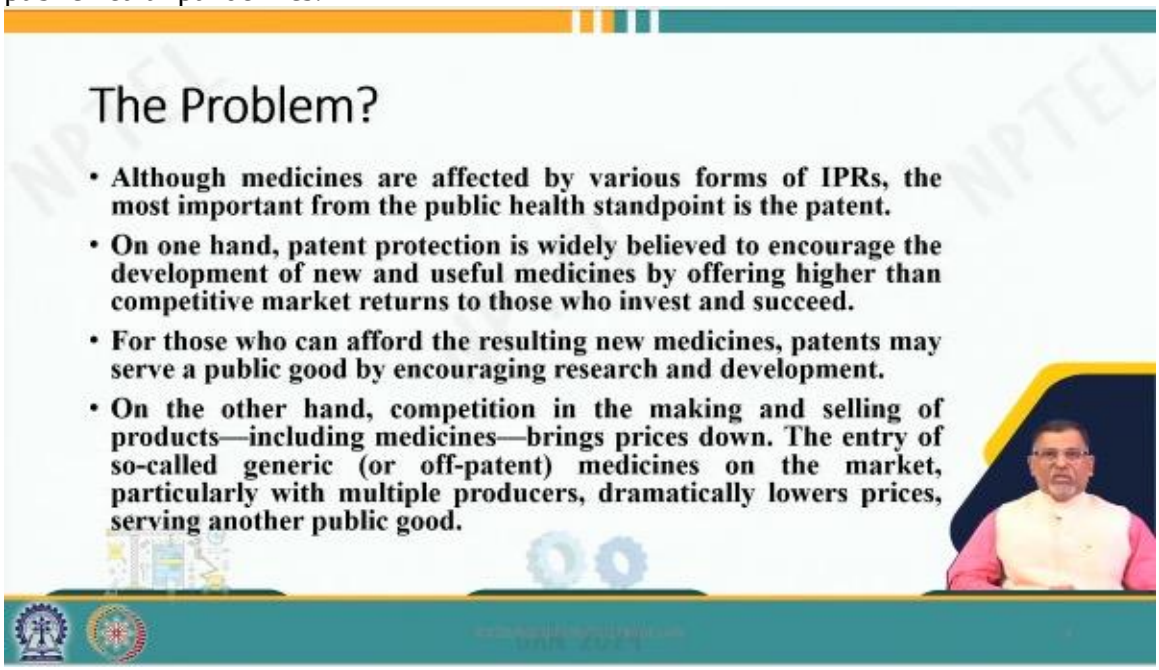


So, as I told you, the focus of this class is on the Doha Declaration.

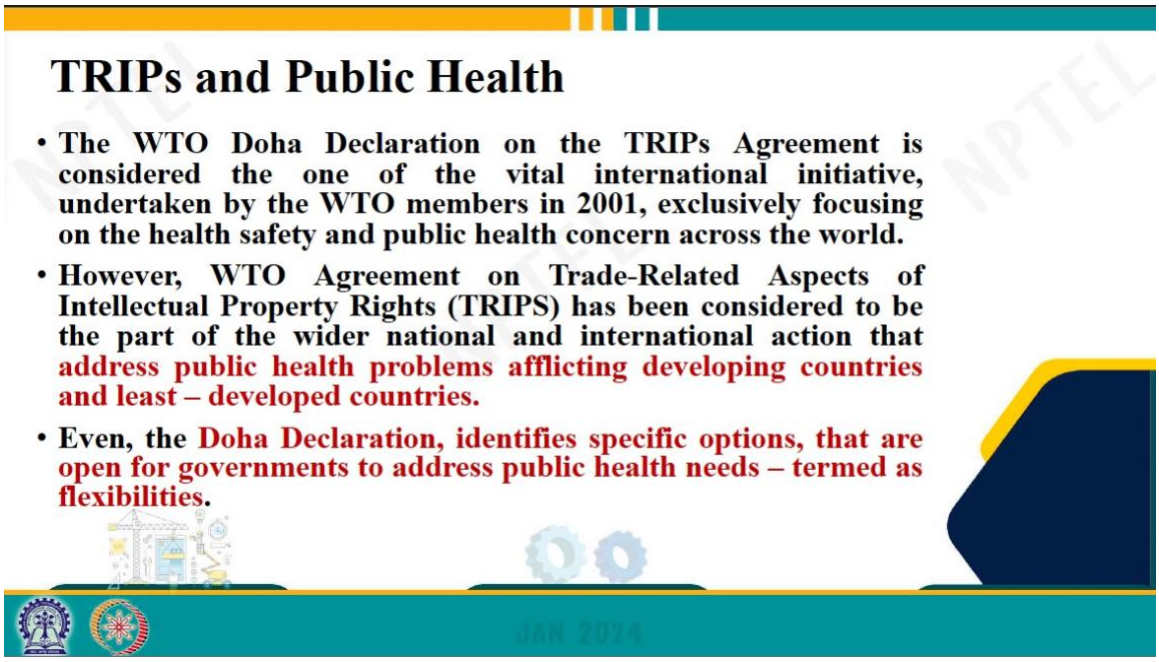


And what happened very recently after the pandemic? So, the pandemic has also caused a lot of problems to the various sectors and the lockdown and, more importantly, the health

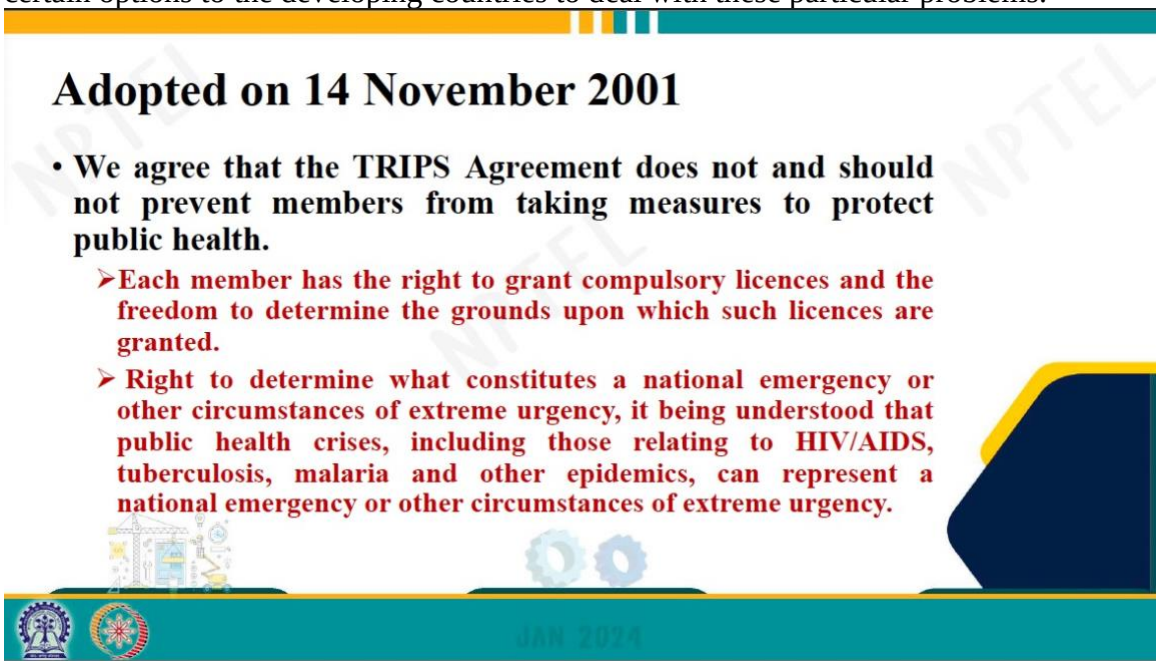
sector was affected, the services in the health sector were affected mainly due to the closure or temporary lockdown of the companies and there was a whole lot of discussion with regard to how to deal with a pandemic like COVID-19. So, the discussion of what happened in 2001 once again, the same discussions came up. So, how are you going to deal with the pandemic? So, whether it is a pandemic like AIDS or it is tuberculosis or it is COVID, all these are of a similar nature. So, there was a severe disruption in the supply of medicines and essential services. So, the problem was the people, the countries that do not have the capacity to manufacture medicines, how they will deal with the situation and public health pandemics.



So, our discussion is mostly on intellectual property versus access to medicines. So, this is the basic discussion. So, the question is whether intellectual property protection affects the supply of medicines because the medicines are covered under the intellectual property regime, the medicines are patented. So, due to the patenting and the monopoly, which is granted for 20 years, whether it is affecting the prices. So, the main allegation against the pharmaceutical companies is that they are exorbitantly charging for medicines, especially the essential medicines, for those who are going to be affected or to deal with the pandemic. So, the IPR, everybody knows that, is an incentive for innovation on one hand and on the other hand, to maintain public health is also very important. So, innovation, patenting encourages people to come out with new medicines, for new diseases and anew medicines are required to deal with new diseases. At the same time, the patenting, whether it is becoming an obstruction to the maintenance of public health is the question. So, while selling these particular products, the main, the whole issue is focused on the prices. The prices of patented medicines and the prices of generic medicines. So, most of the developing countries are dependent on generic medicines because the patented medicines are costly, very costly. So, the affordability question comes up again as a discussion point.

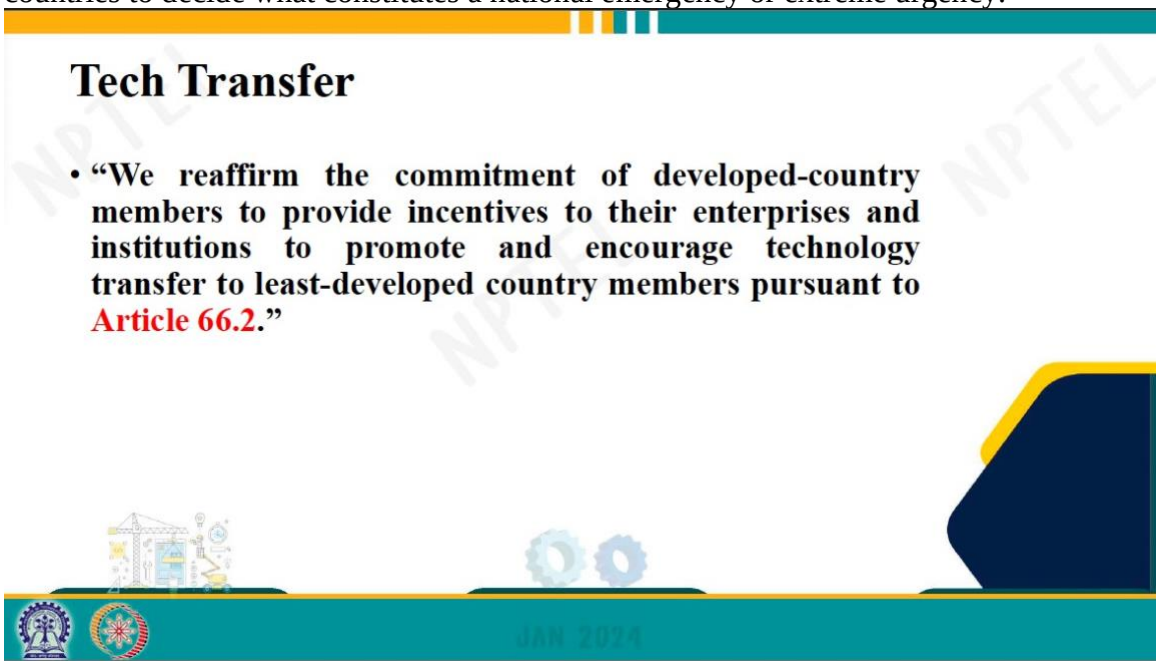


So, in 2001, the WTO - the Doha Declaration what they did was they discussed this particular problem. The problem of the pandemic and the problem of non-affordability and the problem of countries that do not have manufacturing capacities. The WTO members were of the unanimous opinion that every country has the freedom to deal with public health problems, affecting their own countries, especially developing countries. So, the Doha Declaration on public health specifically identifies certain options and gives certain options to the developing countries to deal with these particular problems.

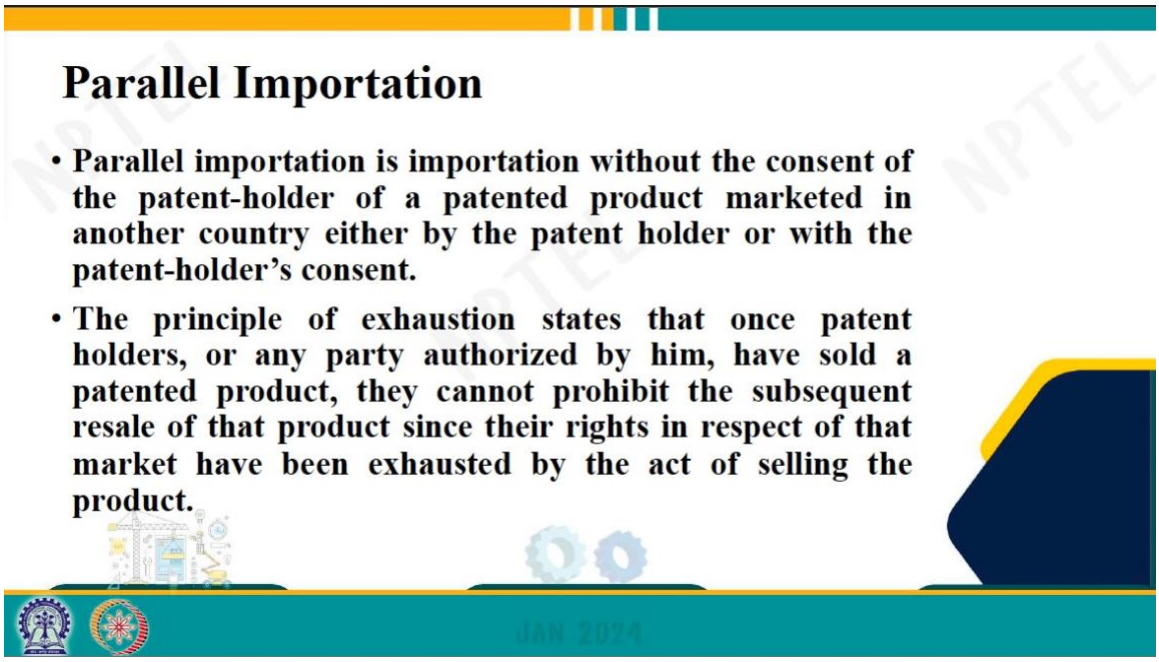


And on 14th November 2001, a Declaration which talks about and says that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. It declares that the TRIPS Agreement is not an obstacle or a barrier to maintaining public health in the member countries. So, every member has a right to grant

compulsory licenses and to determine the freedom of license. So, this is already there in the TRIPS Agreement. And also, the Doha Declaration told what constitutes a national emergency or other circumstance of extreme urgency. So, it depends upon the circumstances in each member country. So, basically, every member country can decide what constitutes a health crisis. So, the old pandemics like HIV-AIDS, Tuberculosis, and Malaria and the new diseases or pandemics like COVID-19, it is up to the member countries to decide what constitutes a national emergency or extreme urgency.



So, this is the Doha provisions and also the Doha Declaration reaffirms the need for Article 66.2 of the TRIPS Agreement for the technology transfer. And Doha Declaration says, we reaffirm the commitment of developed country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country members pursuant to Article 66.2. So, the Declaration urges the developed countries to transfer the technologies to least developed countries and other countries including medicines.



And the Doha Declaration allows parallel importation. What do you mean by parallel importation? This is the importation of goods without the patent holder's consent of a particular patented product marketed in another country. So, it means you import this particular product from another country even though that particular product is patented, and there is no need for the patent holder to consent to import that particular product from another country. So, patent holder consent is not required. So, parallel importation is permitted. So, if a particular medicine is in another market, you can purchase it for a lower price from that market and transport it to your country. So, the patent holder's consent is not required. Secondly, the Doha Declaration very clearly says that the principle of exhaustion is applicable. What is this principle of exhaustion? It says that the patent holder once sold a particular product, a patented product, and he cannot prohibit subsequent resales of that product. His rights are exhausted with the first sale and also exhausted by the act of selling that particular product. So, this is the principle of exhaustion. So, once the product is sold, he does not have any rights over the product, and he cannot enforce his patent rights over that particular product.

Parallel Importation (Contd.)

- Article 6 of the TRIPS Agreement explicitly states that practices relating to parallel importation cannot be challenged under the WTO dispute settlement system.
- The Doha Declaration has reaffirmed that Members do have this right, stating that each Member is free to establish its own regime for such exhaustion without challenge.

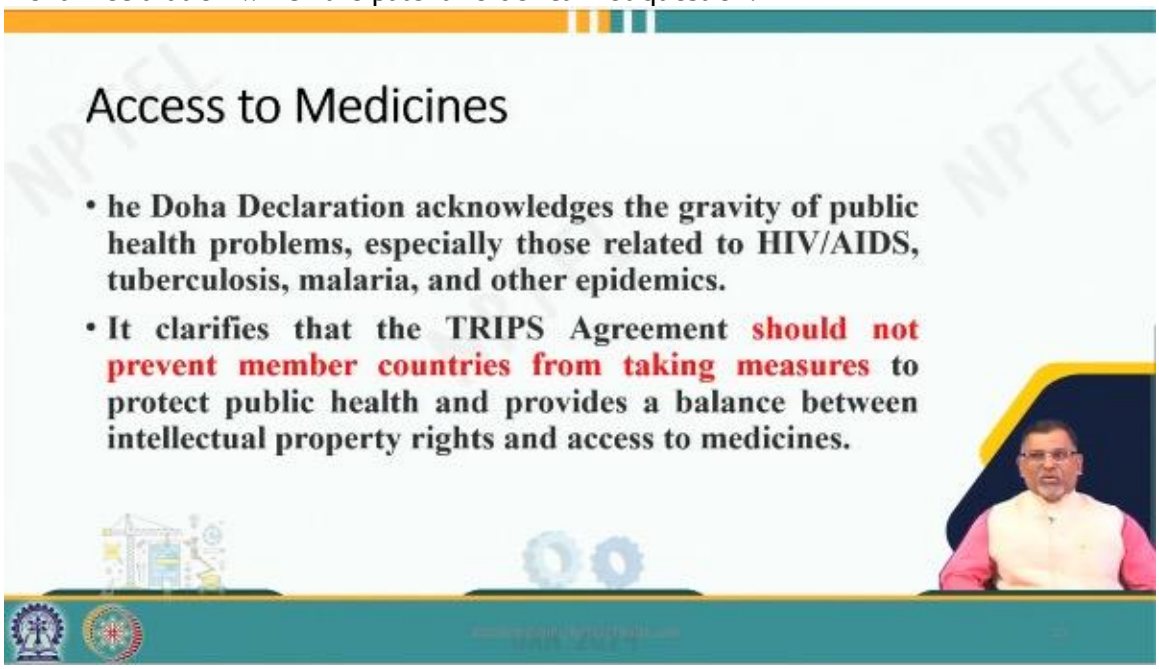
Again, it says that parallel importation cannot be challenged under the WTO dispute settlement system. So, the Doha Declaration made it very clear that parallel importation cannot be questioned. It is not a violation of the WTO Agreement. Also, the Doha Declaration confirms each member to have their own regime for such exhaustion without challenge. So, they can add provisions in their own domestic law to implement these particular provisions.

Parallel Importation (Contd.)

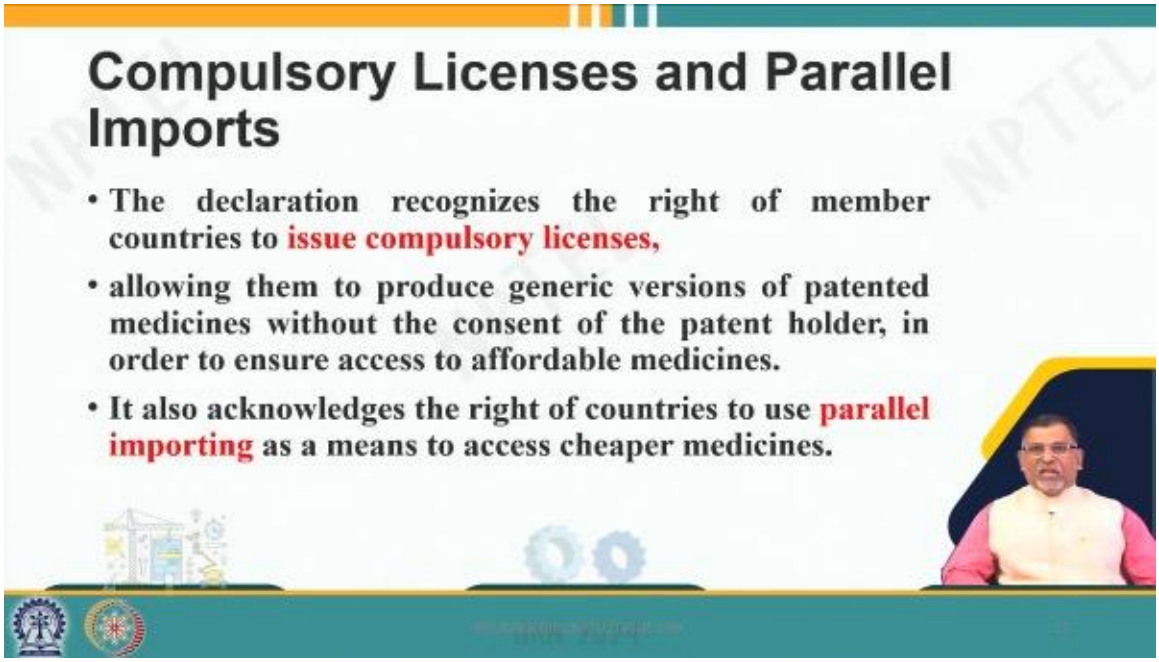
- Since many patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of lower priced patented products.
- Parallel importing can be an important tool enabling access to affordable medicines because there are substantial price differences between the same pharmaceutical product sold in different markets.

Parallel importation is considered to be one of the essential tools enabling access to affordable medicines because you can import these particular medicines which are not available in your market from other markets. There can be price differences, and definitely, there are substantial price differences between markets, and the same pharmaceutical company is selling the medicine not for the same price all over the world.

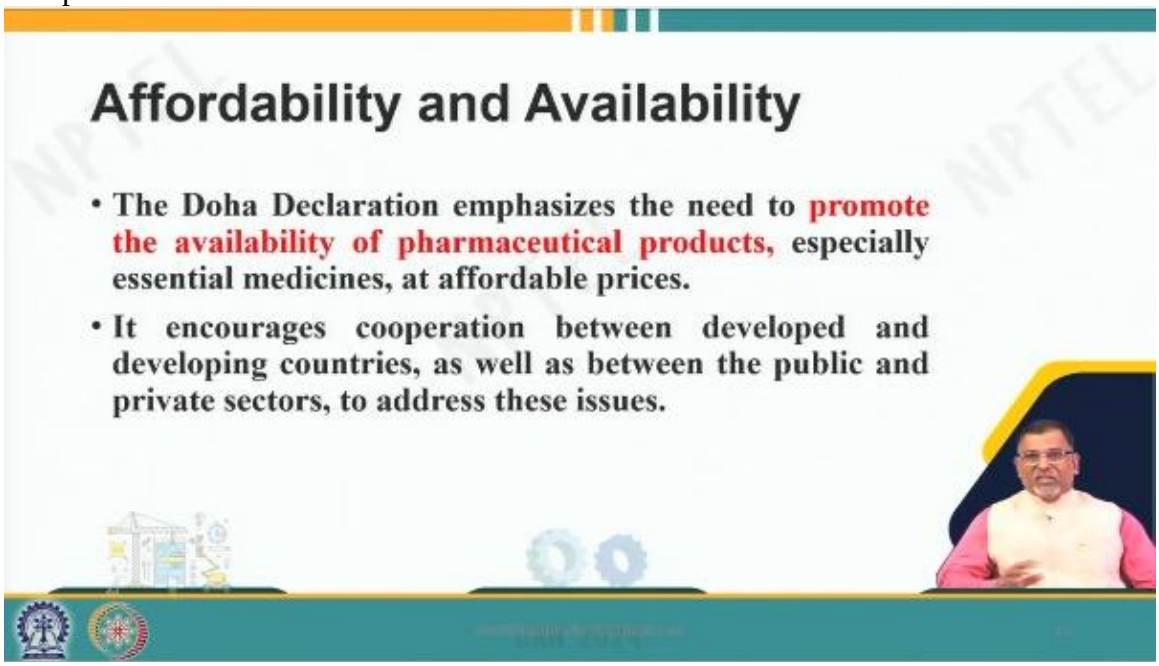
So, what can you do? You can go to the world market, wherever the prices of these particular medicines are the lowest, they can be purchased and imported into your own country. So, this is the parallel importation. So, parallel importation is allowed under the Doha Declaration which the patent holder cannot question.



So, if we closely look into what exactly the Doha Declaration provides for: the Doha Declaration provides for access to medicines, especially the medicines to treat pandemics even including. So, we will come back to COVID-19 later. But the COVID-19 situation was foreseen by the WTO members in 2001 itself, and that is why in 2001 itself, there was this Doha Declaration on Public Health, which clearly says that the TRIPS Agreement should not be an obstacle to take policies, a balance between intellectual property rights and access to medicines. So, public health maintenance should be given primacy or importance over patents, intellectual property protection. So, intellectual property is also important. At the same time, access to medicines is also important.

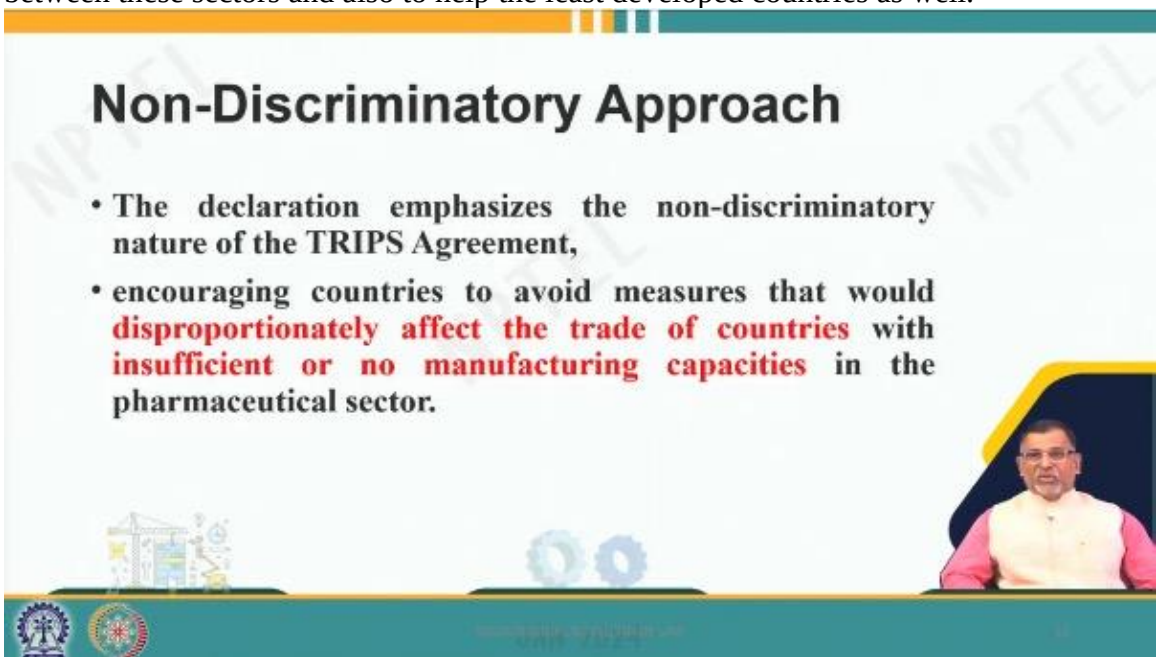


And most importantly the Doha Declaration activated the compulsory licensing provision. So, every member has the right to issue compulsory licenses based on certain grounds. So, it means it is very simple you compulsory license a particular patent and medicines and produce it at your own facilities. So, the patent holder's consent is not required, but you have to pay royalties. So, the affordable medicines: its objective is very clear: to supply affordable medicines to the people who want them. Then another point that we discussed is parallel importation. Parallel importation allows the importation of cheaper medicines.

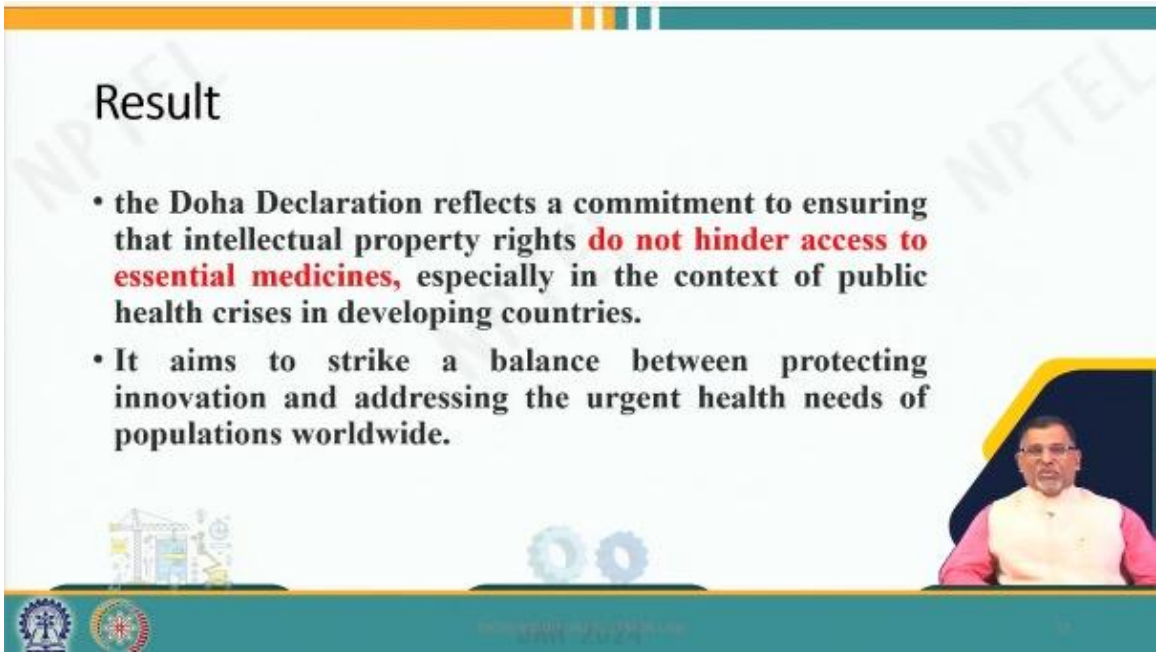


And affordability and availability. So, the Doha Declaration very clearly emphasises the availability and affordability of pharmaceutical medicines. It talks especially about essential medicines. Also it talks about the cooperation between developed countries and

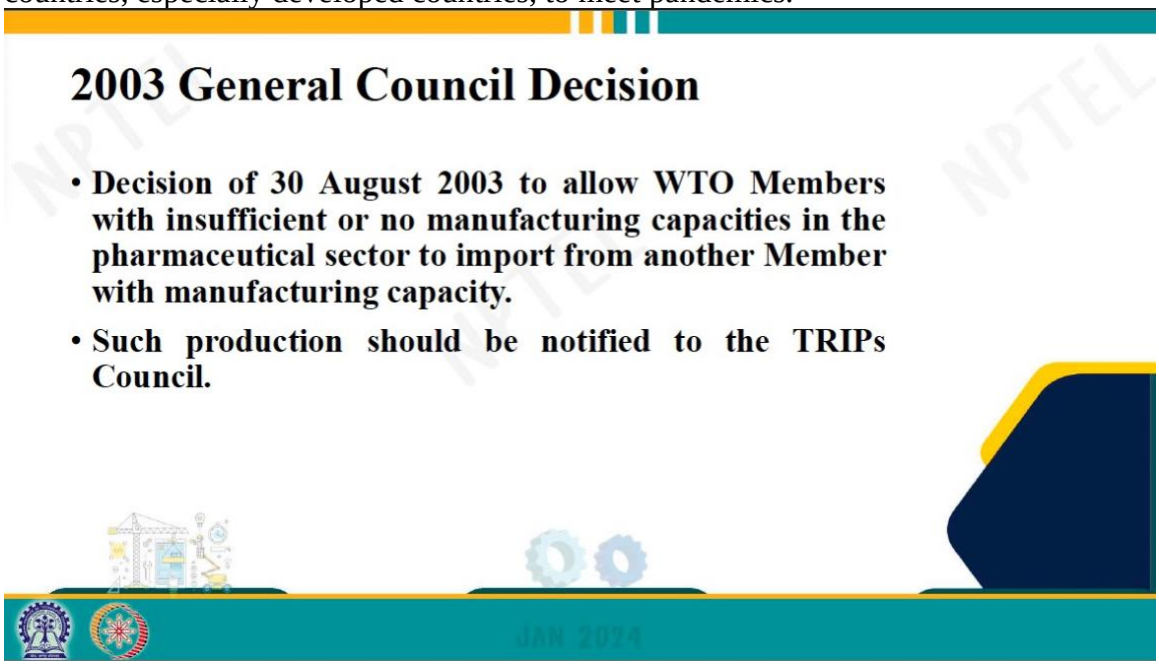
developing countries, the private sector and the public sector, in order to maintain a parity between these sectors and also to help the least developed countries as well.



The Doha Declaration again talks about the non-discrimination principle once again even though it is a part of the WTO Agreement. It says that countries should avoid measures that would disproportionately affect the trade of countries with insufficient or no manufacturing capacities in the pharmaceutical sector. So, we can see that immediately after the 2003 decision with regard to implementing the Doha Declaration on countries that do not have manufacturing capacity, they can issue a license to a country, those who have manufacturing facilities. So, it means if Nepal does not have a manufacturing facility, they can issue compulsory licenses in the name of India and India can manufacture this particular medicine and transport it back to Nepal. So, this special mechanism is provided to the countries those who do not have the manufacturing capacity of medicines.

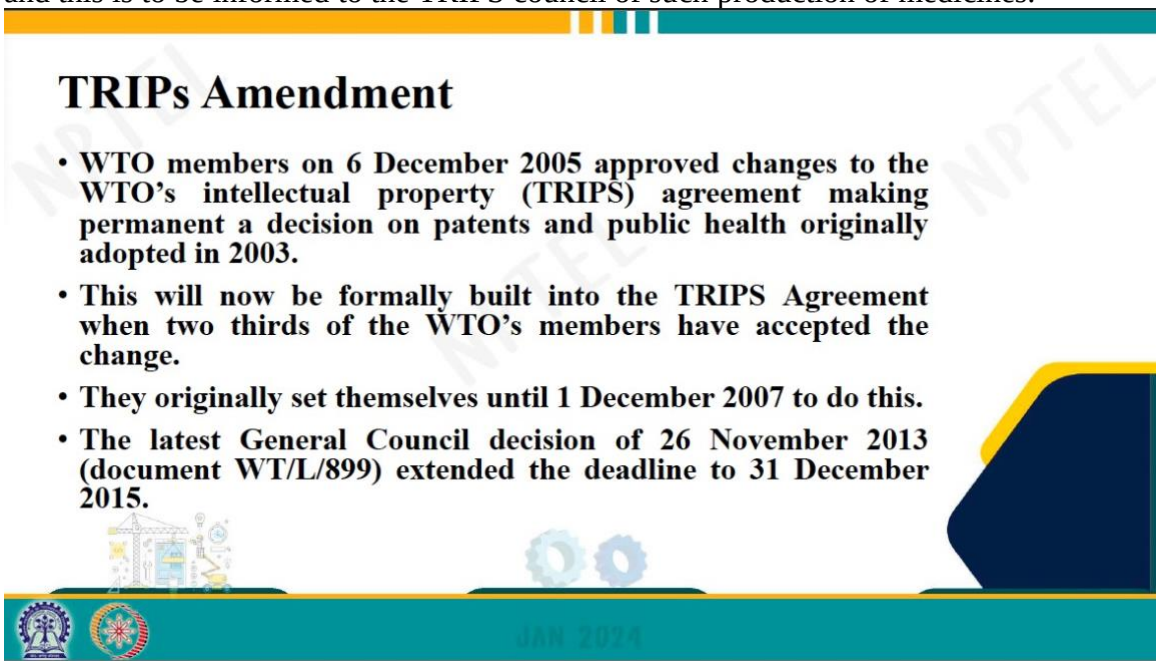


So, the Doha Declaration results are very clear and evident that this is to protect the public health sectors of especially the developing and least developed countries. The TRIPS Agreement should not become a hindrance to the maintenance of public health and also access to medicines. That is a very important point which is put forward by the Doha Development Agenda, and it also clearly talks about striking a balance between protecting innovation, protecting intellectual property and the urgent health needs of countries, especially developed countries, to meet pandemics.



I was talking about the 2003 General Council Decision, and the 2001 Doha Declaration Decision and 2003 Doha Declaration which was implemented through this particular decision, especially with regard to the countries that have insufficient or no manufacturing capacities in the pharmaceutical sector. So, as I told you, it is very simple,

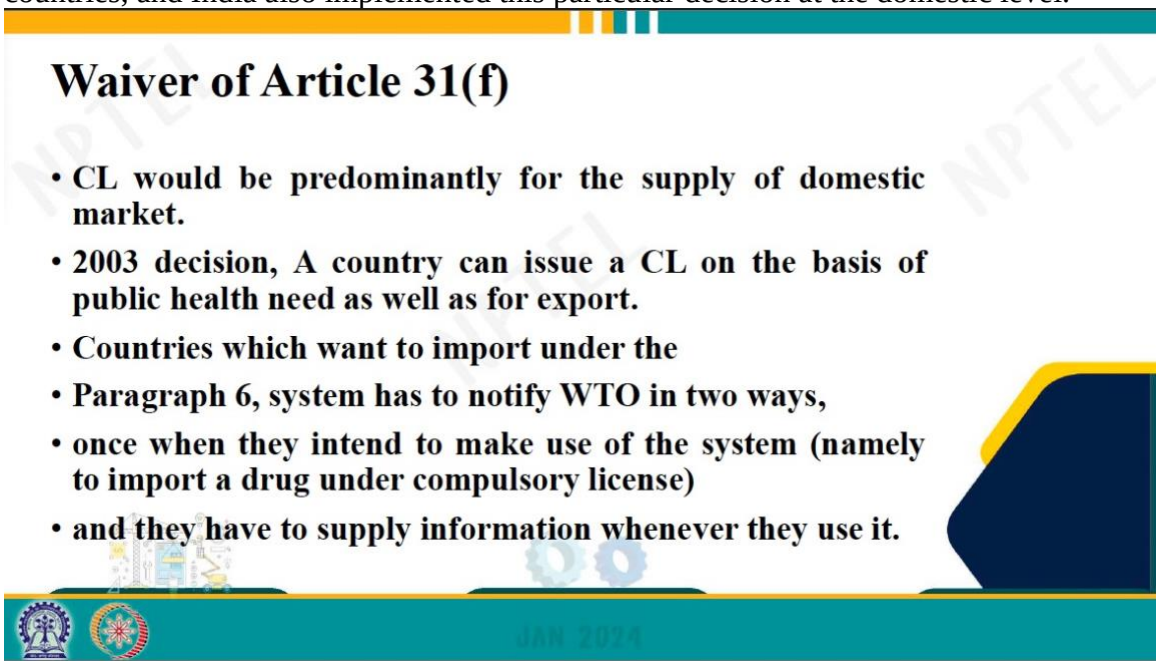
they can issue a compulsory license to a country those who have manufacturing capacity and this is to be informed to the TRIPS council of such production of medicines.



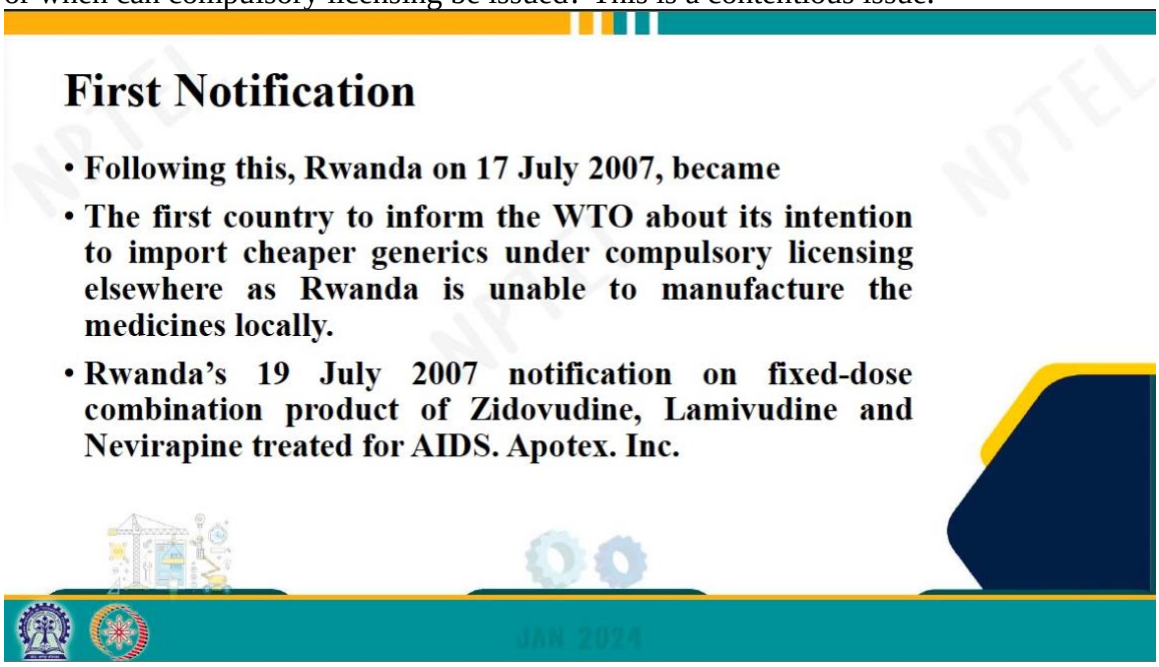
So, we can also see that the TRIPS provisions were amended in 2005 accordingly. So, this approval, these changes are approved by countries. So, the various decisions up to 2013 have extended the deadlines. The approvals and acceptance were extended from time to time, even up to 2015, to deal with this 2003 decision.

You can see that many countries have approved the amendment. There are so many countries that have approved the amendment, and India approved the amendment on March 26, 2007, even though it took a long period of time, most of the countries approved in 2007 and later on in 2011, 2012, and 2013. So, most of the countries

approved during this particular period, 2009 to 2013. So, it became a law in most of the countries, and India also implemented this particular decision at the domestic level.



And then compulsory licensing is always a contentious issue between developed countries and developing countries. So, what kind of compulsory licensing can be issued or when can compulsory licensing be issued? This is a contentious issue.



So, you can see the first notification under the Doha Declaration came in 2007 itself, under the compulsory licensing by Rwanda, Rwanda was unable to make this particular cheaper medicine, generic medicines. So, fixed dose combinations of *Zidovudine* and *Lamivudine* and *Nevirapine.* This was basically, these medicines were for treating the AIDS pandemic. So, Rwanda had issued a compulsory license to manufacture these particular medicines.

Second Notification

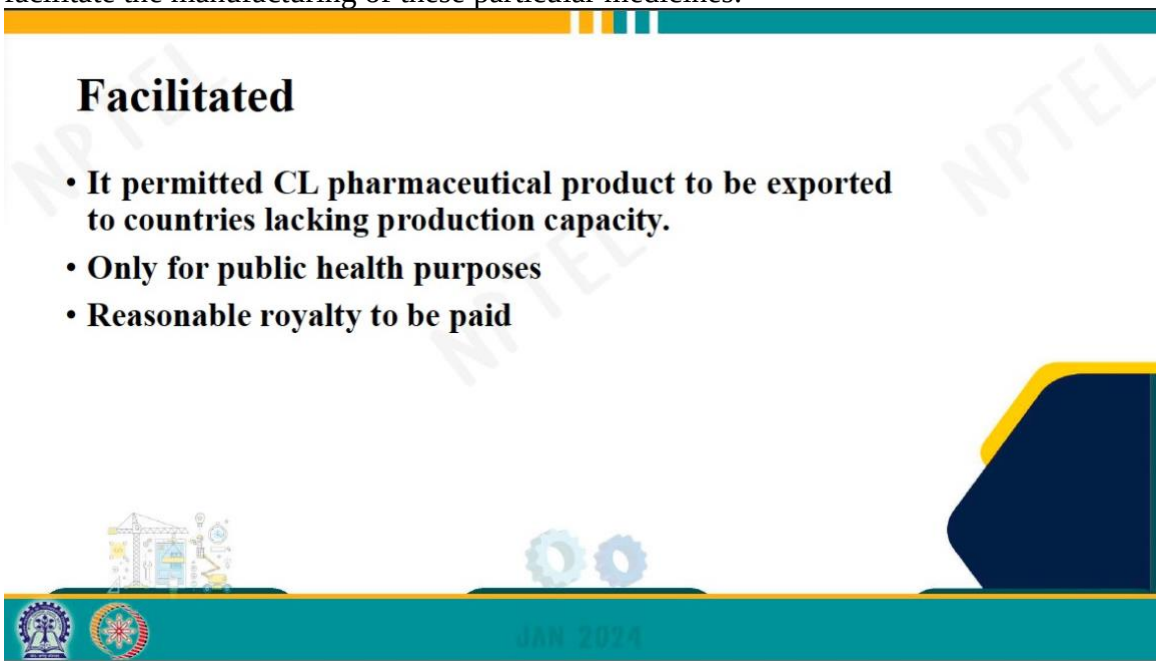
- Canada, on 4 October 2007, the first notification from any government that it has authorized a company to make a generic version of a patented medicine for export under special WTO provisions agreed in 2003.
- The triple combination AIDS therapy drug, TriAvir, can now be made and exported to Rwanda, which is unable to manufacture the medicine itself.

In 2007, you can see Canada's first notification. So, the first notification was for a generic version of a patented medicine for export under the TRIPS regime, and this was also mainly for treating the AIDS pandemic. So, as I told you, if Rwanda does not have a manufacturing facility, you can ask other countries to make it, and Canada made it and sent it back to Rwanda.

- 23 countries announced that, including Hongkong
- China, Israel, Korea, Kuwait, China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates, they are not going to avail the facility under the provision.

And other countries announced, 23 countries around the world announced, including Hong Kong, China and other countries, that they are not going to avail the 2003 facility. It means that they declared that they are not going to issue any compulsory licensing compulsory in accordance with the 2003 decision. It is even interesting to see that China is also on the list of countries that are not going to issue compulsory licenses.

So, you can see many countries amended their domestic law, according to the decision, to facilitate the manufacturing of these particular medicines.



And also, the facility, compulsory licensing is always, I told you that, it is a contentious issue between developed countries and developed countries, or I would say that the countries that have patented medicines and countries that produce generic medicines like India. So, this compulsory license, a special compulsory license, can be issued only for public health purposes, and a reasonable royalty has to be paid to the patent holder.

Criteria for Compulsory Licensing

- Public welfare
- "Non working" of invention
- Exploitation of an improvement invention

	Public welfare	Non working	Improvement exploitation
US	No	No	No
China	Yes	Yes	Yes
Japan	Yes	Yes	Yes
Germany	Yes	No	No
India	Yes	Yes	No

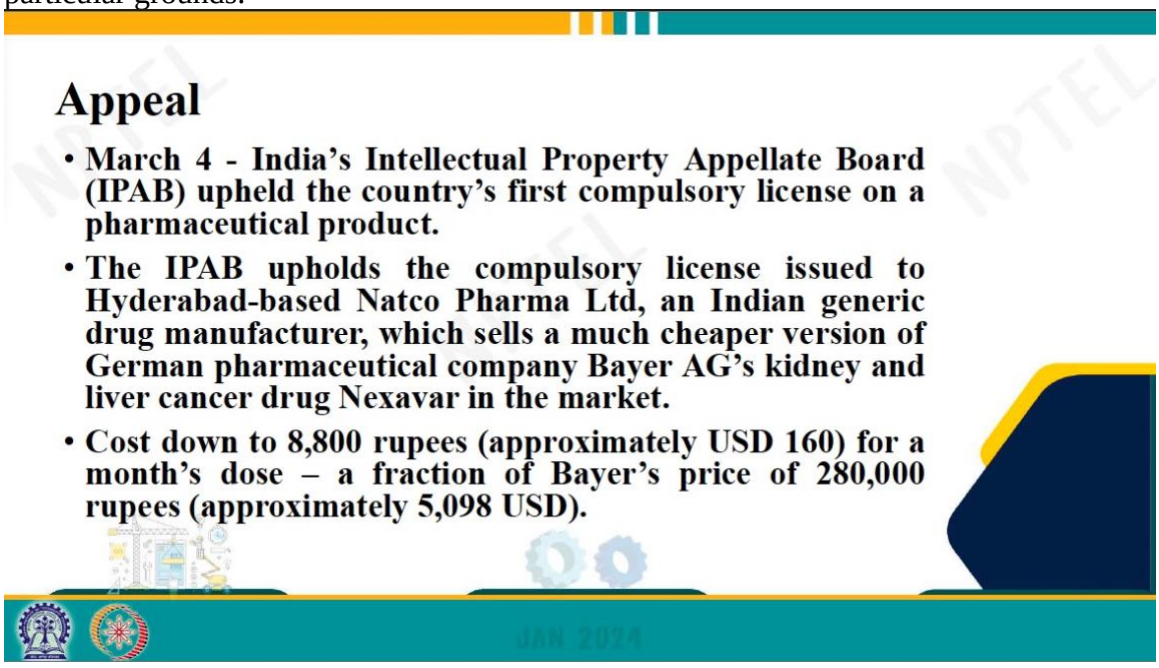
So, we can see the compulsory licensing criteria like public welfare, not working in the country of registration, and the improvement of exploitation. So, public welfare is a provision in many countries, but in most of the countries, non-working is not a ground for compulsory licensing. Improvement exploitation is also a provision in some countries like China and Japan, but not in India. So, the criteria for compulsory licensing is commonly placed in the TRIPS Agreement, but its usage is very less amongst the member countries.

India First CL

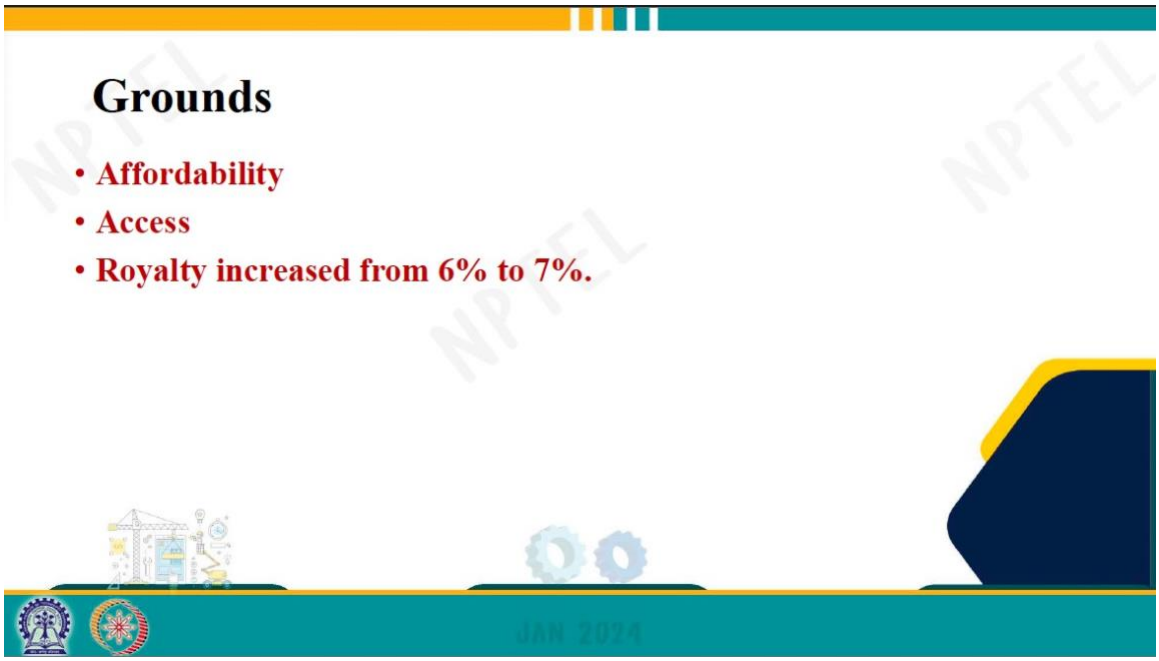
- On 9 March 2012, the then Indian Patent Controller issued the first-ever compulsory licence to Natco Pharma to manufacture an affordable generic version of sorafenibtosylate.
  1. That since Bayer supplied the drug to only 2% of the patient population, the reasonable requirements of the public with respect to the patented drug (Nexavar) were not met.
  2. That Bayers pricing of the drug (2.8 lakhs for a months' supply of the drug) was excessive and did not constitute a "reasonably affordable" price.
  3. That Bayer did not sufficiently "work" the patent in India.

And when you take the Indian case, India issued the first compulsory licensing in 2012, and this compulsory licensing was granted to a domestic pharmaceutical company, Natco Pharma. So, this compulsory license was issued in order to make a generic version of *sorafenibtosylate*. So, basically, you can see that it was against Bayer. So, this wa the first

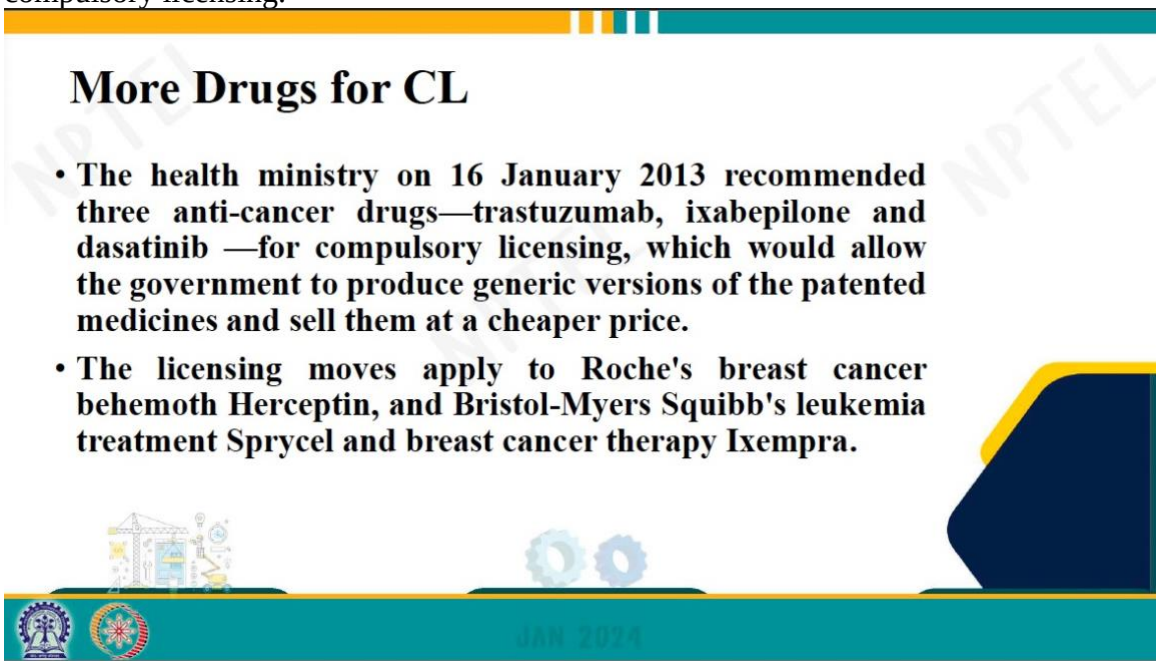
compulsory license to manufacture a generic version of patented medicine. And if you look into the prices, the prices of this *sorafenib* were very high. So, Bayer supplied drugs to only 2 per cent of the patients of the total population, the patented drug *Nexavar*. At the same time, we also have to look into the prices, 2.8 lakh rupees for a month's supply for a patient. This is highly unaffordable for common people in India. But even though Bayer has claimed that it is reasonably affordable, 2.8 lakh rupees per month, we, as a common Indian, know that it is not affordable. So, we know that it was exorbitantly priced. And third reason India showed is that Bayer did not sufficiently work the patent in India: non-working of the patent. So, one is affordability. So, (1) if the supply is very low, (2) exorbitant prices, and (3) non-working of the patent, India invoked all these particular grounds.



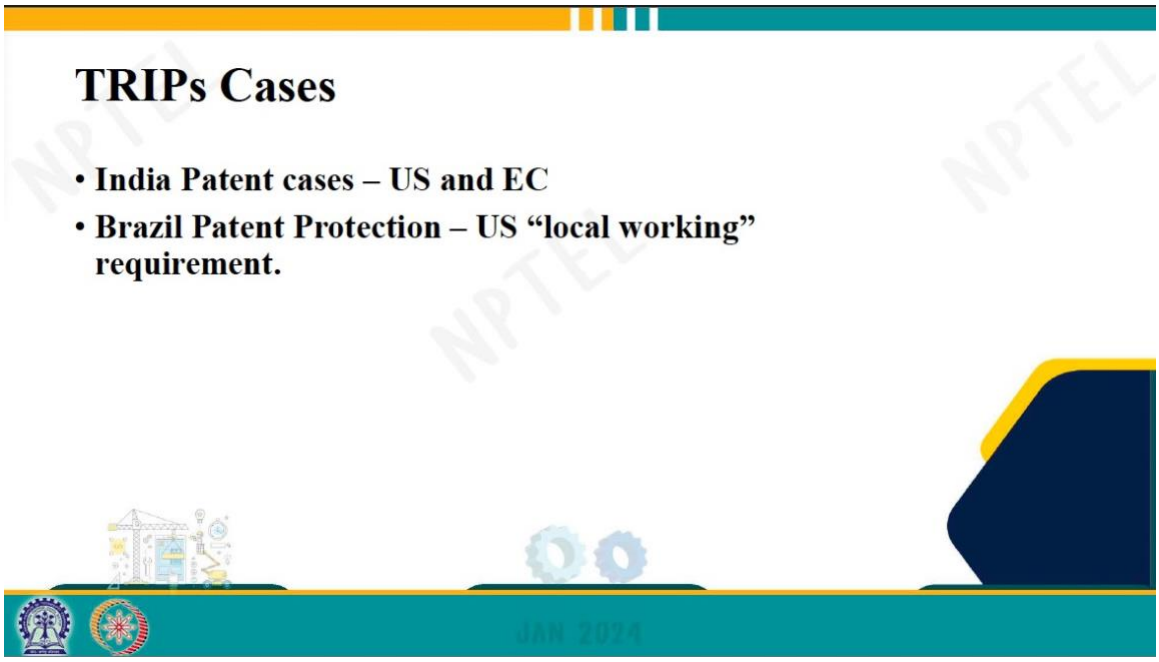
Bayer went on appeal. At that point in time, the Intellectual Property Appellate Board(IPAB) was the appellate authority, and the decision was confirmed by the appellate authority at that point in time. Now, the Intellectual Property Appellate Board(IPAB) is abolished, and the High Courts are dealing with these kind of appeals. So, the first compulsory licensing was granted to Natco Pharma and the cost decreased from 2.8 lakhs to 8800 rupees. So, the prices have gone drastically down many percentages, and the medicine was made affordable to the common people for 8800 rupees. So, that means 5000 dollars to 160 dollars per month. So, this was a drastic change all over the world, and many countries thought of compulsory licensing due to these unaffordable prices.



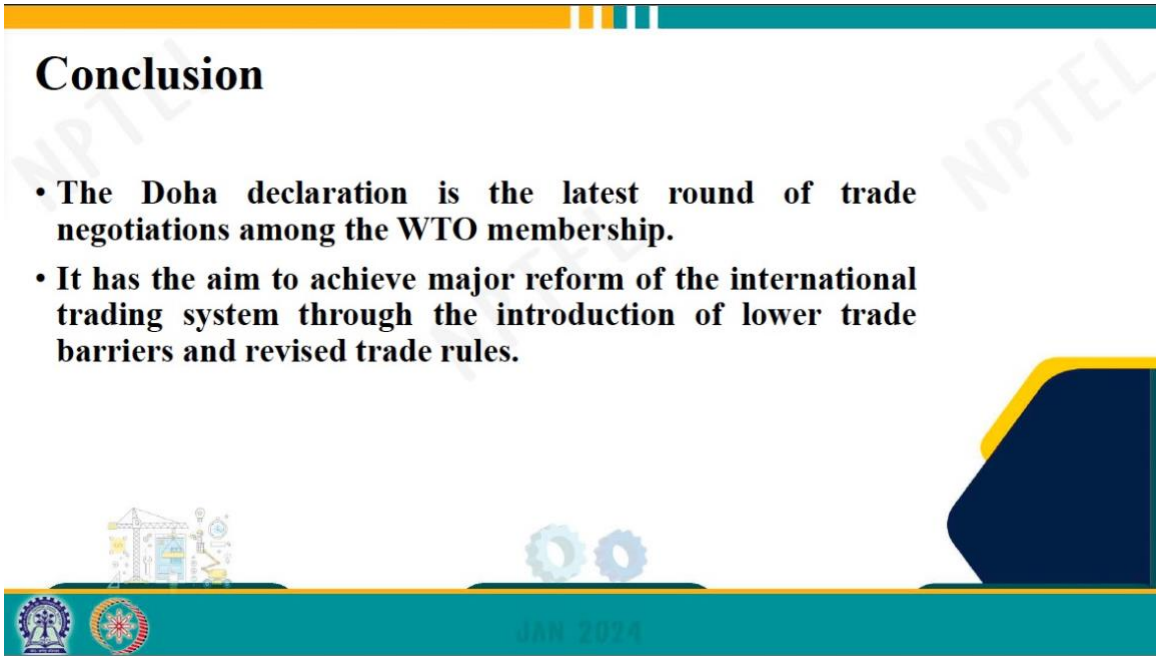
So, affordability is one of the ground, access is another ground, and the royalty and the royalty payments are to be made. Even the IPAB has increased the royalty payment from 6 per cent to 7 per cent, one of the highest in the world ever paid as royalty for any compulsory licensing.



And many countries are going ahead; in some of the cases, there are more applications in India itself, which were rejected by the Controller General of Patents in India.



So, other countries also have come up with similar licenses. So, we can see some of the patent cases that come to the TRIPS Agreement: under the TRIPS Agreement with regard to medicines.



We can see that around 14 cases came to the WTO on TRIPS Agreement. So, the Doha Declaration was a path-breaking decision in 2001 to deal with pandemics. Affordability: Many countries are facing issues with affordability and access to medicines. So, the patented medicines should not exploit the market against the health needs of each and every country. So, developing countries and developed countries also have to have a loss to maintain the drug's prices, and most importantly, the patented medicines cannot be used as a tool for economic exploitation. So, innovations were made for the public good. Even though there was a provision in the TRIPS Agreement for compulsory licensing,

most of the countries were not utilising it. This is mainly due to pressure from the developed countries and multinational pharmaceutical companies, those who have these patents, those who have patented medicines. And the Doha Declaration, reiterates the importance of intellectual property protection, especially for developing countries and countries that do not have the manufacturing capacity. During the COVID-19 time, there were many discussions to amend the TRIPS Agreement again, to have access to the vaccines. So, the pandemics will come again and again. So, patents should not be, and intellectual property should not be a barrier to protecting public health; I would say that for the people of developed as well as developing countries. So, the Doha Declaration is very important in the future as well. So, we will stop here with the module of the TRIPS Agreement.

Thank you.