"The growth and emergence of ipr in india: a comparative analysis of us ipr regime"

DISSERTATION

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The famous saying of Sir Louie Philip stands to this day, "*A teacher is the true mitochondria of an institution*".

This is true in every sense and scenario as It would have not been possible in accomplishing my task of this project without the proper guidance by Our **Honorable Ms.TRISHLA MA'AM.**

It is her abled guidance because of which I have completed my assignment with holistic approach and endeavor.

My gratitude towards THE ALMIGHTY and my family and friends who have always supported in every circumstances.

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ABBREVIATIONS

1. AMC –Antitrust Modernization Commission
2. APEC – Asia Pacific Economic Cooperation
3. DGCI – Drugs Controller General of India
4. EPO – European Patent Office
5. GATT – General Agreement on Tariffs and Trade
6. IMF – International Monetary Fund
7. IPAB- Intellectual Property Appellate Board
8. IPO – Indian Patent Office
9. IPR – Intellectual Property Rights
10. MFN – Most Favored Nation
11. OAPI- African Intellectual Property Organization
12. PCT- Patent Cooperation Treaty
13. R&D- Research and Development
14. TRIPS- The Agreement on Trade Related Aspects of Intellectual Property Rights
15. UPSPTO- United States Patent and Trademark Office
16. WHO- World Health Organization
17. WTO- World Trade Organization
18. WIPO- World Intellectual Property Organization

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CHAPTER 1
INTRODUCTION

Intellectual property rights defined in INDIAN Regime

What is Intellectual Property?[1]

Intellectual property refers to creations of the mind: inventions; literary and artistic works; and symbols, names and images used in commerce. Intellectual property
is divided into two categories:

Industrial Propertyincludes patents for inventions, trademarks, industrial designsand geographical indications.

Copyright[2]covers literary works (such as novels, poems and plays), films,music, artistic works (e.g., drawings, paintings, photographs and sculptures)and architectural design.Rights related to copyright include those of performing artists in their performances,producers of phonograms in their recordings, and broadcasters in their radioand television programs.

What are intellectual property rights?

Intellectual property rights are like any other property right. They allow creators, or owners, of patents, trademarks or copyrighted works to benefit from their own work or investment in a creation. These rights are outlined in Article27 of the Universal Declaration of Human Rights, which provides for the right to benefit from the protection of moral and material interests resulting from authorship of scientific, literary or artistic productions. The importance of intellectual property was first recognized in the Paris Convention for the Protection of Industrial Property (1883) and the Berne Convention or the Protection of Literary and Artistic Works (1886). Both treaties are administered by the **World Intellectual Property Organization (WIPO)**[3]**.**

1-3*WIPO Publication No. 450(E)pg 2*

Why promote and protect intellectual property?

There are several compelling reasons. First, the progress and well-being of humanity rest on its capacity to create and invent new works in the areas of technology and culture.

Second, the legal protection of new creations encourages the commitment of additional resources for further innovation. Third, the promotion and protection of intellectual property spurs economic growth, creates new jobs and industries, and enhances the quality and enjoyment of life. An efficient and equitable intellectual property system can help all countries to realize intellectual property's potential as a catalyst for economic development and social and cultural well-being.

The intellectual property system helps strike a balance between the interests of innovators and the public interest, providing an environment in which creativityand invention can flourish, for the benefit of all.

How does the average person benefit?[4]

Intellectual property rights reward creativity and human endeavor, which fuel the progress of humankind. Some examples:The multibillion dollar film, recording, publishing and software industries – which bring pleasure to millions of people worldwide – would not exist without copyrightprotection. Without the rewards provided by the patent system, researchers and inventors would have little incentive to continue producing better and more efficient products for consumers. Consumers would have no means to confidently buy products or services without reliable, international trademark protection and enforcement mechanisms to discourage counterfeiting and piracy.

What is a Patent?[5]

A patent is an exclusive right granted for an invention –a product or process that provides a new way of doing something, or that offers a new technical solution to a problem. A patent provides patent owners with protection for their inventions.Protection is granted for a limited period, generally 20 years.

4-5*WIPO Publication No. 450(E)pg 3*

Why are Patents necessary?

Patents provide incentives to individuals by recognizing their creativity and offering the possibility of material reward for their marketable inventions. These incentives encourage innovation, which in turn enhances the quality of human life.

What kind of protection do Patents offer?

Patent protection means an invention cannot be commercially made, used, distributed or sold without the patent owner's consent. Patent rights are usuallyenforced in courts that, in most systems, hold the authority to stop patent infringement. Conversely, a court can also declare a patent invalid upon a successful challenge by a third party.

What rights do Patent owners have?

A patent owner has the right to decide who may – or may not –use the patented invention for the period during which it is protected. Patent owners may give permission to, or license, other parties to use their inventions on mutually agreed terms. Owners may also sell their invention rights to someone else, who then becomes the new owner of the patent. Once a patent expires, protection ends and the invention enters the public domain. This is also known as becoming off patent, meaning the owner no longer holds exclusive rights to the invention, and it becomes available for commercial exploitation by others.

What role do Patents play in everyday life?

Patented inventions have pervaded every aspect of human life, from electric lighting (patents held by Edison and Swan) and sewing machines (patents held by Howe and Singer), to magnetic resonance imaging (MRI) (patents held by Damadian) and the iPhone (patents held by Apple).In return for patent protection, all patent owners are obliged to publicly disclose information on their inventions in order to enrich the total body of technical knowledge in the world. This ever increasing body of publicknowledge promotes further creativity and innovation. Patents therefore provide not only protection for their owners but also valuable information and inspiration for future generations of researchers and inventors.

How is a Patent granted?

The first step in securing a patent is to file a patent application. The application generally contains the title of the invention, as well as an indication of its technical field. It must include the background and a description of the invention, in clear language and enough detail that an individual with an average understanding of the field could use or reproduce the invention.

Such descriptions are usually accompanied by visual materials – drawings, plans or diagrams – that describe the invention in greater detail. The application also contains various "claims", that is,information to help determine the extent of protection to be granted by the patent.

What kinds of inventions can be protected?

An invention must, in general, fulfill the following conditions to be protected by a patent. It must be of practical use; it must show an element of "novelty", meaning some new characteristic that is not part of the body of existing knowledge in its particular technical field. That body of existing knowledge is called "prior art".

The invention must show an "inventive step" that could not be deduced by a person with average knowledge of the technical field. Its subject matter must be accepted as "patentable" under law. In many countries, scientific theories, mathematical methods, plant or animal varieties, discoveries of natural substances, commercial methods or methods of medical treatment (as opposed to medical products) are notgenerally patentable.

Who grants Patents?[6]

Patents are granted by nationalpatent offices or by regionaloffices that carry out examinationwork for a group of countries –for example, the European PatentOffice (EPO) and the AfricanIntellectual Property Organization (OAPI). In India, the patents are sole authority of Ministry of External Affairs and local regional office of the same on prior approval.Under such regionalsystems, an applicant requestsprotection for an invention in oneor more countries, and eachcountry decides whether to offerpatent protection within itsborders. The WIPO-administeredPatent Cooperation Treaty (PCT)provides for the filing of a singleinternational patent applicationthat has the same effect as nationalapplications filed in the designated countries. An applicant seeking protection may file one application and request protection in as many signatory states as needed.

6,*WIPO Publication No. 450(E)pg 4*

What is a Trademark?

A trademark is a distinctive sign that identifies certain goods or services produced or provided by an individual or a company. Its origin dates back to ancient times when craftsmen reproduced their signatures, or “marks”, on their artistic works or products of a functional or practical nature. Over the years, these marks have evolved into today’s system of trademark registration and protection. The system helps consumers to identify and purchase a product or service based on whether its specific characteristics and quality – as indicated by its unique trademark – meet their needs.

What do Trademarks do?

Trademark protection ensures that the owners of marks have the exclusive right to use them to identify goods or services, or to authorize others to use them in return for payment. The period of protection varies, but a trademark can be renewed indefinitely upon payment of the corresponding fees. Trademark protection is legally enforced by courts that, in most systems, have the authority to stop trademark infringement. In a larger sense, trademarks promote initiative and enterprise worldwide by rewarding their owners with recognition and financial profit. Trademark protection also hinders the efforts of unfair competitors, such as counterfeiters, to use similar distinctive signs to market inferior or different products or services. The system enables people with skill and enterprise to produce andmarket goods and services in the fairest possible conditions, thereby facilitating international trade.

What kinds of Trademarks can be registered?

Trademarks may be one or a combination of words, letters and numerals. They may consist of drawings, symbols or three dimensional signs, such as the shape and packaging of goods. In some countries, non-traditional marks may be registered fordistinguishing features such as holograms, motion, color and non-visible signs (sound, smell or taste).

In addition to identifying the commercial source of goods or services, several other trademark categories also exist. Collective marks are owned by an association whose members use them to indicate products with a certain level of quality and who agreeto adhere to specific requirements set by the association.

Such associations might represent, for example, accountants, engineers or architects.

Certification marks are given for compliance with defined standards but are not confined to any membership.They may be granted to anyone who can certify that their products meet certain established standards. Some examples of recognized certification are the internationally accepted “ISO 9000” quality standards and Ecolabels for products with reduced environmental impact.

How is a Trademark registered?

First, an application for registration of a trademark must be filed with the appropriate national or regional trademark office. The application must contain a clear reproduction of the sign filed for registration, including any colors, forms or three-dimensional features. It must also contain a list of the goods or services to whichthe sign would apply. The sign must fulfill certain conditions in order to be protected as a trademark or other type of mark. It must be distinctive, so thatconsumers can distinguish it from trademarks identifying other products, as well as identify a particular product with it. It must neither mislead nor deceive customers nor violate public order or morality. Finally, the rights applied for cannot be the same as, or similar to, rights already granted to another trademark owner. This may be determined through search and examination by national offices, or by the opposition of third parties who claim to have similar or identical rights.

How extensive is Trademark protection?

Almost all countries in the world register and protect trademarks. Each national or regional office maintains a Register of Trademarks containing full application information on all registrations and renewals, which facilitates examination, search and potential opposition by third parties. The effects of the registration are, however, limited to the country (or, in the case of regional registration, countries) concerned.

To avoid the need to register separate applications with each national or regional office, WIPO administers an international registration system for trademarks.

The system is governed by two treaties: the Madrid Agreement Concerning the International Registration of Marks and the Madrid Protocol. Persons with a link (be it through nationality, domicile or establishment) to a country party to one or both of these treaties may, on the basis of a registration or application with the trademark office of that country (or related region), obtain an international registration having effect in some or all of the other countries of the Madrid Union.

What is an Industrial Design?[7]

An industrial design refers to the ornamental or aesthetic aspects of an article. A design may consist of three-dimensional features, such as the shape or surface of an article, or two-dimensional features, such as patterns, lines or color. Industrial designs are applied to a wide variety of industrial products and handicrafts: from technical and medical instruments to watches, jewelry and other luxury items; from house wares and electrical appliances to vehicles and architectural structures; from textile designs to leisure goods. To be protected under most national laws, an industrial design must be new or original and nonfunctional.

This means that an industrial design is primarily of an aesthetic nature, and any technical features of the article to which it is applied are not protected by the design registration. However, those features could be protected by a patent.

Why protect Industrial designs?

Industrial designs are what make an article attractive and appealing; hence, they add to the commercial value of a product and increase its marketability. When an industrial design is protected, the owner – the person or entity that has registered the design – is assured an exclusive right and protection against unauthorized copying or imitation of the design by third parties. This helps to ensure a fair return on investment. An effective system of protection also benefits consumers and the public at large, by promoting fair competition and honest trade practices, encouraging creativity and promoting more aesthetically pleasing products.

7, *WIPO Publication No. 450(E)pg 8*

Protecting industrial designs helps to promote economic development by encouraging creativity in the industrial and manufacturing sectors, as well as in traditional arts and crafts. Designs contribute to the expansion of commercial activity and the export of national products. Industrial designs can be relatively simple and inexpensive to develop and protect. They are reasonably accessible to small and medium-sized enterprises as well as to individual artists and crafts makers, in both developed and developing countries.

How can Industrial designs be protected?

In most countries, an industrial design must be registered in order to be protected under industrial design law. As a rule, to be registrable, the design must be "new" or "original". Countries have varying definitions of such terms, as well as variations in the registration process itself. Generally, "new" means that no identical or very similar design is known to have previously existed. Once a design is registered, aregistration certificate is issued. Following that, the term of protection granted is generally five years, with the possibility of further renewal, in most cases for a period of up to 15 years.

Hardly any other subject matter within the realm of intellectual property is as difficult to categorize as industrial designs. And this has significant implications for the means and terms of its protection.

Depending on the particular national law and the kind of design, an industrial design may also be protected as a work of applied art under copyright law, with a much longer term of protection than the standard 10 or 15 years under registered designlaw.

In some countries, industrial design and copyright protection can exist concurrently. In other countries, they are mutually exclusive: once owners choose one kind of protection, they can no longer invoke the other. Under certain circumstances an industrial design may also be protectable under unfair competition law, although the conditions of protection and the rights and remedies availablecan differ significantly.

How extensive is industrial design protection?

Generally, industrial design protection is limited to the country in which protection is granted. The Hague Agreement Concerning the International Registration of Industrial Designs, a WIPO administered treaty, offers a procedure for internationalregistration of designs. Applicants can file a single international application either with WIPO or the national or regional office of a country party to the treaty.The design will then be protected in as many member countries of the treaty as the applicant designates.

What is a Geographical Indication?

A geographical indication is a sign used on goods that have a specific geographical origin and possess qualities or a reputation due to that place of origin. Most commonly, a geographical indication consists of the name of the place of origin of the goods. Agricultural products typically have qualities that derive from their place of production and are influenced by specific local geographical factors, such as climate and soil. Whether a sign functions as a geographical indication is a matter of national law and consumer perception. Geographical indications may be used for a wide variety of agricultural products, such as, for example, “Tuscany” for olive oilproduced in a specific area of Italy, or “Roquefort” for cheese produced in that region of France. The use of geographical indications is not limited to agricultural products. They may also highlight specific qualities of a product that are due to human factors found in the product’s place of origin, such as specific manufacturing skills and traditions. The place of origin may be a village or town, a region or a country. An example of the latter is “Switzerland” or “Swiss”, perceived as a geographicalindication in many countries for products made in Switzerland and, in particular, for watches.

What is an appellation of origin?

An appellation of origin is a special kind of geographical indication used on products that have a specific quality exclusively or essentially due to the geographical environment in which the products are produced. The term geographical indicationencompasses appellations of origin. Examples of appellations of origin that are protected in states party to the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration are "Bordeaux" for wine produced inthe Bordeaux region of France, "Prosciutto di Parma" – or Parma ham – for ham produced in the Parma province of Italy or "Habana" for tobacco grown in the Havana region of Cuba.

Why do geographical indications need protection?

Geographical indications are understood by consumers to denote the origin and quality of products. Many of them have acquired valuable reputations which, if not adequately protected, may be misrepresented by commercial operators. False use of geographical indications by unauthorized parties, for example "Darjeeling" for tea that was not grown in the tea gardens of Darjeeling, is detrimental to consumers and legitimate producers. The former are deceived into believing they are buying a genuine product with specific qualities and characteristics, and the latter are deprived of valuable business and suffer damage to the established reputation of their products.

What is the difference between a geographical indication and a trademark?[9]

A trademark is a sign used by a company to distinguish its goods and services from those produced by others. It gives its owner the right to prevent others from using the trademark.

A geographical indication guarantees to consumers that a product was produced in a certain place and has certain characteristics that are due to that place of production. It may be used by all producers who make products that share certain qualities in the place designated by a geographical indication.

8-9 *WIPO Publication No. 450(E)pg 10*

What is a "generic" geographical indication?

If the name of a place is used to designate a particular type of product, rather than to indicate its place of origin, the term no longer functions as a geographical indication. For example, **"Dijon mustard", a kind of mustard that originated many years ago in the French town of Dijon, has, over time, come to denote mustard of that kind made in many places. Hence, "Dijon mustard" is now a generic indication and refers to atype of product, rather than a place.**

How are geographical indications protected?

Geographical indications are protected in accordance with national laws and under a wide range of concepts, such as laws against unfair competition, consumer protection laws, laws for the protection of certification marks or special laws for theprotection of geographical indications or appellations of origin. In essence, unauthorized parties may not use geographical indications if such use is likely tomislead the public as to the true origin of the product. Applicable sanctions range from court injunctions preventing unauthorized use to the payment of damages and fines or, in serious cases, imprisonment.

What is WIPO's role in the protection of geographical indications?[11]

WIPO administers a number of international agreements that deal partly or entirely with the protection of geographical indications (in particular, the Paris Convention and the Lisbon Agreement). WIPO meetings offer Member States and other interested parties the opportunity to explore new ways of enhancing the international protection of geographical indications.

10-11, *WIPO Publication No. 450(E)pg 13,14*

What are Copyright and Related Rights?

Copyright laws grant authors, artists and other creators protection for their literary and artistic creations, generally referred to as “works”. A closely associated field is “related rights” or rights related to copyright that encompass rights similar or identical to those of copyright, although sometimes more limited and of shorter duration. The beneficiaries of related rights are: performers (such as actors and musicians) in their performances; producers of phonograms (for example, compact discs) in their sound recordings; and broadcasting organizations in their radio and television programs.Works covered by copyright include, but are not limited to: novels, poems, plays, reference works, newspapers, advertisements, computer programs, databases, films, musical compositions, choreography, paintings, drawings, photographs, sculpture, architecture, maps and technical drawings.

What rights do copyright and related rights provide?

The creators of works protected by copyright, and their heirs and successors (generally referred to as “right holders”), have certain basic rights under copyright law. They hold the exclusive right to use or authorize others to use the work on agreed terms. The right holder(s) of a work can authorize or prohibit: its reproduction in all forms, including print form and sound recording; its public performance andcommunication to the public; its broadcasting; its translation into other languages; and its adaptation, such as from a novel to a screenplay for a film. Similar rights of, among others, fixation (recording) and reproduction are granted under related rights.Many types of works protected under the laws of copyright and related rights require mass distribution, communication and financial investment for their successful dissemination (for example, publications, sound recordings and films). Hence,creators often transfer these rights to companies better able to develop and market the works, in return for compensation in the form of payments and/or royalties (compensation based on a percentage of revenues generated by the work). The economic rights relating to copyright are of limited duration –as provided for in the relevant WIPO treaties – beginning with the creation and fixation of the work, and lasting for not less than 50 years after the creator’s death. National laws may establish longer terms of protection.

This term of protection enables both creatorsand their heirs and successors to benefit financially for a reasonable period of time. Related rights enjoy shorter terms, normally 50 years after the performance, recording or broadcast has taken place. Copyright and the protection of performers also include moral rights, meaning the right to claim authorship of a work, and the right to oppose changes to the work that could harm the creator's reputation.Rights provided for under copyright and related rights law scan be enforced by right holders through a variety of methods and fora, including civil action suits, administrative remedies and criminal prosecution. Injunctions, orders requiring destruction of infringing items, inspection orders, among others, are used to enforcethese rights.

What are the benefits of protecting copyright and related rights?

Copyright and related rights protection is an essential component in fostering human creativity and innovation. Giving authors, artists and creators incentives in the formof recognition and fair economic reward increases their activity and output and can also enhance the results. By ensuring the existence and enforceability of rights, individuals and companies can more easily invest in the creation, development and global dissemination of their works. This, in turn, helps to increase access to and enhance the enjoyment of culture, knowledge and entertainment the world over,and also stimulates economic and social development.

How have copyright and related rights kept up with advances in technology?

The field of copyright and related rights has expanded enormously during the last several decades with the spectacular progress of technological development that has, in turn, yielded new ways of disseminating creations by such forms of communication as satellite broadcasting, compact discs and DVDs. Widespread dissemination of works via the Internet raises difficult questions concerning copyright and related rights in this global medium. WIPO is fully involved in the ongoing international debate to shape new standards for copyright protection in cyberspace. In that regard, the Organization administers the **WIPO Copyright Treaty (WCT)**[12] and the **WIPO Performances and Phonograms Treaty (WPPT), known as the "Internet Treaties"**. These treaties clarify international norms aimed at preventing unauthorized access to and use of creative works on the Internet.

12,*WIPO Publication No. 450(E)pg 7*

How are copyright and related rights regulated?

Copyright and related rights protection is obtained automatically without the need for registration or other formalities. However, many countries provide for a nationalsystem of optional registration and deposit of works.

These systems facilitate, for example, questions involving disputes over ownership or creation, financial transactions, sales, assignments and transfer of rights. Many authors and performers do not have the ability or means to pursue the legal and administrative enforcement of their copyright and related rights, especially given the increasingly global use ofliterary, music and performance rights. As a result, the establishment and enhancement of collective management organizations (CMOs), or "societies", is agrowing and necessary trend in many countries. These societies can provide their members with efficient administrative support and legal expertise in, for example,collecting, managing and disbursing royalties gained from the national and international use of a work or performance. Certain rights of producers of sound recordings and broadcasting organizations are sometimes managed collectively as well.

What is the World Intellectual Property Organization?

Established in 1970, the World Intellectual Property Organization (WIPO) is an international organization dedicated to helping ensure that the rights of creators and owners of intellectual property are protected worldwide, and that inventors and authors are therefore recognized and rewarded for their ingenuity.

This international protection acts as a spur to human creativity, pushing back the limits of science and technology and enriching the world of literature and the arts.

By providing a stable environment for marketing products protected by intellectual property, it also oils the wheels of international trade. WIPO works closely with itsMember States and other constituents to ensure the intellectual property systemremains a supple and adaptable tool for prosperity and well-being, crafted to help realize the full potential of created works for present and future generations.

How does WIPO promote the protection of intellectual property?[13]

As part of the United Nations system of specialized agencies, WIPO serves as a forum for its Member States to establish and harmonize rules and practices for the protection of intellectual property rights. WIPO also services global registration systems for trademarks, industrial designs and appellations of origin, and a globalfiling system for patents. These systems are under regular review by WIPO's Member States and other stakeholders to determine how they can be improved to better serve the needs of users and potential users. Many industrialized nations haveintellectual property protection systems that are centuries old. Among newer or developing countries, however, many are in the process of building up their patent, trademark and copyright legal frameworks and intellectual property systems. With the increasing globalization of trade and rapid changes in technological innovation, WIPO plays a key role in helping these systems to evolve through treaty negotiation; legal and technical assistance; and training in various forms, including in the area of enforcement. WIPO works with its Member States to make available information onintellectual property and outreach tools for a range of audiences –from the grassroots level through to the business sector and policymakers – to ensure its benefits are well recognized, properly understood and accessible to all.

How is WIPO funded?[14]

WIPO is a largely self-financed organization, generating more than 90 percent of its annual budget through its widely used international registration and filing systems, as well as through its publications and arbitration and mediation services. The remaining funds come from contributions by Member States.

12,13*WIPO Publication No. 450(E)pg 8*

Intellectual property rights in the USA

If you plan to do business in the USA, or if you are already trading there, it is essential to know how to use, guard and enforce the rights you have over the intellectual property (IP) that you or your business own.

This guide explains about IP rights in general, and gives guidance on how to apply these principles in the USA market. It describes the issues you may face with IP infringement in the USA, offers advice on how you can effectively tackle these, and provides links to sources of further help. Intellectual Property Rights in the USA

What are intellectual property rights? [14]

Intellectual property (IP) is a term referring to a brand, invention, design or other kind of creation, which a person or business has legal rights over. Almost all businesses own some form of IP, which could be a business asset.

Common types of IP include:

- Copyright - this protects written or published works such as books, songs, films, web content and artistic works.
- Patents - this protects commercial inventions, eg a new business product or process.
- Design right - this protects designs, such as drawings or computer models.
- Trade marks - this protects signs, symbols, logos, words or sounds that distinguish your products and services from those of your competitors. IP can be either registered or unregistered.

14,http://www.usitc.gov/intellectual_propertypg 3 col.2

With **unregistered** IP, you automatically have legal rights over your creation. Unregistered forms of IP include copyright, unregistered design rights, common law trade marks and database rights protection for confidential information and trade secrets.

With **registered** IP, you will have to apply to an authority, such as the Intellectual Property Office in the UK, to have your rights recognised. If you do not do this, others are free to exploit your creations. Registered forms of IP include patents, registered trade marks and registered design rights.

International considerations[15]

The USA has been a **World Trade Organization (WTO)** member since 1995. WTO member nations must include some IP protection in their national laws. This means that if you are doing business with the USA, you will find some similarity between local IP law and enforcement procedures, and those in force in the UK.

- is necessary in order to press charges for copyright infringement in Federal courts;
- is necessary to prevent infringing imports from entering the USA; and
- allows you to claim statutory damages and attorney's fees in the case of copyright infringement - rather than needing to prove actual damages

As the copyright owner, only you have the right to copy, change, distribute or publicly display the work, or authorize others to do so. However, if you employ other companies or freelancers for certain works, it could be that they own the copyright - eg an external graphics designer may own the copyright for their commissioned work. It is therefore recommended that you always use a contract to clarify who owns the IP.

15,http://www.usitc.gov/intellectual_propertypg 3 col.5

Treaties and reciprocal agreements: The USA is a signatory to the following international IP agreements:

- the Paris Convention - under this, any person from a signatory state can apply for a patent or trade mark in any other signatory state, and will be given the same enforcement rights and status as a national of that country would be

- the Berne Convention - under this, each member state recognizes the copyright of authors from other member states in the same way as the copyright of its own nationals

- the Madrid Protocol - this is a central system for obtaining a 'bundle' of national trade mark registrations in different jurisdictions, through a single application

- the Patent Co-operation Treaty - this works in much the same way as the Madrid Protocol, but for patent applications

The USA is not a signatory to the Hague Agreement, which allows the protection of designs in multiple countries through a single filing.

Intellectual property rights - systems in the USA

Copyright

In the United States, creative work is automatically protected by copyright as long as it is both:

- Original - ie independently created and not copied from someone else's work.
- fixed in a tangible form - ie easy to see, reproduce or communicate over a long period of time.

Copyright only protects the tangible form of your creative work - it does not protect the idea itself, only the form it takes. For example, if your business has an advertisement, the

actual content is protected by copyright, but it does not prevent others from using a similar idea to create their own advertisement.

Although registration of copyright is not a legal requirement in the USA, it is advisable. This is because it:

- Establishes a public record of ownership and strengthens your position in the case of copyright infringement.

The USA is a signatory to the Berne Convention[16] on copyright. Under this, each member state recognizes the copyright of authors from other member states in the same way as the copyright of its own nationals.

In the USA, work created on or after 1 January 1978 is protected for:

- the life of the author plus 70 years - if the owner is a person

- 95 years from publication or 120 years from the creation of the work, whichever is shorter - if the owner is a corporation or other entity

All other work created before 1978 is governed by the Copyright Act of 1909. This provides initial protection of 28 years, with the chance of subsequent renewal. If the copyright of a published material has expired, it is usually considered to be in the public domain, making it free for anyone to use. Intellectual Property Rights in the USA

Patents

A patent is a governmental grant that allows someone to protect an invention. In the USA, the United States Patent and Trademark Office (USPTO) issues three kinds of patents:

- **Utility patent** - for technological advances and innovations. This lasts a minimum of 20 years from the date of application.

- **Design patent** - for new and original designs for items. This lasts for a 14-year term.

- **Plant patent** - for the invention or discovery of any distinct and new plant varieties that has been asexually reproduced by grafting or selective cuttings (without seed manipulation). This protection is different to plant variety protection which is administered by the United States Department of Agriculture. This lasts for a 20year term from the date of application.

16,http://www.usitc.gov/intellectual_propertypg13 col.7

If you need to pitch an invention or design that has not yet been patented, you should use a non-disclosure agreement or obtain a provisional patent application. You should also keep any and all documents relating to the invention or design.

The September 2011 America Invents Act (AIA) amended US patent law to make it a “first inventor to file” system, which is in line with other patent systems, including the UK. The “first inventor to file” system means that whoever files a patent application first can be awarded a patent. The AIA first-inventor-to-file provisions became effective on March 16 2013.

US law also allows a one-year grace period for an inventor to register a patent from the date of public disclosure. You should note that this is different from European countries, where public disclosure could prevent you from being able to obtain a patent.

Trade marks

Unlike copyright, trademarks are not automatic and are generally only protected if registered in the USA.

In most countries, trade mark rights are established through registration - this is known as ‘First to File’. However, in the USA, as in the UK, the ownership of a trade mark is established by whoever first uses it in commerce. This is known as the ‘First to Use’ system and requires you to actually use the mark in connection with goods or services in order to protect your trade mark. Therefore, if there is a dispute between you and another party over a trade mark, whoever used it first commercially will own the right, even if they did not register it.

However, in order to completely protect your trade mark in the USA, you should also register it through the USPTO. Registering your trade mark also provides several further benefits to you, including:

- publicly declaring your ownership of the trade mark
- helping you to register your trade mark in other countries
- helping you to bring any legal action to the Federal courts and preventing infringing material from being imported
- allowing you to use the registered trade mark symbol (®) with your trade mark

Because registration is not a requirement, there is no limit to the duration of a trade mark in the USA. As long as there is continued use of the trade mark, ownership of the trade mark right is maintained.

Registering and enforcing your intellectual property rights in the USA[17]

Some types of intellectual property (IP) rights in the USA are automatic, but it is recommended that you always register them to both protect yourself and to make the most of your IP rights.

'Priority rights' under the Paris Convention can help in the local registration of trade marks, designs and patents by allowing rights previously registered elsewhere to become effective in the USA, if filed within a time limit.

As a signatory of the Paris Convention, the USA must also provide protection against unfair competition in line with the rules of the Convention.

17,http://www.usitc.gov/intellectual_propertypg13 col.7 rw 3

Patents

To obtain patent protection, you must register your invention with the United States Patent and Trademark Office (USPTO), usually with the help of a patent attorney. You can either apply for a:

- **utility patent** - for innovations and technologies
- **design patent** - for new and original designs
- **plant patent** - for distinct and new plant varieties

Under US law, if your invention is publicly disclosed without a patent, you have a grace period of one year to register your patent.

The application process for patents is complex, and it is highly recommended that you seek advice from a patent attorney before going ahead. A patent attorney will help you make sure that your invention is not already registered by someone else, and will assist you in completing a patent application. You can find a list of registered US patent attorneys on the USPTO website.

The fee for patent applications can vary depending on your application, and the approval process can take a very long time and varies from each application. There is a 50 per cent discount on official fees for registering a patent for small companies, non-profit organizations and universities. There is also a 75 per cent discount on fees for a 'micro entity', though these have strict criteria you must meet in order to be eligible. For example an inventor must not:

- have an annual income more than three times the average household annual income
- have been named on more than four US patent applications
- assign or license their patent to a company or person that has more than three times the average household annual income

There is no legal protection for a patent until it has been approved.

Once your patent is approved, you will need to pay a regular maintenance fee in each country that your patent has been granted. Intellectual Property Rights in the USA

Trade marks[18]

In the USA, it is the first party who uses a trade mark commercially that owns the rights for that trade mark. Trade mark registration is therefore not a legal requirement, but it does hold several benefits. To register your trade mark in the USA, you can either register with the USPTO within the USA or use the Madrid Protocol to gain unitary rights under national or Community Trade Mark registration systems. Registering a trade mark in the USA can be a complicated process, so it is recommended that you seek expert legal advice before proceeding. If you register your trade mark with the USPTO it can also be recorded with the United States Customs and Border Protection (CBP), a bureau of the Department of Homeland Security. This can be done electronically and will help the fight against fake and pirated goods being imported to the USA.

18,http://www.usitc.gov/intellectual_property pg17 col.9:rw 3

Copyright

For copyright, both published and unpublished, no registration is required but registering copyrights with the copyright authorities is advisable.

To register a copyright in the USA, you will need to complete the relevant application form, either online or by sending it to the United States Copyright Office, along with the appropriate fee.

You can also protect your work with a copyright notice - eg by displaying the copyright symbol (©), year of first publication and your name as the copyright owner. This will further deter any copyright infringement of your work and could also help with any legal issues surrounding your copyright.

Enforcing your IP rights in the USA

It is your responsibility to protect your IP, though governmental authorities can help you take steps to prevent and stop any infringements. You should actively monitor the marketplace for any unauthorized use of your IP, and if you think that a person or business has unlawfully used your IP, you should take expert legal advice before contacting an offender or pursuing any sort of litigation.

IP law in the USA is complex and should only be used when other enforcement methods have failed to prevent an infringement. If litigation is necessary, then you should use a lawyer who specialises in IP law. Litigation takes place before either civil courts or administrative tribunals. It is also possible to take action against foreign offenders either through the Federal court or by initiating investigations before the **United States International Trade Commission (USITC)**.

If your copyright or trade mark is registered it can also be recorded with the CBP. The CBP can use enforcement procedures to prevent the entry of goods that infringe your IP rights into the USA. This is a simple and cost effective measure to protect and enforce your IP rights. If you find unauthorized use of copyright material online, you can use the **notice and takedown** procedure to have this material removed. This only works for web sites owned in the USA and involves contacting the internet service provider with a demand to remove or disable access to the unauthorized content. With the help of a lawyer, you can also use a **cease and desist letter**. This warns an offender of your rights and asks them to stop any activity that may cause infringement. There are also several alternative dispute resolution (ADR) methods that can be used. These can involve mediation or arbitration and are often cheaper and faster than litigation. You may also find business associations and other industry-specific associations who can represent you in any dispute you may have involving unauthorized use of your IP.

Protecting your IP

There are various things you can do to make it harder for infringers to copy your product. For example, you could:

- Consider the design of your product and how easy it would be for somebody to reproduce it without seeing your original designs.

- Have effective IP-related clauses in employment contracts for when you hire staff. You should also make sure you educate your employees on IP rights and protection.

- Have sound physical protection and destruction methods for documents, drawings, tooling, samples, machinery etc.

- Make sure there are no ‘leakages’ of packaging that might be used by counterfeiters to pass off fake product.

- Check production over-runs to make sure that the genuine product is not being sold under a different name.

Potential problems faced in the USA and how to deal with them

Intellectual property (IP) laws in the USA are comprehensive, and the authorities and enforcement agencies are capable of dealing with any infringement. Thus the protection offered to foreign and domestic rights owners is of a very high standard.

As a member of the World Trade Organization, the USA is committed to certain minimum IP protection standards. This means that the IP environment in which UK businesses operate in the USA will be familiar for those used to practices in the UK.

To be a success in the USA and internationally, your business must protect its assets with some form of IP rights protection.

Avoiding problems[19]

The most important way to avoid problems when defending IP rights in the USA is to be prepared. To make sure that you can anticipate any potential issues, you should:

- take advice from US IP rights experts
- consult publications and websites on US IP rights and protection in general
- carry out risk assessment and due diligence checks on any organizations and individuals you deal with
- take professional advice from other experts - eg lawyers, local diplomatic posts, business and industryspecific associations and UK trade organizations
- talk to other businesses already doing similar trading in the USA
- consult agents, distributors and suppliers on how best to safeguard your rights
- check with trade mark or patent attorneys to see whether there have been previous registrations of your own IP in the USA

- stick to familiar business methods - don't be tempted to do things differently because you're trading in a different country

Who should take responsibility for your IP protection?

You should make sure that everyone in your business takes some responsibility for IP protection. Many businesses depend on the integrity of their IP and it can often be one of their most valuable assets. So it should be given proper attention by management and employees, as well as other businesses that you have relationships with.

It may be sensible to nominate a manager to have particular responsibility for understanding and protecting your IP rights. In businesses with legal departments, a legally-trained manager would be a good choice. Intellectual Property Rights in the USA

19,http://www.usitc.gov/intellectual_property pg21 col.19:rw 2

Top tips for IP protection in the USA

The most important things you can do to protect your IP rights in the USA are:

- stick to your normal business instincts;
- do as much as you can to prevent infringements in the first place - prevention is better than cure;
- assess the risks of the market and make preparations;
- take self-help measures to protect your IP;
- make sure everyone in your business values its IP, including you;
- register your IP rights;
- create good relationships with organizations that can help you;
- consider mediation and arbitration before using litigation

Where to get intellectual property help in the USA

Whether you're resident in and doing business in the USA, or trading internationally with the country, there are a number of professional organizations that can offer you advice and support:

- **The United States Patent and Trademark Office (USPTO)** provides official patents and trademarks in the USA. (www.uspto.gov)
- The US Copyright Office promotes business through copyright protection. **(www.copyright.gov)**

- British American Business offers members the chance to develop their business through networking and marketing programs, business intelligence and regulatory advice and influence. **(www.babinc.org)**

- British American Chambers of Commerce can offer advice for visiting and resident British business people and a chance to meet others through networking events. **(www.britishchambers.org.uk/business/tradinginternationally/international-contacts.html)**

- The British Embassy in Washington provides help for British nationals wanting to do business in the USA. **(www.gov.uk/government/world/organizations/british-embassy-washington)**

- Chambers and Partners USA provides guidance about the US legal profession. **(www.chambersandpartners. com/USA)**

- Stop Fakes offers information on IP rights and protection in the USA. **(www.stopfakes.gov)**

- **TRANSATLANTIC IPR** Portal offers access to information and resources on IP for business. **(ec.europa.eu/ enterprise/initiatives/ipr/)**

RESEARCH PROBLEM

Intellectual property (**IP**) protection supports the development of knowledge based industries, stimulates **international** trade and encourages investment and technology transfer. **IP rights** can contribute substantially to a company's assets and market value. Some of the highlighted **issues** that are facing negligence regarding implementation, for a long time are: Insufficiency of the regulations, Lack of awareness and respect for IPRs and access rules, and. Lack of efficient application/control of these regulations.

HYPOTHESIS

IPR protection and competitiveness have been connected in the literature since the 1970s, although more prevalently during the late 1970s and 1980s, when IPR protection started to be framed as a competitiveness issue.

Currently, IPR protection, more than being used by companies as a tool to attract investment and create wealth has been recognized as a source of competitive advantage. IPR protection prevents firm innovations from being exposed without any kind of protection and explored by competitors, giving the companies a portion of market power and, sometimes, monopoly power, materialized in the exclusive use and commercialization of their innovations, since they are legally protected from potential violations.

LITERATURE REVIEW

Intellectual Property Rights (IPRs) have become important in the face of changing trade environment which is characterized by global competition due to: high innovation risks, short product cycle, investments in R&D, production and marketing and need for highly skilled human resources.

IPR protection can also be used to increase switching costs, by establishing a standard in the market, since technologies developed further are required to fit or be compatible with the standard, or protecting key components required to operate patented technology which gives the company holding the protection a certain market monopoly in the production and commercialization of these components.

IPRs also foster creativity and innovation of businesses, which are a measure of firm performance. They encourage companies to invest in R&D to develop new, innovative products and services, in the expectation of full returns thereof, if the company is granted an appropriate, stricter protection regime of its innovations, with severe legal sanctions for those who attempt to copy or imitate them, otherwise, the prevalence and scope of innovation most likely decreases. In other words, they operate as a safeguard for creators, innovators and producers, since they feel more at ease to invest time, money and effort on research and development of new technologies and products, knowing that they belong to them even if they are not successful.

Research Methodology

Non empirical research work has been used in this project as the material used in this project mainly consists of the work of people which is already done. Some portions of that work are referred in this assignment and citations are also provided wherever they wereimportant.

Sources of data- The following secondary sources of data have been used in the project-

1. Articles.
2. Books
3. Websites

CHAPTER 2

India's IPR Regime: Reconciling Affordable Access with Patent Protection

The Evolution of India's Modern IPR Regime: Tracing the Origins of the Current Contention between India and the US Pharmaceutical Industry

I. INTRODUCTION

Innovation has been a vital component of the American success story. In fact, the Joint Economic Committee of the U.S. Congress estimates that as much as 50% of all economic growth in the US over the past half-century can be attributed to productivity gains resulting from innovation[21]. Patents have, therefore, been integral to the United States' approach to incentivizing innovation by ensuring that innovators enjoy exclusive rights to the commercial gains from their inventions.

With the impact of globalization over the past three decades, America's competitive advantage has increasingly gravitated towards innovation-intensive, high-technology products as its less competitive sectors have ceded ground to products from lower cost economies[22]. Consequently, the protection of intellectual property rights (IPR) accorded by patents have become all the more central to the United States' ability to preserve its competitive edge, particularly over developing economies that have ample human resources and substantial cost advantages, but lack its innovative capacity.

It is against this background that over the past decade, the United States and India have found themselves increasingly locked in conflict over India's IPR regime. In 2013-14, these disagreements were at the forefront of contention, setting an adversarial tone for the entire discourse on bilateral trade and investment and dampening expectations for the future of bilateral economic ties.

This paper seeks to analyse salient aspects of India's approach to intellectual property rights that have been the crux of contention for the US (and Western) pharmaceutical industry.

The first of these is a provision in the Indian patent law, namely, Section 3(d) of the Patents (Amendment) Act of 2005,that sets a unique benchmark for the patentability of inventions, establishing stringent norms with respect to obtaining pharmaceutical patents.

[22;23]Dia& Lauren; The Comparative advantage of Supply chains of World

The second involves India's perceived propensity for granting compulsory licenses, a provision that enables a country to suspend patent privileges in cases where the best interests of their citizenry are at stake as a result of force majeure or willful exploitation of patent privileges by the patentee.Both these aspects of India's IPR regime have accounted for a handful of recent judicial decisions on pharmaceutical patents, resulting in unfavourable outcomes for major global pharmaceutical manufacturers. Finding little favour from Indian courts that have since upheld the constitutionality of Section 3(d) and the grounds for the granting of India's (so far) singular compulsory license, US firms in particular have raised the issue with their own lawmakers in theU.S. Congress. This has opened the floodgates to relentless and scathing criticism of India in response to what the U.S. Chamber of Commerce has termed "India's attack on innovation".

Wielding the threat of sanctions accorded by Section 301 of the US Trade Act[23], American officials have called upon India to "apply its IP laws in a manner consistent with *recognizedglobal standards*[24]."

This paper seeks to investigate this matter further, by establishing what exactly are the recognized global standards, and how and why has India, if at all, departed from them. Further, it examines whether India's unique iteration of patent laws, as seen in its approach to patentability and post-grant measures such as compulsory licensing, is in violation of its TRIPS commitments.

II. THE EVOLUTION OF INDIA'S PATENT LAW

An understanding of the historical context in which India's patenting laws have evolved is crucial to making sense of the current Indian approach to IPRs. Particularly relevant is the establishing of the historical nature of India's patent laws and how these were amended in 2005 to comply with its commitments under the TRIPS agreement.

Post-Colonial Era

Upon gaining independence from Great Britain in 1947, India's 400 million people represented nearly a fifth of the entire world's population, with the vast majority of them remaining abjectly impoverished[25]. Even as it struggled to reckon with the staggering welfare needs of its citizens, the fledgling Indian government found itself almost entirely dependent on imports manufactured in the West for basic necessities, including medicine[26]. As a consequence, even critical drugs such as insulin or penicillin were priced well out of the reach of large sections of the population[27]. Several scholars have attributed this phenomenon in large part to the Patent Act of 1911 that was configured to distinctly favour the mercantilist interests of the British Empire and was still enforced at the time of India's independence[28]. Specifically, it allowed British manufacturers virtual monopolies over the vast Indian market for finished goods, mostly produced from raw materials imported cheaply from India and various other colonies.

[23;24] section 301 of Trade Tax,1974

[25'26'27]Janice M. Muller: The Tiger awakens; The Tumultuous Transformation of India's Patent System

In order to remedy this situation, in 1949 the Government of India sought an intensive review ofits existing patent laws from a high-powered committee led by an eminent jurist of the erstwhileLahore High Court, BakshiTek Chand[28]. The Chand Committee's report noted, among otherthings, that the prevailing patent law offered inequitably strong protections to foreignmultinationals while acutely constraining the nascent and as yet uncompetitive domesticmanufacturing sector from finding its feet. An injunction won some years later by westernmanufacturer Hoechst in the Bombay High Court against the home-grown Unichem Laboratories[29]over an infringement of its patent for the manufacture of a highly sought after anti-diabetic drugis among the most notably cited examples of this phenomenon.

In 1957, a second committee was constituted under another distinguished judge of the SupremeCourt of India, N. Rajagopala Ayyangar[30], with the intent of building upon the Chand committee'sfindings and crafting legislation "more conducive to national interests".

The Ayyangar committee undertook a detailed study of patent laws and successful public welfaremodels of several other nations. Its recommendations, released in the Ayyangar CommitteeReport of 1959, most notably advocated the abolition of "product" patents in favour of "process"patents following the precedent of Germany, Canada and a handful of other European nations.Together with various other amendments and after much deliberation in the Indian Parliament,these recommendations culminated in the Patents Act, 1970**.**

The adoption of this Act marked a watershed in the history of the domestic pharmaceuticalindustry as it enabled Indian companies to replicate western drugs, laying the foundations for theflourishing Indian generic drug industry as we know it today.

As western pharmaceutical companies began to exit the Indian market for want of protection fortheir intellectual property, Indian companies quickly filled the vacuum and acquired increasingcompetence in reverse engineered generics that sold for a fraction of prices charged by theirwestern counterparts.15 Consequently, the Indian government was able to broaden access tomedicines while simultaneously laying the ground for what has today become among the mostprolific drug manufacturing industries, ranking third globally by annual volume.

However, while the near total departure of the western pharmaceutical industry from Indianshores was hardly lamented, there were adverse repercussions. This period was marked bystagnation in R&D in the domestic pharmaceutical manufacturing sector. Several commentatorshave pointed out that the contraposition of the generic industry's success was the stunting of theinnovative capability of the Indian pharmaceutical industry, including limited exposure toclinical trials and other valuable practices the lack of which continues to plague the industry tothe present day.

[28'29'30] Ibid

Economic Liberalization and TRIPS

Acute economic problems persuaded India to abandon its four-decade-long self-imposedisolation and pursue the progressive liberalization of its economy through active participation inthe Uruguay Round of international trade negotiations that commenced in 1986.

With the United States' success in ensuring the inclusion of patent and intellectual propertyrights in the GATT negotiations[31], The benefits of globalization notwithstanding, it believedthat the strong patent protections required under the Agreement on Trade-Related Aspects ofIntellectual Property Rights (TRIPS) would once again undermine its nascent domestic industryand public healthcare commitments in favour of western pharmaceutical manufacturers and thusunravel the benefits reaped under the Patents Act of 1970.

Initially India resisted, leading the vanguard of a bloc of some fifty developing nations withsimilar patent laws that opposed the TRIPS provisions with similar reservations. However, thelure of trade gains or coercion in the form of trade sanctions from the U.S. prevailed upon anincreasing number of these nations. Eventually, India found itself increasingly isolated.

Unwilling to risk its textile industry to the onslaught of U.S. sanctions or jeopardize prospective IMF loans, India eventually relented and reversed its stance on TRIPS. Nevertheless, it continued to press for balanced provisions that addressed the concerns of developing nations in overhauling their patent laws for TRIPS compliance.

The conclusion of the Uruguay Round in December 1994 culminated in the establishment of the WTO and ratification of GATT. India as a signatory was required to enact IPR legislation in compliance with the requirements set out under the TRIPS agreement. The agreement provided a ten-year grace period intended for developing nations to bring their laws in conformity with TRIPS provisions and allow for adjustments in their judicial system and economies.

Changing India's IP Laws for TRIPS Compliance

For India, amending its laws to be compliant with TRIPS posed a tough but necessary challenge once TRIPS came into force on January 1, 1995. To meet these obligations, India initiated a piecemeal, but nonetheless substantive overhaul of its patent laws to comply with the standards laid down in TRIPS.

Among the first of these, the Government of India enacted the Patents (Amendments) Ordinance of 1994 on December 31, 1994, to buy time while statutory changes to the law were pursued in Parliament. This ordinance, however, expired on March 26, 1995 without a permanent legislative solution from Parliament to meet the TRIPS requirements. The 10th Lok Sabha (the lower house of Parliament) was itself dissolved later in the year, ushering in a period of limbo for India's IPR laws. During this time of political uncertainty, India was twice taken to the WTO dispute settlement panel, once each by the US and EU respectively, that resulted in pronouncements against India.

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[31] www.wto.org

Under the looming threat of trade sanctions, the Indian Parliament[32] added unprecedented impetus to passing the necessary laws. This culminated in three separate amendment Acts in 1999, 2002 and 2005 that made incremental adjustments to the Patents Act of 1970 to make it fully TRIPScompliant.

The Indian Patents Act 1970 was amended in 2005, reinstating "product" patents and making the reverse-engineering or copying of patented drugs without requisite licensing from the patent holder illegal after January 1, 1995. The Act did, however, allow the manufacture of generic versions of drugs patented prior to 1995. Additionally, it adopted the controversial 20-year period of guaranteed protection to patent holders as mandated under Article 32 of TRIPS, while establishing various other measures to strengthen the overall rights of patentees. However, amidst growing disquiet from developing and least-developed nations, the Doha Declaration of November 2001 had, meanwhile, reinforced flexibilities under Article 31 of TRIPS allowing member states to mitigate hardships resulting from adjustment of patent laws to TRIPS standards. With this reassurance, Indian lawmakers retained sections 84 and 92 of the law through which India reserved the right to invoke compulsory licensing, either as a remedy to abuse of patent privileges by the patentee or in the case of national emergencies, respectively. Further, it also inserted Section 3(d) into its amended law that set a higher standard for patentability, particularly with regard to incremental innovation, which added the requirement to demonstrate enhanced efficacy to the previously known substance to be considered patentable.

This was specifically intended to prevent the possibility of patent layering, a strategy that involves the extension of patent monopolies, most often through frivolous incremental changes to a product, a practice commonly known as 'ever greening'.

Both these aspects of India's patent law have formed the locus of recent contention on India's intellectual property regime, which is examined in the following sections of this paper.

III. REVIEWING INDIA'S APPROACH TO PATENTABILITY STANDARDS

Dissecting Section 3(d)

Central to the criticism of Section 3(d) has been the fact that it sets the invention threshold higher than TRIPS, specifically Article 27 (1) which mandates that patentable inventions, whether products or processes across all fields of technology, must be i) new; ii) involve an inventive step; and iii) must be capable of industrial application.

[32] Justice AftabAlam and Justice RanjanaP.Deshai

The contention made by Western pharmaceutical manufacturers and the USTR among others is that the prerequisite for 'enhanced efficacy' under Section 3(d) adds a fourth requirement for patentability in excess of the three already prescribed in TRIPS[33]. The USTR's Special 301 report of 2013 made the following observation with regard to the Indian Supreme Court's judgment in the Novartis case on the basis of section 3(d):

"…the decision appears to confirm that India's law creates a special, additional criterion for select technologies, like pharmaceuticals, which could preclude issuance of a patent even if the applicant demonstrates that the invention is new, involves an inventive step, and is capable of industrial application."

Consequently, India has been exhorted to bring its patentability standards "on par with established international norms". The question that arises is whether the 'established international norms', that presumably refer to a configuration of patentability standards styled after the U.S. model, are the best possible approach, especially for countries with vastly different economic circumstances to those prevailing in the U.S. Further, does India's deviation from this precedent constitute a violation of its commitments under international agreements, namely TRIPS?

These salient issues are considered in the following segments.

Assessing the TRIPS Compatibility of Section 3(d)

At the time it was first enforced in 2005, the amended Section 3(d) of India's patent law was indeed both unprecedented and unique among the world's existing patent regimes.However, that did not necessarily imply it was non-compliant with TRIPS. In marked contrast to the criticism noted above, a significant number of scholars and legal experts (including those from leading US institutions) conducting unbiased independent assessments of the Indian patent law have found Section 3(d) to indeed be compatible with TRIPS. In the corresponding literature, it is widely noted that both the intent and language of TRIPS is geared towards creating a broad framework of minimum standards rather than specifically defining the concepts of novelty, inventive step and industrial applicability. This is particularly true for Article 27 of the agreement that addresses patentable subject matter.

Paragraphs 2 and 3 of Article 27 of TRIPS go on to further delineate the broad conditions under which nations may exclude inventions from patentability. Significantly, para 2 accords nations the ability to exclude the grant of patents to inventions - "*...the prevention within their territoryof the commercial exploitation of which is necessary to protect order public or morality,including to protect human, animal or plant life or health or to avoid serious prejudice to theenvironment…*"It is quite clear, therefore, that the TRIPS agreement affords its member nations a substantial degree of flexibility to tailor their patentability standards to best suit national conditions, as long as they remain within these stipulated boundaries, and provided they are enforced "without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

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[33] The Legal Texts: The Uruguay Rounds and Marrakesh Agreements 1994

In this regard, the requirement of 'enhanced efficacy' stipulated by Section 3(d) of the Indian Patents Act is interpreted as a refinement (albeit a more restrictive one) of the 'inventive step' and 'industrial applicability' guidelines rather than a separate and additional requirement altogether. Writing in the Harvard International Law Journal, R. Banerjee observes: "*Viewed this way, it isby no means the only provision in the world to deny patents to insubstantial derivatives of knownsubstances. In American patent law, an invention may not be patentable if it is obvious to anordinary person skilled in the relevant art, in light of prior inventions and references.*"[34]

In fact, the U.S. Patent Office's Manual for Patent Examination Procedures mandates under Chapter 7[35].that the claimed invention must demonstrate evidence of *unexpected results* when compared to prior art in order to fulfil the requirement of 'non-obviousness' referred to by Banerjee above.

The application of this requirement within the context of our discussion is best demonstrated by the case of *Pfizer vs Apotex (Fed. Cir. 2007).* In its ruling in favour of Apotex, the Court of Appeals for the Federal Circuit invalidated Pfizer's patent on the *besylate salt* of the compound *amlodipine* (the active ingredient in the blockbuster hypertension drug Norvasc), decreeing that it failed to demonstrate "*unexpected superior results"* over the base compound to satisfy the requirement of non-obviousness and thereby did not merit a patent.

It is the opinion of several scholars that this ruling demonstrates patentability requirements within U.S. law that are analogous to the 'enhanced efficacy' condition of section 3(d) of the Indian patent law used to assess patentability of inventions.Therefore, the logic and motive behind Section 3(d) to disallow 'ever greening' by requiring a demonstrable advancement in utility is not entirely without precedent, including in the U.S. where attitudes towards this issue are in a state of flux.

Further, there is indication that the U.S. authorities are becoming increasingly aware of the potentially adverse impact of lower standards of patentability and are gravitating towards defining higher standards of non-obviousness for awarding patents to derivatives of known substances.

For instance, the U.S. Federal Trade Commission's Deputy General Counsel for Policy Studies, in a hearing before the Antitrust Modernization Commission (AMC) on Patent Law Reform in November, 2005 had stated that *"the prevalence of poor quality patents* (in the United States) *isan impediment to competition, and it is an impediment that, by definition, is governmentallycreated and, like private business restraints, harms consumer welfare"*.

The experience of the United States with secondary, poor quality patents including for medicines resulting from the configuration of its patentability requirements, may very likely have served as an inspiration to India in the crafting of its own patent laws enacted in 2005, including section 3(d).

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[34]supra fn.21

[35]supra fn.6

The fundamental difference remains that despite sharing an increasingly unfavourable view of frivolous innovation, the U.S. retains relatively low patentability standards with the intent of incentivizing innovation that do little to inhibit the granting of secondary patents. The burden of distinguishing cases of exploitation or 'ever greening' has been effectively shifted to the judiciary.

Instead of following the tried and tested but evidently problematic U.S. approach to patent laws, India has elected to integrate the 'enhanced efficacy' benchmark into its pre-grant phase as a standard for patentability. Thereby, it has chosen to implement a higher threshold for discerning true innovation, yet this remains well within its rights and obligations accorded by TRIPS. In fact, India's amendment of its patent law has been hailed for avoiding retroactive measures that entail needless private and public expenditure and the burden on the judicial system that is inherent in the U.S. model for addressing ever greening of patents.

Therefore, the generally prevailing opinion among experts is that not only is Section 3(d) of India's law likely to withstand any legal challenge on TRIPS-compatibility raised at the WTO's Dispute Settlement Board (DSB), but it is also an effective and successful model for finding common ground between the dual intents of discouraging the practice of ever greening on one hand and achieving compatibility with TRIPS on the other.

The greatest testament to the success of this unprecedented approach set by India in global patent law is that it has since served as a model for other TRIPS signatories, notably the Philippines and Argentina, whose legislatures have each enacted amendments to their law modelled on section 3(d), after careful consideration.

Section 3(d) and its Impact on Innovation

Another aspect of criticism of Section 3(d) stems from the contention that by setting an extremely high bar for patentability, it discourages incremental innovation and adversely impacts the environment for innovation on the whole.

India made the decision to rely on the criteria for 'enhanced efficacy' as the sole and primary basis for distinguishing between 'true' incremental innovation and more frivolous modifications to existing inventions. In the case of pharmaceuticals, this definition of efficacy is limited to imply "enhanced *therapeutic* efficacy" as reaffirmed by the Novartis judgment and subsequent guidelines published by the Indian Patent Office providing clarifications on the matter.

In its Special 301 report of 2014, the USTR expressed consternation over this issue in the following manner: "*The United States is concerned that section 3(d), as interpreted, may havethe effect of limiting the patentability of potentially beneficial innovations. Such innovationswould include drugs with fewer side effects, decreased toxicity, improved delivery systems, ortemperature or storage stability.*"

Indeed the USTR does have a significant point, that the narrow definition applied by the Indian law for inventiveness disregards some important and beneficial dimensions of improvement when considered with respect to the pharmaceutical sector where breakthrough discoveries, especially those involving entirely new chemical entities (NCEs), are relatively rare. This is a view subtly echoed by the Mashelkar Committee, which in its report on Indian patent law in 2009 recommended *inter alia* that: *"incremental innovations involving new forms,analogs, etc. but which have significantly better* **safety** *and efficacy standards, need to beencourage*d".

The noteworthy aspect of this observation is that it suggested "better safety" standards as an aspect of inventions worthy of consideration to be rewarded, in addition to "better efficacy" provisions which are already extant in the Indian law. The relevance of this observation needs to be further examined in the context of the shifting nature of patent applications that can be expected in the coming years.

Declining Discoveries of NCEs

New Chemical Entities (NCEs), by way of their unique molecular structure and properties, present a far simpler test for patent eligibility as compared to derivatives which fall under the ambit of Section 3(d). However, discoveries of NCEs are increasingly hard to come by, being the exception to the rule rather than the norm, and with most instances likely qualifying as 'breakthroughs' in the pharmaceutical research industry. Data from the U.S. FDA suggests that despite a spike in the past two years, the discovery of NCEs approved by the regulator has been on the decline on the whole since the TRIPS agreement was enacted. This has occurred even as the total number of pharmaceutical patent applications and awards by the U.S. Patent Office annually has continued to rise (Figure 1).

This suggests that in the future, an increasing percentage of pharmaceutical patent applications considered by the Indian Patent Office will be for derivatives or repurposed drugs, often presenting subtle incremental improvements over existing chemical entities. However, the limiting scope of the Indian law discussed earlier may preclude an entire class of genuinely innovative and substantial improvements in pharmaceutical therapies as they fall outside the current purview of what is regarded as genuine incremental innovation.

While India is under no compulsion under the TRIPS agreement to expand the scope of its law, the concern that this limitation may ultimately create disincentives among pharmaceutical manufacturers to pursue the development of drug improvements is genuine. It has been further noted that despite the affinity of Indian drug manufacturers for developing similar refinements to existing drugs, their expertise remains yet unproven in the relatively new and highly complex category of drugs known as *biologics* that constitute the most advanced treatments of diseases such as cancer and so forth. Whether Indian manufacturers are able to fill this emerging void by acquiring the necessary expertise and deploying the very considerable resources required for such research, in the absence of adequate patent protection, remains an open question.

This scenario can adversely impact Indian consumers and manufacturers alike, and should foster an informed debate.

Impact of Section 3(d) on the Awarding of Patents

Despite concerns on the limiting scope of Section 3(d) in the context of future drug discovery trends, what can be established with certainty is that in the nine years since its inception, Section 3(d) has not resulted in discrimination against western manufacturers as is often claimed. In the three fiscal years between April 2010 and March 2013 alone, India's Controller General of Patents, Designs and Trade Marks awarded as many as 1001 pharmaceutical patents, of which 771 (a staggering 77 per cent) were granted to foreign firms from the US and Europe. In fact, the two greatest beneficiaries during this period were US-based pharma giants Eli Lilly and Pfizer[36], who between them secured a total of 68 patents. Further, allegations that Section 3(d) effectively bars all forms of incremental innovation altogether (thus limiting patentability exclusively to NCEs) are also inaccurate. A report prepared by the Indian Pharmaceutical Alliance details a list of 86 drugs that entailed relatively minor variations over pre-existing compounds, yet upon successfully demonstrating enhanced efficacy over the base formulation, had been awarded patents in India up to the year 2010. While an updated study of this nature needs to be replicated, it is a fair assumption that this number is likely to have risen in the four years since this study was last undertaken.

In conclusion, Section 3(d) has functioned just as the Indian legislature had intended when it was included in amendments to India's patent law after much deliberation. India's novel approach to patent law has allowed it to successfully strike a balance between its obligations to TRIPS and its desire to discourage patent ever greening in the best interests of its citizens. While the resulting higher standard for patentability has caused much consternation among western pharmaceutical innovators, there is little evidence that it serves as a discriminatory measure or precludes incremental innovations that do demonstrate enhanced efficacy, a parameter that is being increasingly relied upon globally, including in the US Justice system, to distinguish between 'true' and 'frivolous' innovation. There is indeed room for broadening its definitions (as suggested by the Mashelkar Committee in 2009) in view of future trends in drug discoveries and keeping in mind the overall best interest of patients as well as innovators. With legal opinion increasingly acknowledging Section 3(d)'s intent and compatibility with TRIPS, it is unlikely that a legal challenge will be raised successfully against India's patents law. For the time being, Section 3(d) can be expected to remain an integral aspect of the Indian IPR regime, and risk planning involving patentable subject matter must continue to be framed around this assumption.

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[36] Roy Waldron, Chief Counsel for Pfizer Inc Testimony to U.S. Congress by House of Ways and Means Committee.

IV. COMPULSORY LICENSING

In addition to India's higher standards of patentability, another contentious aspect of India's patent regime is its purported propensity to employ the compulsory licensing provision against (usually foreign) innovators in the Pharma sector.

To begin with, one must be clear that compulsory licensing is neither an Indian construct nor a new phenomenon to global patent regimes.

The Paris Convention of 1883, under Article 5A(2) reads: "*Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.*"

In an extension of the Paris Convention of 1883, the TRIPS agreement reaffirmed the right of member nations to grant compulsory licenses and freedom to determine the grounds upon which such licenses are granted.

The TRIPS agreement states that, for public health reasons, countries may suspend patent protection over drugs. The primary provision for compulsory licensing under Article 31 provides for "Other Use without Authorization of the Right Holder." This provision permits WTO member countries to authorize compulsory licenses for use by the government or third parties subject to certain restrictions.

In the context of India's IPR regime, this issue came into the global spotlight in March 2012, when India's Controller General of Patents awarded Indian generic manufacturer NATCO a compulsory license for producing Bayer's blockbuster kidney cancer treatment S*orafenib tosylate*, widely marketed under the name Nexavar[37].

The proceedings were initiated by NATCO's application for a compulsory license under the provisions of Section 84 of the Indian patent law, after it unsuccessfully approached the patentee for a voluntary license of the product.

The Controller General had found that the patentee's misuse of its privileges satisfied the requirements under Section 84 for a compulsory license for manufacture of the patented product.

Observing that Bayer charged the equivalent of $5,000 for a month's dose of the medication (well beyond the affordability of the vast majority of the Indian public) and imported stock only sufficient for a tiny fraction of the total patient population treatable by the drug, requirements of the public in terms of the supply of the patented product and that it had further failed to provide this at a reasonably affordable price to the public[38].

However, in addition, the Controller also controversially observed that by relying exclusively on imports as opposed to manufacturing locally, the patentee had *"failed to work the patent in theterritory of India"*. This additional rationale employed by the Controller immediately became the focal point of international criticism, entirely shifting attention away from other crucial aspects of the case such as the

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[37] Maulik Vyas, "Bayer challenges IPAB's compulsory license to NATCo pharma on Cancer Drug Nexavar, Economic Times, oct 12,2013

excessive pricing or failure to ensure reasonable access for the public of what is essentially a life-saving therapy, all of which had been central to the public debate and legal proceedings in India. Instead, the ruling gave rise to the allegation that the compulsory license was a part and parcel of a state-sponsored policy for meeting domestic welfare and commercial objectives through the systematic forced localization of drug manufacturing.

Bayer proceeded to appeal the Controller's decision with the Intellectual Property Appellate Board (IPAB), while seeking an injunction against NATCO for the manufacture of a generic version of Nexavar. In March 2013, however, the IPAB upheld the Controller General's decision, while also making a crucial clarification with regard to the application of Section 84 (1)(c) Concerning*the working of patents*. The IPAB opined that the lack of local manufacturing alone did not constitute a failure to work the patent. Nonetheless, Bayer's failure to ensure affordability and accessibility to the public constituted a failure to work the license and was sufficient in itself to justify the compulsory license under the Indian patent law[38].

Some observers are of the view that the requirement of local manufacturing to satisfy the 'working of the patent' stipulated by the Controller was incompatible with the TRIPS agreement In particular, they believe that this consideration breaches Article 27(1) which states that "*patents shall be available and patent rights enjoyable without discrimination as to Whether the products are imported or locally produced*".

The IPAB's subtle modification of the Controller General's interpretation was significant in this regard, as it ensured that the government avoided any transgressions of TRIPS requirements as a result of the ruling against Bayer.

Subsequently, Bayer had sought relief against the IPAB's decision through an appeal before the Bombay High Court. However, Bayer's challenge was dismissed on July 15, 2014 with the presiding Justice Sanklecha stating that *"We don't see a reason to interfere with the orderpassed by IPAB and, therefore, the case is dismissed."* As of May, 2015, Bayer had indicated it may pursue an appeal against the High Court's decision by moving the Indian Supreme Court.

V. PATENT LINKAGE AND DATA EXCLUSIVITY

'Patent Linkage' refers to the regulatory practice of linking the marketing approval of a Pharmaceutical product to the patent status of the original drug in order to ensure that for on patent drugs, marketing approval to a third party of a generic imitation is only granted upon patent expiry or with the consent and acquiescence of the patent owner.

[38] Indian Patent Act 1970, Amended 2005

'Data exclusivity', on the other hand, refers to a policy measure that prevents public access to proprietary clinical testing data that innovator firms present to a regulator to demonstrate drug safety and obtain marketing approvals. Many regulatory regimes in India, the US and elsewhere permit generic companies, who subsequently wish to gain their own approval for the same drug substance, to rely on trial data filed by the innovator company that made the first application in order to avoid a wasteful duplication of efforts and thus decrease the costs and delay in market entry for generics. The generic company must simply demonstrate that their product has the same qualitative and quantitative composition as that product and that it is bioequivalent. The rationale for granting data exclusivity is to compensate the innovator company for the significant risk and cost it assumes in generating the clinical trial data required to obtain a marketing authorization. While it may not necessarily add any new advantages to the market exclusivity enjoyed by approved innovator drugs, the delay in proliferation of clinical data does hand innovator firms a decisive strategic advantage over generic manufacturers.

Patent linkage and data exclusivity, though distinct aspects of the IP regime, are associated in that they both contribute to preservation of the originator's market monopoly for the drug in question. India has so far declined to incorporate provisions for either patent linkage or data exclusivity into its amended Patents Act of 2005. As such, these practices have been a matter of serious contention between innovators and the authorities, rivalling only that caused by Section 3(d) and Compulsory Licensing policies.

In order to examine and appreciate the contrasting positions and rationales on the issue of patent linkage and data exclusivity, it is helpful to understand the background of these policy measures that both found their way into U.S. law with the Hatch-Waxman Act, well before the advent of TRIPS.

Hatch-Waxman and the Advent of Patent Linkage in the U.S.

Some experts of IP law trace the history of rigorous clinical trials to the 'thalidomide tragedy' in Europe where a largely untested 'wonder drug' resulted in grave health consequences for users. Consequently, the U.S. implemented an onerous system that required separate clinical trials for every drug seeking market approval, including generics. Furthermore, during this period, innovator companies in the U.S. had complete and perpetual control of 'clinical trial' data for the duration of the patent.

Subsequently, however, the case of *Roche Products Inc. vs. Bolar Pharmaceutical Co.* heard in the U.S. Court of Appeals Federal Circuit in 1984 was an inflection point with regard to patent linkage and data exclusivity in the U.S. and its subsequent proliferation across some global IP regimes[38].

[38] http.nopr.niscar.res.in/pdf

Bolar Pharmaceuticals, a manufacturer of generics, had been experimenting with Valium, the active ingredient used in Roche's patented drug Dalmane. Its objective was to ascertain the bioequivalence of its own generic product against Dalmane for future FDA approval for marketing upon expiry of the original drug's patent, somewhat abridging the usual duplicative clinical trial process for generics. In its defence, Bolar had argued that its use of the patented product did not constitute infringement based upon an exception for experimental use pre-existent in US patent law.

The Court rejected Bolar's argument drawing upon the 'experimental use exception' on the grounds that Bolar had intended to sell its generic product in competition with Roche's Dalmaneafter patent expiration and, therefore, its experiments had a business purpose.

The Court also found no merit in Bolar's contention on grounds of public welfare where it stated that the need to ensure availability of generic drugs immediately upon patent expiration justified the experimental use of the patented drug, which would otherwise result in an extension of Roche's monopoly beyond the patent expiry date.

Although Bolar Pharmaceutical Co. lost the case, the arguments presented in the course of the proceedings initiated a policy debate in the US Congress resulting in the landmark *Drug Price Competition and Patent Term Restoration Act*, also known as the Hatch-Waxman Act of 1984. This Act sought to implement a compromise between incentivizing innovative drug originators and ensuring the speedier introduction of generics. Among other things, the Act permitted use of patented products in experiments for the purpose of obtaining FDA approval. Furthermore, it also eliminated the need for duplication of costly and time-consuming clinical trials. Under its provisions, generic manufacturers were able to use the data generated by drug originators in seeking approval, thereby vastly easing the market entry of generics following expiry of patents.

However, in order to reassure and placate originator firms, the Act also introduced some important concessions. Under "Patent Term Restoration" the Hatch-Waxman Act awards drugs containing a new chemical entity a period of five years of data exclusivity to compensate for the portion of the patent term lost due to the regulatory approval process. Therefore, during this period, generic competitors are prevented from relying on the clinical data submitted by the original pharmaceutical manufacturer for a competing generic product. Additionally, the Act also introduced a system of patent linkage that essentially places an onus on the applicant to prove to the regulator that the drug for which it seeks approval will not be infringing a preexisting patent.

In accordance with the provisions of the Hatch-Waxman Act, the FDA maintains a list of all pharmaceutical products and uses currently under patent, widely referred to as the 'Orange Book'[39].

[39] RavikantBharadwaj; The impact of patent linkage on marketing generic drugs, journal Of IPR volume 18

Any new applicant seeking marketing approval for a product must indicate in a legally binding manner one of four options with regard to the patent status for its proposed product:
1. There is no existing patent related to the applicant's drug
2. The relevant patent has expired
3. Marketing approval is sought after the existing patent expires
4. The applicant is contesting the validity of the patent

Subsequently, the patentee has a period of 45 days upon notice to bring action for infringement, upon which the approval of the generic drug is automatically delayed by a period of 30 months. Generic firms that are able to prove the invalidity of an existing patent are awarded a 180-day (6-month) period of exclusive marketing rights.

There are significant drawbacks to this provision that is widely seen as affording originator firms far too much leeway to delay generic entry and prolonging monopolies through litigation and strategic patenting. In fact, as a result of this concern, the US Federal Trade Commission undertook a study that concluded, among other things, that this provision led to a proliferation of litigation and disadvantaged smaller firms that were all too often unable to summon the resources to mount a legal challenge to invalidate a patent.

Rather often, generic firms had to resort to out-of-court settlements in the face of the tremendous cost of litigation against originator firms. Ultimately this adversely impacted the consumer by delaying access to generics or increasing the overall cost of the drug as a result of litigation costs.

The EU's Centrist Approach

The European Union has introduced a pharmaceutical policy that harmonizes drug regulation in all of its member countries. Significantly, the EU has taken an approach to finding common ground between innovation and public access that altogether rejects patent linkage in the belief that it delays generic entry and adversely impacts access.

The EU, however, compensates originator firms in this arrangement with some of the longest periods of data exclusivity extant globally. The EU grants full data exclusivity during the initial eight years. Any applications for marketing rights may only be entertained after this eight-year period, but granted only after an additional two-year window, hence a total of 10 years. In some cases, regarding 'new therapeutic indications' of a drug, an additional one year of exclusivity is granted to the originator. Due to this unique staggered arrangement for preserving data exclusivity, the EU data policy is often referred to as the '8 + 2 + 1' system.

The Indian Perspective

India's policy on patent linkage and data exclusivity can be said to still be in a formative state. The legislature and separately the courts, through a handful of rulings, have nevertheless contributed to the delineation of some crucial contours of the policy.

To begin with, in the process of overhauling India's IP regime to comply with TRIPS, the Indian legislature took the first step in defining India's policy on this aspect of the IP regime. With respect to framing the minimum rights conferred on a patentee, Article 28.1 of the TRIPS agreement reads:

"A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having The owner's consent from the acts of: making, using, offering for sale, selling, or Importing (6) for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."[40]

However, under its interpretation of Article 27, read along with Article 39 that deals with the disclosure of proprietary data, the Indian legislature did not feel compelled, in spite of lengthy deliberations, to include any provision for a period of data exclusivity to the originator. Remaining consistent in its disfavor towards provisions that could encourage unwarranted prolonging of patents, the Indian legislature also chose not to include a patent linkage clause, following the same path as the European Union in this regard.

Even so, with the language of TRIPS on this issue being vaguely worded and without an expressly worded statutory policy or directive towards this end, a sense of ambiguity and disharmony prevailed in the initial years following the implementation of the Indian Patents Act of 1970 (Amended 2005). For example, the application form issued by the DCGI to applicants seeking marketing approvals contained a question which required the disclosure of the patent status of the original product, implying patent linkage despite the legislature never having adopted such a clause. Capitalizing on this ambiguity, multinational corporations were able to initially gain some legal ground towards a system of patent linkage, along the lines of the US system governed by the Hatch-Waxman Act.

Most notably among these, in a ruling by the Delhi High Court in 2008 in the case of *Bristol Myers Squibb vs. Hetero Drugs Ltd.,* Bristol Myers Squibb (BMS) secured an ex-parte injunction against Hetero Drugs which had sought marketing approval for its drug 'Dasatanib' which was a generic version of the drug *Sprycel*marketed by the former for the treatment of Chronic Myeloid Leukemia.

The Court added that *"It is expected that the DCGI while performing statutory functions will not allow any party to infringe any laws and if the drug for which the approval has been sought by Hetero Drugs is in breach of the patent of BMS, the approval ought not to be granted to Hetero,"* thereby creating a link between the regulatory approval and patent status of a drug that wasunprecedented in the Indian IP regime. As such, the ruling implied that it was also DCGI'smandate to identify a possible infringement of an existing patent prior to granting marketingapproval to any drug.

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[40]ibid

The decision was, expectedly, widely welcomed by multinational pharmaceutical corporations.

However, experts on Indian intellectual property law such as Shamnad Basheer have noted that the Delhi High Court's decision transgressed existing laws and regulations, particularly in giving legal mandate to the DCGI to link marketing approval with patents.

A subsequent landmark judgment from the Delhi High Court in the case of *Bayer Corporation and Ors vs. the Union of India (UOI) and Ors*on August 18, 2009 finally brought much neededclarity to the issue. Bayer had in this case initially sought an injunction (somewhat similar to theone obtained by BMS in 2008) against Cipla to restrain the granting of a license to manufacture,sell and distribute its drug 'Soranib', which was a generic version of the anti-cancer drugNexavar marketed by Bayer. In its arguments, Bayer argued *inter alia* for the establishment of apatent linkage policy through its reading of the Drugs Act in conjunction with the Patents Act.

In this instance, however, the Court did not find merit in the petitioner's argument, ruling first and foremost that the mandate of the DCGI as the country's drug regulator is limited to examining the safety and efficacy of drugs, for which it was expertly qualified. The Court opined that DCGI is not competent to adjudge cases pertaining to patent law, particularly regarding questions of patent validity or infringement. Therefore, the performance of this role was beyond the drug regulator's mandate.

Furthermore, the Court also ruled that the enactment of an entirely new policy, such as the enforcement of a system for patent linkage, was the exclusive preserve of the legislature, which the court noted had made the conscious decision to omit such a provision for patent linkage in the law. It added that while it was the Court's function from time to time through interpretation of legislation to fill in statutory gaps, to effect such a substantive change in policy would constitute a case of overreach. Therefore, such a policy could only be enacted by the Parliament. The Delhi High Court's judgment in this case marked a watershed in the modern Indian IP regime and was a definitive veto against the incorporation of elements of patent linkage in the Indian system. Furthermore, the decision upheld the so-called 'Bolar provision' of the Indian Patents Act that allowed generic manufacturer's access to clinical data for the development of generic alternatives that could be introduced with minimal delay following patent expiry.

The decision, however, like others before it, invited scathing criticism and an overall miscasting of the Indian patent regime as anti-innovative.

Is Market Exclusivity Impossible in the Absence of Patent Linkage?

A leading consultant on the global IP regime, discussing India's approach to IP policies in a popular IP blog, has written: "*In effect, without patent linkage, the grant of patents forpharmaceutical products cannot assure any exclusivity in the market, and so advanceddeveloping and developed countries with well-functioning patent systems have also made aneffort to implement patent linkage.*"

This observation in many ways reflects the misconception among critics of the Indian IP regime who fear that patents are unenforceable in the absence of a patent linkage provision. Towards this end, the Delhi High Court, in the *Bayer vs. Union of India* case, made a most crucial observation in emphasizing that patent rights are 'private rights' and contingent upon the patent holder's desire to enforce them rather than an obligation of public institutions such as the DCGI. This places the onus of defending a patent against infringement through legal recourse squarely on the patentee and thereby underscores the fundamental difference in approach towards patent linkage followed by the United States and other nations that have adopted such a policy. Further, the patentee is provided sufficient legal recourse under the Indian Patents Act of 1970, which elaborately provides for the procedure for patent opposition and revocation under Sections 25 and 64 respectively.79 Section 104 of the Patent Act also mandates that no court lesser than a District Court should have jurisdiction over matters of patent infringement. This only validates the DCGI's lack of jurisdiction over the matter. This dispensation clearly requires a far more proactive approach from a patentee, without the Convenience of the 'firewall' against patent infringement of sorts created under the Hatch-Waxman Act. However, it also limits opportunities for strategic litigation that, as noted by the US FTC, could otherwise forestall the entry of generics into the market. Prolonged delays in generic entry could have major consequences for Indian patients, the vast majority of whom tend to be precluded from accessing the benefits of on-patent drugs due to their significantly higher prices. On the other hand, it also necessitates a greater level of transparency and access to information from the drug controller in order to allow the patentee to remain abreast of any new applications that may potentially infringe upon an existing patent and take remedial action in a timely manner. These scenarios are highly time-sensitive, as can be seen from Pfizer's experience with Sutent, where a delay in the legal process was sufficient to flood the market with generic supply to the detriment of Pfizer, which ultimately won its appeal. The Controller General of Patents, Designs and Trademarks has made important strides to address concerns in this regard. The "Indian Patent Advanced Search System (InPASS)" launched on February 27, 2015 enables digital access to both granted patents and pending applications for the benefit of all stakeholders.

Does India's Stance on Data Exclusivity make it a Global Outlier?

On the matter of protection of undisclosed information and trade secrets, Article 39 of TRIPS provides the requisite guidelines for member nations. The relevant paragraph (3) of Article 39 reads as follows: *"3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or ofagricultural chemical products which utilize new chemical entities, the submission ofundisclosed test or other data, the origination of which involves a considerable effort, shallprotect such data against unfair commercial use. In addition, Members shall protect such dataagainst disclosure, except where necessary to protect the public, or unless steps are taken toensure that the data are protected against unfair commercial use."*

In order to inform and evolve India's legal framework in accordance with the data protection requirements of Article 39.3 of TRIPS, the Government of India had convened an inter-ministerial Committee in 2004 under Satwant Reddy, then Secretary in the Ministry of Chemicals and Fertilizers. The Committee examined the implications of Article 39 and proposed various approaches to address India's commitments in this regard. In its report dated May 21, 2007, the Committee found that Article 39.3 did not obligate signatories to offer data exclusivity and that the 'Trade Secrecy' provision already extant in Indian law was sufficient in providing protection against unauthorized use or disclosure of confidential data.
Second, current literature advocating the implementation of these policies often invokes comparisons with OECD countries such as Canada, Australia and Singapore, all of which have implemented patent linkage and data exclusivity measures, but also have vastly more advanced economies than India. Curiously enough, this is a context where even China is touted as a role model, having made the unusual commitment to enact both a patent linkage system as well as a six-year period of data exclusivity, absent any binding treaty obligations, and in a noteworthy reversal of its usually protectionist trade policy.
However, as the table below indicates, India's stance on patent linkage is quite consistent with economies of a similar developmental status such as Brazil and Indonesia.

Table: Patent Linkage Practices[41]

Country Patent Linkage Data Exclusivity
Brazil No No
Russia NoYes – 6 years
China Yes Yes – 6 years
South Africa No No
Thailand No Yes - 5 years
Indonesia No No
Philippines No No
Singapore Yes Yes - 5 years
Vietnam No Yes - 5 years
Brunei No No

On the issue of data exclusivity as well, India can hardly be termed an "outlier".
Divergent economic circumstances that prevent the extemporaneous adoption of policies followed by developed nations has been recognized by none other than U.S. Rep. Henry Waxman, the co-author of the Hatch-Waxman Act, who has observed that "(data exclusivity) works in this country because most people in the U.S. have health insurance that pays for essential drugs and because we have a health care safety net to assure that the poorest in our society are not left without medical care and treatment."

[41] www.mirandah.com/pressroom/item/340-patent-linkage-in-asian-countries

"But to impose such a system on a country without a safety net, depriving millions of people of life-saving drugs, is irresponsible and even unethical. In developing countries, we must do everything in our power to make affordable drugs for life-threatening diseases available now".

The Policy on Data Exclusivity Remains in Flux

So far we have demonstrated that India's stance on patent linkage and data security, though a source of distress to western trade negotiators and MNCs, is neither in violation of its TRIPS commitments nor does it make India an outlier among similar developing economies across the globe. Following the Delhi High Court's definitive ruling in this regard, this policy is unlikely to be reversed by the Parliament.

However, Indian policy is far from mature with respect to data exclusivity, where the debate has in fact remained alive and vibrant.

The Satwant Reddy Committee report[42] stirred the pot by recommending a provision granting three years of data exclusivity for firms registering new agro chemicals. While these recommendations were incorporated into the proposed Pesticide Management Bill, 2008, the bill was never passed due to contention over a number of other provisions.

The issue has reportedly remained a crucial sticking point in the India-EU Free Trade Agreement (BTIA) negotiations, preventing progress.

At the same time, a significant section of the Indian pharma industry, comprising domestic research-based firms, had demanded stronger data protection laws to protect their investments in global clinical trials. Breaking ranks with industry associations and patient groups, homegrown firms such as Biocon, Glenmark, Dr Reddy's, Lupin, Bharat Biotech and others have stressed the need for regulatory data protection (RDP) in order to promote innovation and investment in the development of new medicines and clinical research.

Indian Policymakers must take cognizance of this demand as it signals a paradigm shift towards innovation by India's pharma industry.

The three most compelling arguments in favour of a provision of data exclusivity, from the perspective of India's domestic interests, are provided below.

a) To Promote Domestic Innovation

The absence of "an ecosystem conducive to R&D" in India has been widely recognized. As Basheer and others have noted, the provision of an abbreviated pathway for approval of generics has been beneficial both in terms of speedier access for patients and keeping costs low.

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[42] Satwant Reddy and Gurudialsandhu, report on steps to be taken by Govt. of India in context of data protection provision of article 39.3 of TRIPS agreement.

However, it has also created a sense of complacency by enabling domestic generic manufacturers to 'free-ride' on the clinical data generated by innovator firms abroad. As a consequence, Indian firms remain stunted in terms of their clinical testing and associated innovative capabilities. Reddy points out how this free rider effect has created a disincentive in the realm of Ayurveda ever since clinical trials were mandated.
The pattern of increasing innovative output among domestic industries, despite the prevailing incentive to free-ride, must be encouraged. Awarding a period of data exclusivity would certainly add impetus to this important but nascent trend towards innovation among homegrown firms.

b) To Foster Beneficial Improvements to Drugs

Drug regulatory policy operates independently from patent law, even more so in the case of India following the Delhi High Court's express directive in this regard. Therefore, the marketing approval of any new drug is subject to regulatory requirements, irrespective of the patent status. Reddy and other eminent IP experts have pointed out that Rule 122E of the Drugs and Cosmetics Rules 1945 utilizes a definition of a 'New Drug' that differs significantly from the definition of a 'new invention' as enforced by Section 3(d) of the Patents Act.[1] The definition used by Rule 122E includes *inter alia* new forms or claims of existing drugs namely 'new indications, dosage, dosage form and route of administration', all of which are precluded from patentability under Section 3(d) as discussed in previous sections.[2] Many of these have considerable medical utility, particularly in instances where vastly improved safety or fewer side effects are demonstrated. Even though they may not be eligible for a patent, by virtue of their classification as 'New Drugs' per the Drug Rules 1945, they would require extensive clinical testing to obtain marketing approvals. In those cases where clinical trial data from other countries is not available, the nascent prospects of such potentially beneficial new drugs may be left dead in the water as it is unlikely that manufacturers would be willing to assume the risk and investment on clinical trials only to have their data exploited via a rampant 'free-riding' trend along with the absence of legal recourse available to on-patent drugs. With a steadily declining trend in NCE discoveries and a growing propensity for innovation among domestic firms, such cases are likely to occur.

c) To Address the Capability Gaps of the Generic Industry

India possesses a thriving generic industry that has demonstrated an advanced ability to reverse engineer drugs developed elsewhere, thereby providing generic equivalents at vastly lower prices. However, even to date the Indian generic industry's expertise extends by and large only to conventional 'small-molecule' drugs that are fairly straightforward to replicate.

The latest range of biologic medicines, however, are derived from far more complex procedures involving the genetic engineering of living cells rather than through chemical synthesis as in the case of small molecule drugs[42]. With a handful of exceptions, the Indian industry's capabilities in innovating or even replicating biologics remains highly limited. Also, the significant R&D into replication, if at all, can only commence once data exclusivity periods expire in the originator country and the clinical trial data is released to the public. In many cases, there are no alternative sources of such therapies besides the original innovators. A period of data exclusivity would go a long way in providing foreign firms a level of reassurance to make their drugs available in India with minimal delay.

VI. THE DISTINCTION IN PHARMA ECONOMICS IN THE DEVELOPED AND DEVELOPING WORLDS

To mitigate contention on IPR issues, the underlying economics of pharmaceutical patents thatinfluence both firms and governments needs to be examined and understood. What drives the pricing strategies of pharmaceutical firms, or motivates government policies such as compulsory licensing?

In its simplest form, a patent is an exclusive right conferred by a government on an inventor to preclude others from the sale, use or import of an invention for a limited period of time. It is understood that this exclusive right awards the inventor the ability to charge a monopolistic price for the invention that exceeds what would be charged in a perfectly competitive market with several suppliers. This price allows inventors to recoup their investment of time and capital devoted to the research and development of an invention and prospectively also accumulate profit, arguably creating an economic incentive for innovation. There is a resulting burden borne by consumers in the form of higher prices and a deadweight loss incurred by society as a whole for the duration of the patent. However, this transfer of wealth from the consumer to the innovator and the foregone benefits to society is seen as a necessary short-term trade-off for a long-term welfare gain achieved through the future proliferation of the said invention once the patent expires and the overall promotion of innovation.

The case of pharmaceutical patents, however, is distinct in that the costs borne by society in the form of restricted access to a newly invented drug due to higher prices is denominated not in terms of reduced productivity, utility or income, but a direct, negative impact on human health and longevity. Nor is the magnitude of this societal cost uniform across different economies. It is influenced in large part by pre-existing conditions including income levels, inequality, prevalence of disease and the relative pricing of the new drug, among others. As we will demonstrate, this creates a relatively far more difficult and complex public policy issue in least developed and developing economies as opposed to the first world.

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[42]http/www.ipwatchdog.com/

In their seminal work published in 2009 on patent drug pricing and the associated costs to society, Flynn, Hollis and Palmedo proposed that these developing economies characterized by high levels of income inequality demonstrate "highly convex demand curves" for essential medicines with no substitutes, signifying highly variable sensitivity to the unit drug price[43]. The illustrative example below depicts the extremely uneven income distribution in South Africa, a typical developing nation. Among the five lowest deciles representing half the population, no one earns more than $1,500 a year on average. In contrast, the top 10% of the population earns nearly $30,000 a year, some 20 times the lowest decile of society, and alone accounts for 56% of all income earned by the entire population of the country.

VII. EMERGING CHALLENGES

After two years of intense trade contention in 2013 and 2014, stemming in large part fromdisagreements on IPRs that appeared to cloud even the broader India-US relationship, there seems to be an upswing in the discourse. This is in no small part due to diplomatic efforts and the personal rapport shared by Prime Minister Narendra Modi and President Barack Obama, a point underscored by the US Trade Representative himself in an address at an India-US Trade Policy Forum meeting in November, 2014.

The USTR's Special 301 Out of Cycle Review (OCR) of India's intellectual property regime released a few weeks later in December, 2014 resonated these sentiments, lauding India's efforts for having a "meaningful, sustained and effective" dialogue on IPRs.Cementing this significant turnaround of stance, the USTR's report also recognized "India's efforts to institutionalize high level engagement on IP issues and to pursue a specific work programme and to deepen cooperation and information exchange with the United States on IP-related issues under the US India Trade Policy Forum".

Beyond this renewed sense of engagement between the two governments, the fundamental issues on IPRs and their underlying causes still remain unresolved. Many Western stakeholders in the pharma industry retain a strong sense of discontentment with India's IP regime, finding signs of progress severely inadequate. Some industry representatives are particularly concerned about the USTR's change of tune with regard to India, and have gone on record suspecting a secret compromise involving concessions from India in order to earn this respite from the so far relentless heat it has had to face.

What is evident from these reactions is that the pharma industry is unwilling to alter its fundamental approach towards doing business in India. Among its expectations on regulatory reforms, its wish-list continues to include a carte-blanche for setting price and quantities of drugs sold in the Indian market, with any subsidies or rebates at its own discretion.

In the meanwhile, the economics of the Indian market that dictate the compulsions of policymakers and concerned authorities also remain unchanged. A vast section of the population remains mired in crippling poverty, with income inequality worsening by all indications.

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[43]S.flynn,A.Hollis,M.Palmadeo, "Economic Justification for open access to Essential Medicine Patents in developing Countries.

Hence any singular profit-maximizing price set by the pharma manufacturers on patented drugs, without substitutes or generics, will likely price out most of the population and draw the adverse attention of the Indian public health authorities.
In the near future, the three factors outlined below will work to aggravate this conflict of interests.

1) The Growing Convergence in Disease Profiles of the Developed and Developing World

Much of the literature on public health in the developing world has been devoted to the issue of tropical diseases predominant only in the developing world. The recent global Ebola outbreak in West Africa and Dengue fever epidemic in India are just two examples of the all too frequent outbreaks of tropical diseases that largely originate in and most gravely impact the developing world. Further, these epidemics have been stark reminders of how diseases exclusive to the developing world all too often find themselves on the back burner of research priorities of most pharmaceutical companies.
However, several analyses of global healthcare trends suggest that the disease profiles of the developed and developing world demonstrate increasingly converging characteristics. Hence these 'orphan' or 'neglected' tropical diseases are accounting for an ever smaller share of the developing world's disease burden. Instead, non-communicable diseases (NCDs) such as cancer and cardio-vascular disorders, for example, once disproportionately found in the developed world, are increasingly affecting low income countries significantly.
A report published by WEF and the Harvard School of Public Health indicates that over 60% of all deaths in India are already due to non-communicable diseases. Alarmingly, the report further predicts that India stands to lose $4.58 trillion between 2012 and 2030 as a result of non-communicable diseases, an amount well over twice India's current GDP. Cardio-vascular disorders alone will account for $2.17 trillion of this loss[44].In fact, four NCDs alone caused nearly 50% of all disease-related deaths in India in 2014[45].These are cardiovascular disease (26 per cent), chronic respiratory disease (13 percent), cancer (7 per cent) and diabetes (2 percent)[46].Commenting on these findings, David Bloom, Clarence James Gamble Professor of Economics and Demography at the Harvard School of Public Health, attributed the increasing global burden of NCDs to two related demographic phenomena: global population growth and an increasing older population."Unhealthy diets, physical inactivity, harmful use of alcohol and tobacco consumption also drive the development of NCDs. In India, this is no exception, and NCDs are a large and growing challenge for its continued development. But solutions are available to improve the prognosis, reduce costs and create a healthier population," Bloom has added.These emerging trends have a two-fold impact. First, as a consequence, developing markets will become increasingly important to the pharmaceutical industry. The shifting disease burden in conjunction with an increasing ability to pay due to economic growth will drive a significant component of global demand growth for breakthrough therapies for NCDs.

45;46;47 ibid

The Economist has reported that established markets in North America, Europe and Japan are expected to see between 1-4% growth in drug spending between 2012 to 2017.In contrast, drug spending in emerging markets is likely to grow between 10-13% over the same period, with patented drugs being a significant component.

2) India's IP Policy Response to its Evolving Public Health Needs

These shifting considerations already appear to manifest themselves in India's access and affordability priorities, and possibly explain recent trends in the Indian authorities' approach to IP and their willingness to exercise flexibilities afforded by TRIPS to ensure access to advanced drugs.

Pharmaceutical innovators have been contending with IP threats in the form of compulsory licenses, patent denials and revocations in the developing world for several years now. However, there are some of the significant instances globally since 2001 shows, each of the actions taken against privately held intellectual property preceding those by India against Novartis and then Bayer was either for HIV/AIDS or another communicable disease. Further, these were often invoked under the circumstances of a serious threat of a pandemic, as in the case of widespread prevalence of HIV/ AIDS virus in Africa or the later outbreak of the H1N1 Avian influenza ("Bird flu") in East Asia in 2005.

In spite of initial alarm, most global pharmaceutical manufacturers were coming to terms withthe fact that the loss of revenues from such occasional, but drastic, outbreaks of infectious diseases would constitute a cost of business, and were gradually factoring these into their risk models. In India's case, however, the flurry of patent opposition against Oncology and Hepatology treatments signals a marked departure from the erstwhile prevailing trend towards non-communicable diseases. With cancer and other NCDs posing an increasing burden on the health of its population, ensuring access to drug treatments for these diseases is taking center stage in India's public healthcare policy.

Traditionally, the newest and most effective 'breakthrough' treatments for cancer and various other NCDs have been priced at restrictively high prices, determined in part by the market dynamics discussed in the previous chapter.

Even so, the concerned Indian authorities have shown remarkable restraint and so far issued only a single compulsory license for Nexavar. However, the perception has been perpetuated that India is willing to exercise the ability to issue compulsory licenses to ensure that these treatments are made affordable to Indian patient populations, including the predominant economically disadvantaged segments.

In addition, this will become a growing concern at the patent application stage, where applications for innovative NCD drugs will face increasing scrutiny from the regulatory authorities and opposition from various patient and domestic interest groups such as has been seen in a growing number of cases, from Novartis's Glivec to Gilead's Sovaldi.

As such, to the innovative pharmaceutical industry, this perceptibly emerging trend presents a serious and growing threat to an entirely different, and extremely lucrative, dimension of pharmaceutical intellectual property assets. Not only has this IP contributed to the lion's share of industry profits in the post TRIPS era (as the next section will discuss), but so far it has also been considered 'safe' by all accounts.

3) The Patent Cliff

Over the past decade, innovative drug companies have become increasingly dependent on 'blockbuster drugs' – the term used to refer to patented specialty drugs that generate more than $1 billion in sales annually, with many generating revenues as high as over $5 billion in the US alone.

As such, these drugs have played a central role within the pharma ecosystem, accounting for a significant portion of annual revenue and profits and thereby also making a significant impact on share prices. Therefore, research and development as well as the protection of IP pertaining to such 'breakthrough' drugs has been a principal aspect of the success strategy of several pharma firms.

However, a disproportionately large number of patented drugs that have formed the mainstay of pharma profits will see their patents expire in quick succession in the period between October 2011 and December 2016, a phenomenon widely termed as the 'Patent Cliff.' Altogether, these accounted for a whopping $64 billion in revenues in the year 2011.

The loss of exclusivity will throw the doors open for generic manufacture of these drugs from competitors and almost certainly diminish revenues substantially for many firms unless they are able to introduce new blockbuster drugs. So far, this does not bode well for an industry that in 2012 alone lost over $35 billion in global revenue[48].The fallout in 2015 is expected to be nearly as bad, at some $33 billion in lost sales[49].

Worryingly for the pharma industry, the pipeline for novel drugs appears nowhere as prolific as it was in the early 2000s. As the New York Times has reported, there has been a marked decline in the discovery of breakthrough drugs, making them relatively fewer and far in between, even though individually a few of these may indeed be just as lucrative as others have been in the past.111

VIII. ADDITIONAL CHALLENGES PRESENTED BY A TRIPS-PLUS DRIVEN IP LANDSCAPE

From the preceding discussion, it is apparent that the need for a new paradigm in the industry has never been greater in order to avert a serious collision between the innovative pharma industry and governments in the developing world, including India. Any new approach must ensure that the healthcare needs of the economically disadvantaged patients within developing countries are met, without unduly compromising the interests of the pharma industry, in particular their incentive to innovate.

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[48] Thomas Katie, "Drug Makers see a drought ahead", New York Times.

[49] Thomas Katie, "Drug Makers see a drought ahead", New York Times.

A sustained dialogue, with the objective of a gradual fostering of mutual trust and a willingness to collaborate between industry and governments, both in the developed and developing world, is necessary to transform the current contentious state of affairs. However, rather than resign itself solely to accepting some form of compromise towards a resolution, the pharma industry has sought to hedge its options instead by vigorously seeking to rewrite the rules of intellectual property enforcement. This trend is aimed at effecting a broad proliferation of IP policies that set the privileges and standards for patent protection far above those mandated by TRIPS. This approach is most evident in the IP standards pursued through the prospective Trans-Pacific Partnership (TPP), a comprehensive trade agreement between the US and several nations in the Asia-Pacific that could have a transformative impact on trade regimes in the entire world.

The TPP's Approach to IPRs

The language of the TRIPS agreement expressly conveys that the provisions contained within merely present a set of minimum standards that all signatories must meet. The intent was to bring uniformity to intellectual property regimes of members in the light of increased globalization and trans-national trade facilitated by the newly formed WTO. Member nations retained the prerogative to impose higher standards as per their own considerations within the overall framework set by the agreement.

As the case of India has demonstrated, compliance with TRIPS has been no cakewalk for the developing world. Even the minimum standards mandated by the agreement set the bar far higher than pre-existing regimes in most developing nations. Further, compliance has entailed a substantive recalibration of laws and institutions, sometimes overhauling decades-old norms and approaches to IP issues. As such, many of the developing country members are still in the process of finding their feet and maturing their patent regimes along the requirements of TRIPS while mitigating the adverse near-term welfare impact on their citizens.

However, the US and other OECD nations have increasingly found the TRIPS provisions inadequate towards serving their economic interests, particularly with the welfare-friendly interpretation reinforced by the Doha Declaration that has allowed the introduction of novel legislative countermeasures such as Section 3(d) or the liberal use of compulsory licensing to facilitate access.

Consequently, some nations within the TPP have reportedly sought to advance a number of relatively higher 'TRIPS–plus'IPR standards that substantially expand the rights of the patent holder, as revealed by various leaked drafts of the treaty which is being negotiated in secret. Provisions that elicit the most concern in the purported text with regard to pharma patents include:

• Limiting the ability of countries to exercise rights confirmed in the 2001 Doha Declaration, by restricting those rights to a specific list of diseases and situations.

• Limiting the capacity that countries have to restrict secondary patenting and ever-greening by requiring patents on "new uses or methods of using a known product".

• Restricting countries' ability to include important public health flexibilities in their own national laws, for example India's Section 3(d) patent law which requires evidence of "enhanced efficacy", before additional patents can be granted on existing products.
• Restricting countries' ability to use to the full the public health flexibilities recognized in the TRIPS agreement, including compulsory licenses and patent exceptions.
• Mandating that countries include TRIPS-plus measures in their national laws, including patent linkage, patent term extensions and new monopolies based on clinical data exclusivity, including for biological vaccines and medicines, which have never before been included in a US-led trade agreement. Cumulatively, these provisions appear to be edging the IPR norms for developing nations, even those not directly associated with the respective agreements, ever higher even before the dust has settled on compliance processes with the baseline TRIPS requirements.

How India can be Impacted by the TPP

The question arises that if India is not a party to the TPP negotiations, should it be concerned by the provisions of the treaty?
The answer is a definite "Yes." Various nations have from time to time engaged in bilateral agreements (more often than not with at least one of two parties being a nation of the OECD) that have included various measures over and above those stipulated in the TRIPS agreement. These include the introduction of patent linkages and data security or export restrictions and anti-counterfeiting measures[50].The Most Favoured Nation (MFN) clause in TRIPS ensures that acountry that has been accorded MFN status may not be treated less advantageously than anyother country with MFN status by the promising country. Thus, every new broken ground in terms of higher IP standards in a bilateral agreement effectively becomes the new standard for the concerned nation's IP regime for every other MFN trading partner as well.
Owing to either the promise of greater economic benefits or even geostrategic considerations, plurilateral free trade agreements on the regional level such as NAFTA, CAFTA, RCEP, TPP and TTIP have found increasing favor in recent years. Many of these include nations at vastly differing levels of development. The RCEP, for example, counts among its sixteen members ten states belonging to ASEAN along with six states with which ASEAN has existing FTAs. At one end there are the advanced economies of Japan, Australia, Korea, New Zealand and Singapore and at the other end of the spectrum, developing economies like Myanmar, Cambodia and Laos. Ideally, negotiations would seek a common ground incorporating the divergent considerations of each negotiating party.

[50] http/thehindubusinessline.com/todays-paper/tp-economy/india-against-tripsplus-clauses-in-bilateral/trade-pacts/articles1001590.ece

CONCLUSION AND SUGGESTION

There can be no denying the fact that a transparent and predictable regulatory framework for IPRs backed by better IPR enforcement would benefit India's business environment and also advance public interest. That appears to be the intention behind the Indian Government's decision to set up a Think Tank comprising eminent experts to propose a comprehensive IPR Policy based on extensive consultations with stakeholders, both domestic and foreign. Indeed, the draft IPR policy posted for public comments by this expert body acknowledges the significant role of IPRs as a driver of innovation, trade and economic growth.

That said, there can also be no question that broader public interest will continue to remain the paramount consideration for Indian policymakers as they balance public health needs with safeguards and incentives for innovation.

This report finds that section 3(d) of India's patents law and compulsory licensing provisions are TRIPS compliant and in the national interest. Section 3(d) establishes a new threshold for discerning true innovation and has gained acceptance outside India. Compulsory licensing has been used only once and the case in question has stood the test of judicial scrutiny right up to the Supreme Court of India. Given India's prevailing socio-economic conditions, these provisions balance the objectives of promoting innovation, preventing "evergreening" on insubstantial grounds, and ensuring affordable access to essential medicines.

However, there is need to also recognize the evolutionary nature of IP law and practice. The Mashelkar Committee's recommendation on expanding the interpretation of novelty to include incremental innovations and drug improvements that have significantly better safety and efficacy standards need to be considered. Streamlined drug approval channels must be part of India's modernized IP regime.

It is well known that India has not been in favour of Patent Linkage or Data Exclusivity. Neither aspect is mandated by the TRIPS agreement. That said, it will be in the overall interest of India's expanding pharma industry if the government were to design and put in place an efficient system for data protection. Perhaps another Expert Committee needs to look into this area afresh in consultation with relevant stakeholders.

While the focus of this report has primarily been the Indian IP regime for pharma, much needs to be done by Pharma MNCs in the areas of establishing or expanding R&D, working of patents in India, improving delivery mechanisms and adopting appropriate pricing and licensing policies.

It can only be hoped that innovative pharmaceutical companies will look to develop new paradigms for the pricing of life saving drugs for the Indian market better attuned to the economic status of its consumer base. Their future strategies should seek to leverage scale with low-margin high-volumes that have proved so successful for other mass consumption goods.

Drugs with smaller patient populations will require various differential pricing strategies to maximize availability, though government support will also be crucial for the success of such initiatives.

American biotech giant Gilead Sciences has shown the way forward in this regard, offering deep discounts in conjunction with voluntary licenses to Indian generic firms for a number of its breakthrough treatments for HIV and Hepatitis C. Such initiatives will go a long way in bridging the trust deficit between pharma and biotech majors and the Indian authorities, while mitigating threats to the drug innovators' IP.

Ideally, India's business environment should incentivize innovators to conduct an increasing portion of their R&D and drug manufacturing in low cost hubs within India, thereby decreasing the overall cost of drug discovery and development to the benefit of consumers worldwide. A regulatory framework conducive to such a scenario requires serious attention from Indian policy makers.

Finally, while both India and the US have stepped back from the often bitter confrontation of 2013-14 and resumed a measured dialogue on IP, it would be a mistake to accord pharma a central or dominant place in this dialogue. The tendency to focus on one sector alone circumscribes the discussion and does not allow for a constructive and collaborative engagement between the two sides on other important IP issues that foster trade and investment. Significant sectors of US industry are supportive of the IP regime in India. Equally, there are a number of areas of IP congruence and cooperation which are not adequately addressed because of over attention to pharma related issues. This imbalance needs to be remedied.

Even as India moves towards a 21st century IP regime that incentivizes domestic inventions and rewards innovation from all corners of the globe, a balanced and sustained India-US dialogue on IPR issues remains vital to the public and private interests of both nations. Their promising economic partnership will certainly stand to gain if the recent cycle of contention over IPRs can be successfully contained and eventually overcome.

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