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# **Jodhpur National University Law Journal**

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## **INSIDER TRADING LAWS IN INDIA**

**- Mr. Ramesh Bajiya<sup>1</sup>**

Indian corporate law has historical ties to British corporate law. Moreover, after forty years of failed socialist policies, in the 1990s Indian leaders strongly advocated economic liberalization and a move toward an Anglo-American model of corporate law.<sup>2</sup>The early 1990s was a period of extensive reform in India's economy and corporate legal regime. Not only were economic liberalization policies implemented, but new legal institutions were established to implement new rules in India's corporate and securities laws. These new regulatory institutions have been the primary avenue for producing new corporate governance standards.<sup>3</sup>

This section briefly deal with insider trading provisions to see how far it able to counter insider trading practice. It goes on to present an overview of India's corporate and securities laws, as well as the institutions responsible for drafting and implementing these laws, and considers how the insider trading laws may affect the market and small investors<sup>4</sup> . It is essential ensure that the rights of the small investors should be protected to provide a stable economic growth and to maintain the trust in market. According to fiduciary duty theory and misappropriation theory insider trading is a breach of trust and which damages public confidence.<sup>5</sup>

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<sup>1</sup> Assistant Professor Jodhpur National University , Jodhpur Institute of Law

<sup>2</sup> Ananya Mukherjee Reed, Corporate Governance in India, 37 J. Bus. Ethics 249, 249 (2002); Diganta Mukherjee & Tejamoy Gosh, An Analysis of Corporate Performance and Governance in India: Study of Some Selected Industries 6 (Indian Statistical Inst., Delhi Planning Unit, Discussion Paper No. 04-19, 2004), available at <http://www.isid.ac.in/~planning/workingpapers/dp04-19.pdf>.

<sup>3</sup> John Armour & Priya Lele, Law, Finance, and Politics: The Case of India 2 (ECGI--Law, Working Paper No. 107/2008, 2008), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1116608](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1116608).

<sup>4</sup> JONATHAN R. MACEY, "INSIDER TRADING: ECONOMICS, POLITICS, AND POLICY, University Press of America (1<sup>st</sup> ed. 2000)

<sup>5</sup> Bose Jaishree, "Insider trading perspectives and cases "The Icfai University Press Publication, 1<sup>st</sup> Ed, pp. 35-55, (2007)

### **1. Guilt of insider trading.**

Regulation 4, before it was amended in February 2002, provided that any insider who deals in securities or communicates any information or counsels any person dealing in securities in contravention of the provisions of regulation 3 shall be guilty of insider trading. The said Amendment omitted the words "or communicates any information or counsels any person dealing in securities", with the result that now regulation 4 applies only to dealing in securities. Regulation 4 declares that "any insider who deals in securities", but then it provides "in contravention of the provisions of regulation 3 or 3A." It is noteworthy that Regulation 3A does not refer to "insider" as defined in regulation 2(e). It is only regulation 3 that refers to "insider". Regulation 3A has nothing to do with "insider". Be that as it may, the purpose of regulation 4 is unclear; it seems to be a superfluous provision.

### **2. Penalty for insider trading and adjudication.**

Section 15G of the SEBI Act prescribes penalty for insider trading, but it covers only insiders. It does not cover persons who have dealt in securities by using unpublished price sensitive information obtained by them from an insider as contemplated in Regulation 3. According to section 15G,<sup>6</sup> if any insider indulges in any of the acts mentioned therein, he shall be liable to a penalty of Rs. 25 crores or three times the amount of profits made by the insider out of the act of insider trading, whichever is higher. Inevitably, the following things will have to be established (and the adjudicating authority will have to give findings) before a person is inflicted with penalty in the adjudication:

1. First, that the person is an insider within the meaning of regulation 2(e)
2. Secondly, he has indulged in any of the acts specified in the three clauses of the section; and
3. Thirdly, he has made a profit out of insider trading.

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<sup>6</sup> Section 15G of SEBI Act state that Penalty for insider trading.

The acts specified in section 15G, which are liable to be penalized by an adjudicating authority, Unless there are clear findings on these things, the persons being adjudicated cannot be penalized under this section. It is only thereafter that the adjudicating authority can impose a penalty within the limit specified in the section, namely Rs. 25 corers or three times the amount of profits made by the insider out of the act of insider trading, whichever is higher. Section 15I contains provisions regarding adjudication and section 15J specifies the factors the adjudicating officer shall take into consideration while adjudicating case.

- 3. Offence of insider trading and punishment.**—Any contravention of the SEBI Regulations will be an offence under the SEBI Act and the person committing an offence will be, on conviction, punishable under section 24<sup>7</sup> of that Act which provides that whoever contravenes or attempts to contravene or abets the contravention of the provisions of the Act or any rules or any regulations made there under, shall be punishable
- 4.** with imprisonment for a term which may extend to ten years, or with fine which may extend to Rs. 25 corers, or with both. If an offence is committed by a company, the provisions of section 27 shall apply.

### **Mens Rea And Insider Trading**

Under the UK Insider Dealing Act, the offence of insider dealing requires proof that the accused has deliberately abused his position to engage in insider dealing. In other words, the accused must be shown to have been knowingly connected with the company in order that he is convicted of an offence of insider dealing<sup>8</sup>. The requirement that he is knowingly connected with the company means that if the accused is unaware of his connection with the company in whose securities he has dealt in he will not be liable to be convicted

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<sup>7</sup> Section 24 of SEBI Act state that Offences.

<sup>8</sup> JONATHAN R. MACEY, "INSIDER TRADING: ECONOMICS, POLITICS, AND POLICY, University Press of America (1<sup>st</sup> ed. 2000)

and punished. Therefore, it will be necessary for the prosecution to establish that the individual charged with the offence of insider dealing has intentionally dealt in the securities knowing that he is connected with the company.<sup>9</sup>

"The individual must know that he is, or has been, connected with a company; he must know that information which he has obtained by virtue of that relationship is unpublished

### **Mens rea for criminal liability**

Section 24 of the Securities and Exchange Board of India (SEBI) Act, 1992 read with the Securities and Exchange Board of India (Prohibition of Insider Trading) Regulations, 2002<sup>10</sup> (hereinafter referred to as the Insider Trading Regulations) provide the basis for criminal liability for insider trading in India.

Section 24 of the SEBI Act provides for punishment with a fine or imprisonment of any person who "contravenes or attempts to contravene or abets the contravention of" the provisions of the Act or the regulations made under it. The Insider Trading Regulations under the SEBI Act specifically prohibit dealing in securities of a listed public company while in possession<sup>11</sup> of unpublished price-sensitive information, or communicating or counselling such information to a person who is prohibited from dealing in securities while in possession of the information<sup>12</sup>. Any insider who deals in securities "in contravention of" these provisions is guilty of insider trading.<sup>13</sup> The SEBI is given the power to initiate criminal prosecution under s.24 of the SEBI Act as well as issue certain directions such as prohibition on the dealing in securities, declaring the transaction in securities as null and void, or delivery of securities back to the

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<sup>9</sup> Bose Jaishree, "Insider trading perspectives and cases" The Icfai University Press Publication, 1<sup>st</sup> Ed, pp. 35-55, (2007)

<sup>10</sup> Enacted in pursuance of the power conferred on SEBI under s.30 of the SEBI Act, 1992 to make rules and regulations to carry out the purpose of the Act.

<sup>11</sup> It is pertinent to note that under the unamended Insider Trading Regulations, 1992, the requirement was that dealing in securities take place "on the basis of unpublished price sensitive information".

<sup>12</sup> regs 3 and 3A, Insider Trading Regulations 2002.

<sup>13</sup> reg.4, Insider Trading Regulations 2002.

seller, in order to protect the interests of the investors and the securities market, and to ensure compliance with the SEBI Act.<sup>14</sup> Regulations prohibiting the insider trading, the intention/motive of the insider has to be taken cognizance of. It is true that the regulation does not specifically bring in mens rea as an ingredient of insider trading. But that does not mean that the motive need be ignored. In this context I would like to refer to the discussion on mens rea in the Law

Lexicon by Shri Venkatramaiya -"Mens rea - There is a presumption that in any statutory crime the common law, mental element, mens rea, is an essential ingredient. A crime may or may not contain an express definition of the necessary state of mind. A statute may require a specific intention, malice, knowledge, wilfulness or recklessness. On the other hand it may be silent as to any requirement of mens rea and in such a case in order to determine whether or not mens rea is an essential element of the offence, it is necessary to look at the objects and terms of the statute

It has always been a principle of the common law that mens rea is an essential element in the commission of any criminal offence against the common law. In the case of statutory offences it depends on the effect of the statute..... There is a presumption that mens rea is an essential ingredient in a statutory offence, but this presumption is liable to be displaced either by the words of the statute creating the offence or by the subject matter with which it deals <sup>15</sup>

It is to be noted that as per the SEBI Act insider trading is a statutory offence. In this context it is also to be noted that the persons violating the provisions of SEBI Act, rules and regulations are liable to criminal prosecution. The penalty for violation of the provisions of SEBI Act, rules and regulations has been provided in Section 24 of the SEBI Act. As per the said Section 24 the offender "shall be punishable with imprisonment for a term which may extend to ten

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<sup>14</sup> reg.11, Insider Trading Regulations 2002.

<sup>15</sup> State of Maharashtra V Mayer Hans George AIR 1956 SC 722 AT PG. 728

years or with fine, which may extend to twenty five crore rupees or with both". This penalty is the revised one brought in vide amendment effected to the SEBI Act on 29.10.2002. Prior to the said amendment the person found guilty of an offence "was punishable with imprisonment for a term which shall not be less than one month but which may extend to three years or with fine which shall not be less than two thousand rupees but which may extend to ten thousand rupees or with both." Further in terms of section 15G of SEBI Act persons indulging in insider trading are liable to a monetary penalty not exceeding twenty-five crore rupees or three times the amount of profits made out of insider trading whichever is higher (prior to the amendment to the section on 29.10.2002 the maximum penalty liveable was rupees five lakh). The monetary penalty provided in section 15G is in the case of adjudication of the offences by an adjudicating officer appointed by SEBI. Penalty provided in section 24 is "without prejudice to any award of penalty by the adjudicating officer under the Act."<sup>16</sup>The first landmark decision on criminal liability for insider trading, which influenced the 2002 Amendments to a great extent, was Hindustan Lever Ltd v SEBI<sup>17</sup>.

## **II. Investigation And Insider Trading**

### **1. Source Of Power.**

Chapter III of the SEBI Regulations, comprising regulations 5 to 12, .contains provisions regarding SEBI's powers of investigation into insider trading and matters incidental thereto. According to section 11C(a) of the SEBI Act, where

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<sup>16</sup> Rakesh Agrawal Vs. Securities Exchange Board of India (2004)1CompLJ193(SAT), [2004]49SCL351(SAT)

<sup>17</sup> Hindustan Lever Ltd v Securities and Exchange Board of India (1998) 18 S.C.L. 311 (AA), the case threw up several issues with respect to conviction for insider trading. Among these were the definition of an insider (and whether HLL was a connected person who had acquired unpublished price-sensitive information by virtue of such connection); the definition of "unpublished" and "price-sensitive" information; and the power of SEBI to award compensation to the aggrieved party. This analysis will limit itself to the issues surrounding mens rea.

SEBI has reasonable ground to believe that the transactions in securities are being dealt with in a manner detrimental to the investors or the securities market, or any intermediary or any person associated with the securities market has violated any provisions of the SEBI Act or the Rules or Regulations made or directions issued there under it may order investigation into the affairs of such intermediary or person associated with the securities market, and to report thereon to SEBI. It appears that under this provision SEBI may order investigation if it suspects insider trading indulged in by any person (including a company or other body corporate), though the latter part of this provision authorizes SEBI to order investigation only into the affairs of such intermediary or person associated with the securities market. Thus, there is a lack of specific, clear-cut provision empowering SEBI order investigation against a person who is charged with violation of the Regulations.

It may be worthwhile in this behalf to take note of some Supreme Court decisions on the subject of subordinate legislation. It may be noted that as held by the Supreme Court rules or regulations made under a statute must be treated, for all purposes of construction or obligations, exactly as if they were in that Act and are to the same effect as if they were contained in the Act and to be judicially noticed for all purposes of construction or obligations; they cannot be described or equated with administrative directions.<sup>18</sup>

However in **State of Kerala v Abdulla**<sup>19</sup> the Supreme Court held:

"When power to frame rules is conferred by Act, that power must be exercised within the strict limits of the authority conferred. If in making a rule the Government transcends its authority, the rules will be invalid for statutory rules made in exercise of delegated authority are valid and binding only if made within the limits of authority conferred. Validity of a rule whether it is declared

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18 **Peerless General Finance & Investment Co Ltd v Reserve Bank of India** (1992) 2 SCC 343.

<sup>19</sup> AIR 1965 SC 1585.

"to have effect as enacted in the Act" or otherwise is always open to challenge on the ground that it is unauthorized".

A body, to which powers of subordinate legislation are delegated, must strictly act within the powers which are conferred upon it. It cannot act beyond the powers except, of course, to the extent that any other powers which it takes upon itself are justified by the doctrine of implied powers. Where the legislature has conferred any power, it must be deemed to have also granted any other power without which that power cannot be effectively exercised. But before implying the existence of such a power the court must be satisfied that the existence of that power is absolutely essential for the discharge of the power and not merely that it is convenient to have such a power.

"A general power authorizing the Government or other authority to make regulations providing for all or any purposes (whether general or to meet particular cases) necessarily expedient for the administration of the Act or for carrying out the objects of the Act, does not enable the Authority by regulations to extend the scope or general operation of the enactment but is strictly ancillary. It will authorize the provision of subsidiary means of carrying into effect what is enacted in the statute itself and will cover what is incidental to the execution of its specific provisions. But such a power will not support attempts to widen the purposes of the Act, to add new and different means of carrying out or to depart from or vary the plan which the legislature has adopted to attain its ends."

The power of an administrative or executive body to administer a statute and to prescribe rules and regulations to that end is not the power to make law, but the power to adopt rules and regulations to carry into effect the will of the legislature as expressed by the statute. A rule or regulation, which does not do this but operates to create rule out of harmony with the statute, is a mere nullity<sup>20</sup>.

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<sup>20</sup> Bose Jaishree, "Insider trading perspectives and cases" The Icfai University Press Publication, 1<sup>st</sup> Ed, pp. 35-55, (2007)

A rule-making authority has no plenary power. It has to act within the limits of the power granted to it. The basis of the statutory power conferred by the statute cannot be transgressed by the rule making authority. The rules cannot go against the provisions of the enactment and cannot in any manner make any change in the provisions of the enactment and are merely for the purpose of carrying out the essential policy which the legislature has laid down in the enactment itself.

In *Hukumchand v. Union of India* the Supreme Court has observed that the power to make subordinate legislation is derived from the enabling Act and it is fundamental that the delegate on whom such a power is conferred has to act within the limits of authority conferred by the Act. The delegate cannot override the Act either by exceeding the authority or by making provisions inconsistent with the Act.

The SEBI Regulations in regard to investigation are distinct from the UK law in one respect. Under section 177(1) of the Financial Services Act of UK the Secretary of the State is empowered to appoint one or more competent inspectors to carry out such investigations as are requisite to establish whether or not any contravention of the provisions of the Company Securities (Insider Dealing) Act has occurred, and to report the results of their investigations to him, and the inspectors so appointed are entitled to require "any person", whom they consider to be able to give information concerning any such contravention, to produce documents, to attend before them and otherwise give all assistance in connection with investigation<sup>21</sup>.

For instance in an English case, *An inquiry under the Company Securities (Insider Dealing) Act, 1985*, in *re*, the inspectors were appointed by the Secretary of State in December 1986 under section 177 of the Financial Services Act, 1986 to investigate suspected leaks by public servants of price-sensitive information in contravention of section 2 of the Company Securities

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<sup>21</sup> JONATHAN R. MACEY, "INSIDER TRADING: ECONOMICS, POLITICS, AND POLICY, University Press of America (1<sup>st</sup> ed. 2000)

(Insider Dealing) Act, 1985. A journalist was a business correspondent who had written two articles in two national newspapers about two take-over bids stating that one would be cleared by the Monopolies and Mergers Commission and the other referred to it. In both cases he was proved right. In February 1987 the journalist was questioned by the inspectors about the sources of the information on which the articles were based. He refused to disclose information which might enable his sources to be identified. He likewise refused to answer a list of written questions subsequently submitted to him by the inspectors. The inspectors certified his refusal to the court pursuant to section 178(1) of the 1986 Act and the court inquired into the case under that section. The question for the court was whether the journalist had refused to answer "without reasonable excuse" under section 178(2). The lower court held that the journalist had a reasonable excuse for refusing to answer questions about his sources, but the Court of Appeal unanimously allowed the appeal by the inspectors. The appeal by the journalist against the Court of Appeal's judgment was unanimously dismissed by the House of Lords holding, inter alia, that as the inspectors had produced evidence that the journalist's evidence was really needed for their enquiry the purpose of which was the prevention of crime, the journalist did not have 'a reasonable excuse' within the meaning of section 178(2) of the Financial Services Act for refusing to answer their questions. As opposed to this, under the SEBI Regulations, the investigation cannot go beyond an insider and, in certain respects, his associates as specified in regulation 7. The investigator cannot require 'any person' to do any of the things mentioned in regulation 7.

## **2. Circumstances in which investigation may be ordered.—**

In terms of regulation 5, the power of investigation may be invoked by SEBI for the following two purposes:

(a) to investigate into the complaints received from investors, intermediaries or any other person on any matter having a bearing on the allegations of insider trading; and

(b) To investigate suo-motu upon its own knowledge or information in its possession to protect the interest of investors in securities against breach of these regulations.

The SEBI may appoint an investigating authority where it has ordered investigation under this Regulation. Before ordering an investigation SEBI must form an opinion that it is necessary to investigate and inspect books of account, other records and documents of an insider for any of the aforesaid purposes. This formation of the opinion must be based on "written information in its possession". Thus, to be in possession of written information leading to the formation of the opinion is the sine qua non for ordering an investigation.

Regulation 5 is not free from doubts and ambiguities giving rise to confusion. The intention of the draftsman is unclear. Sub-regulation (1) talks about investigation and inspection of books of account, etc. of an insider, but clause (a) of sub-regulation (2) talks about investigation into complaints against alleged insider trading and clause (b) thereof merely envisages investigation "to protect the interest of investors in securities against breach of these regulations". Apart from the linguistic defects, the regulation suffers from the vice of lack of precision and clarity. The purpose of the investigation ought to be to ascertain whether or not there has occurred any contravention of the SEBI Regulations and to report the outcome of such investigation to the SEBI so that in the event that there is a prima facie case of contravention, an appropriate action as provided for in the Act or the Regulations may be taken. .

An investigation may be ordered to be conducted by an investigator, either suo motu i.e., upon its (SEBI's) own knowledge or information

or upon receiving a complaint of facts which constitute contravention of the Regulations, if SEBI is of opinion that there are circumstances suggesting that there has been a contravention of the Regulations. Regulation 5 is clumsy and ambiguous.

### **3. Procedure for investigation.**

Regulation 6 lays down the procedure to be followed by SEBI in regard to investigation into insider trading. Sub-regulation (1) which contains a principle of natural justice requires SEBI to give a reasonable notice to an insider against whom an investigation is sought to be ordered. But such a notice may be dispensed with in the event the SEBI is satisfied that no such notice need be given either in the interest of investors or in the public interest. Needless to state, the satisfaction of SEBI as to the existence of the circumstances necessitating dispensing with the notice has to be an objective one and not the subjective satisfaction. It is true that regulation 6(2) is very widely worded without laying down any criterion or condition for dispensing with the requirement of the prior notice except that SEBI must satisfy itself that no notice should be given "in the interest of investors or in the public interest". However, if the satisfaction is based on no material or on irrelevant material or on any extraneous material, it will vitiate the order of investigation, and may be quashed by a court on judicial review in appropriate proceedings. The power conferred on SEBI by regulation 6(2) is in the nature of an emergency power and has to be used cautiously and sparingly.

It is pertinent to note in this regard the observations of the Supreme Court: "It cannot be laid down as a general proposition that whenever a statute confers a power on an administrative authority and makes the exercise of that power conditional on the formation of an opinion by that authority in regard to the existence of an immediacy, its opinion in regard to that preliminary fact is not open to judicial scrutiny at all.

While it may be conceded that an element of subjectivity is always involved in the formation of such an opinion, but, as was pointed out by this Court in Barium Chemicals the existence of the circumstances from which the inferences constituting, the opinion, as the sine qua non for action, are to be drawn, must be demonstrable, and the existence of such "Circumstances", if questioned, must be proved at least prima facie. Even where the Statute conferring the discretionary power does not, in terms, regulate or hedge around the formation of the opinion by the statutory authority in regard to the existence of preliminary jurisdictional facts with express checks, the authority has to form that opinion reasonably like a reasonable person."<sup>22</sup>

#### **4. Obligations of insider in regard to investigation.**

According to regulation 6(3), on being empowered by the Board, the investigating authority shall undertake the investigation and inspection of books of accounts and insider against whom an investigation is being carried out shall be bound to discharge his obligations as provided in regulation 7.

Regulation 7<sup>23</sup> casts certain obligations on the insider who is investigated into. These obligations are nothing but corresponding powers conferred on the investigator.

By virtue of regulation 7(1), the insider shall produce to the investigator "such books, accounts and other documents in his custody or control and furnish the authority with the statements and information relating to the transactions in securities market within such time as the said authority may require". The expression "relating

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<sup>22</sup> Swadeshi Cotton Mills v Union of India (1981) 51 Comp Cas 210 (SC): Comp LJ 309 (SC).

<sup>23</sup> Regulation 7 of Securities And Exchange Board Of India(Prohibition Of Insider Trading) Regulations, 1992

to the transactions in securities market" indicates that the books and documents required to be produced may include each and every book and document and every piece of information in possession of the insider, and not only those books and documents which relate to the company in relation to whose securities insider trading is suspected to have occurred or relate to the securities of such company.

Regulation 7(2) provides that the insider shall allow the investigating authority to have reasonable access to the premises occupied by such insider and also extend reasonable facility for examining any books, records, documents and computer data in his possession of the stock-broker or any other person and also provide copies of documents or other material which, in the opinion of the investigating authority are relevant. As noted earlier, this provision confers on the investigator the power of 'search' which is described by using the euphemistic expression "to have reasonable access to the premises occupied by the insider".

The words "of the stock broker or any person" would seem to be intended to cover books, records, etc. in the insider's possession whether they belong to him or any other person, or whether they relate to his own transactions or somebody else's.

The power to require the insider to provide copies of "documents or other materials" does not appear to be the power of 'seizure' of documents, etc.

By virtue of regulation 7(3), the investigator is entitled to examine or record statements of any member, director, partner, proprietor and employee of the insider. It is not clear as to what is contemplated by the use of the words "member" and "proprietor". Significantly, the power to examine and record statements is not extended to the insider himself.

The power to examine as mentioned in this provision is not the same as the power to examine a person on oath, nor does it confer on the

investigator the same power as are vested in a civil court under the Code of Civil Procedure, 1908 while trying a suit.

Regulation 7(4) casts on every director, proprietor, partner, officer and employee of the insider to give the investigator all assistance in connection with the investigation, which the insider may be reasonably expected to give. This provision appears to be a modified (but a distorted) version of sub-section (3) of section 209(A) of the Companies Act 1956, which reads: "It shall also be the duty of every director, other officer or employee of the company to give to the person making inspection under this section all assistance in connection with the inspection which ..The company may be reasonably expected to give."

What is actually intended is to provide that it shall be the duty of the insider (who is undergoing investigation) as well as his/its director, officer or employee to give the investigator all assistance in connection with the investigation which he is reasonably expected to give. Curiously, this sub-regulation, like sub-regulation (3), does not extend to the insider the aforesaid duty.

**(5) Investigator's report and communication of findings to the insider.**

Regulation 8 requires the investigator to submit to SEBI a report within one month of the conclusion of the investigation, and regulation 9 enjoins upon the SEBI to communicate to the insider the findings of the investigation. It also enjoins upon SEBI to give him an opportunity of being heard before any action is taken by it in pursuance of the investigation. This provision thus contains two important principles of natural justice, namely, communication of findings and opportunity of being heard.

The insider will also be entitled to give explanations and make a representation, orally as well as in writing, and it is thereafter that SEBI "may call upon the insider to take such measures as SEBI may deem fit to protect the interest of investors and in the interest of the securities market and for due compliance with the provisions of the Act, rules made there under and these regulations", vide regulation 9(2).

**(6) SEBI's power to make order.—**

It is unclear as to why a general order for "due compliance with the provisions of the Act and the rules made there under and these regulations" is contemplated by regulation 9(2). The order should be (so far as the future is concerned) in the nature of a preventive order or a cease and desist one such that the insider shall discontinue and not indulge in any practice of insider trading in future and shall file an undertaking with SEBI to that effect.

What are more confusing are the provisions of regulation 11 vis-a-vis that of regulation 9(2). Regulation 11 repeats almost verbatim the wording of regulation 9(2) except that the former authorizes SEBI to give directions while the latter to call upon the insider to take the measures of the nature mentioned therein. But regulation 9(2) confers on SEBI a general power of issuing such directions as it may think fit in the interest of the investors and the securities market whereas regulation 11 limits the scope of SEBI's powers of issuing directions to the three purposes mentioned therein, namely—directing the insider not to deal in securities in any particular manner; prohibiting the insider from disposing of any of the securities acquired in violation of these regulations; Restraining the insider to communicate or counsel any person to deal in securities.

As noted already, the SEBI's power of issuing directions, whether it be called directions, measures or by any other name, ought to be to issue directions which are of 'cease and desist' nature, like, for instance, that of the MRTP Commission, See section 36D of the MRTP Act, to the effect that SEBI shall, in pursuance of the investigation, by order direct that the practice of insider trading shall be discontinued or shall not be repeated.

It may be noted that any order passed by SEBI in exercise of the power conferred upon it by regulation 11 [or by regulation 9(2)] shall be without prejudice to the criminal liability, if any, that may arise under section 24 of the SEBI Act on conviction of the accused by the criminal court.

### **Conclusion and suggestion**

Company law 1956 is subject to criticism for absence of any direct provisions to tackle the insider trading problem though company's Bill ratified this gross mistake by clubbing section 173. Under this study it seems that there are various loopholes in the regulatory framework which untimely indicate that regulatory create confusion in mind. IMF report and Satyam case have created environment of confusion in mind of common investors. When world is under jaws of depression, Indian markets are trying to protect themselves but Satyam at same time scattered all hopes which resulted sever loss to common investors .It is very difficult to locate the exactly who suffered but no one could deny market and ultimately common investor has to suffer .Indian legislature took a wide connotations to define insider trading It includes directors, officers and employees of a company and related companies, persons with professional or business relationship with a company (e.g. auditors, solicitors, bankers and brokers), large beneficial shareholders, government officials and Stock Exchange employees etc. It also covers "tippers" or persons who receive

information from connected persons. As a matter of course, directors and employees have most (and direct) access to price-sensitive information and are therefore most likely to deal or tip other persons to deal on the strength of such information. However, this practice is not limited to directors but can be engaged in by anyone who has access to such information. In this sense, an outsider may be held to be an insider by virtue of his engaging himself in this practice on the strength of inside information coming to his knowledge or obtained by him either directly by reason of his being connected with the company, or indirectly from anyone who is connected with the company. Thus it seems that regulatory framework is defective and it create confusion in mind though it shows that gravity of insider trading impact but it does not result any fruitful result. On the basis of above discussion, IMF report and Satyam scam shows that there is urgent need to eliminate the loopholes in regulatory framework for better performance. obvious and understandable concern about the damage to public confidence which insider dealing is likely to cause and the clear intention to prevent so far as possible what amounts to cheating when those with inside knowledge use that knowledge to make a profit in their dealing. The practice of insider trading needs to be checked to maintain investor confidence in the integrity of the securities market inasmuch as the use of inside price-sensitive information by insiders for their personal advantage is not only not conducive to good business ethics and morally wrong, but it may damage public confidence in the securities market. Those who advocate prohibition against insider trading on the ground of equity' argue that the law should try to ensure that all individuals in the market are placed on an equal footing, in so far as that is possible. This requires, first, timely and adequate disclosure by companies of price-sensitive information and secondly, the prohibition of dealing on the strength of any such information which is undisclosed. This is designed to maintain investor confidence in the integrity of the market. The practice of insider trading needs to be checked to maintain investor confidence in the integrity of the securities market inasmuch as the use of inside price-sensitive information by insiders for their personal

advantage is not only not conducive to good business ethics and morally wrong, but it may damage public confidence in the securities market. Those who advocate prohibition against insider trading on the ground of equity argue that the law should try to ensure that all individuals in the market are placed on an equal footing.

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## MORALITY AND LAW IN THE INDIAN CONTEXT

Navneet Thanvi \*

Dr. Vikram Sharma \*\*

### **Basic Description of and Assumptions about Morality and Law**

Morality has been defined by numerous jurists but to no avail. Everyone has a different definition of morality and everybody perceives morality in a different sense. Philosophically, morality may refer to some codes of conduct set by a society or religion or group which have been accepted by an individual for his/her own behaviour. The word 'ethics' is commonly used interchangeably with morality and sometimes it is used more narrowly to mean the moral principles of a particular tradition, group or individual.<sup>24</sup> Although the two terms are mistakenly used as synonyms, morals refer to beliefs of an individual or a group or society regarding how people conduct themselves and are based on practices or teachings, while ethics are a set of principles or a philosophy behind them.

Law, like morality, is also a vague term to understand. It should be noted that the notions of law cannot be circumscribed within a few sentences. It is such a broad concept that words fail in their attempt to describe what law actually is. Many jurists have attempted to describe what law is since ages but have failed. This failure may be acknowledged to human psyche which is extremely random and versatile. One common definition of law is that law is a system of rules and guidelines which are enforced through social institutions to govern behaviour.<sup>25</sup>

According to John Austin, law is command of a sovereign backed by the threat of a sanction. Law has been called *Dharma* in Hindu Jurisprudence and *Hukum* in Islamic Jurisprudence while Romans call it *Jus* and French call it

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<sup>24</sup> The Cambridge Dictionary of Philosophy, 1995

<sup>25</sup> Robertson, *Crimes Against Humanity*, 90

*Droit*.<sup>26</sup> Law consists largely of 'ought' propositions prescribing how people ought to behave. These 'oughts' of law are dictated by social, moral and other purposes.

### **The Sphere of Law and Morality**

Law and morality are closely inter-related to each other. Both law and morality are the basis of regulation of the conduct of an individual in a group or a society. Laws, generally, are based on the moral principles of the society which have universally been accepted as morals in the society over years. The aims of morality in its social signification are directed towards increasing social harmony by diminishing the incidence of excessive selfishness, noxious conduct towards others, and other potentially disintegrative forces in social life.<sup>27</sup>

The distinction between law and morals is found in the fact that law regulates the external relations of men while morality governs the inner life and motivations.<sup>28</sup> The theory that the spheres of law and morality are exclusive of each other and also to external and internal conditions of a human being cannot be accepted. Inner conscience of man, as translates into actions, becomes the concern of law; so also, law often imposes standards and actions on proof of internal intentions.<sup>29</sup>

Early stages of the society do not possess any evidence regarding distinctions between law and morals. In ancient times, there was no distinction between law and morals. Later on, some distinctions came to be made in actual practice.<sup>30</sup> A comprehensive philosophical and legal analysis of the gray area in which the foundations of law and morality clash, views these oblique

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<sup>26</sup> Dr. N. V. Paranjape, *Studies in Jurisprudence and Legal Theory*, Central Law Agency, Allahabad, p. 191

<sup>27</sup> Edgar Bodenheimer, *Jurisprudence: The Philosophy and Method of the Law*, Universal Law Publishings, 2006, p. 291

<sup>28</sup> *ibid.* at p. 291-292

<sup>29</sup> *Boston University Law Review* available online at <http://www.bu.edu/bulawreview/>

<sup>30</sup> Ankita Mahajan, *Relation between Law and Morality or Ethics*, Journal for Ethical Sciences Vol.2, 1996

circumstances from two perspectives: that of the person who faces a possible conflict between the claims of morality and law and must choose whether or not to obey the penal code; and that of the people who make uphold laws and must decide whether to treat some with a moral claim to disobey differently from the ordinary lawbreakers.<sup>31</sup>

### **Relation between Law and Morals**

The relation between law and morals can be studied from the following angles:

**Morals as the basis of Law** – As noted earlier, there was no distinction between law and morals in the primitive society. Morals were followed as if they were laws. With the development of the mankind, the State came into being and it picked up those set of rules which were important from the societal view point and put its own sanction behind these rules and enforced them. These rules came to be known as ‘laws’. The residual set of rules which were meant for some supreme good of an individual and their observance could not be ensured by the State was called ‘morals’. Thus, it can be inferred that law and morals have a common source of origin.

**Morals as the test of Law** – It is a universally accepted principle that law must conform to morals. A law that has departed from morality cannot be said to be a valid law. A law cannot depart from the morals.

**Morals as the ends of Law** – The purpose of law is to enforce and maintain morality in the society. Therefore, morals have been considered to be the ends of law often.

### **Distinction between Law and Morals**

Morals are concerned with an individual while law concentrates mainly on the society and lays down rules that concern the relationship of individuals with each other and with the State. Morals lay down rules for molding the character

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<sup>31</sup> Kent Greenawalt, *Conflicts of Law and Morality*, Oxford University Press, 1989

of individuals. Morals look into motive of the conduct while conduct of an individual is the subject matter of law. Observance of morals is totally a matter of individual conscience. No one can be forced to observe law. It is his own personal choice. This is not so in the case of laws. The individual has to submit himself to the will of the legislature and is bound to follow laws. In the words of R. M. MacIver there must be one legal code for all but moral codes vary as much as the individual characters of which they are expressions.<sup>32</sup>

### **Is Law responsible for enforcement of Morality?**

Our behaviour is channelized by both law and morality. This channelization is accomplished primarily through the threat of sanctions if the laws are broken. Law and morality work against the background of other important factors of life that influence our behaviour such as reputational concerns, the cultural concerns, the societal concerns, etc. Law and morality work together to control a vast range of behaviour. The relative character of law and of morality is that of a means of control of conduct.<sup>33</sup>

### **Instances of clash between Morality and Law**

There have been many instances where morality and law have stood face to face. The main reason may be that a practice which is immoral may yet be legal. The concept of morality is totally based on the individual perception. Some of the instances are<sup>34</sup>:

#### **1. Live-in Relationships**

Live-in relationships have been one of the most debated and controversial topics in the recent days. Indian Law did not contain any specific provision regarding Live-in relationship and was silent about the legality of such

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<sup>32</sup> Raj Kumar Pruthi, *Political Ideas and Institutions*, Discovery Publishing House, New Delhi, 2005, p. 114

<sup>33</sup> Steven Shavell, *Law versus Morality as Regulators of Conduct*, American Law and Economics Review V4 N2 2002, p. 228

<sup>34</sup> The list is not comprehensive.

relationships. The controversy was put to rest through a landmark judgment<sup>35</sup> by the Hon'ble Apex Court in 2010. In another judgment, the Allahabad High Court had opined that a man and woman, even without getting married, can live together if they wish to. This may be regarded as immoral by the society, but is not illegal. There is a difference between law and morality. Since then, these relationships have been accorded a legal status. However, Indian society has been conservative always. The Indian society has high morals and still considers such relationships to be a social taboo. The Indian society is more inclined towards the divine concept of marriage and treats such relationships as alien.

## **2. Legalization of Abortion**

The subject of legalizing abortion has been an issue of controversy throughout the history. Much of these debates are related to the question that whether deliberate feticide is unlawful or not. There is a head-on clash between morals and law on this particular issue. According to Christianity, abortion is considered to be a curse and babies in the womb of their mother are regarded as people.<sup>36</sup> The oldest religion of the world, Hinduism, also strongly condemns the practice of abortion. Islam also does not allow abortion in general. The other side of the coin is that there is a section which proclaims logic and fairness in abortion by way of making the choice of abortion a right of the mother, irrespective of the months of gestation.<sup>37</sup> The supporters of this side have associated the right of a female to her body in the form of Right to Abortion at her own will with Right to Privacy and Right to Freedom.<sup>38</sup> In the USA, under the rule of George W. Bush, contraceptive pills were banned under the pretext of being unsafe. This depicts how morality and conservative attitude of the party in the power may influence the general practices of the inhabitants

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<sup>35</sup> S. Khushboo vs Kanniammal (2010) 5 SCC 600

<sup>36</sup> Raymond A. Zwerin and Richard J. Shaprio, *Abortion: Perspective from Jewish Traditions*, Religious Coalition for Reproductive Choices (2008)

<sup>37</sup> Don Marquis, *Why abortion is Immoral*, *Journal of Philosophy*, Vol. 68, 183-202 (1989)

<sup>38</sup> Shanya Ruhela and Soham Banerjee, *International Journal of Humanities and Social Science Invention*, Volume 2 Issue 2, pp. 32 - 37

of the country. Thus, for most of the religions of the world, abortion is a serious moral and ethical issue.<sup>39</sup> Being against the morals of majority of the religions, abortion is allowed in cases of emergency or unwanted pregnancy.

### **3. Same-Sex Relationships**

“God created Adam and Eve, not Adam and Steve”<sup>40</sup>, summaries the attitude and morality towards homosexuality. Same-sex relationship is not a new phenomenon. The moral and religious police have always being opposing it on the ground of it being immoral and against the society which is value based. It has only happened in the recent past that homosexual have come out in open and have started to demand rights for themselves and have started to get their relationships legalized.

### **Concluding Remarks**

The aforesaid instances clearly depict the clash between morality and law. In a progressive society, priorities and needs keep changing with time and it is a matter of personal choice to choose between law and morality. There may be some points of difference between morality and law. Nevertheless, there is a close affinity between both of them. The affinity is so close that the margin between illegal and immoral is not always clear. These two opposing views present a clash situation. Thus, to maintain harmony between the two concepts, it is safer to adopt a path synthesis between the two concepts.

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<sup>39</sup> *ibid.* at p. 33

<sup>40</sup> Victoria Clarke, *What about the children? Arguments against lesbian and gay parenting*, Women’s Studies International Forums, 555 – 570 (2001)

**Searching Success of E-Commerce most significant part in the new era of digital technology and information exploitation**

Dr. ARCHANA RANKA

**Abstract**

Digital technology and system of communication revolutionisations have terribly transformed our daily life, in the 1st decade of 21 century across the globe and particularly in Indian sub-continent. Business born transactions are made normally through computers now a days abandoning old practices. The cyber system enables to create, transmit, store, information and retrieve information. Though people are aware of these benefits but are still reluctant to conduct business or conclude transaction in electric form due to lack of suitable legal framework. Despite many legal provisions do recognise and encourage paper based records and documents even today. Hence the substitution of E-commerce to traditional commerce aims at elimination of the need for paper based transaction thus to facilitate e-commerce, UN commission on international trade Law has adopted the model on E-commerce 1996. India being a signatory has also ventured to facilitate E-commerce and E-governance and consequently enacted, I.T. Act 2000 and amended it in 2003 and 2008. However much still remains to be done without loss of time so as to compete fairly and fearlessly and stand on the same footing as other developed countries of globe do stand to day. Thus the paper aims at to explore the difficulties faced in exploring E-commerce to make it more secure and of course, consumer E-commerce, to make it consumer, oriented too so as to

serve world's greatest and largest democracy. It is also attempted to suggest the measures to eliminate legal forensic obstacle in the perspective of E-commerce.

## **I. Genesis**

**1.1** Originally e-commerce meant the facilitation of commercial transactions electronically, using electronic data Interchange (EDI) and Electronic Fund Transfer (EFT) Both of these were introduced in 1970 permitting business to communicate commercial documents e.g. purchase orders, or invoices electronically and by 1980s there grow the practice of credit cards, automated teller machines (ATM), telephone (mobile) banking, illustrates various new forms of E-commerce including railways and airline passenger seats reservation, typified by the Travicom in the U.K. and Saber in the USA. Online shopping also joined immediately this steam of electronic business i.e. e-commerce. Now by 1990 and afterwards Enterprise Resource Planning System (ERPS), Data Mining and Data Ware Housing stepped in with fastest speed. In 1990 Timberrners Lee invented the world wide web browser and transformed an academic telecommunication network into a worldwide every men's every day communication system called Internet/www though commercial enterprise on Internet was strictly prohibited. In 1994.The first on line shopping was started It took five years to introduce securely protocols, allowing continual connections to the internet. Many Euro and American business companies offered their services through world wide web (www) by the end of 2000. Since then only people began to associate a word E-Commerce with the ability to purchase various goods though internet using secure protocol's and electronic payment services.

## **1.2 Indian Perspective**

According to Indian E-commerce Report,<sup>1</sup> released by Internet and Mobile Association of India(IAMAI and IMRB International). The total online transactions in India was Rs. 9200 crores in the year 2009 and expected reach Rs. 15000 crores by 2010.

Where as NASSACOM<sup>2</sup> has recently while evaluating e-commerce stated that.

- (i) 60% Internet users take credit cards and 90% have mobile phones.
- (ii) This has ensured that e-commerce transaction in India shall gallop by leaps and bound, in forthcoming new era.
- (iii) Out of four NRIS, one NRI would make some form of purchase or other from Indian based web sites.

## **1.3 Some figures across the world's countries Concerning Internet / www.(web) E-commerce.**

- (i) Asia had 42% of world users of Internet i.e. 738 million on separately.
- (ii) Europe had 24% of world users of Internet i.e. 738 million on September 2009.
- (iii) America had 25% of world users of Internet.
- (iv) Asia had 46% of world users in 2007

## **1.4 The fastest growing area in the Middle East**

Administration of the justice in Asian perspective (Accepted objectives of Online Dispute Resolution – Fresh look) and Global E-Commerce (6 June 2011) assert thus:

- (i) Meeting commercial needs of disputant.
- (ii) Clarity and finality of out comes.
- (iii) Limiting of transect costs and overhead expenses.

- (iv) Upholding public policy.
- (v) Enhancing ethics and morality (Fair competition)
- (vi) Societal Needs and interest – satisfying border.

### **1.5 Drawback of IT Act 2000**

Nassacom and CII reports and many other business have observed that some difficulties associated with the information on online contract in the personal formulation of IT Act 2000<sup>3</sup>. It was argued that legal enforceability of E-contracts involving inter- national parties is neither defined nor implicit jurisdiction too. The Act was silent on the matters of taxation and E transaction as the jurisdiction of E-commerce was not defined even in amended IT Act 2009.<sup>4</sup> There was absence of provision for dual key pairs for individual and business.

Most important difficulty was crime control and detection and this had great concern for shy growth of E-commerce The perfectly trained law enforcement agency was not equipped with skillful safe guards to protect privacy and business data collected over internet were not covered under IT Act 2000 The protection of IPRS, (including domain names) did not find place in it. Finally Payment Gateways have to evolve that interbank settlement should be enabled through Real Time Cross Settlements (RTCS).

Since 27.10.2009 most of the difficulties have been attended to be removed by IT,(Central) Act no. 10 of 2009. IT Act 2009 also has amended, IPC 1866, Indian Evidence Act 1872; The bankers Book Evidence Act, 1891 and Reserve Bank of India Act 1934.<sup>5</sup>

In addition to it "The Communication Convergence Bill" is waiting for being enacted by parliament which is concerned with the licensing and registration of powers and regulatory mechanism for telecom, info tech and broad casting sector and replace many categories of licenses to enable service providers to offer a range of services classified as below :-

- (i) To provide our own network infrastructure.
- (ii) To provide net work services
- (iii) To provide network application services
- (iv) To provide content application services
- (v) To provide valued added work application services

The Communication Convergence Bill<sup>6</sup> proposed to repeal (1) Indian Telegraph Act 1885 (2) Wireless Telegraphy Act 1933 (3) Telegraphs wires (unlawful possession) Act 1950 (4) The Telecom Regulatory Authority 1977 (5) The cable T.V. Network Act 1995.

The Bill may or may not take shape of law in near future but these matter were considered while amending IT Act in 2008. IT Act (2000) and the duly amended Act 2009 seeks to remedy most of these problems.

## **II E-commerce**

### **2.1 Brief look at E-commerce**

A document full fills multitude of functions but the E-commerce / business in concerned with two of them are worth displaying

- (i). It can be used as evidence
- (ii). Symbolic function to show and prove ownership. If the document is signed it can be used for :
  - (a) Identifying the source of document
  - (b) Confirming the information
  - (c) Signatory responsibility constituting proof to create characters of information

## 2.2 IT has changed the way business was being conducted.

Now the business is being done paperlessly. Using E-data Inter change (EDI) has made possible to gain benefit of signed document which is computer to computer transmission of business data in standard format and more secure than e-mail the problem of symbolic function on paper is yet to resolved. By providing, "Model UNCIRAL Law" as the basis for IT Act it has brought international (uniformity) in the use e-communication however this contention is also seeking amendment (draft of it can be seen on [http : www.unis.unvienna.org / unis / pressrels / 2005 / unis/961/ html](http://www.unis.unvienna.org/unis/pressrels/2005/unis/961/html)).<sup>7</sup>

Prior to IT Amendment Act 2008, the E records could be authorised by digital signatures only (Sec 3 IT Act) Sec 4 where as provides authenticity to E Records and E signature if affixed (including digital signature under sec. 5).

"Bill gates" has explained digital signature to secure and confidentiality in his book ("The Road to ahead")<sup>8</sup>

The public key encryption is slow and time consuming, so the hash function where which transforms a message into unique shorter fixed length value and it is referred to digest value / hash value one can not reconstruct the original message from hash results. The encryption of hash result of the message with private key of sender is called digital signature. The receiver may obtain hash result by applying public key of sender on line digital signature i.e. decrypting the digital signature through the public key of sender. Thus digital signature and document signed electronically is authenticated.

E Signature (Sec. 3) means :-

- (i) Typing name in E document
- (ii) The click wrap of indicating intent
- (iii) Personal identification number
- (iv) E-mail address
- (v) Manuscript Signature

(vi) Body name verification

(vii) Lastly advanced / or secure E-signature But all one nor reliable

Forging or product a fake a document record is punishable So IPC was amended by sec 91 of IT Act (2009).

By 2008 amendment sec 6A, 7A, and 10A were inserted to increase E governance, particularly sec 10A which accords legal sanctions to the controls inhered in a electronically

Since internet is borderless one can obtain information or conduct business from any part of the world and this is raising legal issues that are to be dealt with globally.

Three cases can be cited in this context for attribution, acknowledgement a dispatch of E Records.

- a. Dow Jones & Company INC. Vs Gutick [2002] HC A56 imported Vs/ Gutniol (2002) CA 56.<sup>9</sup>
- b. Young Vs New Haven decided by US Court of Appeal 4th circuit court.<sup>10</sup>
- c. Katherine Griffs Vs Marianne Luban decided by Supreme Court of the state of minnesota<sup>11</sup>

In internet and net working problems regarding conflict of laws are to be dealt with globally<sup>12</sup> and security concerns (preventive measures) that is cyber slurring also. *There is no shield that can not be Pierced ; no fort that can not be breached, and no computer system cannot be hacked. However e-commerce and IT will loose their relevance unless computer system are secure.* IT Act chapter V to VIII deal with preventive measures and chapter X to XII with civil and criminal liability where as chapter IX and X deal with penalties, compensation and adjudication (R Vs Gold 1987 All ER)<sup>13</sup> affirmed by House of Lord in 1988 (2) All ER 186 and observed and affirmed that conduct of accused amounted to dishonestly going access to relevant prestel data bank by trick this is not a criminal offence.<sup>14</sup> That is matter of legislature/parliament to make for and

which it could do so. Law commission has made, "Hacking" as an offence punishable. Same is the position in India. The IT (Amendment) Act 2008 tries to address these problems (called gray areas) where as data protection is the civil liability (to keep confidentially) loss of privacy is another major work where Internet work is concerned" says Bill Gates<sup>15</sup> Section 43-A and 72-A IT(Amendment) Act 2009 provide for payment of compensation and Sec 46 deal with quantification of damages chap X deal with tribunalisation.

### **III. Offences / Crimes :-**

To tamper computer source document is punishable under sec. 65 and person offending may be penalised by imprisonment for three years or fines upto Rs. 2.00 lakhs.

DOS attack means preventing imprisonment legitimate users of a service from using that service when a web server is flooded with request for information over whelming the system though it harms not the security, but it affects by loss of time, and money due to disruption of services (sec 66 makes it however punishable).

### **IV. Advanced Spyware :**

This is very common problem Sec. 66 deals with it but prior to amendment the section heading was "Hacking" with computer system, asserting sec 43 and 66 punish the offender for imprisonment upto 3 yrs. or 'fines extending up to Rs. 5 lakhs.

### **V. Cyber stalking spam and Spam Phishing and other offences and unsolicited sexual assault Emails.**

Annoyance and frightening is an offence under Sec.. 499 (Defamation) of IPC Criminal intimidation (Sec of IPC 503) are its illustration Also 509 of IPC which, defined insulting modesty of women, form computer offence which is not the case of it directly in addition to IPC.

Obscenity and pornography it is additional menace sec 67, 67 A, 67 B, dealt with by the amendment provides the punishment for imprisonment upto 5-7 year and fine upto Rs. 10 lakhs. in such cases and 67 A and 7B were brought and inserted newly by way of 2008 amendment.

#### **VI. Presentation and Retention of information. :**

Sec. 67 (c) was brought by amendment in IT act 2000 (since 27-10, 2009) which require preservation and retention. In computer world nothing is confidential. Everything could be found out it is till permanently destroyed or over written.

Therefore it is necessary that information should be preserved and retained.

#### **VII. Conclusion and Suggestion :-**

E-commerce is rapidly growing in India as well as in the globe but still the risk of fraud humilities, and credit card security hence have been main concern for the consumers who need legal protect.

Our analysis, thinking and pondering or examination of the scenario put us in dilemma as to what extant how much control should be left with business and how much for the government. Looking specially performance of contract transaction truncation of check, money, transfer through banks and Electronic Fund Transfer of Funds, sanctioning of loans and putting arbitrary conditions by Banks for education or home loans are making human life miserable. The duty and liabilities and accountability is more needed in criminal sector, but it can't escape for civil liability too where-as business practices are to be developed to enhance ethics and morals.

Finally B2C self conduct of code should be made to defend and protect consumer is all the while essential in the post modern India (in recent present period as well on future.) for the success of Email Commerce.

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## FOOTNOTES

1. Indian E Commerce Report – released by IMAI and IMRB – International – (2009)
2. Nassacom
3. IT Act 2000
4. IT Amended Act of 2009
5. Ibid
6. Communication Convergence Bill(Awaited to be enacted)
7. [www.unis.unvienna.org / unis / pressrels / 2005 / unis/961/ html](http://www.unis.unvienna.org/unis/pressrels/2005/unis/961.html)
8. Bill Gates- (The Road to Ahead)
9. 2002 HCA 56 (1)\
10. [http://pacer.ca4.uscourts.gov/ opinion/pdf/012340.p.pdf](http://pacer.ca4.uscourts.gov/opinion/pdf/012340.p.pdf)
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13. R Vs Gold All ER 1987
14. 1988(2) ALL ER 186
15. ‘The Road to Ahead’- Bill Gates

## **PATENTING OF MICROORGANISMS**

**-Dr. P.K. Musha**

- Dr. Nidhi Sandal

### **INTRODUCTION**

A patent is a bunch of exclusive rights granted by the state to an inventor or his assignee upon satisfying certain conditions. The inventor is given a monopoly right over the product for a fixed number of years in exchange for the public disclosure of certain details of a machine, method or composition of matter. The object of patent law is to encourage scientific research, new technology and industrial progress. It stimulates new inventions of commercial utility. The patent is granted for a limited period to the inventor. After the period of expiry of the patent the monopoly goes into public domain. Lately patent regimes around the globe have recognized the utility and innovative prospects of patenting of microorganisms.

In initial days of development of patent mechanisms there was an over burden of Ethical and Moral firewalls surrounding the idea of resting the right of commercial exploitation of certain substances and resources in the hands of a selected few. Patenting by many was opined as a capitalist centric idea. The taboos were even more incasing of patenting life forms, considering the religious, moral and notional values attached. With advancements in Pharmaceutical Industry and increasing stress on biotechnological research, pressure started mounting on policy makers to allow such patenting of basic life forms so as to encourage research and development [R&D] initiatives in the field which can contribute in exploring the unrecognized commercial utility of such life forms. Thus with the landmark decision of the U.S Supreme Court in the case of *Diamond v Chkrabarty*<sup>41</sup> flood gates were open for patenting of microorganism not just in Unites States but as a subsequent after effect , in

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<sup>41</sup> 447, U.S., 303 1980).

various legal regimes around the globe. Section 27 of TRIPS recognize 'Microorganisms' as a patentable subject matter and thus in compliance of the same many nations<sup>4</sup> have now allowed patenting of microorganism through their domestic patent laws.

In today's world, genetic experimentation has become an international commonplace. Developments in genetic research have already provided society with dynamic technological advances. The revolution in biotechnology is one of the most important developments affecting industry in the twentieth century. Biotechnology has captured the attention of all nations. Every country is prepared to spend large funds to promote research and development in biotechnology. New techniques have been developed to create novel life forms. But, the laws regulating and protecting these experiments and their subsequent innovations continue, however, to sputter at an inchoate stage. One reason for the situation can be the different economical and ethical standings of nations which are being tried to be brought under the umbrella provisions of the WTO. This paper makes an attempt to analyze all these legal and ethical issues involving patenting of microorganisms. Apart from throwing light over the evolution of laws governing the field in various nations, the paper also tries to bring to picture, present day status of these legal provisions in light of the new technological advancements. After discussing the status quo around the globe, Domestic provisions in India have been looked into and significant case laws have been discussed. In the last part of the paper the researcher comes up with his conclusion on the issue and put forths his own relevant propositions.

### **AROUND THE GLOBE**

In countries across the world the so called "products of nature doctrine" excluded living matter from patentability. The products of nature doctrine precluded patentability of materials existing in nature, including living matter. Under this doctrine, one could secure patents for fermentation processes and

purified, naturally occurring chemical or biological compounds, as well as patents for microorganisms as a culture or in combination with a carrier. The product claims for the microorganisms, however, were not patentable because they comprised living material - microorganisms.

### **IN UNITED STATES OF AMERICA**

In U.S.A however the case of *Diamond v. Chakrabarty* only that opened new vistas of bringing forms of life, specifically microorganisms under the preview of patenting, in the case Supreme Court of the United States considered the question of whether a microorganism is patentable subject matter under the United States patent laws. Chakrabarty, a microbiologist, sought to patent a genetically engineered bacterium which degrades crude oil; a characteristic which makes it extremely valuable for controlling oil spills. The patent examiner denied *Chakrabarty's* patent claim for the bacteria itself, but allowed his claims for products and processes involving the bacteria. The examiner denied the bacteria patent, finding that a micro-organism is a "product of nature" which, as a living thing, and thus cannot be patented. However when the case reached the Supreme Court, in a 5-4 ruling, the Court held that a live, human-made micro-organism is patentable subject matter under section as a "manufacture" or "composition of matter."

In addition to the *Chakrabarty* decision, revisions in Federal patent policy encouraged increased patenting of living organisms and related processes. Prior to 1980, no single patent policy existed for government-supported research, despite the Federal Government's preeminence in biotechnology related research funding. Instead, each Federal agency developed its own rules, resulting in 26 different patent policies. Under this system, only about 4 percent of some 30,000 government-owned patents were licensed. Furthermore, the government policy of granting nonexclusive licenses discouraged private investment, since a company lacking an exclusive license was unlikely to pay the cost of developing, producing, and marketing a

product. Thus, potentially valuable research remained unexploited. To resolve this problem, Congress passed the Patent and Trademark Amendments of 1980 (Public Law 96-517) as amended in 1984 (Public Law 98-260) to promote efforts to develop a uniform patent policy that would encourage cooperative relationships and to commercialize government funded inventions. From 1980 through 1984 patent applications by universities and hospitals for inventions containing human biological increased more than 300 percent as compared to the previous 5-year period. The policies adopted by Congress in 1980 and 1984, which gave statutory preference to small businesses and nonprofit organizations, were extended to larger businesses (with some exceptions) in 1983. The Technology Transfer Act of 1986 (Public Law 99-502) granted Federal authority to form consortia with private concerns. Executive Order 12591, issued in 1987, further encouraged technology transfer programs, including the transfer of patent rights to government grantees. In combination with the *Chakrabarty* decision, these actions helped spur patent activity.

### **IN EUROPIAN UNION**

After 10 years of debate, the EU adopted Directive on the legal protection of biotechnological inventions in 1998 (Directive). In contrast to the situation in the US, the Directive has clear provisions stating that certain inventions will not be patentable because their commercial exploitation would offend against "order public" and morality. The European Union in the European Patent Convention has defined "biological material" instead of "micro-organism", as - "Biological material means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system" The Directive was incorporated into the European Patent Convention (EPC) in June 1999 and therefore impacts the EPO's examination of European patent applications relating to biotechnology inventions. The Directive directly addresses patenting life forms. Under the Directive (and the EPC and EPC Rules amended as a result of the Directive), plants or animals may be patentable if the technical feasibility of the invention is not technically confined

to a single plant or animal variety. This changed the EPC's prior wording that explicitly excluded plant and animal varieties from patentability. The Directive states at Article 6 that the human body at the various stages of its formation (including the embryo and sequences or partial sequences of genes) is not patentable. However, the Directive states that an element of the human body (including the sequence or partial sequence of a gene) that has been isolated from the body by means of a technical process may be patented even if the structure of the element is identical to that of a natural element. To be patentable under the Directive, as was previously true in the EU, the isolated element must still be novel, involve an inventive step and be capable of industrial application.

### **IN AUSTRALIA**

The Australian patent law defines invention as "any new manner of manufacture."<sup>18</sup> The question of patents for living organisms was considered at length in the case of *Ranks Hovis v McDougall Ltd.'s Application*<sup>42</sup> and the Court held that- "No objection can be taken to a claim to a new organism on the ground that it is something living. Any new variants claimed must have improved or altered useful properties and not merely have changed morphological characteristics which have no effect on the working of the organism; and Naturally occurring micro-organisms per se are not patentable as they represent a discovery and not an invention, but a claim to a pure culture in the presence of some specified ingredients would satisfy the requirement of a technical intervention. The guidelines for a micro-organism in Australian Patent Law states, "What is discovered in nature without any practical application, is a mere chemical curiosity and is not patentable. However, isolated micro-organisms are considered patentable.

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<sup>42</sup> (1976), 46, AOJP 3915.

## **IN JAPAN**

In 1997, the Japanese Patent Office (JPO) published its 'Implementing Guidelines for Inventions in Specific Fields'. Inventions in the biotechnology field in the Guidelines are divided into four types: genetic engineering, micro-organisms, plants and animals. Inventions relating to genetic engineering include those of a gene, a vector, a recombinant vector, a transformant, a fused cell, a recombinant protein, and a monoclonal antibody. Inventions relating to micro-organisms include micro-organisms per se as well as those relating to the use of micro-organisms.

In Japan, micro-organism means yeast, molds, mushrooms, bacteria, actinomycetes, unicellular algae, viruses, protozoa, etc. and further includes undifferentiated animal or plant cells as well as animal or plant tissue cultures.

## **POSITION IN INDIA**

In India, the position was made clear after the 2002 amendment to the Indian Patents Act. Before the amendment, the unamended Section 3(j) of the Act stated that plants and animals in whole or in part thereof including seeds, varieties and essentially biological process for the production of plants and animals are excluded. However in India after the 2002 amendment micro-organisms can be patented provided they satisfy the other requirements.

Sadly there is dearth of judicial dicta with respect to patenting of microorganisms in India. However an unreported Kolkata HC decision throws some light on this aspect. In *Dimminaco AG v Controller of Patents & Design*, The applicant, Dimminaco AG, had applied for a process patent involving the manufacture of a live vaccine for protecting poultry against infectious bursitis. However, the application was rejected by the Indian Patent Office stating that the definition of "invention" in the Patents Act did not include a "living organism" thus any process that resulted in a "live vaccine" would not qualify as a "manner of manufacture". The Kolkata High Court, rejected the findings of

the Indian Patent Office and held that the dictionary meaning of the word 'manufacture' does not exclude the process of preparing a commodity which contains a living substance". Following this decision process patent was issued to the applicant from the patent office. Apart from the above case, another former case is *Vandana Shiva and Ors v. Union of India* which briefly touches upon the issue of patenting of microorganisms in the general light of patenting of all living forms. In the above case, Four petitioners had sought a writ of mandamus restraining the Union of India from signing/ratifying the existing version of GATT Treaty,' or to restrained the Union of India from, agreeing to sign and signing Art. 27.5.3 (b) of the TRIPs Agreement. They also seek a direction for exclusion of *patents on life-forms including plants, animals, human beings produced through biological or microbiological processes, whether natural or modified on grounds of public morality and public order*. They seek a further direction against Union of India from violating the fundamental rights and ensuring their protection while signing the Treaty, the right to health and nutrition ensured by the existing Indian intellectual property regime and patent system which had ensured the exclusion of patents on life forms and patents on products in the area of health and. agriculture on grounds of morality and public order and also in respect of rights of farmers including the right to seed as owners, producers, breeders and innovators etc.

The High Court of Delhi however took the view that the signing of any treaty, in this case the GATT treaty cannot be challenged if there is no infringement of fundamental rights of the citizens. The Court was of the view that it was a *matter of policy* which was best left to the executive. While citing British and American sources it concluded it was best to a non-interfering policy in this regard. The point to note here is the reluctance of the courts to interfere with "a matter of policy" of the executive even if the challenge is based on the grounds of public morality and public order. Since now the matter is some what settled after the decision of the Calcutta High Court, still a binding

decision of the Supreme Court is still awaited to give a final verdict on the issue.

### **CONCLUSION & SUGGESTIONS**

Patenting of life forms may have at least two dimensions. Firstly, there is the ethical question of the extent of private ownership that could be extended to life forms. The second dimension relates to the use of IPRs' concept as understood in the industrialized world and its appropriateness in the face of the larger dimension of rights on knowledge, their ownership, use, transfer and dissemination. The TRIPS Agreement makes it mandatory to provide patent protection to micro-organisms and non-biological and microbiological production of plants and animals. This makes it difficult for the developing countries to exclude inventions within this category altogether. Hence, the strategy should be how to limit the scope of these provisions. As far as the patent protection of micro-organism is concerned, TRIPS does not provide a definition of micro-organism. The national rule-makers must define micro-organism in such a way as to include the following: bacteria, virus, and fungus and algal space.

Another important way to limit the scope of patent protection to biological materials is to make a difference between the concept of invention and discovery. Micro organisms as such occur in nature. If any micro-organism is discovered it cannot be called invention, it falls in the category of discovery. Micro-organism when genetically modified falls in the category of invention because of human input. Genetically modified micro-organism may perform any number of activities. If a researcher is able to research upon a particular activity, and he is allowed patenting of his genetically modified micro organism this will result in blocking of further research on that micro-organism.. Also since only inventions are qualified for patenting, naturally found micro-organisms, DNA structure, genes, blood cells, etc., can be excluded from patent protection. Nations can also exclude certain inventions in biotechnology by

relying on the exclusion provision available under the TRIPS Agreement which permits the state parties to exclude certain inventions which are injurious to health and environment of human and animals. Using this exception a member state can exclude terminator type technologies from patent protection.

The most important difference between the patent law of the India and developed countries is that India do not allow patenting of microorganisms that already exist in nature as the same is considered to be a discovery as per the provisions of the section 3(d) and therefore not patentable. But genetically modified versions of the same microorganisms that result in enhancement of its known efficacies are patentable. European and Australia/US or some other approach better suits the needs of its emerging economy rather Indian approaches in relation to patenting of biotechnological product and processes. Companies and investors venturing into the biotech sector need to fully realize the significant role intellectual property plays in the commercialization process for Biotechnological innovation.

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**PATENTS LAW AND TRIPS: COMPULSORY LICENSING OF PATENTS, AND  
PHARMACEUTICALS**

- Prashant R. Dahat <sup>43</sup>

## **INTRODUCTION**

### **The Evolution of International Patent Law: Scenario Before and After TRIPS**

Harmonization of international intellectual property laws has been the object of

considerable recent effort under both public international law<sup>1</sup> and international trade law. The GATT Uruguay Round Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) resulted in significant steps toward harmonization. However, most of the harmonization efforts implemented to date have focused on procedural matters, such as international patent application procedures, and the duration of patents.<sup>3</sup> The World Intellectual Property Organization (WIPO) conducted negotiations toward substantive harmonization under the auspices of the United Nations.<sup>4</sup> However, WIPO negotiations, whether viewed as favorable to developing or developed nations, were routinely foiled. Conflicting policy concerns resulted in polarized approaches to IPR regulation where in developed nations sought protection of their economic interests and developing nations

sought protection of their sovereign rights. Consequently, under the international public law regime, negotiations for IPR as an isolated issue failed because neither developed nor developing nations compromised.

In 1994, on conclusion of the GATT Uruguay Round, regulation of international IPR shifted from the public law regime to the trade law regime.<sup>6</sup> The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) incorporated significant regulation of international IPR as a requirement for parties to GATT, and was a major first step toward substantive harmonization of international IPR.

Under the trade law the parties compromised. Countries that were parties to GATT were required to comply with TRIPS in order to receive the

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trade benefits available through GATT, namely most-favored nation (MFN) status and national treatment. Further, TRIPS raised the threat of cross-sector retaliation--the imposition of trade sanctions against an economic sector unrelated to IPR. This cross-sector threat created an added pressure to compromise from within third world nations; lobbying from domestic economic sectors unrelated to the IPR debate, such as the textile industry, likely put pressure on governments to enact TRIPS-compliant IPR regulations in order to maintain MFN (most favored nation) status and national treatment. International IPR, including patent rights, was markedly strengthened under TRIPS.

Member nations were required to extend national treatment and MFN status, with respect to IPR, to nationals of other member nations. Parties to GATT were required to extend a minimum standard of protection for IPR. With regard to patents; some minimum protections were expressly defined. Patent protection was required for a minimum of twenty years. Patent protection was required for "any inventions in all fields of technology." Thus, countries that had previously declined on policy grounds to allow patents on certain kinds of inventions (such as pharmaceuticals) or that had no patent systems at all were required to grant patents to the full range of inventions addressed under TRIPS. IPR enforcement procedures were required to be fair, equitable, and not unnecessarily complicated or costly. Further, the GATT Uruguay Round included the Understanding on Rules and Procedures Governing the Settlement of Disputes, which applied to all disputes under GATT, including TRIPS.

The understanding enhanced the ability of the Dispute Settlement Body (DSB) to enforce GATT agreements, including TRIPS, in that it instituted reverse consensus that is, it required consensus to block the DSB panel report and prevent resolution of the dispute. Prior to institution of reverse consensus, any member nation could block resolution of a dispute with a single vote; under reverse consensus, dispute resolution will proceed unless there is consensus among member nations that the DSB panel report should be blocked. TRIPS included some concessions to address the concerns of developing nations regarding policies of economic development and the need to take protective measures. Developing and least developed nations were not required to implement TRIPS immediately. Developing nations received an additional four years and least developed nations received up to ten years to comply. Further, TRIPS provided for compulsory licensing under certain conditions and with reasonable compensation. Despite these concessions,

stronger IPR under TRIPS were highly favorable to developed nations and were viewed by some as coercive provisions that trampled upon developing nations' sovereignty and legitimate concerns. Opportunities exist to interpret TRIPS in a manner that is respectful of both developed and developing nations' policy concerns, ensuring the long-term viability of TRIPS and procuring for all nations the benefits to be derived from innovation promoted by IPR. One such opportunity presents itself in the interpretation of "adequate remuneration" for compulsory licensing of pharmaceutical patents under TRIPS.

### **Definition of Compulsory Licensing**

A '*compulsory license*' is an authorization given by a national authority to a person, without or against the consent of the title-holder, for the exploitation of a subject matter protected by a patent or other intellectual property rights. In some cases, particularly in the area of copyright, 'statutory licenses' are established. These are licenses *ex lege* that may be enjoyed by anyone without being specifically authorized, generally against the payment of compensation to the title-holder.

A compulsory license is an involuntary contract imposed upon a patent holder by a government entity; the compulsory license grants permission to the government entity or a third party to use the IPR to further some political or social objective. Compulsory licenses are a public right reserved by many nations as a safeguard against the dangers inherent in the monopoly granted by a patent. Compulsory licenses may be granted where a patent is acquired or used improperly.

Further, under TRIPS Article 31(a), compulsory licenses can be implemented only where conditions present a compelling need. Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement.

Compulsory licenses may also be granted where a patent holder refuses, typically on economic grounds, to use the patent to make available to the public the product or process protected by the patent. Under such a scenario, the public is denied access to the protected product or process because the patent holder has refused to make it available and has the right to prevent any other party from so doing. If the patented product or process is required to

address a critical need, national and international laws have traditionally provided for compulsory licensing to meet that need.

Innovative pharmaceutical companies have rapidly invented new medicines to fight against chronic conditions and notorious diseases such as AIDS that have plagued the worldwide population. Along with this innovation, however, emerged a lack of accessibility caused by pharmaceutical companies' ever-rising drug prices that are prohibitive to the poorest countries, which coincidentally have some of the sickest populations. While there are legitimate arguments to both sides on whether the increase

in drug prices is a necessary evil,<sup>22</sup> no one can dispute the burdens it places on poor populations.

Even in the United States, many Americans have resorted to filling their prescriptions with drugs from foreign countries.<sup>23</sup> In fact, prices for prescription medication are continuing to rise above the inflation rate.<sup>24</sup> Seeing as how the U.S. boasts one of the richest economies in the world, it is not surprising that one third of the worldwide population does not have any access to essential medication.

### **Compulsory license due to abuse of patent rights by the patent-holder**

Article 8 of the TRIPS Agreement and Article 5A of the Paris Convention deal with the abuse of patent rights by the patentees. These Articles provide that suitable measures could be taken by the government to prevent abuse. Abuses arise when the patentee is charging a high price for his patented product, and the relevant product is not available in sufficient quantities to meet domestic demand either through imports or domestic production by the patentee. The grounds could be stipulated as any one of the following; That the reasonable requirements of the public with respect to the patented invention have not been satisfied. That the patented invention is not available at a reasonably affordable price. That the patented invention is not being worked in different regions of the country to meet demand. The validity of the above grounds would be examined and terms and conditions for grant of compulsory license for any of the reasons stated would be settled by the Controller of Patents in consultation with the patent-holder. There is also no need for the intended enterprise to approach the patent-holder first to apprise him of the abuse. The stipulation in the Indian Patents Act in this respect needs to be suitably modified.

## **Compulsory Licensing Under TRIPS**

TRIPS stand for 'Trade Related aspects of Intellectual Property Rights'. It was instigated by the WTO as a means of 'striking a balance between providing incentives for future inventions and creations in the long term, whilst allowing people to use existing inventions and creations in the short term. In brief it aims to protect the rights of those who invent products and ensure that they are getting the support financially to fund the development of their products, whilst still allowing for the use of the products to support future developments by other individuals or groups. Patents provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions. WTO members have to

provide patent protection for any invention, whether a product (such as a medicine) or a process (such as a method of producing the chemical ingredients for a medicine). Patent protection has to last at least 20 years.

There are some exceptions to this, which are as follows;

- 1) Inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health.
- 2) Diagnostic, therapeutic, and surgical methods for treating humans or animals.
- 3) Certain plant and animal inventions.

So for example, if a country as signed up to the TRIPS agreement and GlaxoSmithKline invent a new drug for TB they can apply to that government for patent protection. When granted this would prevent any generic production by other companies of this drug, preventing pricing competition and ensuring that Glaxo got their money back for the research and development of the drug.

TRIPS does not expressly provide for compulsory licensing. Article 31 of TRIPS,

however, effectively provides for compulsory licensing by allowing "other use of [patents] without the authorization of the right holder. The compulsory licensing provisions under TRIPS have limitations, the most significant of which include:

- (1) the compulsory license may be granted only after reasonable negotiations have failed (this provision may be waived in case of national emergency);
- (2) the scope and duration must be limited to the purpose for which the license was authorized and must cease if and when conditions change to eliminate the purpose;
- (3) the license must be exclusive and non-assignable;
- (4) the license shall be used predominantly for the supply of the national market of the granting nation; and
- (5) the right holder shall be paid adequate remuneration under the circumstances of each case.

The limiting provisions under Article 31 have been described by developed countries as too liberal and by developing countries as too restrictive. However, Article 31(a), which states that “authorization of such use by compulsory license shall be considered on its individual merits,” apparently suggests that the DSB will have significant leeway in balancing the respective interests of developing and developed nations when it interprets Article 31. Article 31 (k) of TRIPS offers a procedure for remedying anti-competitive practices. Where the situation of resorting to anti-competitive practice by the patentee has been determined after judicial or administrative process, and that the need to remedy the practice has been notified by the government in the official gazette, the Controller of Patents will issue a compulsory license to remedy the situation. The terms and conditions of the compulsory license will be decided by the Controller of Patents.

### **Compulsory Licensing in India**

The Indian experience shows, the grant of compulsory licenses is riddled with technical absurdities. Under Section 84 of the Patents Act, an application for the grant of compulsory license can be made to the Controller of Patents only after the expiration of three years from the date of the grant of a patent.

In a world where diseases spread in epidemic proportions, a monopoly to manufacture and market a life-saving drug for three years can result in certain havoc.

The Section also requires the person making the application to set out the nature of interest and provides an opportunity for the patent holder to

oppose the application. All this may sound fine in the interest of natural justice, but as compulsory licensing would be resorted to in emergency situations; any difficulty in seeking a grant would unnecessarily delay the process. Delay in getting access to life saving drugs would literally be a matter of life and death.

Chapter XVI of the Patents Act deals with compulsory licenses. This chapter is drafted a long the lines of Article 31 of the TRIPS Agreement. It is pertinent to note that the Article deals only with “use” and not with “manufacture” of patented articles.

So far, compulsory licensing has been generally understood to include a right covered by the patent. Currently, only process patent is available for drugs and medicines. Accordingly, a compulsory license so granted will be to the extent of the preceding process patent.

Moreover, under the Indian Patents Act, the grant of compulsory license is available only for drugs patented under the Act. It does not provide for compulsory licensing of drugs patented elsewhere. This loophole has been exploited by many pharmaceutical majors who prefer to export their drugs into India and have chosen not to apply for a patent in India.

## THE NEED FOR THE COMPULSORY LICENSING IN PHARMACEUTICALS

### **Risks of Arbitrage and Counterfeit Drugs**

Arbitrage, also called “parallel trading” and “diversion” within the context of

international trade, is a problem that manifests when a buyer purchases products at below market price and subsequently exports the products to another market where they are priced higher. In terms of economics theory, arbitrage essentially shifts surplus from the producer to the consumer. A good example of this practice occurs between Canada and the United States.

The general consensus is that pharmaceutical arbitrage poses a danger to innovation because it undermines already-existing efforts to provide affordable drugs through differential pricing and reduces the revenue needed to keep pharmaceutical research and development a profitable investment. However, Kevin Outterson, J.D., has written a fantastic article suggesting that arbitrage in the pharmaceutical industry is not a serious threat to innovation, and may even benefit society by making drugs more affordable. Unlike many articles that limit the scope of analysis to economics principles when

discussing the effects of arbitrage, Outterson consistently weighs his economic analyses against social welfare.

Still, this is currently the hottest topic for economists regarding whether providing access to drugs through compulsory licensing will have a detrimental effect on the market, and consequently hinder innovation - perhaps because the U.S. Congress recently passed the Pharmaceutical Market Access and Drug Safety Act in 2004. There is a wide range of opinions that speak to how the new law will affect the pharmaceutical market. Adding to the controversy is the lack of uniform rules for protecting the rights of patent holders. That is, TRIPS does not address whether patent rights are exhausted once patented products are sold into the market stream. In fact, TRIPS does not currently mandate its members to adopt any specific measures to prevent arbitrage as a precondition to compulsory licensing. There is, however, a provision requiring drugs made under compulsory licenses to be designated by distinctive packing, colors and shapes to help quickly detect acts of arbitrage and identify the source of production or export. The distinctive look requirement can also help the WTO adopt a uniform rule of exhaustion for pharmaceutical products that are manufactured under a compulsory license. For now, the WTO requires members who import and export pharmaceutical products under a compulsory license to send notice of the details of the transaction, such as name of the drug, name and address of the manufacturer, name and address of the importer, quantity, and duration. However, importers are only expected to take "reasonable measures" to prevent re-exportation.

A similar risk to arbitrage that is frequently included in compulsory licensing discussions is the production and export of counterfeit drugs with no therapeutic value. This is perhaps the most severe threat to public health as people will not be able distinguish a counterfeit drug by its physical appearance. Pharmaceutical companies argue that compulsory licensing with no clear standards against arbitrage will increase the probability that consumers in developed countries will inadvertently purchase dangerous substitutes in efforts to purchase cheaper drugs.

According to Outterson, however, empirical evidence tends to show that the threat of counterfeit drugs is overstated for several reasons. First, he points out that counterfeit drugs should be distinguished from functional, generic copies of patented drugs. Narrowing counterfeit drugs to non-functional copies that lack the active ingredient, he then cites authority claiming that the majority of the non-functional counterfeit drugs are produced domestically. Furthermore, he reasons that as drug prices fall, there will be less incentive for

criminals to produce counterfeit drugs because the of the unattractive profit margin. Moreover, patented drugs, not cheap generics, are the target of counterfeiters, so increased availability of low-cost generic drugs would actually dissuade counterfeiting.

### **Will There Be Enough Exporting Members?**

TRIPS now extend compulsory licensing privileges so that nations without

manufacturing capacity can import drugs. However, evidence suggests that this provision will fail in its efforts to improve access to patented drugs. Amir Attaran, an immunologist and lawyer, makes this argument based on history of compulsory licenses. According to history, compulsory licensing has rarely been used for any reason. The explanation for the under-use, or rather lack of use, lies in international politics. Many developing countries want to attract future investment and technology; therefore, they choose not to issue compulsory licenses because it might show a lack of respect for intellectual property rights and consequently decay trade relations or scare off investors.

Furthermore, if countries are reluctant to issue compulsory licenses for the benefit of their own people, it is even less likely that they will use this measure to assist another

country that lacks manufacturing capacity. In other words, the Hong Kong Declaration permanently amended TRIPS so that countries with limited manufacturing capabilities could import drugs because nations that issue compulsory licenses no longer have to manufacture drugs for a predominantly domestic use. The problem in achieving that purpose is that it relies on countries with manufacturing capacity to first issue compulsory licenses.

### **Are We Seeing Improved Access To Drugs?**

In order to maximize their profits, companies across industries utilize differential pricing schemes, sometimes more generally referred as price discrimination. The pharmaceutical industry is no exception and has engaged in differential pricing by segmenting the market based on political borders and income classes. Under this practice, the poorest countries were offered the lowest prices within the range but failed to successfully deliver essential drugs to the people.

Since the Implementation Decision was adopted in 2003, the potential threat of compulsory licenses has moved companies to voluntarily make

proactive efforts to realistically make their drugs accessible. Some have dramatically lowered prices while others have offered voluntary, royalty-free licenses. And while governments have not yet issued compulsory licenses, Brazil, a middle-income country, has actively used it as a threat to negotiate lower prices for AIDS drugs.

In contrast, many still argue that the compulsory licensing provisions have not helped bring drugs to those in need. Some low-income nations like Thailand, Colombia, and South Africa have been pressured by powerful nations like the U.S. to adopt more rigorous intellectual property laws during free trade negotiations. Other countries simply lack coordinated efforts within the government or found the application process too onerous. The emerging pattern tends to show that the leveraging capacity of compulsory licensing depends on the relative political strength of the licensing country. Considering the fact that most poor countries do not have political pull, it looks as though compulsory licensing and differential pricing negotiations in the near future will not

make significant will not make significant effect on access to medicine.

## CONCLUSION

### **The Road Ahead and Potential Solutions for the betterment of patents**

Progress towards providing equal access for drugs has been slow. It is not yet certain whether more education and assistance in filing for compulsory licenses or whether TRIPS provisions can even help developing countries overcome the intimidation factors of powerful governments.

For the effective use of this compulsory licensing is to develop and maintain a set of lists that universally recognize diseases that can be considered a threat to public health and drugs that are automatically eligible for compulsory licenses. Another suggestion is for WTO to adopt a uniform socio-economic model to determine whether a nation is eligible to grant compulsory licenses. Adopting a model prevents abuse and ensures that not just any nation can use compulsory licensing to gain cheaper access to drugs.

One method is to conduct a benefit-detriment analysis that compares the monetary loss suffered by the pharmaceutical company with the aggregate social benefit. Another solution, proposed in a recent article by Outtersen, is to establish a systematic buy-out mechanism for the patent rights to identified essential drugs with limitations to a particular geographic market. This would

not only circumvent the controversial issue of granting compulsory licenses and provide drugs at production cost. One obvious method

for improving access to patented drugs is to finance public pharmaceutical research. This way, patented drugs can directly enter the public domain. One proposal, by U.S. Representative Dennis Kucinich, is to finance pharmaceutical research through a set of competing publicly supported research centers and offer prize money for breakthroughs. Granted that this proposal was intended for application in the U.S. only, it still has merit.

The notion is that as more patented drugs are directly placed in the public domain, pharmaceutical companies would be forced to compete with similar drugs that are already being sold in the market as generics, thereby driving down prices.

In compulsory licensing matters, TRIPS should be interpreted in a manner that respects the legitimate policy concerns of both developed and developing nations. When a compulsory license of a patent for a critical pharmaceutical is granted for public use in a developing country, where a pharmaceutical company has targeted no investment and has no expectation of profits, “adequate remuneration” in TRIPS Article 31(h) should be interpreted to mean “without compensation.” At the same time, TRIPS Article 31(f) should be interpreted as not allowing production under compulsory license for export and gray market sale of the patented product. Such interpretations of TRIPS’ provisions provide one possible means of resolving the general conflict between developed countries

who seek stronger IPR protection for economic benefit, and developing countries who seek to acquire and apply new technology to address their citizens’ pressing needs.

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1 Laurinda L. Hicks & James Holbein, “Convergence of National Intellectual Property Norms in

International Trading Agreements”, 12 Am. U.J. Int’l L. & Pol’y 769, 781 (1997). The World Intellectual Property Organization (WIPO), a specialized United Nations agency, has conducted extensive negotiations on harmonizing international intellectual property laws. WIPO administers the Paris Convention, which requires national treatment but does not provide for

minimum levels of protection for IPR; *See*, Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305.

2 Hicks & Holbein, *supra* note 1, at 783-84. The results of the General Agreement on Tariffs and Trade (GATT), Uruguay Round of Multilateral Trade Negotiations, included the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, Legal Instruments-- Results of the Uruguay Round vol. 31, 33 I.L.M. 81, 83-111 (1994) [hereinafter TRIPS]. GATT established the World Trade Organization (WTO), which was the administrative agency for TRIPS. WTO Agreement, I.L.M. at 1144-52. TRIPS required minimum standards for both procedural and substantive aspects of intellectual property protection, enforcement mechanisms under a Dispute Settlement Body.

3 Intellectual Property and Communications Omnibus Reform Act of 1999, Pub. L. No. 106-113, § 1000(a) (9), 113 Stat. 1501 (1999) (codified as amended in scattered sections of 35 U.S.C.) (bringing United States procedures for patent filing, publication, and duration closer to the world model).

4 Hicks & Holbein, *supra* note 1, at 781.

5 Jean M. Dettmann, "GATT: An Opportunity for an Intellectual Property Rights Solution", 4 *Transnat'l L.J.* 347, 356 (1991) (observing that, under the public law regime, each nation has a vote, so that developing nations can form voting blocs that give them leverage to counteract developed nations' power).

6 Robert Weissman, "A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries", 17 *U. Pa. J. Int'l Econ. L.* 1069, 1114 (1996).

7 There are 105 party nations of which 70 are developing nations. Detlef F. Vagts, *Transnational Business Problems* 66 (1998).

8 If a member nation is found to have violated TRIPS, the WTO has the authority to impose unilateral sanctions under which the violating nation may forfeit national treatment and most favored nation status. Hicks & Holbein, *supra* note 1, at 783.

9 TRIPS, *supra* note 2, Articles. 3, 4. Article 3, "National Treatment," requires that member nations "shall accord to the nationals of other Members treatment

no less favorable than that it accords to its own nationals with regard to the protection of intellectual property”; *See also*, Article. 3. Article 4, “Most-Favoured-Nation Treatment,” requires that, with regard to protection of intellectual property, advantages granted by a member to the nationals of any other country shall be granted immediately and unconditionally to the nationals of all other members. *Refer*, Article 4. Further, because TRIPS is annexed to GATT, violation of TRIPS can subject a member nation to generalized trade sanctions encompassing trade issues outside the IPR realm.

10 TRIPS, *supra* note 2, Article 1.

11 *Ibid.* Articles. 27-34.

12 *Ibid.* Article. 33.

13 *Ibid.* Article. 27.

14 General Agreement on Tariffs and Trade 1994, WTO Agreement, *supra* note 2, Annex 1A, Articles. 22, 23, 33 I.L.M. at 1182-83; Understanding on Rules and Procedures Governing the Settlement of Disputes, WTO Agreement, *supra* note 2, Annex 2, Article. 1, 33 I.L.M., at 1226.

15 DSU, *Infra* note 65, Article. 16, 33 I.L.M. at 1235

16 TRIPS, *supra* note 2, *Ibid.* Article. 31.

17 Weissman, *supra* note 6, at 1075.

18 Ruth L. Gana, “Prospects for Developing Countries Under the TRIPS Agreement”, 29 Vand. J.

Transnat’l L. 735, 755 (1996) (arguing that the need to make pharmaceuticals available to the population of a developing country at an affordable rate should constitute a valid ground for invoking an exception under TRIPS).

19 Thomas McCarthy, McCarthy’s Desk Encyclopedia of Intellectual Property 51-52 (1991).

20 Hicks & Holbein, *supra* note 1, at 813

21 “Compulsory licensing of pharmaceuticals and TRIPS: World Trade Organization”, rue de Lausanne 154, CH-1211 Geneva 21, Switzerland; note has been prepared by the Information and Media Relations Division of the WTO Secretariat to help public understanding. It is not an official interpretation of the WTO agreements or members’ positions, September 2006.

22 Marcia Angell, "The Truth about Drug Companies", N.Y. Rev. Books, July 15, 2004. Written by the former editor for New England Journal of Medicine, the book paints the pharmaceutical industry as corrupt and corrupting.

23 Pharmaceutical Research and Manufacturers of America, PhRMA Statement: AARP Allegations Inaccurate, Flawed (2006), The other side of the coin - this is a statement from the pharmaceutical industry that disputes allegations of drug price inflations by referring to a recent decrease in the rate of drug price increases.

24 The New Yorker: The Critics: High Prices - How to Think About Prescription Drugs - by Malcolm

Gladwell: The author focuses on rising drug spending in the U.S. and takes the middle ground by

attributing rising drug prices to the costs associated with research and design in addition to marketing and attributing the higher spending to higher consumption of patented prescription drugs over generics.

25 "Compulsory licensing: Suggestions for change": By B K Keayla, Convener, National Working Group on Patent Law, and Trustee and Secretary General of the Centre for Study of Global Trade System and Development.

26 TRIPS, Article 31.

27 TRIPS, *supra* note 2.

28 *Ibid.* Article. 31.

29 *Ibid* Article 31 (b).

30 *Ibid* Article 31 (c), (g).

31 *Ibid* Article 31 (d), (e).

32 *Ibid* Article 31(f).

33 *Ibid* Article 31(h).

34 Owen Lippert, "One Trip to the Dentist is Enough: Reasons to Strengthen Intellectual Property Rights Through the Free Trade Area of the Americas", 9 Fordham Intell. Prop. Media & Ent. L.J. 241, 275-76 (1998).

35 Weissman, *supra* note 6, at 1114 (noting that the Article 31 requirements for adequate remuneration and manufacture predominantly for the domestic market are prohibitively restrictive unless interpreted to favor developing countries' interests).

36 See, 'Breaking' patents — Effective use of compulsory licensing: Feroz Ali at [www.hinduonnet.com](http://www.hinduonnet.com).

37 Bryan C. Mercurio, "TRIPS, Patents, and Access To Life-Saving Drugs in the Developing World", 8 Marq. Intell. Prop. L. Rev. 211, 242-44 (Reasoning that the ambiguous provision for "adequate remuneration" invites future disputes). Technically, arbitrage is the more general term, and parallel trade is the narrower term used to describe arbitrage involving intellectual property. For this discussion, arbitrage will be considered synonymous to parallel trading.

38 Kevin Outterson, "Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets", 5 Yale J. Health Pol'y, L. & Ethics 193 (2005).

39 Kevin Outterson, in a heuristic approach, argues that (1) a system dependent on voluntary differential pricing to deliver affordable drugs to poor populations is likely to fail and (2) the vast majority of pharmaceutical innovation takes place in a handful of countries, thus making it non rival. Furthermore, he asserts that pharmaceutical arbitrage will not harm innovative pharmaceutical companies because the market is supra-optimal and challenges those who oppose this view to support their claims with transparency and allow the public domain to evaluate pricing and production costs. See, Outterson, *supra* note 38.

40 Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334 109th Cong. (2005).

41 See TRIPS, *supra* note 9 at Article. 6 ("For the purposes of dispute settlement under this Agreement, subject to the provisions of [National Treatment] and [Most-Favoured-Nation Treatment] nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.").

42 The accounts of day-to-day discussions and negotiations can be found on the WTO website. WTO Ministerial Conferences, Cancun 5th Ministerial, at [http://www.wto.org/english/thewto\\_e/minist\\_e/min03\\_e/min03\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min03_e/min03_e.htm) (last visited Oct. 15, 2006),

(Requiring importing Members to take “reasonable measures within their means” to prevent re-exportation; however, developed countries must provide financial and technical support if requested).

43 Outterson, *supra* note 38.

44 Amir Attaran, “Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution”, 17 *Emory Int’l L. Rev.* 743 (2003).

45 In an idealistic economic model, goods are sold at near production cost. However, businesses recognize that consumers are willing to pay more for products that have greater demand. Thus, companies use various analyses to determine the highest price that a customer is willing to pay. What results is the same product being sold at different prices to different buyers. This is a very crude description of differential pricing. For more information, please economics references; See, Wikipedia.org, Price Discrimination, at [http://en.wikipedia.org/wiki/Price\\_discrimination](http://en.wikipedia.org/wiki/Price_discrimination) (last visited Oct. 30, 2006); See also, Outterson, *supra* note 38 at 203-06 (explaining the different types of differential pricing); Aidan Hollis & Peter Ibbott, “How Parallel Trade Affects Drug Policies and Prices in Canada and the United States”, 32 *Am. J. L. & Med.* 193, 198-204 (2006) (differential pricing in the pharmaceutical industry).

46 There have been many dramatic price cuts since 2001, when the Doha Declaration first proposed crossborder compulsory licensing. However, these price cuts have not significantly increased access to drugs. In 2004, Merck granted a voluntary, royalty-free license to a South African drug manufacturer, perhaps to prevent South Africa from beginning the trend of exercising the right to issue a compulsory license; See Outterson, *supra* note 38 at 226-27.

47 Krohmal, Noah Novogrodsky on “Compulsory Licensing in Ghana - the Continuing Barriers to

Affordable Medicines”, Consumer Project on Technology (Nov. 9, 2006), at <http://www.cptech.org/blogs/drugdevelopment/2006/11/noah-novogrodsky-on-compulsory.html>

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## **THE IMPORTANCE OF SECTION 8-A UNDER THE DOWRY PROHIBITION ACT 1986**

Divya Katti\*

### **Introduction:**

The practice of dowry has emerged as a major social evil in contemporary India. In early days the idea behind giving dowry to girls at the time of marriage was to provide them with some financial security at the time of need. This custom has now become a curse (shapa). The so called educated male candidates have made it customary to demand and squeeze valuables from the girl's parents. Here the offence has taken the garb of an inalienable right of the groom's family. Later this evil practice has slowly started spreading to other religious groups. Hence the Parliament has passed the Dowry Prohibition Act, 1961 was enacted to provide an effective to dowry deaths which were continuing despite then prevailing laws. Its object is to prohibit giving and taking dowry. This Act as no tooth to bite the culprits. Therefore this Act has been substantially amended by the Amendment Acts, in 1984 and 1986.<sup>44</sup>

### **Amendment Act 43 of 1986-Statement of Objects and Reasons.-**

The Dowry Prohibition Act, 1961 was recently amended by the Dowry Prohibition (Amendment) Act, 1984 to give effect to certain recommendations of the joint Committee of the Houses of Parliament to examine the question of the working of the Dowry Prohibition Act, 1961 and to make the provisions of the Act more stringent and effective. Although the Dowry Prohibition (Amendment) Act, 1984 was an improvement on the existing legislation, opinions have been expressed by representatives from women's voluntary organizations and others to the effect that the amendments made are still inadequate and the Act needs to be further amended.

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<sup>44</sup> Dr.S R Myneni, "Women and Law", 2<sup>nd</sup> ed reprint, Asia Law House Publication, Hyderabad, 2013,p225

2. It is, therefore, proposed to further amend the Dowry Prohibition Act, 1961 to make provisions therein further stringent and effective. The salient features of the Bill are :-

(a) The Minimum punishment for taking or abetting the taking of dowry under section 3 of the Act has been raised to five years and a fine of rupees fifteen thousand.

(b) The burden of proving that there was no demand for dowry will be on the person who takes or abets the taking of dowry.

(c) The statement made by the person aggrieved by the offence shall not subject him to prosecution under the Act.

(d) Any advertisement in any newspaper, periodical journal or any other media by any person offering any share in his property or any money in consideration of the marriage of his son or daughter is proposed to be banned and the person giving such advertisement and the printer or publisher of such advertisement will be liable for punishment with imprisonment of six months to five years or with fine up to fifteen thousand rupees.

(e) Offences under the Act are proposed to be made non-bailable.

(f) Provision has also been made for the appointment of Dowry Prohibition Officers by the State Governments for the effective implementation of the Act. The Dowry Prohibition Officers will be assisted by the Advisory Board consisting of not more than five social welfare workers (out of whom at least two shall be women).

(g) A new offence of "dowry death" is proposed to be included in the Indian Penal Code and the necessary consequential amendments in the Code of Criminal Procedure, 1973 and in the Indian Evidence Act, 1872 have also been proposed.<sup>45</sup>

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<sup>45</sup> [www.wcdhry.gov.in/women\\_Acts/dowry\\_act.pdf](http://www.wcdhry.gov.in/women_Acts/dowry_act.pdf)

### **The Dowry Prohibition Act, 1986:**

In order to remove the major loopholes existing in the Dowry prohibition Act, 1961 the amendment was brought replacing the word consideration and inserting the word 'in connection' with the marriage. As a result of this amendment, now any money or valuable security paid before or after or at the time of marriage, it amounts to dowry.<sup>46</sup> Hence if the demand is made long after the marriage, the same could constitute a dowry. The definition now states that anything given in connection with the marriage and given either before, at the time of or after the marriage would be dowry.<sup>47</sup>

The punishment for giving and taking dowry was increased to a minimum period of imprisonment for five years and fine not less than Rs.15000/- or equivalent of the value of such dowry, whichever was more.<sup>48</sup> The demanding of dowry was also made punishable for a period of not less than six months, which could be extended to two years and a fine;<sup>49</sup> dowry has made cognizable and non-bailable offence.<sup>50</sup> This means that the police were bound to investigate all offences related to dowry under the Act. In the previous Act there was no limitation on the period within which a dowry complaint could be filed. An important provision in the Act was the burden of proof on the complainant to the person being prosecuted for dowry. This meant that once the case started, the person who was accused would have to prove that he had not taken dowry.<sup>51</sup>

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<sup>46</sup> P.K, Das, "Protection of Women from Domestic Violence, Act and Rules", 3<sup>rd</sup> ed, Universal Law Publishing Co., Pvt. Ltd, New Delhi, 2009, p 87

<sup>47</sup> Sec 2 of the Dowry Prohibition Act: Definition of Dowry- In this Act, 'dowry' means any property or valuable security given or agreed to be given either directly or indirectly, by one party to a marriage to the other party to the marriage; or by the parents either party to the marriage.

<sup>48</sup> Legal News and Views, " Law relating to dowry Offences", A Social Action Trust Publication, New Delhi, May 2006, p 19.

<sup>49</sup> S M Afzal Qadri, "Criminology", Eastern Book Co., 5<sup>th</sup> ed, 2005, p.530

<sup>50</sup> Ibid, p-530 (Sec 8 of Dowry Prohibition Act)

<sup>51</sup> O.P. Mishra, " Law Relating to Women and Child", Cental Law Agency, Allahabad, 1<sup>st</sup> ed, 2001, p 218 ( Sec.8-A of Dowry Prohibition Act.)

In ***Gurumukh Singh and another v/s State of Himachal Pradesh***<sup>52</sup> after the amendment, the court have in this case also made to define the term 'Dowry' means "a property or valuable security given or agreed to be given either directly or indirectly by one party to another party to a marriage". In another case ***Rajeev v/s Ram kishan Jaiswal***<sup>53</sup> the court decided that any property given by parents of the bride as consideration to the marriage to the bride groom or his relatives in connection with the marriage, the same would constitute dowry under the Act.<sup>54</sup>

Where dowry is demanded at the time of settlement of marriage by either of the party as a consideration for the marriage, is said to dowry. This is shows that anything demands, as a consideration for the settlement of marriage constitutes dowry. In ***K.R.Soorachari v/s state of Karnataka***,<sup>55</sup> a demand of dowry through his wife and his nephew's wife, finding of trial court completely ignored the cogent and reliable evidence on record, which proved the case of prosecution that dowry was demanded and paid. The Supreme Court convicted accused and held that, such a finding ignoring relevant evidence cannot be sustained even in an appeal against acquittal.<sup>56</sup>

But if the dowry items were not demanded as a part of consideration for the marriage they would not constitute dowry, it was stated in ***Harbans Singh v/s Smt. Gurucharan Kaur***<sup>57</sup>, likewise any demand of property or valuables, after the celebration of marriage, which was not demanded at the time of settlement of marriage as consideration would constitute dowry, and land

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<sup>52</sup> (1997) Cri. 240 (H.P)

<sup>53</sup> (1994) Cri.L.J, 255 Allahabad

<sup>54</sup> N.A.Zuberi, "The Protection of Women from Domestic Violence Act and Rules", 1<sup>st</sup> ed, Allahabad Law Agency, Faridabad, 2008, p 130.

<sup>55</sup> (2006) SCC p.101

<sup>56</sup> Legal News and Views, by Dr.Gourav Koushik, "Legal Provisions Relating to Dowry Prohibition And Some Recent Judgments", A Social Action Trust Publication, July 2007, p 5.

<sup>57</sup> 1990 Cr.L.J.(Del) 1591

assigned as a gift as consideration for the marriage also constitute a part of dowry.<sup>58</sup>

Whereas in *Madhusudan Malhotra v/s K C Bhandari*,<sup>59</sup> the Supreme Court observed that, furnishing of a life of ornaments and other household articles such as refrigerator, furniture, and electric appliances etc., at the time of the settlement of the marriage amounts to demand of dowry within the meaning of section 2 of the Dowry prohibition Act.<sup>60</sup> Recently the Supreme Court, has ruled that demands for money and presents from parents of a married girl at the time of birth of her child or for other ceremonies, as is prevalent in the Indian society, cannot be construed as dowry to make it a punishable offence.<sup>61</sup>

### **Restoration of Dowry:**

After the death of the married women then the question arises that, who is the custodian of the articles which are given to bride at the time of marriage. In *Rajeev v/s Ram Kishan Jaiswal*,<sup>62</sup> the Allahabad High Court observed that, when a women dies issueless, the article received by her as a part of dowry to be returned to her parents rather than to her husband. In another case *Manas Kumar Dutt v/s Alok Dutt*<sup>63</sup> in this case the Orissa High Court observed that, where the wife is within less than three months of her marriage, the husband cannot claim the dowry articles which were given to her wife and the same is required to be transferred to her parents. This clearly shows that whatever the dowry articles received by the wife are required to be transferred to her parent not to her husband.<sup>64</sup>

### **Conclusion:**

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<sup>58</sup> State of Himachal Pradesh v/s Nikku Ram, 1995, Cr.Lj 4184

<sup>59</sup> 1988 Cr.IJ.360

<sup>60</sup> Supra Note 10 p 131

<sup>61</sup> Supreme Court Decision Dt.on 31<sup>st</sup> January 2008, Times of India, 1 Feb.2008

<sup>62</sup> Supra Note 9.

<sup>63</sup> (1990) Cri.LJ 115 (Ori)

<sup>64</sup> Dr.Mamta Rao, "Law Relating to Women and Children" 3<sup>rd</sup> ed, 2012, Eastern Book Co, Lucknow, p.141.

In conclusion since giving and taking dowry is a social evil, and the law alone cannot help to eradicate it. The need of the day is for a collective consciousness and change of heart and attitude. The community should be involved in prevention and investigation of crimes against women. There is need for gender sensitization of law enforcement agencies for effective reprisal of violence and proper representation of women in police force.

### **Implementation :**

Even after the campaign and amendments in the Dowry laws there has not been any lessening of the evil of Dowry .A writ was filed in the Supreme Court in the year 1997 praying that the Central and the State government should frame rules under Section 9 and 10 of the Dowry Prohibition Act 1961 and providing for additional functions to be performed by the concerned officers under Section 8B of the Act. It also pleaded for appointment of Dowry Prohibition Officers by states as required under Section 8B ,to furnish details regarding the working of Dowry Prohibition Officers wherever they have been appointed and for setting up of Advisory Boards as mandated under Section 8B of the Act. Various interim orders were passed and it was submitted that most of the states have framed rules under this act and Dowry prohibition officers have been appointed in most 66 states.

we further

- Direct the Union of India and the States to take more effective steps to implement the provisions of the Dowry various rules framed there under. In that process, they are also directed to activate the Dowry Prohibition officers. It directed the Central Government to frame rules under Section 9(2)(b) of the Act if it has not already been framed.
- It directed the respondents to take steps to ensure that submitting of the list as contemplated by the act and the rules is strictly implemented.
- We direct the Union of India and the State government to consider whether appropriate rules cannot be framed for compelling males,

seeking government employment, to furnish information on whether they had taken Dowry and if taken, whether the same has been made over to the wife as contemplated by Section 6 of the Act, calling for such information also from those already in employment. Since it is necessary to arouse the conscience of the people against the demand and acceptance of Dowry.

- We also direct the Union of India and the State Governments to take steps for the effective stepping up of anti-dowry Literacy among the people through Lok Adalats, radio broadcasts, television and newspapers. These directions will be implemented and continue to be implemented rigorously by the respondents.

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- Manas Kumar Dutt v/s Alok Dutt, (1990) Cri.L.J (Ori) 115
- Rajeev v/s Ram Kishan Jaiswal, (1994) Cri.L.J (All) 255.

## The Role of WIPO in Access to Medicines

- **Jaya Kathju**

### Abstract:

Public health matters are basic to the growth aspiration and financial development of developing and least-developed countries. However, access to medicines remains a point of significant tension and, at times, intense discord among state and non-state actors over the role and impact of the patent system on public health. This chapter briefly considers the nature of WIPO's functions and suggests ways in which the organization could positively exercise its tremendous technical assistance capacity consistent with facilitating access to medicines. The chapter begins by reflecting on WIPO's mandate in an international environment in which competing visions of the IP system continue to engender challenges to the norms WIPO is tasked to supply and defend. How effectively WIPO positions itself in the access to medicines arena could be significant for the organization's long-term ability to defend its relevance to key challenges facing the global economy and which are indisputably central to the emergence of a more stable global IP social compact.

### Introduction

The World Intellectual Property Organization (WIPO) is at the forefront of some of the most significant challenges facing the global economy today, not the least of which is access to medicines. This is not necessarily because WIPO should, or wants to be, the focus of globalization's most vexing problems. But WIPO predictably has a role because intellectual property (IP) protection, as the orthodox narrative recounts, is a critical component of public and private responses to these shared global concerns. Public health matters are particularly fundamental to the development aspirations and economic growth of developing and least-developed countries.<sup>65</sup> Even in the developed economies, there is an indisputable link between healthcare availability, the cost of pharmaceutical products, and economic growth.<sup>66</sup> Yet, access to

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<sup>65</sup> See INT'L MONETARY FUND, HEALTH AND DEVELOPMENT: WHY INVESTING IN HEALTH IS CRITICAL FOR ACHIEVING ECONOMIC DEVELOPMENT GOALS (2004), available at <http://www.imf.org/external/pubs/ft/health/eng/hdwi/hdwi.pdf>; Tania Bubela et al., Wicked Issues for Canada at the Intersection of Intellectual Property and Public Health: Mechanisms for Policy Coherence, 4 MCGILL J.L. & HEALTH 40, 40–41 (2011) (noting OECD focus on public health in developing countries); Health Overview, WORLD BANK, <http://www.worldbank.org/en/topic/health/overview> (last visited Aug. 9, 2013) ("Strengthening health systems is at the center of the World Bank's global strategy for health, nutrition, and population.").

<sup>66</sup> See Michael Chernen, *Health Care Spending Growth: Can We Avoid Fiscal Armageddon?*, 47 INQUIRY 285 (2010) (discussing the negative impact of health care spending on economic health); Steven Ney, *Making Sense of the Global Health Crisis: Policy Narratives, Conflict, and Global Health Governance*, 37 J. HEALTH POL., POL'Y &

medicines remains a point of significant tension and, at times, intense discord among state and non-state actors over the role and impact of the patent system on public health. In the minds of many observers and commentators, the considerable challenge of making drugs accessible to the world's most vulnerable citizens has transformed the patent system—and pharmaceutical patents in particular—into the poster child of all that is wrong with IP harmonization under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).<sup>67</sup> The global debate over access to medicines spans two related public international law frames, namely humanitarianism and human rights.<sup>68</sup> The complementary ends of these two regimes overlay and at times supplant the economic imperatives of the private rights that are at the heart of the global patent system,<sup>69</sup> as evidenced by the Doha Declaration on TRIPS and Public Health.<sup>70</sup> Of the many international institutions that deal with access to medicines and global health governance, WIPO arguably is the least involved with the structures and processes that directly shape *national* obligations to supply public goods such as healthcare, or that determine appropriate responses to public health crises. Government health agencies, humanitarian departments, human rights, foreign and defense ministries, and powerful international humanitarian organizations such as the International Red Cross or Médecins Sans Frontières (MSF) all are a far cry from the IP agencies, trade, investment, or commerce ministries with which WIPO has traditionally been associated.

Moreover, the diverse legal and policy mandates of national actors in the field of public health involve constitutional and governance issues unique to the specific local environment in which they operate, interwoven with humanitarian aid efforts and any related conditions imposed when and as cases of specific threats to health and human well-being arise. Put simply, the complex legal, normative, and institutional landscape within which solutions to

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L. 275 (2012) (“[R]ising health care costs threaten economic growth.”)

<sup>67</sup> See Amir Attaran, *Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution*, 17 EMORY INT’L L. REV. 743 (2003) (critiquing TRIPS); Rudolf V. Van Puymbroeck, *Basic Survival Needs and Access to Medicines - Coming to Grips with TRIPS: Conversion + Calculation*, 38 J.L. MED. & ETHICS 520 (2010); Haochen Sun, *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health*, 15 EUR. J. INT’L L. 123 (2004) (describing negative impact of on access to essential medicines)

<sup>68</sup> See Michael N. Barnett, *Humanitarianism Transformed*, 3 PERSP. ON POL. 723 (2005) (noting that some define humanitarianism to include, among other things, access to medicines); E. Richard Gold, *Patents and Human Rights: A Heterodox Analysis*, 41 J.L. MED. & ETHICS 185 (2013) (noting human rights dimension of access to medicines and TRIPS);

<sup>69</sup> The TRIPS Agreement recognizes that intellectual property rights are private rights. TRIPS Agreement, pmbl. P.A.O. & 2 Others v. Attorney Gen. (High Court of Kenya, 2012), [http://kenyalaw.org/Downloads\\_FreeCases/85611.pdf](http://kenyalaw.org/Downloads_FreeCases/85611.pdf) (“Should the Act be implemented as it is, the danger that it poses to the right of the petitioners to access essential medicine which they require on a daily basis in order to sustain life is far greater and more critical than the protection of the intellectual property rights that the Act seeks to protect. The right to life, dignity and health of the petitioners must take precedence over the intellectual property rights of patent holders.”)

<sup>70</sup> Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.

access to medicines must emerge as part of the legal and humanitarian responses to disease is not a terrain in which WIPO has historically had much experience or credibility. Yet, because patent rights are a major underpinning for pharmaceutical innovation, WIPO recently has assumed a visible role in addressing access to medicines and global public health.<sup>71</sup> The extent and impact of its involvement remain difficult to measure.

In this chapter, I briefly consider the nature of WIPO's functions and suggest possible ways in which the Organization could positively exercise its tremendous technical assistance capacity consistent with facilitating access to medicines. I begin by reflecting on WIPO's mandate in an international environment in which competing visions of the IP system continue to engender challenges to the norms WIPO is tasked to supply and defend.

## **WIPO and Institutional Identity**

### *A. The WIPO Mandate in the Context of Public Health*

From its obscure beginnings in the late 19th century as an administrative headquarters providing managerial functions for Member States of the principal IP conventions,<sup>72</sup> WIPO's mandate "to promote the protection of intellectual property throughout the world through cooperation among States"<sup>73</sup> has placed the Organization at the epicenter of debates about a number of global issues such as climate change, food security, and public health. In recent years, WIPO has undertaken numerous initiatives and partnerships with other international organizations to exercise influence in the global discourse on these issues and to be part of evolving solutions.<sup>74</sup> But given that WIPO's principal charge is norm-setting activities to protect, strengthen, and harmonize IP rules,<sup>75</sup> its role in relation to problems, the solutions to which require consideration of ways to constrain the impact of IP on social welfare, potentially raises questions of constitutional magnitude for the Organization. These questions are particularly weighty with respect to public health and access to medicines and there are strong reasons one might urge reticence on WIPO's part.

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<sup>71</sup> See Int'l Ctr. for Trade & Sustainable Dev. (ICTSD), *WTO, WIPO and WHO Examine Role of Patent Information in Access to Medicines*, 15 BRIDGES WKLY. TRADE NEWS DIG., Mar. 2, 2011, available at <http://ictsd.org/i/news/bridgesweekly/101767>; *Access to Medicines: Patent Information and Freedom to Operate: A Joint Technical Symposium by WHO, WIPO and WTO* (Feb. 18, 2011), available at [http://www.wipo.int/meetings/en/2011/who\\_wipo\\_wto\\_ip\\_med\\_ge\\_11/program.html](http://www.wipo.int/meetings/en/2011/who_wipo_wto_ip_med_ge_11/program.html).

<sup>72</sup> Paris Convention for the Protection of Industrial Property, as last revised at the Stockholm Revision Conference, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 303; Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as revised at Paris on July 24, 1971 and amended in 1979, S. Treaty Doc. No. 99-27 (1986).

<sup>73</sup> WIPO Convention art. 3, 2186 U.N.T.S. 121.

<sup>74</sup> WIPO, *Climate Change*, <http://www.wipo.int/globalchallenges/en/climate> (last visited Aug. 9, 2013); WIPO, *Food Security*, <http://www.wipo.int/globalchallenges/en/food> (last visited Aug. 9, 2013); WIPO, *Public Health*, <http://www.wipo.int/globalchallenges/en/health> (last visited Aug. 9, 2013).

<sup>75</sup> WIPO, *About WIPO*, <http://www.wipo.int/about-wipo/en/> (last visited Aug. 12, 2013).

Pharmaceutical patents have historically been a sensitive area of norm-setting in global patent law.<sup>76</sup> As is well known, the uneven scope and availability of protection for pharmaceutical patents across countries in large part fueled the resolve of the developed countries to conclude the World Trade Organization (WTO) TRIPS Agreement.<sup>77</sup> While formal agreement on core standards in TRIPS created improved opportunities for norm convergence in patent law, domestic application of these norms continues to reveal unabated interest in major developing countries, and in the international community, to apply global patent rules in ways that best serve national interests, notwithstanding domestic patent legislation that mirrors those of the developed countries, or is at times even stronger. This is of course no different from what occurs in the developed countries as well.<sup>78</sup> Invariably, national patent policy must respond to domestic political and economic pressures or face countervailing skepticism that erodes public confidence in the regime more broadly.<sup>79</sup>

### *B. WIPO, Domestic Institutions and Public Health*

The TRIPS Agreement safeguards the unilateral exercise of domestic authority by assuring in Article 1 that “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”<sup>80</sup> So long as the implementation of TRIPS norms is filtered through legitimate national institutions and processes, the outcomes are far less likely to be successfully challenged as non-compliant,<sup>81</sup> even when those outcomes diverge from what prevails in other Member States. The Indian Supreme Court’s decision in *Novartis Ag v. Union of India et. al.*,<sup>82</sup> which rejected Novartis’s application for its cancer fighting drug Glivec

<sup>76</sup> See Kitsuron Sangsuvan, *Separation of Powers in Intellectual Property Rights: Balancing Global Intellectual Property Rights or Monopoly Power in the Twenty-First Century by Competition Law*, 26 N.Y. INT’L L. REV. 16 (2013) (“Patents on pharmaceutical products have been a highly controversial issue since the establishment of TRIPS.”).

<sup>77</sup> See Robert Weissman, *A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT’L ECON. L. 1076–77, 1082–85 (1996) (describing the pharmaceutical industry’s campaign for TRIPS).

<sup>78</sup> See Kate H. Murashige, *Harmonization of Patent Laws*, 16 HOUS. J. INT’L L. 591 (1994) (“Intellectual property policy, and in particular patent policy, is regarded as an instrument of national interest.”); Haley Stein, *Intellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World*, 3 NW. J. TECH. & INTELL. PROP. 160, para. 41 (2005) (“Patent policies have historically been enacted to further national interests.”).

<sup>79</sup> Ruth L. Okediji, *Towards a Global Patent Law Canon*, in PATENT LAW IN GLOBAL PERSPECTIVE (Ruth L. Okediji & Margo Bagley eds., forthcoming 2013) [hereinafter Okediji, *Global Patent Law Canon*].

<sup>80</sup> See Agreement on Trade-Related Aspects of Intellectual Property Rights art. 1(2) Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

<sup>81</sup> In the seminal TRIPS dispute between the U.S. and India, a WTO Appellate Body agreed that India’s purported implementation of the mailbox and pipeline provisions in TRIPS Articles 70(8)(a) and 70(9) was non-compliant with India’s obligations. However, this was due in no small part to a lack of evidence that India’s chosen mode of implementation, so-called administrative instructions, was consistent with India’s normal lawmaking process, making the alleged instructions of dubious legal character. See Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997).

<sup>82</sup> *Novartis Ag v. Union of India, et. al.*, Nos. 2706-2716 OF 2013 (SLP(C) Nos. 20539-20549 OF 2009) (2013) available at <http://supremecourtindia.nic.in/outtoday/patent.pdf>.

despite its protection in many other countries, is illustrative. There, India's Patent Act<sup>83</sup> embodied the standards required by the TRIPS Agreement, yet the Court applied those standards with a particular view of the patent system and its role in protecting inventions in the context of unique policy trade-offs and national interests.<sup>84</sup> Other examples might include recent amendments in China and Brazil requiring mandatory disclosure of the source of genetic material associated with an invention, the violation of which carries severe sanctions up to forfeiture of the patent.<sup>85</sup> In short, national patent systems often reflect policy biases that tilt the practical operation of global norms in preferred directions without violating the letter of the treaty.<sup>86</sup> This suggests that credible, if contestable, forms of implementation consistent with national public interests and determined through appropriate institutional processes likely will be more insulated from threats of WTO sanctions even if trade partners are otherwise displeased.<sup>87</sup> WIPO is far less positioned to intervene in such cases on grounds that particular interpretations of patent norms are consistent or otherwise with the global patent *acquis*.<sup>88</sup> Not only does WIPO lack any institutional facility or authority to issue such analysis, but more importantly, the well acknowledged political tenor of unresolved debates within the WTO over the social bargain embedded in the TRIPS Agreement cannot be justifiably mediated by the one-size-fits-all approach, which historically has been WIPO's chief undertaking.

Until very recently, WIPO was conspicuously absent from global public policy debates about public health and, some may argue, it was curious if at all only for reasons of institutional self-interest. But as the chief custodian of the globalized IP norms that influence policy responses to technology deficits, WIPO's involvement is understandably viewed by other international organizations as an important component of global responses to these problems. For example, WIPO is identified as a stakeholder by the World Health Organization (WHO) in the implementation of the latter's Global Strategy and

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<sup>83</sup> Patent Amendment Act, No. 15 of 2005 [India].

<sup>84</sup> *Novartis Ag. v. Union of India*, *supra* note 19, at ¶ 66.

Provisional Act No. 2.186-16, Aug. 23, 2001 (Genetic Heritage & Traditional Knowledge) [Brazil], <http://www.wipo.int/wipolex/en/details.jsp?id=5897>; Patent Law of the People's Republic of China art. 26 (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, amended Dec. 27, 2008, effective Oct. 1, 2009).

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<sup>86</sup> Indeed, Article 1 of TRIPS does not subject this discretion over implementation to the limiting catch-phrase "provided that such measures are consistent with the provisions of this Agreement." This proviso attaches to the first sentence in Article 1 and other TRIPS provisions, such as Article 8, recognizing that countries may act to protect certain public interest objectives. See also TRIPS Article 40(2).

<sup>87</sup> The U.S. Trade Representative has critiqued the India Supreme Court's *Novartis* decision. U.S. Trade Rep., 2013 Special 301 Report 38 (2013), <http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf>.

<sup>88</sup> Indeed, in those few instances where WIPO's opinion has been invited by a WTO dispute panel, the response has been merely factual (Dinwoodie and Dreyfuss 2009).

Plan of Action on Public Health, Innovation and Intellectual Property.<sup>89</sup> A recent, joint, high-level joint study by the ‘triumvirate’ of organizations formally tasked with various aspects of global public health issues—the WHO, WIPO and the World Trade Organization—also reflects a meaningful shift in WIPO’s effort to participate in the public health dialogue.<sup>90</sup>

## II. WIPO’s Role in TRIPS Implementation

### A. WIPO or the WTO in Influencing Domestic Patent Flexibility?

WIPO’s technical assistance activities, directed primarily at developing and least developed countries, have profoundly shaped domestic understanding of the appropriate implementation of patent norms in those jurisdictions,<sup>91</sup> including the perception of how much wiggle room is afforded under TRIPS standards to address barriers to access to medicines. From producing model patent laws,<sup>92</sup> to training programs for IP offices and officials,<sup>93</sup> and other forms of “technical assistance” projects,<sup>94</sup> WIPO designs, deploys and oversees a pervasive network of activities that directly and indirectly infuse domestic laws of developing and least developed countries with strong normative predispositions, consistent with the interests of maximalist patent standards and, typically, minimalist public interest limitations.<sup>95</sup> So while overtly

<sup>89</sup> WHO, GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY 23–31 (2011), available at [http://www.who.int/phi/publications/Global\\_Strategy\\_Plan\\_Action.pdf](http://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf).

<sup>90</sup> WHO, WIPO & WTO, PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY, AND TRADE (2012), available at [http://www.wto.org/english/res\\_e/booksp\\_e/pamtiwhowipowtoweb13\\_e.pdf](http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf).

<sup>91</sup> See CAROLYN DEERE, THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES (2008); Sean M. Flynn et al., *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT’L L. REV. 105 (2012); Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP*, 18 J. INTEL. PROP. L. 476 (2011) (referring to WIPO technical assistance as a “very powerful” process); Sean A. Pager, *Accentuating the Positive: Building Capacity for Creative Industries into the Development Agenda for Global Intellectual Property Law*, 28 AM. U. INT’L L. REV. 292–93 (2012) (noting deficiencies in WIPO technical assistance from developing country perspective); Peter Yu, *Intellectual Property Training and Education for Development*, 28 AM. U. INT’L L. REV. 311 (2012) (suggesting improvements to WIPO technical assistance to benefit developing countries); see also World Intell. Prop. Org. Secretariat, *An External Review of WIPO Technical Assistance in the Area of Cooperation for Development*, Doc. CDIP/8/INF/1 (Sept. 1, 2011) (by Carolyn Deere Birkbeck & Santiago Roca).

<sup>92</sup> WIPO, MODEL LAW FOR DEVELOPING COUNTRIES ON INVENTIONS (1979), available at [ftp://ftp.wipo.int/pub/library/ebooks/ModelLaws/840e\\_vol\\_1.pdf](ftp://ftp.wipo.int/pub/library/ebooks/ModelLaws/840e_vol_1.pdf).

<sup>93</sup> See William New, *US, WIPO Training Programme on IP Rights in Africa Comes Under Fire*, INTELL. PROP. WATCH (Feb. 12, 2012), <http://www.ip-watch.org/2012/02/12/us-wipo-training-programme-on-ip-rights-in-africacomes-under-fire>; William New, *WIPO Defends Involvement in IP Enforcement Meeting in the Philippines*, INTELL. PROP. WATCH (Oct. 24, 2011), <http://www.ip-watch.org/2011/10/24/wipo-defends-involvement-in-ip-enforcementmeeting-in-the-philippines> (describing complaints that WIPO promotes rights-holders’ interests).

<sup>94</sup> Geneva Declaration on the Future of the World Intellectual Property Organization (Oct. 4, 2004), available at <http://www.cptech.org/ip/wipo/futureofwipodeclaration.pdf> (urging reform of WIPO technical assistance programs to promote development rather than strong IP protection).

<sup>95</sup> See MICHEL KOSTECKI, INTELLECTUAL PROPERTY AND ECONOMIC DEVELOPMENT: WHAT TECHNICAL

intervening with the administration of the TRIPS Agreement may be implausible for WIPO, it is WIPO, not the WTO, that has been most powerful in influencing, establishing, and nurturing the domestic normative context in which TRIPS norms are implemented.

The core obligations of the TRIPS Agreement build upon the substantive norms of the classic WIPO treaties, namely the Paris Convention and the Berne Convention.<sup>96</sup> Both of these instruments have an enduring legacy in defining the expectations of countries about the scope of international protection available, the rights granted to foreigners, and the economic impact of global IP protection.<sup>97</sup> WIPO has long been at the forefront of expanding the reach of these treaties globally, and in developing a narrative about the role of IP in economic development. Indeed, given how significantly WIPO has been involved in defining the domestic landscape of IP laws in many developing and least-developed countries, there is no question that the difficulty in persuading local officials of the degree and right to exercise national discretion in TRIPS implementation strategies is likely strongly linked to the precedential effect of WIPO's activities in those countries since their independence.<sup>98</sup>

### *B. The Political Economy of Public Health*

In both developed and developing/least-developed countries, providing access to medicines is a quintessentially political undertaking with which governments at all levels are deeply involved.<sup>99</sup> Price regulation of drugs,<sup>100</sup> outright subsidies to consumers,<sup>101</sup> compulsory licensing of patents,<sup>102</sup> and

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ASSISTANCE TO REDRESS THE BALANCE IN FAVOUR OF DEVELOPING NATIONS? (2006), *available at* <http://ictsd.org/i/ip/18075/?view=document>.

<sup>96</sup> TRIPS Agreement, art. 2.

<sup>97</sup> See Okediji, *Global Patent Law Canon*, *supra* note 15.

<sup>98</sup> See Ruth L. Okediji, *WIPO-WTO Relations and the Future of Global Intellectual Property Norms*, 39 NETH. Y.B. INT'L L. 69 (2008) [hereinafter Okediji, *WIPO-WTO Relations*]; Ruth L. Okediji, *The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System*, 7 SINGAPORE J. INT'L & COMP. L. 315 (2003) [hereinafter Okediji, *Developing Country Participation*].

<sup>99</sup> See Jonathan Liberman, *Combating Counterfeit Medicines and Illicit Trade in Tobacco Products: Minefields in Global Health Governance*, 40 J.L. Med. & Ethics 326 (2012) ("The relationship between access to medicines and intellectual property rights--most prominently patents--has long been the subject of fierce political and legal battles, fought out in a multiplicity of international and national fora."); Taiwo A. Oriola, *Against the Plague: Exemption of Pharmaceutical Patent Rights as a Biosecurity Strategy*, 2007 U. Ill. J.L. Tech. & Pol'y 309 ("The debate about pharmaceutical patents and access to medicine is an enduring subject of legal, economic, and political discourse").

<sup>100</sup> See Joel Lexchin, *The Pharmaceutical Industry and the Pursuit of Profit*, in *THE POWER OF PILLS: SOCIAL, ETHICAL AND LEGAL ISSUES IN DRUG DEVELOPMENT, MARKETING, AND PRICING* 11, 15 (Jillian Claire Cohen, Patricia Illingworth & Udo Schuklenk eds., 2006) (stating that the US is one of the few developed countries that does not use price controls for pharmaceuticals).

<sup>101</sup> See Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 386 (2010) (noting the US pays over \$50 billion in annual subsidies to consumers to purchase patented pharmaceutical products).

<sup>102</sup> See JEROME REICHMAN & CATHERINE HAZHENZAL, *NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS, AND AN OVERVIEW OF THE PRACTICE IN CANADA*

regulatory incentives<sup>103</sup> are all examples of tools deployed in developed countries to facilitate and safeguard the government's capacity to provide essential health services to the public. In short, rarely is the public's access to drugs in any country left solely to the vicissitudes of the proprietary interests of pharmaceutical patent owners regardless of the level of economic maturity. As scholars have already established, compulsory licenses for pharmaceutical goods have been more widely used in the developed countries than is commonly acknowledged,<sup>104</sup> despite the often harsh reactions to similar attempts by developing and least developed countries.<sup>105</sup> The fact is that government procurement of drugs imposes significant externalities on fiscal budgets,<sup>106</sup> causing governments to maneuver between regulatory measures to directly contain costs, or tamper with the robustness of patentability criteria such as nonobviousness to curb patents over pharmaceutical products.<sup>107</sup>

## Conclusion

Sustainable access to medicines is viewed most passionately in humanitarian terms as an international challenge encompassing issues of poverty, innovation, human rights, and economic development. Large scale humanitarian efforts, such as those witnessed at the height of the HIV epidemic in Sub-saharan Africa, will always have a role to play in addressing access to medicines. But access to medicines cannot, and should not, be addressed on humanitarian grounds alone. To do so would unfairly erode the right and the responsibility of developing and least-developed countries to develop national patent, competition, and other legal regimes necessary to secure public welfare goals. It would make them perpetual recipients of charity instead of masters of their own public good. And it would eliminate pressure to hold the international patent system accountable for the ends for which it is justified and on which WIPO's very existence is premised.

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AND THE UNITED STATES OF AMERICA (2003), available at <http://ictsd.org/i/publications/11764/?view=document>.

<sup>103</sup> See Jay R. Thomas, *Toward a Theory of Regulatory Exclusivity*, in PATENT LAW IN GLOBAL PERSPECTIVE (Ruth L. Okediji & Margo Bagley eds., forthcoming 2013).

<sup>104</sup> See Jerome H. Reichman, Comment, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. Med. & Ethics 247 (2009).

<sup>105</sup> See Ahmed Abdel Latif, *Change and Continuity in the International Intellectual Property System: A Turbulent Decade in Perspective*, 3 WIPO J. 37–42 (2011) (discussing “harsh” reactions by industrialized countries and multinational companies to the use of compulsory licensing by developing countries).

<sup>106</sup> See G. GALLEGRO, THE AUSTRALIAN HEALTH CARE SYSTEM AND HIGH COST MEDICATIONS (HCMS) 27 (2006), available at <http://ses.library.usyd.edu.au/bitstream/2123/1008/2/02whole.pdf> (“Pharmaceuticals account for over 20% of the total health spending in France and Italy.”); Sichelman, *supra* note 37.

<sup>107</sup> See Alan Devlin, *Patent Law's Parsimony Principle*, 25 BERKELEY TECH. L.J. 1722 (2010) (stating that “fields in which patents are the undisputable foundation of ongoing innovation, such as in the pharmaceutical industry, should receive more lax nonobviousness assessments” and further stating that the US does not apply a stringent nonobviousness requirement to pharmaceuticals).

## **Role of Law in Workforce Diversity**

- Ms.Neha Soni

### **Abstract**

The Article about the role of diversity in the development of the organization. Employees of any organizations are different in terms of Age, Cultural Background, Physical Abilities and Disabilities, Race, Religion, Sex, and Sexual Orientation, Education, Income, Personality Ethnicity , Gender , Language, Discrimination and National origin diversity . The workforce has important legal, moral, social, and practical ramifications which are presented in this paper. The composition of the workforce in the United States has grown increasingly more diverse ethnically.

**Key words:** Workforce Diversity , Organization Performance , Age, Cultural Background, Physical Abilities and Disabilities, Race, Religion, Sex, and Sexual Orientation, Education, Income, Personality Ethnicity , Gender , Language, and National origin diversity , Discrimination.

### **Introduction : Role of law in Workforce Diversity**

Workforce diversity is simply how diverse is the workforce in legal Organizations .There are several people with a mix of cultures, age, background, race, and etc . If there are many people that have differences then you have a diverse workforce. Workforce diversity is simply how diverse is the workforce.

Workforce Diversity defines diversity as:-

- (1) The representation of multiple groups within a prescribed environment, such as a workplace.
- (2) Differences between cultural groups and
- (3) Respecting cultural differences by recognizing that no one culture is intrinsically superior to another. Further distinguish between primary and secondary dimensions of (or influences on) diversity. Primary (also referred to as visible or immutable) dimensions of diversity include age, ethnicity, gender, physical abilities and race. Secondary dimensions of diversity are those that can be changed, any of religion, education, marital status, etc. We are working in a multicultural and multigenerational workplace. The culture brings different values, beliefs, attitudes and behaviors.

Workforce diversity may refer to representations of various races, genders and religious backgrounds; today's concept of workplace diversity is all-encompassing. These variables, considerations are also made on personality, age, cognitive style, skills, education, background and etc. The focus of workplace diversity now lies on the promotion of individuality within an organization, acknowledging that every person can bring something different to the table. A legal issue, employers implementing work often encounter resistance by managers. These managers may improperly deny meritorious

requests for flexibility or evaluate an employee who has taken advantage of a work initiative more harshly. In most legal organizations, Heads hold the keys to ultimate success are the benefits are to be achieved. Workforce diversity goes beyond a company's legal obligations to comply with equal opportunities and non-discrimination legislation. Companies that employ diverse workforces encourage different perspectives and promote learning from alternative perspectives. A diverse workforce should reflect the society in which the company operates in terms of race, gender, physical and mental ability, ethnicity, age, class, spiritual practice and sexual orientation. Employing a diverse workforce requires a company to create a culture that respects conflicting opinions and promotes the dignity of each member of the workforce. Employees of any organizations are different in terms of Age, Cultural Background, Physical Abilities and Disabilities, Race, Religion, Sex, and Sexual Orientation, Education, Income, Personality Ethnicity , Gender , Language. Diversity initiatives are now common place in corporate companies. The term of the “Workforce Diversity” is almost never defined. Workforce Diversity is often described in conclusory or circular terms that do little to cement a common understanding of the term.

The training managers should communicate the role & importance of this program to the ultimate success of the legal organizations. Effective administration should be an element of supervisors and managers performance evaluations. Trained managers to understand that employees should not be disadvantaged in performance reviews or career advancement because of participation in work. The employee involvement through satisfaction surveys, group meetings and exit interviews to gain important workforce input on work. An organization that is committed to a diverse workforce, therefore, is one that aims to harness a pool of individuals with unique qualities, seeing this combination of differences as a potential for growth rather than opportunities for conflict. The workgroups that are demographically diverse are likely to be less effective in workgroup contexts that emphasize competition oriented cultures than in contexts that do not emphasize competition-oriented cultures. Workgroups that are demographically diverse are likely to be more effective in workgroup contexts that pursue growth oriented business strategies than in contexts that do not pursue growth-oriented business strategies. Workgroups that are demographically diverse are likely to be less effective in workgroup contexts that emphasize competition oriented cultures than in contexts that do not emphasize competition-oriented cultures. workgroups that are demographically diverse are likely to be more effective in workgroup contexts that emphasize competition oriented cultures than in contexts that do not emphasize competition-oriented cultures.

### **Objective of the Study**

To evaluate the Role of Law in workforce diversity in the workplace:-

- 1.** Diagnose the impact of Age, Cultural Background, Physical Abilities and Disabilities, Race, Religion, Sex, and Sexual Orientation, Education, Income,

Personality Ethnicity , Gender , Language, and National origin diversity , Discrimination.

2. Identify some dimensions of personality, and show how they influence behavior in legal organizations.
3. Diagnose the role, values and attitudes in legal organizations.
4. Identify new forms of careers and their role on individual and organizational performance.
5. Identify the costs and benefits of family friendliness in the workforce.
6. Show how cross-cultural differences can influence behavior and attitudes in the workforce.

### **Assumptions**

The role of law in workforce diversity has met with mixed, mostly weak results over the years. Legal organizations have invested a great deal of money, time, and emotion in trying to help their employees “Workforce Diversity” in vain hopes of positively impacting the organization’s bottom line. The present study argues that the failure to realize gains from managing diversity stem from a basic misunderstanding of the nature of diversity itself, resulting in the view that it is both inevitable and inherently good. Once freed of these assumptions, managers can begin to truly manage diversity from a strategic perspective, insuring that their diversity strategy is consistent with other aspects of their competitive strategy, culture, and structure. The model also workforce diversity to answer the crucial question of why diversity is being introduced or increased in the organization. Different reasons reflect different goals. Workforce Diversity consultants were quick to point out that academic research had identified many positive aspects of a diverse workforce.

### **Literature Review**

Literature review finds both positive and negative effects of diversity on teamwork. This article is useful for diversity who wants a thorough understanding of the findings on team diversity benefits and drawbacks. It is also analyzes extensively the gaps in practical research and theoretical development. The covers how to organize team processes to maximize positive outcomes and to mitigate the negative effects of team diversity. Based on current understanding of diverse work groups, the workforce diversity is harder to build since diverse teams in organizations require significant additional human costs. They assert that a human resources based case for workforce diversity, which they define as “Role of Law in Workforce Diversity” and is a stronger argument for persuading senior management to embrace workplace diversity and team workgroups. A review of cross-cultural training: Best practices, guidelines and research needs. This article is an excellent resource for the Legal Heads responsible for training programs for expatriate employees.

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## **Introducing the Human Right to Medicine and the Challenges before the International Community\***

**Dr. Om Prakash Siravi**

*Pahalaa sukh nirogi kaya*<sup>108</sup> i.e. health is the first and foremost happiness. It is the pleasure of pleasures. Health is a fundamental human right, indispensable for the exercise of all other human rights and that is why all human rights are said to be interdependent and interlinked. Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.<sup>109</sup> Right to health has been recognised in number of international documents.<sup>110</sup> The factors affecting right to health are plenty; (to name a few, poverty, literacy, environment, way of living, employment, working conditions, medical facilities, child marriage) and access to medicine is one of them. In this paper the author tries to establish right to

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<sup>108</sup> *“pahalaa sukh nirogi kaya, dusara sukh ghar me maya, teesara sukh pativrata naree, chautha sukh putra aagyakari, panchwa sukh samaj me aage, chhatha sukh rajneeti me pichhe”*, an old saying in Hindi.

<sup>109</sup> Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19<sup>th</sup> June – 22<sup>nd</sup> July 1946; signed on 22<sup>nd</sup> July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7<sup>th</sup> April 1948. The definition has not been amended since 1948.

<sup>110</sup> *E.g.* - The Universal Declaration of Human Rights, 1948, article 25.1.

- International Covenant on Economic, Social and Cultural Rights, 1966, article 12.1 & 12.2.
- European Social Charter, 1961.
- Declaration of Alma Ata, 1978, declaration V, VI & VII.
- African Charter on Human and People’s Rights, 1981, article 16.
- Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, 1988, article 10.
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- CEDAW, article 12.

medicine as a human right and an integral part of the right to health and highlights the challenges it has to confront.

**Right to medicine-** Gone are the days when people preferred herbs to cure diseases. After the advent of allopathic medicines, the use of herbs has been nearly outdated. Due to increasing dependence on the medicine it has now become a *sine qua non* to achieve health that first and foremost there should be easier and cheaper (in some cases) access to medicines. Therefore the right to medicine is an integral part of the right to health and necessary the most to achieve the highest attainable standards of health. It plays a pivotal role in achieving and maintaining health. A functioning health system depends upon availability, affordability, accessibility and acceptability of the medicine. In this connection various medicines can be classified as follows-

- **Conventional or mainstream medicine-** It refers to allopathic medicine which refers to the use of drugs to cure diseases.
- **Alternative medicine-** It includes homeopathy, naturopathy and herbal medicine.
- **Branded medicine-** It is the conventional medicine produced by the innovator.
- **Generic medicine-** It is a copy of branded medicine containing exact active ingredients. Generic medicines are substantially cheaper than branded ones as there are no costs related to research and development.
- **Counterfeit medicine-** A medicine which is deliberately and fraudulently mislabelled with respect to identity and, or source.<sup>111</sup> Counterfeiting can apply to both branded and generic products.
- **Substandard medicine-** A medicine which has incorrect ingredients or wrong ingredients, poor quality ingredients, no active ingredients, insufficient active ingredients, contamination, poor stability, or poor packaging.

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<sup>111</sup> Available at: <http://www.who.int/medicines/services/counterfeit/faqs/03/en/> (Visited on Sept. 24, 2013).

Every year, almost 10 million people die all over the world because they do not have access to existing medical treatments. In a presentation to the participants<sup>112</sup>, Anand Grover, the UN Special Rapporteur on the Right to Health, pointed to figures from the WHO which estimates that a third of the world's population does not have ready access to essential medicines. Grover said that unlike in high income countries, in low and middle income nations, 50 to 90 percent of the cost of medicines is paid out of the patient's own pocket. The situation is exacerbated, Grover said by low rates of health coverage in many places, for example, in Latin America only thirty five percent, in Asia only ten percent and in Africa only eight percent of the population is covered.

There is a huge inequity, inequality and injustice in access to medicine. In the most impecunious parts of Africa and of Asia, more than half the population does not have access to essential drugs. Many medicines are and have been for many years out of reach of the people in developing countries. Because of globalisation and new international trade rules, the situation may even get worse in the near future. In such a catastrophe it is maintained that access to medicine is not only an integral part of right to health but also inevitable for the exercise of other human rights. In fact, for millions of people around the world, the full enjoyment of the right to health remains an illusive goal, due to (*inter alia*) the hurdles to access to medicines of good quality, affordable and in a timely fashion, especially in developing countries. This constitutes a challenge to human dignity, the basis of all human rights, including the rights to life, health and development of all persons. From a human rights perspective, access to medicines is intrinsically linked with the principles of equality and non-discrimination, transparency, participation, and accountability. States are obliged to develop national health legislation and

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<sup>112</sup> In Human Rights Council, while adopting the Resolution 12/24 on "Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" on October 12, 2009.

policies and to strengthen their national health systems. For this purpose, key issues related to access to medicines must be taken into account such as: sustainable financing, availability and affordability of essential medicines, price and quality control, dosage and efficacy of medicines, procurement practices and procedures, supply chains, etc.

**Right to medicine may encompass the following:**

- Equal access to medicine, that is without discrimination,
- availability of original medicines,
- to right person, the right dose, the right medicine, at right time and in right way<sup>113</sup>,
- free availability of medicines to the poor,
- availability of more expensive medicines at cheaper rates,
- free and easy access to essential medicines as specified by WHO and many nations and
- prohibition on sale of medicines without prescription of doctors.

**Right to medicine in international Human Rights documents-** Right to health has been recognised in many human rights documents as discussed earlier<sup>114</sup> but the role of medicine in the attainment of health was internationally recognised for the first time<sup>115</sup> by the UN Human Rights Council in its resolution<sup>116</sup> on “Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”. The Council recognized<sup>117</sup> that access to medicine is one of the

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<sup>113</sup> Available at: [http://www.wapc.org/pdf/newsletters/yukReport\\_Spring08.pdf](http://www.wapc.org/pdf/newsletters/yukReport_Spring08.pdf) (Visited on July 21, 2013).

<sup>114</sup> See *supra* note 3.

<sup>115</sup> In the Millennium Summit in 2000 the UN adopted Millennium Development Goals (MGDs) which consisted, *inter alia*, Target 8E: In co-operation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries. So the signals of awareness for access to medicine can also be found in the MGDs.

<sup>116</sup> A/HRC/RES/12/24, XIIth Session, 12-10-2009.

<sup>117</sup> *Id.* clause 1.

fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. It stressed, *inter alia*, also the responsibility of States to ensure access to all, without discrimination, of medicines, in particular essential medicines, that are affordable, safe, effective and of good quality. Reaffirming the Universal Declaration on Human Rights and the International Covenant on Economic, Social and Cultural Rights, emphasising the Millennium Development Goal regarding health and recalling the Declaration on the Right to Development the Council recognised access to medicines as one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health<sup>118</sup> emphasised on the States' primary responsibility for enhancing the access to medicine. The report disclosed that pharmaceutical companies instead of fulfilling their shared responsibility acted as obstacles in the discharge of States' duty in relation to access to medicine and therefore the Special Rapporteur laid down Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.<sup>119</sup> The preamble to the Guidelines says that achievement of the Millennium Development Goals, such as reducing child mortality, improving maternal health, and combating HIV/AIDS, malaria and other diseases, depends upon improving access to medicines. Medical care and access to medicines are vital features of the right to the highest attainable

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<sup>118</sup> UNGA, A/63/263, 63<sup>rd</sup> Session, Item 67(b), 11-08-2008. It contains two main sections: as accountability is one of the central features of human rights, section I discusses the importance of effective, transparent, accessible and independent accountability mechanisms in relation to the right to the highest attainable standard of health. Section II and the annex to the present report, containing the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, which set out the human rights responsibilities of pharmaceutical companies in that context.

<sup>119</sup> *Id.* annex.

standard of health. The guidelines ask the companies to pay attention on the needs of the disadvantaged while framing policies having any bearing upon access to medicine.<sup>120</sup> They require the companies to be transparent<sup>121</sup> and accountable<sup>122</sup>. They should produce medicine conforming WHO Good Manufacturing Practice Guidelines.<sup>123</sup>

Besides these major documents on right to medicine, a *Manifesto for a Human Rights Based Medicine*<sup>124</sup> **was elaborated in May 2008 in Venice, at a meeting promoted by Emergency about the health sector in Africa, at which the Ministers of health of eight African countries participated. It declares that** the “Right to be Cured” as a basic and inalienable right belonging to each and every member of the human community. It appeals to other Health Authorities and Humanitarian Organisations to sign this Manifesto and to join in promoting an EQS<sup>125</sup> based medicine.<sup>126</sup>

**Imprints of facets of access to medicine in Indian municipal law-** Many Indian statutes contain certain provisions very germane to access medicine. They are as follows-

- **The Drugs and Cosmetics Act, 1940-** To ensure quality of drugs Chapter Four of the Act deals with manufacture, sale and distribution of drugs and cosmetics. It prohibits manufacture and sale of misbranded, adulterated and spurious drugs.<sup>127</sup>

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<sup>120</sup> *Id.* guideline 5.

<sup>121</sup> *Id.* guideline 6 & 8.

<sup>122</sup> *Id.* guidelines 9-14.

<sup>123</sup> *Id.* guideline 20.

<sup>124</sup> So far, the *Manifesto* has been undersigned by: Central African Republic, Chad, Democratic Republic of Congo, Djibouti, Egypt, Eritrea, Ethiopia, Rwanda, Sierra Leone, Somalia, Sudan, South Sudan, Uganda.

<sup>125</sup> Equality, Quality and Social Responsibility.

<sup>126</sup> Besides, The Charter of Fundamental Rights of the European Union also contains some important provisions in this respect. In paragraph 2 of Article 3 of the Charter special attention is given to medicine and biology. Article 35 of the Charter deals with the right of access to health care.

<sup>127</sup> The Drugs and Cosmetics Act, 1940, section 16.

- **Drugs (Price Control) Order, 1955-** Drug is one of the essential commodities under the Essential Commodities Act, 1955. Therefore an order has been issued which lays down the procedure for fixing the prices of the drugs. Under the said Order, the retail price is required to be displayed on the label of the container of the formulation and no person can charge exceeding the price printed on the label. With a view to securing compliance of the order, State Governments have authorized the officers of the Directorate to look after the enforcement of the Order.

- **The Pharmacy Act, 1948-** It seeks to regulate the profession and practise of pharmacy. Section 43 of the Act ensures availability of right medicine. It lays down that only registered pharmacist persons can compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner. Whoever contravenes this provision is punishable with imprisonment upto six months or with fine upto one thousand rupees or with both.

- **The Industries (Development and Regulation) Act, 1951-** It is an Act to provide for the development and regulation of certain industries. Section 2 lays down that it is expedient in the public interest that the Union should take under its control the industries specified in the First Schedule. The Schedule includes Drugs and Pharmaceuticals also.<sup>128</sup> Thus pharma industry is regulated by the Union of India.

- **The Factories Act, 1948-** The Act deals with provisions relating to age and working conditions of labour in factories. Section 45 of the Act is very germane so far as right to medicine is concerned:

“Section 45, First-aid appliances-

1. There shall in every factory be provided and maintained so as to be readily accessible during all working hours first- aid boxes or cupboards equipped with the prescribed contents, and the number of such boxes or cupboards to be provided and maintained shall not be less than one for

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<sup>128</sup> The industrial (Development and Regulation) Act, 1951, Schedule First, Entry 22.

every one hundred and fifty workers ordinarily employed at any one time in the factory.

2. Nothing except the prescribed contents shall be kept in a first- aid box or cupboard.

3. Each first- aid box or cupboard shall be kept in the charge of a separate responsible person who holds a certificate in first- aid treatment recognised by the State Government and who shall always be readily available during the working hours of the factory . . .”

• **The Indian Penal Code, 1860**- Chapter XIV titled Of Offences Affecting Public Health etc defines certain offences relating to drugs and contains certain penal provisions as follows:

Section 274, Adulteration of drugs- Whoever adulterates any drug or medical preparation in such a manner as to lessen the efficacy or change the operation of such drug or medical preparation, or to make it noxious, intending that it shall be sold or used for, or knowing it to be likely that it will be sold or used for, any medicinal purpose, as it had not undergone such adulteration, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine which may extend to one thousand rupees, or with both.

Section 275 provides for penalty for sale of or issue from a dispensary for medical purposes of adulterated drugs. Section 276 penalises sale of or issue from a dispensary for medical purposes of different drugs or preparation.

**Access to ‘essential medicines’**- The term “access” is defined by the United Nations Development Group as “having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk from the homes of the population.”<sup>129</sup> According to WHO<sup>130</sup> essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance,

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<sup>129</sup> MDG Gap Task Force Report 2008 at 36.

<sup>130</sup> Available at: [http://www.who.int/topics/essential\\_medicines/en/](http://www.who.int/topics/essential_medicines/en/) (Visited on July 27, 2013).

evidence on efficacy and safety, and comparative cost-effectiveness. They are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. Access to health care including access to essential medicines is a matter of justice. Access to basic medicines makes the difference between life and death, and is a crucial link in realizing the right to health. Rather the most apparent threat to human rights is the inability of people to achieve access to expensive medicine, particularly in the context of HIV and AIDS. The Committee on Economic Social and Cultural Rights interpreted right to health as: "States Parties ... have a duty to prevent unreasonably high costs for access to essential medicines."<sup>131</sup>

The right also finds place in one of the principles of International law of Warfare that is *fides etiam hostis servanda* which includes that during the outbreak of war the supply of life saving drugs should not be affected. The lack of access to essential medicines for almost 2 billion poor people stands as a direct incongruous to the fundamental principle of health as a human right. The WHO is playing the role of a crusader in this connection since 1970. It laid down the first Model List of Essential Medicines in 1977. The WHO has published a list of core essential medicines and a complementary list as well, and it encourages countries to establish their own lists.<sup>132</sup> Many states have made national lists of essential medicines and medicine policy. These national lists are critical as countries set priorities for their national drug policy and make decisions about how to allocate resources for national health budgets. Essential medicines are a core area of focus for the Millennium Development

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<sup>131</sup> Committee on Economic, Social and Cultural Rights, General Comment No. 17 on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author, UN doc. E/C.12/GC/17, 12 January, 2006, para. 35.

<sup>132</sup> The Ministry of Health and Family Welfare in India has also prepared a National List of Essential Medicines, 2011, available at <http://www.mohfw.nic.in/showfile.php?lid=785>, (Visited on Aug. 25, 2013).

Goals. MDG Target 8.E states: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.

**Essential Medicines and WHO**<sup>133</sup>- WHO has laid down the criteria for selection of essential medicines which are; disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. It has formed Expert Committee on Drug Dependence, Expert Committee on the Selection and Use of Essential Medicines and Expert Committee on Specifications for Pharmaceutical Preparations. According to WHO the concept of essential medicines is global and forward-looking. It incorporates the need to regularly update medicines selections to reflect new therapeutic options and changing therapeutic needs; the need to ensure drug quality; and the need for continued development of better medicines, medicines for emerging diseases, and medicines to meet changing resistance patterns. It has framed Medicines Strategy which aims at framing and implementing policy; ensuring access; ensuring quality, safety and efficacy; and promoting rational use of medicines. In the 54<sup>th</sup> World Health Assembly it urged the member-states to make every attempt to promote equitable access to medicine and to provide financial support and technical co-operation to member-states in need to expand access of their populations to essential drugs.<sup>134</sup> It has come up with a new approach to measurement that is; a joint Health Action International (HAI) – WHO project initiated at the WHO-NGO Round Table in 2000. This project has developed technical guidance for a standard approach to the measurement of the prices people pay for key medicines.

For the purpose of quality assurance, WHO Member States follow WHO for expertise and guidance in regulation, safety and quality assurance of medicines through development and promotion of international norms, standards, guidelines and nomenclature. Such activities include guideline development, workshops and training courses, coordination and promotion of pharmaco-

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<sup>133</sup> Available at: <http://www.who.int/medicines/topics/en/> (Visited on Aug. 28, 2013).

<sup>134</sup> WHA54.11, 21-05-01.

vigilance for global medicine safety, regulatory and other information exchange, and review of narcotic and psychotropic substances.

WHO is very meticulous regarding selection of the essential medicines. Careful selection of a limited range of essential medicines results in a higher quality of care for patients, better management and use of medicines and more cost-effective use of health resources. WHO supports countries in the selection of essential medicines by publishing the Model List of Essential Medicines, which serves as a guide to the development of national essential medicine lists. The inclusion criteria for the List are proven safety and efficacy, well-understood therapeutic qualities and reasonable price or cost. Most of the drugs on the List are generic products and only fifteen are patented products. The essential-drugs concept has been for many years a key strategy to help improve access to essential drugs and contribute to improved health. Over 140 countries have adopted national essential drug lists and access to essential drugs has increased. WHO is the secretariat for the Expert Committee on Selection and Use, the group of experts responsible for revising and updating the Model List of Essential Medicines. The WHO Model Lists of Essential Medicines has been updated every two years since 1977. The current versions are the 18<sup>th</sup> WHO Essential Medicines List and the third WHO Essential Medicines List for Children updated in March 2011.

**Barriers to access medicine-** Right to medicine does not seem to be a difficult right to fulfil but there are certain apparent and hidden factors which have material bearing on availability and affordability of medicines and that is why a right based approach has to be adopted to access medicine. They include poverty, inadequate national commitment, obstacles created by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, doctor-pharmaceutical company concern, fraudulent pharmaceutical companies producing duplicate medicines, poor supply of essential medicines<sup>135</sup> and the

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<sup>135</sup> This is the case with eflornithine (DFMO), used in the treatment of human African trypanosomiasis, better known as 'sleeping sickness'. Sleeping sickness is caused by a parasite transmitted by the tsetse fly and affects

current incentive structure for research and development of medicines and vaccines to address priority health needs of developing countries.

On the other hand the access to essential medicines is affected not only by the production, distribution, and pricing of medicines, but also by the lack of incentives for research and development of drugs needed to treat diseases in developing countries, by functioning health systems, so that drugs are part of a rational system of quality treatment and care, as well as by infrastructure, so that they can be delivered to all areas where they are needed.

### **IPR: as a barrier to access the essential medicines-**

IPRs can help ensure that creative productions are protected from unauthorized modification and that their authors receive royalties or licensing income from the reproduction of their work. Patents prohibit the unauthorized reproduction of a vast range of products and productive processes. Such patent protections are more problematic, morally, than copyrights, especially when they confer property rights in biological organisms (like seeds used in food production) and in molecules used in medicines. Patents of these kinds are morally problematic insofar as they, directly or indirectly, obstruct access by the poor to basic foodstuffs and essential medicines.

The Member states of the World Trade Organization adopted the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1994 to work toward global protection of intellectual property rights. TRIPS is the most important international agreement on the protection of patents, copyright and trademarks. It has acknowledged the nexus between intellectual property rights and public health from its inception. Article 8 of TRIPS, which applies to all Member States, addresses the need to balance patent rights and public health by allowing States to adopt measures necessary to protect public health and nutrition as long as such measures are consistent with the provisions of

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30,000 people per year. In the advanced stage, the parasite affects the central nervous system. If left untreated, the disease will lead to death. *Available at:* <http://www.twinside.org.sg/title/twr120c.htm> (Visited on Sept. 17, 2013).

this Agreement. However, due to protection by patents, medicines become expensive and therefore beyond the reach of the poor. Pharmaceutical companies answer against this objection that they use the profits for further research. However in reality they have ended up with 'nothing-new' or 'me-too' type products. In view of expensive drugs, the health of the people of developing countries seems to be at stake. Will they have to wait for the drug for twenty years?

Article 31 of TRIPS Agreement permits governments of members to mandate manufacturing of generic pharmaceuticals in some cases which is termed as 'compulsory licensing'. However clause (f) is detrimental to the interests of the developing and under-developed countries because it limits the distribution of drugs manufactured under compulsory licenses to the domestic markets of that member only.<sup>136</sup> Thus the exportation of medicines manufactured under compulsory licenses is restricted but TRIPS did not offer an effective solution for nations without the capability to manufacture drugs. The developing countries that lack the capacity to manufacture their own generic medicines could not take advantage of the compulsory licensing provision.

**Conclusion and suggestions-** Medicine thus appears to be inevitable for the fulfilment of the right to health and therefore access to medicines must be made easy and affordable. It can make difference between life and death of an individual. But access to medicine is obstructed by many factors and therefore it has to be recognised as a human right and enforced by adopting a right-based approach. Many destitute nations are deprived of access to essential medicines especially for people suffering from AIDS and other life-threatening diseases. TRIPS Agreement also acts as a barrier to access to medicine because it primarily contains commercial interests and lacks humane contents. Following steps can be taken to ensure access to medicines-

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<sup>136</sup> "Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.": Article 31(f), TRIPS Agreement.

- Incorporation of such provisions in the constitutional law of countries as a part of fundamental rights.
- Imposition of obligations on the government and other stakeholders with regard to the access to essential medicines and provision of health-care services, with emphasis on vulnerable groups;
- Formation and implementation of a national medicines policy to fulfil these obligations.
- Regular reporting on the progressive realisation of the right to health and access to essential medicines.
- Humanisation of TRIPS Agreements and other international trade agreements especially with respect to essential medicines and primacy of protection of public health over commercial interests in such agreements.
- Some alternative methods of world-wide sharing of research and development costs should be developed.
- Encouragement to parallel imports by incorporating in municipal patent laws especially in developing countries as it is permitted in the TRIPS Agreements. Parallel imports are cross-border trade in a product without the permission of the manufacturer. It takes place when there are price differences for the same product in different countries.
- A number of essential drugs are already not included in the Essential Drug List. All the AIDS drugs (except AZT for the prevention of mother-to-child infection) and certain new antibiotics are not included even when infectious diseases such as HIV and tuberculosis are responsible for a large proportion of deaths occurring between the ages of 15 and 59 years in low- and middle-income countries.<sup>137</sup>
- Amendment in Article 31(f) of the TRIPS Agreement which restricts export of medicines manufactured under compulsory license and results in deprivation of the poor countries of the medicines.

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<sup>137</sup> Available at: <http://www.twinside.org.sg/title/twr120c.htm> (Visited on Oct. 17, 2013).

- Promotion to differential pricing that is, charging different prices from different buyers. So a drug manufacturer can charge less price from poor countries and higher from the rich. For this purpose,
  - the seller must have some control over price,
  - he must be able to identify and separate consumers according to varying price sensitivities; and
  - chances of re-sale from low-priced markets to high-priced markets must be removed that is, market segmentation must be assured.

## **Stem Cell Research and its Regulation in India**

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Human embryonic stem cell (HESC) research has only recently begun in India. India is a developing country with the goal of achieving fully industrialised status in the year 2025 and biotechnology has been identified as an engine of economic growth for the country.

HESC research has significant medical importance offering the promise of cures for patients suffering from various diseases. As master cells, stem cells can give rise to wide range of cells and tissues. They are blank cells, or slates, that have yet to become specialised. Unlike fully mature cells, they have a variety of potential futures.<sup>138</sup>

Most debates on HESC research are conducted in western developed countries like United Kingdom (UK), United States of America (USA) and Australia. The majority of the texts on the subject are written in western countries with western perspectives. The policies, guidelines and law in these countries are also highly developed. However, elsewhere, especially in emerging economies including India, there is limited literature written on this area and this contributes to the challenge for this topic. Acknowledging the gap in the literature, the thesis investigates the extent of the research involving HESC in the country and examines if there is a regulatory lacuna in this area.

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<sup>138</sup> Definition by Johnson and Selwood in Johnson MH & Selwood L, 'Nomenclature of Early Development in Mammals' (1996) 8 *Reproduction, Fertility and Development* 759-764

As HESC research raises issues of deep religious significance, it is especially controversial in a nation which is multi-racial, multi-cultural and multi-religious. Hinduism is the main religion in with the majority of the population being Hindu. There are also significant numbers of Christians, Buddhists, Jains and Sikhs in the country. Internationally, theologians and representatives for the various religious groups argue both in favour of and against HESC research. There is a lack of consensus about the moral status of the human embryo as well as the ethics and morality of research using embryos. The cultural and religious diversity of a society makes the task of reaching a consensus challenging.

The types of stem cells used in research are adult stem cells and HESCs. Stem cells from embryos are pluripotent, that is, they can grow into every tissue type in the body.<sup>139</sup> They could become any type of cell to form skin, bones, organs and other body parts. They could be used to create any number of cell types that people with injuries or disease in need of transplants might benefit from receiving. Whilst doctors can transplant tissues and organ cells, they are often limited by lack of organ donors. Potentially, stem cells will allow the growth of required tissue when it is needed.

Research utilising HESCs remains in early stages, making it uncertain whether stem cells derived from human embryos<sup>140</sup> will ultimately prove useful in curing diseases and spinal cord injuries. It is premature to decide which

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<sup>139</sup> Definition by Johnson and Everitt in Johnson MH & Everitt BJ, *Essential Reproduction*, 5th edition, Blackwell Science Ltd, Oxford, 2000

<sup>140</sup> Findlay JK et al 'Human Embryo: A Biological Definition' (2007) 22 *Human Reproduction* 905-911

approaches will prove most useful and for which diseases. Due to the unsettled state of the science, stem cell research, both adult and embryonic, is being funded by public and private funding agencies around the world in order to make the potential of stem cells a reality. However, there are several important ethical issues with HESC research that have to be explored and addressed.

### **WHAT ARE STEM CELLS?**

Stem cells are master cells that have the ability to produce different cells and tissues. As blank slates/ immature cells, they have yet to become specialised.<sup>141</sup> Unlike fully mature cells, stem cells have a variety of potential futures. They have the unique capacity to develop into specialised/differentiated cells that carry out the specific functions of the body. This means they can become any type of cell to form skin, bones, organs and other body parts.

When a cell divides, each new cell has the potential to either remain a stem cell or to become another type of cell with a more specialised function. This unique characteristic makes them appealing for scientists seeking to create new cells to replace lost or damaged cells, and in the past few decades, scientists have gradually deciphered the processes by which unspecialised stem cells become specialised cell types in the body.<sup>142</sup>

Stem cells are found in all humans and are important research tools for use in the study of normal and abnormal human embryo development,

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<sup>141</sup> Definition by Johnson and Everitt in Johnson MH & Everitt BJ, *Essential Reproduction*, 5th edition, Blackwell Science Ltd, Oxford, 2000

<sup>142</sup> *ibid* at pg. 29

discovering new genes, testing drugs and other substances that cause birth defects. They are a renewable source of cells for tissue transplantation, cell replacement and gene therapies. They are touted as being useful in research and treatment of such diseases as Parkinson's, Alzheimer's, stroke and other neurodegenerative diseases and diabetes.

### **THE DISCOVERY OF STEM CELLS**

For centuries, scientists have known that some animals including starfish, newt, salamander and lizards- have the ability to regenerate missing parts of their bodies. Humans share this ability with these animals to some limited extent while a missing leg or a finger cannot be replaced, human bodies constantly regenerate blood, skin and other tissues. <sup>143</sup>

In the 1950s, experiments with bone marrow established the existence of stem cells in human bodies, leading to the development of bone marrow transplantation, a therapy now widely used in medicine. This discovery raised hope that doctors could regenerate damaged tissue with a new supply of healthy cells by drawing in the capability of stem cells to create many of the body's specialised cells. As a consequence, researchers were motivated to attempt to identify similar cells within the embryo. Early studies of human development proved that cells from the embryo have the capabilities of producing every cell type in the human body. In the 1980s scientists were able to extract embryonic stem cells from mice. In 1998 a team led by Dr James

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<sup>143</sup> *Prohibition of Human Cloning for Reproduction Act 2002 and Research Involving Human Embryos Act 2002* (Heerey Report) at 44-54

Thomson of University of Wisconsin was the first to isolate HESC. Human stem cells lines were derived from blastocysts which had been cultured from donated excess/ spare IVF embryos.

### **THE CONTROVERSIES OF HESC RESEARCH IN INDIA**

In many nations, including multi-religious India, HESC research has been, and is increasingly the subject of controversy, primarily because all extractions of HESCs involve the destruction of human embryos. The debate is discussed within various religious institutions and with people of different faiths. In laboratories, scientists have had to learn to reflect on the ethical and legal ramifications of their work. Despite the controversy, it is argued here that the promise of HESC research is probably sufficient justification to allow it to proceed, provided that it is governed by strict regulations and effective enforcement procedures. This synopsis will investigate options for regulating this controversial research and propose a best practice regulatory model for India.

The destruction of human embryos for the purposes of extracting HESCs presents an ethical and moral dilemma. Proponents of HESC research argue that it could lead to therapies for the patients in future. Opponents argue that the research has uncertain prospects and involves a process that destroys human lives. These two opposing positions reflect different views in respect to whose life matters more, whether the lives of patients or the lives of human embryos which are destroyed in the process of harvesting their stem cells for research. The argument raises questions about the obligation to heal patients,

the respect and protection owed to nascent human lives, and the manipulation of human lives for the benefit of others.<sup>144</sup>

The moral debate includes whether it is morally and ethically wrong to first create and then destroy a human embryo, whether cloned or not, in order to harvest its cells, and the concern about the treatment of nascent human life, that is, treating the seeds of the next generation as mere raw material for satisfying current human needs. While it is important to seek and provide medical treatment for patients and the injured, it is also important to honor moral limits that respect all lives and that refuses to secure the good of human beings by sacrificing the lives of others.

These are difficult questions. The moral issue surrounding HESC research leaves the status of the embryo highly contested. It is unclear whether human embryos are legally and morally considered as human lives from the moment of conception or at some later stage of development.

Other ethical issues also arise from HESC research, particularly concerns about the exploitation of women and the risk that the therapeutic cloning research may lead to reproductive cloning. This thesis takes the position that it is morally permissible to use early stage human embryos in research under strict regulation as that would not transgress moral boundaries.

These arguments focus broadly on whether the human embryo has meaningful interests and moral rights sufficient to justify the prohibition on

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<sup>144</sup> R Green, 'Can We Develop Ethically Universal Embryonic Stem-cell Lines?' (2007) p.8

HESC research.<sup>145</sup> This raises the question whether the early embryo in the first 14 days should be regarded as a human embryo or a collection of cells and therefore considered a pre-embryo. The destruction of the embryo, for the purposes of the extraction of stem cells from it, occurs around the fifth day after the first cleavage division. Questions are also raised as to whether the somatic cell nuclear transfer (SCNT) blastocyst, which does not involve egg and sperm fertilisation, should be regarded as a human embryo as there is no evidence that the blastocyst, if implanted in the body of a woman, can result in a live birth.<sup>146</sup>

These debates have been explored extensively in Australia<sup>13</sup> but in India, the discussions are both less advanced and more diverse.

### **THE MORAL STATUS OF A HUMAN EMBRYO**

The discussion of the moral status of an embryo can be traced back to the pre-Socratic philosopher Heraclitus. Aristotle wrote of the ensoulment of the human at a particular stage. In the western world, since the sexual revolution of the 60s, with the discovery of birth control pill and debates on the legality of abortion, there have been ongoing debates on the moral status of the human embryo with the question of when ensoulment occurs. In 1978, when the world's first in vitro fertilisation (IVF) baby test-tube baby was born, the debate re-emerged in a report in the UK.<sup>147</sup> In 1997, the creation of Dolly, the sheep, generated new debates on issues arising from cloning and stem cell

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<sup>145</sup> NHMRC Embryo Research Licensing Committee, *Information Kit* (2008)

<sup>146</sup> NHMRC Embryo Research Licensing Committee, *Information Kit* (2008)

<sup>147</sup> *ibid.*

research, which included the moral debate of human embryos as evident in the reports in countries like the USA and Australia. At present, this continues to be a debatable issue in the discussion of the use of reproductive technologies not only in the western world but also in other societies such as the Muslim world. The key to the argument of the moral status of the human embryo is the moment at which personhood or a soul is acquired. With reference to western academic literatures, this notion is debated ethically with three different views put forward.

### **Pursuing research within reasonable bounds**

This argument raises the principle of proportionality in considering research. Experience in some jurisdictions has shown that HESC research can be carried out within reasonably proportionate bounds with strict regulations and the enforcement of the regulations. For instance, in Australia, the relevant legislation, the *Research Involving Human Embryos (RIHE) Act 2002*, creates a national scheme whereby researchers are licensed for each research project that involves use of an embryo.

The key feature of the scheme is a licensing regime restricted to the use of excess ART embryos, that is, those embryos that have been created in order to achieve a pregnancy but which, after a period of frozen storage, are no longer needed for this purpose. The aim of the scheme is to allow research on human embryos but only in limited circumstances. The *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 (Amendment Act 2006)* which, *inter alia*, amended the *RIHE Act 2002*,

permits research on cloned embryos but the approval to be granted is strictly limited to the first 14 days of development, a point when the primitive streak is formed and before organ differentiation occurs.<sup>148</sup>

## **THEOLOGICAL APPROACH**

Religious views have been prominent in debates and reports on cloning and stem cell research. They are informed by ethical, theological and legal issues.

The debate on the moral status of the human embryo is closely linked to philosophical and religious perspectives on the subject of human embryonic stem cell (HESC) research.

Islam is a monotheistic religion with a belief in one God. Its teachings provide a complete and comprehensive way of life, encompassing all fields of human endeavours, spiritual and material, individual and societal, economics and politics, national and international. 'The instructions regulating a Muslim's daily activities, *shariah*/ Islamic law/ jurisprudence, apply to all Muslims, everywhere and at all times. As bioethical deliberations are inseparable from religion, Islamic bioethics is decided in accordance with *shariah*. As a dynamic and relevant entity, it also applies to contemporary emerging biotechnologies including HESC research.<sup>149</sup>

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<sup>148</sup> Chalmers D & Nicol D, 'Embryonic Stem Cell Research: Can the Law Balance Ethical, Scientific and Economic Values?' at 101

<sup>149</sup> Nordin M, '\_Islamic Medical Ethics amidst Developing Biotechnologies' <http://www.fimaweb.net/main/medicalethics/islamicmedicalethicsamidstdevelopingbiotechnologies.doc>

For centuries, Muslim scholars have discussed issues of *ruh*/ soul. In the past four decades, this issue has been addressed in the context of increasingly successive scientific developments and advances in biomedical topics including birth control, abortion, in-vitro fertilisation (IVF), research on embryos, embryo banking, stem cell research and genetic engineering.<sup>150</sup>

The Quran, which was revealed by Allah to Prophet Mohamad, is the primary source of teachings for Muslims. The Hadith, which contains the sayings of Prophet Muhammad, is the second most important source of teachings.<sup>151</sup>

The Hindu religion is a polytheistic religion which holds a belief in many gods. The purpose of its philosophy is to extinguish human sorrow and suffering.<sup>152</sup> Suffering is inborn, part of life and thus cannot be avoided. The ultimate objective is to obtain a good life, overcome sorrow and achieve enlightenment through prayers and penance. Hinduism attributes suffering and misery to *karma*, the moral law of cause and effect, and teaches that most sufferings are caused by humans in failure to harmonise their thoughts and deeds in accordance with God's law.

There is no central authority in Hindu religion that makes pronouncement of the religion's official position. The resolution of ethical dilemmas depends on the guru/ spiritual leader and in conferences, held

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<sup>150</sup> *ibid*

<sup>151</sup> *supra*

<sup>152</sup> S Promta, '*Human Cloning and Embryonic Stem Cell Research*'

mostly in India, the leaders of different sects give their interpretations of such issues.<sup>153</sup>

Hindus believe that life begins at conception, the beginning of a soul's rebirth from a previous life. In the context of abortion, Hinduism is opposed to the deliberate killing of an embryo or foetus except to save the life of the mother. According to the Hindu *Vedas*/ religious texts, all lives are sacred, whether humans, animals or plants.<sup>154</sup>

There is no clear rule in Hinduism as to the ethics of HESC research. If the destruction of the embryos in the research is considered as an extraordinary and unavoidable circumstance that is done for greater good, the Hindu religion may accept the research as ethically justified. There have been no objections raised against the research.<sup>155</sup>

### **TO REGULATE HESC RESEARCH OR NOT?**

While the aim is to explore appropriate models of regulation for the India government to adopt to regulate HESC research, a preliminary inquiry is whether it is essential or even desirable to regulate HESC research at all. It might be argued that in India, it is preferable to adopt minimum regulation or to leave the research as totally unregulated as this facilitates free, unfettered and uninhibited research for the scientific community in the country. However, there are persuasive insights offered by eminent people in favour of adopting

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<sup>153</sup> *ibid.*

<sup>154</sup> *ibid.*

<sup>155</sup> Letchumanan R, 'Human Cloning, A Hindu Perspective' paper presented at a 'Seminar on Reproductive Cloning of Human Beings' 2002

regulation, as explored below. Michael Kirby makes a compelling argument in favour of regulation, particularly for contentious areas of research. He gives the example of human reproductive cloning where he asserts that for the law to say nothing about the reproductive cloning of human beings is to give green light to experiments in that technology. He further explains that nothing then exists to restrain [scientists] except for their own ethical principles, any institutional ethics clearance requirement, the availability of funding and their prospects of a market [and their religious convictions]'. Thus where there is no regulation to prohibit or regulate an activity, scientists may decide to pursue controversial experiments out of simple interest and sheer curiosity. Kirby asserts that while proponents of technological innovation have often favoured containment of law and a libertarian approach to development of technology, yet most lawyers recognise that there are limits. He warns that the absence of regulation will mean that the society has effectively made a decision to permit the technological advances to occur without impediment. He stresses that limits must be clearly expressed and upheld in an effective way

Francis Fukuyama also argues that it is essential to regulate biotechnology.<sup>156</sup> He expresses concerns that unregulated biotechnology poses an insidious threat to society's way of life and compromises human dignity. He explains that:

“the people in Brave New World may be healthy and happy, but they have ceased to be human beings. They no longer struggle,

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<sup>156</sup><https://philosophy.as.uky.edu/sites/default/files/Gene%20Regime%20%20Francis%20Fukuyama.pdf>

aspire, love, feel pain, make difficult choices, have families or do any of the things that we traditionally associate with being human. They no longer have the characteristics that give us human dignity. He adds there is a fear that, in the end, biotechnology will cause us in some way to lose our humanity, that is some essential quality that has always underpinned their sense of who we are and where we are going.”

Regulation of scientific research is not a new subject. In the context of biotechnology, 100 nations are enacting specific regulatory instruments to regulate controversial areas of research. In Australia, for example, the *Gene Technology Act 2000* was passed to regulate research on genetically modified organisms (GMOs), the aim is to protect the health and safety of people and to protect the environment.

Legislation is not the only form of regulation. There is, for instance, soft law in the form of guidelines, an approach adopted for the regulation of research in India examines whether India should move to the next level by introducing legislation to regulate HESC research in future. In Australia, the decision has already been taken to pass legislation to regulate research involving human embryos. This is primarily because legislation promotes certainty and clarifies what is permissible for scientists.

Therefore it is argued that in India, passing legislation to regulate HESC research will provide greater likelihood of clear parameters, scope and legal

protections to scientists and ensures transparency and accountability as evident in the Australian regulatory regime.

In Sherley v. Sebelius<sup>157</sup>, the U.S. Supreme Court held that it won't review a challenge to federal funding for embryonic stem cell research, putting to bed a controversy that once threatened to cut off support for such studies.

The court's refusal to consider an appeal in this case<sup>158</sup> ends a more than 3-year effort by the plaintiffs, two adult-stem-cell researchers, to stop NIH backing of the work, which holds the promise of treatments for a variety of diseases, but which depends on the destruction of days-old human embryos. As is typical practice, the court did not give reasons for declining to hear the case.

## **REGULATUION IN INDIA**

The zeal exuded by the Government of India has led to the prompt identification of stem cells as a niche area requiring intense focus. Its translation in real-time is evidenced by its ever-increasing patronage in the form of grants towards infrastructure development and operational activities.

The Stem Cell Task Force (SCTF), constituted in 2003 was entrusted with the responsibility of evaluating project proposals, pushing the formulation of protocols, monitoring and also for evaluating results.

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<sup>157</sup> 644 F.3d 388 (D.C. Cir. 2011)

<sup>158</sup> *supra*

There was a proposal for “stem cell priority fund” with possibilities of including ICMR, DST and DRDO.<sup>159</sup>

India is a significant contributor to the global market for stem cells and is growing at a rate of 15% according to Dr. Satish Totey. With such a tremendous growth potential, the need for stringent regulations is widely felt. This has been aptly summarised by Prof. M.K. Bhan of DBT when he announced the setting up of “Institute for Stem cells and Regenerative Medicine” in Bangalore saying, “we have a broad strategy to recognise the biology of stem cells and create practical accessible therapies. The way we see it in India is that while promoting science and technology strongly, we want to follow world-class standards of ethics, regulation and engage the civic society in terms of getting their consensus.”

Realising the complicated ethical, social and legal issues involved in this field, ICMR took up the reins and laid down the “National Guidelines of Stem Cell Research and Therapy 2006”. One of its salient features of the report is the classification of stem cell research under permissible, restricted and prohibited categories. The research pertaining to adult and umbilical cord blood stem cells would be classified as permissible. It would require approval from Institutional committee. However, embryonic stem cells research falls under restricted category. It can be carried out with the approval of Institutional Committees and National Apex Committee. Research pertaining to reproductive cloning, introducing animal embryos in human, etc. has been categorized as prohibited.

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<sup>159</sup><http://annalsofneurosciences.org/journal/index.php/annal/article/viewArticle/241/895>

A distinction has been made between establishing embryonic stem cell lines from spare embryos and embryos specifically made for the purpose, including both in vitro fertilization and somatic cell nuclear transfer techniques. The former is placed in the permissive category provided spare embryos are obtained in an ethically acceptable manner while the latter is restricted in its category to require specific scientific justification and proof of technical competence of the investigator. It has been done to dissuade frivolous creation of embryos for establishment of hES cell lines.

This notification issued by the Ministry of Health and Family Welfare includes provisions relating to umbilical cord blood banking. This notification defines 'umbilical cord blood' as the whole blood including Hematopoietic Progenitor Cells (HPC) collected from placental and/or umbilical cord blood vessels after the umbilical cord have been clamped. This notification also includes the requirements for collection, processing, testing, storage, banking and release of umbilical cord blood derived stem cells. Provisions relating to quality control such as haematological, microbiological and instrumental testing have also been made in this notification. Provisions for disposal of waste and infectious materials have also been included.

These guidelines for stem cell research have been issued by Department of Health Research and Department of Biotechnology of Indian Council for Medical Research. These guidelines contain comprehensive provisions relating to general and specific principles of Stem Cell Research. Responsibility of investigators, institutes and sponsors for conduct of stem cell research has

also been fixed by these guidelines. These guidelines also provide a mechanism for review and monitoring of stem cell research. Permissible areas of research along with restricted and prohibited areas have also been expressly mentioned in these guidelines.

These guidelines make provision for therapeutic uses of stem cells and also for prevention of their misuses. These guidelines provide that all stem cell therapy other than bone marrow transplantation (BMT) shall be treated as experimental. It should be conducted only as clinical trial after approval. Cells used in such clinical trials must be processed under GTP/GMP standards.

These guidelines also provide for banking of biological tissues. These guidelines mention that the following points should be specifically considered while collecting umbilical cord blood for banking:

- i. No harm should occur to the donor fetus.
- ii. Exact timing of the clamping of umbilical cord should be defined.
- iii. Parents should be correctly informed regarding risks and benefits involved.
- iv. Free informed consent should be obtained from both the parents. If there is disagreement between the parents, the mother's wish shall prevail.
- v. ID card should be issued for voluntary donation to enable preferential access/benefits in future in case required for self/relatives. Such units may also be used for unrelated individuals.

- vi. Standard Operative Procedures (SOPs) for collection, transportation, processing, storage (cyro-preservation) and release for clinical use of umbilical cord blood cells should be clearly laid down.
- vii. Period of preservation for self-use later in life should be defined.
- viii. Detailed protocol for release of umbilical cord units for clinical use should be in place. This should include follow up plans for assessing safety and efficacy of cord blood stem cell therapy.