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Issues Challenges of Patentability of Generic Drugs in India

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ABSTRACT

Generic drugs are the same as those already approved in the dosage type, safety, strength, path, consistency and performance characteristics of an already approved brand name medication. Only after a thorough review by FDA and after a certain period of time the generic drugs be available, the brand name version is exclusively on the market. This is because new drugs are generally protected by patents, like all new goods and the emerging pharmaceutical R&D scenario in India has several constraints in the context of global models and approaches for new drugs from concept to market. India should give a thought on the growth and of the pharmaceutical market and on how to balance the cost of innovation in drug research and universal access to the fruits of this research.

I. INTRODUCTION

Time and again the importance of generic prescribing has been emphasized, primarily to reduce the cost of drugs. There are two concepts to be understood here, one is generic vs. patented drugs and the other is a drug's "brand name" vs. "non-proprietary name" or "generic name." Although, our article primarily describes the Indian scenario, it can be extrapolated to other countries also[3].It is a well-known fact that generic drugs are "drugs that are usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights". Bioequivalence is a sine qua non to generic drugs. Good quality bioequivalence studies will help to ensure safety, efficacy, and potency of a generic drug. When it is said that doctors should prescribe generic drugs, it means that they should prescribe drugs manufactured by other companies after expiry of patent of parent drug of the innovator company. Very often, generic prescribing is misconceived as prescribing by a drug's generic name or non-proprietary name All generic drugs have a brand name as well as a non-proprietary name but all drugs

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[3] Cameron A., Mantel-Teeuwisse A., Leufkens H., Laing R. (2012). Switching from originator brand medicines to generic equivalents in selected developing countries: how much could be saved? Value Health 15, 664–673 10.1016/j.jval.2018.01.30.

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having a non-proprietary name (generic name) may not be generic drugs.

II. STATUS OF SECTION 3 (D)

(A) Ingredients of Section 3 (d)

The section is read as an exception to patentability and is applied before the three tests of patentability is satisfied under section 2 (1)(j)[4]. It has three parts and one explanation. The section states something like this that these are not inventions within the meaning of Patents Act.

(1) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance; or

2. the mere discovery

(i) of any new property or new use for a known substance; or

(ii) of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Section 3(d) can be made applicable before filing of patent and even after determining the three prerequisites of patentability. The section has been formulated in a manner that it satisfies three steps of patentability i.e. novelty, inventive step and industrial application. Once these three steps are cleared, Section 3 (d) can be made applicable. The section encompasses concept of novelty through words used 'new form'. 'new property', 'new use', 'new product' and 'new reactant' while inventive step is determined through the usage of words like 'known substance', 'known efficacy', and 'known process'. And lastly industrial application through 'efficacy', use of known substance or process. The first and the third parts contain a conditional exception to patentability i.e. the exception can be overcome when certain conditions mentioned in the parts are present. The second part, however encompasses an absolute exception to patentability.[5]

1. What are Inventions

The first part of section 3(d) and explanation clearly illustrates that mere discovery of a new form of known substance is not patentable unless it is proved that the new substances has such properties which are totally different from the earlier property and has resultant in the increased efficacy. In this situation the discovery of enhanced efficacy will be regarded as a component

[4] Indian Patent Act, 1970, 2(1)(j)

[5] Suryakanta Swain*, Ankita Dey, Chinam Niranjan Patra and Muddana Eswara Bhanoji Rao, Pharma Regulations for Generic Drug Products in India and US: Case Studies and Future Prospectives, Swain et al., Pharmaceut Reg Affairs 2014, 3:2 DOI: 10.4172/2167-7689.1000119.

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of utility or usefulness which is in similar to practical application of a discovery under British patent law[6].

In pharmaceutical inventions, the term property of known substance is referred to physiochemical properties of the drug such as the solubility of the drug in aqueous and other mediums, the stability of the drug in solution, bioavailability, interactions between the drug and excipients (inert substances). The first part of s 3 uses the term 'efficacy' to describe the property of a drug. Thus the first part deals with an increase or improvement of a known property of a known substance, whereas the second part concerns with a new property of a known substance. [7]

This means that when part first of the section is taken it reveals that new form of a known substance will qualify as an invention if there is an increased efficacy in the known property of the substance and here first part will not be affected by the second part which bans a new property. However if new enhancement is considered as a new property then second part can be made applicable. Also when first part is read in the light of second part, it would emerge that the only way the first part can be read is to cover patents for improvements, Here comes provisions for improvements under the Patents Act.[8]

2. What are not inventions

Standard of Novelty Per Se New Use

The Patent Act explicitly says that novelty is required per se not for the new use. It is an age old principle followed by India whereas countries like UK have relaxed the rules for allowing novelty of use to be patented.

The TRIPS Agreement has explained patentability of new use in the following manner saying it is silent about the new uses of known substance inclusive of second or subsequent therapeutic uses for pharmaceutical products, eg aspirin for heart ailments or AZT, which is an anti-cancer drug found out that its' new usage can ne for treating HIV/AIDS which is not patentable as per Art 27 of the TRIPS agreement where it is referred to patentability of products and processes not of usage. Therefore it can be deduced that novelty does not include new usage of known substances.[9] However it will be every illogical to grant new patents for already known

[6] Genetech Inc's Patent (1989) RPC 147, PP 208, 240 (CA)
[7] VK Ahuja**,** Intellectual Property Rights in India 45-47 (1st Edition, Volume 1, Lexis Nexis, 2009)
[8] Patents Act 1970, ss 2(1)(q) and 54.
[9] Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries, OUP, 2001, P 104.

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substances as earlier patent will cover all forms of uses and purposes for which invention can be applied.[10]

(B) Industrial Application

New Product by Known Process

An invention has to possess subject matter where substances provided are not only new but also useful. The degree to which qualification for patent can take place when it will be seen that substances produced is truly new, rather than just being an additional members of a known series (homologues). Also their useful qualitites must be inventor's own discovery rather than just mere prediction of previous results.[11]

(C) Constitutionality of Section 3(D)

1. NOVARTIS V. UOI & ORS.[12]

Issue: *Whether the appellant is entitled to get the patent for the beta crystalline form of a chemical compound called Imatinib Mesylate which is a therapeutic drug for chronic myeloid leukemia and certain kinds of tumours and is marketed under the names "Glivec" or "Gleevec".*

If that be so, then the case of the Appellant appears in rather poor light and the claim for patent for beta crystalline form of Imatinib Mesylate would only appear as an attempt to obtain patent for Imatinib Mesylate, which would otherwise not be permissible in this country.In view of the findings that the patent product, the beta crystalline form of Imatinib Mesylate, fails in both the tests of invention and patentability as provided under Clauses (j), (ja) of Section 2(1) and Section 3(d) respectively.In view of the findings that the patent product, the beta crystalline form of Imatinib Mesylate, fails in both the tests of invention and patentability as provided under Clauses (j), (ja) of Section 2(1) and Section Atomic En respectively, the appeals filed by Novartis AG fail and are dismissed with cost .[13]

Analysis: As per section 3(d) new use of known substance is not an invention and so has been upheld in this case. The case was tried to take a turn when Novartis made the argument stating that Section 3(d) is unconstitutional as it is vague and not in compliance with TRIPS agreement. However it can be substantiated with the practice followed in the country that any law made by parliamentcan only be struck down on two grounds 1. Lack of legislative competence 2

[10] Patents Act, Sec 48, Rights of Patentee
[11] Farbwerke Hoechust AG v. Unichem Laboratories 1969 RPC 55 P. 66, AIR 1969 Bom 255.
[12] Novartis Ag v. Union of India, (2013) 6 SCC 1
[13] *Supra* f.n. 12

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Violation of any of the fundamental rights guaranteed in Part III of the Constitution, There cannot be any other grounds. Thus primarily law cannot be aborted on the ground of non compliance with TRIPS agreement.[14]

Consecutively when any law prescribes a departure from international law, judges being organs of the State usually practice in passing judgements in favor of Municipal law. [15]

Lastly court took a narrower view because if Novartis had won and gotten it's patent issued there would have been failure on part of public good with monopolistic pricing. Also generic companies had to stop the production of generic medicine Gleevec.

2. Boehringer Ingelheim vrs Cipla[16]:

Facts:

This case is one of the unique and landmark cases where the patent was revoked after it was granted. In the instant case, a German pharmacy company Boehringer Ingelheim filed a patent application in 2003, for *crystalline tiotropium bromide monohydrate* in Delhi Patent Office. Intermed Labs Pvt. Limited filed a pre-grant opposition against it in 2007 & the matter was heard but the claim was rejected and was recommended for grant of patent. After, few years in 2013 Cipla filed a post grant appeal against the Boehringer's Patent, Cipla has been marketing the generic version of Tiotropium Bromide Monohydrate under the brand name 'Tiova' since 2003. Cipla alleged that the drug was obvious and did not present any significant change in the therapeutic efficacy, which is a must criteria for granting a patent under Section 3(d) of the Indian Patent Act.

Issue: *Whether the monohydrate crystal form of tiotropium bromide demonstrate any significant change in 'therapeutic efficacy' as essential under Section 3(d) of the Patents Act.* ?

Held:

The Patent office in its judgment, noted the followings with relation to applicability of s. 3(d) of Patent Act:

- Physical Stability of the compound during formulation is not the sole factor for enhancing the therapeutic efficacy of the drug as required by section 3(d)
- Stability does not have any relation with the therapeutic efficacy.

[14] State of Andhra Pradesh v. McDowell & Co. AIR 1996 SC 1627
[15] Gramophone Co of India Ltd v. Birendra Bahadur Pandey AIR 1984 SC 667
[16] Patent No.254813 (Application No: 558/DEL NP/2003)

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- Grant of a patent in other countries cannot be cited as a proof of inventiveness.

Analysis: The judgment clearly stated that the product was a result of mere trial and error and does not involve any inventive skill as required for granting patent and even referred to the Chinese Supreme Court Stand with relation to Boehringer's Patent Application, where also the patent application was rejected because of lack of any inventive skill. As, per Indian Patents Act it is pretty clear that it denies grant of patents to molecules invented before January 1995. Further, under Section 3(d) of the Indian Patents Act, the act also prevents granting of patents to salts, esters etc of substances invented before January 1995, unless it is proven that its efficacy is significantly enhanced by the Patent applicant.

3. F. Hoffmann-La Roche Ltd. & Anr. v Cipla Ltd[17]

Facts & Issues:

In this case the dispute basically arises for the patent rights of the compound Erlotinib Hydrochloride which has been sold by Roche under the trade mark name of 'Tarceva' worldwide, including India for treatment of lung Cancer. It was also granted patent in India in 2007. In the same year, Cipla an Indian Pharmaceutical Company started selling a generic version of Erlotinib Hydrochloride in the Indian under the name 'Erlocip'. In retaliation Roche filed a plea of injunction against Cipla in the Delhi High Court to prevent the marketing and selling of Erlocip.[18] But its appeal was rejected by the Division Bench of Delhi High Court on the basis of sec.3(d) and its objective of protecting public interest as, the price of Cipla Erlocip was three times cheaper. Aggrieved by this, Roche Ltd moved to the Hon'ble Supreme Court through SLP for relief, but it was also denied and the case went on for trial. Also, in that while Cipla filed a petition in the Delhi High Court for revocation of Patent granted to Roche Ltd. For Tarceva claiming that:

- Patent was invalid because 'erlotinib' was a derivative form of Quinazolin.
- The invention, as stated in the complete specification and claims was obvious or did not involve any inventive step as required by the act under s. 3(d)

The single judge bench accepted the pleas of Cipla & held that though Roche had a valid patent, but Cipla could not be held for infringing it. Against this order of single bench, both Cipla& Roche Ltd again filed an appeal before the Division Judge Bench of Delhi High Court in the year 2015.

[17]Cipla Ltd. v. F. Hoffmann-La Roche Ltd. & Anr. (RFA (OS) 103/ 2012
[18] Maitryee Dixit, Roche v. Cipla- The Sense of An Ending, Spicy IP, (February 21, 5:06pm) https://spicyip.com/tag/roche-vs-cipla

Division Bench Judgment & Analysis:

The division bench finally held that, Cipla has infringed the Patent rights of Roche Ltd and also imposed a fine of Rs. 5 lakhs on Cipla. Bench observed that, the main purpose of Section 3(d)[19] is basically at increasing innovative approach in pharmaceutical sector. The bench also laid down a threshold for determining, as to what will qualify as "same" or "known" substance and what as "new". Stated that, "*when something is same/known substance then the derivative of such substance is present in the explanation of section 3(d)would be covered under the same protection as that exists for the known substance. The rejection of the patent application for Polymorph B by the Indian Patent Office clearly indicates that there was a lack of sufficient matter to suggest that Polymorph B qualified as a "new product" for consideration under Section 2(1)(j) of the Patents Act for patentability and should therefore be regarded for all practical purposes as the old product itself i.e. Polymorphs A+B."* This observation of the bench was clearly in contrast with that of its earlier decision, where it considered Section 3 (d) promotes subsequent expansion of existing chemical substances, compounds, technologies which are helpful in fulfilling the health requirement of the public and balance public goods. This notion has been negated in the final observations and innovation has been given more weightage over public interest, while considering section 3(d).

III. CONTEMPORARY STANDING OF GENERIC DRUG LAWS

This topic is something we cannot simply discuss without discussing the other aspects of generic drug patenting and also licensing.

(A) Rationale of patent

Patent is acknowledgment to the type of IP showed in innovation. Licenses are allowed for patentable innovations, which fulfill the prerequisites of curiosity and utility under the stringent examination and restriction methodology recommended in the Indian Patents Act, 1970, however there isn't even an at first sight assumption with regards to the legitimacy of the patent granted[20].

Most nations have built up national administrations to give assurance to the IPR inside its purview. But on account of copyrights, the assurance allowed to the innovator/maker in a nation, (for example, India) or an area, (for example, European Union) is confined to that region where security is looked for and isn't legitimate in different nations or regions. For instance, a

[19] The Patents Act, 1970, 3(d)

[20] New Delhi Commercial Law Publisher (India) Private Ltd; 2005. Anonymous. The Patents Act, 1970 as amended by Patents (amendment) Act 2005.

patent conceded in India is substantial just for India and not in the USA. The essential explanation behind protecting a development is to profit through selectiveness, i.e., the innovator or his trustee would have an imposing business model if:

(a) the innovator has made an imperative creation in the wake of considering the alterations that the client, and

(b) on the off chance that the patent specialist has depicted and guaranteed the creation effectively in the patent determination drafted, at that point the resultant patent would give the patent proprietor a selective market.

The patentee can practice his restrictiveness either by advertising the protected innovation himself or by authorizing it to an outsider.

The accompanying would not qualify as licenses:

(I) A creation, which is negligible or which claims anything clear or as opposed to the settled normal law. A development, the essential or planned utilization of which would be in opposition to law or profound quality or harmful to general wellbeing

(ii) A disclosure, logical hypothesis, or numerical technique

(iii) A unimportant revelation of any new property or new use for a known substance or of the simple utilization of a known procedure, machine, or device unless such known process brings about another item or utilizes no less than one new reactant

(iv) A substance acquired by an insignificant admixture coming about just in the collection of the properties of the segments thereof or a procedure for creating such substance

(v) A minor plan or re-course of action or duplication of a known gadget each working freely of each other in its own specific manner

(vi) A strategy for agribusiness or agriculture

(vii) Any procedure for the restorative, surgical, therapeudic, prophylactic indicative, helpful or other treatment of people or any procedure for a comparable treatment of creatures to render them free of ailment or to build their monetary esteem or that of their items

(viii) A creation identifying with nuclear vitality

(ix) A creation, which is as a result, is conventional information

1. How Compulsory Licensing was approved in the TRIPS Agreement of 1994

Hardly any subjects in global protected innovation law have been as disputable as of late as the one we are going to look at. In the 1980s and mid-1990s, a Diplomatic Conference endeavored

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to overhaul the most seasoned universal tradition giving some insurance to protected creations outside of the residential laws[21]. Those endeavors separated, to a great extent in light of the fact that created and creating nations couldn't concur on the forces that legislatures should hold to issue necessary licenses or on the reason for which these forces could be exercised. The disappointment of this Conference, held under the sponsorship of the World Intellectual Property Organization (WIPO), induced the innovation sending out nations to connect future arrangements concerning worldwide licensed innovation assurance to the Multilateral Trade Negotiations, known as the Uruguay Round, which got in progress in 1986. The final product was Annex IC of the Agreement Establishing the World Trade Organization of 1994, which fused another, complete and generally hoisted set of global least measures of patent security into the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

The TRIPS Agreement subjected the activity of this energy to specific preconditions, including an obligation to advise and consult with the influenced patentees under normal conditions; however these particular conditions, among others, are postponed on account of "national crisis or different conditions of extraordinary criticalness or in instances of open noncommercial [i.e., government] use[22]." Moreover, the very presence of these conditions just amplified the authenticity of each going along government's entitlement to fall back on necessary authorizing at whatever point its household self-intrigue so required[23].

(B) Economist perspective

Most economists would concur that, ideally, originator pharmaceutical organizations would evade the danger of necessary permitting by evaluating their items so near the negligible cost of creation that needy individuals around the globe could stand to purchase them[24]. Assuming that ways could be found to keep items sold at low costs to poor nations from being re-sent out as parallel imports to rich nations, the originator providers could, in principle, cost separate their items based on per capita GDP. They would along these lines get a vast volume of offers at low net revenues in the poorest nations, counterbalance by higher valued deals in center salary nations, and absolutely restraining infrastructure estimated incomes in nations that decay

[21] Paris Convention for the Protection of Industrial Property, March 20, 1883, as revised at Stockholm (1967), 21 UST 1583, 828 UNTS 305 [hereinafter cited as Paris Convention].
[22] TRIPS, supra note 4, at art. 31(b).
[23] Indeed, it was the United States' inability to distinguish its routine exercise of government use licenses from other compulsory licenses that led to the breadth of article 31 in the first place.
[24] For a view consistent with that of the patent-based drug industry, see P. M. Danzon and A. Towse, "Differential Pricing for Pharmaceuticals; Reconciling Access, R&D and Patents, " AEI-Brookings Joint Center for Regulatory Studies, Working Paper No. 03–7, 2003, at 28–29

to organize value controls, for example, Medicare and private protection advertises in the United States.

Value separation would, thusly, diminish the deadweight misfortune — that is, misfortunes that happen when customers who might purchase the items can't bear to do as such — without causing the originator organizations to offer underneath cost. Accepting that the originator organization hopes to recover its R&D expenses and make the greater part of its benefits in rich OECD (Organization for Economic Cooperation and Development) countries[25], pitching similar items to huge quantities of destitute individuals at low costs (yet at the same time over the minimal cost of creation) should regardless return benefits at any rate practically identical to those of non specific makers, who are not altruistic foundations and who gainfully advertise off-patent prescriptions in poor nations . Financial specialist F. M. Scherer made this point unmistakably when he set up that worldwide welfare would be enhanced if the poorest nations were allowed to free ride on pharmaceutical innovation[26].

So for what reason do the pharmaceutical organizations — with conceivably one later yet rambunctious exception decrease to get away from the warmth by clearly receiving an ideal value separation methodology (combined with official understandings to restrain parallel fares, which generally remain splendidly legitimate under article 6 of the TRIPS Agreement? One legitimate answer, gave by Patricia Danzon and Adrian Towse, is that the originator organizations are careful about supposed "reference valuing" in rich OECD nations that keep up value control administrations for pharmaceuticals. If the originator organization productively sold its medication in Ruritania for a penny a pill, controllers in Occitania may recoil from enabling it to charge fifty or a hundred dollars for a similar pill, regardless of whether those controllers saw impeccably that the organization must recover the regularly refered to (yet at the same time disputable) billion dollar cost of R&D that each new FDA-endorsed particle purportedly incurs. Hence, Danzon and Towse propose an arrangement of mystery refunds that may advance more prominent value segregation by restricting the outside controllers' capacity to find the costs really charged to merchants in poor nations at use as reference costs in rich countries[27]. One of Danzon's partners as of late proposed a comparable plan of estimating obscurity and mystery rebates for the worldwide immunization acquirement

[25] K. Outterson and A. Kesselheim, "Market-Based Licenses for HPV Vaccines in Developing Countries, " Health Affairs 27, no. 1 (2008): 130–139,
[26] F. M. Scherer, "A Note on Global Welfare in Pharmaceutical Patenting, " World Economy 27, no. 27(2004): 1127–1142, at 1141.
[27] Ibid

framework[28].

1. Why do generic medicines cost less than brand-name medicines?

Generic medications or solutions wind up accessible simply after a thorough audit by FDA[29] and after a set timeframe that the brand-name adaptation has been available only. This is on account of new medications, as other new items, are typically shielded by licenses that deny others from making and offering duplicates of a similar medication. The patent ensures the organization's interest in the medication's advancement by giving the organization the sole ideal to offer the medication while the patent is basically. Since it requires such a long investment to offer another medication for sale to the public, this time of eliteness permits sedate organizations to recover the expenses related with putting up another medication for sale to the public. FDA likewise gives certain times of showcasing selectiveness to mark name sedates that can restrict the endorsement of bland medications. Once these licenses and advertising exclusivities lapse (or if the licenses are effectively tested by the non-generic drug company), the generic drug can be approved.

Generic drugs additionally tend to cost not as much as their image name partners since non-specific medication candidates don't need to rehash creature and clinical (human) contemplates that were expected of the brand-name drugs to exhibit security and viability. This is the reason the application is called a "condensed new medication application." This, together with rivalry between the brand-name sedate and various generic drugs, is a substantial piece of the reason generic medicines cost considerably less.

Indeed, different non specific organizations are regularly endorsed to showcase a solitary item; this makes rivalry in the commercial centre, ordinarily bringing about lower costs.

The reduction in forthright research costs implies that, albeit nonexclusive pharmaceuticals have an indistinguishable restorative impact from their marked partners, they are commonly sold at generous rebates, an expected 80 to 85% less, contrasted and the cost of the brand-name medication. As indicated by the IMS Health Institute, generic drugs saved the U.S. social insurance framework $1.67 trillion from 2007 to 2016[30].

- Contemporary standing of generic drugs laws

[28] S. McElligott, “Addressing Supply Side Barriers to Introduction of New Vaccines to the Developing World, ” American Journal of Law & Medicine 35

[29] The Food and Drug Administration federal agency of the United States Department of Health and Human Services.

[30] Quintiles IMS Institute: Reports (February 18th, 2:30pm), http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports

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- Uniformity of generic drugs
- Position of generic drugs

IV. UNIFORMITY OF GENERIC DRUGS

(A) Compulsory patent licensing in Africa

Africa has the most elevated malady trouble on the planet and keeps on relying upon pharmaceutical imports to meet general wellbeing needs. As Asian producers of nonexclusive prescriptions start to work under a more protectionist licensed innovation administration, their capacity to fabricate drugs at costs that are reasonable to poorer nations is ending up more encircled.

To acquire costly drugs, particularly on the off chance that they are protected, a current report attempted under the support of the WHO prescribed the utilization of political strain to accomplish differential evaluating and the utilization of lawful adaptabilities accessible under the TRIPS Agreemen[31]t. The utilization of political weight can be significantly upgraded through the arrangement of an African unhindered commerce zone. As a feature of its command, the TRIPS Council stipulated that if a creating or slightest created WTO part nation is a piece of a provincial exchange assention (RTA) inside the setting of the WTO, merchandise delivered in or imported under a necessary permit to that nation can be traded to other creating nations or to minimum created part nations in the RTA that offer the medical issue the products are expected to reduce, given that half of the gatherings to the RTA[32] are perceived as slightest created nations by the United Nations. This arrangement enables creating nations to total their business sectors to make the making of a nearby pharmaceutical industry more attractive[33].

More than half of the nations in Africa are presently perceived by the United Nations as slightest created nations. An African RTA will along these lines make it conceivable under WTO law to issue mandatory licenses for the importation of medications that can course without exchange or legitimate obstructions inside the mainland. An African unhindered commerce zone will likewise give a generous, financially feasible market and will hence break down a noteworthy concern, brought up in a current proof based examination, about whether

[31] Cameron A, Ewen M, Auton M, Abegunde D. The world medicines situation 2011: medicines prices, availability and affordability (WHO/EMP/MIE/2011.2.1). Geneva: World Health Organization; 2011., http://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch6_wPricing_v6.pdf [accessed 19 February 2018].

[32] World Trade Organization [Internet]. Amendment of the TRIPS Agreement: General Council decision of 6 December 2005 (WT/L/641). Geneva: WTO; 2013. http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm [accessed 19 February 2018].

[33] Yu PK. Access to medicines, BRICS alliances, and collective action. Am J Law Med. 2008;34:345–94.

neighborhood creation would yield a substantial business showcase opportunity. There is in this manner a convincing need to construct a territorial organization together to fabricate solid pharmaceutical assembling limit, as well as to encourage exchange inside the African locale.

(B) Shall the patenting system be uniform globally?

The India patent law is an excellent bit of patent enactment that is meant to adjust the interests of both the normal man and the designers. After the presentation of item patent administration an extensive variety of pharmaceutical items can be protected in India. Before applying for the patent the specialists should precisely mull over the criteria of patentability and exhortation of a patent master is exceptionally alluring in this regard. Once procured patent rights can be exchanged through task or permitting to different people or organizations. Associations, for example, scholarly establishments and colleges not having adequate assembling or showcasing limits can utilize licenses as a powerful apparatus for the innovation exchange. These associations can outsource their protected items/procedures to outsiders and consequently they can acquire incomes to recover the speculations made in the advancement of such items/forms. Necessary permit give a chance to advertise the licensed items under specific conditions.

Despite the fact that the issue of poor access to solutions in Africa did not start with the reception of the TRIPS Agreement, the understanding has exacerbated it. Proceeded with dependence on outside guide won't resolve the issue. As rising economies in Asia start to execute a more protectionist licensed innovation system, Africa is not recommended to keep depending on non specific producers in Asia for access to moderate pharmaceuticals. There is subsequently a critical requirement for Africa to start building up a solid pharmaceutical assembling limit. Despite the fact that it may be especially troublesome for a solitary African nation to do this, nations can pool assets through a monetary coalition as an African RTA to build up a limit sufficiently solid to give pharmaceuticals to the mainland.

The advantages Africa stands to pick up from creating solid assembling limit in the pharmaceutical division are tremendous: of the 54 completely perceived sovereign states in Africa, 33 are positioned as slightest created nations by the United Nations[34] and are in this way qualified to decline to allow licenses for pharmaceuticals until July 2021. Accordingly, building a solid assembling limit on the landmass at this stage not exclusively will encourage the creation of non specific medications in the mainland yet in addition will make the viable utilization of necessary licenses substantially simpler and appealing. Nearby creation of

[34] United Nations Office of the High Representative for the Least Developed Countries [Internet]. Landlocked developing countries and small island developing states: least developed countries. New York: UN-OHRLLS; 2013. Available from: http://www.unohrlls.org/en/ldc/25/ [accessed 18 February 2018].

pharmaceuticals, combined with the development of an African organized commerce region, will encourage the development of medications inside the mainland, without exchange boundaries or extract obligations, inflexibly prompting less expensive medications all through Africa. It will likewise goad human advancement and enhance the innovative base of the mainland. Until the point that Africa creates nearby assembling limit and generously lessens the present boundaries to organized commerce on the landmass, the compelling utilization of necessary licenses is probably going to remain a profoundly overwhelming errand.

The Canadian permit of right, which went on for over 50 years, without a doubt set up that nation's hearty generic industry, in spite of the fact that pundits fight that it demoralized the foundation of an examination based pharmaceutical area in the meantime. Both the generic industry and any examination based organizations must, obviously, work in the shadow of bigger U.S. contenders, and under the administrative requirements of national and common general well-being programs.

The present condition of the pharmaceutical business demonstrates that IPR are by and large ridiculously fortified and manhandled to the detriment of rivalry and buyer welfare. The absence of hazard and advancement with respect to the medication business underscores the imbalance that is happening to the detriment of open great. It is a shamefulness that can't be cured by authoritative change alone. While congressional endeavors to close escape clauses in current statutes, alongside new enactment to reduce also troublesome business practices of the pharmaceutical business, may give some alleviation, antitrust law should suitably step in[35]. While antitrust laws have properly investigated certain business hones utilized by the pharmaceutical business, for example, mergers and acquisitions and understandings not to contend, there are a few different practices that should be tended to. The allow of licenses on minor components of an old medication, reformulations of old medications to secure new licenses, and the utilization of publicizing and brand name advancement to expand the boundaries for non specific market participants are for the most part regions in which antitrust law can help balance out the harmony between remunerating development and safeguarding rivalry[36].

Clearly administration of IP and IPR is a multidimensional assignment and calls for a wide range of activities and systems which should be lined up with national laws and universal arrangements and practices. It is never again determined simply by a national point of view. IP

[35] Gottlieb S. Drug firms use legal loopholes to safeguard brand names. BMJ. 2000;321:320.
[36] Glasgow LJ. Stretching the limits of intellectual property rights: Has the pharmaceutical industry gone too far? IDEA J Law Technol. 2001;41:227–58.

and its related rights are genuinely impacted by the market needs, advertise reaction, cost associated with making an interpretation of IP into business wander et cetera. At the end of the day, exchange and trade contemplations are vital in the administration of IPR. Diverse types of IPR request distinctive treatment, taking care of, arranging, and techniques and engagement of people with various space information, for example, science, building, drugs, law, fund, promoting, and financial aspects. Every industry ought to develop its own particular IP approaches, administration style, procedures, and so on relying upon its zone of claim to fame. Pharmaceutical industry at present has a developing IP technique. Since there exists the expanded plausibility that some IPR are invalid, antitrust law, consequently, necessities to advance in to guarantee that invalid rights are not being unlawfully declared to build up and look after ill-conceived, but constrained, imposing business models inside the pharmaceutical business. Still numerous things stay to be settled in this specific situation.

V. POSITION OF GENERIC DRUGS

(A) Indian Scenario

The Pharma business is a standout amongst the most serious "information driven" areas. Pharmaceutical research is exorbitant and unusual in nature. Result of the exploration can be as another, imaginative and valuable item or process. In this exceptionally aggressive market, it is basic for the pharmaceutical organizations to shield their creations from any unapproved business use by procuring patent rights over the developed item or process. Pharmaceutical licenses in India can be ordered under after classifications . This arrangement depends on the rundown of Pharma licenses gave by the Indian patent office on its site.

1. Drug compound licenses

These licenses guarantee a medication compound by its substance structure fundamentally. These patent cases are typically alluded as Markush write claims. A Markush guarantee is a claim with numerous "practically comparable" concoction elements permitted in at least one sections of the medication compound.

Medication compound licenses give the broadest conceivable assurance to the organization's item, since different organizations are not permitted to get ready such medication by any course of amalgamation or deliver/offer any definition involving this medication before the expiry of said patent.

2. Formulation of Piece of Patent

These licenses guarantee a particular innovation to set up a plan or potentially amount of its

key fixings. For instance, ayurvedic hostile to retroviral organization for treatment of Acquired Immuno Deficiency Syndrome[37].

- Synergistic mix Patents

Medication cooperative energy happens when at least two medications connect with each other such that it improves or amplifies at least one impacts of those medications. Licenses can be acquired on new synergistic blends of the medications.

These licenses depend on the strategies used to take care of particular innovation related issues like adjustment, taste concealing, increment in the solvency and so forth[38].

A pharmaceutical detailing having a covered taste, the concealing of which continues amid organization of the definition, specifically as a suspension in a fluid vehicle, portrayed in that it involves in any event the accompanying components: an) a cellulosic polymer which is dissolvable in natural solvents yet basically insoluble in water, paying little heed to the pH; a methacrylic polymer which is solvent in a corrosive medium and for all intents and purposes insoluble at an impartial or antacid pH and a dynamic fixing circulated in a homogeneous way and in the sub-atomic state in the blend, which is as an atomized lattice; b) a basic specialist of a natural nature or a basic salt, which is pharmaceutically adequate; c) an adsorbent operator."[39]

- **Polymorph Patents**

Polymorphs are diverse physical structures or gem structure of a definitely known compound. Polymorphs are typically arranged to decrease pollutions or increment security of the mixes.

Part of Section 3(d) in polymorph protecting

Allow of polymorph licenses in India is mostly administered by the segment 3(d) of the Patents Act, 1970. This area was altered under the Patents (Amendment) Act, 2005. The segment[40] states The segment 3(d) plans to keep the "regularly greening of licenses" by giving that lone those pharmaceutical subordinates that show fundamentally improved "adequacy" can be protected. The area 3(d) guarantees that the new structures can be licensed just on the off chance that they are extremely worthy, and accordingly licenses should not be allowed for paltry developments. It tosses light on the Indian government's arrangement of compensating the creators/scientists on their actual scholarly endeavors and in the meantime protecting the

[37] Ducray P. Compounds of formula I and a process for their preparation.
[38] Weimar C, Bundschuh D, Hatzelmann A, Schudt C, Beume R. Synergistic combination of roflumilast and salmeterol.
[39] *Ibid*
[40] Mathew J, Sivakumar MR, Acharya P. A crystalline form B4 of atorvastatin magnesium and a process thereof. Indian Patent IN 237261, 2009.

general population intrigue and making them accessible basic items, for example, drugs at reasonable costs.

- **Biotechnology License**

Biotechnology includes the utilization of living beings or natural materials in the planning of pharmaceutical items. Biotechnology licenses cover an extensive variety of demonstrative, remedial and immunological items.

For example, above Indian patent no. 234072 was the primary item patent conceded by the Indian Patent office after the establishment of item patent administration in 2005. The patent is possessed by F. Hoffmann-La Roche Ltd., Switzerland[41].

- **Process licenses**

A procedure patent does not assert the item fundamentally, rather it just covers another and innovative procedure to create a specific item[42].

Section 92A[43] of the Patents Act, 1970 states that: "*obligatory permit might be issued for fabricate and fare of protected pharmaceutical items to any nation having inadequate or no assembling limit in the pharmaceutical division for the concerned item to address general medical issues, gave that such nation has conceded mandatory permit or permitted the importation of licensed pharmaceutical items from India[44]. The Controller should, on receipt of an application in the endorsed way may give an obligatory permit exclusively for make and fare of the concerned pharmaceutical item to such nation under the predetermined terms and conditions*."

This arrangement tends to the general wellbeing worries of the nations having deficient or no assembling limit in the pharmaceutical segment to execute the choice of the TRIPS chamber on Para 6[45] of the Doha Declaration on TRIPS Agreement and Public Health. According to this arrangement the obligatory permit is accessible just for (a) the protected pharmaceutical item (b) make and fare to any nation having lacking or no assembling limit in the pharmaceutical division and (c) the item tending to the general medical issues in such nation.

[41] Section 3(d) of the Patents (Amendment) Act, 2005, No. 15 of 2005 (April 4, 2005).
[42] Gunter G, Terzo S, Kumar SK. An aqueous, human serum albumin-free interferon solution. Indian Patent IN 234072, 2009.
[43] Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances
[44] http://ipindia.nic.in/ipoNew/compulsory_License _12032012.pdf 21) Section 92A of the Patents (Amendment) Act, 2005, No. 15 of 2005
[45] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health. Decision of the General Council of 30 August 2003.

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(B) What is a swiss patent?

If a patented substance is being used for different purpose, it is known as a Swiss patent because it was first given in Switzerland in 1984.Novelty, inventiveness and Industrial applicability are the basic criteria for patentability. If the use of any substance or composition for a particular medical purpose is new than the claim in that particular application which is directed towards the use would be considered as novel. Despite the fact that the same substance had been earlier brought into use for a different purpose.[46]

Therefore, Satisfying the criteria for patentability the second or any further medical use of the substance or the composition can be subjected to patentability for the usage of that particular substance for the manufacture of a medicament for a specified medical use.

These type of claims are called as 'Swiss-type' or 'Swiss-style' claims. The reason behind calling such claims as Swiss type claims is that it was decision of the Swiss Federal Intellectual Property Office in 1984 which firstly allowed to grant the patentability to these type of claims. Swiss type claims are not universally permissible. They are permissible based on the condition that the national patents law should permit them. However, some major patent offices do allow the patentability of the new usage of a particular substance.. In US the claims for the patentability of the new usage of particular substance are accepted and are subjected to be patentable. Swiss type claims are being drafted in a way that they are made to avoid the prescription against the patentability of method of treatment claims.

Therefore the grant of such patent claims does not become a requirement in the US. The Swiss type claims are being accepted by the USTPO.[47] new methods of treatment were not considered as being capable of patented by the European patent office (EPO)based on the reason that they cannot be used for industrial application. However after allowing the Swiss type claims by the patent office in Switzerland, Enlarged Board of Appeal of the European Patent Office (EPO), allowed the patentability of such claims. In the *John Wyeth and Brothers Ltd's Application and Schering AG's Application* (1985), it was held by the Enlarged Board of Appeal of the EPO that any method of new use of particular substance cannot be permitted.the new usage of the product of the medical treatment can only be permitted when the usage is novel and that the novelty lies in therapeutic use and not in the method of manufacture.

The Swiss type claims can be explained in the following manner:

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[46] Ollier Peter, *Why India's Patent Battles Matter.*, Managing Intellectual Property, Vol. No. 179, Issue 179 (May 2008), pp. 26-29.

[47] Armstrong Daniel, *The Arguments of Law, Policy and Practice against Swiss-Type Patent Claims*, Victoria University of Wellington Law Review, Vol. 32, Issue 1 (March 2001), pp. 201-254.

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- The use of (substance X) in the manufacture of a medicament for the therapeutic and/or prophylactic treatment of (medical condition Y).' *This is the usual form of a Swiss-type claim.*
- 'The use of (substance X) in the preparation of (an anti-Y agent) in ready-to-use drug form for treating or preventing (medical condition Y).' *The expression "in ready-to-use drug form" was intended to mean "as presented for sale", i.e. packaged.* 'The use of (substance X) in the manufacture of (an anti-Y agent) in a package together with instructions for its use in the treatment of (medical condition Y).'

However, a method of treatment claim can be disguised in the form of Swiss-type claims, for e.g.:

- 'The use of substance X in the treatment of disease Y.

It is must that the novelty and the inventiveness required for the patentability of Swiss claims should be from the novel medical use and not the manufacture of any medicament. This makes it clear that any previous disclosure of a method which makes the medicament wont anticipate the Swiss claim in itself for the anticipation of the Swiss claim it is must that the citation should reveal both the method behind preparing that particular medicine and also the treatment claimed for the same. The approach followed here is in the consistency with the one which has been followed in the Federal Court in the case of Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 4) [2015] FCA 634).[48]

(C) Position of Swiss Patent in India

The Indian Patents Act, 1970 (the Act) does not does permit new use for a known substance. as per Section 3(d) of the Indian patents Act, 1970 Act the mere discovery of any particular new property or any new use of a known substance doesn't result in invention and thus cannot be patented. New property or new use for the known substance does not fall within the ambit of any invention and thus is not patentable. As per the Indian patents Act, the claims which are directed towards the process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or animals are not permissible.[49]

Due to the commencement of Indian Patents (Amendment) Act, 2005, it will be possible to have a patent on the substance which are intended to be used or have the capability to be used as a medicine or drug.As per the section 3 (d) of the Act, "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that

[48] THE INDIAN PATENTS ACT, 1970, sec 3. cl.d.
[49] Ghoshray Saby , *John Marshall Review of Intellectual Property Law*, Vol. 13, Issue 4 (2014), pp. 719-760.

substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant".

Consequently, for obtain the patent in case of the second or the subsequent usage of a medicament, it is must that the therapeutic efficacy must be enhanced or there should be at least a new reactant which has been employed in its manufacture. [50]Section 3(d) of the Indian patents act makes it mandatory that the composition or substance need to be novel, should be inventive enough to be patented and have a industrial application.On the other hand in Swiss-type claim format, the rule of absolute novelty does not exist. The mere discovery of any previously unrecognized and useful property of a particular drug does not fall within the ambit of novel in India and hence is not subject to patentability.[51]

The Act considers salts, esters, ethers, polymorphs, metabolites, pure form, particle size, [52]isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance to be the same substance, unless they differ significantly in properties with regard to efficacy.[53] This particular section of the Indian Patents Act makes it clear that the Swiss-type claims are not eligible for patentability in India.[54].Any sort of improvement made to the substance won't lead to the patent protection in india. In India only a new chemical entity or a new medical entity is granted protection.[55] Formulations, such as, combinations of pharmaceuticals, changes in dosage form, new use of a known medicament, etc, are considered not patentable as there is lack of inventive step.[56]

A third and equally important reason for allowing "Swiss-type" claims would be to support and encourage individual inventors and the small and tiny sector of the industry, [57] which can exploit their research and techno-entrepreneurial skills to patent new uses of known molecules

[50] Ollier Peter, *India's Patent Law Faces New Scrutiny*, Managing Intellectual Property, Vol. No. 177, Issue 177 (March 2008), pp. 22-22.
[51] Fyan Susan, *Pharmaceutical Patent Protection and Section 3(D): A Comparative Look at India and the U.S. Virginia Journal of Law & Technology*, Vol. 15, Issue 2 (Fall 2010), pp. 198-226.
[52] Rai Rajnish Kumar, *Patentable Subject Matter Requirements: An Evaluation of Proposed Exclusions to India's Patent Law in Light of India's Obligations under the Trips Agreements and Options for India* , Chicago-Kent Journal of Intellectual Property, Vol. 8, Issue 1 (2008), pp. 41-84.
[53] Bennett William J., *Indian Pharmaceutical Patent Law and the Effects of Novartis AG v. Union of India* , Washington University Global Studies Law Review, Vol. 13, Issue 3 (2014), pp. 535-558,
[54] Liu Jodie, *Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act* , Harvard International Law Journal, Vol. 56, Issue 1 (Winter 2015), pp. 207-228.
[55] Naolekar, P. P., *Judicial Activism & Patent Law* , National Law School of India Review, Vol. 20, Issue 2 (2008), pp. 119-130.
[56] Azam M. Monirul, *The Experiences of TRIPS-Compliant Patent Law Reforms in Brazil, India, and South Africa and Lessons for Bangladesh* , Akron Intellectual Property Journal, Vol. 7, Issue 2 (2015), pp. 61-100.
[57] Tercier Pierre; Devitre, Dilber, *The Public Policy Exception - A Comparison of the Indian and Swiss Perspectives* , Indian Journal of Arbitration Law, Vol. 5, Issue 1 (July 2016), pp. 7-34.

at affordable costs to themselves[58]. Even if they do not have the skills, infrastructure and resources to develop and market the products, they can resort to the licensing route to reap adequate rewards.[59]

Notwithstanding the grey areas, India has a strong reason to debate whether it is in the interest to provide for "Swiss-type" claims[60] as patentable subject matter.[61] The compulsions that would warrant such a pro-active approach [62]are based on Indian capabilities, opportunities and limitation of resources, needed for drug discovery, development and marketing.[63]

The emerging pharmaceutical R&D scenario in India has several constraints in the context of global models and approaches for new drug discovery.[64] None of the Indian companies or national laboratories has the total capabilities, skill or adequate resources for the development of new drugs from concept to market.[65]

In the prevailing western model of new drug research, it is estimated that the costs involved in drug discovery and marketing for a new molecule is as high as $600 million, figures outside the reach of any Indian company or consortium of companies. [66]It would be prudent to work towards discovery of new indications for marketed drugs or known molecules, [67] where the costs for such efforts could be a fraction of what it costs for total drug development.

To succeed in such ventures, one needs a rational approach at the pre-clinical stage of testing [68]for new indications and optimal clinical acumen to capitalise on the serendipitous observations in the clinic, particularly of unexpected side-effects.[69] As per the The Indian

[58] Turrill Zoee Lynn, Finding the Patent Balance: The Novatis Glivec Case and the Trips Compliance of India's Section 3(D) Efficacy Standard [notes], *Georgetown Journal of International Law*, Vol. 44, Issue 4 (2013), pp. 1555-1588.
[59] M., Gopakumar K., *Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime* , Law and Development Review, Vol. 3, Issue 2 (2010), pp. 326-368.
[60] Mueller Janice M., T*he Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation* , University of Pittsburgh Law Review, Vol. 68, Issue 3 (Spring 2007), pp. 491-642.
[61] Ho, Cynthia M., *Unveiling Competing Patent Perspectives*, Houston Law Review, Vol. 46, Issue 4 (2009), pp. 1047-1114.
[62] Hubbard William, *Competitive Patent Law* , Florida Law Review, Vol. 65, Issue 2 (April 2013), pp. 341-394.
[63] Kumar Swarup, *Patentability of Biological Material(s) - Essentially, Therapeutic Antibodies - in India* , *SCRIPTed*, A Journal of Law, Technology and Society, Vol. 5, Issue 3 (December 2008), pp. 582-593.
[64] Gangjee Dev, *Non Conventional Trade Marks in India* , National Law School of India Review, Vol. 22, Issue 1 (2010), pp. 67-96.
[65] Winner Ellen P., *Practical Effects of the Patent Cooperation Treaty and the European Patent Convention on Domestic Technology Management and Patent Practice* , Journal of the Patent Office Society, Vol. 62, Issue 7 (July 1980), pp. 419-436.
[66] Emmanuel Kolawole Oke, *Incorporating a right to health perspective into the resolution of patent law disputes*, *Health and Human Rights*, Vol. 15, No. 2 (December 2013), pp. 97-109.
[67] Anitha Ramanna, *Policy Implications of India's Patent Reforms: Patent Applications in the Post-1995 Era*, *Economic and Political Weekly*, Vol. 37, No. 21 (May 25-31, 2002), pp. 2065-2075.
[68] Steven Lubar, *The Transformation of Antebellum Patent Law*, *Technology and Culture*, Vol. 32, No. 4, Special Issue: Patents and Invention (Oct., 1991), pp. 932-959.
[69] Bronwyn H. Hall, *Patents and patent policy*, *Oxford Review of Economic Policy*, Vol. 23, No. 4,

Patents Act, it is mandatory that for the substance the composition to be patentable, the composition should be novel, and should also involve inventiveness and should have an industrial application. On the other side the Swiss type claim doesn't hold the rule of absolute novelty. Section 3(d) of the Indian Patents Act stipulates that for obtaining the patent for the subsequent usage of medicament, the therapeutic efficacy should be improved or at least there should be a new reactant in the components of that particular manufactured process. Due to the robust approach of the Indian Patent system, the exclusion of allowing patentability to the Swiss type claims the pharmaceutical industries have shown a disinclination towards the further improvement of a known drug or discovery of new therapeutic use of a known substance. therefore the pharmaceutical industry doesn't welcome the decision of India in exclusion of Swiss-type claim format. It is It is apparent that pharmaceutical research does not halt on patenting of one pharmaceutical activity, [70] due to ongoing research the same drug may be found to have other beneficial properties which was previously unrecognized. [71]

(D) The basis for exclusion

The reason behind the exclusion of Swiss patent is that it might lead to the ever greening of that chemical entity, because of ever greening the pharmaceutical companies try to secure patents on larger scale of complex and many a times highly speculative patents by way of minor modifications, went through minor modifications, when the original patent over the active compound of a brand-name drug is due to expire.[72]

By way of ever greening of the patents the multinational pharmaceutical companies succeeds in the retaining of large profits from their blockbuster drugs for as longer as possible. The Pharmaceutical companies in countries like US have been adopting the Swiss-type claim format as a monopolization strategy to evergreen their patented drugs.[73] These subsequent patents cover different forms of the substance or minor variation and everything from aspects of the manufacturing process to tablet color[74], or even a chemical produced by the body when the drug is ingested and metabolized by the patient.[75]

INTELLECTUAL PROPERTY (WINTER 2007), pp. 568-587.

[70] Biswajit Dhar, C. Niranjan Rao, *Third Amendment to 1970 Patent Act: An Analysis*, *Economic and Political Weekly*, Vol. 39, No. 52 (Dec. 25-31, 2004), pp. 5568-5571.

[71] Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978-2002, The Review of Economics and Statistics,* Vol. 89, No. 3 (Aug., 2007), pp. 436-453.

[72] Patent Rights, *Patent Abuse*, *Economic and Political Weekly*, Vol. 42, No. 3 (Jan. 20-26, 2007), pp. 179-180.

[73] MORTEN WALLØE TVEDT, One Worldwide Patent System: what's in it for developing countries?, *Third World Quarterly*, Vol. 31, No. 2 (2010), pp. 277-293.

[74] Lisa Larrimore Ouellette, PATENT EXPERIMENTALISM, *Virginia Law Review*, Vol. 101, No. 1 (March 2015), pp. 65-128.

[75] Ellen 't Hoen, A victory for global public health in the Indian Supreme Court, *Journal of Public Health Policy*,

(E) India and Global Scenario

In Australia, the Australian Patent Office, does permit the patentability of Swiss-type claims only in 1998.The case which led to the patentability of Swiss type patent was after the case of *Bristol-Myers Squibb v Faulding.in this case two patents* had claims which were directed to the methods of administering the known use of anti-cancer drug(*Taxol*) at a particular dosage for a length of time that was demonstrated to be effective. It was decided that the patents are not valid since they were about the treatment of life threatening disease and it is generally not convenient to allow such patents.This decision lead to patentability of Swiss type claims in Australia.

While in the U.S "Swiss-type" claims, have been grated patentability, other countries are working on slow pace for accepting the standards of patentability for the new use of a known molecule.in UK, The English Court of Appeal IN THE case of Bristol-Myers-Squibb case held that the scope of second medical use should be restricted to new, but distinctly different therapeutic applications and not for new modes of administration.

Various countries in North America, West Europe and Japan, New Zealand are favour of allowing patentability to "Swiss-type" claims. In a landmark decision, the New Zealand Court of Appeal ruled in favour of "Swiss-type" claims in a patent, providing a legal precedent to other courts including in other countries. Several other cases in the European courts and the U.S. also have endorsed "Swiss-type" claims. It has, however, been pointed out that a distinction may be made between a new benefit of a known use of a known molecule, example, a new Taxol formulation that reduces unwanted neutropenia, and a totally new use.Malaysia is one of the few developing countries that has incorporated in its patent law a provision for accepting claims drafted as uses of compounds to treat medical problems.

(F) Patents (Amendment) Bill, 2003

The currently pending Patents (Amendment) Bill, 2003 which has been proposed towards the amendment of the sub-section (d) of Section 3 of the Act for the substitution of the words ‘new use’ with ‘mere new use’.[76] If the currently pending bill get passed, it would be implied the only the mere use of a already known substance won't be patentable. However any new use of a particular known substance used for producing any useful and non obvious end result will be patentable. Therefore the new use of a particular drug in a known or a new way to produce a

Vol. 34, No. 3 (August 2013), pp. 370-374.

[76] Manisha Singh Nair, India: Indian Patents Law Indirectly Recognizes ‘Swiss-Type’ Claims’, http://www.mondaq.com/india/x/30975/Federal+Law/Indian+Patents+Law+Indirectly+Recognizes+SwissType+Claims, last accessed on 18th Feb'18.

non-obvious and useful result would be patentable. With this the proposed amendment in the Act paves a way for allowing the Swiss type claims in India.[77]

India should seriously give it a thought to include "Swiss- type" claims; or in other words, utility patents, specifically in the pharmaceutical sector, in the pending bill so as to have a good contribution of pharmaceutical industry on global stage. The second reason includes the potentiality of the developing products which is based on the second reason would be the potential of developing products based on traditional systems of medicine, [78] in which the full area of a new therapeutic applications beckons attention for development.[79] In fact, in this area, India needs to evolve less stringent standards of patentability to capitalise [80]on the country's rich and long heritage of knowledge[81] in healthcare practices and products.[82]

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[77] Basheer Shamnad, India's Tryst with Trips: The Patents (Amendment) Act, 2005 [article], *Indian Journal of Law and Technology*, Vol. 1, Issue (2005), pp. 15-46.
[78] Murphy Halliburton, *India and the Patent Wars: Pharmaceuticals in the New Intellectual Property Regime*, Cornell University Press, ILR Press (2017).
[79] Brent B. Allred, Walter G. Park, *Patent Rights and Innovative Activity: Evidence from National and Firm-Level Data, Journal of International Business Studies*, Vol. 38, No. 6 (Nov., 2007), pp. 878-900.
[80] Murphy Halliburton, *India and the Patent Wars: Pharmaceuticals in the New Intellectual Property Regime*, Cornell University Press, ILR Press (2017).
[81] C NIRANJAN RAO, *Long-term Trends in Patent Applications in India, 1948-2010*, *Economic and Political Weekly*, Vol. 47, No. 41 (OCTOBER 13, 2012), pp. 69-73.
[82] Sierra Dean, *India's Controversial New Patent Regime: The End of Affordable Genetics?*, *The International Lawyer*, Vol. 40, No. 3 (FALL 2006), pp. 725-736.

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