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# PATENT TERM EXTENSION FOR BIOLOGICS: A COMPARATIVE ANALYSIS OF EU, US, AUSTRALIA AND INDIA

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## Abstract

Patent Term Extension(PTE) is the extension of the term of patent. It is usually granted to products which requires approval from various authorities so as to commercialize and market it. Such products include pharmaceutical drugs of humans and animals, food and colour additives, medical devices etc. The Patent Extension Term varies in different countries and are regulated by different authorities.35 U.S. Code § 156 grants patent extension term to biologics. In EU, SPCs are granted to biologics by European Council regulations. While the US grants market exclusivity through Hatch-Waxman Act, 1984 to chemical drugs; Biologics Price Competition and Innovation (BPCI) Act of 2009extended the same to biologics. In European Union, the European Council Regulation extends patent of chemical drug as well as biologics through Supplementary Protection certificates( SPCs).[2] In Australia, patent extension term is granted to biologics through Australian Patents Act, 1990.[3]Biologics are the products which are manufactured or synthesized from living organisms. These biologics are gaining traction because of it wide application for treating various diseases The advent of biosimilars which are the products highly similar to biologics, is also a reason because of which there is fear among pharmaceutical companies. India, at present do not have patent extension term or market exclusivity as it is developing country dependent on technology of developed countries. It is to be analysed whether Indiashould grant patent extension term to biologics.

Keywords*: Biologics, Biosimilars, Patent Extension Term, Supplementary Protection Certificate*

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[2]Council Regulation 469/2009.
[3]Australian Patents Act, 1990, S.70.

## Literature Review

### Theoretical Framework

Biologics, a product of biotechnology is the new ray of hope in healthcare industry. Biologics are molecules extracted from living cells and treated using proteins, DNA, through recombinant technology.[4] However, compared to chemical drugs, these larger molecules are more sensitive to the environment and therefore less stable. The high complexity of its structure further creates challenges to determine its pathway once the molecule is administered in a living organism.[5] Thus biologics require high level of safety standards and rigorous clinical testing to be approved which makes it time consuming. Therefore, many countries offer patent term extension for the time lost due to clinical trials and testing for biologics. Patent extension term means extension of patent for a certain period for the time. This acts as a boost to the biologics industry and it helps the manufacturers to recover the high costs of producing biologics through adequate length of monopoly in the market.

Biosimilar is another term associated with biologics. Biosimilar is a highly similar product as that of a biologic.[6] In common parlance, it is called generic version of biologic. Biosimilars use the information and data of reference biologic to create the drug at a cheaper rate. The biosimilars offer access to medicines which are otherwise of exorbitant cost.Biosimilars can be marketed as soon as the patent of biologic expires. This was also one of the reasons for grant of patent extension term.

### Conceptual Framework

India currently does not have any provision for patent extension term or market exclusivity for biologics.[7] The question is whether India needs a patent extension term for biologics. *Patents and Development: A Non-Governmental Organization View prior to Revision of the TRIPS Agreement*[8]by Richard Gerster, discusses the view point of Switzerland government. Switzerland government with respect to patent extension term said that patent extension term may be detrimental to the developing countries as they are primarily importers of technology. In the chapter, *India's Free Trade Agreement: Implication for Access to Medicines in India and*

[4]Kristina M. Lybecker, The Biologics Revolution in the Production of Drugs, FRAISERINSTITUTE, (Mar. 21, 2020, 10:16PM), https://www.fraserinstitute.org/sites/default/files/biologics-revolution-in-the-production-of-drugs.pdf.

[5]*Id.*

[6]EMA, Biosimilar medicines: Overview, EMA,(Mar. 21,2020, 10:19 PM), https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview.

[7]Guidelines On Similar Biologics,2016.

[8]Richard Gerster, *Patents and Development: A Non-Governmental Organization View prior to Revision of the TRIPS Agreement*,1 J. World Intell. Prop. 605 (1998)

*the Global South*, by Kajal Bharadwaj[9],the author refers to a study by Korean National Health Insurance Corporation. As per the study, if patent term extension is granted by India even for 4 years , it would lead to significant increase in cost to the government and decrease of 9% in consumption. The author also talks about the impact of data exclusivity provisions in developing countries. Data exclusivity was imposed on developing countries like Jordan, Guatemala by US FTAs and it was found that almost 79% of the medicines did not have a generic equivalent. However, in India where there was no provision for data exclusivity, access to medicines at lower cost through generic was possible. In the book, *Trans-Pacific Partnership Agreement: A Framework for Future Trade Rules?* edited by Abhijit Das, Shailja Singh, the author takes a similar view that adhering to patent extension termswill adversely impact India. The author opines thatthey are less about promoting innovation and more about monopolizing and facilitating windfall profits. India needs to take care of thedomestic stakeholders.Article titled, *Biotechnology Patenting in India: Will Biogenrics Lead a Sunrise Industry to Bio innovation*[10], by Janice Muller discusses this issue. The article discusses the growth of certain Indian industries which are doing well in the biosimilar industry and therefore more focus should be on biosimilar industry.In the article, *Biosimilars in India: Current Status and Future Perspective*[11], by Bikash R. Meher et al, the author analyses the biosimilar market in India and concludes that India can become a leading manufacturer of biosimilar drugs. Patent extension term for biologics may be detrimental to the biosimilar industry.

However, there is no concrete study which establishes the link between grant of patent extension term for biologics and the growth of biosimilar industry and analysing comprehensively whether India needs a patent extension term for biologics. Most of the literature focuses on patent extension term of chemical entities. However, biologics are significantly different from chemical entities and there is a need to analyse whether India needs patent extension term for biologics.

## Statement of Problem

India has a fast growing biotechnology industry and can be a great market for biosimilars in India. Patent extension term can grant necessary boost to the biotechnology industry. However, it is not determined whether India can compete with the global players in the field of biologics. It is to be analysed whether India should adopt a patent extension term for biologics or focus on

[9]HANS LOFGREN,POLITICS OF THE PHARMACEUTICAL INDUSTRY AND ACCESS TO MEDICINES, WORLD PHARMACY AND INDIA,(Routledge 2018)

[10]Janice M. Mueller, *Biotechnology Patenting in India: Will Bio-Generics Lead a Sunrise Industry to Bio-Innovation*, 76 UMKC L. Rev. 437 (2007).

[11]Meher BR et al, *Biosimilars in India; Current Status and Future Perspectives*. 1 J Pharm Bioallied Sci. 12 (2019)

monetizingon biosimilars.

## Introduction

A patent protects any invention which is novel and capable of industrial use. A patent grants an exclusive right to the inventors over the product or process which they have invented for 20 years. The condition to grant of patent for an invention is the disclosure of the invention to public. Thus, patent law aims to promote research and development as well as benefit the society by adding to the knowledge pool. Patent is an important tool when it comes to business and competition. A patent gives a competitive advantage over other players in the market as it monopolizes the invention in favour of the patent holder. In some cases, this competitive advantage cannot be achieved within 20 years of patent protection. With developing technologies such as biologics, 20 years is insufficient to convert the invention into a commercial product and market the same due to its complex nature. Biologics means those pharmaceutical substances which are extracted or produced or even synthesized using living organisms. They include recombinant proteins, blood cells, somatic cells etc. The process of using these biologics for therauptic purposes includes a long process of converting them into commercial products, clinical tests to check toxicity and approval by the regulatory bodies. Therefore, the patent protection of 20 years may expire by the time this long procedure is completed. The threat of biosimilars entering in the market as competitions to the biologics is another issue faced by the pharmaceutical companies. Many countries therefore has offered patent extension term so that these products can cope up with the long procedures and market their product to gain monetary benefits. India however do not have any provision of patent extension in Indian Patents Act, 1970.Biotechnology is a growing industry in India and research and development has seen a boost in the recent past. Therefore, it is a requirement that India should be ready to tackle these issues when the time comes. This paper aims to comparatively analyse the patent extension laws and other regulatory approaches of USA, European Union, Australia and India to understand patent extension term and their impact on biosimilars and thereby analysing whether India should grant patent extension term for biologics.

## Meaning and Concept of Biologics

Biologics in simple words can be said to be as the products which share the make-up of a chemically derived drugs but they are in fact the product of living systems. When compared to a chemical drug, biologics are relatively larger in molecular size and have a heterogenous structure i.e. it may contain various strands of amino acids. Some people include small organic molecules in the category of biologics. Some feel that any complex molecule which is

biologically derived can be called as biologics even if it's not produced by a living system directly. Others say that molecules which may not be highly complex but are simply extracted out of a living organisms can be considered as biologics. For e.g.:- Estrogen Hormones extracted from urine of a pregnant mare called as Premarin.[12]

Biologics work by altering a gene or protein so that the gene or protein behaves in a desired way. Since genes of many species such as mice and rats are similar to human being, it allows testing of such manipulation of genes to see if the desired results can be achieved. The main process involved in creating such biologics is called Recombination of DNA. Recombination of DNA involves various processes such as isolating DNA from a human cell and splicing the DNA to create sticky ends. Thereafter the DNA segment is inserted into a bacterium cell where it combines with the DNA of the bacterium cells. Thereafter, the effect of the inserted DNA fragment can be observed when the organism start expressing the traits of the DNA. When this method is used for developing a therapy for treating a disease, it involves much more complex procedures and steps.

When it comes to biologics, the immune system reacts more strongly when compared to chemical drugs. It is because of the larger molecular size of biologics compared to the small size of chemical drugs. The human body is able to identify larger biologics and release antibodies to fight the foreign bodies. This nullifies the effect of biologics causing a failure of intended therapy. Also, biologics consists of various strands of amino acids and therefore may have impurities. This causes inconsistencies when biologics are prepared in batches. One batch of biologics may differ from another batch of same biologics because of the impurities involved. However, the quality of the batches remain same and they go through rigorous clinical trials to ensure their safety. Another fact about biologics is that they are fragile and complex in nature which makes its manufacturing time consuming and relatively hard compared to chemical drugs. This complexity of biologics cause them to be more expensive than chemical drugs.

However, they can offer better treatments for diseases such as cancer, rheumatoid arthritis, ulcerative colitis, ankylosing spondylitis, Crohn's disease, Diabetes, infertility, Asthma and many more diseases.[13]

## Need of Patent Extension Term for Biologics

[12]Morrow, T.& Felcone, *Defining the difference: What Makes Biologics Unique*,24Biotechnology healthcare 26 (2004).

[13]**Rawla, P. et al, *Role of biologics and biosimilars in inflammatory bowel disease: current trends and futureperspectives*, 215 Journal of inflammation research 220, (2018).**

Biologics are complex medicinal products which are derived from a living organisms and created using recombinant DNA technology. This complexity in their manufacturing process makes it time consuming. Moreover biologics require higher number of clinical trials due to its complex nature to establish safety. This again adds to the already time consuming manufacturing process. A patent is usually granted for 20 years in most of the countries. It takes 97 months on average for a biologic to be developed compared with 90 months for a new pharmaceutical product. Over the years the average time to develop a biologics has increased. This may not seem to be a huge difference at first glance but the pharmaceutical companies may lose up to $ 312 million worth of sale of biologics.[14]Moreover, the biologics have to pass the scrutiny of Food and Drug Administration to be able to put their products in the market for consumption. Due to the complex nature of biologics, FDA requires more number of clinical trials and higher degree of safety against toxicity when compared against chemical drugs. Also, the research for biologics are usually funded by venture capital firms who do not invest in industries involving high risks and uncertainties. It is also believed that biologics make narrow patents compared to chemical patents which is undesirable for venture capitals.

All these factors make it justifiable for a biologic to receive patent extension for the time consumed in manufacturing and clinical trials required by Food and Drug Administration. Another reason for granting patent extension term for biologics is the threat of biosimilars looming over them. Biosimilars are medicinal products which are highly similar to an approved biologic and do not have any clinically meaningful differences. There can be differences when it comes to clinically inactive components of the medicine. Biosimilars receive approval of the Food and Drug Administration by showing that their quality, efficiency and immunological and biochemical safety is according to the standards of the biologic they referred to. Biosimilars are usually permitted to enter in the market when patents on the biologic expires. Therefore the life of patent of biologic is restricted due to its complex nature of manufacturing, regulations of FDA and their monopoly is at threat of biosimilars.

The US and European Countries have witnessed a splurge in manufacturing of biosimilars by various industries. However, it is important to note that biosimilars are different from what we call as generic drugs. Generic drugs are bioequivalent of the innovative drugs. Generic drugs are those drugs which are structurally and in therauptic equivalent to the innovative drug whose patent has expired.Biologics are complex in structure and consist of various amino acids

[14]Mark Metzke, *Increasing Follow-on Biologics Competition with a New Biologics Act*, 39 AIPLA Q. J. 357 (2011).

combined in a definite sequence to give a particular trait. This makes biologics possess various structural and post translational changes when compared to generic drugs. This structural differences may be caused due to difference in environment or conditions also and it may cause variation in the same batch of biologics. Therefor it is possible that one biological product may not be entirely identical to another biological product of the same batch. This creates more risk when assessing the safety and immunological efficiency of the biosimilar product. The complexity of biosimilars is not fully understood yet and therefore it poses a greater risk than generics.

## Patent Term Extension and Market Exclusivity in the United States

In the US, all medicinal products need to be approved by the Food and Drug Administration. Biologics are regulated under Public Health Service Act, 1994 and the companies have to apply for a license through Biologics Licensing Application to market the drug. For approval from FDA, the company should meet the safety and efficacy standards set by FDA through various clinical trials. The lengthy process of approvals from FDA often cut shorts the patent term of the biologics. In the US, a patent is granted for 20 years. However, the FDA approval on average takes around 8 years and sometimes it can go as high as 25 years. Hence, by the time the FDA approves the biologic, the innovator company might have lost their time to make profit out of their innovation. Therefore, the US has the provision for patent term extension. The patent extension term in the US is granted for 5 years for drugs, biologic and class III medical devices. Biologics are given the benefit of patent extension under 35 U.S. Code § 156. In General, the patent extension term is granted to the first of the kind drug which is approved by FDA. The statute says that any human drug product of which the active ingredient is salt or ester or ester of the active ingredient or combination of such active ingredient are eligible for patent extension term. However combination product of previously approved drugs are not eligible for patent extension. Moreover, the entire term of the patent is extended and it is not limited to individual claim. However, it is to be noted that patent extension is only granted for FDA approved uses and not for other commercial uses.

The Hatch- Waxman Act, 1984 provides for Abbreviated New Drug Application process for generic manufactures. Under this proves, generic manufacturers may obtain FDA approval by basing it on the already approved innovator drug and showing that the generic drug is bioequivalent of the innovator drug. Bioequivalent means that the generic drug consists of the same active ingredient with similar strength, efficiency and potency. A generic drug is termed to be the equivalent of the innovator drug if both the products “do not differ significantly with

respect to their rate and extent of their active ingredients becoming available at the site of action on or in the body." The Hatch -Waxman Act,1984 therefore ensures that generic manufacturers are able to enter the market and it makes it necessary for the innovators to share the safety and efficacy data of their drug with these generic manufacturers. To compensate for this, the innovator drug manufacturer are given market exclusivity. It means that FDA cannot approve a generic drug until the duration of market exclusivity of the innovator drug expires.

However, Hatch-Waxman Act,1984 does not apply to biologics. FDA's statutory interpretation of the Act excludes biologics from the benefits of ANDA. Therefore, the biosimilar manufacturer has to wait till the patent expire to apply for approval through Biomedical License Application and it must develop its own safety and efficacy standards. Some small less complex biologics can however opt for NDA approval under FDCA and they are eligible for pathway under Section 505(b)(2) but they are excluded from ANDA. This becomes complicated as there are no clear cut guidelines as to which biologics qualify for NDA and which do not.

The provision of market exclusivity was extended to biologics also through Biologics Price Competition and Innovation(BPCI) Act of 2009. This resulted after a series of public meetings on biosimilars by Food and Drug Administration of the US. Biosimilars were granted approval by FDA so as to ensure access to medicine to lower strata of society at low costs. By virtue of Patient Protection and Affordable Care Act, 2010, FDA gained the authority to regulate biosimilars. Biosimilars were the highly similar versions of biologics they used as reference. The biologic which is chosen as reference is usually one which is already approved by FDA. For example Omnitrope used Genotropin as reference and it was an already approved biologic. However the first biosimilar to be approved under Biological Price Competition and Innovation Act, 2009 was Zarxio which used Neupogen, a licensed biologic.[15]

The biologics get market exclusivity for 12 years underPublic Health Service Act, 1944.[16]Biosimilars are known as follow-up biologics(FOB) in the US. During this 12 year period, FDA is prohibited to grant license to a follow up biologic which uses the biologic as a reference. A follow-up biologic can file abbreviated biosimilar license application( abLA)after 4 years of approval of biologic.However they cannot market their product until the expiry of 12 years market exclusivity granted to biologic.[17] Compared to generic drugs, it is a much longer period as innovator drugs receive market exclusivity only for 5 years under Hatch- Waxman

[15]Terry Mahn, *Uncertainty in Patent Term Extension for Biologics*, FISH&RICHARDSON,( Mar. 21, 2020, 10:46PM), https://www.fr.com/news/uncertainty-in-patent-term-extension-for-biologics/.
[16]Public Health Service Act, 1994, § 351(k)(7)(C ).
[17]42 U.S.C. §. 262(k)

Act, 1984.[18] Moreover, the first approved follow up biologic receives exclusivity period which may range from 12 months to 42 months as it depends on various factors. However first approved generic is granted only a one year extension.[19]In some cases, the approval of biosimilars may be delayed in cases where there is a final court decision regarding patents or infringement suits pending against the biosimilar. Therefore they are given 18 months of market exclusivity post decision or dismissal by the court[20]If the innovator biologic file an infringement suit against the first approved biosimilar, the innovator biologic can maintain market exclusivity throughout the duration of the infringement suit. Only when the court gives its final decision or dismissal of the case, biosimilar is granted market exclusivity for 18 months. If the innovator biologic prolongs the infringement suit to 42 months or more, the subsequent biosimilar i.e. the biosimilar after the first approved biosimilar must wait 42 months after the approval of the first biosimilar[21]

There are cases where the biosimilars do not have to face any infringement suits. However, the subsequent biosimilar cannot enter the market until 18 months of exclusivity period is over for the first approved biosimilar. However, the innovator and the biosimilar manufacturers can enter into agreement for sharing market exclusivity period. Hatch Waxman Act, 1984 provides market exclusivity in case of patent litigation but that's not the case in Public Health Services Act, 1994.

Orphan drugs are those drugs which cure life threatening diseases. When it comes to orphan drugs, the FDA will not approve a biosimilar having the same principal molecular or structural form till expiry of 7 years.[22]Minor differences such as difference in AA sequence of a protein or post translation reactions will not be considered in this case. However, if the biosimilar is clinically superior to the innovator biologic in terms of safety and efficiency, approval may be granted. However, this approval is only granted after the expiry of 12 years market exclusivity given to the innovator biologic. Moreover, if the applicant conducts a study in paediatric population at the written request of FDA, then 6 moths extension of market exclusivity is further granted. However, there is no extension of patents in this case.[23]

The position of EU though similar to US and offers patent extension term as well as market

[18]FDA, *Patent and Exclusivity*, FDA, (Mar. 21, 2020, 10:51PM),https://www.fda.gov/media/92548/download.
[19]Public Health Service Act, 1994, § 351(k)(6)(A).
[20]Public Health Service Act, 1994, § 351(k)(6)(B).
[21]Public Health Service Act, 1994, § 351(k)(6)(C)(i).
[22]*Supra* at 18.
[23]*Id.*

exclusivity for biologics, there are minor differences in both regimes.

## Patent Term Extension and Market Exclusivity in European Union

In European Union, biosimilars are approved under the 2004 framework of European Medicine Evaluation Agency. European Union is the first among all to grant approval to a biosimilar which was a growth hormone somatropin in 2006. Since then, EU has been setting example for approving biosimilars as well as establishing extensive safety procedures. All biosimilars have to go through EMEA for approval. The biosimilars can also be approved at national levels. Under EMEA, when company applies for market authorisation, data is evaluated by EMEA's scientific communities on human medicine and safety called as Committee for Medicinal Products for Human Use (CHMP) and The Pharmacovigilance Risk Assessment Committee (PRAC) and EU experts on biological medicine called as Biosimilar Working Party. The review by them consists of a scientific opinion which is then sent to European Commission which thereafter grants marketing authorisation to the company.[24]The traditional drugs and their generics are tested on the basis of bioequivalence but the same approach could not be followed for biologics and biosimilars due to safety and efficacy concerns. Therefore under the EMEA's regime, it has to be shown that there are no meaningful differences in safety or efficacy between a biologic and a biosimilar. The applicant company has to follow the guidelines issued by EMEA and go through consultation and comparability tests to establish that the quality, safety and efficiency of the biosimilar is same as the biologic. The manufacturing process needs to be consistent throughout and the proof for the same should be produced. The applicant company should also go through toxicity tests and prove the comparable immunogenicity. This is usually proven by using clinical trials.

The European Union has a flexible approach when it comes to determining the extent of clinical trials required to prove the safety and efficiency of a biosimilar. Approval of a biosimilar therefore depends on manufacturing process, clinical tests, analytical procedures and it may vary from case to case. In some cases, the applicant may have to go through the entire process to establish safety and efficacy and in some cases, the safety and efficacy test of the innovator biologic may be enough.

However one peculiar feature about EU's regime is that a biosimilar which is in reference to a biologic does not mean that it is interchangeable or can act as a substitute for the reference biologic. This decision as to whether biosimilar can be a substitute for biologic depends on the

[24]EUROPEAN MEDICINES AGENCY, *How the committees work*, EUROPEAN MEDICINES AGENCY, (Mar. 21, 2020, 10:55PM),https://www.ema.europa.eu/en.

individual member state. This creates hurdles for the biosimilar manufacturer a EMEA's approval is not the only approval needed. Till date, no member state has approved the substitution of a biologic.

The length procedure of approval created the need for extending the patent term of biologics so as to provide them incentive to go further in the research of treating diseases using biomedicines. In EU, Supplementary Protection Certificates are granted to extend the patent term for medicinal products which have gone through regulatory procedures for approval.[25] The medicinal product may be for human consumption or for veterinary purposes. All member states of European Union grant SPCs. Even Norway and Iceland by virtue of being members of European Economic Area grant SPCs.[26] SPCs are granted to patents with claim of the active ingredient present in the medicinal product, method of producing such active ingredient, application or use of such active ingredient or preparation of the active ingredient.

Another criteria for grant of SPCs is that there has to be a patent already granted to the product in the country where the SPC is sought. In case of combination products, it is necessary that the combination product must be a distinct invention if it contains an active ingredient for which SPC is already granted. However in certain situations, SPC may be granted for a previously authorised medical product if it is shown that a new therapeutic use is discovered for an already approved active ingredient. Moreover, SPC has to be separately applied in each country for protection.[27]

When it comes to market exclusivity, the original biologic obtains market exclusivity for 8 years from EMEA and during this time, EMEA will not accept application of any other biosimilar. After the original biologic is approved, another two years extension is granted starting the date on which the approval is granted. This exclusivity period may be extended if the biologic is granted market approval for a new indication. This extension can only be granted once. Biosimilars are not allowed to market their products neither on old nor new indications.[28]

The position of Australia is different from EU as well as US. However, there are certain similarities when it comes to approval of biosimilars.

## Patent Extension Term and Data Exclusivity in Australia

[25] EC Regulation 1768/92.

[26]Cohausz & Florack, *The need-to-know facts about patent term extensions in Europe*,IAM MEDIA,(Mar. 21, 2020, 10:58 PM), https://www.iam-media.com/need-know-facts-about-patent-term-extensions-europe.

[27]*Id*

[28]Sonia Ribeiro, Data exclusivity, market protection, orphan and paediatric rewards, EMA, (Mar. 21, 2020, 11:00PM), https://www.ema.europa.eu/en/documents/presentation/presentation-data-exclusivity-market-protection-orphan-paediatric-rewards-s-ribeiro_en.pdf.

In Australia, a patent extension term is granted for 5 years to standard patentees. According to section 70 of the Australian Patents Act, 1990, a standard patentee can apply for patent extension term to the commissioner after fulfilling certain criteria given under the section.

For a patent extension, following criteria must be fulfilled:-

- The pharmaceutical substance if claimed in the patent, must be disclosed and if there is a process using recombinant DNA technology to produce a pharmaceutical substance, then it must be disclosed too.
- The substance or the goods in the claim should be included in Australian Register for Therauptic Goods. ARTG is a database which can be referred by public to know which therauptic goods can be provided in the market of Australia.[29]
- Patent extension is only granted if there is a gap of five years between the date of patent and date of approval by the regulatory bodies.
- Patent extension term must not have been previously granted

As per Section 71 of the Australian Patents Act, 1990, an application for patent extension has to be submitted within 6 months of the date of grant of patent or date of first ARTG registration. However, the period of 6 month scan be extended as decided in the case of Alphapharm Pty Ltd v H Lundbeck[30].Australia does not provide any extension for paediatric studies.[31]

The Therapeutic Goods Amendment Act,1998 grants data exclusivity for new goods containing a new active component. A new active component is a substance with a therapeutic effect. This includes biotechnology products which requires approval of Therauptic Goods Administration as per the explanatory memorandum of the Act. Data exclusivity means that TGA cannot use original manufacturer's data without consent to grant approval to a biosimilar.However, there is no market exclusivity provision in Australia.[32]

In Australia, biosimilars are not considered as bioequivalent of biologics by TGA and the manufacturer has to rely on one's own data to prove its efficacy, safety and reliability. However, if the drug is already registered in Australia and marketed in Australia for substantial period of time, data of reference product can be used. In case, the drug is not registered in

[29]Archna Roy, *Comparative Analysis of Canadian 'Certificate of Supplementary Protection' with USA and Australian 'Patent Term Extension' and European 'Supplementary Protection Certificate',* 167 Journal of Intellectual Property Rights 172(2018).

[30]Alphapharm Pty Ltd v H Lundbeck,A/S (2014)FCA 1185

[31]*Supra* at 29

[32]Sarah Hennebry, When a 20 year patent term just isn't enough: Market and data exclusivity, FPA PATENTS, (Mar. 21, 2020, 11:05 PM), https://fpapatents.com/resource?id=483.

Australia, then bridging study needs to be submitted which shows the comparability of the reference product and a drug already registered in Australia. The Biologicals Regulatory Framework and the Australian Regulatory Guidelines for Biologicals (ARGB) in 2011 regulate the marketing of biologics and biosimilars. The guidelines are similar to EU guidelines for approving biosimilars including clinical trials, toxicology tests, efficiency tests etc.[33]

While Patent Extension is granted in Australia, EU, and the US, position of India is different.

## Position of India

In India, patent extension term is not granted. The debate whether patent extension should be granted in India for the delays happening due to patent prosecutions and regulatory delays, is ongoing. Patent Office itself causes delays when it comes to processing of patent applications. Moreover, authorities such as National Biodiversity Authority may also cause delays in getting approvals. India at present do not grant any patent extensions. The first case which questioned the need for patent extension was *Nitto Denk Corp vs Union of India*[34]where the patentee asked for compensation for the time consumed in examination process by granting them either through waiver of maintenance fees or by granting them patent extension. However, it was held that the proposal of extension of patent was not suitable to India as 20 years itself is considered to be a long monopoly. Further, it was held that through policy measures, the delays in examination, prosecution and grant of patent applications can be taken care of. However, new dimensions have evolved with the upcoming of bio medicinal industries.

It is estimated that many biologics are facing expiry of patents in the year 2020. Therefore, there is ample opportunity for biosimilars to enter the market. Biosimilars can provide same treatment at a lower cost and can provide access to medicine for all strata of society. Indian Players participate in regulated markets o EU and USA and has been successfully granted approvals for their biosimilars. For example, Biocon is the first Indian pharmaceutical company to get approval of its biosimilar from United States Food and Drug Administration.

Witnessing the biosimilar spurge in India, Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorisation in India, 2016 were issued. These guidelines lay down the standards for development and evaluation of biosimilars. The guidelines define biosimilar as a biological product which is produced through genetic engineering and is similar in terms of safety, efficacy and quality to a reference biologic that has already been granted approval for marketing by the Drug Controller General of India on the basis of a complete

[33]Biosimilar Medicine Regulation, 2018

[34]Nitto Denko Corp. v. Union of India & Ors. (W.P. (C) 3756/2013)

dossier and historical evidence of safe use in India. When the reference biologic is such that it has not been approved in India, it will be considered case to case. For example, if the biologic is approved in a jurisdiction such as EU and US which has a well-established regulatory system and has been in use for at least 4 years in those jurisdiction, the approval may be granted.

For approval of a biosimilar, it is necessary to show that the biosimilar is highly similar to the biologic in reference and this can be achieved by comparison studies, pre-clinical and clinical trials.

The situation with respect to patenting of biosimilars in India is tricky. A biosimilar which is not squarely covered under a patent claim of the innovator biologic may be granted patent by the patent office. There are currently no criteria for market exclusivity or patent extension term which is protecting the innovator biologic. At the same time, the biosimilars are granted patents if they are not infringing the patent claims of the innovator biologics. Moreover, grant of patent is not a criteria for approval from Drug Controller General. This causes instability and threat for the industries focusing on manufacturing of biologics.

- Trade Secrets can be used to protect data. Article 39.3 of TRIPS does not need data exclusivity.

Many industries use trade secrets as a means to protect their biologics. However, this causes an informal monopoly in the market causing high prices for biologics. In India, where many people lack access to medicine, trade secrets in medicinal products should not be promoted. However, a longer monopoly is also not preferred in a country like India.

## Patent Extension Term for Biologics and its Impact on Biosimilars: Comparative Analysis of US, EU, Australia

Patent Extension term differs in US and EU, and Australia. In the US, the Drug Price Competition and Patent Term Restoration Act or Hatch- Waxman Act, 1984 grants patent term extension up to 5 years, however, the total patent term should not be extended more than 14 years after approval date by FDA. This period can be extended for another 6 months if a study of paediatric population is to be conducted.

The European Union also provides for patent extension for 5 years through Supplementary Protection Certificate. However, the total patent term should not be more than 15 years after approval by European Medicines Agency. In EU also, additional 6 months protection is given to the claims involving medicinal preparation to treat children.

In Australia, the Australian Patents Act, 1990 grants patent extension for 5 years by application to the Commissioner. There is no further extension for paediatric trials in Australian regime. T Thus, when it comes to patent extension, the provisions for extension in US and EU are similar. However, Australia has a different system. The main differences are discussed below:-

- In the US and Australia, the term used for granting extension of patent is Patent Extension Term( PTE), while in the EU, Supplementary Protection Certificate(SPCs) are used to denote extension of patent.
- In the US, Hatch Waxman Act, 1984, 35 U.S.C § 156 deals with extension of patents of chemical drugs and Biologics Price Competition and Innovation(BPCI) Act, gives patent extension to biologics. In EU,Council Regulation (EEC), Regulation (EC), Patents (SPCs for Medicinal Products), Patents (SPCs for Plant Protection Products), Patent Fee Rules are the main regulations which handle extension of patents. In Australia, the Australian Patents Act, sections 70- 77 deal with patent extension term.
- In the US, patent term extension is granted by United State Patent and Trademark Office. In Europe, the patent term extension is to be approved by every country specifically. In Australia, Patent is granted by the patent office of Australia.
- In the US, if patent claims contain unapproved products, then the patent rights of other products will also expire along with the original product. Another patent cannot be taken on the unapproved product later after approval. In EU, the patent protects only medicinal or plant products which are to be placed in the market and have a patent protection or those which are approved by the regulatory before the expiration of the patent. In Australia, patent extension are only granted to good listed in Australian Register for Therauptic Goods and when there is difference of 5 year period between

the date of patent and date of approval by the regulatory bodies.

- In the US, the maximum market exclusivity is granted for 14 years and additional 6 months is given for paediatric exclusivity. In EU, market exclusivity is given for 2 years and 6 months of extension is granted for paediatric exclusivity. In Australia, there is no market exclusivity provision.
- In US, orphan drugs are granted 7 years of market exclusivity, while in EU, orphan drugs are granted 10 years of market exclusivity.[35]Market exclusivity can also be extended for 2 years in EU for orphan drugs. It is to be noted that the market exclusivity

[35]Carolyne Hathaway et al, *Exclusivity Strategies in the United States and European Union,* LW,(Mar 21, 2020, 11:09 PM),https://www.lw.com/upload/pubcontent/_pdf/pub2655_1.pdf.

can be reduced to 6 years as well if the product no longer requires market exclusivity as it is profitable enough to justify such an action. There are no such provisions in Australia.

- The extension of patent includes patent term adjustment under 154(b) in US. In EU and Australia, there is no provision for patent term adjustment.
- The request for patent term extension should be made within 60 days from the approval date. In EU, the application for patent extension should be made within 180 days of the date of approval. In Australia,an application for patent extension has to be submitted within 6 months of the date of grant of patent or date of first ARTG registration.
- In the US, period of extension can be reduced by way of patent adjustment term. If the applicant hasnot acted with due diligence, that period is decreased from the term of patent extension. The extended patent term is calculated by taking the period of regulatory review period and subtracting the entire pre grant regulatory review period and the entire time during which applicant did not act with due diligence and half of the regulatory period which is the testing phase and half of the pre grant testing phase. In European Union and Australia, no such provision exists.

The US and EU have similar provisions when it comes to granting patent extension terms for biologics as well as granting market exclusivities. However, the growth of biosimilars in both the markets have a stark difference. Biosimilars in Europe are increasing in terms of manufacturing as well as sales. The safety and efficacy tests in Europe are well trusted and this might be the reason for growing sales of biosimilars. The current guidelines of Europe also enables the growth of biosimilars but it does not limit the growth of biologics and innovation in biologics.

In contrast to EU, US has a slow growth of biosimilars. Most of the biosimilars face hurdles when they aim to enter the market. The challenges are usually created by big pharma companies who uses unfair methods of contracting and counter dealing to limit the price advantage which a biosimilar has. Biosimilar manufacturers incur high manufacturing cost and with the uncertainties and risks in the US market, they are reluctant to invest in it. The Biosimilars Act, at the first glance seems to promote market for biosimilars so as to facilitate access to medicine for all. However, there are many hurdles in the Biosimilars Act which stops the manufacturers from developing biosimilar. Coupled with the highly complex manufacturing process and higher degree of scrutiny for safety, toxicity and efficiency, the innovator biologics can capture the market for a longer period of time with infringement suits and negotiations. This uncertainty

discourages manufacturers from focusing on biosimilar. In fact, developing a biologic might be an easier path for many of them.[36]Another problem faced in US is that consumers are not willing to shift from well-known biologics until and unless they start creating some side effects or toxicity. There are many practical difficulties when it comes to the market in US.

Australia's patent extension term has limited the growth of generic industry and also led to increased costs of pharmaceutical products. It was found that Australia's effective patent term after providing patent term extension was longer than the effective patent term of the US. This resulted in longer monopoly and domination of Australian market by US.[37]

## Strategy for India

India as of now has not implemented any patent extension terms or non-patent exclusivities. There are various reasons for India to not grant patent extensions. India do not have a patent linkage system which is necessary for implementation of such provisions. India have not entered into any trade agreements which necessitates grant of patent extension. The TRIPS agreement also does not require any member country to grant patent extensions. However, there was pressure exerted on India to grant patent extension especially to pharmaceutical companies through agreements like Trans-Pacific Partnership and Regional Comprehensive Economic Partnership. These agreements constitute a regime which is known as TRIPS plus and is curated majorly for the benefit of big pharmaceutical companies. Even though India has managed to negotiate to remove patent extension provisions from RCEP agreement for now, there are chances that developed countries may press for such provisions again. In India, patent extension term may be a hurdle for the generic companies on the basis of which Indian pharmaceutical industry is thriving. When it comes to biologics, major players belong to US and EU. Currently India has not advanced in the biotechnology industry to compete with US and EU. If India grants patent extension term for biologics, it will create an extended monopoly of biologics and only foreign players will benefit. . If patent extension term is provided for biologics in India, similar treatment has to be given to other countries as per TRIPS agreement. This will increase competition for domestic players and domestic players at present cannot compete with US and EU. Patent extension term is an effective tool to promote biologic industry. The extended monopoly is not detrimental to a well-established biotechnology industry similar to that EU.

[36]Brougher J. T, *The Biosimilars Act: Promoting or Discouraging the Development of Generic Biologics?: A tug-of-war between generic and innovator biologics seems to be where drug developers are headed,* 22 Biotechnology healthcare 22 (2010).

[37]The Harris et al,*Pharmaceutical Patents Review Report,*IP AUSTRALIA, (Mar. 21,2020, 11:12PM),https://www.ipaustralia.gov.au/about-us/public-consultations/archive-ip-reviews/pharmaceutical-patents-review.

However, biologic industry in India is at nascent stage and needs promotion. The market size of Indian biotechnology industry is hardly 2% of the global biotechnology industry.[38]

Moreover, Indian pharmaceutical industry is rapidly growing and there is a huge market for biosimilar in Asian countries. 70% of the world population lives in Asia and countries are looking at new solutions to provide uniform and standardized health care for all citizens. Thus there is a need for regulatory authorities to step up in creating frameworks so as to make use of the opportunities as well as be prepared for the upcoming challenges . It is imperative that India focus on development of local pharmaceutical industries and provide them support to enter into the market of and biosimilars and thereby reducing the imports and dependency on foreign players.

India grants approval to biosimilar only if such biosimilar is approved by a well- regulated system and marketed for at least 4 years. Grant of patent extension term to biologics may not seem like a threat to biosimilar industry as biosimilars can only be marketed after expiry of patent of biologic. However, as seen in US, evergreening techniques and filing infringement suits and other strategies may be adopted by the pharmaceutical companies to delay the entry of biosimilars. Manufacturing biosimilars requires huge investments and the instability may deter domestic players to manufacture biosimilars. Moreover, granting patent extension term to biologics will disincentivise domestic players in investing in innovative biologics.

## Conclusion and Suggestions

Biologics is a rapidly developing area which has the potential to cure large number of diseases. The pharmaceutical industries can make use of this opportunity to grow as well as develop innovative biologics to help people. India being a developing country may face many hurdles when it comes to competing with foreign players in the biologics market. However, it is important to attract investments in India as India needs knowledge and expertise in the field of biologics to make most of the opportunity. Moreover, India needs a good health care mechanism which is affordable for everyone. Hence, biosimilar may be the future tool for India in creating access to healthcare for all. India has great potential to tap the resources and manufacture biologics. However, to acquire the technology and know- how, it is important to boost biotechnology industry by government. The government can opt for various fund allocation programmes or tax reduction initiatives to enhance research in biologics. However, patent extension term for biologics is not the solution.

[38]IBEF, Biotechnology industry in India,IBEF( Mar. 21, 2020, 11:14 PM), https://www.ibef.org/industry/biotechnology-india.aspx.

However, currently India will benefit more from biosimilar market. India can follow the path of US, where the first biosimilar is granted one year market exclusivity by FDA. This is not the need of the hour as biosimilar industry is thriving in India at present. However, this might be required when there are influx of large number of players in the market and an incentive would be required to boost the production of biosimilar.

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