EDUPHORE IAS
WEEKLY CURRENT AFFAIRS

Topic of the week: TRADE RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPS)

TRADE RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPS)

WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)was negotiated in the 1986-94 Uruguay Round. It introduced Intellectual property rules into multilateral trading system for the first time. It came into force on January 1, 1995.

Areas covered by the TRIPS Agreement

1. Copyright and related rights
2. Trademarks, including service marks
3. Geographical Indication
4. Industrial designs
5. Patents
6. Layout-designs (topographies) of integrated circuits
7. Undisclosed information, including trade secrets

What are Intellectual Property Rights?

- **Creators aregiven the right to prevent others from using their inventions, designs or other creations— and to use that right to negotiate payment in return for others using them. These are "intellectual property rights".**
- Example: Books, paintings and films come under copyright; inventions can be patented; brand names.
- **Governments given creators incentive to produce ideas that will benefit society as a whole**.

Origin of TRIPSAgreement

- **Ideas and knowledge were increasingly becoming important part of trade**. Most of the value of new medicines and other high technology products is in the amount of invention, innovation, research, design and testing involved.
- Protection provided to creatorsin the form of IPR widely varied across world. As IP becameimportant part of trade, it led to tensions in international economic relations.
- increasing commercialisation and commodification
- **TRIPS Agreement is an attempt to narrow the gaps in the way these rights are protected around the world, and to bring them under common international rules.**
- It establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. In doing so, it strikes a balance between the long term benefits and possible short term costs to society.

Issues Covered By TRIPS

The agreement covers five broad issues:

1. How the basic principles of the trading system and other international IP agreements should be applied
2. How to give adequate protection to IPR
3. How countries should enforce those rights adequately in their ownterritories
4. How to settle disputes on intellectual property between members ofWTO
5. Special transitional arrangements during the period when the newsystem is being introduced.

Basic Principles

1. National treatment: It provides for treating one's own goods and foreign goods equally.
2. Most-favoured-nation treatment: Equal treatment of all member nations and trading partners in the WTO.
3. Additional important principle: **IP protection should contribute to technical innovation and transfer of technology. Both producers and users should benefit, and economic and social welfare should be enhanced.**

How to Protect IP: Common Ground Rule			
1.	**Trademark**	• Agreement defines what types of signs must be eligible for protection as trademarks, and what the minimum rights conferred on their owners must be. • It says that service marks must be protected in the same way as trademarks used for goods.	• The trademark is initially registered for a period of 10 years. • The period of 10 years is calculated from the date of filing of the application.
2.	**Geographical indications**	• GI does not only say where the product was made. More importantly, it identifies the product's special characteristics, which are the result of the product's origins. • Examples include "Champagne", "Scotch", "Tequila". • TRIPS Agreement says countries have to prevent this misuse of place names.	It is registered for a period of 10 years and the registration may be renewed from time to time for a period of 10 years at a time.
3.	**Industrial designs**	Owners can prevent the manufacture, sale or importation of articles bearing a copy of the protected design.	• Industrial designs must be protected for at least 10 years. • In India the maximum validity of a registration under the (Indian) Designs Act, 2000 can be 15 years.
4.	**Copyright**	Rights that creators have over their literary and artistic works.	• Copyright lasts for 60 years. • In the case of original literary, dramatic, musical and artistic works the 60- year period is counted from the year following the death of the author.
5.	**Patents**	**Exclusive right to make, use and sell an inventive product or process**.	**Patent protection must be available for inventions for at least 20 years, for both product & process, in almost all fields of technology**.
6.	**Integrated Circuit Layout**	Basis for protection- **Washington Treaty** on Intellectual Property in respect of Integrated Circuits, under WIPO.	Protection must be available for at least 10 years.
7.	**Undisclosed information and trade secrets**	• Trade secrets and other types of "undisclosed information" which have commercial value must be protected against breach of confidence. • Reasonable steps to keep the info secret. • Test data submitted to governments must be protected against unfair commercial use.	Trade secret remains valid as long as one does not discover it independently.

PATENTS

What is a patent? What is the justification for a patent rights ?
A patent is a conferral by the state of an exclusive right to make, use and sell an inventive product or process. Patent laws are usually justified on 3 distinct grounds:
i) People natural and moral right to claim control over their inventions.
ii) Utilitarian premise: Exclusive licenses promote invention and therefore benefit society as a whole.
iii) Individuals must be allowed to benefit from the fruits of their labour and merit, that when a person toils to produce an object, the toil and the object be come inseparable.
iv) Recoup amounts invested by them in research and development.
Each long been a matter of contest, especially in application of claims of monopoly over pharmaceutical drugs and technologies.

A trade-off: Prices vs Innovation

Developing countries key objective

- Ensure ability of new medical treatments, at affordable prices, to patients in the region.
- The adoption of a process patent regime for pharmaceuticals helped in meeting this objective.
- It allowed pharmaceutical firms in developing countries to specialise in the production of cheap, generic versions of on-patent drugs for domestic markets, as well as for export to other countries

Developed countries key objective

- Higher prices are necessary to ensure the delivery of new medical treatments in the future.
- Product patentsand the legal monopoly rightsenable patent-holding pharmaceutical companies to price above marginal cost, and thereby, to recoup the large, fixed, research and development costs incurred by them in developing new drugs.
- It ensure incentives for future research and innovation activity.

- For 'global' diseases, product patents will imply higher prices for new drugs in developing countries, with little or no offsetting dynamic gain, in the form of higher rates of medical research and innovation.
- In the case of 'poor country' diseases such as malaria and TB, on the other hand, stronger intellectual property protection, while necessary, may not, by itself, be sufficient to induce new, improved and affordable medical treatments for these ailments
- Industrialised nations viewed IPRs as comparable to right of physical property, whereas India and other developing nations seen it "fundamentally as an economic policy question."
- India initially resisted the inclusion of IPRs in the WTO but ultimately signed the agreement. India did so because the WTO was a take it or leave it agreement (either a member accepts all the agreements or none, leaving no scope for partial agreement), and India hoped to gain concessions in textiles and agriculture in exchange for giving in on IPRs.

DOHA DECLARATION 2001

- It was widely believed that product patents result in monopolies and hence to high prices.
- There was a growing concerns in the developing countries about access to medicines at prices that their citizens could afford.
- The outcome was Doha declaration 2001 on TRIPS Agreement and Public Health -"the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health".
- It recognised WTO members' right to protect public health andto promote access to medicines for all.
- WTO members have the right to use the provisions in TRIPS, which provide flexibility for this purpose.

Features:

Public health and nutrition

Articles7 and 8 of the TRIPS Agreementrequire that WTO members must ensure that the IPR laws give due consideration to issues like protection of **public health and nutrition**and not merely serve the interests of the owners of intellectual property.

Compulsory License

- **Compulsory licences**,has been embedded in the patent system for preventing abuse of patent monopoly.
- Every WTO member has "the right to grant compulsory licences and freedom to determine grounds upon which such licences are granted"

Evergreening

- Evergreeningis *a* major cause for concern. It relates mainly to **patenting of so-called incrementally modified drugs (IMDs)**, which could include new formulations, new combinations of active ingredients.
- It is a disadvantage for the consumers since these IMDs have contributed substantially to rising prices of medicines.
- Adequate safeguards were therefore needed in India to be provided in the TRIPS-consistent patent law.

For a competitive regime

- Within the scope of the TRIPS agreement, basically three things can be done to ensure competition and competive prices:
    1. Provide exemptions from grant of patents in certain cases
    2. Provide exceptions to product patent rights in certain cases
    3. Provide compulsory licences to non-patentees to produce and sell the product

Patent Regimeof India

Background

Colonial-era	Laws that were inherited expressly allowed for pharmaceutical patents.
Ayyangar Committee 1959	A committee chaired by **Justice N. Rajagopala Ayyangar** objected to this on ethical grounds. • Access to drugs at affordable prices suffered • Foreign corporations used patents to suppress competition and thus, medicines were priced at exorbitant rates
Patent Act 1970	2. In line with recommendations of Justice Rajagopala Committee, Patents Act 1970 was passed. Monopolies over pharmaceutical drugs altogether removed, with protections offered only over claims to processes. India's Patents Act, 1970 exempted 'food or medicine or drug' from product patenting. • It led to growth of generic manufacturers in India. • Lifesaving drugs made available to people at more affordable prices.
WTO	**WTO** binding set of rules governing intellectual property. In the proposal's vision, countries which fail to subscribe to the common laws prescribed by the WTO would be barred from entry into the global trading circuit.
TRIPS **1995**	**TRIPS**came into being in 1995. Indian patents Act was amended in 2005 to make it TRIPS compliant.

Amendments of Patent act

- Under TRIPS agreement, member countries which did not provide product patent protection, when the TRIPS agreement came into force (on January 1, 1995), are required to grant such protection within 10 years, i.e, by January 1, 2005.
- For India, with respect to pharmaceuticals, it implied shifting from a patent regime that granted only process patents of 7 years' duration (Indian Patents Act, 1970) to one that, by January 2005, must provide for product patents of 20 years' duration.
- Mailbox provisions: Pending the introduction of such a product patent system, member countries were required to start the system of receiving applications for product patents (mailbox provisions) and granting exclusive marketing rights.
- To comply with the TRIPS requirements, the Patents Act, 1970 was amended by the **Patents (Amendment) Act, 1999** to introduce the system of Exclusive Marketing Rights (EMR).

Criticism of TRIPS adhered Patents Regime: In the view of COVID Pandemic

1. Yale Law School professor Amy Kapczynski wrote that compelling signatories to introduce intellectual property laws like those in the global north was nothing short of a scandal.
2. Drugs that reduced AIDS deaths in developed nations were placed out of reach for the rest of the world. For India manufactured generic versions of these medicines, which was made possible because obligations under TRIPS hadn't yet kicked in against India, prices came down.
3. **Funded by public money**: Public money accounted for more than 97% of the funding towards the development of the Oxford/AstraZeneca vaccine.
4. Research is usually driven towards diseases that afflict people in developed world.
5. Joseph Stiglitz current system of patents: "Those unfortunate enough to have the disease are forced to pay the price and that means the very poor in the **developing world are condemned to death**"
6. A new form of "**feudal calculus"**

Way forward : An Alternative

- Joseph Stiglitz is one of many who has proposed a **prize fund for medical research** in place of patents. Replaces patents with prizes
- More efficient and more equitable.
- Incentives for research will flow from public funds while ensuring that the biases associated with monopolies are removed.

COMPULSORY LICENSING

It is a situation where a **government allows an agent to produce a patented product without the consent of original patent-owner.** Article 31 of the TRIPS Agreement permits such authorisation.

- Conditions: The grant of compulsory licensing is subject to certain conditions aimed at protecting the legitimate interests of the patent-holder.
- It requires that prior attempts be made to obtain such rights at reasonable commercial terms from the patentee and where these fail and a compulsory licence is issued, that adequate remuneration be paid to the original rights holder.
- Waiver of conditions: These requirements are waived or diluted, in case of 'national' or 'other circumstances of extreme urgency', or where these are issued for 'public non- commercial use' .
- Dispute: The issue of compulsory licences is subject to the WTO's dispute settlement mechanism. The burden of proof rests on the issuing country.
- South Africa Example: Compulsory licensing gives developing countries a bargaining chip that can be used to negotiate better terms with multinational pharmaceutical companies. By threatening to authorise a compulsory licence for importation of the AIDS-triple therapy from Cipla-India, South Africa was able to bring down the prices offered by MNCs for this treatment from US$10,000 per patient per year in May 2000 to approximately $700 per patient per year by April 2001.

The Covid Pandemic: India- South Africa Joint Petition for a waiver

- On October 2 2020, India and South Africa a joint petition to the WTO, requesting temporary suspension of rules under TRIPS. Waiver to the extent that protections by TRIPS impinged on containment and treatment of COVID19.
- The initiative is guided by the spirit of need for **global collective action, global justice for right to access basic healthcare.**
- It gathered support from more than 100 nations. But a small group of states — U.S., EU, U.K. and Canada among them — continues to block the move. Their reluctance comes despite these countries having already secured the majority of available vaccines.
- If allowed, countries in position to facilitate a **free exchange of know how and technology about the production of vaccines.**

Covid: India- South Africa Joint Petition

- There are two types of IP rights that are used to control competition — patents and trade secrets.
- As far as patents are concerned, the government can issue a compulsory licence and ensure freedom of operation for any potential manufacturer.
- But there is a regulatory system that acts as an enforcement agency for protection of trade secrets. As a result, even if you have a compulsory licence, it would be difficult for a non-originator company to produce a vaccine very quickly.
- If you produce a small molecule, the regulatory agency (RA)never looks at what kind of manufacturing process is followed to produce a generic version, like paracetamol. What it looks for is whether it is paracetamol or not and the company gets marketing approval.
- In the case of vaccines, RA insists that the non-originator company follows the process of the originator.
- But this process is not in the public domain and is kept a trade secret.
- We don't have a compulsory licence to reveal that information to the potential non-originator company. **The only agency which can do such sharing with the potential manufacturer is the RA.** But it treats the dossier submitted by the original manufacturer as a trade secret.
- India and South Africa approached the WTO, asking that they be given the right to waive the protection and enforcement of certain IPs in the case of COVID19 medical products. That waiver, if adopted, can be used by the regulatory agencies to share the dossiers with potential manufacturers to speed up the process.
- So, potential manufacturers in India, China or Brazil have the technological capability without the help of the originator, but the regulatory frame work insists that replication requires them to prove clinical safety and efficacy, which are time consuming.
- We need to take two pronged action. The RAs need to waive clinical trials by developing an accelerated pathway for the non originator company, and the national RA should share the dossier with the potential manufacturer.

PATENT (AMENDMENT) RULES, 2020

- Amendment provides new format for patentees and licensees to disclose the extent to which they have commercially worked or made the patented inventions available to the public in the country.
- Form 27 has been amended to that effect.

Need for Info disclosure:

- For 20 yr patent, India's patent law imposes a duty on the patentee to commercially work the invention in India to ensure that its benefits reach the public.
- A failure of this duty could trigger compulsory licensing or even subsequent revocation of the patent.
- Info on the extent of the working of the invention in India is critical to check abuse of patent monopoly.
- Accordingly, section 146 (2) requires every patentee and licensee to submit to the Patent Office an annual statement explaining the extent to which they have worked the invention in India.
- This statement help determine whether the patentee has worked the invention in India and made it sufficiently available to the public at reasonable prices.

Form 27

- Form 27 is the form prescribed for patentees and licensees to furnish statements regarding working of their patent in India.
- It is **mandatory under the (Indian) Patents Act, 1970 for every patentee and every licensee to file a statement as to the extent of commercial working of a granted patent in the Indian territory.**

The form now requires the patentees and licensees to provide only for the following information:

- Whether the **patent has been worked or not**,
- **If the invention has been worked**, the revenue or value accrued in India from manufacturing and importing the invention into India,
- **If it has not been worked**, reasons for the same and the steps be ing taken towards working

Amendments to Form 27 (2020)

- It must be **furnished in respect of every financial year within 6 months** from the expiry of every financial year. (Earlier, it was within 3 months)
- There will be **one form for multiple patents.**
- It no longer required to provide any information in respect of the quantum of the invention manufactured/imported into India, the licenses and sublicenses granted during the year and the meeting of public requirement at a reasonable price.
- Removal of requirement of submitting any licensing information, including the disclosure of even the existence of licenses.
- Omission to mandate disclosure of details such as the price of the invention, its estimated demand, the extent to which the demand has been met.

Background to the amendment

- A PIL was filed Shamnad before the Delhi High Court in 2015.
- The PIL alleged rampant nonfiling and defective filing of Form 27 by patentees/ licensees and sought direction to government to strictly enforce the rules and take action against the violators.
- It also asked for reform of Form 27, arguing that the information it sought was grossly insufficient to ascertain the extent of the working of the patent.
- Government acknowledged that the Form 27 format was problematic and provided an undertaking to the court to effect appropriate amendments.
- Central government published the Patent (Amendment) Rules, 2020 to that effect.

Critical view

1. It has watered down the disclosure format, and this could hamper the effectiveness of India's compulsory licensing regime which depends on full disclosure of patent working information.
2. This in turn could hinder access to vital inventions including lifesaving medicines, thereby impacting public health.
3. **Insufficient data**: Data on merely the revenue/value accrued from manufacturing/importing the invention may be insufficient in determining the extent to which it has been worked and its public requirement has been met.
4. **Basic data omitted**: The most basic data for assessment is **quantum or the total units of the invention manufactured/imported in India.** Its disclosure by Bayer in Form 27 played a crucial role in grant of India's first compulsory license to Natco for the anticancer drug Sorafenib/Nexavar.
5. **Omission of Licensing info**: Patentees/licensees can just self-certify that they've worked the patent without having to support the claim with the data on how they've done so, including through licensing/sublicensing the patent.
6. **Other omissions:** Without info on invention price, estimated demand, it is extremely difficult to ascertain whether the invention has been made available to public in sufficient quantity and at affordable price.

IPRs and Food: Is TRIPS Agreement in India favour?

The Dilemma: Protecting the right of innovators vs adhering to the universal right to food security.

Setting Up of India's Patent Practices

- In agriculture, the debate on the implications of the TRIPS Agreement has revolved around **plant variety protection, another form of IPR, rather than patents.** This is because TRIPS allows for exclusions of plant varieties from patents.

IP Rights and Protection of Plant Genetic Resources

- TRIPS expanded the scope of IPRsin plant varieties.
- Article 27.3 (b) of TRIPS Agreement outlines the obligations of WTO members wrt plant variety protection and asks them to respectively set up an "**effective sui generis system**" to achieve this end.
- Two other significant regulations in terms of IPRs in plant genetic resources have been the IU and the Convention on Biological Diversity (CBD).

IU: Adopted by the FAO Conference in 1983, the IU is the first international agreement to address issues relating to access and proprietary claims to PGRs for food and agriculture.

- It is non-binding on its members.
- It recognised PGRs as the common heritage of mankind and endorsed that it be made freely available across states.

CBD: The CBD largely enshrined the same principles, with the exception of being binding to member states.

- Though both the CBD and IU pay heed to the essentiality of local and traditional systems of knowledge, they are largely viewed with respect to their contribution to the conservation of biodiversity, rather than from a viewpoint of "intellectual contribution."
- It is these legislations that have influenced and informed India's own domestic legislation towards the protection of the PGR.

- A number of provisions and concepts in TRIPs, UPOV [International Union for the Protection of New Varieties of Plants], the IU and CBD broadly inform the key elements of India's draft legislation.
- India uses the sui generis option to construct legislation that establishes Plant Breeders' Rights based on the UPOV model, and articulates a concept of Farmers' Rights that derives from the IU.

The TRIPS impact

- With the signing of TRIPS Agreement, India abandoned the common heritage framework.
- India's Protection of Plant Varieties and Farmers' Rights Act **allowed for breeders or farmers to claim IPR for their varieties,** provided as long as they met the criteria of novelty, distinctness, uniformity and stability.
- India's step away from the common heritage framework, which viewed plants and seeds as free resources rather than commodities to be owned, was largely because it was argued to enable biopiracy.
- That is, resources from India could be freely accessed by firms from more advanced countries, who could then use it to make patentable products, thus reaping profits at the behest of Indian resources and labour.
- It is argued that communities and farmers in India are the rightful owners of the country's resources and should be able to claim compensation for any use of these resources.

Drawbacks of TRIPS Agreement and Potential Backlash for India

- Agricultural crops have been spreading across the world for centuries, due to which it would be difficult to identify the origin of a crop or even to determine its rightful owners for compensation.
- Over the years, many resources have been collected and placed in international gene banks. Thus, for access there would arise the need to negotiate with several countries.
- India's position itself is not merely of a supplier. As a recipient of genetic material from other countries, India would need to negotiate for materials required to meet its demands.
- The overall financial and legal resources spent on tracking and proving cases for IPRs would prove to be a big logistical hindrance.
- Suman Sahai notes that the core of the TRIPS Agreement ignores the fundamental right to food security by being callous towards rural and tribal communities, and their livelihoods.
- Patents on biological materials strike at the root of self-reliance in agriculture, denying rural and tribal communities the ability to even earn their livelihoods.
- The share of tradefar from becoming a vehicle of development, has decreased.

Way forward

- India should lead the efforts for conceptualising a new system that retains the common heritage framework's fundamentals with respect to food security, and simultaneously avoids the costs of a privatised bilateral system.
- A single national legislation on farmer's rights or community rights would be inadequate. Companies could just refuse to access the resources from and/or invest in India, and could perhaps obtain the materials from countries that don't have a similar system of rights.
- India and other developing countries could use the negotiations to establish an international concept of farmer's rights.
- India could strengthen its own legislation in this regard by coordinating its efforts with other countries. OAU's model law, for instance, provides interesting features of the farmer's rights concept.
- Suman Sahai recommends that TRIPS should be compliant with the CBD, which acknowledges the role of local communities and traditional systems of knowledge in contributing towards biodiversity. Without this, a universal right, such as access to food security, would remain a reality only preserved for the privileged few.