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**50. CORPORATE SOCIAL RESPONSIBILITY IN INDIA AN OVERVIEW**

Payal Vishal Cholera, Ph.D, Viva College of Commerce Arts & Science, Virar West  
Research Scholar

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**Abstract**

*We are living in a world surrounded with numerous problems related to environment and society. CSR (Corporate Social Responsibility) is a means to sort out these problems to some extent because business is a part of society. Earning more and more profits is a natural phenomenon of every business unit but social responsibility is an obligation to the people living inside and outside the business organizations. Business comes in contact with various groups of society such as owners, employees, customers, government, suppliers etc. The responsibility of business, which includes satisfaction of these parties along with the owner, is called social responsibility of business. This paper tries to bring a common understanding of the concept of CSR, based on global practices, Indian tradition, and the intent and provisions of the Companies Act, 2013. It then goes on to bring out the key aspects of clause 135 of the Companies Act, 2013 and the recently released draft rules, and highlights its implications to companies.*

**Keywords:** Company, Corporate Social Responsibility(CSR) India.

**Introduction:** The evolution of corporate social responsibility in India refers to changes over time in India of the cultural norms of corporation engagement of corporate social responsibility (CSR), with CSR referring to way that businesses are managed to bring about an overall positive impact on the communities, cultures, societies and environments in which they operate. The fundamentals of CSR rest on the fact that not only public policy but even corporates should be responsible enough to address social issues. Thus companies should deal with the challenges and issues looked after to a certain extent by the states. Among other countries India has one of the oldest traditions of CSR Ever since their inception, corporates like the Tata Group, the Aditya Birla Group, and Indian Oil Corporation, to name a few, have been involved in serving the community. Through donations and charity events, many other organizations have been doing their part for the society.. But CSR practices are regularly not practiced or done only in namesake especially by MNCs with no cultural and emotional attachments to India. Much has been done in recent years to make Indian Entrepreneurs aware of social responsibility as an important segment of their business activity but CSR in India has yet to receive widespread recognition. If this goal has to be realised then the CSR approach of corporates has to be in line with their attitudes towards mainstream business- companies setting clear objectives, undertaking potential investments, measuring and reporting performance publicly

Objectives:

- To study the CSR status in India.
- To understand the meaning and various models of CSR
- To study the policies governing CSR in India.
- To study the challenges faced by CSR in India.
- To make suggestions for accelerating CSR initiative

**Research Methodology:** The research paper is an attempt of exploratory research, based on the secondary data sourced from journals, magazines, articles and media reports. Different news articles, Books and Web were used which were enumerated and recorded.

The Four Phases of CSR Development in India

The history of CSR in India has its four phases which run parallel to India's historical development and has resulted in different approaches towards CSR. However the phases are not static and the features of each phase may overlap other phases.

**The First Phase** In the first phase charity and philanthropy were the main drivers of CSR. Culture, religion, family values and tradition and industrialization had an influential effect on CSR. In the pre-industrialization period, which lasted till 1850, wealthy merchants shared a part of their wealth with the wider society by way of setting up temples for a religious cause. Moreover, these merchants helped the society in getting over phases of famine and epidemics by providing food from their godown and money and thus securing an integral position in the society. With the arrival of colonial rule in India from the 1850s onwards, the approach towards CSR changed. The industrial families of the 19th century such as Tata, Godrej, Bajaj, Modi, Birla, were strongly inclined towards economic as well as social considerations. However it has been observed that their efforts towards social as well as industrial development were not only driven by selfless and religious motives but also influenced by caste groups and political objectives.

**The Second Phase:** In the second phase, during the independence movement, there was increased stress on Indian Industrialists to demonstrate their dedication towards the progress of the society. This was when Mahatma Gandhi introduced the notion of "trusteeship", according to which the industry leaders had to manage their wealth so as to benefit the common man. "I desire to end capitalism almost, if not quite, as much as the most advanced socialist. But our methods differ. My theory of trusteeship is no make-shift, certainly no camouflage. I am confident that it will survive all other theories." This was Gandhi's words which highlights his argument towards his concept of "trusteeship". Gandhi's influence put pressure on various Industrialists to act towards building the nation and its socio-economic development. According to Gandhi, Indian companies were supposed to be the "temples of modern India". Under his influence businesses established trusts for schools and colleges and also helped in

setting up training and scientific institutions. The operations of the trusts were largely in line with Gandhi's reforms which sought to abolish untouchability, encourage empowerment of women and rural development.

**The Third Phase:** The third phase of CSR (1960–80) had its relation to the element of "mixed economy", emergence of Public Sector Undertakings (PSUs) and laws relating labour and environmental standards. During this period, the private sector was forced to take a backseat. The public sector was seen as the prime mover of development. Because of the stringent legal rules and regulations surrounding the activities of the private sector, the period was described as an "era of command and control". The policy of industrial licensing, high taxes and restrictions on the private sector led to corporate malpractice. This led to enactment of legislation regarding corporate governance, labour and environmental issues. PSUs were set up by the state to ensure suitable distribution of resources (wealth, food etc.) to the needy. However the public sector was effective only to a certain limited extent. This led to shift of expectation from the public to the private sector and their active involvement in the socio-economic development of the country became absolutely necessary. In 1965 Indian academicians, politicians and businessmen set up a national workshop on CSR aimed at reconciliation. They emphasized upon transparency, social accountability and regular stakeholder dialogues. In spite of such attempts the CSR failed to catch steam.

**The Fourth Phase:** In the fourth phase (1980 until the present) Indian companies started abandoning their traditional engagement with CSR and integrated it into a sustainable business strategy. In the 1990s the first initiation towards globalization and economic liberalization were undertaken. Controls and licensing system were partly done away with which gave a boost to the economy the signs of which are very evident today. Increased growth momentum of the economy helped Indian companies grow rapidly and this made them more willing. Globalization has transformed India into an important destination in terms of production and manufacturing bases of TNCs are concerned. As Western markets are becoming more and more concerned about labour and environmental standards in the developing countries, Indian companies which export and produce goods for the developed world need to pay a close attention to compliance with the international standards.

**Current State of CSR India:** As discussed above, CSR is not a new concept in India. Ever since their inception, corporates like the Tata Group, the Group, and Indian Oil Corporation, to name a few, have been involved in serving the community. Through donations and charity events, many other organizations have been doing their part for the society. The basic objective of CSR in these days is to maximize the company's overall impact on the society and stakeholders. CSR policies, practices and programs are being comprehensively integrated by an increasing number of companies throughout their business operations and processes. A growing number of corporates feel that CSR is not just another form of indirect expense but is important for protecting the goodwill and reputation, defending attacks and increasing business

competitiveness. Companies have specialised CSR teams that formulate policies, strategies and goals for their CSR programs and set aside budgets to fund them. These programs are often determined by social philosophy which have clear objectives and are well defined and are aligned with the mainstream business. The programs are put into practice by the employees who are crucial to this process. CSR programs ranges from community development to development in education, environment and healthcare etc.

For example, a more comprehensive method of development is adopted by some corporations such as Bharat Petroleum Corporation Limited, Maruti Suzuki India Limited. Provision of improved medical and sanitation facilities, building schools and houses, and empowering the villagers and in process making them more self-reliant by providing vocational training and a knowledge of business operations are the facilities that these corporations focus on. Many of the companies are helping other peoples by providing them good standard of living.

**The Companies Act 2013:** The Companies Act, 2013 In India, the concept of CSR is governed by clause 135 of the Companies Act, 2013, which was passed by both Houses of the Parliament, and had received the assent of the President of India on 29 August 2013. The CSR provisions within the Act is applicable to companies with an annual turnover of 1,000 crore INR and more, or a net worth of 500 crore INR and more, or a net profit of five crore INR and more. The Act lists out a set of activities eligible under CSR. Companies may implement these activities taking into account the local conditions after seeking board approval. The indicative activities which can be undertaken by a company under CSR have been specified under Schedule VII of the Act. The draft rules (as of September 2013) provide a number of clarifications and while these are awaiting public comment before notification, some the highlights are as follows:

Surplus arising out of CSR activities will have to be reinvested into CSR initiatives, and this will be over and above the 2% figure

The company can implement its CSR activities through the following methods:

Directly on its own

Through its own non-profit foundation set- up so as to facilitate this initiative

Through independently registered non-profit organisations that have a record of at least three years in similar such related activities

Collaborating or pooling their resources with other companies

Only CSR activities undertaken in India will be taken into consideration

Activities meant exclusively for employees and their families will not qualify

A format for the board report on CSR has been provided which includes amongst others, activity-wise reasons for spends under 2% of the average net profits of the previous three years and a responsibility statement that the CSR policy, implementation and monitoring process is in compliance with the CSR

objectives, in letter and in spirit. This has to be signed by either the CEO, or the MD or a director of the company. Governance Clause 135 of the Act lays down the Fiscal year 2014-15 onwards, also require companies to set-up a CSR committee consisting of their board members, including at least one independent director. The Act encourages companies to spend at least 2% of their average net profit in the previous three years on CSR activities.

List of activities under Schedule VII

Eradication of extreme hunger and poverty

Promotion of education

Reducing child mortality and improving maternal health

Combating HIV-AIDS, malaria and other diseases

Environmental sustainability

Employment enhancing vocational skills

Contribution to Prime Minister's relief fund

The CSR committee will be responsible for preparing a detailed plan on CSR activities, including the expenditure, the type of activities, roles and responsibilities of various stakeholders and a monitoring mechanism for such activities. The CSR committee can also ensure that all the kinds of income accrued to the company by way of CSR activities should be credited back to the community or CSR corpus.

**Conclusion:** CSR has gone through many phases in India. The ability to make a significant difference in the society and improve the overall quality of life has clearly been proven by the corporates. Not one but all corporates should try and bring about a change in the current social situation in India in order to have an effective and lasting solution to the social woes. Partnerships between companies, NGOs and the government should be facilitated so that a combination of their skills such as expertise, strategic thinking, manpower and money to initiate extensive social change will put the socio-economic development of India on a fast track.

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**Critical study about the woman's status and her rights in this 21<sup>st</sup> century.**

Research Scholar – Sushama Satpute

Shri JTT University, Rajasthan

Guide-Dr. Anil Yadav

Co.Guide- Dr.SmitaKarve.

**Abstract-**Women in India, as is well known have never been treated well even at home or while at work. We are in 21<sup>st</sup> century women are being educated. They try to prove themselves by maintaining balance between household chores and office work. Different laws have been passed for the empowerment of women in India. Still she is the victim of unequal status in the society, in the house and even at workplace. **This research paper aims at finding out the lacuna in the legal provisions and mentality of the people in the society and highlight issues and challenges related to it.** Women also have right to live a life with dignity and respect. Somewhere this right to live a life and personal liberty as per article 21 of the constitution get violated.

**Key words-** Unequal treatment, women's status, empowerment, Article 21 of Constitution, legal provisions

**Introduction-**

*"It is impossible to think about the welfare of the world unless the condition of women is improved. It is impossible for a bird to fly on only one wing." — Swami Vivekananda.*

Women are backbone of our society. She is being educated and performing different roles at various stages in offices, corporates, banks, business etc. Women are now entering in different professional fields. But still she is illtreated by the society. Different laws have been enacted for the upliftment of women in our country. Many legal provisions are there to provide equal status to woman in the society. This male dominated society is not ready to accept her existence independently. Even if many laws are in the favour of woman she is not ready to raise her voice against the society to treat her in better way. Most of the times women are responsible to prevent the other woman from raising. The mentality of the people should be changed. Upbringing of the children in the society should be in such a way that all are human beings with equal human rights. Gender discrimination should not be taught to the children so that they would not treat woman unequally in the future. As per Constitution Article 21 states that "No person shall be deprived of his life or personal liberty according to a procedure established by law. According to Bhagawati, J, Article 21 "embodies a constitutional value of supreme importance in a democratic society." Iyer, J, has characterized article 21 as "the procedural magna carta protective of life and liberty.

**Objective of the study –**

This research paper aims at-

1. Protecting rights of women.
2. To create awareness among the people of the society about her rights.
3. To prevent gender discrimination.
4. To treat her with respect and dignity.

5. To think about Yoga and Pranayam to live a healthy life.

**Hypothesis-** Woman in the society is given equal status at all stages of socioeconomic factors.

**Research Methodology** – This paper is basically descriptive and analytical in nature. The data used in it is purely from secondary sources.

**Analysis** -Under Hindu succession Act, 2005 daughter has given equal status and share in the ancestral property like son. But does she get her share? The answer to this question is negative. In most of the families she has been told that she has no concern about it. In Dowry Prohibition Act, 1961 there are many provisions to curb this custom. Giving and taking dowry is an offence as per the Act. Still Dowry Death are happening in the society. There are some customs related to dowry act which are still followed by some communities in this 21<sup>st</sup> century. Women are working, doing jobs or businesses, earning money still they don't have right to take decisions about purchasing or selling the property in the family. The researcher observed that this male dominated society not allowing her to express her views about many matters. Domestic Violence Act, 2005 has been enacted. Several punishments are given under it though women are afraid of filing complaints regarding cruelty under Domestic Violence Act, 2005. Prohibition Of Sexual Harrassment at workplace Act, 2013 was enacted but its provisions are not strictly followed by all private and public sectors. Strict actions must be taken for the implementation of all the laws so that safety of women at every stage can be possible. Though there are various provisions and Acts for the protection of women, the people in the society not taking it seriously and following the laws. This attitude of the people should get changed so that peace and harmony can be brought in the society. This stability can also be responsible for the progress of the nation. Women would also get due respect from the people and healthy atmosphere can be. Women are also human beings and not only showpiece to take all the advantages. She must be treated with humanity and with dignity then only strong foundation of progressive nation can take place. Right to live a life with respect and dignity is her right as a human being. As per our constitution this right of women get violated because of illtreatment by the society. Yoga and exercises can be helpful to overcome this problem in somehow. Women has stress because of illtreatment and with the help of Pranayam and otheAsanas she can get relief. Mentality of the people and their behaviour also can be changed if they somewhere try to change themselves and their orthodox thinking. Yoga and Pranayam will be helpful these people to change themselves. Law touches all the aspects of life and so Yoga abhyas and performing some exercises can be helpful to live a life in healthy manner.

**Conclusion-**The researcher finally conclude that-

Women are considered as vulnerable group of the society in this 21<sup>st</sup> century also. Article 21 of the constitution should not get violated. As per constitution Article 21 states that noman can be deprived of his or her right to live life. Various laws have been enacted for the protection of women still she is deprived of her respect and dignity. Equal status as a human being which she should get at all socioeconomic sections from the society is not getting. Mentality of the people is to be changed that she is a woman and she is only for doing some specific kind of work. Strict punishments should be given and even those punishments should be made strong sothat the people will think before considering woman weaker section of the society. Even Yoga Abhyas and some exercises like Pranayam, meditation can be helpful to live life in healthy manner and to have healthy thinking to consider the humanity towards women.

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## **Women Director-A good step towards women empowerment**

Author's Name:- Vishal Mohan Gadhave and **Dr. Smita Karve (Guide)**

Research Scholar of JJTU

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### **Abstract:-**

As it is given under the Constitution of India, there is prohibition of discrimination on the ground of religion, race, caste, sex, place of birth. It talks about the equality before the law or the equal protection of the laws. Male-female discrimination observed at different employment, where at the top levels is often given to male. Now the community and government with the development and growth also noticed that there should be amendment in existing laws for female which will make stronger to them.

Empowerment of female is not only playing role in organization but also to take part at the top management level decisions. It is found that in most of European nations female are appointed as executive on panel of corporate. It is also from research that European nations have appointed more female as executive on panel of organization.

As notified by the Government in Companies Act, 2013, there must be one female executive on panel of corporate and due to this there has been a change in monetary performance of the organization. This paper focuses that appointment of female executive on board made empowerment of female.

**Keywords:-** Companies Act, 2013, Female Executives, Women Empowerment

**Introduction:-**The initiative which is taken by the administration is the existence of one female executive on the panel of corporate. This arrangement is mentioned under the new amended Companies Act, 2013. As per the arrangement of section 149 (1) it is compulsory for every recognized stock exchange organization requires to select one female executive within twelve months from the beginning of the second condition to section 149(1) of the enactment. It is given that any public organization having offer capital of rupees hundred crores or more income of rupees three hundred crores or more as on the last date of accounted monetary records will also select one female executive within the one year from the beginning of the second condition to section 149(1) of the enactment.

Organizations have given time limit of six months from the date of establishment they have to implement this provision of appointment of one female executive on the board of directors. It is also further provided under the rules that those who are already registered companies under the old enactment those companies will have to comply this mandatory requirement within one year and for the new companies registered under the new Companies Act, 2013 those companies will have comply this requirement within six months from the date of registration. If it is found that there is no appointment of female executive, and then executive will be selected within three months by the board or not after instant next meeting of board, whichever is later. India has also implemented same as in Spain, France, Norway, Italy and Belgium in this regard.

### **Objectives of Study:-**

1. To study and recognize the need for female executive on the board.
2. To do a comparative study of India and Norway company governance norms.
3. To comprehend the Board's presentation after the selection of Woman Director.
4. To understand the need for an independent woman director.
5. To study about how to remove the obstacles for non-appointment of Women Directors

**Research Methodology:-**

In this paper an effort has been taken to study appointment of female executive will lead to better performance of organization and also empowerment of female in relation to Companies Act, 2013. An author has opted secondary sources as a data collection like books, References from the Libraries, etc.

**Women Empowerment in Corporate level:-**

This initiatives taken by the government is start for empowerment of women. Owing to appointment of female executive on board will enhance the capability of female, their contribution with the new ideas and innovation. Female who are interested will get a platform to challenge their potential and intelligent. It is studied that four percent of female executives are appointed in public recognized stock exchange organization. This less depiction in higher position is because of other reasons. According to few researchers it is considered as problems of talent retention. Organizations which are having female as an executive on their panel of board it is found that there is a greater monetary performance as compared with the others as per current Catalyst Bottom Line Report. Again, it is given as per report that organization which is having three or more female executives as above ordinary presentation. It is observed that women executives have more motivation for alteration in presentation as organizations deal with risk powerfully. This regulation will give more advantages. However arrangement does not give minimum education and class of female executive can be taken into consideration; it will be having impact that organizations will select more female executives from promoter's family and friends

**Contribution in corporate social responsibility:-**

As from the view point of Corporate Social Responsibility (CSR) as mandatory under the Companies Act, 2013, the role of female executive in corporate governance will increase involvement of them. It is observed that due to appointment of female as an executive it is an active participation for CSR activities, selecting the important things and preparing structure of job for administration to concentrate more on objective of an organization. It is given that organizations which are having more number of female as executives definitely more funding from these executives as per the statement by Catalyst and Harvard Business School. This indicates that female executives at a greater level of involvement in case of CSR. It is suggested that female executive could be given the accountability of selection and evaluating human resource policy to make sure good employment atmosphere of male and female. Due to female executive, organization will be having more concentration of human, female executive will involve in stability of processes of trade and think about wellbeing and safety of workers. It is evaluated that because of selection of more female executive on board will bring male-female equality for panels and administration and resulted in increased company performance, more income on equity, income on sales, income on sales as well as return on capital engaged. This guideline in only starting, but its execution will depend upon whether members and promoters will accept or not in general. It is considered not as implementation, but a need.

**Comparative study of Indian and Norway Companies Act:-**

- As per one of the provision given under the Companies Act, 2013 that every organization will be having minimum one executive on its panel and organization can increase more than fifteen executives by passing resolution in board of directors meeting.

- But already there is execution of this structure in nations like Spain, France and other nations also.
- As it happened in Norway where organizations were notified by their Ministry that they should modify their plan of selecting female executives on board otherwise allocation in the form of reservation will be started.
- After one year, enactment was started that forty percent of allocation of female executive on panel of public organizations earlier when this provision was started it was not compulsory but afterward there was less implementation in the year 2006 as it was considered as compulsory and the female representation on board reached to forty percent.
- If this provision is not implemented then concern organization will have to face consequences as fine which can be prolonged for rupees ten thousand and if it will happen further rupees one thousand will be fine per day.

It is clear that by creating regulation or provisions will not improve performance of the organization as member of company but actually the person who is having talent can add his value to the organization.

**Conclusion:-** Although such regulation will bring equality towards female and it will also result in raising the number of female at the higher position of an organization, but there is less implementation of this provision given under the Companies Act, 2013. It is significant that female will not be appointed as executive in the organization as they are female but it is also to accept potential and skill in them. As it is given under the enactment female should be appointed only on basis of her qualification and capabilities as a executive of the panel of corporate level. It is a truth that by appointment of female as executive in the organization will reach top level provided procedure for selection of executive is correct. The action which is taken by the government will assist female to continue their appearance in the corporate globally. It is observed that many different organizations have arranged the plan to give training to female for the post of board members. It is study made by experts that organization involvement has resulted as motivation to a lot of female to reach at position of executive. Globally, this miracle has spread and numbers of nations have initiated provision of compulsion of gender quotas in corporate level.

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## **Indian Legislation Promotes Women Empowerment: A study with reference to Indian Companies Act**

Author's Name:- Vishal Mohan Gadhve and Dr. Smita Karve (Guide)

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### **Abstract:-**

It is observed that from the early stage, culture of Indian has often ruled by male person in the family. Female are not taking into consideration and they are subordinate to male. Now owing to time there has changed. In India different enactments are framed for giving protection and particular position of female.

In the year 2013, Government has announced the new Companies Act, established with compulsory arrangement of female executive on panel of executives of recognized stock exchange and other organizations. As given under the new enactment it is mandatory for all organizations to comply with norms. This amendment in Companies Act brings female position as executive on panel of recognized stock exchange organization. This amendment has been carried out with object of changes in gender diversity on company panel of executives. Various nations have considered different procedures for maximum demonstration of female on company top workplaces. This new enactment of Companies has made equality between male and female. This paper focuses that appointment of female executive on board made empowerment of female.

**Keywords:-** Panel of Executives, Companies Act, 2013, Female Executives, India

### **Introduction:-**

The orthodox culture of Indian continuously restricted female from entering into the public places and female were considered as lower status as compared to male in the community. The journey of female was already decided in proper form. Due to lack of education and complete thoughtlessness in the primarily male dominated community, with the highest comfort of male supremacy, male-female comparison guaranteed that the status of women was pathetic even among the most advanced people. It is found that female was not getting similar position as to male due to that they were not allowed to taken active participation in management level. Although women support males and community for development and innovation in every important area of local and communal life, communal male-female partiality has hampered their own progress. Partiality on the basis of male-female personality includes dissimilarity, omission, restraints or favorite based on male-female personality, which has the object or effect of harming similarity before the law or similar security of the regulations or the appreciation, pleasure or application basic liberty onan similar ground.

### **Objectives of Study:-**

1. To understand the want of enablement of female.
2. To evaluate the alertness of enablement of female in India.
3. To offer useful recommendations in the light of conclusions.
4. To measure and examine the depiction of female executives on panel of executives of Indian companies.

### **Research Methodology:-**

In this paper an effort has been taken to examine the empowerment of female in India in context to Indian Companies Act. An author has opted secondary sources as a data collection like books, References from the Libraries, etc.

**Gender Prejudice Issue:**-It is observed by the community that there is discrimination against female, especially in case of public area as well as local area, where female there is favour to male as compared to the female. It is happened in corporate level where there is discrimination found as to male and female like promotion, etc. In spite of provision as to equal opportunity in case of public employment under the Constitution of India but it is not more implemented in the corporate field. It is observed that there are rarely cases where female has got opportunity to use their skill. There are instances at higher level management in case of Indian organizations it is observed that more partiality against female. It is usually happened in organizations female are giving soft jobs with simple jobs appears to be comprehensive view.

**Indian Perspective of Women on the Board of Directors:**-In the year 1956 the Companies Enactment passed by legislature with covering all aspects related to the administration of the corporate governance with prior permission of the Central Government. As compared with the Companies Act, 1956 there are new provision introduced in new amended Act of 2013 like Corporate Social Responsibility, Cross Border Merger, conversion procedure, issue of preference shares, etc. One important feature of the new Companies Act, 2013 is that there must be at least one female on the panel of executives in specific class of organizations. The usefulness of the arrangement in the new amended enactment depends upon implementation and compliance as mentioned under the enactment. Every recognized stock exchange public organization will be having minimum thirty three percent of aggregate number of executive as independent executives. It says-

1) Every organization will be having panel of executives including of individuals as executives and will have:-a in case of a public organization at least three executives, in case of a private organization two executives, and in case of One Person Company one executive and

b. a maximum of fifteen executives:-

It is given that an organization cannot appoint more than fifteen executive without passing particular resolution in board of directors meeting. It is further given that such class or classes of organizations as may be given will have at least one female executive. Therefore, another part of the section clearly states that there will be appointment of one female executive by different types of organizations. As specified by the Rules 2014 of the organization regarding selection and conditions for executive states variety of the organizations. As per the rule it is given that every recognized stock exchange organization will appoint one female executive within one year from the beginning of the second proviso to section 149(1) of the Act. Every public organization other than recognized stock exchange organization having a paid up share capital of rupees hundred crore or more or turnover of rupees three hundred crore or more as on last date of latest accounted monetary records will appoint one female executive within one year.

#### **Global Outlook of Female Executives on Board:-**

Without any legal order or provision, Organizations in India are opposed to provide sufficient demonstration to female on their panel of executive although there is shortage of qualified female to appoint in company offices. Worldwide there are different nations who have taken

initiatives for appointment of female on panel of executives and also have taken precautions to change female representation in their panel. There is momentous rise in the status of female on company panel as it is declared forty percent allocation for female executive in Iceland and Norway. It is observed that allocation of female is also in other nations like Israel, Belgium. In other nations it is voluntary arrangement or follows or explain type norm.

Nations like America and Australia also have accepted that there is a need of appoint of female on panel of executives which will lead to empowerment of female. It is compulsory in America that every organization has to show female percentage on the board of directors or whether they have appointed female executives in their board. But it is observed that the process of female contribution of female in board has been reduced.

#### **Women Directors in India:-**

- Bala Deshpande, Managing Director, New Enterprise Associates India
- Ms. Vishakha Mulye, Executive Director, ICICI Bank Limited
- Dr. AshaBhandarker, Shareholder Director, United Bank of India
- Dr. Purnima Gupta, Director, State Bank of India
- Director KakuNakhate, President and Country Head (India), Bank of America Merrill Lynch
- AnuradhaRao, Public Interest Director, National Stock Exchange of India
- Ms.PadmajaChundurur, Managing Director & Chief Executive Officer, Indian Bank
- RenukaRamnath, Founder, Managing Director and CEO at Multiples Alternate Asset Management
- NainaLalKidwai, Group General Manager and Country Head of HSBC India.
- RenuSudKarnad, Additional Non-Executive Director of HDFC
- Smt Ketaki Bhagwati, Independent Non-Executive Director, Axis Bank
- Ms. RevathyIyer, Director, National Bank for Agriculture and Rural Development (NABARD)

#### **Need of Women on board:-**

- Professionals consider that female executive in an organizations can work more efficiently with risk.
- Female can have good skill to understand the problems of workers, customers, members and other participants in the organization.
- Female have a tendency to concentrate on lengthy predictions.
- Female executive Sizemore comfortable to understand the requirement of female than men which will promote popular goods and facilities
- Research indicates that there is need of three female executives to modify panel room in corporate level.
- The monetary performance of the organization will change in three comprehensive views like profit on equity and profit on sales and profit on invested capital

#### **Conclusion & Suggestions:-**

Female is the need of time but also creates good image in terms of better governance. There should be more contribution of female in panel of executives at corporate level and more contribution in different activities in the organization. Without having female executive on panel of corporate will show that existence of glass ceiling through which female are not

allowed to appear at the top management level of the organization. Due to introduction of Companies Act, 2013 power of female has become more strengthen on panel of company. Currently few companies have implemented the new provision under the Companies Act, 2013. If there are more interference in the Companies Act will make more change. Therefore the burden of proof lies upon the board members that they have to make more appointment of female executive on the board. It is serious for companies that require to follow with the enactment, to have better appreciative of the duties and accountability in ensuring compliance with the Act

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**Insecure female maid servants and their undefined rights.**

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**Abstract-**In this 21<sup>st</sup> century the globalization has a call by all the states across the world. Due to advanced technology and science the world is coming near. We easily travel from one country to another by airways. A call for fair globalization has been given by International Labour Organization. The role of workers play vital role in this. India is densely populated so workers are borrowed from India to other foreign countries. In other countries man power is not abundant. The term worker is defined by the Labour law in India. In different countries this word has wide explanation as per the laws passed in the favour of workers. The workers are working in two different sectors like formal and informal. The workers, domestic servants, female maid servants are working under the unorganized sector. **The research paper focuses** on the issues faced by the female maid servants. These servants did not get the meaning under the heading workers as per the labour law in India. In some foreign countries specifically some laws are passed but those laws are also not sufficient to define the rights of these female maid servants. The role of law is very important to get security to the workers who are working under the unorganized sector, specifically female maid servants. The research paper emphasizes mainly on the rights of the female maid servants who are considered as vulnerable group of the society.

**Key Words - Law, female maid servants, workers, rights, justice.**

**Introduction-**India is a country under developing category. It is the second country to have largest population across the world. It is densely populated region. The poverty is also at high level. It is the country where agriculture is the main occupation of the people living in rural areas. Agriculture is mainly based on the good climate which is responsible for the growth of the crops. Industrialization and globalization is increasing day by day at worldwide level. It is responsible to increase pollution on the mother earth. Due to the pollution the climatic changes taking place at peak level. The heat increased on the earth causing global warming. The carbon dioxide level increased in such a way that it affects rainfall. No sufficient rainfall is responsible for the drought. Drought is the reason so that they do not have water to drink. The temperature increase is in such a way that the ground level of water is also falling down. The water level in the wells also decreases. There is no water for the crops to grow. Sometimes rainfall is too much for many months beyond rainy season causes crops to damage. The farmer being hopeless to get money in such situations migrate from the rural areas to urban areas in search of job or any other work. The poverty increases in such a way that they do not have money to eat food. They borrow loans to mitigate money problem. The debt is not paid by them within the time so they come to the metropolitan cities to earn money. They do not have accommodation for living and to take shelter. They live in poor conditions. Their wives are ready to do any kind of work which can support their families. They act as a maid servant in the houses of employers. They have no educational qualifications also. These female are not having skill to perform the job in offices. They easily select to work as maid servants at any salary. The salary is very low as per the work. The female are working in 6 to 7 houses every day without weekly off. These female are not able to give quality time for their family and children. These females are working whole week without leave. They do not get maternity leave. They do not get yearly sick leave. These are the conditions in India. These female or their minor girl child also engage



themselves to do all these work. In some cases it has been observed that these female travelled from our country to another to work as a maid servant through agents. These agents take benefit of their poor conditions and fix their rates for any payments. These female are not much educated so the undue advantage is taken by the employer in India and even by the agents who provide them employment in other foreign countries.

#### **Review of Literature –**

**ChandramouliKodandarama (2018)** elaborated in their ‘Women Domestic Workers in India: An Analysis’ article the situations responsible for increase in number of female domestic workers. Decrease in agricultural produce and uncertain climatic conditions are responsible for migration of people from rural area to urban area

**Rufina Augustine &Rupesh Kumar Singh (2016)** in their article‘Conditions and Problems of Female Domestic workers’ highlighted on the conditions and problems of the female domestic workers in Lucknow city. These female workers become victim of mental, physical and sexual harassment at workplace with no security.

**D’souza Asha( 2010)**highlighted in the journal paper ‘Moving towards decent work for domestic workers: An overview of the ILO’s work’ about the International labourOrganisations guidelines to have defined structure for the work of these domestic workers.

**Bhattacharjea, A. (2006)** in article‘Labour market regulation and industrial performance in India: A critical review of the empirical evidence’ written about the appointment of these labours by contractors at any cost. In India there is need to have proper legal structure for these labours working conditions.

#### **Objective of the study -**

1. To define the rights of the female maid servants
2. To secure the interest of the female as a maid servants in their employment
3. To regularize the working conditions of these female maid servants
4. To protect the rights and interest of the weaker section of the society.

**Research Methodology–** This research paper is basically descriptive and analytical in nature. In this research paper an attempt has been specifically taken to analyze the insecurity faced by the female maid servants. This paper finally analyse the socioeconomic status of the women in India. According to the need the data is taken from the secondary sources

**Sampling method –** Random

**Sample size-** 50 female maid servants

**Dataused in research-** Primary data

**Method of Data collection-** Questionnaire

#### **Hypothesis-**

H1-The female maid servants have insecure working conditions.

H2-The female maid servants in India have sufficient legal provisions to protect their rights.

**Analysis-**There are no specific laws in favour of these female maidservants. The working conditions are not defined. They are considered under the unorganized sector so they cannot be the beneficiary of the laws which are for workers in India. Labour law not accepted these maid servants under the concept workmen. These female easily become the victim of physical, sexual, mental and economic harassment. This harassment must be stopped and secure working conditions must be provided to them by our government. The main object of progressive nation can be completed when these female will get justice through the formation of specific legal provisions. These female are also human being and they have some human rights.The violation of these human rights take place easily because of no laws for their benefits till the year 2020. The government has to take steps in the interest of these female maid servants. Specific rules and enactments must be passed to secure the rights of these maid servants. The female who are going out of the country to work as a maid, has to be

checked that the misuse of these female should not be done by selling them in foreign countries. In cities majority of educated women who come under white collar are working in offices. They do not get much time to do household chores like washing utensils, clothes, cleaning floors, cooking and many such household chores so they always prefer to give employment to these needy and poor females. Their wages are not fixed and they do not have bargaining power so its benefits are taken by the employers. The unions of these maid servants are not formed. There is no platform to raise their voice against the injustice as they are not organized. They have any health issues for which they do not get sick leave. They work even if they are sick. The employment performed by these female have no legal provisions. It is yet not legalized so the rights of these female are ignored. The society is not ready to accept them as human being. They have also family life and their children are also assets of the nation. She has to grow them with proper nourishment and nurture them with good manners. She do not get time for her own children. She accepts the work as a female maid servant to educate her children and to fulfill the basic needs of their family.

The Indian government has not passed specific laws to protect their rights. These female are worried about the future of their children. In any insecure surrounding these female work to fulfill their needs. The basic needs of the family are food, clothing and shelter. These female are from the poor families. They do not have house to live. They live in slum areas. Sometimes these families take shelter under the bridges, railways etc. These female easily become ready to work for the lower payments.

The agents take benefits of these unfavourable conditions. The undue advantage is taken by the agencies which send these female or young girls to work as a maid in foreign countries. There are no defined conditions for these servants. The working conditions for these female maids are not defined so the benefits are taken by the society. The lower payment is the main thing which is highlighted here. Another issues like sexual and physical harassment of these female maid servants by the employer who appoints them.

The harassment is also responsible to lower the confidence of these female. Morally and financially they get exploited. The globalization is taking place rapidly. The man power from India is sent to the other foreign countries but the manpower in the form of female servants is misused. This misuse is specifically because of the reason of not having legal provision in the favour of these females. The insecurity in the form of harassment must be prevented. Specific authorities must be appointed. The authorities which will define the rights of these female maid servants are necessary.

#### **Findings –**

As per the data collected from the questionnaire prepared for the female maid servants it is clear that the rights of these female maid servants get violated. The working conditions are not defined so the exploitation of these females take place at the place of employment.

1. The study finally reveals that 90% of the female maid servants are of the opinion to have defined rights and working conditions for them.
2. The female maid servants are not considered as a worker in India.
3. The research states that 84% of these female have no secure working conditions.
4. They have no legal provisions to protect their interest as a maid servant.
5. There is violation of human rights of these female maid servants.
6. To take their grievance to proper authorities the Grievance redressal system must be set up by the government for them.

#### **Conclusion –**

**The researcher finally** has gone to the conclusion that-

The globalization is speedily capturing the world. The workers are also human being. The rights of every human being must be protected. The female maid servants in India are insecure as they do not have any legal provisions to protect their right as a human being while working

as a female maid servants. Specific laws must be enacted in the interest of these females. There is need to change the mentality of the society towards the female maid servants. The nation can progress socially, economically by protecting all such weaker sectors of the society.

The government has to take initiative to define the rights of these female maid servants. If one group of the society remains insecure then the progress of the nation is also in danger. The economic, social and political development of the society and nation is possible only through the sound legal system for every human being. These female maid servants are also human being and they have also human rights. It is a need to protect the rights of these insecure female maid servants. The media has to also create awareness about the undefined rights of these female maid servants.

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## ACCESS TO MEDICINES AND COMPULSORY LICENSING IN THE POST TRIPS SCENARIO

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**ABSTRACT:-** Patent enables the patentee to have monopoly rights for his invention by government of any country to prevent others from making, using, selling or offering for sale his invention for trade without his consent for twenty years from the filing of the said patent. The idea behind agreeing for Trade Related Intellectual Property Rights (TRIPS) is to enable the easy business exchange worldwide and to provide the same for public welfare. Further it would also enable the countries to devise a system for permitting access to affordable medicines globally. The origin of TRIPS by world Trade Organization was with the thought of devising common minimum requirements for safeguarding intellectual property rights in TRIPS member nations. Access to medicines is observed as basic right and should be pre-emptively safeguarded by governments of all nations. In recent years, discussions on connection between the pricing of medicines and patent rights have attracted every eye. It's the pricing mechanism which decides the access of newer medicines especially to the third world countries. This article thus emphasizes on the basic TRIPS requirements, its flexibilities and different options of using compulsory licensing as device to gain access to drugs at reasonable cost for all third world nations specifically in post TRIPS scenario. It also describes the advantages and disadvantages of using CL as device for access to drugs and also describes the newer means or methods (like using medicines patent pool for licensing the patented medicine) adopted recently in the pandemic situation that the world faced for access to medicines in lieu of compulsory licensing.

### INTRODUCTION:-

**Access to Drugs and Barriers:-** Access to drugs is considered as fundamental right of all citizens in India. However, with recent advent of newer Patent Laws in India and across the world has made medicine also a commodity. Thus, access to medicines Thus, access to drugs is seen as biggest hurdle for well-being of society at large because of costing of the drugs. Filing and safeguarding drug patents have become more predominant after formation and implementation of Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement which requires common minimal rules for safeguarding of IP rights. As we're aware, the TRIPS Agreement significantly have synchronised the life of patent for at least twenty years from the filing date of the patent and authorized patent grant for all technical inventions. The full implications of the TRIPS Agreement for health are yet emerging, however, it would completely unfold in upcoming years. Discussion on result of IP protection on access to drugs is not newer than the awareness towards the access for HIV medicines few years ago. Current attention towards compulsory licensing as therapy to undue effects of exclusive patent rights is proof of its existence long back. It's reported by WHO that innumerable complications regarding development and availability of affordable drugs imitate the total communal health schemes in least developed nations. It must be noted that there has not been significant progress as regards development of drugs and medicines that may be needed to treat the patients in the poor countries because it is difficult for these pharma companies to manufacture goods given the cost incurred towards the research and development for producing

drugs. Thus, proper investments and definite procedures are required to be implemented by national authorities to make the essential drugs available at affordable costs to less socio-economic society. The IP privileges also stir unfair costing. Normally, an inventor always wants to keep the revenue and the development on arising from the invention and that keeps them away from making any contract or promise related to same on their own. The more the protection to the patents, the more would be the price of the drugs and medicines. New drugs would be produced which are under patent protection but this will not necessarily mean easy access to medicines because of the high cost of these medicines and drugs. As an end result, the availability of affordable drugs gap between advanced and growing nations will amplify. Organisations like World Intellectual Property Organization (WIPO) ensure that the nations of the world are compliant with patent laws but they do not have a solution to address the health issues and requirements of the people in the developing countries. Most of the time many of these organisations have to withstand the pressure exerted by large corporates who are the owner of patents and have other intellectual property rights. Many NGO's including Médecins sans Frontières (MSF) have been instrumental in getting the attention to the various provisions of TRIPS which if effectively used can ensure greater access to medicines. Forced license, permitting one nation to permit usage of patent without the permission of the patentee is one such provision. Thus, it is may be helpful to have a tool like forced contract or license to make the vital drugs available at affordable cost in least developed nations. As per Article 31 of TRIPS, the intellectual property rights shall remain with the patent holder who shall be paid adequate remuneration as per the situation. An initial meet between different countries on use of compulsory license to make essential drugs available at affordable cost was held in the year 1999 for anti-HIV drugs at the Palais des Nations in Geneva. In the same year, MSF arranged a meeting in Amsterdam on improving availability of affordable drugs. The minutes released ("Amsterdam Statement") mentioned about forming a team at WTO for the same cause for third world nations and forming guidance work for same. This team would look into usage of the compulsory license to improve availability of drugs across world. Further, it was also to help developing instruments and methods for improving drug distribution to nations with less or no manufacturing capability for the drugs. In a similar context, during his September 2015 official visit to United States, Prime Minister of India, Mr. Narendra Modi addressed representatives of multinational pharmaceutical companies and presented India's point of view. He mentioned: "I understand you want to be compensated for R & D investments, however, at the same time, India needs affordable medicines for its population. And this is not only about India but the whole world. Mankind requires continuous R & D of new drugs for a higher quality of life. You need to be able to devote the right energy to that. And this can be done by changing the formulation of drug to sustain a patent, but by inventing things that make a difference to mankind."

He further stressed three essential points:

- "Countries like India should decide their own destiny..."
- Affordable access is key...
- We need to examine the high cost of monopoly..."

These place in the right perspective, the importance of innovation and that of access, which is central to this paper.

**Introduction to TRIPS:-** India signed TRIPS Agreement in 1994 and became the member of the WTO. As a part of harmonization with the TRIPS Agreement, Indian Patent Act was amended in 2005. Reason behind

implementation of TRIPS was not only to safeguard the rights of minority patent holders but the bigger aim was to serve commerce and business development too.

#### **DOHA Declaration:**

- The Assertion on the TRIPS Agreement and Public Health, was assumed by the WTO in November 2001 in a ministerial conference held at Doha.
- The Assertion avowed the independent right of sovereigns to take precautions to safeguard well-being of common people, through the usage of compulsory licensing and parallel importation and device newer rights for economically poor nations by permitting them to delay the implementation of product patents for pharmaceuticals and safeguarding of clinical data publication till 2033 at least.

The big pharmaceutical companies reacted bit bitterly towards the Doha Assertion and to few applications of CL. As a result, developing nations using TRIPS flexibilities were automatically destined to receive harder inspection by developed nations. However, the bigger growth prospects are available in third world nations as trade in developed nations is deteriorating, either because of inundation and very slow progress in newer inventions. Further, the additional safeguards of TRIPS in free trade contracts plus political situations have curtailed the complete exploration of TRIPS flexibilities. Therefore, it can be mentioned that with the advent of time, the efficiency of CL might also be either lost or a better option would be available or devised to promote rivalry, specifically to enable the capability of the nations to export drugs manufactured through CL.

#### **Compulsory Licensing (CL) provision in TRIPS**

Article 30 and 31 of TRIPS describe the minimum requirements for grant of CL.

**Article 30 of TRIPS** mentions about the limited exceptions as listed towards rights granted through patents if they do not “unreasonably prejudice the legitimate interests of patentee, considering the legitimate interests of the third parties.”

**Article 31 mentions about** terms for the usage without consent of the patentee. Member nation might grant for CL in circumstances of national or extreme emergency or in cases of public non-commercial use.

Thus, after implementation of TRIPS, interestingly many developing countries in early years viz. between 2000-2010, tried making the extensive use of TRIPS and its flexibilities to procure medicines at affordable costs for their citizens using either CL or threat to grant CL (to Innovator companies) or government use options. For example, Malaysia (for three HIV drugs), Mozambique (CL for HIV drug), Indonesia (CL for govt use on two HIV drugs), Zambia, Thailand (CL for clopidogrel), Brazil (Govt threatened Abbott to reduce price of lopinavir/ritonavir in 2005), Equador (CL for HIV drug), Taiwan (CL for oseltamivir), etc.

#### **INDIA SECENARIO:**

##### **Indian Patent Act [Amended in 2005]**

➤ TRIPS came into being from 1989. India became member of WTO in the year 1995. As a result, India amended its Patents Act in 2005 to meet with TRIPS provisions.

**CL in INDIA:-**With the amendment of new Patent Law, India allowed product patents for pharmaceuticals and agricultural products. The new TRIPS provisions of CL were also included in the amended Act. In reaction to the same, Dr. Yusuf Hamied, Chairman of Cipla, mentioned in one of his public addresses after the amendment of the Act that India has around 80 million people who are suffering from heart ailments around 60 million people who had asthma and an equal number of people who had diabetics besides 110 million people who had some form of mental illness, 50 million suffering from hepatitis and 1 in 3 Indians who had latent T.B. According to him, a

vast majority of the Indian population lived without proper sanitation. Thus, it was necessary to ensure easy access to medicines to maximum people as possible. This according to him can only be achieved by having a **pragmatic licensing policy** and payment of adequate royalty to the owner of patents. Exactly, in the New Amended Patent Act of 2005 included different sections to allow such CL in India (Section 84-Section 94). The major conditions for grant of CL are:

CL can be availed after the expiry of 3yrs from the date of the grant of a patent if the below conditions are fulfilled:

- Reasonable requirements of the public with respect to the patented invention have not been satisfied,
- Patented invention is not available to the public at a reasonably affordable price.
- Patented invention is not worked in the territory of India

Further as per sec. 92, under certain situations defined as “national emergency”/“extreme urgency”/ public non-commercial use for which CL can be granted subject to other conditions in the Act. This provision is under the discussion recently due to existing pandemic situation globally. However, till date, only one CL has been granted in India (details as mentioned below).

### **COMPULSORY LICENSING (CL) CASES IN INDIA**

#### **I. Bayer and Natco’s litigation (Nexavar<sup>R</sup>)**

1. Natco filed request for compulsory license for Bayer’s Nexavar<sup>R</sup> in Aug. 2011. The Controller gave a chance to both parties to present their side and decided in March 2012. The Controller granted the said CL based on the following reasons/facts:

1. Bayer was selling the medicines to two percent people; therefore, it can be mentioned that Bayer was not fulfilling the reasonable requirements.
2. Bayer was selling the medicine at about two lakh eighty thousand for one month’s medicine and this cost was considered as exceptionally higher thus Bayer did not fulfill the criteria of “reasonably affordable cost. Natco made the medicine available at the cost of only rupees eight thousand eight hundred per month (Cipla later made it available for rupees six thousand eight hundred forty per month).
3. Bayer was unable to “work” the patent in India to the required extent as per Patent Act. After this one, there was one more attempt of CL application from BDR pharma for the drug Dasatinib, which was rejected by Indian Patent Office. Hence, it’s evident that the procedure to grant compulsory license is pretty complex and time-consuming. Hence, there are no more CLs granted after Nexavar<sup>R</sup>. Most of the time it is argued that the mechanism of compulsory licensing would not always be beneficial for the pharma companies as it would eat up their profits which would have a drastic effect on the funds that are left with them for the research and development of new drugs and thus adversely affect innovations in the country. Also, since they have the sword of compulsory license dangling on them, they might indefinitely postpone any new investment in the field of research and development and may prefer other options like trade secrets over patent protection. However, this may not be completely true as statistics suggest that it has not been the case that issue of compulsory licenses have resulted in a fall in the number of innovations in the country....! It is seen that the government has a very important role to play in ensuring easy access to medicines apart from the intellectual property law and policy prevailing in a particular nation that would be able to tackle the issue of grant of compulsory licenses. In such cases, **voluntary license** can serve as a good option. Voluntary licenses, would be beneficial to pharma companies who manufacture drugs and would also prevent action in the form of compulsory licensing. This would ensure availability of drugs at affordable prices. Voluntary licensing will still ensure the companies make a profit, albeit at a

lower price, whereas any intervention by the government would lead to a huge fall in the price of the drug which would be without the consent of the owner of the patent. Thus, if we consider India's example, there are at least half a dozen such alliances already in place till date in India. This includes a technology transfer agreement signed between Strides Arcolab Ltd of India and Gilead Sciences Inc. of USA for manufacture of drugs to treat HIV/AIDS and agreement entered by Hoffman La Roche Ltd of Switzerland with Emcure Pharmaceuticals Ltd of India. The other agreements which did not have technology transfer included Merck and Co. Inc's Indian unit MSD Pharmaceuticals Pvt Ltd and Sun Pharmaceuticals Industries Ltd for sale of two patented drugs for diabetes namely Janumet<sup>R</sup> and Januvia<sup>R</sup> in domestic market which were sold in different brand names. Another Switzerland based company Novartis AG entered into an agreement with Lupin Ltd in India to sell its patented drug Onbrez for treatment of chronic obstructive pulmonary disease (COPD) whereas Bayer planned to licence its drugs for India through its domestic venture with Cadila Healthcare Ltd. Therefore, the following were the options that Indian pharma generics devised after TRIPS as opportunities:

a. Increase in expenditure on Research and Development – There has been a drastic increase in the amount that has been spent on the research and development by the Indian pharma companies.

b. Out-licensing Inventions: The R & D industry in India is not yet equipped for complete New chemical entity (NCE) research mode and hence the companies in India are out-licensing molecules to multi-national companies after phase-I and clinical trial completions. Viz. Dr. Reddy's licensed NCE DRF 4158 to Novartis.

c. In-licensing agreements: Recently, Indian pharma generics want to enter into agreements with multi-national companies for promotion of their products in India and abroad. These agreements have in their scope marketing, development of the product in the domestic market and sharing of profits with multi-national companies. This makes the drugs and medicines available to the vast population at affordable prices in India.

d. Carrying out Research and Development in collaboration: This involves one pharma company collaborating with another pharma company for development and production of drugs and medicines. Thus, Ranbaxy had a collaboration with GSK in the research and development of respiratory products.

Recently, few of Indian companies have also done collaboration with foreign companies and universities for research and production of Covid-19 medicines.

e. Out-licensing alliance: This would include out-licensing of their molecules by multi-national pharma companies to their Indian counterparts for ensuring flow of regular royalty income with minimum investment and a larger geographical spread viz. Roche out-licensed oseltamivir to Hetero to manufacture and supply to India and other 110 countries.

f. Outsourcing: This includes outsourcing of the entire process of development and production by the multi-national companies of the drug to the developing countries like India where it would be more cost-effective.

g. Setting up production facilities: This would include setting up of production facilities abroad by the Indian companies viz. Lupin in USA, Dr. Reddy's in UK and China, and Sun in USA etc. which would ensure faster approval to these Indian pharma companies in foreign market.

h. Marketing alliance: It has been observed that many of the multi-national companies have entered into alliance with domestic pharma companies for having a larger



geographical presence. So as evident from above facts, many countries initiated taking benefits from TRIPS flexibilities including India.

The joint study conducted by WHO, WTO & WIPO in 2013 highlighted various factors that determine free access to medicines namely indirect taxes, differential pricing etc. which has a direct effect on the price of the drugs and their procurement.

When one analyses the progress made so far in the field of research and development including the mandate by the WTO, the same might be summarised as follows:

**Creation of a patent pool** which would ensure easy access to medicines and make treatment of diseases like AIDS and Covid-19 affordable apart from facilitating the creation of new fixed-dose drug combinations that would meet the needs of the patients in the developing countries. These pools are voluntary and would have compulsory licenses as well as voluntarily license which are granted to patentee, as for Patent Pool (MPP) which was a creation with funds from the French initiative UNITAID. There seems to be no fixed solution with them for the problem of access to medicines. Also, existence of MPP meant that the WHO would no more advocate the implementation of the flexibilities of the TRIPS agreement. **Recent license of Remdesvir** from Gilead through MPP is biggest example of such kind. Thus, achievements for the said improvements is not assured. Coercions from the pharma aapocalypse, commercial losses and local disinvestment would be created. Local, financial and government leaders might be intending for more self-beneficial contracts and obtain remote franchises other than selecting the basic health requirements of common people. Therefore, patent laws and machineries would surely aid in repairing link between the revenue driven research and communal health urgencies. Thus, we can say that compulsory licensing is definitely a primary tool which developing countries can implement to ensure easy access to necessary medicines. The campaign for access to medicines have now extended to non-communicable diseases too specifically as is seen in recent time of pandemic in the world.

**CONCLUSION:-** India showcases an important model for tightening the basic patentability requirements & adoption of flexibilities available under TRIPS, which can avoid the complex and debatable CL devises. India embraced 2 major options through Indian Patent Amendment Act 2005 which would be helpful in examining the query: Sec. 3(d) -the efficacy requirement and sec 11 - "automatic compulsory license". Because of these and other proactive provisions, CL till date has not become prominent subject in India...Thus, Regulatory measures would go a long way in this regard to make the drugs and medicines easily available to the vast majority of the population and thereby setting off any increase in the pricing of medicines that may be caused as a result of patenting of the pharmaceutical products. As observed, WHO has taken many steps as regards the nexus of innovation, access and intellectual property rights which includes formulating of a global strategy to promote competition which would have the effects of easy access to drugs and medicines at an affordable price. Finally, the international community, including patent-holding and generic pharmaceutical companies, should consider supporting patent pools as a tool for improving the management of IP for access and innovation.

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## EFFECT OF COVID -19 ON INDIAN PHARMA GENERICS BUSINESS: PROMENADING IN PROVEN DIRECTIONS

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**ABSTRACT:-** The world faced vicious 2020 amid pandemic situation due to covid-19 infections. The continued lock down affected all the businesses world wide and affected economies of most of countries very badly. Amid the search for suitable vaccine for the said virus, there is lot of debate happening across the world for waiving off the patent monopoly rights to grant access to medicines or vaccines to developing or least developed countries. It's noticeable that during this pandemic, it's equally important to make the essential medicines not only effective (or found to be effective) against covid-19 infection but also against the side infections which worsen the conditions of covid infected patients. Viz. Diabetes, blood pressure, etc. It was observed that the big pharma multinational companies were found to be hesitant to do so for obvious reasons. Thus, till date, the debate on the same has not been concluded. Amongst these, on Indian front, the Indian pharma generics are seen following an intelligent legal pattern to move towards early entry of drugs during subsistence of the patent. This has enabled the access to those costly and essential medicines to patients at affordable price. Though, this may not be true for all cases, but has certainly helped few ones. Though it may not be the correct legal strategy but is interesting to observe the trend. The article herein discusses the recent two examples of dapagliflozin – an antidiabetic drug and ticagrelor -an anti-platelet drug and their legal battle in India by Indian Pharma Generics.

**INTRODUCTION:-**Year 2020 was particularly remarkable for Indian Pharma Generics in many ways. India too faced the heat of lock down due to Covid-19 pandemic globally. While the entire world including Indians were waiting for new vaccine to deal with Covid situation from pharma companies, few of Indian pharma generics also joined the race in searching for effective vaccine for covid-19. Thus, at focus were only the patients with Covid-19 and the medicines that would be effective and available for covid-19. Though, a large Indian population suffered from other life style diseases too. The access for medicines for those diseases still remains an issue in India through the pandemic too. Specifically, the patients with diseases like diabetes, blood pressure, cancer, etc were designated as “high risk” (likely to be infected with covid-19 virus) by the doctors. Thus, it is important to check the availability for medicines to treat those diseases also became prime requirement. Unfortunately, just before the pandemic struck world, the battle for access to these diseases was yet on in India. The multinational pharma companies either import the newer drugs for the said diseases or tie up with big pharma companies in India to sale these drugs at ‘their price’. This pricing makes the said newer therapies unavailable for common patient population. To break the monopoly of the multinational pharma giants, the Indian pharma generics keep trying various legal options including filing and fighting patent challenges. The patent challenges are well-known methods to enter the market early (on winning the patent challenge). The few recent challenges fought by Indian pharma generics aimed to have early market entry or to dissuade the extension of monopoly rights by pharma giants. Among these challenges, there is seen a particular pattern of attacking the multinational pharma giants. We'll learn about the same via the example of recent anti diabetic drug – Dapagliflozin's challenge in Indian Courts.

## DAPAGLIFLOZIN – CASE FACTS AND PRELIMINARY INJUNCTION DENIAL BY DELHI HIGH COURT

AstraZeneca moved to Delhi High Court against very many pharma companies in order to stop pharma companies from marketing generic dapagliflozin in India before all its said patents on the drug expire in India. AstraZeneca tried asserting its patents on these companies and wants to injunct them from marketing the generic form of the drug. There are eleven companies that are within the suit namely, Emcure pharma, Torrent, Ajanta, Natco, Intas, Alkem, USV, Zydus pharma, Eris, Micro laboratories, etc. When Natco decided to enter India market in March 2020 with generic form of the drug, Astra decided to file suit against them. Astra mentioned that using the benefit of lock down because of covid situation, Natco entered the India market with generic form of the medicine of approximate cost of Rs. Twenty crores as per the submissions to Court by the innovator. In reply of the same, Natco defended that they've stopped manufacturing and selling until end of year 2020. However, it was not possible to recall the stock which has already gone to market, they were ready to sign off guarantee document from bank for their core rupees in favor of Astra if they lose the case. The case had an interesting twist when 5 other pharma companies also decided to enter in the market after Natco, like, Zydus, MSN, Alkem, Eris etc. once the base patent for the said drug expires in October 2020. To be more precise, the basic (genus) patent on Dapagliflozin - which made the profit of approx. \$154000 million through world-wide sales of Farxiga<sup>R</sup> (from the year 2019), the said generic form is yet having another patent which expires in May 2023. The pharma companies are chasing this particular patent. In India, AstraZeneca markets dapagliflozin and its combination with Metformin through Sun Pharma and Abbott Pharma as licensee of the patents. Though the pharma generics assert in their submission to High Court that they're just distributor's only and not licenses. There were series of hearings that happened between March to November 2020 for the above-mentioned Indian pharma generic companies versus AstraZeneca in Delhi High Court. Let's have a more closure look at the facts to understand the grounds of challenge.

**Facts:** - The case revolves around two patents – which were initially filed by BMS and later assigned to AstraZeneca in 2014. That is the genus patent, IN205147 (hereinafter the '147 patent) and the species patent, IN 235625 (hereinafter the '625 patent). The said patents have US equivalent patent family (which is US'126 as genus patent and US'117 as the species patent). The '147 patent expired in India on October 2, 2020. The Indian species patent, the '625 patent expires on May 15, 2023. The pharma generics submitted to the Court that dapagliflozin moiety cannot be safeguarded by more than one patent. The first patent, the '147 patent had expired in October 2020 and hence AstraZeneca's monopoly rights over the drug has expired and therefore, the preliminary injunction over the second patent's extended monopoly, should not be granted. This would surely make the drug unavailable to common public for three more years. In answer to AstraZeneca's preliminary injunction suit, the generic pharma companies filed the counter arguments re invalidity for the '625 patent too. This made the case bit complex and led to series of hearings. In the invalidity arguments for the '625 patent, the pharma generics relied on the ground of anticipation by the '147 patent. This came from the US family patent wherein the "terminal disclaimer" was filed for the equivalent US patent of the '625 patent over the US genus patent (the US '126 patent) to overcome the rejection by US patent examiner of 'obviousness type double patenting' during prosecution of the said patent. This is a judicially created doctrine in USA and this usually averts the

monopoly extensions by the innovators when mere variations from earlier patents is claimed which is not distinctive for another patent. In other words, this would help to keep the unjustified monopoly extension away. The very fact that innovators filed terminal disclaimer for the species patent, it clarifies that the invention as disclosed in the second patent is not patentably distinctive. However, the patentee did not agree to same and mentioned it just as procedure to overcome the examiner's objection towards the grant of the patent. Further, the pharma generics also alleged the '625 patent as vulnerable to revocation under section 64(1)(a) read with section 13(1)(b) of the Patent Act for lack of novelty in view of *prior claiming* over genus patent (the '147 patent). The pharma generics argued herein that the fact that innovators sued the pharma generics over the family equivalent of the IN '147 is USA for infringement of dapagliflozin, it's evident that the IN equivalent genus patent discloses and covers dapagliflozin. Thus, with the expiry of genus patent, the monopoly rights on the said drug also should expire. The same drug once disclosed cannot be covered and asserted again (specific species too) through the species patent. Further, the said IN '625 patent is vulnerable to revocation for lack of novelty in view of prior claiming by the genus patent -IN '147 patent. Thus, it would fail to satisfy inventive step definition too as per the Act in view of no technical advance (as known or published earlier) or economic significance and is therefore obvious to the person skilled in the art. The innovators tried to defend the above-mentioned allegations by submitting the declaration by Dr. Washburn asserting the enhancements of the invention but the learned Judge denied the same mentioning that the said declaration was sworn in April 2020 which is much after the priority date of the patent and the validity of the patent should only be assessed by the date of priority of the patent.

Astra Zeneca further tried to plead on Public interest but hereto the facts did not run in their favor...

Followed by these, The Judge then shifts to Astra Zeneca's submissions regarding the balance of convenience, and irreparable harm. Judge mentions that in his view, the pharma generics have been able to set up a credible challenge and establish, at least at the preliminary injunction stage, the vulnerability of the suit patent, even if the balance of convenience is in favor of Astra, the injunction cannot be granted. The Judge also addresses the public interest point before final concluding his judgement. He's recorded the prices as made available to him of the innovators and that of pharma generics (specifically of Intas and Alkem) and shown that clearly the difference in prices of drugs ranges between 250% to 350% (Innovator's price is this much higher than generics). Therefore, as is apparent, if pharma generics were allowed to manufacture and market their drugs, it would be far cheaper. He then finally concludes by denying the injunction and asking the generics to maintain the sales record as audited till further full trial in case in first quarter next year. Thus, this November decision came with good news of dapagliflozin -an important diabetes drug being available to common public at an affordable price. However, the interesting part of this story lies in its repetition.

**Promenading in Proven Directions:** - The denial of preliminary injunction by Delhi High Court to allow the pharma generics to continue marketing till the final invalidity trial decision is not new to India. In sense, if we look at few recent examples, this seems to be the current modes operando by pharma generics. To understand this a bit more clearly, lets look at earlier scenario for another drug – Ticagrelor - effective as platelet inhibitor as well as for preventing a serious or life-threatening heart attack or

stroke. Ticagrelor too is AstraZeneca's drug. AstraZeneca has three patents for Ticagrelor in India (viz. IN '907, IN'984 and IN'674 patents). Of these, IN '907 is genus patent whereas IN'984 is species patent which claims ticagrelor in its crystalline form. In this case too, in mid-2019, Natco, Micro and Dr. Reddy decided to launch the product containing Ticagrelor before the expiring of the said patents. The '907 patent was due to expire on Dec 2, 2019 and the rest two patents after the same. AstraZeneca filed the suit on these companies and requested to grant injunction from Delhi High Court. In defense, the said pharma generics, alleged the validity of the patents. The pharma generics submitted that AstraZeneca did not reveal about one more of their patent – IN 229 which expired in 2018 and the said '229 patent claimed the Markush structure of the ticagrelor moiety which was disclosed later in the IN'907 and IN'984 patents. They also mentioned that Astra Zeneca was using the '229 patent to file their marketing requirements to Indian Patent Office. Thus, that should be considered as the genus patent and therefore, AstraZeneca is attempting to extend the monopoly of their patent rights for ticagrelor. The pharma generics also pointed out that the said patents lacked novelty by prior claiming (similar to the later case of Dapagliflozin as discussed in this paper earlier), the said patents were obvious and also unpatentable as per section 3(D) of the Patent Act (as the '984 patent claims crystalline form of the drug). The pharma generics also argued that there was nothing in these later two patents to show the efficacy of ticagrelor as the compound was covered in earlier genus patent. However, AstraZeneca tried counter arguing - at the time of filing of second one, the first patent was not published (i.e. the '907 patent) and thus said patent wouldn't be considered as known earlier. Further, they mentioned that the genus patent was structurally close but the later patent claimed specific form having superior efficacy and lower dose and they tried to substantiate these facts through the expert affidavit of Dr. Robert Riley. The Learned Judge noted that Court would require an expert to decide prior claiming, that is whether ticagrelor was covered within expired patent claiming genus or main structure. However, court decided that patents under litigation weren't novel and were not connected with the IN'229 patent and AstraZeneca failed to explain the therapeutic efficacy of the disclosure for later patents as compared to the earlier one. Thus, the Judge took a safer or restrictive approach, depending on earlier Supreme Court verdict (Imatinib Judgment of Novartis and Union of India against each other) and agreed that pharma generics had good grounds for challenging the validity of the patents under litigation and AstraZeneca has failed to explain the irreparable harm so balance of convenience lies favoring generics. Therefore, denied injunction and allowed the generic version of ticagrelor to be continued in Indian market at much cheaper rate.

**Continued Story:** - In between ticagrelor launch and dapagliflozin launch, in similar manner in the beginning of year 2020, the pharma generics, tried launching Apixaban. The story here too deals with the genus and species patent. However, in this case, unfortunately, the generics were not successful as the patentee was able to prove the efficacy of the specific compound claimed in species patent over the same disclosed in the genus patent. The above examples show that in recent years, the pharma generics have learned to follow specific scheme viz. first to file revocation with Patent Office (optional) followed by preparing for launch and launching the product (or launching commercial lot sufficient to take up market need for at least 6-8 months) nearing the genus patent expiry and then preparing to fight the preliminary injunction (most cases successfully by counter alleging the validity of suit patents) as filed by the Innovator. This seem to have been the known path to walk smoothly!

**CONCLUSION:-** It's evident during this time of pandemic that medicines are accessible to public at an affordable price. This access is important for covid-19 vaccines as well as for the essential and important drugs for the allied diseases or diseases which can worsen in their state because of Covid infections. However, the issue of access to medicines for common people is a subject of discussion from many years after implementation of TRIPS to countries. Recently, a while ago the pandemic broke down and during the same, the pharma generics seem to have device an intelligent strategy to gain early entry in the Indian market with cheaper and effective generic versions of such important medicines. The article discussed two such examples of ticagrelor and dapagliflozin in detail. While its little early to mention whether this would work for few more in line further, one thing is noticeable. The court's refusal to favor the patent on account of its advanced age seems reasonable, taking into consideration the record of rejection for secondary patents to pharma. Thus, in this pandemic era where people have recently woken up to scream for access to medicines (even demand waiver of patent monopoly rights for important and essential medicines for poor countries), the Indian Court's plea of its commitment under TRIPS and Doha declaration to balance the patent rights with right to access to medicines offers a grand message against ever-greening of pharma patents.

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