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## THE DATA EXCLUSIVITY DEBATE IN INDIA: TIME FOR A RETHINK?

Prashant Reddy T.\*

*Data exclusivity or regulatory marketing exclusivity is a concept that has been subject to much debate in the Indian context – with specific reference to the Indian pharmaceutical and agro-chemical industries. This debate has been carried on in the backdrop of obligations under the TRIPS as well as the Indo-EU Free Trade Agreement.*

*In this paper, the author discusses the concept of data exclusivity in the light of the existing regulatory regime for pharmaceuticals and agro-chemicals in India. He also examines various Committee reports to glean the Indian stance on data exclusivity for agro-chemicals as well as pharmaceuticals and the contradictions therein. The paper proposes data exclusivity as an incentive for drug companies to conduct clinical trials, particularly local clinical trials in India rather than free-riding on foreign trials. Although such local clinical trials are in the interest of public health, they remain almost prohibitively expensive. Therefore, it is necessary that the conduct of such trials is incentivised. As the high threshold for patentability in India deters patents from being employed as such incentive, this paper nominates data exclusivity as a possible solution.<sup>§</sup>*

### INTRODUCTION

For the last few years India has been witness to several debates on the suitability of a data exclusivity regime for the country, initially in the context of TRIPs and later in the context of the proposed Indo-EU FTA.<sup>1</sup>

By way of a brief introduction, ‘data exclusivity’, which is also known as ‘regulatory data protection’, aims to provide a period of marketing exclusivity for those manufacturing pharmaceuticals or agro-chemicals. Such marketing exclusivity is granted only for those pharmaceuticals and agrochemicals

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<sup>§</sup> Supplied by Editorial Board.

\* B.A. LLB, (Hons.) National Law School of India University (’08). Masters of Law (Law, Science & Technology) Stanford Law School (’13). The author would like to thank the readers of SpicyIP for comments on earlier drafts along with other people from industry and the legal practice who lent him their valuable time in reviewing earlier drafts of this paper. Last but not the least, the author would like to thank the Editorial Board of IJLT for their assistance with this paper.

<sup>1</sup>K.G. Narendranath, *IPA takes on global pharma majors rejects data exclusivity obligation*, ECON. TIMES (Oct. 25, 2002) available at: [http://articles.economictimes.indiatimes.com/2002-10-25/news/27354556\\_1\\_data-exclusivity-ipa-undisclosed-test](http://articles.economictimes.indiatimes.com/2002-10-25/news/27354556_1_data-exclusivity-ipa-undisclosed-test); Susan Finston, *Data exclusivity law brooks no delay*, HIN. BUS. LINE., (Jul. 18, 2006) available at: <http://www.thehindubusinessline.in/2006/07/18/stories/2006071800221100.htm>; PTI, *India against inclusion of data exclusivity in any FTA*, ECON. TIMES (Apr. 6, 2011) available at: [http://articles.economictimes.indiatimes.com/2011-04-06/news/29388653\\_1\\_data-exclusivity-drug-seizure-issue-data-protection](http://articles.economictimes.indiatimes.com/2011-04-06/news/29388653_1_data-exclusivity-drug-seizure-issue-data-protection)



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which are required by the law to go through rigorous clinical trials or field trials, in order to validate safety and efficacy of the product.<sup>2</sup> The limited period of exclusivity allows the first mover, who has conducted the extensive testing, to recover the costs of the clinical or field trials, failing which there would be no incentive for any of the other firms to conduct extensive testing for any of their products.<sup>3</sup>

The Indian stand on 'data exclusivity', be it the reports of Government of India (GoI) or Parliamentary Standing Committees, has been quite perplexing and marked by several contradictions and oversights not to mention the occasional gaffe. For instance, in a press release put out by the GoI during the Indo-E.U. FTA negotiations, the Minister for Industry & Commerce was quoted as stating that data exclusivity is well beyond the provisions of Article 39.3 of TRIPs and that India does not provide data exclusivity for pharmaceuticals and agro-chemicals.<sup>4</sup> The statement was factually incorrect because unlike the pharmaceutical industry, the agro-chemical industry in India has had a data exclusivity regime since 2007, albeit through delegated legislation and not parliamentary legislation.<sup>5</sup>

In fact, at the time of the press release, the very same Government was actively trying to push for the Pesticide Management Bill, 2008 in Parliament; which bill would not only strengthen but also lengthen the existing data exclusivity regime for the agro-chemical industry.<sup>6</sup> For the GoI to make such a gaffe during sensitive trade negotiations is probably without precedent. More interestingly however this statement also exposes the contradiction of denying data exclusivity for the

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<sup>2</sup>See generally Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPs Agreement*, 45 HARV. INTL. L.J. 443 (2004)

<sup>3</sup>*Id.*

<sup>4</sup> Article 39.3: Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. BS Reporter, *India will not provide data exclusivity: Anand Sharma*, BUS. STAN. (Mar. 30, 2011) available at: <http://www.business-standard.com/india/news/india-will-not-provide-data-exclusivity-anand-sharma/430285/>; PRESS INFORMATION BUREAU: *Anand Sharma Chairs Consultative Committee of Parliament on Challenges in IPR-International and Domestic*(Mar. 29<sup>th</sup>, 2011) available at: <http://pib.nic.in/newsite/erelease.aspx?relid=71341> (For text of the press release)

<sup>5</sup>*Infra* n. 64.

<sup>6</sup>*Infra* n. 62.

pharmaceutical sector on the grounds that it is 'TRIPS-plus' but actively pushing for a 'data exclusivity' regime for the agro-chemical sector.

Gaffes aside, there is a need to understand the policy debates that preceded the GoI's decision to proceed with data exclusivity for agro-chemicals in order to explain the contradiction in not extending similar protection to the pharmaceutical sector. Why is it that the GoI applies the TRIPS yardstick to deny data exclusivity for the pharmaceutical sector, while applying a different yardstick for approving a 'data exclusivity' regime for the agrochemical industry? Working towards this end, this article aims to examine key policy documents which influenced the GoI's decision on data exclusivity and explain the oversights and shortcomings with the arguments against a data exclusivity regime for the pharmaceutical industry in India.

The essay hopes to force a rethink of the present GoI position on a 'data exclusivity' regime for pharmaceuticals and at the very least stir the pot with some new arguments

The basic structure of this essay will be as follows:

- (i) Part I seeks to introduce the concept of data exclusivity followed by a discussion of the regulatory regime for Indian pharmaceuticals;
- (ii) Part II seeks to examine the Indian policy debates on data exclusivity and the contradictions therein, with specific reference to reports on the subject commissioned by the GoI or the Parliament.
- (iii) Part III seeks to question the assumption that it is acceptable for India to free-ride off foreign clinical trial data instead of conducting its own clinical trials on the Indian population in order to validate drugs on the Indian people who often are of a different genetic disposition from the population in the more developed countries and who also live in a different socio-economic context from people in the more developed countries. This part of the essay seeks to establish a direct link between the regulatory requirement for local clinical trials in India and a data exclusivity regime to incentivise such clinical trials in India. If it can be argued that India should conduct more rigorous clinical trials on Indians, it necessarily follows that India can no longer free-ride off clinical trial data in foreign countries to grant its regulatory approvals. Once it is established that India cannot free-ride off foreign clinical trial data, it follows that India will have to put in place measures to incentivise clinical trials

on Indians, especially since the threshold for patent protection in India has been placed so high. In the circumstances, data exclusivity could effectively prove to be just the incentive required to encourage more companies to conduct local clinical trials.

(iv) Part IV, seeks to examine the possibility of spurring innovation in the pharmaceutical industry, especially in the areas of Fixed-Drug-Combination (FDC) and traditional knowledge (TK) medicine. Incentives for innovation in both of these areas are poorly served by Indian patent law and a data exclusivity regime may serve as a better incentive.

## PART I – PHARMACEUTICAL INNOVATION, DRUG REGULATION & CLINICAL TRIALS IN INDIA

Pharmaceutical innovation is, by any measure, one of the most complicated ventures faced by mankind and according to widely accepted estimates it can easily take up to almost a decade and close to a billion U.S. dollars to deliver a new drug from the laboratory to the market.<sup>7</sup> Most pharmaceutical innovation begins in the laboratory with the screening of thousands of chemicals to either identify or synthesis a suitable drug candidate for the disease in question.<sup>8</sup> Once a suitable drug candidate is identified, it is required to undergo rigorous clinical trials on animals, initially and later on human beings in order to establish both safety and efficacy of the drug.<sup>9</sup>

The history of rigorous clinical trials can be traced to the tragic ‘thalidomide tragedy’ in Europe. The U.S. was saved from this tragedy due to the vigilance of its drug regulator, the USFDA. The ‘thalidomide tragedy’ however led to a fundamental restructuring of the manner in which pharmaceutical drugs would be tested for safety and efficacy.<sup>10</sup>

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<sup>7</sup>See generally Di Masi et. al., *The Price of Innovation: new estimates of drug development costs*, 22 J. HEALTH ECON. 151 (2003).

<sup>8</sup>See also Di Masi et. al., *Cost of innovation in the pharmaceutical industry*, 10 J. HEALTH ECON. 107(1991).

<sup>9</sup>*Id.*

<sup>10</sup>See generally Food & Drug Administration (FDA) – *Legislation* – available at <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm>; See also Food & Drug Administration (FDA) – *Thisweek in FDA History – July 15, 1962* – available at <http://www.fda.gov/AboutFDA/WhatWeDo/History/ThisWeek/ucm117836.htm>.

It is likely that several drugs will fail to cross this barrier i.e. they may be efficacious but unsafe in the long run or they may not demonstrate the same level of efficacy as predicted during laboratory tests. If a drug clears this final threshold it will enter the market and may proceed to become a blockbuster drug which earns billions. However if the drug fails to clear the threshold of regulatory approval it will result in the sinking of the entire investment into the development of the new drug. Given the claimed investments and the risk in the innovation process it is hardly a surprise then that firms involved in the innovation process seek significant protection in the form of 'data exclusivity' and patent protection.

At this stage it is necessary to highlight the conceptual difference between patenting and data exclusivity since both concepts are often confused in the Indian context. The intellectual property in the invention or discovery of a new drug is usually protected by filing a patent application. Usually a patent application is filed at the very initial stages, almost as soon as the drug candidate demonstrates some efficacious properties during in-vitro testing. Not every patented drug will necessarily make it to the market since the patenting process is absolutely distinct from the regulatory process which certifies the safety and efficacy of the drug for the patient market. Therefore while patenting is based on whether the drug in question is novel and inventive when compared to prior art, regulatory approval for marketing of the drug is based on how safe and efficacious the drug is on both animals and human beings. 'Data exclusivity' is linked to the regulatory process i.e. the clinical data submitted by the innovator to the regulatory cannot be used by the regulator to grant generic pharmaceutical companies approval to manufacture generic versions of the same drugs.<sup>11</sup>

Traditionally, innovator firms in the U.S. had complete and perpetual control of 'clinical trial' data i.e. life-long exclusivity over their clinical data. In principle, any generic firm could enter the market, subject to the patent status of the drug, provided that such a firm could carry out its own clinical trials and submit its own data to the regulator.<sup>12</sup> However, there was enough empirical evidence to demonstrate that generic firms were reluctant to carry out their own clinical trials due to the costs

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<sup>11</sup>See generally Uttam Gupta, *Data-Exclusivity vs patent: The myths and the realities*, HIN. BUS. LINE., (May. 16, 2006).

<sup>12</sup>See generally, Ashlee B. Mehl, *The Hatch Waxman Act and Marketing Exclusivity for generic drug manufacturers: An entitlement or an incentive?*, 81CHI.-KENT L. REV. 649 (2006).

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involved and also because of ethical issues of replicating clinical trials.<sup>13</sup> All of this changed when the U.S. Congress enacted the Drug Price Competition and Patent Term Restoration Act (also known as the 'Hatch-Waxman Act') in the year 1984.<sup>14</sup>

The aim of this legislation was to increase competition amongst generic pharmaceuticals with an intention to lower the overall prices of drugs for the patient. The legislation sought to achieve this objective of lowering its drug prices by simplifying the process for granting regulatory approval to generic drugs. Pertinently, the legislation waived the requirement for generic firms to duplicate expensive and ethically problematic clinical trials which had already been conducted by the innovator firm.<sup>15</sup> Instead, generic firms were granted marketing approvals for their drugs, on the basis of clinical data generated by the innovator, provided that the generic firm was able to establish that its drugs were bioequivalent to the innovator drugs.<sup>16</sup> Bioequivalence tests establish that both drugs are chemically equivalent therefore confirming that the generic drug will act in a manner similar to the innovator drug.<sup>17</sup> Given that bioequivalence tests were relatively inexpensive when compared to duplicating entire clinical trials it was no surprise that these amendments spurred the development of a whole new generic pharmaceutical business in the U.S.A.<sup>18</sup>

However in order to maintain some incentive for innovator firms to continue conducting clinical trials, especially in cases where the innovator firm would not enjoy patent protection, the U.S. Congress continued to give innovator firms a 5 year period of data exclusivity during which no other firm could enter the market through mere bioequivalence trials.<sup>19</sup>

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<sup>13</sup>*Id.*

<sup>14</sup>*Id.*

<sup>15</sup>*Id.*

<sup>16</sup>*Id.*

<sup>17</sup>*Id.*

<sup>18</sup>*Id.*

<sup>19</sup>*Id.*

The above is the brief history of ‘data exclusivity’ in the U.S.A. Eventually the concept of data exclusivity as a sui generis mode of protection spread to other jurisdictions across the globe.<sup>20</sup> Before going any further on the ‘Data Exclusivity’ question it is first necessary to discuss in some detail the drug regulation scheme under the Drugs and Cosmetics Act, 1940 which is the legislation that governs the pharmaceutical regulatory sphere in India.

#### **THE REGULATORY REQUIREMENTS UNDER INDIAN LAW FOR NEW DRUG APPROVALS**

The Drugs & Cosmetics Act, 1940 (“DCA”) is the primary legislation covering the sphere of drug regulation in India. This legislation which was enacted in 1940, even before India declared its independence from the British has remained in place with a few minor amendments. The DCA is quite a skeletal legislation which only lays down a legal framework for the institutions which are required to carry out regulatory functions along with definitional clauses on sub-standard or spurious or misbranded drugs. The primary regulatory requirements, including the clinical trial protocols, are delegated by the DCA to the GoI which for its part has enacted the Drugs and Cosmetics Rules, 1945 (“DCR”).<sup>21</sup> These rules can be amended by the GoI without prior approval from Parliament and as such these rules or any amendments to them are rarely ever debated in Parliament. Discussed below are the key provisions which lay down the requirements for clinical trials for new drugs in India.

**(i) Rule 122E – Definition of ‘New Drug’:** Contrary to the normal scheme of Indian legislations, the definition of ‘New Drug’ is found in the DCR, 1945 and not the DCA, 1940. The relevant rule is Rule 122E.<sup>22</sup> This provision classifies a new drug into the three following categories:

(a) Any drug, *“including bulk drug substances, which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority”*;

(b) A new drug already approved by the licensing authority for *“certain claims, which is now proposed to be marketed with modified or new claims, namely indications, dosage, dosage form (including*

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<sup>20</sup>See generally Valerie Junod, *Drug Marketing Exclusivity under United States and European Union Law*, 59 FOOD DRUG L.J. 479.

<sup>21</sup>S. 33 of the Drugs & Cosmetics Act, 1940.

<sup>22</sup>Part XA of the Drugs & Cosmetics Rule, 1945.

*sustained release dosage form) and route of administration*". It should be noted at this stage, that new uses or incremental innovations not resulting in increasing therapeutic efficacy are not patentable under Section 3 of the Indian Patents Act, 1970.

(c) "*A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz. indications, dosage form and route of administration*". This component of Rule 122E, pertaining to 'fixed dose combinations' ("FDC") will have to be read along with Appendix VI to the DCR, 1945. The Appendix specifies in some detail the various clinical trial requirements for FDCs of different permutations and combinations. For instance, if one or more of the active ingredients are new, the resulting FDC will necessarily have to undergo clinical trials. If both active ingredients constituting the FDC have been individually approved, the resulting FDC may still be required to undergo clinical trials. Similarly if the ratio of active ingredients in an already approved FDC is sought to be changed, there may be a need to carry out clinical trials depending on certain parameters.

**(ii) The clinical trials requirements – Rule 122A, Rule 122B & Schedule Y to the Drugs & Cosmetics Rules, 1945:** Rules 122A & 122B lay down the regulatory requirements to either import into India or manufacture in India a *new drug* as defined in Rule 122E. Both Rules 122A (Import) & Rule 122B (Manufacture) require that new drugs meet the regulatory requirements laid down in Schedule Y to the DCR, 1945.<sup>23</sup>

'Schedule Y', which is titled 'Requirement and Guidelines on Clinical Trials for Import and Manufacture of New Drug', lays down the requirements for the three phases of clinical trials. According to Schedule Y, the three phases of a clinical trial are as follows:

**Phase I:** The main objective of Phase I of clinical trials is to determine the maximum tolerated dose in humans; pharmacodynamic effects; adverse reactions, if any, with their nature and intensity; and pharmacokinetic behaviour of the drug as far as possible.

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<sup>23</sup>The relevant portion of the provision reads as follows "(2) *The importer of a new drug when applying for permission under sub-rule (1), shall submit data as given in Appendix I to Schedule Y including the results of local clinical trials carried out in accordance with the guidelines specified in that Schedule*";

**Phase II:** The main objective of Phase II of clinical trials is to evaluate the effectiveness of a drug for a particular indication or indications in patients with the condition under study and to determine the common short-term side-effects and risks associated with the drug. While Phase I trials are carried out on a small group of healthy volunteers, Phase II trials are required to be carried out on a small group of patients.

**Phase III:** Also known as “therapeutic confirmatory trials”, these are the most rigorous and extensive phase of trials and are designed to “*to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population.*” This phase tests the dosage related effects, usage in different population groups, in different stages of disease and the safety/efficacy of the drug in combination with other drugs. Phase-III trials are typically the most extensive and by implication the most expensive.<sup>24</sup>

**(iii) Waiver of Clinical Trials:** While the clinical trial requirements themselves seem to be rather rigorous, Schedule Y actually begins by providing an exemption from conducting Phase I, Phase II & Phase III clinical trials in those cases where the drug has already received foreign regulatory approval. Given that most new drugs are introduced in the market after they have received foreign regulatory approval, the Indian drug regulator, routinely, exempts manufacturer or importers, of the new drug, from carrying out any clinical trials and approval is instead granted on the basis of bio-equivalence tests.<sup>25</sup> However even if all three phases of clinical trials are waived, Schedule Y, still requires local clinical trials on 100 Indian patients.<sup>26</sup> The logic behind local clinical trials is to confirm the safety and efficacy of the drug on Indian patients since it is presumed that clinical trials carried out predominantly in Western countries, on Western populations need to be re-confirmed on Indian people who maybe genetically different from western population and also live in a different socio-economic context.<sup>27</sup>

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<sup>24</sup>DiMasi; *supra* note 7.

<sup>25</sup>*Infra* n. 77.

<sup>26</sup>The relevant part of the definition reads: *If the drug is already approved/ marketed in other countries, phase III data should generally obtained on at least 100 patients distributed over 3-4 centres primarily to confirm the efficacy and safety of the drug, in Indian patients when used as recommended in the product monograph for the claims made.*

<sup>27</sup>*Infra* n. 69.



Predictably, a proviso in Rule 122 A (Import) or Rule 122B (Manufacture) allows for the Indian drug regulator to waive even local clinical trials on Indian patients on the grounds of ‘public interest’. The proviso reads as follows: “*Provided that the requirement of submitting the results of local clinical trials may not be necessary if the drug is of such a nature that the Licensing Authority may, in public interest decide to grant such permission on the basis of data available from other countries.*” The grounds of ‘public interest’ are not explained and as will be explained in a later Section of this essay, this provision has come under withering criticism from a Parliamentary Standing Committee.<sup>28</sup>

## PART II – THE ‘GREAT INDIAN DEBATE’ ON THE REQUIREMENT OF A DATA EXCLUSIVITY REGIME FOR PHARMACEUTICALS AND AGRO-CHEMICALS

The ‘data exclusivity’ debate in India essentially began with the negotiation and eventually the signing of TRIPs. In fact, the focus of the debate continues to be Article 39.3 of TRIPs. The provision reads as follows:

*3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.*

As evident from a reading of the text, Art. 39.3 required member-countries to protect test-data related to trials of pharmaceutical or agricultural chemical products to be protected against “unfair commercial use”. Since TRIPs never defined the meaning of “unfair commercial use”, the entire debate surrounding Art. 39.3 is centred on this one phrase.<sup>29</sup>

While the innovator’s lobby in the US and Europe interpreted that particular phrase as requiring India to put in place a ‘data exclusivity’ regime, the lobby of generic companies, left-leaning academics and generic pharmaceutical companies interpreted the phrase as requiring at the most a ‘data protection’ regime wherein the drug regulator would be mandated to ensure the confidentiality of the submitted information, while continuing to grant approvals to generics on the basis of such

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<sup>28</sup>*Infra* n. 78.

<sup>29</sup>See generally Watal, Jayashree, *Intellectual Property Rights in the WTO and Developing Countries* (2001) pp. 201-204.

confidential information.<sup>30</sup> In order to resolve the conflict on the interpretation of Article 39.3 the GoI commissioned at least one study and carried out yet another study by itself.

This Section of the paper will briefly summarize the above studies along with some other reports, such as reports by Parliamentary Standing Committees which although not binding on the GoI, have great persuasive value on the policy making apparatus of the GoI.

**(i) The CUSAT study:** The first comprehensive study on ‘test-data protection’ was conducted by the School of Legal Studies at the Cochin University of Science & Technology (CUSAT) in January, 2004, with funding from the Department of Commerce, Ministry of Commerce & Industry, Government of India.<sup>31</sup>

This study, titled ‘Study on Testdata Protection in India’ was reportedly “*undertaken to identify the suitable mode of protection of test data in India considering the interest of the Indian industry, while complying with the TRIPS obligations.*”<sup>32</sup> Towards this end the CUSAT study focussed on three objectives: (a) The TRIPS requirements under Article 39.3; (b) The existing safeguards for ‘protection of test-data’ in India & (c) The perspective of the Indian Pharmaceutical Industry on the topic.

After examining the history of TRIPs and the negotiating history of Article 39.3 TRIPs the CUSAT study concluded by stating: “*the argument that data exclusivity is the only mode to protect test-data against unfair commercial use is not correct*”.<sup>33</sup> Further the report also stated that “*data exclusivity will only be a TRIPS plus approach and not bound by member countries*”.<sup>34</sup> Instead, the study suggested that the bar against “unfair commercial use” in Article 39.3 could be restricted to “*protection through non-disclosure*” which prohibited others “from accessing this test data for unfair commercial use” i.e. giving ‘test data’ the

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<sup>30</sup>See generally: Carlos María Correa, *Protection of data submitted for the registration of pharmaceuticals: Implementing the standards of the TRIPs agreement*, SOUTH CENTRE (2002); Position Paper – *Data Exclusivity: A Major Obstacle to Innovation and Competition in the E.U. Pharmaceutical Sector*, European Generic Association (EGA) (2000); Position Paper – *Regulatory Data Protection – A building block for pharmaceutical R&D*, Organization of Pharmaceutical Producers of India (2008).

<sup>31</sup>Prof.N.S.Gopalakrishanan et. al., *Study on Test-data Protection in India*, CUSAT (2005) at (This study was later published as a book by the Eastern Book Company).

<sup>32</sup>*Ibid* at p [v];

<sup>33</sup>*Ibid* at p. 45;

<sup>34</sup>*Id.*

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status of confidential or trade secret information.<sup>35</sup> This mode of protection would still allow the introduction of generics on the basis of bio-equivalence data and would have little effect on keeping generics from the market.

With regard to the requirements of the domestic Indian pharmaceutical industry, the study, after extensive consultations with the domestic generic pharmaceutical industry, concluded that the Indian industry “was demanding strong protection of confidentiality” for test-data but not a data exclusivity regime.<sup>36</sup> As a result, the CUSAT study limited its recommendations to the introduction of new laws pertaining to the non-disclosure of test-data submitted to the pharmaceutical and agro-chemical regulatory authorities.<sup>37</sup> The demand for data exclusivity or ‘non-reliance’ on the test-data of innovator companies by follow on generics was clearly rejected by the study. It must be noted, that ‘data-protection’ per se, i.e. a mere confidentiality of clinical trial data is no longer the most pressing demand of the innovator pharmaceutical lobby in 2013 because companies like GSK and Roche have announced their intention to make available all clinical trial data publicly available, in order to ensure that the medical community has access to complete information.<sup>38</sup>

The CUSAT study did not include within its purview any of the possible beneficial effects of a data exclusivity regime on public health, especially the utility of the data generated from local clinical trials on Indian citizens. Furthermore, the CUSAT study despite raising a warning flag with regard to drug regulatory mechanism in India and calling for “putting effective systems” in place, omits to critically examine the manner in which local clinical trials were being supervised by the DCGI.<sup>39</sup> As will be explained later in this article, the requirements of local clinical trials have a direct bearing on the need for data exclusivity and it is absolutely crucial to study the manner in which these studies are being administered.<sup>40</sup>

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<sup>35</sup>*Ibid* at p. 45-46.

<sup>36</sup>*Ibid* at p. 46.

<sup>37</sup>*Ibid* at p. 46-48.

<sup>38</sup> Rupert Neate, *GlaxoSmithKline to publish clinical trial data*, GUARDIAN (Feb 5, 2013) available at:<http://www.guardian.co.uk/business/2013/feb/05/glaxo-smith-kline-publish-clinical-trial-data> (last visited on 4th March, 2013)

<sup>39</sup>*Supra* note 32 at p.45.

<sup>40</sup>*See generally* Part III.

**(ii) Report of the Inter-Ministerial Committee setup by the Government of India:** Towards the end of the 10 years period provided to India to make its laws TRIPs compliant, the Government of India constituted a special inter-ministerial committee to examine the data exclusivity issue.

This committee constituted on the 10<sup>th</sup> of February, 2004 was headed by Mrs. Satwant Reddy, Secretary and Mr. Gurdial Singh Sandhu, Joint Secretary, to the Department of Chemicals & Petrochemicals, Govt. of India. The Committee also had as its members, representatives from other relevant Ministries of the Government of India.<sup>41</sup> The final report submitted by the Committee was officially titled “Report on steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPs Agreement”<sup>42</sup> (Hereinafter ‘Reddy Committee Report’).

The ‘office memorandum’ constituting the Committee required it to examine and consider the steps to be taken by the Government of India in the context of the provisions of Article 39.3 of the TRIPs Agreement, for the protection of undisclosed regulatory information.<sup>43</sup> The Committee was also required to look at whether data protection can be offered under the existing legal provisions or whether the Government was required to create a new mechanism.<sup>44</sup>

In its final report submitted on the 31<sup>st</sup> of May, 2007 the Committee examined separately the requirements of the agro-chemical industry, the pharmaceutical industry & the traditional medicine sector. Surprisingly, the Committee made different recommendations for each sector i.e. it recommended a ‘data exclusivity’ regime for agro-chemicals but only a ‘non-disclosure’ or confidentiality regime for the information submitted by the pharmaceutical sector and the sector of traditional knowledge medicines industry i.e. the test data would be considered confidential but a regulator could still depend on this information to grant approvals to generics. The detailed reasoning of the committee for each sector is explained below:

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<sup>41</sup>The committee had a total of 15 members, most of whom were bureaucrats from various Ministries also had as its members academics, lawyers and the Drug Controller General of India.

<sup>42</sup>Mrs. Reddy et. al., *Report on steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPs Agreement*, GOVT. OF INDIA (2007).

<sup>43</sup>Notification No.11025/7/2003-PI-II, Department of Chemicals and Fertilizers, Ministry of Chemicals and Fertilizers, Government of India, 19<sup>th</sup> February, 2004.

<sup>44</sup>*Id.*

**(a) The Agro-chemical industry:** The Committee assessed the suitability of a ‘data exclusivity’ regime for the agro-chemical industry without any discussion on the minimum international obligations that India was required to fulfil under Article 39.3 of TRIPs.

Instead, the Committee adopted a more ‘nationalistic approach’ i.e. it decided to approach the issue of ‘data exclusivity’ not from the perspective of TRIPs but instead on the overall effect of such a policy on India and its farmers. The Committee very pertinently notes that India cannot depend on foreign data while approving the safety and efficacy of agro-chemicals since “*efficacy tests for agro-chemicals must be repeated in every country, even in several regions in a country due to differences in crops, pests, agronomical practices, climate conditions and terrains.*”<sup>45</sup>

The committee also noted that as a result of India not providing ‘data exclusivity’ protection to agro-chemicals, the Indian farmers were being deprived of the latest agro-chemicals since there was no way for originator companies to protect their test-data from being exploited by free-riders.<sup>46</sup>

As a result the Committee recommended that test data generated by originator agro-chemicals be given a three year ‘data exclusivity’ term during which the regulatory authority could not rely on the data of the originator to grant approvals to generics.<sup>47</sup>

**(b) The Traditional Medicines industry:** While assessing the requirement of a ‘data exclusivity’ regime for the traditional Indian medicines, a category of medicines that is formally recognized under Indian law, the Committee once again stayed away from any TRIPs analysis, focussing instead on the existing incentives under the law for innovation of traditional knowledge. The Committee notes that in the absence of patent protection for traditional knowledge under the Patents Act, 1970, there are few incentives for the traditional medicine industry to continue innovation.<sup>48</sup> The committee also notes that the Government was in the process of establishing a regulatory mechanism for traditional medicines and that the sector would have to conduct rigorous trials to validate the safety and efficacy of these medicines.<sup>49</sup> Given the increasing regulatory demands of the

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<sup>45</sup>*Supra* n. 43 at p. 23-26.

<sup>46</sup>*Id.*

<sup>47</sup>*Ibid* at p. 39 (para 7.4).

<sup>48</sup>*Ibid* at p. 36-37; Section 3(p) expressly prohibits the patenting of traditional knowledge.

<sup>49</sup>*Id.*

sector and the lack of any other incentives for the sector, since patent protection is banned for traditional medicines, the Committee recommended a five year ‘data exclusivity’ regime be granted for traditional medicines for the following purposes<sup>50</sup>:

*“i) Data in support of new use or new dosage forms for traditionally used medication.*

*ii) Data generated in respect of standardization of products.*

*iii) Data generated for safety / efficacy / stability / quality / process standardization of an existing or a new product.”*

**(c) The Pharmaceutical industry:** With regard to the pharmaceutical industry, the Committee was of the opinion that India’s minimum requirements under Article 39.3 of TRIPs would be fulfilled by strengthening the ‘data-protection’ laws to ensure that the drug regulators maintained the confidentiality of the ‘test data’ submitted to it.<sup>51</sup> It however recommended, that in the long run, India should move towards a ‘data exclusivity’ regime for even pharmaceuticals and went ahead to suggest a possible model for the same.<sup>52</sup>

Interestingly, the Committee distinguishes its recommendations for the agro-chemical industry and the pharmaceutical industry on the grounds that while the former could not depend on ‘foreign data’ for regulatory approval in India, the latter industry was allowed to depend on ‘foreign data’ for regulatory approval within India. In pertinent part the report states: “Unlike pharmaceuticals, efficacy tests for agro-chemicals must be repeated in every country, even in several regions in a country due to differences in crops, pests, agronomical practices, climate conditions and terrains.”<sup>53</sup>

As noted elsewhere in the Committee’s report, the law in India allows companies to secure approvals on the basis of ‘foreign test-data’ and data from local clinical trials on a small number of Indian patients along with bio-equivalence tests. According to the report, the cost of local clinical

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<sup>50</sup>*Ibid* at p. 42-43.

<sup>51</sup>*Ibid* at p.44.

<sup>52</sup>*Ibid* at p. 46-53.

<sup>53</sup>*Ibid* at p.23.

trials and bio-equivalence tests is a “far simpler exercise requiring much less time, effort and money than conducting the full set of clinical trials”.<sup>54</sup>

The Committee therefore links its final recommendations on data exclusivity for ‘pharmaceuticals’ to the requirements of regulatory laws in India. However, if the regulatory requirements of the law itself are questioned, the conclusions of the Committee will have to be re-examined.

The question therefore that will be examined at a later stage in this essay is the paradox of India prescribing rigorous local trials for agro-chemicals but exempting pharmaceuticals from the same. This is important because as explained earlier the requirement for ‘data exclusivity’ is intrinsically linked to the regulatory requirements of Indian laws.

**(iii) Report of the Parliamentary Standing Committee on the ‘Patents & Trademarks System in India’:** This Parliamentary Committee, consisting of 30 odd Members of the Indian Parliament, across party lines, was conducting a general study on the ‘Patents & Trademarks System in India’ and it tabled its final report before Parliament on October 24<sup>th</sup>, 2008.<sup>55</sup>

Since major pharmaceutical organizations for both innovator and generic companies along with ‘access to medicine’ NGOs had deposed before the Committee, the issue of ‘data exclusivity’ was also examined by this Committee.<sup>56</sup> In pertinent part the Committee notes:

*“The Committee feel that conceding to demand for Data Exclusivity would amount to agreeing to TRIPS plus provisions.”<sup>57</sup>*

*“5.48 Since the consequences of Data Exclusivity are quite serious, the Committee strongly recommend that the Government should not fall prey to such demands of MNCs.”<sup>58</sup>*

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<sup>54</sup> *Ibid* at p.15.

<sup>55</sup> 88<sup>th</sup> Report on Patents & Trade Marks System in India, Department Related Parliamentary Standing Committee on Commerce, RajyaSabha, Parliament of India (2008).

<sup>56</sup> *Ibid* at para 5.47-5.48.

<sup>57</sup> *Ibid* at para 5.47.

<sup>58</sup> *Id.*

For reasons best known to the Committee it did not make any reference to the Reddy Committee report despite the same being brought to its notice by one of the organizations which deposed before the Committee.<sup>59</sup>

The Committee also completely failed to acknowledge the fact that the Government of India had already implemented a ‘data-exclusivity’ regime for the ‘agro-chemical’ industry through a notification of the Central Government.<sup>60</sup> If the Committee had taken note of this particular fact, it would have been hard-pressed to state that India should not adopt a ‘data-exclusivity’ regime merely because it is a ‘TRIPs-plus’ regime.

**(iv) Report of the Parliamentary Standing Committee on the ‘Pesticide Management Bill, 2008’:** In 2008 the Central Government, acting on the recommendations of the Reddy Committee Report, incorporated a ‘data exclusivity’ clause into the Pesticide Management Bill, 2008 which was subsequently introduced into Parliament on the 30<sup>th</sup> of September, 2008 by the Ministry of Agriculture, Government of India.<sup>61</sup> Clause 12(6) of this Bill, which is the ‘data exclusivity’ clause, prohibited the Indian regulators from relying on the data submitted by an originator for granting approval for a period of 3 years. As is the usual practice the Bill was referred to a Parliamentary Standing Committee for examination and public consultations. Not only did the Standing Committee approve of the ‘data exclusivity’ clause, it recommended that the period of ‘data exclusivity’ be extended from 3 years to 5 years.

In pertinent part the report states *“In order to encourage the introduction of newer pesticide molecules in the country, the Committee recommend that the data protection period should be increased to five years. Applicants may be asked to declare in their applications the ‘Trade Secret Data’ that require protection. However, Central Government should have the power to disclose the ‘Trade Secret Data’ information when it is absolutely essential in public interest.”*<sup>62</sup>

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<sup>59</sup>*Ibid* at Annexure IX.

<sup>60</sup>*Infra* n. 63.

<sup>61</sup>46<sup>th</sup> Report on the ‘Pesticide Management Bill, 2008’, Department Related Parliamentary Standing Committee on Agriculture (2008).

<sup>62</sup>*Ibid* at para 33.



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Unlike the other Parliamentary Standing Committee referred to earlier, this particular committee made no reference to TRIPs at all. The Pesticide Management Bill, 2008 has been pending before the Parliament of India for the last four years.

It may also be pertinent to mention that the Government of India was so keen to enforce a 'data exclusivity' regime in India that instead of waiting for Parliament to pass the aforementioned Bill, it issued two notifications creating a 'data-exclusivity' regime for the agro-chemical industry.<sup>63</sup>

### PART III: THE IMPORTANCE OF LOCAL CLINICAL TRIALS TO INDIAN PUBLIC HEALTH – THE MISSING LINK IN THE DATA EXCLUSIVITY DEBATE

#### **A. THE LINK BETWEEN LOCAL CLINICAL TRIALS AND DATA EXCLUSIVITY**

By implication, most of the Indian arguments against data exclusivity for pharmaceuticals presume that India does not need to provide an incentive for clinical trials in India since it can effectively 'free-ride' off the regulatory data that pharmaceutical companies are bound to generate for the prosperous markets of North America & Europe. Such a negotiating strategy bears close resemblance to India's historic decision in 1970 to do away with pharmaceutical patents.<sup>64</sup>

The assumption in that case was that regardless of the legal position in the Indian market, pharmaceutical companies would continue with innovation for foreign markets.<sup>65</sup> It is however doubtful whether such logic can be replicated in the context of local clinical trials which are carried out to validate drugs in the socio-economic-genetic context of the Indian sub-continent. In other

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<sup>63</sup> No.17-2/2006-PP.I dated 30<sup>th</sup> October, 2007, Department of Agriculture & Co-operation, Ministry of Agriculture, Government of India, F.No.17-2/2006-PP.I dated 18<sup>th</sup> February, 2008, Department of Agriculture & Co-operation, Ministry of Agriculture, Government of India;

<sup>64</sup> See generally Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 IND. J. L. & TECH. 15 (2005). One of the main reasons given by the Government of India to justify the decision to bring back pharmaceutical patents in 2005, apart from its TRIPs obligation, was the hope that Indian companies were capable of carrying out pharmaceutical innovation for neglected diseases i.e. diseases afflicting developing countries like India and which were ignored by western pharmaceutical companies who were more concentrated on drugs for diseases affecting the more prosperous markets of the West. This dream of Indian scientists focussing on Indian diseases was partly realized when Indian scientists at Ranbaxy successfully concluded clinical trials of the first low-cost Indian drug against malaria. See generally Mansi Mithel, *Ranbaxy launches home-grown malaria drug*, BUS. WORLD, Apr. 30, 2012. Available at: <http://businesstoday.intoday.in/story/ranbaxy--malaria-drug-synriam/1/24381.html>

<sup>65</sup> See generally N.R. AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW (1959).

words, the innovator firm has to carry out such trials exclusively for the Indian market and it is only incentives in the Indian market that are going to influence the decision of the innovator firm.

If there is a consensus on the fact that such local clinical trials are vital to meet the public health requirements of Indian patients, it follows that Parliament must provide innovators an incentive to carry out local clinical trials in India. In normal circumstances if a pharmaceutical drug already had patent protection, there would be no need to grant an added incentive to carry out local clinical trials. Instead, the drug regulator could withhold regulatory approval until such tests are carried out.

However as we have witnessed in India, a large number of drugs on the market do not have patent protection due to a high threshold under the Indian Patent Act, 1970 and if India were to mandate local clinical trials without any added incentive, it is possible that most pharmaceutical companies would have little or no incentive to carry out such trials without added incentives since the law does not prevent their competitors from 'free-riding' on the original clinical trial data.

Data exclusivity could be one such incentive for pharmaceutical companies to carry out local clinical trials. As explained earlier, the requirement of local field trials for testing pesticides in local Indian conditions was one of the main reasons that the Indian Government is pushing for a data-exclusivity regime for agro-chemicals. The issue thus that we are required to examine in this context, is whether the Indian govt. has factored in the importance of 'local clinical trials', while arguing against a data exclusivity regime for pharmaceutical companies.

#### **B.THE REPORT OF THE PARLIAMENTARY STANDING COMMITTEE ON HEALTH & ITS IMPLICATIONS FOR LOCAL CLINICAL TRIALS**

In the budget session of the Indian Parliament in 2012, the Parliamentary Standing Committee on Health & Family Welfare, which has as its members 30 MPs, from across the political spectrum, had tabled a damning report on the state of drug regulation in India.<sup>66</sup> The report, which is probably the first ever comprehensive study of the Indian drug regulatory framework focussed on the functioning of the Indian drug regulator and also the manner in which local clinical trials were being routinely waived by the drug regulator without any cogent reasoning.

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<sup>66</sup>59<sup>th</sup> Report, *The functioning of the Central Drug Standard Control Organization (CDSCO)*, Department Related Parliamentary Standing Committee on Health, Rajya Sabha, Parliament of India (2012).

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In a scathing indictment of the drug regulator - the CDSCO – the report stated the following “*The Committee is of the firm opinion that most of the ills besetting the system of drugs regulation in India are mainly due to the skewed priorities and perceptions of CDSCO. For decades together it has been according primacy to the propagation and facilitation of the drugs industry, due to which, unfortunately, the interest of the biggest stakeholder i.e. the consumer has never been ensured.*”<sup>67</sup>

On the point of local clinical trials, the parliamentary panel examined three specific points: (i) The importance of local clinical trials for India; (ii) the regulatory requirements for local clinical trials in the DCR, 1945 & (iii) the manner in which local clinical trials were being waived.

Given the scathing and eloquent critique by the Panel report, the writer has extracted in whole, the relevant statements made by the Panel:

**(i)The importance of local clinical trials for India:** The committee had the following to state on the issue of local clinical trial in India: “*The basic purpose of Phase III trials is to determine if there are any ethnic differences that can alter the metabolism, efficacy and safety of the drug when administered to patients of different ethnicities living in India (such as Indo-Aryans, Dravidians, Mongoloids, Tribals etc.). There is evidence that the effect of some drugs can vary among various ethnic groups. For example, the blood levels reached after intake of lipid lowering agent rosuvastatin are far higher in Asians, compared to Europeans and North American Caucasians, Hispanics and Blacks needing lowering of dosage. Failure to lower dose in Indians can result in severe toxicity, including life-threatening muscle injury leading to fatalities. Hence, testing drugs in the Indian ethnic groups is of paramount importance before approving any drug of foreign origin.*”<sup>68</sup>

This issue raised by the Committee is of utmost interest in the Indian context since it questions a longstanding assumption that India could free-ride on foreign regulatory approvals, especially approvals granted by the United States Federal Drug Regulatory Authority (USFDA). It should also be noted that the rationale provided by the Committee in order to push for more local clinical trials on Indians, has also been used in the West to

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<sup>67</sup>*Ibid* at para 2.2.

<sup>68</sup>*Ibid* at para 7.10;

question the practice of outsourcing clinical trials to countries like India which differ in their genetic makeup from countries in the West.<sup>69</sup>

Although the Committee does not exactly examine the manner in which USFDA approvals are granted, the writer has sought to fill in this minor oversight, by explaining the ethnicity and race requirements for clinical trials in the USA.

Traditionally, USFDA 'Guidance for the Industry' on 'Collection of Race and Ethnicity Data in Clinical Trials'<sup>70</sup>, have recommended that data be collected in the following format for different races: (a) American Indian or Alaska Native (b) Asian (c) Black or African American (c) Native Hawaiian or other Pacific Islander (d) White.<sup>71</sup> Although there is no separate category for Indians, the definition of 'Asian' stretches from persons having origins in the Far East to persons from the sub-continent i.e. from Japan to Pakistan.<sup>72</sup> Prima facie, this classification seems to be suspect since a majority of Indians are not of the Mongoloid race as is the case with most people who have their origins from countries like China or Japan. In fact, India is one of the most genetically diverse populations. It must be remembered that the USFDA guidance is not binding and recent studies have concluded that an overwhelming majority of patients enrolled in clinical trials in the US are 'white'.<sup>73</sup> It is worrying to note such statistics because the USFDA is often considered to be the gold-standard when it comes to the issue of regulatory approval for pharmaceutical products.

It should also be noted that the lack of local clinical trials is a global problem not limited to India. While studying the AIDs situation in Africa, the All Party Parliamentary Group (APPG) of the United Kingdom has complained of 'missing information' for the African patients infected with the HIV+ve virus since most clinical trials were designed for the

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<sup>69</sup>Seth Glickman etc. *Ethical & Scientific Implications of the Globalization of Clinical Research*, N. ENG J. MED 816-823 (2009).

<sup>70</sup>*Guidance for Industry: Collection of Race & Ethnicity Data in Clinical Trials*, USFDA (2005) available at: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126396.pdf>

<sup>71</sup>*Ibid* at p. 5.

<sup>72</sup>*Id.*

<sup>73</sup>Evelyn et. al., *Participation of Racial/Ethnic Groups in Clinical Trials and Race Related Labelling: A Review of New Molecular Entities approved 1995-1998*. 93 Journal of the National Medical Association (2001).

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markets of developed countries. In pertinent part the report stated “*As well as missing medicines and diagnostics there is missing data about the suitability of some of the existing medicines for a developing country context. Clinical trials are often designed with a view to registration in the developed world, to capture maximum commercial benefits.*”<sup>74</sup>

It may help to mention, that there has been a long-standing demand even within the U.S., for making available clinical trial information as per various subsets including sex, race and ethnicity. In response, the U.S. enacted, in July 2012, the Food and Drug Administration (FDA) Safety and Innovation Act (FDASIA) which “*makes available information about differences in safety and effectiveness of medical products according to demographic subgroups, such as sex, age, racial, and ethnic subgroups, to health care providers, researchers, and patients.*”<sup>75</sup> This new requirement however extends to only reporting requirements and does not extend to mandatory clinical trials on a more diverse range of patient groups.

Given the above circumstances, the GoI probably needs to re-examine the kind of clinical data that is being submitted to the USFDA and take steps to incentivise the collection of more data on the native Indian population, from different parts of the country to ensure that the medical community has more accurate information on the effects of pharmaceutical drugs on different groups. In order to incentivise such trials, the GoI will have to provide some kind of incentive such as a ‘data exclusivity’ regime.

**(ii) The regulatory requirements for local clinical trials in the DCR, 1945:** On the point of re-examining Indian regulatory requirements, the Committee had this to say: “*The Committee is of the view that taking into account the size of our population and the enormous diversity of ethnic groups there is an urgent need to increase the minimum number of subjects that ought to be included in Phase III pre-approval clinical trials to determine safety and efficacy of New Drugs before marketing permission is granted. In most western countries the required numbers run into thousands. However since the major objective in India is to determine the applicability or otherwise of the data generated overseas to Indian*

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<sup>74</sup> The Treatment Time Bomb: Report of the Enquiry of the All Party Parliamentary Group on AIDS into Long-Term Access to HIV Medicines in the Developing World (2009) (U.K) at p. 26.

<sup>75</sup>S. 907, Food and Drug Administration Safety and Innovation Act (FDASIA); See also Press Release, *Clinical trials reporting by sex, race and ethnicity signed into law*, The Society for Woman’s Health Research, (July 2012) available at <http://www.womenshealthresearch.org/site/News2?page=NewsArticle&id=13470>

*population, the requirement should be re-assessed and revised as per principles of medical statistics so that major ethnic groups are covered. A corresponding increase in the number of sites so as to ensure a truly representative sample spread should also be laid down in black and white. Furthermore, it should be ensured that sites selected for clinical trials are able to enrol diverse ethnic groups. For domestically discovered drugs, the number of subjects should be revised as well. This can be easily achieved by changes in the Good Clinical Practice (GCP) guidelines.*<sup>76</sup>

If the above recommendation of the Committee is accepted by the GoI, and it is hard to see as to how the Govt. is going to ignore such a recommendation, the regulatory authorities will have to re-examine why and how innovator firms will carry out local clinical trials when they have no way to prevent free-riders from entering the markets on the basis of such data thereby corroding the competitive advantage of the innovator firms. As explained earlier, this question is all the more pertinent given the high threshold for pharmaceutical patent protection in India.

**(iii) The manner in which local clinical trials were being waived:** While studying the manner in which the Indian drug regulator was conducting local clinical trials on the Indian population, the committee noted, and shockingly so, that a total of 31 new drugs were approved for the Indian market in the period of 30 months without any local clinical trials being conducted in India.<sup>77</sup> The local clinical trials were reportedly waived on the basis of the ‘public interest’ provision in Rule 122A & B. When the Regulator was asked for the basis of determining ‘public interest’ to waiver local clinical trials, it was not given a satisfactory answer. In pertinent part, the report states “*The Ministry explained that under the rules, DCGI has the power to approve drugs without clinical trials in “Public Interest.” No explanation is available as to what constitutes Public Interest. How can approvals given to foreign drugs without testing on Indians be in Public Interest?*”<sup>78</sup>

When the regulator attempted to defend its actions on the basis that these drugs had been tested rigorously in foreign countries, the Committee countered this by stating that the

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<sup>76</sup>*Supra* n. 68 at para 7. 29.

<sup>77</sup>*Ibid* at para 7.16.

<sup>78</sup>*Ibid* at para 7.17.

regulator was waiving local clinical trials on mere presumptions that the drugs would work similarly on Indians and that the committee had not been offered any evidence to prove this presumption.<sup>79</sup> Commenting on how most of foreign clinical trials were being conducted on ethnicities not found in India, the Committee reminded the regulator that “*The interest is in those ethnicities that live in India, not Slavs, Caucasians, Hispanics and Negroes.*”<sup>80</sup>

**(iv) Incentivizing local clinical trials through a data exclusivity regime:** It follows from the report of the Parliamentary Committee, that the GoI should seriously consider revising the clinical trial rules to ensure that larger Phase III, clinical trials are conducted on various sub-groups of the Indian population. The obvious issue that presents itself at the juncture, is whether innovator pharmaceutical companies or for that matter, even generic pharmaceutical companies will invest in such clinical trials without the added incentives. Normally a patent regime would have provided such an incentive but as we have seen in India, the threshold for patentability is extremely high and the Indian patent office has been liberal in turning down patent applications filed by innovator pharmaceutical companies. Would these companies invest in clinical trials, knowing fully well that generic pharmaceutical companies could free-ride of their data and enter the market at a much lower price? Or would generic pharmaceutical companies invest in clinical trials knowing well that their competitors would free-ride off their data? The answer is likely in the negative in both cases.

If pharmaceutical companies are expected to invest in local clinical trials, it follows that the State will have to give them some kind of incentive and as things stand now, a data-exclusivity regime appears to be the best model to incentivise such trials.

#### PART IV: INCENTIVIZING PHARMACEUTICAL INNOVATION THROUGH A DATA EXCLUSIVITY REGIME

Conventionally, pharmaceutical innovation has always been viewed through the prism of patent law. However there are circumstances in which patent law cannot incentivise innovation. Two such

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<sup>79</sup>*Ibid* at para 7.19

<sup>80</sup>*Id.*

examples are pharmaceuticals based on traditional knowledge and fixed-dose combinations of either new or existing pharmaceuticals. For reasons, explained below, although both classes of pharmaceuticals are not patentable, they still have to go through a rigorous clinical trials process before being approved for sale to the public.

**(A) CREATING INCENTIVES FOR INNOVATION IN THE TRADITIONAL KNOWLEDGE BASED PHARMACEUTICAL INDUSTRY:**

The provision barring the patenting of traditional knowledge in the Patent Act, 1970 reads as follows:

*Section 3 (What are not inventions) (p) – an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.*

The above provision is a sub-provision of Section 3 of the Patent Act, which describes all that subject matter which is not patentable in India. Section 3(p) was inserted into the Act through the Patent (Amendment) Act, 2002. This provision was introduced in the backdrop of several much publicized cases in the U.S. and Europe where attempts were made to patent properties of neem, turmeric and basmati despite the fact that these properties had been known in India for several hundred years.<sup>81</sup>

While the overall intention behind Section 3(p) is laudable, it does point to the need of providing other incentives to stir innovation in the traditional knowledge sector, especially since India enjoys a comparative advantage in this sector because of its long history in traditional knowledge related medicines.<sup>82</sup>

The three broad categories of traditional medicines dealt with under the Drugs and Cosmetics Act, 1940 are as follows: Ayurvedic, Siddha and Unani drugs.<sup>83</sup> These traditional medicines are considered to have several advantages over the allopathic medicines and have been providing

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<sup>81</sup>Soutvik Biswas, *India hits back in 'bio-piracy' battle*, BBC (Dec. 7, 2005) available at [http://news.bbc.co.uk/2/hi/south\\_asia/4506382.stm](http://news.bbc.co.uk/2/hi/south_asia/4506382.stm) (last visited March 1, 2013).

<sup>82</sup>See generally Priyanka Pulla, *Ayurveda: Hoax or Science?*, OPEN (Feb. 1, 2013) available at <http://www.openthemagazine.com/article/living/ayurveda-hoax-or-science> (last visited March 1, 2013).

<sup>83</sup>See generally Chapter IVA, Drugs & Cosmetics Act, 1940.



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increasingly stiff competition to allopathic industry. The greatest selling point of these traditional medicines is that they are natural in the sense that they are usually not chemically synthesized.<sup>84</sup>

However as noted by a report of the World Health Organization (WHO) just because a medicine is 'natural' it does not automatically follow that the medicine is 'safe'.<sup>85</sup> The same WHO Report states that there is a common belief that long use of a medicine, based on tradition, assures both safety and efficacy. Most importantly the WHO Report notes that several of these medicines are being used outside of their traditional cultural and social context and that some of these medicines are used in combination with heavy metals and chemicals.<sup>86</sup> Given these concerns the WHO Report recommended that such traditional medicines be brought within the ambit of national drug regulatory systems.<sup>87</sup> This demand for more clinical trials has also been backed by a Section of the medical community which has been demanding concrete scientific evidence of the validity of these traditional knowledge based drugs.<sup>88</sup>

In India the Drugs and Cosmetics Act regulates and monitors only the manufacturing of Ayurvedic, Siddha and Unani medicines. There is no mechanism for requiring these drugs to go through clinical trials and there have been few trials involving Ayurvedic drugs.<sup>89</sup> The logic for this conclusion seems to be that traditional medicines which have worked for centuries do not require fresh validation.

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<sup>84</sup>See generally Birgit Heyn, *Ayurveda: The Indian Art of Natural Medicine and Life Extension* (1990) & Chopra A, Doiphode VV. *Ayurvedic medicine-core concept, therapeutic principles, and current relevance*, Medical Clinics of North America. 2002; 86(1):75–88.

<sup>85</sup>THE IMPORTANCE OF PHARMACO-VIGILANCE: SAFETY MONITORING OF MEDICINAL PRODUCTS, World Health Organization (2002) at p.21.

<sup>86</sup>*Id.*

<sup>87</sup>*Ibid* at p. 23.

<sup>88</sup>Rakesh Kalshian, *Old Drugs, New Bottles*, OUTLOOK, (June 07, 1999) available at <http://outlookindia.com/article.aspx?207589> (last visited March 1, 2013).

<sup>89</sup>See generally Lodha R. Bagga A, *Traditional Indian systems of medicines*, Annals of the Academy of Medicine, 2000 Jan-29(1):37-41.

In response to the above mentioned concerns, the GoI had announced that it would make it mandatory to conduct pre-clinical and clinical trials for new Ayurvedic formulations.<sup>90</sup> It was hoped that the validation of these new Ayurvedic formulations through clinical trials would not only help in establishing the safety and efficacy of these drugs but also boost international regulatory and consumer confidence in these drugs.<sup>91</sup> The government is yet to put in place any regulations requiring mandatory clinical trials.

This proposal of the Government however has come under fire from the manufacturers of Ayurvedic medicines, their main objection being that the cost of clinical trials would drive up the costs of the drugs.<sup>92</sup> Although none of these industries have articulated their concerns in terms of the 'free-rider' problem, this does seem to be one of the reasons for opposition to a stronger regulatory regime. If the entire industry is allowed to free-ride off the clinical results that were generated by one company, through considerable investment, then in that case it is unlikely that any company would have an incentive to generate clinical data. Therefore in order to incentivise the generation of clinical data it is absolutely necessary to provide some kind of exclusivity to the company generating such clinical data, through considerable investment.

A 'data exclusivity' incentive is completely in sync with the Central Government's recent move to enforce higher regulatory standards for the industry. This recommendation is also keeping in line with the Reddy Committee Report which in pertinent part stated the following:

*“As per WHO study, traditional medicines are popular with almost 70% of the Indian Population. Since most of these medicines are already in the public domain, there is no patent protection for these under the Indian Patent Act. There is, however, a need to develop proprietary medicines based on the raw materials described in the classical texts by promoting greater research and development, improving their efficacy and to find new uses for these. Data protection can play an important role in this regard. It was discussed that a*

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<sup>90</sup>C.H.Unnikrishnan, *Ayurvedic drugs too will need to be clinically tested, say govt.*, MINT (Jul. 7, 2010) available at <http://www.livemint.com/Home-Page/fcpNVX6GXqmJCnQ4TWkNuJ/Ayurvedic-drugs-too-will-need-to-be-clinically-tested-says.html>(last visited March 1, 2013).

<sup>91</sup>*Id.*

<sup>92</sup> P. K. Krishnakumar, *Clinical trials for new Ayurvedic formulations find few takers*, ECON. TIMES (Feb 18, 2009) available at [http://articles.economictimes.indiatimes.com/2009-02-18/news/27639980\\_1\\_ayurvedic-drugs-clinical-trials-new-ayurvedic](http://articles.economictimes.indiatimes.com/2009-02-18/news/27639980_1_ayurvedic-drugs-clinical-trials-new-ayurvedic)(last visited March 1, 2013).

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*fixed period of data protection for five years with non-reliance by the Drug Regulator on the data submitted by the first applicant while approving second and subsequent applicants, should be appropriate.”<sup>93</sup>*

It is time for the Government to seriously consider implementing the above recommendations of the Reddy Committee Report.

### **(B) CREATING INCENTIVES FOR INNOVATION IN THE FIXED-DOSE-COMBINATION (FDC)**

#### **CLASS OF PHARMACEUTICAL INNOVATION:**

FDCs deserve a special mention in this article because for better or for worse, the Indian pharmaceutical industry is churning out these FDCs at a prodigious rate.<sup>94</sup> As was the case with traditional knowledge, FDCs are not patentable in most cases, in large part, due to Section 3(e) of the Patent Act, 1970 discussed below:

Section 3 (e): *A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance:*

This provision of the Patents Act renders un-patentable ‘a mere admixture resulting only in the aggregation of the properties of the components thereof’. This provision specifically affects FDCs because this class of drugs consists of formulations of two or more active ingredients combined in a single dosage form and where one or both of the active ingredients may have already received regulatory approval.

However not all FDCs are un-patentable. Those FDCs showing a ‘synergistic effect’ are patentable under Section 3(e). A FDC is considered to demonstrate a synergistic effect, when the FDC results in a magnification, and not a mere aggregation of properties of the individual drugs. Only FDCs showing a mere aggregation of properties of the individual drugs are considered to be not patentable under Section 3(e).

FDCs have a significant role to play in public health because a single FDC can treat more than one disease at the same time. From the perspective of doctors operating in a challenging environment, FDCs are invaluable to patient care because these drugs increase patient compliance substantially.

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<sup>93</sup>*supra note 43* at 6.4.3.

<sup>94</sup>*See generally* Chandler Gautam & Lekha Saha, *Fixed Dose Combinations (FDCs): Rational or Irrational – A viewpoint*, BR J CLINPHARMACOL. 2008 MAY; 65(5): 795–796.

The reason for this is the fact that the patient will now have to take only one drug instead of two or three or more drugs. This can be a boon for patients who are being treated for complex diseases like AIDS and tuberculosis, both of which require a multi-drug treatment and the WHO has been extremely appreciative of the role played by FDCs in the treatment of the aforementioned diseases.<sup>95</sup> In the absence of a FDC, patients may often forget to consume the different medication, leading to complication in their treatment regimens and even dangerous side-effects such as resistance to future treatment. Easy and increased compliance of patients makes the overall treatment safer, more effective and substantially cheaper.<sup>96</sup>

Although FDCs are un-patentable per se, these drugs may still be subject to the requirement of clinical trials. As per Rule 122E of the Drugs and Cosmetics Rules, 1945, a Fixed Dose Combination is a 'new drug' thereby necessitating clinical trials. For certain categories of FDCs especially those involving a new active ingredient it is mandatory to carry out clinical trials.

Such clinical trials require investment and the pharmaceutical company planning to introduce a novel FDC into the market will be required to invest substantial resources in order to establish the safety and efficacy of the FDC. The question therefore is whether or not a pharmaceutical company will have an incentive to create a novel FDC even though it will not be provided with any form of monopoly marketing or manufacturing rights, either under patent law or data exclusivity legislation?

The answer to this question is both a yes and a no.

As noted by one Report by the U.K. Parliament on the treatment of AIDS in Africa, Cipla, a leading Indian pharmaceutical company was one of the first players in the market to create a novel FDC by combining three known active ingredients which had already been invented by three different companies.<sup>97</sup> The Report commended Cipla for creating this novel FDC because not only did the FDC greatly simplify the treatment of HIV/AIDS in Africa, but also because the drug was attractively priced.<sup>98</sup> The Report also very pertinently pointed out that Cipla created this FDC in

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<sup>95</sup>*Fixed Dose Combinations for HIV/AIDS, Tuberculosis and Malaria*, World Health Organization, (2003) available at <http://apps.who.int/medicinedocs/en/d/Js6172e/> (last visited March 1, 2013).

<sup>96</sup>*Ibid* at p. 30.

<sup>97</sup>*Supra note* 75 at p. 26.

<sup>98</sup>*Id.*

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reaction to the market demand and had done so despite no patent (or data exclusivity) incentives for the same.<sup>99</sup>

At first glance the above observation seems to change the rules of the game of pharmaceutical innovation especially because substantial amounts had to be sunk into clinical trials that were carried to validate the safety and efficacy of the drugs for not only the WHO pre-qualification program but also US FDA approval.

The counter-point to this debate that is often missed is the unique set of conditions that were usually attached to the sale of some of these novel FDCs at a truly attractive price. The conditions as noted in a new report by the New York Times noted that: “each country must submit large, irrevocable purchase orders and pay cash. Someone other than the drug company must bear the costs of registering each drug in each country, which might include lobbying Parliament or fighting patent lawsuits. There also must be a guaranteed supply of the raw active ingredients at fixed prices.”<sup>100</sup>

Such conditions basically assured companies like Cipla with economies of scale, a constant cash flow, an uninterrupted supply chain and a possible waiver of the cost for expensive clinical trials (which is usually the only substantial investment in developing a new FDC). Pharmaceutical companies were able to negotiate such conditions and achieve economies of scale because of the fact that the campaign against AIDS in Africa was being spearheaded by a handful of international organizations, which collectively represented millions of patients thereby lowering transactions costs for negotiations as also facilitating bulk orders at a low cost.

Moreover some of the expensive clinical trials carried out to validate the FDCs created by Indian Pharmaceutical Companies were funded by Institutions such as The European and Developing Countries Clinical Trials Partnerships (EDCTP).<sup>101</sup> The EDCTP was instrumental in funding the

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<sup>99</sup>*Id.*

<sup>100</sup> Donald G. McNeil, *Plan to bring generic AIDS drugs to poor nations*, N.Y.TIMES, (Apr. 6, 2004) available at <http://www.nytimes.com/2004/04/06/health/plan-to-bring-generic-aids-drugs-to-poor-nations.html>(last visited March 1, 2013)

<sup>101</sup>Press Release, *HIV/AIDS infected children can now benefit from a European and Developing Countries Clinical Trials Partnership-funded trial*, European and Developing Countries Clinical Trials Partnerships, IP/07/1336 (Sept. 14, 2007) available at

clinical trials of a crucial FDC for children affected with HIV/AIDS.<sup>102</sup> This drug was the first paediatric FDC approved by the USFDA for the treatment of AIDS.<sup>103</sup> The main intention behind explaining in such great detail the causes for such low-priced FDCs is not to belittle the achievements of Cipla. The reason instead for going into such details is to point out the unique conditions behind these novel attractively priced FDCs. It is unlikely that such conditions will replicate themselves in other markets for diseases other than AIDS because there is no other disease against which has managed to capture the political activism that has fuelled the sustained campaign against AIDS.

How then does one provide an incentive to pharmaceutical companies to develop new FDCs for diseases other than AIDS? This question is of special significance for the Indian Pharmaceutical Industry which has created a massive market for such drugs in India by flooding the market with FDCs of nearly every permutation and combination. Ordinarily, if new FDCs were being constantly introduced into the market there would be no need to provide any additional incentive. The truth however is that several of the hundreds of FDCs marketed in India were objected to by the Indian drug regulator on the grounds that there were either 'irrational' or that their safety and efficacy had not been validated through clinical trials.<sup>104</sup> The drug regulator has faced a stiff fight from the industry which has fought tooth and nail against the ban.

The most recent concern has been expressed by the Parliamentary Standing Committee which expressed extreme distress at the state of affairs regarding regulation of the FDCs and it urged the government to ban and prohibit several FDCs. In pertinent part the report states "*There is a need to make the process of approving and banning FDCs more transparent and fair. In general, if an FDC is not approved anywhere in the world, it may not be cleared for use in India unless there is a specific disease or disorder prevalent in India, or a very specific reason backed by scientific evidence and irrefutable data applicable specifically to India that*

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<http://europa.eu/rapid/pressReleasesAction.do?aged=0&format=HTML&guiLanguage=en&language=EN&reference=IP/07/1336>(last visited March 1, 2013).

<sup>102</sup>*Id.*

<sup>103</sup>*Id.*

<sup>104</sup>DCGI lifts ban on certain FDCs, INDIAN. EXP. (Jul. 16, 2013) *available at* <http://www.indianexpress.com/news/dcgi-lifts-ban-on-certain-fdcs/336641> (last visited March 1, 2013).

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*justifies the approval of a particular FDC. The Committee strongly recommends that a clear, transparent policy may be framed for approving FDCs based on scientific principles.*<sup>105</sup>

The solution is not to impose a blanket ban on FDCs. The solution lies in better regulation and incentives to validate innovative FDCs through clinical trials. The DCGI is now attempting for better regulation but since there is no patent protection for a good portion of new FDCs it is also necessary to discuss the issue of a complete lack of incentive for private firms to invest in clinical trials in the absence of a data exclusivity regime.<sup>106</sup> The reason for this reluctance is that such innovators of novel FDCs have no means to avoid the very same ‘free-rider’ problem that we discussed in the context of the traditional knowledge medicine sector.

If clinical trials are conducted for a new FDC, the resulting product will necessarily have to be priced higher in order to recover the costs of the trials. Competitors however will be able to skip potentially expensive clinical trials by getting approval for their FDCs by establishing the bio-equivalence of their product with the first FDCs that has gone through the clinical trials. The competitors will be able to sell their FDCs minus the cost of clinical trials therefore ensuring that their product is cheaper than the company which has carried out the clinical trial. As a result the innovator of the FDC will have to incur losses and will be dissuaded from developing new FDCs which require clinical trials. As a result there will be no FDCs left to copy. This is a classic case of the tragedy of the commons. There is thus a need for some kind of exclusive monopolistic rights in order to stimulate research and development of those novel FDCs that cannot be protected under patent law.

In the opinion of this author a period of data exclusivity for FDCs which have been validated through clinical trials, conducted through considerable investment, will provide an adequate incentive for the development of new FDCs. A period of data exclusivity will ensure that for a limited period of time no other manufacturer will be allowed regulatory approval on the basis of the clinical data generated by the originator FDC. The period of monopoly will allow the originator FDC to recover the costs of the clinical trials plus profits.

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<sup>105</sup>*Supra note 67* at para 9.8.

<sup>106</sup>*See* Letter from DCGI to all State Drug Regulators regarding approval of safety and efficacy of FDCs, Jan 15, 2013 *available at* [http://cdsco.nic.in/Approval\\_of\\_the\\_safety\\_and\\_efficiency\\_of\\_FDC.pdf](http://cdsco.nic.in/Approval_of_the_safety_and_efficiency_of_FDC.pdf) (last visited March 1, 2013).

## CONCLUSION: THE WAY AHEAD FOR THE INDIAN DEBATE ON 'DATA EXCLUSIVITY'

Like most IP-related debates in India, the data exclusivity debate has often been overtaken by concerns regarding its effects on pricing and access to medicine. While these concerns are legitimate, it is also necessary for Indian policymakers to understand that quality of clinical trial data available to the medical community is as important as pricing. Pricing issues need to be dealt with frameworks other than the IP frameworks. The most efficient way to deal with the issue of pricing is through 'price-control' legislation.

As demonstrated in this paper, the rationale behind the GoI applying the TRIPS yardstick of 'data exclusivity' differently to the pharmaceutical and agrochemical industry is unclear. If the GoI were to accept the Parliamentary Standing Committee's recommendation to conduct more local clinical trials in India there is little doubt that the GoI will have to introduce some kind of incentive to induce innovator firms to carry out such trials on Indian citizens.

Such an incentive could be in the form of data exclusivity or government funding of clinical trials. Similarly, the incentive requirements for innovation in the field of traditional knowledge medicine and fixed-dose-combination, both of which are not patentable under Indian law, will be well-served by data exclusivity incentives.

To this end, the GoI must review the need for a data exclusivity regime along with a substantial review of India's drug regulatory framework.

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## THE CENTRAL MONITORING SYSTEM AND PRIVACY: ANALYSING WHAT WE KNOW SO FAR

Jaideep Reddy\*

### ABSTRACT

*State-run surveillance is as old as the ages, but the wired state of our lives has put it in the spotlight more now than perhaps ever before. Our communication and data can often be veritable repositories of all that we are, and many governments today have the technological means to give them relatively easy access to most of our private data. Civil society around the world has therefore naturally expressed concern over the increasing scope of State surveillance.*

*The Central Monitoring System (hereafter, "CMS") is a new technology for State surveillance in India, and is in the nascent stages of implementation. It was in 2009, amidst the first hints of information from government sources about this new technology that concern began to arise in civil society in India about the impact of the new form of surveillance on private data and communication.*

*This paper, based on an analysis of the little and scattered official information available on the CMS, discusses, from a privacy viewpoint, the extent to which the CMS is likely to change the landscape of State surveillance in India from what it is today. A tentative evaluation is also made of whether the CMS looks likely to achieve the security-privacy balance, followed by certain suggestions that may help in achieving such a balance.*

### INTRODUCTION

Official information on the CMS is scarce, and the little material that is available has tended to give the public and sections of the media the impression that the CMS will facilitate threateningly direct and sweeping surveillance.<sup>1</sup> Activists are also worried that the CMS is being designed without public

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<sup>1</sup>See, e.g., Rohin Dharmakumar, *Is CMS a Compromise of Your Security?*, FORBES INDIA, July 9, 2013, available at <http://forbesindia.com/article/real-issue/is-cms-a-compromise-of-national-security/35543/1>, last accessed January 26, 2014; Anurag Kotoky, *India sets up elaborate system to tap phone calls, e-mail*, REUTERS, June 20, 2013, available at <http://www.reuters.com/article/2013/06/20/us-india-surveillance-idUSBRE95J05G20130620>, last accessed January 26, 2014; Maria Xynou, *India's 'Big Brother': The Central Monitoring System (CMS)*, CENTRE FOR INTERNET AND SOCIETY, April 8, 2013, available at <http://cis-india.org/internet->

debate, and will work in a non-transparent manner, thereby facilitating arbitrary access to, and misuse of, private data and communication.<sup>2</sup>

This paper explores the various known and proposed features of the CMS, with a view to analyse the extent to which the CMS, as such, may warrant the above and other privacy concerns. This paper analyses the CMS as a surveillance tool as such, and does not separately discuss the concerns about the manner in which State surveillance in general is conducted in India.<sup>3</sup> This analysis is made, first, by looking at the changes that the CMS makes to the existing surveillance system, and, next, by tentatively assessing the CMS ('tentatively', because of the fledgling stage the CMS is at today) against various standards seeking to protect privacy in the conduct of State surveillance. Preceding the analysis of the CMS is a brief statement of the law governing privacy and surveillance in India.

In analysing the CMS, I rely as such on official sources for information, and to a supplementary extent, on official sources as reported in the media.

## PRIVACY AND SURVEILLANCE IN INDIA

In India, the right to privacy is a judicially evolved right. It derives its authority from interpretations of Article 21 of the Constitution, which guards against the deprivation of a person's "*life or personal liberty except according to procedure established by law.*" The features of the right to privacy in India are currently as follows:

1. It is the right to be let alone.<sup>4</sup>

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governance/blog/indias-big-brother-the-central-monitoring-system, last accessed January 26, 2014. *See also infra* nn. 24-29 and accompanying text.

<sup>2</sup>*Ibid.*

<sup>3</sup>*See, e.g.,* Bhairav Acharya, *Turning India into a Surveillance State - II*, THE HOOT, November 20, 2013 (observing, "[i]n India, the laws that allow communications interceptions are minimal, they do not conform to global best practices and they do not accord the protections afforded by the laws of many other liberal democracies."), available at <http://www.thehoot.org/web/Turning-India-into-a-surveillance-state----II/7150-1-1-12-true.html>, last accessed January 26, 2014; Elonnai Hickok, *Why India needs a Snowden of its own*, YAHOO! NEWS INDIA, October 23, 2013 (stating, "[t]he gaps in the Indian surveillance regime are many and begin with a lack of enforcement and harmonization of existing safeguards and protocols."), available at <http://in.news.yahoo.com/why-india-needs-a-snowden-of-its-own-054956734.html>, last accessed January 26, 2014.

<sup>4</sup>R. *Rajagopal v. State of Tamil Nadu*, (1994) 6 SCC 632.

2. It can only be infringed by a more powerful countervailing interest, including a compelling State interest of paramount importance.<sup>5</sup>
3. It is a fundamental right, under Article 21 of the Constitution.<sup>6</sup>
4. One's privacy right extends to oneself, one's family, marriage, procreation, motherhood, child bearing and education "among many other matters".<sup>7</sup>
5. The dictum under Article 17 of the International Covenant on Civil and Political Rights, 1966 that "[n]o one shall be subject to arbitrary or unlawful interference with his privacy, family, human or correspondence, nor to lawful attacks on his honour and reputation" is relevant to the right to privacy in India.<sup>8</sup>

Also to note, discussions are currently rife about a *sui generis* privacy law. A draft Privacy Bill prepared by the Department of Personnel and Training<sup>9</sup> was leaked to the public in 2011, and the said Bill is reportedly undergoing revision.<sup>10</sup> In October, 2012, a Group of Experts on Privacy constituted by the Planning Commission, Government of India, and chaired by Justice A.P. Shah, submitted its report formulating a set of 'national privacy principles'. The report analysed existing laws, and recommended certain points for consideration in the drafting of a new Privacy Act.<sup>11</sup>

On the interface between State surveillance and privacy, there is a pivotal judgment of the Supreme Court of India in *People's Union for Civil Liberties v. Union of India*.<sup>12</sup> In the judgment, the Court found

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<sup>5</sup>*Gobind v. State of Madhya Pradesh*, (1975) 2 SCC 148.

<sup>6</sup>R. Rajagopal, *supra* n. 4; *People's Union for Civil Liberties v. Union of India*, *infra* n. 12.

<sup>7</sup>R. Rajagopal, *ibid*.

<sup>8</sup>*People's Union for Civil Liberties*, *infra* n. 12.

<sup>9</sup>The Department of Personnel and Training is an agency under the administrative control of the Ministry of Human Resource Development, Government of India.

<sup>10</sup>Bhairav Acharya, *India: Privacy in Peril*, FRONTLINE, July 12, 2013, available at <http://www.frontline.in/cover-story/india-privacy-in-peril/article4849211.ece>, last accessed January 26, 2014.

<sup>11</sup> PLANNING COMMISSION, GOVERNMENT OF INDIA, REPORT OF THE GROUP OF EXPERTS ON PRIVACY (CHAIRIED BY JUSTICE A P SHAH, FORMER CHIEF JUSTICE, DELHI HIGH COURT) (16<sup>th</sup> October, 2012).

<sup>12</sup>*People's Union for Civil Liberties*, (1997) 1 SCC 301.

that the tapping of telephones by the State, which is done under the Indian Telegraph Act, 1885 (*hereafter*, “Telegraph Act”), was being carried out without adequate safeguards.<sup>13</sup> The Court thereby laid down certain procedural safeguards to protect individuals’ privacy rights.<sup>14</sup> These safeguards were subsequently legislatively incorporated in the Indian Telegraph Rules, 1951 (*hereafter*, “Telegraph Rules”). While the Court in *People's Union for Civil Liberties* did not explicitly mandate such safeguards for monitoring and surveillance in forms other than telephone tapping, the substance of the Court’s guidelines in the case were incorporated in relation to the surveillance of “*information through any computer resource*” in the form of the Information Technology (Procedure and Safeguards for Interception, Monitoring and Decryption of Information) Rules, 2009 (*hereafter*, “IT Monitoring Rules”), made under the Information Technology Act, 2000 (*hereafter*, “IT Act”).

Presently, the procedure for monitoring under the Telegraph Act, the IT Act, and the rules framed thereunder, is briefly as follows:

1. To initiate interception, a written order, with reasons recorded, directing interception is to be made by the Central or State Government, acting through the Secretary in the Ministry of Home Affairs or Secretary in charge of the Home Department, respectively.<sup>15</sup>
2. The statutory thresholds for interception are (any of): “*the interest of the sovereignty or integrity of India*”, “*defence of India*”, “*security of the State*”, “*friendly relations with foreign States*”, “*public order*”, “*preventing incitement to the commission of any offence*”, and “*investigation of any offence*”.<sup>16</sup>

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<sup>13</sup>*People's Union for Civil Liberties, ibid*, ¶¶ 42, 46.

<sup>14</sup>*People's Union for Civil Liberties, ibid*, ¶¶ 47-55.

<sup>15</sup> Rule 419-A(1), Telegraph Rules, and Rule 2(d), IT Monitoring Rules. In unavoidable circumstances, the order may be issued by an officer not below the rank of Joint Secretary of the Government of India. In emergencies, where obtaining prior directions for interception from the above mentioned officers is not feasible, the most senior or second most senior officer of the concerned law enforcement agency is required to approve the interception; confirmation from the Home Secretary or Joint Secretary, as the case may be, would then be required within a period of seven days. *See* Rule 419-A(1), Telegraph Rules, and Rule 3, IT Monitoring Rules.

<sup>16</sup>*See* Section 5(2), Telegraph Act, and Section 69(1), IT Act.

3. The officer directing interception is to “*consider the possibility of acquiring the information by other means and [such direction of interception] shall be issued only when it is not possible to acquire the information by any other reasonable means.*”<sup>17</sup>
4. The written order directing interception is to be forwarded to a Review Committee which is to be constituted by the Central and State Governments, separately.<sup>18</sup> The Review Committees consist of three high-ranking officers of the executive wing of government.<sup>19</sup>
5. The directions for interception are to be conveyed to telecommunications service providers (*hereafter*, “TSPs”) by law enforcement agencies and the requested data is to be granted by the TSPs upon receipt of such directions.<sup>20</sup>
6. The concerned Review Committee is to meet at least once in two months and assess whether the directions of interception are in accordance with the Telegraph Act and the IT Act, and if it finds that such directions are not so, it may set aside the order for interception, and order for destruction of copies of the intercepted material.<sup>21</sup>

### CONCERNS OF THE PUBLIC

Since the news of the government’s plans for the CMS became public - and more so in the wake of the revelations by Edward Snowden on surveillance by the United States’ National Security Agency - the Indian public and media have expressed concern on the apparently sweeping powers of monitoring that are to be facilitated by the CMS.<sup>22</sup> The CMS has also received international

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<sup>17</sup> Rule 419A(3), Telegraph Rules, and Rule 8, IT Monitoring Rules.

<sup>18</sup> Rule 419A(2), Telegraph Rules, and Rule 7, IT Monitoring Rules.

<sup>19</sup>Rule 419A(16), Telegraph Rules. For the Central Government, the Review Committee is to consist: Cabinet Secretary as Chairman; Secretary to the Government of India in charge of Legal Affairs, as Member; and, Secretary to the Department of Telecommunications, Government of India, as Member. For State Governments, the Review Committees are to consist: Chief Secretary as Chairman; Secretary Law / Legal Remembrancer In-charge, Legal Affairs, as Member; and, Secretary to the State Government (other than the Home Secretary), as Member.

<sup>20</sup> Section 5(2), Telegraph Act; Rule 419A(7) and (9), Telegraph Rules; and, Section 69(3), IT Act.

<sup>21</sup> Rule 419A(17), Telegraph Rules, and Rule 22, IT Monitoring Rules.

<sup>22</sup>*See, e.g., India to set up a central monitoring system*, LOSS OF PRIVACY, November 30, 2009 (demonstrating concern freshly in the wake of the first government announcements on the CMS), available at

attention; Human Rights Watch, the well-known international human rights advocacy organisation, expressed its view that the CMS appears to threaten the human rights of privacy and free speech.<sup>23</sup>

Various sections of the media and the public have expressed the main reasons why the CMS poses a threat to privacy as follows:

1. The lack of public documentation to explain the scope, functions, and technical architecture of the CMS betrays a lack of transparency, and transparency is necessary in the conduct of surveillance in democratic societies.<sup>24</sup>
2. There is a lack of adequate legal safeguards governing the use of a powerful surveillance tool such as the CMS,<sup>25</sup> and adequate legal safeguards include:

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<http://www.lossofprivacy.com/index.php/2009/11/india-to-set-up-a-central-monitoring-system/>, last accessed January 26, 2014. After the Snowden leaks, more extensive opinions have been made, expressing anxiety over the potential sweep of the CMS; see *infra* nn. 24-29, and accompanying text.

<sup>23</sup>India: *New Monitoring System Threatens Rights: Safeguards Needed to Protect Privacy, Free Speech*, HUMAN RIGHTS WATCH, JUNE 7, 2013, available at <http://www.hrw.org/news/2013/06/07/india-new-monitoring-system-threatens-rights>, last accessed January 26, 2014. See also, Jillian C. York, *NSA Leaks Prompt Surveillance Dialogue in India*, ELECTRONIC FRONTIER FOUNDATION, July 10, 2013, available at <https://www.eff.org/deeplinks/2013/07/nsa-leaks-prompt-surveillance-dialogue-india>, last accessed January 26, 2014; Pranesh Prakash, *How Surveillance Works in India*, NEW YORK TIMES (INTERNATIONAL EDITION: INDIA), July 10, 2013, available at <http://india.blogs.nytimes.com/2013/07/10/how-surveillance-works-in-india/>, last accessed January 26, 2014.

<sup>24</sup>Bhairav Acharya, *The Central Monitoring System: Some Questions to be Raised in Parliament*, CENTRE FOR INTERNET AND SOCIETY, September 19, 2013, available at <http://cis-india.org/internet-governance/blog/central-monitoring-system-questions-to-be-asked-in-parliament>, last accessed January 26, 2014; Anurag Kotoky, *India sets up elaborate system to tap phone calls, e-mail*, *supra* n. 1; Danish Raza, *India's Central Monitoring System: Security can't come at cost of privacy*, FIRSTPOSTINDIA, available at <http://www.firstpost.com/india/indias-central-monitoring-system-security-cant-come-at-cost-of-privacy-944475.html>, last accessed January 26, 2014; Human Rights Watch, *India: New Monitoring System Threatens Rights: Safeguards Needed to Protect Privacy, Free Speech*, *supra* n. 23; Shalini Singh, *Lethal surveillance versus privacy*, THE HINDU, June 22, 2013, available at <http://www.thehindu.com/opinion/lead/lethal-surveillance-versus-privacy/article4837932.ece>, last accessed January 26, 2014; Rohan Joshi, *India's Central Monitoring System*, THE TAKSHASHILA INSTITUTION, July, 2013, available at <http://takshashila.org.in/wp-content/uploads/2013/07/India%E2%80%99s-Central-Monitoring-System-Rohan-Joshi.pdf>, last accessed January 26, 2014.

<sup>25</sup>Jillian C. York, *NSA Leaks Prompt Surveillance Dialogue in India*, *supra* n. 23; Rohan Joshi, *India's Central Monitoring System*, *ibid*; Danish Raza, *India's Central Monitoring System: Security can't come at cost of privacy*, *ibid*.

- A procedure for judicial authorisation of surveillance,
  - Checks on the rights and duties of the functionaries carrying out surveillance, and
  - Checks on the use and disclosure of the information gathered through surveillance.<sup>26</sup>
3. Since the nature of surveillance under the CMS is mass-based and direct, as opposed to the extant target-based mechanism which is routed through requests to TSPs, existing legal safeguards pertaining to surveillance will not suffice for the CMS.<sup>27</sup>
  4. In the absence of proper safeguards, the CMS may cause widespread and unwarranted infractions of privacy rights.<sup>28</sup>
  5. The CMS appears to require the aggregation of the nation's communications data in a single, centralised location, and such aggregation would make the data highly susceptible to security breaches.<sup>29</sup>

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<sup>26</sup>Pranesh Prakash, *How Surveillance Works in India*, *supra* n. 23; Rohin Dharmakumar, *Is CMS a Compromise of Your Security?*, *supra* n. 1; Bhairav Acharya, *India: Privacy in Peril*, *supra* n. 10; Karishma D'Souza, *The Central Monitoring System (CMS) and the International Principles on the Application of Human Rights to Communications Surveillance*, CENTRE FOR LAW AND POLICY RESEARCH, September 23, 2013, available at <http://clpr.org.in/the-central-monitoring-system-cms-and-the-international-principles-on-the-application-of-human-rights-to-communications-surveillance/>, last accessed January 26, 2014; Shalini Singh, *Lethal surveillance versus privacy*, *supra* n. 24.

<sup>27</sup>Elonnai Hickok, *Why India needs a Snowden of its own*, *supra* n. 3, (observing, “[e]ven if the Central Monitoring System were to adhere to the legal safeguards and procedures defined under the Indian Telegraph Act and Information Technology Act, the system can only do so partially, as both provisions create a clear chain of custody that the government and service providers must follow – that is, the service provider was included as an integral component of the interception process”). See also Bhairav Acharya, *The Central Monitoring System: Some Questions to be Raised in Parliament*, *supra* n. 24; Rohan Joshi, *India's Central Monitoring System*, *supra* n. 24; Bhairav Acharya, *India: Privacy in Peril*, *supra* n. 10.

<sup>28</sup>Bhairav Acharya, *India: Privacy in Peril*, *ibid*; Shalini Singh, *Lethal surveillance versus privacy*, *supra* n. 24.

<sup>29</sup>Opinion of Bhairav Acharya, expressed in conversation with the author on December 9, 2013. Notes of the conversation are on file with the author.

## ANALYSING THE CMS

As mentioned previously, there is limited official information on the CMS available in the public domain. The resources that are publicly available on the subject are the following: statements in Parliament; recent amendments to the wordings of TSPs' licenses, granted under the Telegraph Act; annual reports of the Department of Telecommunications (a department of the Ministry of Communications and Information Technology, Government of India (*hereafter*, "DoT")); publicly available documents of the Centre for Department of Telematics (*hereafter*, "C-DoT"); a response to the author's application under the Right to Information Act, 2005 (*hereafter*, "RTI Act"); and statements by government officials and agencies reported in the media. This article bases its analysis on these various resources. As is apparent, few of these resources are sources of binding law. They are, in the most part, expressions of governmental intent. However, as of the date of writing, they are the best that we can use to paint a true and fair picture of the scheme of the CMS and to analyse its features.

### **A BRIEF BACKGROUND**

In the DoT's annual report for the year 2007-08, it was stated that "[t]he requirements for the Project on Central Monitoring System [were] finalized by TEC after detailed deliberations with various Security Agencies."<sup>30</sup> (The 'TEC' is the Telecommunication Engineering Centre, an agency of the DoT).<sup>31</sup>

In the above statement, it is not clear what these requirements were, what these deliberations were about, or which security agencies were involved in the deliberations. However, we may surmise that requirements for the CMS were finalised based on the needs expressed by the security agencies for effective monitoring from the point of view of security.

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<sup>30</sup>DEPARTMENT OF TELECOMMUNICATIONS, MINISTRY OF COMMUNICATIONS AND INFORMATION TECHNOLOGY, ANNUAL REPORT (*hereafter*, "DOT ANNUAL REPORT") 2007-2008 43, available at [http://www.dot.gov.in/sites/default/files/English%20annual%20report%202007-08\\_0.pdf](http://www.dot.gov.in/sites/default/files/English%20annual%20report%202007-08_0.pdf), last accessed January 26, 2014.

<sup>31</sup>DOT ANNUAL REPORT 2012-2013 43 ("*Telecommunications Engineering Centre (TEC) is the technical wing of the Department of Telecommunications*"), available at [http://www.dot.gov.in/sites/default/files/Telecom%20Annual%20Report-2012-13%20%28English%29%20\\_For%20web%20%281%29.pdf](http://www.dot.gov.in/sites/default/files/Telecom%20Annual%20Report-2012-13%20%28English%29%20_For%20web%20%281%29.pdf), last accessed January 26, 2014.



The annual reports of the DoT for the years 2007-08 to 2009-10 stated that the “*architecture and dimensioning*” of the CMS was finalised by C-DoT, and the research and development for the CMS project was on-going.<sup>32</sup> The annual report for the year 2009-10 further stated, “*The lab Data Centre has been made operational. The dimensioning of the CMS Data Centre has been completed and the process initiated for setting-up the required infrastructure for connecting to the TSPs and conducting trials and later, services.*”<sup>33</sup> On a broader note, it is confirmed that C-DoT is the government agency entrusted with the execution of the CMS project,<sup>34</sup> while the operation of the CMS (which stage we have not yet reached) is to be carried out by the various regional Telecom Enforcement Resource and Monitoring (TERM) cells which work under the administrative authority of the DoT.<sup>35</sup>

In 2011, the Cabinet Committee on Security (CCS) approved the CMS project.<sup>36</sup> In the same year, a pilot run of the CMS was initiated in New Delhi, whereby two TSPs were connected with the CMS infrastructure and access to communications facilitated by them was given to two law enforcement agencies.<sup>37</sup> The latest official news on the status of the CMS is that the pilot implementation of the CMS is continuing, and that the installation of a key component of the CMS, the ‘Intercept, Store and Forward’ (ISF) server,<sup>38</sup> has begun on the premises of TSPs in seven different licensed service

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<sup>32</sup>DOT ANNUAL REPORT 2007-2008 43, *supra* n. 30; DOT ANNUAL REPORT 2008-2009 49, available at [http://www.dot.gov.in/sites/default/files/AR\\_English\\_2008-09\\_0.pdf](http://www.dot.gov.in/sites/default/files/AR_English_2008-09_0.pdf), last accessed January 26, 2014; DOT ANNUAL REPORT 2009-2010 53, available at [http://www.dot.gov.in/sites/default/files/final\\_0.pdf](http://www.dot.gov.in/sites/default/files/final_0.pdf), last accessed January 26, 2014.

<sup>33</sup>DOT ANNUAL REPORT 2009-2010 80, *ibid*.

<sup>34</sup>Answer by Mr. Milind Deora dated February 19, 2014, to unstarred question number 4181 asked by Dr. Dilesh Narayan Rane, in the 15<sup>th</sup> Session of the 15<sup>th</sup> Lok Sabha, available at <http://164.100.47.132/LssNew/psearch/QResult15.aspx?qref=150407>, last accessed April 13, 2014; response of the DoT dated January 6, 2014, to the author’s RTI application bearing Application Registration No. DOTEL/R/2013/60886, and dated December 9, 2013 (both the application and response are on file with the author).

<sup>35</sup>DOT ANNUAL REPORT 2012-2013 60, *supra* n. 31.

<sup>36</sup> Answer to unstarred question number 1598 asked by Rajeev Chandrasekhar the 229<sup>th</sup> Session of the Rajya Sabha, available at <http://rajyasabha.nic.in/>, last accessed January 26, 2014 (direct link not available).

<sup>37</sup>DOT ANNUAL REPORT 2011-2012 86, available at [http://www.dot.gov.in/sites/default/files/AR%20Englsih%2011-12\\_0.pdf](http://www.dot.gov.in/sites/default/files/AR%20Englsih%2011-12_0.pdf), last accessed January 26, 2014.

<sup>38</sup>*Infra* n. 44; DOT ANNUAL REPORT 2012-2013 84, *supra* n.31.

areas of the DoT.<sup>39</sup> A February 2014 statement of Mr. Milind Deora declared that the CMS “*has been planned to be implemented in phased manner in about 3 years.*”<sup>40</sup>

### **ANALYSING THE FEATURES OF THE CMS**

In our analysis of the CMS, it may be best to closely read quotations of government statements about the system, so that we can have a clear picture of the government’s intent. Discussed below are the features of the CMS that result from various government statements.

#### **Central and direct**

At its heart, the CMS is a “*centralized system to monitor communications on mobile phones, landlines and the internet in the country.*”<sup>41</sup> Through it, “[*direct [e]lectronic [p]rovisioning of target numbers by Government agencies without any manual intervention from Telecom Service Providers*]” is proposed, with the expectation that “[*interception through CMS will be instant as compared to the existing system*]”.<sup>42</sup>

What does it mean that the CMS is a ‘centralized system’? There is a plan for the setting up of a Central Monitoring Centre (CMC) which will aggregate all of the nation’s communications, upon forwarding by various Regional Monitoring Centres (RMCs) that are to be located in the several licensed service areas of the DoT.<sup>43</sup> ‘Intercept, Store and Forward’ (ISF) servers installed on the premises of TSPs, will as the name suggests, intercept, store and forward data passing through the TSPs’ channels to the RMCs.<sup>44</sup> Graphically, we can understand this scheme as in the following page:

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<sup>39</sup> The seven licensed service areas in which the installation of ISF servers has commenced are New Delhi, Haryana, Kolkata, Karnataka, Mumbai, Rajasthan, and Tamil Nadu. *See* DOT ANNUAL REPORT 2012-2013 84, *supra* n. 31.

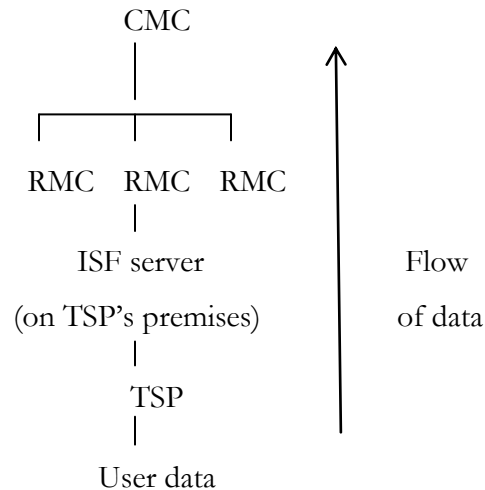
<sup>40</sup> Answer by Mr. Milind Deora dated February 19, 2014, to unstarred question number 4181, *supra* n. 34.

<sup>41</sup> *Centralised System to Monitor Communicaitons [sic]*, Press Information Bureau, Government of India, November 26, 2009, available at <http://pib.nic.in/newsite/erelease.aspx?relid=54679>, last accessed January 26, 2014. In the actual proceedings in Parliament, the Minister was asked, “*whether Government proposes to set up a centralized system to monitor communications on mobile phones, landlines and the internet in the country*”, to which he replied in the affirmative. *See* Answer to unstarred question number 772 asked by Nand Kumar Sai the 218<sup>th</sup> Session of the Rajya Sabha, available at <http://rajyasabha.nic.in/>, last accessed January 26, 2014 (direct link not available).

<sup>42</sup> *See* Answer to unstarred question number 772 asked by Nand Kumar Sai, *ibid.*

<sup>43</sup> *See* DOT ANNUAL REPORT 2012-2013 84, *supra* n. 31; DOT ANNUAL REPORT 2011-2012 86, *supra* n. 37.

<sup>44</sup> Amendments to the Unified License agreement, Unified Access Services (UAS) License agreement, Unified License (Access Services) agreement, CMTS License agreement, each *vide* letters from the Access Service Cell



The CMS is ‘direct’ in the sense that, contrary to the present system under which the law enforcement agencies make their requests to TSPs, surveillance under the CMS will no longer involve any parties other than government agencies.

#### The CMS Authority

The proposal of the CMS to be ‘central and direct’ does not give the law enforcement authorities automatic and unrestricted access to all private data. The current mode of operation, based on requests for data to TSPs, is to be replaced by a scheme wherein law enforcement agencies would be making their requests to a new authority that has been referred to as the ‘provisioning authority’ and the ‘CMS authority’. It has been officially stated that, “*Law Enforcement Agencies (LEAs) are not able to provision the target themselves and the provisioning authority is not able to see the content of the intercepted communication* (emphasis added).”<sup>45</sup> Also, an internal note of the DoT is reported to mention a ‘CMS authority’ in the context of the same role, stating, “[*t*he law enforcement agency (LEA) cannot provision for

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of the DoT to the respective licensees, dated October 11, 2013, bearing File No. 800-12/2013-AS.II, and available at <http://www.dot.gov.in/sites/default/files/DOC231013.pdf>, <http://www.dot.gov.in/sites/default/files/DOC231013-004.pdf>, <http://www.dot.gov.in/sites/default/files/DOC231013-005.pdf>, and <http://www.dot.gov.in/sites/default/files/DOC231013-006.pdf>, respectively; last accessed January 26, 2014. *See also* *ibid*.

<sup>45</sup>See Answer to unstarred question number 1598 asked by Rajeev Chandrasekhar, *supra* n. 36.

*interception and monitoring and the CMS authority cannot see the content but would be able to provision the request from the LEA.*<sup>46</sup>

This CMS authority or provisioning authority is therefore an authority that is distinct from a law enforcement agency, and appears to be contemplated to have charge of the operation of the monitoring system. The scheme appears to be that the CMS authority is to carry out the monitoring and interception of data, upon a duly made request by an authorised law enforcement agency.

#### Facilitation of law enforcement concerns

Since the purpose of the CMS is to “*strengthen the security environment in the country*”,<sup>47</sup> and since monitoring is done based on the requirements of the law enforcement agencies,<sup>48</sup> the CMS creates certain new tools to facilitate the work of these law enforcement agencies.

There is proposed to be a “[c]entral and regional database which will help Central and State level Law Enforcement Agencies in Interception and Monitoring”.<sup>49</sup> It is not clear what this database will consist of. The possibilities are, data intercepted; data sought to be intercepted; targets; and/or, potential targets. There are also to be “[f]ilters and Alert creation on the target numbers”.<sup>50</sup> This presumably means that filters will be used to mine desired data from the mass of data available, and alert creation will keep law enforcement agencies updated on the activities of their targets. Also, meta-data is available: an envisaged salient feature of the CMS is mentioned as, “*Call Data Records (CDR) analysis and data mining on CDRs to identify call details, location details etc. of the target numbers*”.<sup>51</sup>

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<sup>46</sup> Joji Thomas Philip, Leslie D’Monte, and Shauvik Ghosh, *Your telco could help spy on you*, LIVEMINT, July 30, 2013, available at <http://www.livemint.com/Politics/rpWFidJroLgpLQ6yKdR3pJ/Telcos-to-soon-link-with-government-monitoring-system.html>, last accessed January 26, 2014. *See also* Danish Raza, *India’s Central Monitoring System: Security can’t come at cost of privacy*, *supra* n. 24 (referring to an internal note of the DoT to the same effect).

<sup>47</sup> Answer to unstarred question number 772 asked by Nand Kumar Sai, *supra* n. 41.

<sup>48</sup> We can infer this from the statement, “*provisioning of the targets as required by Law Enforcement Agencies (LEAs)*”, as mentioned in DOT ANNUAL REPORT 2011-2012 58, *supra* n. 37, and DOT ANNUAL REPORT 2012-2013 60, *supra* n. 31.

<sup>49</sup> Answer to unstarred question number 772 asked by Nand Kumar Sai, *supra* n. 41.

<sup>50</sup> *Ibid.*

<sup>51</sup> *Ibid.*

### Security of intercepted data; safeguards over monitoring

The government envisages that “*functions will be performed on secured electronic link and there will be minimum manual intervention*”,<sup>52</sup> and that this will enhance the secrecy of interception, as well as protect individuals’ privacy rights.<sup>53</sup> Since TSPs will no longer to be in the picture for monitoring, the two relevant parties are the law enforcement agency and the CMS authority. To govern this relationship, the former Minister of State for Communications and IT, Milind Deora, has told us, “*CMS has an inbuilt mechanism of check and balance, wherein the Law Enforcement Agencies (LEAs) are not able to provision the target themselves and the provisioning authority is not able to see the content of the intercepted communication*”.<sup>54</sup>

Another mechanism being put forth as a safeguard by the government is the “*auto generation of audit trail of command logs related to interception and monitoring, which works as a deterrent to any unauthorized provisioning*”.<sup>55</sup> Such logs are said to be non-erasable records, and the DoT is reported to have stated that the logs can be “*examined anytime for misuse*”.<sup>56</sup>

At this point, it is not clear precisely what these logs will contain, and whether they will be comprehensive enough to hold errant authorities accountable for misuse of the surveillance systems. While certain logs are maintained under the Telegraph Rules and the IT Monitoring Rules, there is no defined mechanism for their inspection by any authority.<sup>57</sup>

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<sup>52</sup> *Ibid.*

<sup>53</sup> *Ibid* and Answer to unstarred question number 1598 asked by Rajeev Chandrasekhar, *supra* n. 36 (where enhanced secrecy as a feature of the CMS is noted); Milind Deora on Central Monitoring System, available at <http://www.youtube.com/watch?v=rwTsek5WUfE>, last accessed January 26, 2014, 3:13 minutes to 3:27 minutes (where the Minister states, “[*the Central Monitoring System*] is precisely being set up to safeguard your privacy and ... protect our national security”). See also Joji Thomas Philip, Leslie D’Monte, and Shauvik Ghosh, *Your telco could help spy on you*, *supra* n. 46 (where an internal note of the DoT is reported to state that the CMS “*will rather enhance the privacy of the citizens*”).

<sup>54</sup> See Answer to unstarred question number 1598 asked by Rajeev Chandrasekhar, *supra* n. 36.

<sup>55</sup> *Ibid.*

<sup>56</sup> Joji Thomas Philip, Leslie D’Monte, and Shauvik Ghosh, *Your telco could help spy on you*, *supra* n. 46 (reporting that an email reply by the DoT to a questionnaire and an internal note of the DoT, both, state, “[*further, a non-erasable command log will be maintained by the system, which can be examined anytime for misuse, thus having an additional safeguard*”).

<sup>57</sup> The provisions on the maintenance of records of monitoring are Rule 419-A(8), Telegraph Rules and Rule 16, IT Monitoring Rules. Rule 419-A(8) of the Telegraph Rules states, “*The officer authorized to intercept any*

### Compliance with law

The former Minister for Communications and Information Technology, Milind Deora, in his statement of August, 2013, was at pains to state that surveillance under the CMS is subject to the safeguards for monitoring contained in the Telegraph Act, including the requirement for authorisation of interceptions, destruction of intercepted records periodically, sharing of intercepted data, and checks against unlawful interception and monitoring.<sup>58</sup> While Mr. Deora did not explicitly state that the IT Act and the IT Monitoring Rules are intended to be complied with, we may surmise such intention, since the IT Act and the IT Monitoring Rules prescribe norms similar to those under the Telegraph Act and the Telegraph Rules.

## CHANGES TO THE PRESENT SCHEME OF SURVEILLANCE

The chief changes that the CMS will make to the present scheme of surveillance are discussed below.

### **1. TECHNOLOGICAL CHANGES, BRINGING DATA AT THE GOVERNMENT'S FINGERTIPS**

In contrast with the current targeted, request-based system of surveillance, the CMS contemplates a system where the government (through the CMS authority) would sit at the helm of the wired and wireless data passing through the nation's communication channels. The removal of the request-based system may be a double-edged sword. While TSPs did act as a third party to private data, and therefore another source of leaks and potential breaches of privacy rights, they may have kept an

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*message or class of message shall maintain proper records mentioning therein, the intercepted message or class of messages, the particulars of persons whose message has been intercepted, the name and other particulars of the officer or the authority to whom the intercepted message or class of messages has been disclosed, the number of copies of the intercepted message or class of messages made and the mode or the method by which such copies are made, the date of destruction of the copies and the duration within which the directions remain in force.” Rule 16 of the IT Monitoring Rules states, “Maintenance of records by designated officer.— The designated officer of intermediary or person in-charge of computer resource authorised to intercept or monitor or decrypt any information shall maintain proper records mentioning therein, the intercepted or monitored or decrypted information, the particulars of persons, computer resource, e-mail account, website address, etc. whose information has been intercepted or monitored or decrypted, the name and other particulars of the officer or the authority to whom the intercepted or monitored or decrypted information has been disclosed, the number of copies, including corresponding electronic records of the intercepted or monitored or decrypted information made and the mode of the method by which such copies, including corresponding electronic records are made, the date of destruction of the copies, including corresponding electronic record and the duration within which the directions remain in force.”*

<sup>58</sup>See Answer to unstarred question number 1598 asked by Rajeev Chandrasekhar, *supra* n. 36.

unofficial check on arbitrary surveillance powers to an extent, as they were privy to the monitoring system.<sup>59</sup> With requests not having to be made to TSPs, the operation of surveillance now solely rests with the government.

## **2. A NEW OFFICE**

Essential to the proposed working of the CMS is the new office of the ‘CMS authority’, also referred to as the “provisioning authority”. The CMS authority is at the centre of much power, and there has so far been no mention of the exact contours of its role and its rights and duties, or whether such role, rights and duties have been definitively finalised by the government, even internally. Significantly, the government does not appear to contemplate any regulation to especially govern the CMS authority’s functioning.<sup>60</sup>

Also, it is not completely clear how this new office will play out in relation to the TERM cells of the DoT. While it is clear that the government contemplates that the CMS authority is responsible for interception of communications and forwarding of these communications to law enforcement agencies, annual reports of the DoT suggest that TERM cells will also be involved in implementing the CMS once it is functional.<sup>61</sup>

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<sup>59</sup>See, e.g., Bhairav Acharya, *India: Privacy in Peril*, *supra* n. 10 (opining, “[n]o doubt, trusting private persons with the power to intercept and store the private data of citizens is flawed. The leaking of the Niira Radia tapes, which contain the private communications of Niira Radia taped on the orders of the Income Tax Department, testifies to this flaw. However, bypassing private players to enable direct state access to private communications will preclude leaks and, thereby, remove from public knowledge the fact of surveillance.”); Shalini Singh, *Lethal surveillance versus privacy*, *supra* n. 24 (opining, “[h]owever, this means that the checks-and-balance system provided by the nodal officers in mobile networks — which discovered the illegal request for BJP leader Arun Jaitley’s CDRs, leading to the arrest of three persons including a Delhi police constable — will no longer exist.”)

<sup>60</sup> Answer to unstarred question number 1598 asked by Rajeev Chandrasekhar, *supra* n. 36 (mentioning only the Telegraph Act and Telegraph Rules as the legal framework surrounding the CMS); response of the DoT dated January 6, 2014, to the author’s RTI application, *supra* n. 34 (stating, “[l]awful interception and monitoring under CMS is governed by Section 5 (2) of Indian Telegraph Act 1885 read with Rule 419A of Indian Telegraph (Amendment) Rules, 2007.”). None of the above sources contemplated any regulation which would take into account the particular role of the CMS authority.

<sup>61</sup>DOT ANNUAL REPORT 2012-2013 60, *supra* n. 31.

### **3. AUTOMATICALLY GENERATED AND NON-ERASABLE LOGS**

While there exists in the Telegraph Rules a provision requiring the intercepting officer to maintain certain records relating to the monitoring,<sup>62</sup> the government appears to contemplate different types of records when it speaks of an “*auto generation of audit trail of command logs related to interception and monitoring*” as mentioned previously. Unlike the keeping of records under the Telegraph Rules presently, this audit trail of command logs is automatically generated each time surveillance is carried out. While it is not clear exactly what the logs will record, the fact that they are not manually generated, and that they are represented to be non-erasable is different - and if developed carefully, a step forward - from the current scheme of surveillance.

#### TENTATIVELY EVALUATING THE CMS AGAINST STANDARDS FOR PRIVACY IN SURVEILLANCE

In the evaluation of a system of State surveillance of communications, we may assume the ultimate end to be an appropriate balance between State surveillance and individuals’ privacy.<sup>63</sup> Therefore, in our tentative evaluation of the CMS, we must assess how much the CMS helps or hurts India’s chances of achieving this balance.

In making the evaluation, we will discuss only the CMS and the law that is or may be relevant to it as such. We will not critique the scheme of surveillance law in India as a whole.

We can use the various authorities listed below to arrive at standards for privacy safeguards in State surveillance, all of which express views on the boundaries of such surveillance:

1. The United Nations General Assembly resolution on the right to privacy in the digital age, passed on December 18, 2013.<sup>64</sup>

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<sup>62</sup>*Supra* n. 57.

<sup>63</sup>*See, e.g.*, the observations of the unanimous opinion in *People’s Union for Civil Liberties*, *supra* n. 12 (stating “[i]t is no doubt correct that every Government, howsoever democratic, exercises some degree of subrosa operation as a part of its intelligence outfit but at the same time citizen’s right to privacy has to be protected from being abused by the authorities of the day.”)

<sup>64</sup> General Assembly, United Nations, *The right to privacy in the digital age*, A/RES/68/167 (68<sup>th</sup> session, December 18, 2013)(*hereafter*, “G.A. Resolution”). *See* United Nations Research Guides and Resources, *Resolutions adopted by the General Assembly at its 68th session* (mentioning the document number and date of



2. The International Principles on the Application of Human Rights to Communications Surveillance, formulated by a consensus of various civil society organisations (including Privacy International and the Electronic Frontier Foundation), and privacy and technology experts, and launched on July 31, 2013.<sup>65</sup>
3. The Report of the Special Rapporteur, Frank La Rue, on the promotion and protection of the right to freedom of opinion and expression, made to the United Nations Human Rights Council, and dated April 17, 2013.<sup>66</sup>
4. The General Comment of the United Nations Human Rights Committee on the right to respect of privacy, family, home and correspondence, and protection of honour and reputation, under the International Covenant on Civil and Political Rights (ICCPR), expressed in 1988.<sup>67</sup>

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adoption of the resolution; an adopted copy of the resolution was not available at the time of writing), available at [http://www.un.org/depts/dhl/resguide/r68\\_en.shtml](http://www.un.org/depts/dhl/resguide/r68_en.shtml), last accessed January 26, 2014. The draft resolution of the above-mentioned General Assembly resolution is available at <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N13/544/07/PDF/N1354407.pdf?OpenElement>, last accessed January 26, 2014. The draft resolution was approved by the General Assembly without a vote. See Department of Public Information, News and Media Division, United Nations, *General Assembly Adopts 68 Resolutions, 7 Decisions as It Takes Action on Reports of Its Third Committee*, available at <http://www.un.org/News/Press/docs//2013/ga11475.doc.htm>, last accessed January 26, 2014.

<sup>65</sup>See *International Principles on the Application of Human Rights to Communications Surveillance*, July 10, 2013 (hereafter, “International Principles”), available at <https://en.necessaryandproportionate.org/text>, last accessed January 26, 2014; Carly Nyst, *Introducing the International Principles on the Application of Human Rights to Communications Surveillance*, PRIVACY INTERNATIONAL, July 31, 2013, available at <https://www.privacyinternational.org/blog/introducing-the-international-principles-on-the-application-of-human-rights-to-communications> last accessed January 26, 2014.

<sup>66</sup> Human Rights Council, United Nations, *Report of the Special Rapporteur on the promotion and protection of the right to freedom of opinion and expression, Frank La Rue, A/HRC/23/40* (23<sup>rd</sup> Session, April 17, 2013) (hereafter, “Special Rapporteur’s Report”), available at [http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session23/A.HRC.23.40\\_EN.pdf](http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session23/A.HRC.23.40_EN.pdf), last accessed January 26, 2014.

<sup>67</sup> Human Rights Committee, *General Comment No. 16 on Article 17 (The right to respect of privacy, family, home and correspondence, and protection of honour and reputation)*, (32<sup>nd</sup> session, April 8, 1988) (hereafter, “General Comment No. 16”), as reproduced in *International Human Rights Instruments*, United Nations, *Compilation of General Comments and General Recommendations adopted by Human Rights Treaty Bodies* 191, HRI/GEN/1/Rev.9 (Vol. I)

While the precise views of each of the above are separate and not identical, there is mutual focus on the fact that in order to be considered legitimate, and for the security-privacy balance to have a chance of being achieved, State surveillance must function with *legality* and *transparency*. Each of the above authorities demand that the working of State surveillance be subject to legality through clear and precise law, which law itself must look to safeguard the right to privacy.<sup>68</sup> The above authorities also recommend transparency in the use of State surveillance techniques and powers.<sup>69</sup> Three of the four authorities listed above further suggest that transparency would be strengthened by having

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(May 27, 2008), available at [www.ohchr.org/Documents/HRBodies/TB/HRI-GEN-1-REV-9-VOL-I\\_en.doc](http://www.ohchr.org/Documents/HRBodies/TB/HRI-GEN-1-REV-9-VOL-I_en.doc), last accessed January 26, 2014.

<sup>68</sup>G.A. Resolution, *supra* n. 64, ¶4(c) (“[t]he General Assembly calls upon all States ... [t]o review their procedures, practices and legislation regarding the surveillance of communications, their interception and collection of personal data, including massive surveillance, interception and collection, with a view to upholding the right to privacy and ensuring the full and effective implementation of all their obligations under international human rights law”); International Principles, *supra* n. 65 (“[a]ny limitation to the right to privacy must be prescribed by law. The State must not adopt or implement a measure that interferes with the right to privacy in the absence of an existing publicly available legislative act, which meets a standard of clarity and precision that is sufficient to ensure that individuals have advance notice of and can foresee its application.”); Special Rapporteur’s Report, *supra* n. 66, ¶50 (“[w]ithout explicit laws authorizing [surveillance] technologies and techniques, and defining the scope of their use, individuals are not able to foresee – or even know about – their application.”); General Comment No. 16, *ibid*, ¶3 (“[i]nterference authorized by States can only take place on the basis of law, which itself must comply with the provisions, aims and objectives of the [International Covenant on Civil and Political Rights]”).

<sup>69</sup>G.A. Resolution, *ibid*, ¶4(d) (“[t]he General Assembly calls upon all States [t]o establish independent national oversight mechanisms capable of ensuring transparency and accountability of State surveillance of communications, their interception and collection of personal data”); International Principles, *ibid* (“States should be transparent about the use and scope of communications surveillance techniques and powers. They should publish, at a minimum, aggregate information on the number of requests approved and rejected, a disaggregation of the requests by service provider and by investigation type and purpose. States should provide individuals with sufficient information to enable them to fully comprehend the scope, nature and application of the laws permitting communications surveillance. States should enable service providers to publish the procedures they apply when dealing with State communications surveillance, adhere to those procedures, and publish records of State communications surveillance.”); Special Rapporteur’s Report, *ibid*, ¶¶ 91, 92 (recommending transparency in almost exactly the same words as the above quoted text of the International Principles); General Comment No. 16, *ibid*, ¶10 (“[i]n order to have the most effective protection of his private life, every individual should have the right to ascertain in an intelligible form, whether, and if so, what personal data is stored in automatic data files, and for what purposes. Every individual should also be able to ascertain which public authorities or private individuals or bodies control or may control their files. If such files contain incorrect personal data or have been collected or processed contrary to the provisions of the law, every individual should have the right to request rectification or elimination.”)

oversight mechanisms to supervise the functioning of the surveillance authorities and be an interface to the public, so that surveillance authorities can be held accountable where necessary.<sup>70</sup>

Pitting these values against the CMS, the following position emerges:

### **1. TRANSPARENCY IN SURVEILLANCE**

There has been no public debate on the CMS either at its conception or at its current stage. Information on the CMS has not been made clearly and publicly available. Further, in response to the author's application under the RTI Act, despite a detailed enquiry on all aspects surrounding the CMS, the DoT's response was not forthcoming. It did not provide any but the most basic and already publicly available information, citing the national security exception under the RTI Act, and relying on a narrow definition of the word "information" under that Act.<sup>71</sup>

Regarding transparency through oversight mechanisms in the CMS, while some level of such mechanisms seem to be contemplated (since the DoT is reported to have stated that the logs maintained under the CMS can be "*examined anytime for misuse*"),<sup>72</sup> we can only speculate as to the actual fact and extent of such oversight mechanisms. Moreover, there is nothing to suggest that oversight would be conducted by a judicial authority, or even a functionary other than those government agencies responsible for surveillance.

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<sup>70</sup>G.A. Resolution, *ibid*; International Principles, *ibid* ("States should establish independent oversight mechanisms to ensure transparency and accountability of communications surveillance. Oversight mechanisms should have the authority to access all potentially relevant information about State actions, including, where appropriate, access to secret or classified information; to assess whether the State is making legitimate use of its lawful capabilities; to evaluate whether the State has been transparently and accurately publishing information about the use and scope of communications surveillance techniques and powers; and to publish periodic reports and other information relevant to communications surveillance."); Special Rapporteur's Report, *ibid*, ¶ 86 ("[t]he provision of communications data to the State should be monitored by an independent authority, such as a court or oversight mechanism.").

<sup>71</sup> Response of the DoT dated January 6, 2014, to the author's RTI application, *supra* n. 34. The only information given was: (a) "*Centralized Monitoring System is a Security Project of Govt. of India for lawful interception and monitoring. This project is being executed by C-DOT across the country including Bengaluru.*" (b) "*Cabinet Committee on Security (CCS) has approved this project on 16.06.2011*"; (c) "*Lawful interception and monitoring under CMS is governed by Section 5 (2) of Indian Telegraph Act 1885 read with Rule 419A of Indian Telegraph (Amendment) Rules, 2007.*" Answers to 5 queries were wholly or partially withheld stating that the "*information sought is related to security of nation hence exempt under Section 8 (1) (a) of RTI Act 2005*", while answers to two other queries stated, "*[t]his is a question and does not fall under the definition of information under RTI Act*".

<sup>72</sup>*Supra* n. 56 and accompanying text.

## **2. LEGALITY SURROUNDING SURVEILLANCE**

As mentioned above, the CMS brings into play a new office viz. the ‘CMS authority’, also called the ‘provisioning authority’, and is meant to have a system of comprehensive maintenance of logs. The maintenance of logs requires regulation to enhance the privacy safeguards in surveillance, while the CMS authority requires regulation to ensure the most minimum level of privacy in the conduct of surveillance. We can say this because of the enormous scope of misuse of the power held by the CMS authority’s office, absent sufficient regulation.<sup>73</sup> After all, a pilot run is underway at this moment, and even to this limited extent, regulation over a surveillance functionary as important as the CMS authority and the use and storage of the data collected by the CMS is called for.

Moreover, with requests not having to be made to TSPs, surveillance is now operated solely by the executive wing of government. The safeguards of the CMS, discussed previously, are meant to quell the power associated with this. Nonetheless, none of these safeguards take away from the centralisation of power at the executive wing of government.

Therefore, without discussing the shortcomings of the existing jurisprudence surrounding surveillance in India,<sup>74</sup> it still appears that there is a fair development of regulation required to say that there is legality surrounding the working of the CMS. What is of concern is that government sources appear to be under the impression that the Telegraph Act and Telegraph Rules alone, as they stand today, would act as sufficient regulation for the CMS.<sup>75</sup>

The inbuilt safeguards of the CMS, namely, the fact that access to data is mediated through a CMS authority who will not be able to access the content of the data monitored, and that logs will be maintained about all interceptions, appear to hold promise, but they hold no water absent sufficient legality and transparency in the entire mechanism of the CMS.

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<sup>73</sup> The only caveat to this statement is that if there are failsafe technical safeguards preventing the CMS authority’s misuse of its power, we may not need regulation over such power. There is nothing to suggest so far that such failsafe technology is in place or is in the pipeline.

<sup>74</sup>*Supra* n. 3.

<sup>75</sup>*Supra* n. 60.

## TENTATIVE SUGGESTIONS FOR IMPROVEMENT

### **1. PUBLIC COMMENTS**

Before implementation of the CMS (beyond the current pilot runs), the scheme of the CMS as developed so far ought to be made public as far as practicable, along with calls for objections and/or suggestions.

### **2. UPDATED LAW**

New law governing the CMS should be considered, to govern the rights and duties of functionaries, especially the CMS authority; specifications of logs to be maintained, and other legally relevant technical details; and to create an *ombudsman* authority to supervise the CMS authority.

The substantive rights under the CMS may be incorporated as part of the Telegraph Act, IT Act, and proposed Privacy Act.

### **3. SECURITY OF DATA; DETAILED LOGS**

Data collected by the CMS is proposed to be aggregated on a large scale in one location (the CMC). It is suggested that in the interest of securing such data against malicious activity, the data be subject to strong encryption at a minimum of a 128-bit level.<sup>76</sup> The encryption key ought to be securely stored with the CMS authority using cryptography technology that prevents the key from being subject to any single point of security breach.<sup>77</sup>

With respect to the surveillance logs proposed to be maintained, in order to be useful tools for accountability, such logs should contain the name and designation of the officer carrying out the interception, and all content about the monitored data including any meta-data, such as the IP addresses (for online data), IMEI numbers (for data originating from mobile devices), and/or PSTN numbers (for data originating from landline devices), as applicable, of all parties to the data.<sup>78</sup>

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<sup>76</sup>Opinion of Vinod Vaikuntanathan, expressed in comment to a draft of this paper, on January 5, 2014.

<sup>77</sup>*Ibid* (“There are cryptographic tools for distributed storage of (encrypted) data and distributed computation over them, without ever transferring all the data to a single location and without ever creating a single point of failure. This is made possible by tools such as “secret sharing” and “threshold encryption” that were developed in the cryptography community in the 1980s. The fundamental idea is to distribute the data in a few, say ten, locations so that an adversary that compromises, say, four out of ten locations does not learn anything about the data.”)

<sup>78</sup> Opinion of Bhairav Acharya, *supra* n. 29.

## CONCLUDING REMARKS

The CMS is in one sense merely a new technology for surveillance, and in that sense, it may be asked why any legal analysis is relevant to it, as distinct from the law surrounding surveillance in general. The answer is that, as detailed above, the CMS creates new legal powers and responsibilities, and alters existing legal relationships. This merits legal analysis specific to the CMS.

Regarding the new legal powers, responsibilities, and relationships created by the CMS, I have suggested that the values of legality and transparency - which are essential to a security-privacy balance - may go a-begging if public authorities do not soon hasten to consciously uphold these values in the implementation of the CMS. One way that public authorities may begin to do this is to consider implementing the suggestions discussed in the preceding Section of this paper.

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## OF BOLLYWOOD SONGS, FILM PRODUCERS AND COLLECTING SOCIETIES: LOCATING THE RIGHTS OF THE COMPOSERS

Poorna Mysoor\*

### Abstract

*Bollywood films are known for their songs, and in many cases Bollywood films are known because of the songs. It is not merely in Bollywood films that songs have a significant role, but also in the lives of myriad composers, lyricists, singers and so on, lending an opportunity for their creative expression in addition to serving as a means of livelihood. Ideally, it should be possible for composers to be able to earn an income by composing music for films, as well as by being a member of a collecting society in such a way as to maximize their returns. From the bundle of rights they have, the composers should be able to transact with both the producers and the collecting societies, but with rights that do not overlap. However, in reality the rights could get tangled in a legal quagmire between the collecting society and film producers, as each demands exclusivity. The article is an attempt to show how the rights of composers is meddled with by both the film producers and the collecting societies, leading to gross unfairness in the distribution of the returns from exploitation of their rights. To this end, the article examines the UK Court of Appeal decision in B4U Network (Europe) Limited v Performing Rights Society Limited, which upheld the rights of the collecting society, and compares it with the Indian Supreme Court decision in Indian Performing Rights Society v Eastern India Motion Pictures, where the rights of the film producers was upheld. This article then goes on to examine what it means to the composers if the film producers' rights trump those of the collecting societies. The article also explores how the amendments introduced to the Indian Copyright Act in 2012 address the situation.*

### INTRODUCTION

*'Integral to Bollywood films are the songs and dances. The songs comment on the narrative, express a character's sentiments and afford an opportunity for the film to display extravagant choreography, costumes, set design and cinematography.'* Moses LJ

So begins the seemingly innocuous judgment of Moses LJ in *B4U Network (Europe) Limited v Performing Rights Society Limited (B4U case)*.<sup>1</sup> In these words Moses LJ captures the role and essence of songs in Bollywood films.<sup>2</sup> As Bollywood celebrates hundred years since the release of the first film,<sup>3</sup> it must be admitted that over this long journey, the song (and dance) sequences have become the single most enduring feature of Bollywood films.<sup>4</sup> It is not merely in Bollywood films that songs have a significant role, but also in the lives of myriad composers, lyricists, singers and so on, lending an opportunity for their creative expression, in addition to serving as a means of livelihood. In other words, Bollywood as a film industry supports within itself a thriving music industry.<sup>5</sup>

Collecting Societies developed as a mechanism to manage the rights of creators in a society with a growing number of content users, matched by the growing number of technological options through which the content is utilised.<sup>6</sup> Bollywood songs are extensively consumed independently of

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<sup>1</sup>*B4U Network (Europe) Limited v Performing Rights Society Limited* [2013] EWCA Civ 1236 [1].

<sup>2</sup> "Bollywood" is a name for the Indian popular film industry, based in Mumbai (Bombay), according to Oxford English Dictionary, at <http://www.oxforddictionaries.com/definition/english/Bollywood?q=bollywood>, last visited 10 December 2013. The term Bollywood is used here to represent the Indian film industry in general, which is more often than not rich in music content.

<sup>3</sup> "A hundred years ago, on 3rd May 1913, an avid, small-town photographer from Maharashtra, Dhundiraj Govind Phalke (aka Dadasaheb Phalke), who is now known as the father of Indian cinema, produced the first full-length Indian feature film, *Raja Harish Chandra*." Astha Gill, *Bollywood turns 100 – a long journey for Indian cinema*, The Upcoming, 30 May 2013, available at <http://www.theupcoming.co.uk/2013/05/29/bollywood-turns-100-a-long-journey-for-indian-cinema/>, last visited 18 November 2013.

<sup>4</sup> Sangeeta Gopal and Sujata Moorti, 'Introduction', Sangeeta Gopal and Sujata Moorti (eds), *Global Bollywood: Travels of Hindi Song and Dance* 1 (2008). The author notes that a film by name *Alam Ara* released in 1931, establishing song, dance and music as an intrinsic part of Indian film.

<sup>5</sup> Gregory D. Booth, *Preliminary thoughts on Hindi popular music and film production: India's "culture industry(ies)"*, 1970–2000 9:02 South Asian Popular Culture 215 (2011), DOI: 10.1080/14746689.2011.569075, available at <http://dx.doi.org/10.1080/14746689.2011.569075>, last visited 18 November 2013.

<sup>6</sup> Economists typically claim that collecting societies are an effective way of overcoming the problem of high transaction costs for administering copyright in some markets. Christian Handke, *Economics of Copyright Collecting Societies* 38(8) IIC 937 (2007) at 939.



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the films. It makes it all the more essential that the composers<sup>7</sup> become members of a collecting society, so that the earnings from the consumption of their creation can be maximized.

Ideally, it should be possible for the composers to be able to earn an income by composing music for films, as well as by being a member of a collecting society in such a way as to maximize their returns. From the bundle of rights they have, the composers should be able to transact with both the producers and the collecting societies, but with rights that do not overlap. However, in reality the rights could get tangled in a legal quagmire between the collecting society and the film producers, as both demand an assignment of rights that overlap. For example, the composers should be able to transact with the film producers only for the right to have their work incorporated in a film, leaving all other rights including the right to publicly perform the works in the composers' own control, which they can assign or licence to a collecting society. Instead, the film producers demand assignment of all rights in relation to the work of composers, including the right of public performance, so that if the composers do become members of a collecting society, they end up assigning the right of public performance, resulting in an overlap of rights with the film producers. Besides, these assignments are often in relation to works that will come into existence in the future, adding another layer of complexity as to whose rights take priority when the work comes into existence.

In resolving this legal quagmire, if a court decides that the rights of the producers should take priority, in the absence of a fair arrangement for the payment of royalties, the composers could be left with a lump sum payment, not representing the value of all the rights so assigned. On the other hand, if the collecting society has priority, then there is some hope that the composers will receive some royalties, considering that a collecting society is set up for that very purpose. However, if the collecting society is mired in bad governance, then the composers might lose even the little hope of collecting royalties for the use of their works. This article presents legislative and judicial response to the rights of composers of film music vis-à-vis the film producers and collecting societies.

In Section I, the article will consider the situation where the collecting society's rights gain priority over the rights of the film producers. To demonstrate this, this article draws on the example of the

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<sup>7</sup> Unless specifically stated, the word 'composer' in this article is used in an inclusive sense to denote not only composers who compose music to the songs, but also lyricists who compose words to the song.

*B4U* case, a recent decision of the UK Court of Appeal,<sup>8</sup> which is unique in many respects. To begin with, the subject matter of this case was a Bollywood song. The composers as well as the producer of the film were Indian parties. Further, the assignment of the composer's rights in favour of the film producer was signed in India and was subject to Indian laws. Since the alleged act of infringement took place in the UK, the UK courts exercised their jurisdiction over this case. This demonstrates the multijurisdictional manner in which the rights play out.

In Section II, the article goes on to explore the commercial implications of the ruling in the *B4U* case. In this Section, the article examines the consequences of the collecting society's rights trumping the producer's rights. It further demonstrates how the sequence of agreements entered subsequent to the assignment to the collecting society could lead to further litigation. Since such litigation could arise in India, the position of Indian law is also examined.

Moving forward, in Section III the article presents the situation where the rights of the producer are upheld over the rights of the collecting society. For this purpose, the article draws on the example of the landmark decision in *Indian Performing Rights Society v Eastern India Motion Pictures* (the *EIMP* case).<sup>9</sup> In reviewing this case, similarities between the issues presented between the *EIMP* case and the *B4U* case are discussed, highlighting also the differences in the facts and their implications. A review of the old in the light of the new always reveals details that may not have been apparent before.

In the fourth and concluding Section, the article goes on to examine the consequences of the producers' rights trumping the collecting society's rights, and what it means to the rights of the composers. It further examines the amendments introduced to the Indian Copyright Act, 1957 (ICA) in 2012.

## SECTION I

### **FACTS OF THE *B4U* CASE**

The case is about a song (the Song) composed by the two composers, Salim and Suleiman Merchant (the Composers), who are, fortunately for them (as will be discussed below), not parties to this suit.

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<sup>8</sup>The Court of Appeal decision was given on 13 October 2013.

<sup>9</sup>*Indian Performing Rights Society v Eastern India Motion Pictures* AIR 1977 SC 1443, 1977 SCR (3) 206.

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The facts are that the Composers became members of the Performing Rights Society (the PRS) in 2004, by transferring to the PRS ‘absolutely for all parts of the world *the rights* which belong to [them] on the date of the Agreement or which [*they*] *may acquire or own* whilst [they] remain [PRS’s] member.’<sup>10</sup> It is interesting to see here that the Court of Appeal took these ‘*right’s*’ to include the right to perform a work in public and the right to communicate it to the public.<sup>11</sup> The High Court on the other hand specifically referred to the provision in the Agreement that spelt out these ‘*rights*’ to be the performing right and the film synchronisation right.<sup>12</sup> The implications of this are discussed presently. A noteworthy point here is that an assignment to the PRS is absolute, which means that the assignor reserves no rights to herself.

Later in 2008, the Composers were commissioned by Dharma Productions Private Limited (the Producer), a certain producer of Bollywood films, who is also, fortunately for its own sake, not party to this suit. The commission was to provide services of directing music for a certain film the Producer was going to produce, and to compose songs for the film, including the Song. The Commissioning Agreement provided for the scope of engagement and the assignment of rights as follows.<sup>13</sup> The provisions are reproduced verbatim, as it would not be an exaggeration to say that the above assignment clauses typify the broad sweep of assignments extracted by Bollywood producers in general.

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<sup>10</sup>*B4U* [2013] EWCA Civ 1236 at [3], emphasis supplied by Moses LJ in the original transcript. The words correspond to clause 2(a) of the Standard Terms of Assignment provided on the website of the PRS, available at <http://www.prsformusic.com/joinus/writer/Pages/prs-standard-terms.aspx>, last visited 18 November 2013. It would be reasonable to assume that the agreement between the Composers and the PRS was substantially in the form set forth under the Standard Terms of Assignment.

<sup>11</sup>*B4U* [2013] EWCA Civ 1236 at [43]. However, under the Articles of Association of the PRS, the right of public performance is defined under Article 1(xix)(b) to include the right of communication to the public. This definition is imported into the PRS Standard Terms of Assignment under clause 1(a).

<sup>12</sup>*Performing Rights Society Limited v. B4U Network (Europe) Limited*, [2012] EWHC 3010 (Ch) [10]. The provision within the Agreement with the PRS referred to are clauses 1(f)(i) and (ii), which match with the PRS Standard Terms of Assignment.

<sup>13</sup>*B4U* [2013] EWCA Civ 1236 at [4].

## "1. ENGAGEMENT

*(a) The producer engages the Music Directors [the Composers] to inter alia create, recreate, write, arrange, orchestrate, conduct, perform, record and deliver to the Producer [Dharma] music to be included in the Film ... and provide all services usually rendered by a music director to a first class Animated Film ('Services'), on the terms and conditions contained in this Agreement...*

## 2. COPYRIGHT

*(a) The Music Directors hereby confirm and agree that the entire copyright (if any) or any performer's rights, if any, or any other rights arising from the Services or the product of the Services of the Music Directors, including without limitation the Music shall vest with the Producer as the first owner of the same pursuant to this contract of service executed. This shall be applicable to all present and future work arising out of the Services. This right shall be exercised for the whole period of the right and in all territories of the world;*

*(b) The Music Directors hereby expressly consent to the incorporation of the Music and the performance of the Music Directors, if any, arising consequent to the rendering of the Services in the Film. Consequent to the same the Music Directors confirm that the Music Directors do not have and shall not exercise any performer's rights under the provisions of the Copyright Act 1957 ('the Act');*

*(c) Without prejudice to the aforesaid, in the event of any copyrights or any other rights, including performer's rights being vested by law in the Music Directors, in respect of the Music, the Music Directors hereby assign to the Producer without any limitation, reservation or condition the entire copyright and performer's rights and all other right, title or interest of whatsoever nature ... whether vested, contingent or future in or to the product, results or proceeds ... of the Services ... whether now known, or in the future created to which the Music Directors are now or may at any time after the date of this Agreement be entitled by virtue of or pursuant to any of the laws in force in any part of the world to hold to the Producer, its successors, assignees, and licensees absolutely for the whole period of such rights for the time being capable of being assigned..."*

In 2009 the composers completed composing the Song and the Song was synchronised into the film.<sup>14</sup> The High Court judgment also indicates that the PRS was informed of the composition of the Song for the film.<sup>15</sup>

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<sup>14</sup> The title of the song is 'Shukran Allah' and the title of the film is 'Kurban'.

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Now we come to the parties to the suit. B4U Network (Europe) Limited (B4U Network) is a satellite television broadcaster, specializing in broadcasting Bollywood movies and music videos. By a complex web of licenses,<sup>16</sup> B4U Network acquired rights to broadcast the Song and aired it through its network. The PRS claimed that B4U Network infringed its copyright in the Song by broadcasting the song on its channel without authorisation.

At the High Court, Vos J, gave a summary judgment in relation to the Song, on the basis that B4U Network had no prospect of successfully defending its case.<sup>17</sup>

### **LEGAL ISSUES AND ANALYSIS OF THE *B4U* CASE**

Neither at the time of entering into the agreement with the PRS, nor at the time of entering into the commissioning agreement had the Composers yet composed the Song. In other words, the issue was one of future copyright, and the manner in which it can be assigned.

#### Legal context

To begin with, the court recognizes it to be quite straightforward under Section 9(1) read with Section 11 of the UK's Copyright, Designs and Patent Act, 1988 (CDPA) that the person who creates a work is the first owner of any copyright in it.<sup>18</sup> What completes the legal context is Section 91(1) of the CDPA, which provides that an agreement in writing by the prospective owner of copyright to assign future copyright to another person will have the effect of making the assignee the owner of copyright when it comes into existence,<sup>19</sup> which had the effect of overcoming the requirement of an additional legal assignment after the work came into existence.<sup>20</sup>

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<sup>15</sup>*Performing Rights Society* [2012] EWHC 3010 (Ch) at [16].

<sup>16</sup> In the High Court decision Vos, J does try to unravel the various licenses. *Performing Rights Society* [2012] EWHC 3010 (Ch) at [15]-[18].

<sup>17</sup>*Performing Rights Society* [2012] EWHC 3010 (Ch) at [68].

<sup>18</sup>*B4U* [2013] EWCA Civ 1236 at [17]. Moses LJ further states that there is no suggestion by either party that any of the exceptions in section 11(2) or (3) are applicable. *Ibid.*

<sup>19</sup> Section 91(1) of the CDPA has been reproduced here: Where by an agreement made in relation to future copyright, and signed by or on behalf of the prospective owner of the copyright, the prospective owner purports to assign the future copyright (wholly or partially) to another person, then if, on the copyright coming into existence, the assignee or another person claiming under him would be entitled as against all other persons to require the copyright to be vested in him, the copyright shall vest in the assignee or his successor in title by virtue of this subsection.

### Arguments presented

The counsel for B4U Network contended that the Song was never owned by the Composers, since Section 91 had the effect of assigning legal and equitable ownership of the copyright to the Producer. Since the agreement with the PRS required the rights that the Composers may acquire or own, and the Composers never acquired or owned the rights, no rights were assigned to the PRS.<sup>21</sup>

For his part, the counsel for the PRS contended that the copyright clearly belongs to the PRS as the agreement operates as a ‘present assignment of future rights’ and takes precedence over the commissioning agreement as prior in time.<sup>22</sup>

### Operative part of the decision

Moses LJ responded to the counsel for B4U Network that the issue was not what the Composers owned, but rather what they might have owned.<sup>23</sup> By virtue of Sections 9 and 11 of the CDPA, the Composers might have owned copyright in the Song. By a combination of the operation of Section 91(1) and the rules of priority in equity, copyright vests with the first assignee, namely the PRS.<sup>24</sup>

He further agreed that Section 91(1) had the effect of transferring legal and equitable ownership in the Song, without even staying with the Composers in a *scintilla temporis*. He admits that it is strange to think of an assignor who never becomes an owner, but it is a statutory construct, just as much as the whole concept of copyright is a statutory construct.<sup>25</sup>

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<sup>20</sup>Moses LJ explains that Copyright Act of 1911 did not have this provision, and the rules of equity generally applied. The situation was that when an assignment in future copyright was created, it only gave rise to an equitable interest, and no rights in law. In order for a legal right to materialise, a further assignment of copyright once it comes into existence was required. In order to overcome this difficulty, it was enacted by way of statute, originally as section 37 under the Copyright Act of 1956 and then as section 91 under the CDPA that an assignment of future copyright will still have the effect of assigning legal as well as equitable rights. This eliminated the need for a further legal assignment once the copyright work came into existence. *B4U* [2013] EWCA Civ 1236 at [9]-[10].

<sup>21</sup>*B4U* [2013] EWCA Civ 1236 at [7], [18].

<sup>22</sup>*B4U* [2013] EWCA Civ 1236 at [34].

<sup>23</sup>*B4U* [2013] EWCA Civ 1236 at [22].

<sup>24</sup>*B4U* [2013] EWCA Civ 1236 at [23], [27], [29].

<sup>25</sup>*B4U* [2013] EWCA Civ 1236 at [23].

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In summary, Kitchin LJ identified four aspects to Section 91(1):<sup>26</sup>

- The agreement should be in writing and signed by or on behalf of the prospective owner;
- The assignment operates to vest the legal and equitable title to the copyright in the assignee as soon as the copyright comes into existence. The copyright does not pass through the assignor;
- The expression prospective owner is to be construed accordingly;
- This Section operates only if the assignee would be entitled as against all other persons to require the copyright to be vested in him. This reflects the equitable principles which provide the foundation for the provision and in particular the basic rule that the person whose equity attached to the property first will be entitled to priority.

On this basis, Kitchin LJ and Underhill LJ agree with Moses, LJ, that the PRS should have copyright in the Song.

### SECTION II

#### **COMMERCIAL IMPLICATIONS OF THE *B4U* CASE**

The *B4U* case has implications not only in relation to the parties to the litigation, but also vis-à-vis those who are not parties to this case. It is also essential to articulate how this case, set in its norms of its industry, could be a representative of many such cases in Bollywood.

The counsel for B4U Network makes a point about the commercial effect of an arrangement whereby composers are left with little or no freedom to monetize their rights by way of accepting commissioning arrangements, threatening their ability to earn a living.<sup>27</sup> Both Moses LJ and Kitchin LJ disagree with this on the basis that there is no sufficient evidence of this, and that the PRS has a track record of protecting around 10 million songs for its members and its agreements have included substantially the same clause 2(a) for very many years.<sup>28</sup> Even Vos, J at the High Court level realises

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<sup>26</sup>*B4U* [2013] EWCA Civ 1236 at [38]-[41].

<sup>27</sup>*B4U* [2013] EWCA Civ 1236 at [33].

<sup>28</sup>*B4U* [2013] EWCA Civ 1236 at [30] (Moses LJ); [33] (Kitchin LJ).

that what he has to decide might have ramifications beyond the Song, but he chooses to decide the matter on law.<sup>29</sup>

It is easy to sympathise with the judges, as a construction in any other way would have been perverse to the express provisions of the agreements and the law. As emphasised above, the rights assigned to both the PRS and the Producer were in absolute terms without reservation. The conclusion had to be that the rights were mutually exclusive.

#### Within the facts of the case and between the parties to the litigation

In order to appreciate how the rights in conflicting agreements might play up, it is essential to understand the scope of these rights themselves. The PRS accepts assignment of one or both these rights – the right of synchronizing with the film and the performance right in which the right of communication to the public is subsumed.<sup>30</sup> Each of these rights is considered below. Since the agreement with the PRS was subject to the UK law and the Commissioning Agreement subject to Indian laws, the scope and extent of these rights both under the UK and Indian laws need to be determined.

- **Synchronisation of the Song into the film**

This is a right of particular relevance to Bollywood, since so many composers depend on this industry for their work to be accepted as commissions. There is no reason why the Composers in this case should have assigned this right to the PRS, knowing that they would like to reserve the freedom to negotiate terms with the producers of Bollywood films. As for the Producer, this is truly the essence of the rights assigned by the Composers, without which all the services rendered by the Composers would be reduced to a naught. As the High Court judgment suggests, the Composers did assign this right to the PRS and hence, could not have assigned it to the Producer.

Such incorporation of the Song into the film without the authorisation of the true owner, namely the PRS, makes it an act of infringement under the UK law to the extent that it involves copying of

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<sup>29</sup>*Performing Rights Society* [2012] EWHC 3010 (Ch) at [3], [4].

<sup>30</sup> Article 1(xix)(b) of the Articles of Association of the PRS includes the right of communication to the public within the right of public performance.



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the work.<sup>31</sup> Under the Indian law, the right to make a film or sound recording in respect of the work is an act expressly restricted by copyright in a musical work.<sup>32</sup> Therefore, incorporating the Song in the film without the permission of the PRS is an infringement of this specific right of the PRS. It is a peculiar situation where the Composers have become infringers of the works they themselves created.<sup>33</sup> Interestingly, if it can be argued that the musical works incorporated in the film as a whole (and not just the Song), form substantial part of the film, then under the Indian law copyright might not subsist in the film at all.<sup>34</sup>

- **Performance right and the right of communication to the public**

This right is again significant to the Producer in order to be able to distribute the film by way of a broadcast, cable transmission or live internet streaming of the Song. If the Composers have already assigned these rights to the PRS in totality, no further assignment to the Producer would be possible.

The right of public performance has quite a broad sweep and includes performance that are both physical and through mechanical means under the UK law.<sup>35</sup> Under the Indian law, although performance is only defined in relation to the right of the performers, it is possible that a definition of a performance similar to that of the UK could be derived.<sup>36</sup> The right of communication to the

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<sup>31</sup> Section 17 of the CDPA. It is interesting to note here that the CDPA does not protect the right of incorporating a literary, musical or dramatic work into a film as a separate right restricted by copyright.

<sup>32</sup> Section 14(1)(a)(iv) of the Copyright Act, 1957. In this article, cinematographic film and film are used interchangeably.

<sup>33</sup> There is no issue of substantiality under both the UK and the Indian law since the Song in its entirety was taken. For a discussion on substantiality, see *Designers Guild v Williams* [2000] WLR 2461, 2426.

<sup>34</sup> Section 13(3) of the Copyright Act, 1957. Although this provision appears to have been incorporated to ensure that the lack of originality requirement for cinematographic films do not result in copies of old films being produced, this provision could nevertheless be used here.

<sup>35</sup> Under Section 19(2) of the CDPA, performance includes any mode of visual or acoustic presentation, including presentation by means of a sound recording, film or broadcast of the work. Under Article 1(xviii) of the Articles of Association of the PRS, performance includes any mode of acoustic presentation, including any such presentation by means of a sound recording, film, communication to the public, or by any other means.

<sup>36</sup> Section 2(q) defines performance in relation to performer's rights to mean any visual or acoustic presentation made live by one or more performers.

public is described under the UK law as including electronic transmission, broadcasting and making the work electronically available to the public in such a way that members of the public may access it from a place and at a time individually chosen by them.<sup>37</sup> The right of communication to the public under the EU law (which applies to the UK) includes anything from turning a television on in a pub, to connecting televisions to broadcasts in a hotel room.<sup>38</sup> Under the Indian law, the right of communication to the public means making any work available for being seen or heard or otherwise enjoyed by the public directly or by any means of display or diffusion other than by issuing copies of such work, regardless of whether any member of the public actually sees hears or otherwise enjoys the work so made available.<sup>39</sup>

The question then arises as to what happens to the film as a whole. Since a film is an independent copyrightable work,<sup>40</sup> under the UK law it is more likely that the Producer might still be entitled to publicly perform and communicate the film as such to the public, but without any of the songs. This is because it is not only the Song, but all musical works created by the Composers which are assigned to the PRS. As such, it can certainly be argued that the music created by the Composers is important to the Composer's body of work<sup>41</sup> as well as to the audience.<sup>42</sup> On the other hand, under the Indian law, due to the decision in the *EIMP* case as will be described below, the Producer

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<sup>37</sup> Section 20 (2) of the CDPA.

<sup>38</sup>See Poorna Mysoor, *Unpacking the right of communication to the public: a closer look at international and EU copyright law*, IPQ 166-185 2013, for an explanation of the ingredients of this right of communication to the public, and the various situations where the CJEU has held a communication to the public to have taken place.

<sup>39</sup> Section 2(ff) of the Indian Copyright Act, 1957. The explanation to this section states that for the purposes of this clause communication through satellite or cable or any other means of simultaneous communication to more than one household or place of residence including residential rooms of any hotel or hostel shall be deemed to be communication to the public.

<sup>40</sup> Section 5B (1) of the CDPA recognises 'film' as a separate copyrightable work, and section 9(2)(ab) recognises the producer and principal director as the owner of the copyright. Under the Indian Copyright Act, 1957, section 13(1)(b) recognises cinematographic films as works and section 17(1)(b) recognises the person at whose instance the film was made to be the owner of the copyright.

<sup>41</sup> The test to be applied here is whether the part used by the defendant is a substantial part of the claimant's copyright work, not whether it is a substantial part of the defendant's work. *Warwick Films v. Eisinger* [1968] 1 Ch 508; also *Designers Guild v Russell Williams* [2000] 1 WLR 2416, 2420, 2426.

<sup>42</sup>*Hawkes & Sons v Paramount Film Service* (1934) 1 Ch D 593, 609 (CA).

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becomes the owner of the songs composed by the Composers, together with being the owner of the film.<sup>43</sup>

It is evident from the above analysis that a prior assignment to the PRS deprives the above aspects of the rights of the Composers which are of core importance to the Producer.

### Within the facts, but beyond the parties to the litigation

Sometimes what is not stated in a judgment could be more significant than what is stated. The fundamental premise is that the Composers did not have the rights they assigned to the Producer. As a result, the Producer did not have the rights it could have licensed to the distributors. Although neither of the judgments at the High Court or appellate stage give any information about the consideration, it is entirely plausible that the Composers received consideration for assigning rights they did not have to the Producer, and the Producer received consideration for licensing the rights it did not have to the distributors. B4U Network, having lost this appeal, and no further appeal filed,<sup>44</sup> will be left with having to once again pay the true owner, the PRS, for broadcasting the Song.

As such, two distinct but related actions are possible:

- first, an action by B4U Network against the chain of licensors leading to the Producer for a declaration that the license is void and for the restitution of the license fee paid for the use of the rights the Producer never had;
- second, the Producer suing the Composers for a declaration that the assignment of Composers' rights to the Producer is void and for the restitution of the commission fee for assigning the rights the Composers never had.

Since the Producer and the Composers are parties located in India, Indian courts are likely to have the opportunity to resolve this legal tangle, should the Producer decide to act.

There is a possibility of a third cause of action too, unless a settlement is negotiated. It is that the synchronisation of the Song in the film by the Producer also infringes the rights of the PRS.

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<sup>43</sup>*EIMP* 1977 SCR (3) 206, 223. See below Section III for further discussion on this case.

<sup>44</sup> The solicitor representing B4U Network, Mr Nick Rose of Field Fisher & Robinson confirmed by email on 11 December 2013 that no leave for further appeal to the Supreme Court was filed.

Therefore the PRS can claim that the use of the Song by the Producers should have been authorized by the PRS, obviously since the Composers did not have rights to assign.

Under the proviso of Article 7(b), the Articles of Association of the PRS state that it is possible for a composer (member) to request the PRS to assign the film synchronisation right to the film producer who commissioned the composition, provided that the PRS obtains from the producer of the film an agreement in a form satisfactory to the PRS, providing payment to the PRS of such fees either by way of a lump sum payment or share of receipts or royalties, in respect of any exhibition of the film incorporating the composition in the cinemas in the US.<sup>45</sup> It may not be possible to press this provision to services, as this Article applies only to the cinemas in the US. It flies in the face of logic as to why it should only be restricted to cinemas and no other forms of distribution such as broadcasts and cable transmission, and why it should be geographically restricted to the US, when film viewership is truly global.

Be that as it may, the Composers also have a right under Article 7(cc) and (cd) to request the PRS to assign back some of the categories of the rights and forms of utilization listed therein.<sup>46</sup> It is wholly conceivable that the Composers have accepted commissioning work not only from the Producer, but also from other producers in Bollywood post becoming members of the PRS. It would make sense for the Composers to rely on these provisions and gain back control over rights of relevance to them. This is again problematic in that this would only work prospectively, whereas the transactions between the Composers and the Producer on one hand and between the Producer and distributors on the other took place between 2008 and 2010. The PRS may not gloss over the fact that the Producer still needs to pay a license fee to the PRS for its use of the rights between 2008 till date.

At a more general level, it is entirely plausible that the Composers have accepted commissions for other Bollywood films by the same or different producers post becoming members of the PRS. Likewise, it is plausible that many other composers of Bollywood music have become members of a collecting society and continue to accept their works to be commissioned by Bollywood producers

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<sup>45</sup>Available at <http://www.prsformusic.com/SiteCollectionDocuments/About%20MCPS-PRS/PRSMEMANDARTS2010%20-%20WEB%20VERSION.pdf>, last visited 18 November 2013.

<sup>46</sup> Articles 7(cc) and (cd) of the PRS Articles of Association incorporate various categories of rights and forms of utilisation such as broadcasting rights, film production right, television rights and the like.

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for providing music to films. Regardless of the specific rights assigned to the collecting societies, considering the broad sweep of the assignment to the producers, an overlap and ensuing complications along the lines described above are all too plausible.

Given all these complications that a ruling in favour of the PRS has produced, one wonders if the motivation of the counsel for B4U Network in arguing that an assignment to the PRS taking priority threatens the Composers' ability to earn a living, was actually directed towards preventing further litigation as described above. An assignment of rights to the PRS does not have to mean that the composer loses out on all abilities to monetize the rights. On the contrary, it is the job of the PRS to ensure that the Composers' rights are monetized and they get their returns. Instead of the Composers negotiating directly with the Producer, the PRS would be negotiating on the Composers' behalf. If this were to happen, it might be that the financial returns to the Producers would be based on the terms and scales of the PRS. The only loss to the Composers would be their freedom to negotiate their own terms. As will be demonstrated in the *EIMP* case below, considering how unfairly the producers treat the composers in framing the contractual terms, one wonders if it might be preferable for the composers to be represented by a collecting society in all their negotiations after all.

However, a word of caution that the collecting societies would be a better option for the composers only so long as they enjoy good governance in the distribution of royalties. As will be discussed below, when a collecting society, in this case the IPRS, is historically governed badly, even this option could fail to generate any returns for the composers.

### SECTION III

#### **THE FACTS OF THE *EIMP* CASE AND ARGUMENTS PRESENTED**

The facts in brief were that the Indian Performing Rights Society (IPRS), a collecting society set up under the ICA, published in 1969 a tariff laying down the fees, charges and royalties that it proposed to collect for the grant of licences for performance in public of works in respect of which it claimed to have authority to grant such licences. Eastern India Motion Picture Association (the EIMP), an association of the producers of films, challenged the imposition of tariffs on the basis that they were

the owners of the respective films along with the sound track.<sup>47</sup> We must pause here and point out that whereas the *B4U* case concerned a song, the composers, the film and the producer, all of whom were specifically identifiable, the *EIMP* case concerned in general a genre of work, namely the works of composers and lyricists and an association of film producers. The implications of this are that in the *EIMP* case neither the actual assignment clause in favour of the IPRS (as it stood 1969) nor the actual assignment clause in favour of the producers was stated in the High Court or the Supreme Court judgment. Further, the exact terms of the tariff and the class of users it applies to were also not stated. Two distinct problems arise here: first, the nature and extent of overlap of rights between the assignment to the IPRS and to the producers, and second, the issue of priority.

What we know from further elaboration of the facts in the High Court judgment is simply that the terms of assignment in favour of the IPRS when composers become members of the society, covered not only the existing rights but also the rights in future works of the assignor.<sup>48</sup> From the arguments presented by the counsel for the IPRS before the High Court, we know further that the IPRS required the film producers to seek permission of the IPRS to perform the musical work in public, regardless of whether it was a part of the film or otherwise.<sup>49</sup> The basis on which the IPRS argued was that a musical work is a separate work which entitles the composers to the right of public performance under Section 14(1)(iii), and a film incorporating a musical work will have to seek the permission of the composer to publicly perform such musical work.<sup>50</sup> Therefore, it is somewhat clear that the only right that was assigned to the PRS was the public performance right, in relation to the present and future works.

The *EIMP* for their part contend that they are the first copyright-holders of the cinematograph films including the musical work contained in the sound track.<sup>51</sup> As the owner of an independent copyrightable work, the producers are free to exercise their rights over the film, and the composers cannot defeat their rights. They further argued that the film includes sound track, and therefore, all

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<sup>47</sup> *EIMP v IPRS*, AIR 1974 Cal 257, para 1.

<sup>48</sup> *EIPM* AIR 1974 Cal 257 at paras 19 and 25.

<sup>49</sup> Such permission would entail payment of a tariff to the IPRS, which is the subject matter of challenge in this case. *EIMP* AIR 1974 Cal 257, para 1.

<sup>50</sup> *EIPM* AIR 1974 Cal 257 at paras 19 and 25.

<sup>51</sup> *EIPM* AIR 1974 Cal 257 at para 1.

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rights in the film include rights in the sound track incorporating any music.<sup>52</sup> However, they did not establish before the court what rights they would require from the composers to be assigned in order to make a film incorporating the composer's works.

The EIMP first took the matter to the Copyright Board, where they did not succeed. They then appealed to the Calcutta High Court, which found in their favour. The IPRS then filed an appeal to the Supreme Court, where the findings of the High Court were upheld, but with a dictum.

### LEGAL ISSUES AND ANALYSIS OF THE *EIMP* CASE

Since the assignment to the IPRS also included future copyright, it is not only the works that the composers created before entering into such assignment, but also those that come into existence after such assignment should have been considered. In the absence of the specific assignment clauses to rely on, the following situations should have been considered by the court:

- (i) Works that were created before entering into an assignment with the IPRS, the rights which had already been assigned to the film producers; the question then is whether any rights of the composers survive the incorporation of their work in a film, which can then be assigned to the IPRS.
- (ii) Works that are created after entering into the assignment with the IPRS, which then subsequently get incorporated into films; the question then is whether the terms of the assignment to the IPRS are so absolute that a further assignment to the producers is not possible.

The second situation is akin to the question that arose in the *B4U* case. Since the rights assigned to the PRS and the Producer in that case appeared to overlap under the UK law, the rule of priorities was applied to uphold the PRS's rights. In the *EIPM* case, the second situation was not considered, although argued upon in the High Court without specifically dealing with priority.<sup>53</sup> Neither the

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<sup>52</sup> 1977 SCR (3) 206 at 215.

<sup>53</sup> It was argued that the moment there is an original composition it is saddled with a copyright in favour of the IPRS due to the provision on future copyright. The law prevents the composer from bringing into existence anything which is not assigned to the IPRS. From this point of view the cinematograph film owner's copyright in the sound track cannot be born inasmuch as before it could be born it stood assigned to the IPRS. *EIMPAIR* 1974 Cal 257, at para 31.

issue of priority nor the issue of copyright in future works was discussed in the Supreme Court judgment. At the same time, it was also not clear if the courts were only considering the first situation. It would appear that regardless of when the work was created, so long as it was created for being incorporated into the film, the producer's rights will be upheld.

### Legal Context

The producers relied on the fact that a film is an independent copyrightable work<sup>54</sup> and that a bundle of rights attach to the films (independently of other works in the film).<sup>55</sup> But the most powerful provision relied on was Section 17(a) of the ICA, which states that when a film is made for valuable consideration, the person at whose instance it was made is the first owner of the copyright, in the absence of any agreement to the contrary. This differs from the UK law which states that the producer and the principal director are the authors of films<sup>56</sup> and in general, authors are the first owner of copyright in such work.<sup>57</sup> No reference to valuable consideration is made, unless it is in the course of employment.<sup>58</sup>

On the other hand, the most powerful provision the IPRS relied on was Section 13(4) of the ICA, which states that when any work or a substantial part of any work goes into the making of a film or sound recording, the copyright in such film or sound recording does not affect the separate copyright in such work or its part. In contrast, the UK law provides that the subsistence of copyright in the film does not prevent the existence of copyright in the sound track of the film as a sound recording.<sup>59</sup> However, no other work that goes into the making of a film is specifically mentioned. The IPRS also relied on Section 18(1) of the ICA, which permits the assignment of future work, provided that such assignment only takes effect once the work comes into existence. This provision appears similar to the UK law, except that the Indian law, surprisingly, is more simply worded.

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<sup>54</sup> Section 13(1)(b) of the ICA.

<sup>55</sup>Section 14(d) of the ICA.

<sup>56</sup>Section 9(2)(ab) of the CDPA. It may be noted that the principal director was added by way of an amendment in 1996.

<sup>57</sup>Section 11 (1) of the CDPA.

<sup>58</sup> Section 11(2) of the CDPA.

<sup>59</sup>Section 5B(5) of the CDPA.



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### Operative part of the decision

It appears that the Copyright Board gave the simplest and the clearest solution to the issue. Although badly paraphrased in the High Court judgment,<sup>60</sup> it appears that the Copyright Board gave Section 13(4) of the ICA its fullest meaning. The Copyright Board appears to have expressed the view that in the absence of proof to the contrary, when a composer's work is incorporated into a film with the composer's consent, all that the composer is deemed to have done is to license or assign her right to make a film out of the work. All rights, including the right of public performance, are reserved by the composers by virtue of Section 13(4) of the ICA. To the extent that the public performance of a film involves performance of the musical work assigned to the IPRS, it is within the powers of the IPRS to charge a license fee for such public performance of films. It would appear that to the Copyright Board it does not matter if the assignment to the IPRS took priority or not, as the rights assigned are quite distinct, unless there is proof that there was an assignment to the producers and that it was broader than the mere right of making a film out of the work.

As stated above, the EIMP did not produce any term of assignment as an example. It is possible for the Copyright Board to have proceeded on the assumption that there was no assignment, but only a consent given, for the incorporation of the composer's work into the film. In that case, the composer's right to make a film out of her work is only licensed, and not assigned. However, even if the EIMP's contention that an assignment of rights took place is to be believed, such assignment would only be restricted to the composer's right of making a film out of her work. Unless the contract with the composer provided that the valuable consideration was also for the composer licensing or assigning the right of publicly performing the composer's work incorporated in the film, a separate permission to screen the film incorporating the composer's work would be necessary. Given that the composers have a distinct right to make a film out of their work, it would stand to reason that in the absence of evidence to the contrary, only this right would be involved in a transaction with the film producers.

Unfortunately, the Supreme Court relied on a completely different logic. The Supreme Court held that once composer parts with a *portion of his copyright* by authorising a film producer to make a

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<sup>60</sup>EIMP AIR 1974 Cal 257, at para 4.

cinematograph film in respect of her work and thereby, have her work incorporated or recorded on the sound track of a cinematograph film, the film producer acquires on completion of the cinematograph film a distinct copyright over the film. The Supreme Court went on to state that this copyright gives the film producer the exclusive right inter alia of performing the work in public, both in respect of the visual images and the acoustic portion, including lyrics or musical works, to be heard in public. Therefore, the Supreme Court took the view that no permission of the composer for the performance of her work in public was necessary.<sup>61</sup>

Even within the above argument, it is essential to note that the Supreme Court believes that the composer parts with only a portion of her copyright and not all of it absolutely. In recognition of Section 13(4) Jaswant Singh J, held that the composer retains the right of performing her work in public for profit *otherwise than as a part of the cinematograph film* and he cannot be restrained from doing so.<sup>62</sup> This finding was further reinforced by Krishna Iyer, J as a footnote to Jaswant Singh, J's judgment.<sup>63</sup> This is dictum, though important, goes only so far as posing itself to be a half-hearted compensation for the composers.

If the judges had concluded here, it would have saved much confusion. Jaswant Singh, J continued to answer the question whether the producer of a film who engages a composer defeats the rights of the composer by engaging him. To begin with, the question is unhappily worded, and the answer even more so. Obviously, the question needs to be qualified to specify the rights and the extent of their application, though the word 'defeated' still seems inappropriate. The question should have been whether the composer loses her right to public performance of her works to the extent that the works are played as part of the public performance of the film. Considering what the judges had ruled before, the response to this question should have been that the valuable consideration under Section 17(a) represents assignment of the composer's right to public performance of her works to the extent that the works are played as part of the film. This would have ensured that the right of the composers to publicly perform their works independently of the film would have been retained.

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<sup>61</sup> 1977 SCR (3) 206, 221-222 (emphasis supplied).

<sup>62</sup>*Id.* at page 222 (emphasis supplied).

<sup>63</sup>*Id.* at page 224.

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Instead, Jaswant Singh, J reasoned that the implication of the producer engaging the composer for valuable consideration, and becoming the owner of the copyright in the film is that no copyright subsists in the composer *of the music so composed* unless there is a contract to the contrary between the composer of the lyric or music on the one hand and the producer of the cinematograph film on the other. On this basis, Jaswant Singh, J concludes that by engaging the composer to compose music for a film, the producer of the film defeats the copyright of the composer.<sup>64</sup> This final determination of the court stayed as the operating part of the decision, rather than the part that says the composer only parts with a part of the copyright and is free to exploit her rights in her works independently of the film for which they were created.

If the Supreme Court's only objective was to drive home the point that the composers of music cannot defeat the rights of producers of a film *in the film*, then simply asserting that the film is a separate copyrightable work with rights associated of its own would have been sufficient. There was no need for the judges to go a step ahead to say that the engagement of the composers by the producers *defeats* the rights of the composers *in their own compositions*. This falsely conveys the message that the composers lose all their rights, including the rights to exploit their music independently of the film for which it was composed. A harmonious construction of the judgment should be that the producer becomes the first owner of the works incorporated in the film so long as these works are publicly performed together with the film. A composer on the other hand, is free to retain the right to publicly perform her works independently of the film.<sup>65</sup>

What the legislative provisions in India provide for is a default position where a composer allows the incorporation of her works into a film, and she transacts only with her right to make a film out of her work and nothing more. A transaction<sup>66</sup> in relation to any other rights must be specifically provided for by a contract. However, what this decision has made the default position to be is that

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<sup>64</sup>*Id.* at page 223 (emphasis supplied). This was the same line of argument followed by the High Court where relying on section 17(a) of the ICA, it held that when a composer for the first time composes something for incorporation into a film for valuable consideration, then the producer is the first owner of *such composition*. AIR 1974 Cal 257, at para 33.

<sup>65</sup> A similar argument is advanced in Nikhil Krishnamurthy, *IPRS v. EIMPA – Performing Right or Wrong?* 1 MIPR A-169, A-175.

<sup>66</sup> The neutral term transaction is used here instead of the term license or assignment. Whether a transaction is a license or an assignment also depends on the terms of the contract.

where a composer allows the incorporation of her works into a film, she assigns all her rights to the producer of the film, and the producer becomes the copyright owner of not just the film, but also the composer's works. If the composer wishes to retain any rights, such reservation must be specifically provided for.

## SECTION IV

### **COMMERCIAL PRACTICES OF FILM PRODUCERS**

Regardless of what the decision in *EIMP* case says, in order to ensure that composers are not able to assert independent rights, the producers of films usually require a very broad assignment of rights to be effected in their favour. An example of the terms of this assignment is reproduced in the context of the *B4U* case above. A typical assignment will have some or more of the following aspects:

- (i) The composers agree that the *entire* copyright or *any performer's right* that arise out of them providing services of directing music to a film, vests with the film producer *as the first owner* of the copyright; this vesting provision appears to be born out of Section 17(a) of the ICA, which confirms first ownership of copyright with the person at whose instance a film is made, leaving really no right at all with the composers in their own works;
- (ii) All present and future works are included, since the agreement is entered into presumably at time when none of the works would have come into existence;
- (iii) The assignment is for the whole of the copyright period, which means that the heirs of the copyright owner cannot benefit from the work;
- (iv) The assignment covers the whole world, so that the producer is free to publicly perform the song anywhere in the world;
- (v) The composers agree not to exercise their performer's rights, in that the composers cannot themselves perform the works they create outside of the services rendered for the film producer;
- (vi) Even if by law any copyright vests with the composers, such rights also stand assigned; this provision appears to have been meant to overcome Section 13(4) of the ICA, which provides for separate existence of copyright in works that constitute a film;

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- (vii) If the composers become entitled to any other right now known or in future instituted in any part of the world, such right stands assigned to the producer.

Indeed, it is hard to think of an assignment clause more comprehensive than this. With an assignment clause of this kind, it does not matter what the *EIMP* case says in its main judgment or in its dictum, the contractual terms will be given full effect to. In practice, the film producer further assigns the rights in the music to a recording company.<sup>67</sup> Since the first assignment to the film producers would have already stripped the composers of their rights, it does not matter the extent of rights the recording companies have as an assignee or licensee of the film producers.

Regardless of whether the film producer has the rights in music or the recording company, the following two questions arise: does the consideration for this unduly broad assignment represent the true value of the work and its potential for further commercial exploitation? The answer has always been no in relation to the Indian film industry. The industry practice of the film producers has been to pay the composers a lump sum amount, after which the composers' rights extinguish.<sup>68</sup> However, the songs in the film are not only exploited for years to come as part of the film, but also independently or by selling the music rights to a record label.<sup>69</sup>

An unfair distribution of returns underpins both the exploitation of the music as part of the film and independently of the film. The recognition of the exploitation of music independently of the film had, at least, found its expression in the dictum in the *EIMP* case. In contrast, the unfairness in the exploitation of music *as part of the films* had not even been contemplated. The only reference to this right was in the arguments of the IPRS in the *EIMP* case and the decision of the Copyright Board.

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<sup>67</sup> Indeed, this is what happened in the B4U case where the Producer purported to acquire the music rights from the Composers and then licensed it to a recording company, which in turn, through a chain of licenses finally led to B4U Network claiming the rights in the Song. *Supra* note 16.

<sup>68</sup> Shamnad Basheer and Prashant Reddy, Submissions to the Standing Committee on HRD regarding the Copyright Amendment Bill, p. 10.

<sup>69</sup> See Nitin Masilmani, *Face the Music*, Intellectual Property Magazine, September 2012, p.30, where the author says that the producer of a successfully leveraged film could recover a sizeable component of his overall investment entirely through sale of music rights.

In this sense, giving this right back to the composers would have established a just and fair distribution of returns.<sup>70</sup>

### **ISSUES OF GOVERNANCE WITH THE IPRS**

A related question arises: are the composers still able to earn their returns from the collecting societies? An assignment so broad as the one above would mean that the composers are left with no rights they can assign to the collecting society. However, the IPRS as a collecting society has been in existence for decades,<sup>71</sup> to collect royalties for works of composers (including composers of film industry) being performed in public independently of the film.<sup>72</sup> If the amounts earned by the composers from the collecting societies were so significant, the instances of utter penury of some of the composers in the past would not have been cited while lobbying for the recent amendments to the ICA.<sup>73</sup>

It has been convincingly argued that there was a concerted effort on part of the record companies (as assignees of film producers) to take over the governance of the IPRS, so that the record companies can walk away with all the royalties from the exploitation of the composers' rights.<sup>74</sup> It has also been argued that over time record companies began realizing that in any event, under the

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<sup>70</sup> A similar argument is presented in Kirti Dahiya, *Cinematographic Lyricists Right to Royalty: Myth or Reality?* 16 JIPR 335 (2011) at pp.338-339.

<sup>71</sup> The original signing date of the Memorandum of Association of the IPRS is 18 August 1969, available at <http://iprs.org/pdf-files/Memorandum-of-Association-17-4-2013-200513.pdf>. A list of composers is at this link: <http://www.iprs.org/cms/Membership/Members/Composers.aspx>; a list of lyricists is at this link: <http://www.iprs.org/cms/Membership/Members/Authors.aspx>. Both links last visited 17 December 2013. Though accessed post the Copyright Amendment Act, 2012, many of the veteran artists listed therein were members well before the coming into force of Copyright Amendment Act, 2012.

<sup>72</sup> For a detailed explanation on how the composers earned royalties from the IPRS, see Nikhil Krishnamurthy, *Waxing Lyrical on Royalties – An analysis of the Author-Centric Amendments proposed to the Indian Copyright Act, 1957*, <http://spicyip.com/2010/03/guest-post-waxing-lyrical-on-royalties.html>, last visited 18 December 2013.

<sup>73</sup> Shamnad Basheer and Prashant Reddy, Submissions to the Standing Committee on HRD regarding the Copyright Amendment Bill, p. 10.

<sup>74</sup> Prashant Reddy, *Rights of Lyricists and Composers*, 5 NUJS L. Rev 469 (2012), at pp.487-510. The author painstakingly argues here how the record label Saregama (formerly HMV) used the courts to manipulate the internal governance of the IPRS, exhaust the defendants and drive them into giving up fighting; at the same time also using the internal mechanism of the IPRS itself to call for General Meetings to surreptitiously amend the Articles of Association to the music labels' advantage.

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terms of the assignment the composers owned no rights at all and hence the IPRS stopped paying any royalties to the composers since 2005.<sup>75</sup> The IPRS does go on record to say that it was only publishers of music i.e. the recording companies who were able to prove ownership, and not the composers, which is why they had not paid the composers.<sup>76</sup> Unfortunately, the efforts of record companies were indeed in conformity with the ICA before the amendments in 2012, which in any event only provided for the control of the IPRS to the owners of copyright rather than the composers and authors.<sup>77</sup> However, evidently there is a conflict of interest between record companies on one hand and composers on the other, raising concerns of governance if the composers are not appropriately represented.

Therefore, the issue was not only with the broad assignment terms with the film producers, but also the governance of the IPRS itself which spelled doom for the composers' effort to earn royalties from the exploitation of their rights. In this light we will need to examine whether the amendments introduced to the ICA in 2012 set right this unfairness.

### **LEGISLATIVE RESPONSE TO THE PLIGHT OF THE COMPOSERS**

In order purportedly to bring about a fairer distribution of royalties, the Copyright Amendment Act, 2012 was passed, and came into effect on 8 June 2012.<sup>78</sup> The amendments to some extent reflect a victory of the hitherto unorganised group of composers and lyricists, coming together to lobby the government to bring about changes to the law, rather than using the courts and the internal mechanism of the IPRS to counter the actions of record companies.<sup>79</sup>

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<sup>75</sup> Nikhil Krishnamurthy, *Waxing Lyrical on Royalties – An analysis of the Author-Centric Amendments proposed to the Indian Copyright Act, 1957*, <http://spicyip.com/2010/03/guest-post-waxing-lyrical-on-royalties.html>, accessed on 18 December 2013.

<sup>76</sup>The Director's Report of the IPRS, 2010-11, <http://www.iprs.org/cms/IPRS/AnnualReport/DirectorsReport20102011.aspx>.

<sup>77</sup> Before the amendment, Section 35(1) of the ICA stated that every copyright society shall be subject to the collective control of the owners of rights under this Act.

<sup>78</sup> The Gazette bringing the law into force can be viewed at <http://copyright.gov.in/Documents/NOTIFICATION-20062012.pdf>, last visited 18 December 2013.

<sup>79</sup> Prashant Reddy, *Rights of Lyricists and Composers*, 5 NUJS L. Rev 469 (2012). The author describes here how Mr Javed Akhtar, a noted lyricist, led the lobbying by lyricists and composers to the victory, culminating in the amendment to the ICA.

Under this Act, the following changes have been made:

- (i) A proviso to Section 17(e) has been added that states that nothing contained in Sections 17(b) and (c) (that deal with first ownership of film and first ownership by employment, respectively), shall affect the right of the author of literary, musical, dramatic and artistic work. This provision adds nothing new, since Section 13(4) had already clearly stated that the separate existence of copyright in the works constituting the film is not affected.<sup>80</sup>
- (ii) Three provisos to Section 18(1) have been added, as follows:
  - a. No assignment that deals with a ‘mode or means of exploitation’ not in existence or in commercial use at the time of the assignment will be given effect to, unless the assignment makes a specific mention of it;<sup>81</sup> this attends to the issue of evolving technology and newer forms of exploitation.<sup>82</sup>
  - b. The second proviso, which is the most important provision for the present discussion, can be discussed under the following three parts:
    - i. Composers whose works are incorporated in a film shall have a right to receive equal share of royalties as the producer of the film, but only to the extent that such royalties are received for any communication to the public other than as a film in cinema halls. In essence, this provision reinforces the dictum in the *EIPM* case to the extent that it recognised the survival of the right of public performance of the composer in their works other than as a film.<sup>83</sup> It goes a step ahead in stating that the composers will be entitled to

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<sup>80</sup> Clause 9.18 of Parliamentary Subcommittee’s 227<sup>th</sup> Report on Copyright Amendment Bill, 2010 submitted to the Rajya Sabha on 23 November 2010, indeed claims exactly this.

<sup>81</sup> By this provision, the clause in the assignment of Composers to the Producer in the *B4U* case that refers to future rights will not be enforceable, to the extent that such rights relate to a new form of exploitation.

<sup>82</sup> This amendment was brought about purportedly to address the issue of significant loss incurred by the composers from the use of their works in ringtones, a mode of exploitation they had not envisaged before assigning their rights. Prashant Reddy, *Rights of Lyricists and Composers*, 5 NUJS L. Rev 469 (2012), at p. 485.

<sup>83</sup> Clause 9.18 of Parliamentary Subcommittee’s 227<sup>th</sup> Report on Copyright Amendment Bill, 2010 submitted to the Rajya Sabha on 23 November 2010, indeed claims exactly this.



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royalties even if their work is communicated to the public as part of the film, but outside the cinema halls, such as television, broadcasts, etc. What is also new about this provision is that the obligation regarding equal sharing of royalties had not been statutorily dictated in the past.

Ideally, the equal share of royalties should have also been extended to the communication to the public *in* cinema halls.<sup>84</sup> Considering the opposition of the producers even to share royalties for communication to the public outside cinema halls, it may have been highly unlikely that a proposal of this nature could be considered. A starting point could have been a statutory requirement to share royalties on an on-going basis, and leave the percentage to be mutually negotiated. Once the composers get their 'foot in the door', so to speak, further lobbying could materialise in future.

- ii. the composers are not allowed to assign the right to receive royalties to any person, except by way of transmission to their legal representatives or by way of assignment to a copyright society. This provision reinforces the status of an assignment to a collecting society as being a permissible manner of distribution.<sup>85</sup> This also formalizes the role of a collecting society such as the IPRS in distribution of the returns from exploitation of rights. If the IPRS had indeed stopped paying royalties to the composers as claimed, this provision would bring the much needed certainty.

- iii. any agreement to the contrary is void.

- c. The third proviso has exactly the same provision, but in relation to sound recordings.
  - (iii) Section 19(8) is added whereby it is provided that an assignment contrary to the terms and conditions of the rights already assigned to a collecting society is void. By this

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<sup>84</sup> A similar view is taken in Shamnad Basheer and Prashant Reddy, Submissions to the Standing Committee on HRD regarding the Copyright Amendment Bill, p. 11.

<sup>85</sup> The logic of this provision seems to go against the arguments raised by the counsel for the B4U Network who argued that an assignment to a collecting society taking precedence threatens the ability of composers to earn a living. However, it has been argued that this is not necessarily the case in Section II, final paragraph.

provision the Parliament has upheld the rights assigned to the collecting society. This would mean that if a case similar to the *B4U* case arose in India now, and the composer in question is already a member of a collecting society, a later assignment to a producer contrary to the terms of the assignment to the collecting society would be void.

- (iv) Sections 19(9) and (10) have been introduced, which essentially reinforce the provisions of Sections 18(1), second and third proviso.
- (v) Section 35(1) was amended to bring the collective control of the copyright society not only under the owner of rights, but also the authors of rights. In addition, Section 35(2) was introduced to ensure that there is equal representation of both the copyright owners and authors (essentially composers and lyricists). Moreover, Section 35(4) was introduced to ensure that there is no discrimination between the rights of copyright owners and authors, and all members enjoy equal rights. These are big strides towards better governance, but there is a fear that this could result in deadlocks while taking important decisions on royalty sharing, given that the interests of owners and authors are significantly adverse to each other.<sup>86</sup> Equal representation between authors and composers is also followed in the UK, with the PRS being an example. However, the PRS also has two external directors and an executive director who constitute the board of directors of the PRS, who will potentially bring in the much needed neutrality in resolving tough issues of revenue sharing.<sup>87</sup>

Although some of these amendments reinforce the provisions already in existence, and to the extent that these amendments bring certainty to the rights of the composers and formalize some of their rights, the amendments are welcome. However, they are not as revolutionary as might have been, had they included the rights of the composers to share in the revenues of the exhibition of the film.

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<sup>86</sup> Prashant Reddy, *Rights of Lyricists and Composers*, 5 NUJS L. Rev 469 (2012), at p. 522.

<sup>87</sup> The constitution of the current board of directors of the PRS can be found at the following link: <http://www.prsformusic.com/aboutus/governance/PRSboard/Pages/default.aspx>, last visited 3 April 2014.

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The constitutionality of the amendments to Sections 17, 18 and 19, *inter alia*, is being challenged by the film producer Bharat Anand.<sup>88</sup> The constitutional validity as well as the market implications (or the absence thereof) of these amendments will unfold in the not too distant future.

### CONCLUSION

In summary, the ideal situation would be the way the Copyright Board conceived it in the *EIMP* case, where a composer can part with only the right of making a film out of her work, be it by way of licence or by way of assignment. That would leave the composer with all the freedom to exploit the other rights, be it by way of becoming a member of a collecting society or otherwise. In this sense, the collecting society will also have the right to receive royalties for the exhibition of the films incorporating the music, for and on behalf of the composers. In this ideal situation, the collecting society is also presumed to distribute the royalties fairly.

The worst case scenario is an assignment by a composer to a film producer along the lines quoted in the *B4U* case. Such assignments do not even give any room for the composers to exploit the musical works independently of the film. Effectively, such assignments bypass even the dictum in the *EIMP* case. In addition, the rights in music get assigned to the recording companies, which then go on to license further rights to broadcasters or cable television channels, in addition to becoming members of the collecting societies to claim revenues for the exploitation of the music independently of the film.

An equally sub-optimal scenario is like in the *B4U* case, where the composers assigned not only the public performance right, but also the right to synchronise the musical works into the film, to a collecting society. The track record of either the PRS or the IPRS in negotiating terms for film synchronization right with the film producers has not been tested. Indeed, the IPRS has historically never expressed inclination to manage any rights other than those that relate specifically to performance of literary, dramatic and musical works. In addition, considering the historical malfunctioning of the IPRS and the hawkish nature of record companies in taking control over it as explained above, this option would be unattractive to composers.

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<sup>88</sup> Prashant Reddy, *The constitutional challenge by film producers to the Copyright (Amendment) Act, 2012*, <http://spicyip.com/2013/05/the-constitutional-challenge-by-film.html>, last visited 17 December 2013.

It is these worst case scenarios stated above which the Copyright Amendment Act, 2012 tries to redress. However, as stated above, this amendment only creates a statutory right of equal share in royalties for communication to the public of the composers' works other than through the exhibition of film in cinema halls. Though a step in the right direction, it does not go far enough to share the royalties from the exhibition of the film itself. Further, equal representation in the collecting societies by both composers and copyright owners might become stumbling block in their functioning.

One must wait and see how the industry moulds itself around these amendments. Until then, the saga continues for the composers in their search for a fairer distribution of returns for works they create. It is only hoped that in this sequel, the composers will find the classic Bollywood happy ending.

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# OVERCOMING INDIA'S FOOD SECURITY CHALLENGES: THE ROLE OF INTELLECTUAL PROPERTY MANAGEMENT AND TECHNOLOGY TRANSFER CAPACITY BUILDING

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*The growth of the Indian economy after Independence has had little impact on the food security of the country. The paper analyses the development of advanced crop varieties through the use of agricultural technologies (hereinafter "agbiotech") within the technology transfer system, a framework which comprises of the interactions of intellectual property rights law and agricultural research and development in India. Through this, the author argues that agricultural innovation in India is failing due to the absence of connections within the technology transfer system and advocates for the creation of a national program aimed at advancing IP and tech-transfer capacity in agbiotech.\**

## INTRODUCTION

On that spectacularly auspicious day in August 1947, when India attained independence, the day on which the esteemed last Viceroy of Her Majesty's British Indian Empire, Lord Louis F.A.V.N. Mountbatten lowered the Union Jack, handed over sovereignty, and fondly waved goodbye to India

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\* Supplied by Editorial Board.

amongst the cheering throng of deliriously joyful and optimistically hopeful Indians proudly watching the raising of the Indian flag, respectfully and patriotically saluting as the saffron, white and green gently fluttered in the warm summer breeze, who could have possibly foreseen that within little over a decade the country would be facing a humanitarian disaster: the specter of catastrophic annihilation due to widespread famine? Food security in India was an issue then, in the decades that followed and perhaps today more than ever, as the entire global community faces the economic, environmental and demographic uncertainties of the new century.

However, in India, food insecurity appears to be particularly egregious (relating to the “hunger index”, a measure of degree of food deprivation): *“It is evident that India’s performance with respect to hunger is abysmal not only in relation to other large developing countries like China, but even in comparison to the rest of South Asia, with only Bangladesh having a higher value of the index. Indeed, India’s index value is close to that of Zimbabwe, a country which is in the throes of severe hyperinflation and collapse of domestic food markets. Within India, some of the supposedly richest states with the most rapid recent growth of GDP, such as Maharashtra, Karnataka and Gujarat perform very poorly on the hunger index, clearly much worse than Kerala and even worse than Assam.”*<sup>4</sup> This is additionally alarming, considering the recent rapid economic development in India, where the gross national income has nearly doubled coincidentally as the level of hunger remains stagnant, or ominously begins to show signs of worsening.<sup>5</sup>

Pragmatically speaking, what are the options to confront this looming threat to food security in India? What are the constraints? And, as this article seeks to address, what are the opportunities towards sustainably addressing this in India as the 21<sup>st</sup> century unfolds?

This paper examines and analyzes one potentially important and crucial factor to address food security in India: accelerating the development and deployment of advanced crop varieties (food, fibre, feed and fodder, e.g., grain, vegetables, cotton, and animal forage) via application of advances in agricultural technologies, including, but not limited to, biotechnology, genetic-marker assisted breeding, genomics and plant tissue culture methodologies (for the purposes of this paper, these

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<sup>4</sup> Sunildro L.S. Akoijam, *Food Security: Challenges and Issues in India*, 1 THE INTL. J.’S RES. J. OF ECON. & BUS. STUD. 1 (2011).

<sup>5</sup> ICRISAT, *Seeding Success Through Innovation and Technology*, 2012, Food 360<sup>0</sup>, November 5-6, 2012, Hotel Taj Krishna, Hyderabad, India. 2012.

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technologies in aggregate are referred to as agbiotech).<sup>6</sup> A key consideration which will impact whether agbiotech mitigates food security threats in India is efficiency of the technology transfer (tech-transfer) system; this includes the complex interaction of intellectual property rights (IPR) laws, treaties, policy, practice and management with both public and private sector agricultural research and development (R&D) enterprises of India.

As presented in this paper, when viewed as a system, agricultural innovation in India is failing. A solution is needed, and recommended herein. This paper argues that the system has failed due to a lack of connections among the various components of the system; tech-transfer offices (TTOs) can serve as intermediaries to facilitate connections in this system via focused IP management and related tech-transfer activities; however, TTOs are, at best, nascent throughout India, indicating that this represents a key weak link in the system.

What is advocated here, therefore, is a dedicated, focused and strategic national program for accelerating IP and tech-transfer capacity in agbiotech: the establishment of a National Agricultural Innovation Academy at the National Academy of Agricultural Research Management (NAARM). A National Agricultural Innovation Academy would address the agricultural system failure in India, serving as a hub for IP law, policy, practice and management in order to raise awareness, facilitate advocacy, accelerate education, thereby advancing tech-transfer and catalyzing the application of agbiotech to India's food security crisis. Operationally, the National Agricultural Innovation Academy would focus resources, align policy initiatives, prioritize programs and coordinate activities via training a new generation of Indian IP professionals, forging global networks and creating a sustainable foundation in human capital and institutional infrastructure which would radiate out to all corners of India.

However, currently, with regard to tech-transfer, agricultural productivity and food security in India, it appears that there is a systemic dilapidation that urgently requires remediation and modernization: *“The technology diffusion mechanism for the agricultural sector in the country is through the National Agricultural Research Systems (NARS) of the Indian Council of Agricultural Research (ICAR). The technology system has not been able to make any new breakthrough in agriculture since the Green Revolution [i.e., the 1960s]. [L]ow*

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<sup>6</sup> Alois Leidwein, *Food Security, Climate Change and IP Rights*, WIPO MAGAZINE 3/2011 (2011).

*productivity since the 1990s has been linked to weak support systems of non-responsive agricultural research, broken-down extension mechanisms, and inadequate seed production, distribution and regulation.”*<sup>7</sup> In the face of such institutional inefficiency and bureaucratic inertia, there is a critically urgent and pressing need for reevaluation, reinvestment and realignment of priorities. Therefore, whether, or not, agbiotech can effectively foster food security largely depends on the efficiency of the technology transfer system in India, that is, the human capital and institutional infrastructure specifically tasked with managing IP, driving innovation and thereby accelerating development and deployment of agbiotech as a cost effective, environmentally compatible and sustainable solution for India’s capability and capacity to adequately provide wholesome food to its growing population.

### FOOD SECURITY AND INDIA

Broadly defined, “*food security is achieved when ‘all people at all times have physical and economic access to food that is sufficient to meet dietary needs for a healthy and productive life’. In this sense, achievement of food security implies producing ... sufficient food and making it accessible to all individuals throughout the year and on a sustainable basis from year to year. ... Food security thus connotes freedom from hunger and malnutrition.*”<sup>8</sup> This is something that has not been achieved in India, and the threat of greater food insecurity looms.

India is facing a convergence of factors, which are expected to exacerbate an already tenuous food security scenario:

**Population increase:** 1.6 billion by 2050<sup>9</sup>

**Land resources (use):** reallocation of prime arable land (“diversion of cultivated land for non-agricultural purposes”) to special economic zone development will reduce already dwindling agricultural production capacity in India.<sup>10</sup>

**Decline in crop productivity:** India’s crop productivity is, relative to other Asian countries, amongst the lowest; depletion of soils and ground water for irrigation are contributing factors.<sup>11</sup>

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<sup>7</sup> ICRISAT, *supra* n. 5.

<sup>8</sup> Shabd S. Acharya, *Food Security and Indian Agriculture: Policies, Production Performance and Marketing Environment*, 22 AG. ECON. RES. REV. 1 (2009).

<sup>9</sup> <http://www.bbc.com/news/world-asia-22907307>

<sup>10</sup> P. S. Brahmanand et. al, *Challenges to Food Security in India*, 104 CURRENT SCIENCE 7, 841 (2013)



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**Biological factors:** These include herbivorous insect and arthropod crop pests, plant pathogens (nematodes, bacteria, fungi, viruses), weeds; in addition, loss in natural biodiversity has disrupted ecosystem balance.<sup>12</sup>

**Land resources (degradation):** Due to, among other factors, erosion, decline in fertility and widespread mismanagement of limited arable land and pasture.<sup>13</sup>

**Water resources:** Pressure on freshwater resources will mount, as competition among agriculture, industry and urban centres intensifies India is expected to go below the freshwater scarce threshold within 20 years time. Of India's 143 million hectares of arable land, 63 million are irrigated.<sup>14</sup>

**Climate change:** For India, the most impactful factors include increase in temperature and changes in precipitation, i.e., droughts and floods.

**Significant shifts in arable land usage away from rice, wheat and maize production** (i.e., between 2000 and 2010, thousands of hectares) to biofuel (jatropha) and medicinal plant (amla, ashwagandha, sarpagandha) cultivation.<sup>15</sup>

**Change in markets and demand** due to extensively accelerating urbanisation.

Recent decline in major food crop productivity due to several (biotic and abiotic) factors.<sup>16</sup>

Based on current population data and demographic trends, it has been estimated that to meet domestic demand, Indian agriculture needs to grow at 3 percent per annum, which includes not only greater food production, but also greater diversification of food products to meet the market

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<sup>11</sup> R. T. Gahukar, *Food Security in India: The Challenge of Food Production and Distribution*, 12 J. OF AG. & FOOD INFO. 3/4, 270 (2011).

<sup>12</sup>*id.*

<sup>13</sup>*id.*

<sup>14</sup> Brahmanand, *supra* n. 10.

<sup>15</sup>*id.*

<sup>16</sup> National Academy of Agricultural Research Management, *NAARM Vision 2050*, Indian Council of Agricultural Research (2013), [http://www.naarm.ernet.in/images/stories/documents/publications/naarm\\_vision2050\\_2jul2013.pdf](http://www.naarm.ernet.in/images/stories/documents/publications/naarm_vision2050_2jul2013.pdf).

demand of a rapidly emerging Indian middle class.<sup>17</sup> This will have to be accomplished predominantly on extant arable land via fourfold, threefold and twofold increases in land stewardship, water productivity and energy efficiency respectively.<sup>18</sup>

Indeed, by 2020, projections suggest that food supply will be inadequate to meet the demand of a growing population, with a stagnant agricultural system unable to keep pace with both diversified and increased demand, with a very real scenario of starvation as a potential consequence.<sup>19</sup> The Indian government has not adequately addressed issues of hunger and food security. *“Despite persisting food insecurity, efforts by the Indian government to eliminate poverty and hunger are still lacking. Political and social mobilization to make food security a resonant demand that cannot be ignored is therefore essential.”*<sup>20</sup> As reiteratively made clear throughout this paper, this has been, and unfortunately continues to remain, a recurring theme in recent Indian history.

### THE GREEN REVOLUTION; THE GENE REVOLUTION

By 1960, scarcely 13 years after achieving independence from the British Empire, India faced famine. This was brought on by a constellation of factors, e.g., droughts, inadequate post-independence land reform and little, if any, technological advances in agriculture. Initially, massive food aid in the form of grain shipments from the United States averted a humanitarian disaster; this was the US PL-480 Program. However, a more sustainable solution was needed to address the chronic issue of food insecurity in India: the Green Revolution, which American scientist, plant pathologist, humanitarian, and Nobel Peace Prize laureate, Dr. Norman Borlaug led. Borlaug and his team rapidly and efficiently, using an accelerated method of conventional plant breeding, developed and introduced Green Revolution varieties of wheat, rice, maize and bajra.<sup>21</sup> These crop varieties were dwarf/semi-dwarf, shorter statured, non-lodging, photoperiod insensitive and high yielding (cereal crop yields tripled in some areas, due to these new, semi-dwarf varieties). The Green

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<sup>17</sup>*id.*

<sup>18</sup>*id.*

<sup>19</sup> Gahukar, *supra* note 11.

<sup>20</sup>*id.*

<sup>21</sup> Alyssa Panning and Kishore G. Kulkarni, *Technology for Growth: Indian Green Revolution*, 8 SCMS J. OF INDIAN MGMT. 3, 47 (2011).

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Revolution varieties also had enhanced disease and insect resistance, accelerated maturation to heading, tolerance to moisture and temperature fluctuations, and greater responsiveness to added fertilizer.<sup>22</sup> Introduction and adoption of the Green Revolution high yielding crop varieties generated yield increases of up to threefold,<sup>23</sup> saving millions from starvation in India. The greatest success of the Green Revolution was realized in the states of Punjab and Haryana.<sup>24</sup>

Still and all, at the time there was no lack of internal Indian political opposition to implementing the Green Revolution as a strategic imperative to forestall the looming human catastrophe; however, the Indian government (ultimately persuaded and motivated by the compelling advocacy of Dr. M.S. Swaminathan), nevertheless eventually recognized that this was a crucial program that had to move forward lest starvation and death continue unabated. India was thereby rescued again from the jaws of famine by a group of U.S. and international organizations, working together under the leadership of Borlaug: the International Center for Maize and Wheat Improvement (CIMMYT), International Rice Research Institute (IRRI), US Agency for International Development (USAID), along with donor agencies such as Rockefeller and Ford Foundations. Whereas the Green Revolution in India has subsequently been the object of intense reappraisal and even criticism,<sup>25</sup> as Kolady succinctly notes: *“The current tendency is to overstate the problems of Green Revolution while forgetting the appropriate counterfactual situation: what would have been the extent of hunger, poverty, and malnutrition without the increased productivity of rice and wheat in the context of the high population growth rate?”*<sup>26</sup>

Today, India once again faces the distinct possibility of food shortages. A new Green Revolution is needed, but one that taps a new source of sustainable innovation in agriculture: agbiotech, the Gene

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<sup>22</sup>*id.*

<sup>23</sup> Govindan Parayil, *The Green Revolution in India: A Case Study of Technological Change*, 33 *TECH. & CULTURE* 4, 737 (1992).

<sup>24</sup> Clark G. Hilden, *India and the Green Revolution*, United States Educational Foundation in India (1988). Available at <http://files.eric.ed.gov/fulltext/ED322073.pdf>.

<sup>25</sup> S. K. Das and H. Tripathi, *India's Green Revolution: Fact and Fallacy*, 5 *INTL. J. OF BIO-RESOURCE AND STRESS MGMT.* 1, 153 (2014).

<sup>26</sup> Deepthi Kolady, *Technology Failure or State Failure? A Comparison of Green Revolution and Gene Revolution Technologies in India*, 2013, Annual Conference 2013: Agrarian Crisis in India?, April 5-6, 2013, Cornell University, Ithaca, NY, USA. 2013.

Revolution. The potential benefits of the Gene Revolution are wide-ranging and significant, including food security, poverty alleviation, environmental stewardship and conservation of water, biodiversity and natural resources:

In addition to increasing food production and reducing poverty, transgenic crops [agbiotech] could alleviate some environmental problems caused by intensive agriculture. For instance, farmers who grow Bt crops can reduce their use of chemical pesticides that do harm to non-target species such as bees. Herbicide-tolerant crops let them decrease their use of the most toxic compounds, albeit with an overall increase in lower-toxicity herbicides. Herbicide-tolerant crops are also associated with the adoption of low- or no-till cropping practices, which reduce soil erosion and the disruption of soil structure and microbial communities. Thus, transgenic crops could help bring about a “doubly green revolution.”<sup>27</sup>

In addition, whereas the Green Revolution focused on major grain commodity crops, requiring crop management approaches, that is a comprehensive management package, input intensive agriculture and the application of inorganic fertilizers and pesticides,<sup>28</sup> the Gene Revolution seeks to address issues that smallholder farmers encounter on marginal land, who raise and produce important, albeit neglected, “orphan crops”:

*“Traits of special interest to the developing world include nutritional enhancement and resistance to production stresses such as [heat], drought, salinity, disease and pests. Crops that provide the majority of their food supply and livelihoods—rice and wheat—are being neglected, as are a variety of “orphan crops” (such as [cassava, eggplant, papaya, banana plantain], sorghum, pearl millet, pigeon pea, chickpea and groundnut). Those are staple foods in some regions and have also been largely passed over by conventional agricultural research programs.”<sup>29</sup>*

The Gene Revolution in India can therefore move the benefits of advanced agbiotech innovation in agriculture to arable land that does not have access to irrigation: *“The first Green Revolution targeted irrigated areas. The second [Gene Revolution] must focus on rainfed (unirrigated) areas, which cover 60% of India’s farmland, and support the vast majority of its rural poor. Drylands produce half the country’s cereals, 77% of its*

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<sup>27</sup> Terri Raney and Prabhu Pingali, *Sowing A Gene Revolution*, 297 SCIENTIFIC AMERICAN 3, 104 (2007).

<sup>28</sup> Hilden, *supra* note 24.

<sup>29</sup> Terri Raney and Prabhu Pingali, *supra* note 27.

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*oilseeds and 85% of its pulses.*"<sup>30</sup> Currently, this is precisely where improvements are most sorely needed in Indian agriculture. The Green Revolution forestalled catastrophic starvation in India by focusing on major grain commodity crops (wheat and rice) via conventional plant breeding in conjunction with high-input agricultural practices, e.g., irrigation and fertilizer. The Gene Revolution, in contrast, can address marginalized sectors of the population, tailoring innovation to address a broader range of challenges, e.g., heat, drought, flooding, etc., and therefore, in a very real sense, it would complement the accomplishment of the Green Revolution and extend the societal benefits to this century and beyond:

*"The original green revolution transformed Asia [e.g., India] from a continent stalked by hunger into one that could think and plan beyond the next harvest. It helped lay the foundation for the continent's economic miracle and made possible Asia's demographic transition from high fertility and high mortality to smaller, richer families. The second green revolution [Gene Revolution] will not do that. But it should complete the first one, mainly by bringing benefits to the poorest, who missed out first time round. It will help mechanise and move more people off farms and into more productive labour. And it should prevent Asia slipping back under the shadow of hunger and all the political and social disruptions that such misery causes. Few other things can promise as much." (Emphasis added)*<sup>31</sup>

### AGBIOTECH CROPS IN INDIA

In general, the status of agbiotech in India is an ongoing saga. Notwithstanding its importance to the Gene Revolution in India, and its importance to sustainable food security, progress in agbiotech continues to creep forward. Over the past three decades, there indeed has been a distinct series of (measured) steps:

*"Status of Biotech crops research and use of biotech food/ agricultural products in India*

- *Genetically Modified Organisms (GMOs) and products thereof including GM crops are regulated products in India under the "Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro*

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<sup>30</sup> R. B. Singh, *A Second Green Revolution?*, International Center for Agricultural Research in the Dry Areas (ICARDA) (2014), available at <http://www.icarda.org/second-green-revolution>.

<sup>31</sup> The New Green Revolution: A Bigger Rice Bowl - Another Green Revolution is Stirring in the World's Paddy Fields, THE ECONOMIST (May 10, 2014).

*Organisms/ Genetically Engineered Organisms or Cells” notified by the Ministry of Environment and Forests through Notification No. 621 in Official Gazette of Government of India on December 5, 1989 under the provisions of the ‘Environment (Protection) Act, 1986’. These rules and regulations commonly referred as ‘Rules 1989’ cover areas of research, as well as large scale applications of GMOs and their products.*

- *Bt cotton is the only commercially approved biotech crop in India.*
- *In 2010, the Government of India (GOI) announced a moratorium on the approval process for Bt brinjal (eggplant).*
- *In May 10, 2012, on the Writ Petition (Civil) no. 260 of 2005 of Aruna Rodrigues Vs Union of India, the Supreme Court of India instituted a six-member Technical Expert Committee to review and recommend biosafety risk assessment studies for genetically modified (GM) crops.*
- *This Technical Expert Committee has recommended stopping open field trials on all genetically modified crops until a new set of conditions is enforced and a ten year moratorium on field trials of Bt transgenics in all food crops.*
- *Under current Indian regulations, all biotech food/ agricultural products or products derived from biotech plants/ organisms must receive formal approval from the Genetic Engineering Appraisal Committee prior to commercialization or imports (the GEAC is India’s apex biotech regulatory body).*
- *Soybean oil derived from Round-up Ready soybeans (glyphosate-resistant soybeans) is the only biotech food/ agricultural product currently approved for import.*
- *In India processed food products derived from genetically engineered products (where the end-product is not an LMO – a Living Modified Organism) do not require approval from GEAC for production, marketing, import and use in India. As processed food products are not replicated in the environment, they are not considered to be an environmental safety concern under the 1989 EPA. However, imports of products that are LMOs continue to be under the purview of GEAC and the 1986 EPA.”<sup>32</sup>*

As pointed out by Kolady et al., growth in the Indian seed industry has also expanded, with a positive impact on investment in new crops, technologies and concomitant IPR protection, to a great extent via plant variety protection (PVP) pursuant to the 2001 PPV&FR Act. The sequential loosening, via nine crucial steps, of state control over the seed industry has facilitated this process:

*“Indian Seed industry Policy Initiatives*

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<sup>32</sup> ICRISAT, *supra* note 5.

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1. *Seeds Act (1966)* Established variety release, seed certification and testing systems and established state monopoly over seed production and distribution for important food crops.
2. *National Seeds Project (1977–1991)* Led to the formation of state seed corporations and strengthened the seed system infrastructure in the country.
3. *Seed Control Order (1983)* Regulated seed dealers through dealer licensing.
4. *Industrial Licensing Policy (1987)* De-reserved Indian seed industry permitting private companies to produce and market seeds.
5. *New Policy on Seed Development (NPSD) (1988)* permitted import of germplasm for research, import of commercial vegetable seed and conditional import of seeds for coarse grains, pulses and millets.
6. *New Industrial Policy (1991)* permitted foreign direct investment in the seed industry.
7. *The Seeds Bill (2004, still pending in parliament)* proposes mandatory registration of all varieties and replaces the *Seeds Act of 1966* and the *Seed Control Order of 1983*.
8. *Protection of Plant Varieties and Farmers' Rights Act (2001)* provides an effective system for protection of plant varieties and incentives to strengthen the seed industry and the availability of high-quality seed for farmers.”<sup>33</sup>

Perhaps there is no better manner to illustrate agbiotech in India than the few salient examples, presented herein below: Bt Eggplant, Cabbage and Cotton. Whereas they represent agbiotech innovations which have, in the case of Bt cotton, or could have, in the case of Bt eggplant and cabbage, advance the Gene Revolution in India, they exemplify the steady, albeit gradual, progress stumbles, rather than marches, forward.

### **BT EGGPLANT**

Bt Eggplant (or brinjal; genetically engineered via cloning of the *Bacillus thuringiensis* insecticidal protein gene) is India's first genetically modified vegetable crop. Eggplant production in India is important because it is largely grown by smallholder farmers, yet is damaged heavily due to

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<sup>33</sup> Deepthi Elizabeth Kolady, David J. Spielman and Anthony Cavalieri, *The Impact of Seed Policy Reforms and Intellectual Property Rights on Crop Productivity in India*, 63 J. OF AG. ECON. 2, 361 (2012).

infestation by the Fruit and Shoot Borer (FSB), with yield losses of up to 70%.<sup>34</sup> The Bt eggplant technology is effective against FSB, with 98% insect mortality in shoots and 100% in fruits, at the same time requiring 77% less insecticides than non-genetically engineered control eggplant; there also up to 116% increase in yield over conventional hybrids and 166% increase in Open Pollinated Varieties (OPVs), with a decrease in insecticide application, reducing farmers' exposure to chemicals and pesticide residues in the vegetable itself. It has been estimated that farmers should achieve a net economic benefit of ca. Rs. 16,299 (US\$330) to Rs. 19,744 (US\$397) per acre from Bt eggplant.<sup>35</sup>

Mahyco (an Indian seed company with a 26 percent ownership stake held by Monsanto Inc.)<sup>36</sup> has developed a Bt eggplant hybrid using the cry1AC gene of Bt.<sup>37</sup> This agbiotech product, however, has encountered administrative roadblocks on its journey towards commercial release.<sup>38</sup> The same technology is being utilized by Tamil Nadu Agricultural University (TNAU) and the University of Agricultural Sciences (UAS), Dharwad for the production of backcrossed, OPVs of Bt eggplant. In addition, Bt eggplant using the cry1AC gene is also being developed by the Indian Institute of Horticultural Sciences (IIHR); the National Research Center on Plant Biotechnology (NRCPB) has successfully developed a Bt eggplant variety that expresses the cryFa1 gene and which has been successfully transferred to a number of seed companies such as BejoSheetal, Nath Seeds, Vibha Seeds and Krishidhan Seeds, for potential commercialization.<sup>39</sup>

Despite having met all the regulatory requirements for its approval and release, the Minister of Environment and Forests, whom the decision for the commercial release of Bt eggplant was passed

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<sup>34</sup> K. Marichamy and A. Ganesan, *Bt Brinjal – India's first biotech crop*, 1 SCIENCE PARK RESEARCH JOURNAL 14 (2013).

<sup>35</sup> Vijesh V. Krishna and Matin Qaim, *Estimating the Adoption of Bt Eggplant in India: Who Benefits from Public Private Partnership?*, 32 FOOD POLICY S23 (2007). Also see: Vijesh V. Krishna and Matin Qaim, *Potential Impacts of Bt Eggplant on Economic Surplus and Farmers' Health in India*, 2007, AAEA, WAEA & CAES Joint Annual Meeting, July 29-August 1, 2007, Oregon Convention Center, Portland, Oregon. 2007.

<sup>36</sup> <http://www.monsantoindia.com/MHPL.html>

<sup>37</sup> Marichany, *supra* note 34.

<sup>38</sup> D.A. Russel, B. Uijtewaal, V. Dhawan, D. Grzywacz, R. Kaliaperumal, *Progress and Challenges in the Bt Brassica CIMBAA Public/Private Partnership*, in THE SIXTH INTERNATIONAL WORKSHOP OF THE DIAMONDBACK MOTH AND OTHER CRUCIFER INSECT PESTS 10-27 (R. Srinivasan, Anthony M. Shelton, Hilda L. Collins eds., 2011).

<sup>39</sup> Marichany, *supra* note 34.



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to, undertook extensive consultation for several months and eventually declared a delay in its release until further undefined studies were performed. Therefore, whereas the crop variety has undergone rigorous scientific evaluation pertaining to safety of food, environment, human and animal health, and biodiversity, it has encountered administrative and bureaucratic reevaluation and delays, stalling commercialization and eventual deployment to benefit Indian agriculture and smallholder farmers in particular.<sup>40</sup> Now, to further complicate matters with the release of Bt eggplant, “*An Indian government agency has agreed to sue the developers of genetically modified (GM) eggplant for violating India's Biological Diversity Act of 2002. India's National Biodiversity Authority (NBA) is alleging that the developers of India's first GM food crop—Jalnabased Maharashtra Hybrid Seeds Company (Mahyco) partnered with St. Louis based seed giant Monsanto and several local universities used local varieties to develop the transgenic crop, but failed to gain the appropriate licenses for field trials.*”<sup>41</sup>

### **BT BRASSICA**

*Brassica oleracea* (genetically engineered via cloning of the *Bacillus thuringiensis* insecticidal protein gene) is an important vegetable crop in India with an annual production of 6.3 million tons, but it is heavily affected by diamondback moth infestations which cause an annual loss of about US\$16 million leading to the frequent application of insecticides and increased production input costs. The development of transgenic cabbage expressing insect resistance using Bt technology is a potentially cost effective management solution for the widespread problem.<sup>42</sup>

A number of institutions in India have initiated work on developing Bt Brassica varieties. There is discussion between ICAR and Bayer Crop Science regarding the development of a cry1B/cry1C gene construct for use in the transformation of important Brassica crops, the technology for which would be wholly held by the public sector and may be expanded for use in kale as well.<sup>43</sup> Additionally, this agbiotech application could be integrated into other cabbage improvement

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<sup>40</sup> Russel, *supra* note 38.

<sup>41</sup> Lucas Laursen, *Monsanto to Face Biopiracy Charges in India*, 30 NATURE BIOTECH. 1 (2012).

<sup>42</sup> William Hennessey, Aarushi Gupta and Stanley P. Kowalski, *Practice Driving Policy: Ag-Bio-Technology Transfer as Capacity Building*, in HANDBOOK ON AGRICULTURE, BIOTECHNOLOGY AND DEVELOPMENT 314 (Stuart J. Smyth, Peter W. B. Phillips and David Castle eds., 2014).

<sup>43</sup> Russel, *supra* note 38.

programs in India, e.g., in FY 2012-13, IARI commercially released Pusa Cabbage Hybrid 1, an early-maturing hybrid variety with resistance to black rot disease, improved yield and tolerance to high temperature, in three north Indian states.<sup>44</sup>

A noteworthy case is the Collaboration on Insect Management for Brassicas in Asia and Africa (CIMBAA), a public-private partnership (PPP) formalized in 2005 for the dissemination of Bt Brassica. Between 2005 and 2009, CIMBAA's research collaborators were able to complete transformations on both cabbage and cauliflower, and by the middle of 2009, the preferred cabbage and cauliflower lines had been selected for efficacy trials held in north and south India. However, the project stalled and sputtered in 2010 when some of its key partners (AVRDC, Cornell University) withdrew from the partnership citing liability and licensing stewardship issues, as well as discouragement due to delays in the release of Bt eggplant. As a result, field, laboratory work and further development has ceased despite having reached an advanced stage.<sup>45</sup>

### **BT COTTON**

Bt cotton, genetically engineered via cloning of the *Bacillus thuringiensis* insecticidal protein gene,<sup>46</sup> the only agbiotech crop which has been widely commercialized and produced in India, is a spectacular success story.<sup>47</sup> In India, Bt cotton production has generated \$51 billion (US) in profit, clearly demonstrating the benefits of this advanced agbiotech innovation to Indian farmers; this extra income was realized via increased yields of bales of cotton fibre, reduced labor in the fields and, the environmentally friendly reduction in the application of chemical pesticides.<sup>48</sup> A systematic analysis by Pray and Nagarajan has provided compelling evidence for the broader positive commercial and

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<sup>44</sup> Indian Agricultural Research Institute *Annual Report*. New Delhi, India: Indian Agricultural Research Institute, 2013, available at [http://www.iari.res.in/files/Annual-Report\\_2012-13.pdf](http://www.iari.res.in/files/Annual-Report_2012-13.pdf).

Indian Agricultural Research Institute, *Varieties Developed at IARI*, Indian Agricultural Research Institute (2010), available at [http://www.iari.res.in/index.php?option=com\\_content&view=article&id=1253&Itemid=53](http://www.iari.res.in/index.php?option=com_content&view=article&id=1253&Itemid=53).

<sup>45</sup> Russel, *supra* note 38.

<sup>46</sup> ISAAA, Pocket K No. 6: Bt Insect Resistant Technology, 2013, available at <http://www.isaaa.org/resources/publications/pocketk/6/default.asp>

<sup>47</sup> Kolady *supra* note 26.

<sup>48</sup> Judit Berman et. al, *Can the World Afford to Ignore Biotechnology Solutions That Address Food Insecurity?*, 83 PLANT MOL. BIOL. 1/2, 5 (2013).

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societal impact of this agbiotech innovation.<sup>49</sup> As the authors point out: “*Agbiotech has positively affected research and development in the Indian seed industry, possibly by greatly increased actual and expected market size in the seed industry, which increased research and development ... increased appropriability, which is the ability of firms to capture the economic benefits of new technologies because of the regulations [and/or] ... greatly increased technological opportunities for developing new traits ...*” However, the authors also make clear that the IPR appurtenant to the Bt agbiotech innovations is, presumably, predominantly non-Indian owned: “[F]oreign companies dominate agricultural biotech patenting: 78 patents have been granted to foreign firms and only one has been granted to an Indian company”.

Access to Bt cotton in India has been largely driven by international private sector collaborations with deals and joint ventures effectively accelerating the transfer of this technology to farmers across the country: “*Mahyco-Monsanto Biotech (MMB) - a 50:50 joint venture between Mahyco and Monsanto Holdings Pvt. Ltd. sub-licensed the Bollgard II and Bollgard technologies to more than 30 Indian seed companies. Each Indian seed company has introduced the Bollgard technology into their own germplasm. Indian farmers now have a choice of over 300 Bt cotton hybrid seeds. Bollgard is used by more than 6 million Indian farmers.*”<sup>50</sup>

### TECH-TRANSFER IN INDIA, AN OVERVIEW

In developed, innovation-driven, knowledge-based economies, such as the U.S.A., the U.K. and Israel, successful tech-transfer involves a chain of steps to be accomplished effectively, some of which may run simultaneously and may not necessarily be in the same order as listed here:

- 1) Conceptualization and creation of a technology that is market-worthy and beneficial to the industry;
- 2) Procurement of adequate IPR protection in the appropriate jurisdictions in a timely and efficient manner;
- 3) Identification of potential industry partners that may benefit from the commercialization of the technology within their business unit and also have the capacity to successfully evaluate and commercialize the technology into a useful end-product;

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<sup>49</sup> Carl E. Pray and Latha Nagarajan, *Role of Biotechnology in Stimulating Agribusiness R&D Investment in India*, 16 *AGBIOFORUM* 2, 104 (2013).

<sup>50</sup> <http://www.monsanto.com/improvingagriculture/pages/history-of-bollgard-cotton.aspx>

- 4) Demonstration of proof-of-concept of the technology by the inventor, an external party, or both, possibly through a joint development or corporate-sponsored research agreement;
- 5) Upon demonstration of the technology's value proposition and de-risking via additional research, implementing a technology license agreement with the company on pre-negotiated financial terms;
- 6) Monitoring periodically the commercialization of the licensed technology, its time to market, as well as the distribution and receipt of royalty payments from the licensee based on the set financial terms.

Whereas this model is appropriate in these developed countries, India will likely need to adapt tech-transfer, especially in agbiotech, to address its current food security challenges and level of innovation, whether such innovation is present or needs to be developed or absorbed.

Most of the research in India is motivated by research publication, granted patents, and the prestige that result, and not by tech-transfer and its potentially significant returns to the inventor as well as the community. This reflects the stasis in India, which is especially the case in the public sector agricultural research and development. *“So far, governance of agricultural research in India has largely meant adopting government laws, rules and procedures in a command and control regime. While this mode of governance was adequate in the early phases of the growth of NARS, it is no longer so in view of the pluralistic nature of research and tech-transfer, and demands for more speedy, effective and efficient performance with greater transparency and accountability of decision processes.”*<sup>51</sup> The traditional system still prevails, and the transition from the public goods based Green Revolution to a global innovation based, transactional, proprietary Gene Revolution requires refinement and development of a system through which agbiotech innovation moves.

As noted by Graff: *“Most [Indian] academic intuitions still lack IP management capacity, with the exception of the leading Indian Institutes of Technology (IITs) and a few other universities. TTOs or centers are now found at:*

*IIT New Delhi*

*IIT Bombay*

*IIT Kharagpur*

*IIT Kanpur*

*IIT Guwahati*

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<sup>51</sup> National Academy of Agricultural Research Management, *supra* note 16.

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*IIT Roorkee*

*IIT Chennai*

*Delhi University*

*Govind Ballabh Pant University of Agriculture & Technology, Pant Nagar*

*Bidhan Chandra Krishi Vishwavidyalaya*

*Jadavpur University*<sup>52</sup>

Hence India does have a TTO foundation, and has several tech-transfer establishments, some of which have been long-existent (e.g. NRDC, FIIT) and others that are relatively recent (e.g. ICAR's IP&TM Unit).<sup>53</sup> India has, since fairly recently, begun to see developments in agbiotech transfer capability in some of its key publicly owned, agricultural R&D institutions such as ICAR.<sup>54</sup> Many such institutions have made an effort to take on human resources that would oversee the protection of early-stage innovations, through the implementation of dedicated 'IP Cells', or in other words, the Indian TTOs (e.g. ICAR, NBPGR).<sup>55</sup> Despite these developments, some important challenges and drawbacks remain in the effective management of agricultural IP, mostly due to lacking awareness of

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<sup>52</sup> Graff GD. 2007. Echoes of Bayh-Dole? A Survey of IP and Technology Transfer Policies in Emerging and Developing Economies: In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.), MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. *available at* [www.ipHandbook.org](http://www.ipHandbook.org).

<sup>53</sup> See National Research Development Corporation, *Mission*, National Research Development Corporation (2014), <http://www.nrdcindia.com/mission.htm>; See Also Foundation for Innovation and Technology Transfer, *About FIIT*, Foundation for Innovation and Technology Transfer – Indian Institute of Technology Delhi (2004), *available at* <http://www.fitt-iitd.org/about-fitt.aspx>; See Also Indian Council of Agricultural Research, *Commercialisation of Technology: Intellectual Property & Technology Management (IP&TM) Unit*, Indian Council of Agricultural Research (2010), *available at* <http://www.icar.org.in/en/node/372>.

<sup>54</sup> See Indian Council of Agricultural Research, *Commercialisation of Technology: Intellectual Property & Technology Management (IP&TM) Unit*, Indian Council of Agricultural Research (2010), *available at* <http://www.icar.org.in/en/node/372>.

<sup>55</sup> *Id.*; See Also National Bureau of Plant Genetic Resources, Technologies and IPRs: Institute Technology Management Unit (ITMU), National Bureau of Plant Genetic Resources (2013), *available at* [http://www.nbpgr.ernet.in/Technologies\\_and\\_IPRs.aspx](http://www.nbpgr.ernet.in/Technologies_and_IPRs.aspx).

tech-transfer opportunities.<sup>56</sup> Primarily, while these institutions have adopted an aggressive strategy for IPR protection for their agricultural innovations (i.e. mostly in the form of plant variety protection), the same cannot be said for their efforts in the utilization and commercial dissemination of these technologies as so far there are apparently no immediate records of agbiotech transfer success stories that are attributable to these Indian TTOs.<sup>57</sup> A summary of several TTOs and tech-transfer organizations follow.

#### **NATIONAL RESEARCH DEVELOPMENT CORPORATION**

Before IPR had been established in India to the extent that they exist today, the National Research Development Corporation (NRDC) had already begun working on technology commercialization for the benefit of the public. Established in 1953 with the objective to promote, develop and commercialize the technologies and know-how coming from various Indian R&D institutions, it may be entitled as the oldest government organization for tech-transfer. However, it is notable that this institution appears to have not undertaken any tech-transfer projects and technologies pertaining to improved crop varieties.

NRDC's website enlists certain major technologies licensed by NRDC in India over the past decade, these include innovations in agriculture, chemistry, food and the life sciences.

Among these is the rice husk particle board, which utilizes rice husk waste and has been the subject of patents filed in India and many other rice growing countries. This board has emerged as a versatile substitute for wood in a wide range of applications. It should be noted that the information provided by NRDC apparently does not include readily accessible data on the ownership of IPR related technologies, nor is information about the types of agreements between NRDC and various innovating bodies. The role of NRDC as an interface between the innovating organization and the one that implements it, however, is an important aspect of its mission.

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<sup>56</sup> Purohit, Shashwat, *SpicyIP: IP Management in Indian Agricultural Research*, UNH Law Blawgs: ITTI: The International Technology Transfer Institute at UNH Law (31 May, 2009), *available at* <http://blogs.law.unh.edu/iti/2009/05/spicyip-ip-management-in-india.html>.

<sup>57</sup>*Id.*; *See Also* Protection of Plant Varieties & Farmers' Rights Authority, India, *List of Registered Varieties Certificate Issued Upto Dates: 01.04.2014*, Protection of Plant Varieties & Farmers' Rights Authority, India (2014), *available at* [http://www.plantauthority.gov.in/List\\_of\\_Certificates%20upto%2001.04.14.mht](http://www.plantauthority.gov.in/List_of_Certificates%20upto%2001.04.14.mht).

### **COUNCIL FOR SCIENTIFIC AND INDUSTRIAL RESEARCH (CSIR)**

This premier industrial R&D organization in India is an autonomous body established in 1942 by a government resolution. It is recognized as one of the world's largest publically funded R&D organizations. *"In 1996, CSIR developed an IP policy for the purpose of maximizing 'the benefits of CSIR from its intellectual capital by stimulating higher levels of innovation through a judicious system of rewards, ensuring timely and effective legal protection of its IP' and forging strategic alliances from enhancing the value of its IP. As a part of the implementation process CSIR has also established an R&D, Planning and Business Development Division, responsible for tech-transfer and licensing, as well as an Intellectual Property Management Division, responsible for filing and prosecuting patent applications, managing IP portfolio and even litigating IP matters. It should also be noted that as early as 1990, CSIR has introduced a royalty sharing system to reward scientists and since, several other research centers followed its footsteps".*<sup>58</sup>

CSIR's role in science and technology human resource development is noteworthy. A pioneer of India's IPR movement, CSIR today is also strengthening and building on its patent portfolio: CSIR filed 174 patents in India and 220 abroad during the year 2010-2011 whereas it was granted 260 patents in India and 361 abroad during the year. CSIR has (according to its 2010-2011 Annual Report) 3046 foreign patents and 2278 Indian patents in force. Continuing to create niches in technology licensing, CSIR has signed a unique deal with M/s Nostrum Pharmaceuticals Inc., USA for world-wide licensing of clinical development of new generation thrombolytic molecules. CSIR will be receiving over US\$ 150 million through various milestone payments and royalties. This is an outstanding example of Public-Private-Partnership that will ultimately benefit humankind. The effort is part of CSIR's endeavour of providing affordable healthcare.

### **INDIAN INSTITUTES FOR TECHNOLOGY (IITs) AND INDIAN INSTITUTE OF SCIENCE (IISc)**

While NRDC has identified the essential industry-academia gap in the ecosystem, the IITs and the IISc are heavily focused on bridging that gap. Both of these premier institutions have established designated offices to manage the protection of IPR and overlook their tech-transfer activities.<sup>59</sup> The IITs, with nearly each of their numerous nationwide branches, have such offices in place.<sup>60</sup>

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<sup>58</sup> Julia Siripurapu, *An Overview of Technology Transfer Practices in India, as of 2007*, 42 LESNOU 573 (2007).

<sup>59</sup>*id.*

<sup>60</sup>*id.*

**IIT DELHI**<sup>61</sup>

Currently, the Foundation for Innovation and Technology Transfer (FIIT) is the autonomous body that handles the patent filing, IP marketing and tech-transfer activities. It was established in 1992 with the primary motive of helping IIT-Delhi build partnerships with the industry such that the institution can devise programs to conduct applied research and customize technology as per industry needs. FIIT is also in the process of commercializing a range of technologies. As an example, it is marketing a protective coating technology that is useful for preserving fresh produce in hot climates and is in demand from various tropical and sub-tropical countries where it could solve the grievous problem of preserving fresh produce. *“IIT- Delhi has its IP policy which allows the institute to retain ownership of the inventions developed by IIT Delhi person while working at the institute. The inventions developed through sponsorship may be owned by the institute or may be jointly owned. The IP management policy of the institute includes invention disclosure requirement, assessment of the innovations, patent filing procedure and commercialization of IP. 60% of the revenue is shared by the inventor, 20% to the institute and 20% to the department where the invention came from.”*<sup>62</sup> However, as was the case with NRDC, FIIT has not dealt with innovations pertaining to crop improvement, primarily because IIT-Delhi does not contain an agricultural school within its institutional capacity.<sup>63</sup>

**IIT BOMBAY**<sup>64</sup>

*“Established in 1972, the Industrial Research and Consultancy Centre (IRCC) at IIT Bombay is responsible for fostering R&D activities at the institute, serving as an interface between the institute and industry, the administration and management of sponsored research programs; and protecting, managing and commercializing the Institute's IP assets. The IRCC also manages the Technology Business Incubation program funded by government agencies to encourage and support academic entrepreneurship.”* IIT - Bombay joined the Association of University

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<sup>61</sup> Partha Bhattacharya, *Technology Transfer from a Technical University: A Case Study of IIT Delhi*, 10 J. OF INT. PROP. RIGHTS 413 (2005).

<sup>62</sup> Siripurapu, *supra* note 58.

<sup>63</sup> See Foundation for Innovation and Technology Transfer, *About FIIT*, Foundation for Innovation and Technology Transfer – Indian Institute of Technology Delhi (2004), <http://www.fitt-iitd.org/about-fitt.aspx>; See Also Indian Institute of Technology Delhi, *Academic Units*, Indian Institute of Technology Delhi (2011), available at <http://www.iitd.ac.in/>.

<sup>64</sup> Arumugam V. and Karuna Jain, *Technology Transfer from Higher Technical Institutions to the Industry in India - A Case Study of IIT Bombay*, 17 J. OF INT. PROP. RIGHTS 141 (2012).



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Technology Managers (AUTM) in 2006. Since then, it has been successful in generating considerable sponsored research and achieving IPR protection for technologies coming out of IIT-Bombay. "IIT - Bombay has an IP management policy that deals with ownership rights decided by an assignment between the inventor and the institute. It further states the rules related to ownership in a sponsored research, evaluation of the invention by a committee, filing of national and international patent applications, commercialization of IP and revenue sharing".<sup>65</sup>

### **IIT KANPUR**

The research and development office at IIT-Kanpur functions as the interface between the institute and research sponsors and is responsible for the initiation and administration of sponsored research projects. In 2001, IIT Kanpur established the SIDBI Innovation and Incubation Centre (SIIC) Small Industries Development Bank of India (SIDBI) to promote R&D activities and entrepreneurship in the institute. According to the Director's Annual report of 2012 - 2013, "*during the year, twelve technologies developed at the Institute were licensed for commercialization while the institute filed eighteen national patents including two design patents. Twenty-two companies are currently being incubated at SIDBI Innovation and incubation Centre (SIIC) while twenty-one have graduated. SIIC has successfully incubated eight Bio-Tech Companies with two more in the pipeline.*"<sup>66</sup>

### **IIT KHARAGPUR**

"Established in 1982, the Sponsored Research and Industrial Consultancy (SRIC) center is the IPR and Industrial relations cell at IIT-Kharagpur. SRIC serves as the institute's connecting wing with government and industrial sponsors for the purpose of initiating and managing research and consulting projects. Since the inception the center has administered 1,221 sponsored research projects valued at approximately \$21.3 million."<sup>67</sup> The Centre's website states, "*the institute has an IP policy which strongly believes that the Intellectual Property Rights of a person are not only to be protected but also commercially exploited. The institute is also active in organizing workshops and seminars to enlighten the faculty, scientists and students on various IPR issues. 127 patents have been filed so far on various innovations/ development of technologies, of which about 25 patents have been granted. A few tech-transfer agreements*

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<sup>65</sup> Siripurapu, *supra* note 58.

<sup>66</sup> IIT Kanpur, Director's annual report of 2012-2013 available at [http://www.iitk.ac.in/dord/templates/r\\_d/data/Annual\\_Report/Annual\\_Report\\_2012-13.pdf](http://www.iitk.ac.in/dord/templates/r_d/data/Annual_Report/Annual_Report_2012-13.pdf)

<sup>67</sup> Siripurapu, *supra* note 58.

*have been made on enzyme based unhairing process using agro-residues, acid-proof cement & allied products from rice-husk ash, low cost portable weigh bridge, nano-sized zirconia powder, heat resistant cable insulants, etc are two major know-how transfers that have been finalized.”<sup>68</sup>*

### **INDIAN INSTITUTE OF SCIENCE (IISc)**

The IISc has created several interfaces with the industry. The Institute established the Center for Scientific and Industrial Consultancy (CSIC) in 1975 for the purpose of promoting and enhancing its existing relations with industry and engaging in tech-transfer transactions. IISc took a further step in commercializing its technologies by setting up the Society of Innovation and Development in 1991. During the fiscal year 2004 -2005, CSIC and SID initiated approximately 270 industry sponsored research projects.<sup>69</sup> *“A rigorous IP policy has been set-up by the institute that lays down the rules related to the ownership and profit sharing of the innovations from IISc. The institute also has partnership agreements with Think Village, LLC Boulder, Colorado, USA and Intellectual Ventures Asia Pte. Ltd. Singapore, to help market IISc's IP to industry and enable the IISc's researchers in the fields of IP productivity and commercialization.”<sup>70</sup>*

### **INDIAN COUNCIL OF AGRICULTURAL RESEARCH AND AFFILIATES**

The Indian Council of Agricultural Research (ICAR), which is among the top, public-funded agricultural organization in India, recognized the need for a systematic management of its technologies and services for the purpose of transfer and commercialization of those technologies into end products beneficial for the public.

As articulated by Elsy et al.:

*“The Indian Council of Agricultural Research (ICAR) is the apex body for planning, promoting, coordinating and undertaking research and its application in agriculture and associated sciences at Central and State Agricultural Universities, colleges and other agricultural organizations across the country. In response to the changing scenario of technology generation, protection and dissemination, ICAR has developed a policy framework for intellectual property management and tech-transfer/commercialization. This policy is for stimulating research and promoting enterprise growth, all for the ultimate benefit of the farming community. These guidelines became effective October 2, 2006 (ICAR, New Delhi, India, 2006). Many of*

<sup>68</sup> <http://www.iitkgp.ac.in/sric/>

<sup>69</sup> Siripurapu, *supra* note 58.

<sup>70</sup> <http://www.ipcell.iisc.ernet.in/ip/aboutus.html>

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*the State Agricultural Universities are now developing their own policies for IP protection and management in tune with the ICAR guidelines.”<sup>71</sup>*

In addition, recognizing agriculture as the principal source of livelihood for over 58% of the Indian population and the main driver of India's economic growth, as well as wanting to act upon the detrimental reduction in the growth rate of agricultural GDP in the past several years, ICAR, with the help of funding from the World Bank and the Government of India, devised the National Agricultural Innovation Project (NAIP) to seek new strategies and innovative solutions to combat the slowing GDP as well as meeting the average farmer's lopsided input-output ratios. In 2006, ICAR implemented the establishment of a decentralized, three-tier IP management infrastructure, wherein

The first tier enables individual research institutes affiliated with ICAR to enter into commercial license agreements with interested industry partners (public or private) having the potential to develop products in that particular scientific space.

The middle tier consists of five Zonal Technology Management & Business Planning and Development Units (ZTM&BPD, or hereafter, BPDs) that act like their very own indigenous TTOs undertaking the commercialization efforts for those ICAR affiliates that fall under their respective geographic zones. Many of these BPDs offer incubation and business consultation services to aspiring entrepreneurs and startups whose business plans revolve around one of ICAR's technologies.

For the third tier, ICAR has established a central Intellectual Property & Technology Management Unit (IP&TM) primarily for the purpose of overseeing international patent filings, while at the same time overseeing policy matters related to tech-transfer and public-private partnerships.

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<sup>71</sup> Cheruvathoor Elsy, U. Deepa and Karim Maredia, Intellectual Property Protection, Management and Technology Transfer Policies and Practices in India, in USAID, USDA-ARS, USDA-FAS and Michigan State University, *Intellectual Property Policies and Technology Transfer Practices in the South Asia Region*, 2008, Proceedings of the Special Session Organized at the Association of University Technology Managers (AUTM), February 29, 2008, San Diego, CA, USA. 2008. pp 11-20. See also Indian Council of Agricultural Research, *ICAR Guidelines for Intellectual Property Management and Technology Transfer/Commercialization*, Indian Council of Agricultural Research (2006).

ICAR has via the “*mandate of the Institute Technology Management Unit (ITMU) [pursued] registration of patents, facilitation of contract research projects and consultancies by the Institute scientists, IPR, and interaction with the agri-business industry.*” For example, ICAR has “*With reference to protection of intellectual property ... filed six new patents, renewed nine patents, protected eight varieties of different crops with PPV & FRA and signed 15 MOUs for commercialization of LARI technologies.*”<sup>72</sup>

### **STEM - SOCIETY OF TECHNOLOGY MANAGERS**

Initiated by Sathguru Management Consultants Pvt. Ltd., STEM is a non-profit organization that provides a facilitative environment for successful tech-transfer processes and promotes best practices. This organization is like the AUTM (Association of University Technology Managers) of India. It provides an environment that is supportive to entrepreneurship and contributes to the professional development of technology management professionals in diverse technical domains and provides proper guidance and assistance to inventors and corporations in matters of IPR.

*"The main goals of the governing council are:*

- 1. To offer a platform for Technology Management professionals to facilitate their knowledge by peer interactions.*
- 2. To promote best practices in Technology Management and engage in capacity-building.*
- 3. To operate as a catalyst in professional development of technology managers for commercial benefits of innovations.*
- 4. To organize annual meetings and seminars to benefit Tech-transfer professionals nationwide.*
- 5. To spread awareness among the stakeholders about Intellectual Property Laws and its increasing importance.*
- 6. To help inventors and corporations in dealing with Intellectual Property including the practical situations and the legal ramifications involved.*
- 7. To promote the economic growth of the constituent members."*<sup>73</sup>

Although, the organization has had annual IP summits since its conception in 2008 and these events have been supported by AUTM, it is hard to believe the unpopularity of STEM amongst the premier research institutes and organizations in India. .

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<sup>72</sup> Indian Agricultural Research Institute, *supra* note 44.

<sup>73</sup> <http://stemglobal.org/>

## IP LAWS AND TREATIES RELATING TO AGBIOTECH IN INDIA, AN OVERVIEW

Hereinbelow is a brief overview of laws and treaties which are related to agbiotech and tech-transfer related thereto. This is only a cursory overview, purely illustrative in nature to introduce this aspect of the “agbiotech innovation system”, and the reader is advised to seek references with greater depth to better understand these bodies of law.

### **PATENTS**

“On December 26, 2004 the Indian government promulgated the Patents (Amendment) Ordinance 2004 and also the Patents (Amendment) Rules, 2005 to comply with the TRIPS obligations. The patents are administered by the Controller General of Patents, Designs and Trademarks under the control and supervision of the Ministry of Commerce and Industry, Department of Industrial Policy and Promotion, Government of India. The Head Office of the Patent Office has been established at Kolkata and branches are located in Mumbai, New Delhi and Chennai. The Office of the Controller General is in Mumbai. India became the 98th contracting state of the PCT on September 7, 1998, and as such, nationals and residents of India are entitled to file international patent applications at any of the country's Patent Offices.”<sup>74</sup> It should be noted that the language of Section 3(j) is a verbatim translation into India law of Article 27.3 (b) of TRIPS Agreement (India signed TRIPS in 1994): “Parties may exclude from patentability plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, parties shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.”

### **PROTECTION OF PLANT VARIETIES**

“Article 27.3 (B) of the TRIPS states that member countries are required to grant protection of plant varieties either by patents or by an effective sui generis system or by any combination of these. India has opted for a sui generis system and enacted The Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPV & FR) and Rules 2003. It is unique in that it is the only one that covers both plant breeders' and farmers' rights. It protects the IP rights of farmers in respect to their contribution made at any time in conserving, improving and making available plant genetic resources for the development of new plant varieties. The Central Government has established the Protection of Plant Varieties and Farmers' Rights Authority for implementing the PPV & FR Act. Plant varieties that conform to the criteria of

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<sup>74</sup> Cheruvathoor Elsy, *supra* note 71.

*distinctiveness, uniformity, stability and novelty are registerable under this Act. Plant Breeders' Rights are the same for the breeder of a variety and breeder of essentially derived variety (EDV) (PPV & FR Act, 2001)."*<sup>75</sup>

### **BIOLOGICAL DIVERSITY**

*"India is one of the eight Vavilsonian centers of origin and diversity of cultivated plants and is one of the 12 mega centers of biodiversity at the global level. It is estimated that there are at least 45,000 species of plants and 77,000 species of animals in the country and it is ranked 10th among the plant rich countries of the world. Numerous endemic species are present in the biodiversity hotspot areas of Western Ghats and Eastern Himalayas and hence India has taken initiatives to protect its sovereign rights over biodiversity in tune with CBD (The Convention on Biological Diversity, India Signed onto the CBD in 1992 and then ratified in 1994). The Biological Diversity Act, 2002 enacted the various provisions for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising from the use of biological resources and knowledge, and for matters connected therewith or incidental thereto. It is instrumental in protecting the IP rights over biological material in India."*<sup>76</sup>

*"The conservation and sustainable use of biodiversity, based on local knowledge systems and practices, are engrained in Indian ethos and enshrined in the Constitution of India (Article 48A and Article 51(g)). Other Key laws and treaties related to biodiversity specifically in the agricultural sector include the Protection of Plant Varieties and Farmers' Rights (PPV & FR) Act and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)"*<sup>77</sup>

*"The ITPGRFA [The International Treaty on Plant Genetic Resources for Food and Agriculture, which India signed and ratified in June 2002] was adopted by the FAO conference in November 3, 2001, stating its objectives to be the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security. Notwithstanding the reference to the CBD, however, it bears emphasizing that the ITPGRFA represents a marked departure from the approach of the CBD. Whereas the CBD represents an assertion of national sovereign ownership of biological diversity generally, and thus apparently envisages a series of bilateral negotiations over access to such diversity and benefit sharing, the ITPGRFA represents a waiver of those sovereign*

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<sup>75</sup>*id.*

<sup>76</sup>*id.*

<sup>77</sup> <http://www.cbd.int/countries/profile/default.shtml?country=in>

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*rights with respect to the sixty- four food and feed crops that are included in the ITPGRFA's Multilateral System which creates a form of limited common property in crops that account for the bulk human nutrition.*<sup>78</sup>

### **BAYH-DOLE LEGISLATION**

India is one of the countries that is contemplating in transplanting the Bayh-Dole structure in its IP legislations based on the skeletal model provided under the Bayh-Dole Act of 1980 in the United States. The Indian Government introduced the Protection and Utilization of Public Funded Intellectual Property Bill 2008 in the Upper Parliament in January 2009. The Bill is currently undergoing scrutiny, e.g. by a Parliamentary standing committee, after which it may pass before the two houses of Parliament for approval. Much like its U.S. parent, this bill vests institutes with the right to acquire title to patents for inventions derived from publically funded research and development grants, etc. The Bill purview may extend beyond patents, covering other forms of IP such as copyright, plant varieties, semi-conductor layout and trademarks.<sup>79</sup>

### CURRENT POLICY; CONTINUING CONSTRAINTS

Ironically, although the Gene Revolution embodies enormous promise to stabilize food security in India well into the current century, as with the Green Revolution of 50 years ago, policy paralysis, linked to inadequate and disorganized human capital and institutional capacity, once again presents challenges and obstacles for coherent application of such advanced agbiotech innovation to address pressing food security issues facing India.<sup>80</sup> This apparently extends to an inability of the public sector to drive the development of appropriate agbiotech applications sorely needed in India to address food security threats, whether via research and development in the public sector agricultural system, e.g., universities and government institutes, or more importantly, via public-private partnerships to accelerate the development and deployment of crucial agbiotech innovations: "The Indian seed companies such as Rasi Seeds and Nuziveedu Seeds lead the Bt cotton seed market. In

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<sup>78</sup> Charles R. McManis and Eul Soo Seo, *The Interface of Open Source and Proprietary Agricultural Innovation: Facilitated Access and Benefit-Sharing Under the New FAO Treaty*, 30 WASH. U. J. L. & POL'Y 405 (2009).

<sup>79</sup> Shamnad Basheer and Shouvik Guha, *Outsourcing Bayh-Dole to India: Lost in Transplantation?*, 23 COLUM. J. ASIAN L. 269 (2010). Mrinalini Kochupillai, *The Protection and Utilization of Public Funded Intellectual Property Bill, 2008: A Critique in the Light of India's Innovation Environment*, 15 J. OF INT. PROP. RIGHTS 19 (2010).

<sup>80</sup> Kolady, *supra* note 26.

this context, instead of arguing that it is the role of the State to protect farmers from multinational companies, *wouldn't it be more meaningful to ask why public sector is not successful in developing Bt cotton hybrids or varieties ... ?*<sup>81</sup> This situation appears to not be inconsistent with the observations of Pingali and Raney, who lament that the Gene Revolution will be stymied unless developing countries (e.g. India) invest in building an institutional foundation which will facilitate its sustainable implementation: “Only if formidable institutional challenges are met can transgenic crops achieve their full potential to improve the livelihood of farmers in the developing world”.<sup>82</sup>

As further articulated by Pingali and Raney, the urgency for transition from the public goods based Green Revolution to a global innovation based, transactional, proprietary Gene Revolution increases in direct proportion to food insecurity:

*“The past four decades have seen two waves of agricultural technology development and diffusion to developing countries. The first wave was initiated by the Green Revolution in which an explicit strategy for technology development and diffusion targeting poor farmers in poor countries made improved germplasm freely available as a public good. The second wave was generated by the Gene Revolution in which a global and largely private agricultural research system is creating improved agricultural technologies that flow to developing countries primarily through market transactions. The Green Revolution strategy for food crop productivity growth was based on the premise that, given appropriate institutional mechanisms, technology spillovers across political and agro-climatic boundaries can be captured. A number of significant asymmetries exist between developed and developing, e.g.: agricultural systems, market institutions and research and regulatory capacity. These asymmetries raise doubts as to whether the Gene Revolution has the same capacity to generate spillover benefits for the poor. A strong public sector – working cooperatively with the private sector – is essential to ensure that the poor benefit from the Gene Revolution. (Emphasis added).”<sup>83</sup>*

The pressing question that must be addressed in order to move from Green Revolution to Gene Revolution involves the necessity in developing countries, e.g., India, for a fundamental policy shift with corresponding capacity building initiatives. As pointed out by Pingali and Raney, “[t]hree

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<sup>81</sup>*id.*

<sup>82</sup> Terri Raney and Prabhu Pingali, *supra* note 27.

<sup>83</sup> Prabhu Pingali and Terri Raney, *From the Green Revolution to the Gene Revolution: How Will the Poor Fare?*, FAO ESA WORKING PAPER NO. 05-09 (2005).



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*interrelated forces are transforming the system for supplying improved agricultural technologies to the world's farmers. The first is the strengthened and evolving environment for protecting IP in plant innovations. The second is the rapid pace of discovery and growth in importance of molecular biology and genetic engineering. Finally, agricultural input and output trade is becoming more open in nearly all countries.” (Emphasis added)<sup>84</sup>*

In addition, the reality is that, over the past several decades the private sector has performed the bulk of research in crop improvement with regard to agricultural innovation (agbiotech), e.g., multinational corporations such as DuPont, Syngenta, Bayer and Monsanto, with public sector, e.g., the various research universities, national agricultural research systems (NARS) and the CGIAR (Consultative Group on International Agricultural Research), albeit of crucial and ongoing importance, proportionally contributing less: “*The World's top ten multinational bioscience corporations' collective annual expenditure on agricultural research and development is nearly three billion U.S. dollars. In comparison the CGIAR, which is the largest international public sector supplier of agricultural technologies, spends less than 300 million U.S. Dollars annually on plant improvement research and development.*” (Emphasis added)<sup>85</sup>

Therefore, this, when viewed in the context of the advocacy of Pingali and Raney (as rearticulated), i.e., that “[a] strong public sector – working cooperatively with the private sector – is essential to ensure that the poor benefit from the Gene Revolution”, unequivocally indicates that facile ability to catalyze dynamic international collaborative research and development in agbiotech will depend on the forging of PPPs as engines to drive the Gene Revolution and thereby address food security in India.

Hence, as this clearly implies, advanced innovations in agriculture, largely owned by the private sector, will be the fuel to drive the Gene Revolution. The ability to identify, access, absorb, adapt and apply such agricultural innovations to the given agricultural challenges which developing countries need to address will determine how effectively the Gene Revolution can be implemented, which, in turn, will impact management of ongoing food security concerns in countries such as India. What will this require? A dedicated and focused commitment to strategically build capability and capacity in human capital and institutional infrastructure for managing IP and tech-transfer in

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<sup>84</sup>*Id.*

<sup>85</sup>*Id.*

order to accelerate implementation of Gene Revolution solutions for food security and poverty alleviation in India needs to be prioritized at all levels. Once again, Pingali and Raney point out that “[d]eveloping countries are facing increasing transactions costs in access to and use of technologies generated by the multinational sector. Existing international networks for sharing technologies across countries and thereby maximizing spillover benefits are becoming increasingly threatened. *The urgent need today is for a system of technology flows which preserves the incentives for private sector innovation while at the same time meeting the needs of poor farmers in the developing world.*” (Emphasis added)<sup>86</sup> The urgent need to address “a system of technology flows” is the commitment to capacity building stated immediately hereinabove. There is no alternative. The inexorable juggernaut of globalization is driving the rapid expansion of a global innovation market. Agricultural innovations are included in this market, bought, sold, leased and exchanged via various transactional mechanisms, with IP rights playing a key component facilitating transactions and movement of agbiotech innovation ultimately to where it is most needed, e.g., the marginalized, dry-land, smallholder farmers.

## CONCLUSIONS AND RECOMMENDATIONS

The reality of India’s pressing food security has been repeatedly articulated in workshops, symposia, summits, impact fora and white papers:

*“The Indian agricultural sector needs to be revitalised to meet the demand of food and nutritional security of a growing population amidst challenging situations. While the first Green Revolution helped in meeting the production demands in the 1960s, the next revolution needs to focus on holistic development of the sector and sustainable in the long run. The key to revitalising the Indian agricultural sector lies in successfully establishing an Agricultural Innovation System based on a convergence strategy, in which the civil society, public and private sector comes together to develop solutions to sustain productivity, provide opportunities for innovation leading to growth of sector and thus boost the economy. The system should leverage on the strengths of each stakeholder and harness innovative technologies in order to reform the sector which will help in supporting the livelihood of millions of people engaged in the agricultural value chain.”* (Emphasis added)<sup>87</sup>

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<sup>86</sup>*id.*

<sup>87</sup> ICRISAT, *supra* note 5.

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How can such a broad policy aspiration become strategically focused and operationally implemented? That is, what will it take to move from well-intentioned, policy-laden, sincere rhetoric towards tangible reality that is increasingly and urgently needed? It will be necessary to move away from crippling paradigms and advance towards informed strategy.

First of all, it's time to move from relentless academic analysis and policy fora towards action. For example, whereas theoretical population increase models have been applied to analyze impact that demographic momentum will have on food security in India, these sorts of analyses, albeit satisfying basic academic instincts and intellectual urges, are no longer necessary and actually quite pointless when it comes to the situation in India. Just as one might see a tractor trailer truck careening onward, it is obvious that India's convergence of population and food availability is an urgent and critically important issue that demands action and not only analysis, policy discussions and aspirational proclamations of what "should" be done. One can analyze the speed and direction of the oncoming truck with great accuracy, and then be smashed into oblivion; likewise, the food security of India can be analyzed until another famine crisis arises, perhaps several decades in the future, and one can then witness the catastrophe. Or, one can take action, and begin to build a system which will address the issues: as a sand pile will stop truck, so an efficiently functioning ag-innovation system in India will overcome food insecurity, a Gene Revolution which will foster sustainable stability and move India towards greater knowledge-based economic development.

Furthermore, in India, all too frequently, an unproductive mix of activist agendas<sup>88</sup> and misinformed anxiety dominate public discourse; as when discussions turn to IP, patents and agriculture, there is no lack of hand-wringing apprehension with little, if any, coherent analysis of the global role of IP as a property rights system that, in fact, facilitates and accelerates the movement, absorption, adoption and development of crucial innovations in agriculture. For example, whereas the hereinbelow mentioned appears to embody legitimate concerns, perhaps it would be wise to temper such angst-ridden rhetoric with a more balanced and informed appraisal (e.g., just which patents is the author referring to?) of the precise role of the IP system in driving innovation and development: "*Under the*

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<sup>88</sup> E.g. *see* Farming Free: An Interview With Food Sovereignty Activist Vandana Shiva, *available at* <http://www.motherearthnews.com/nature-and-environment/food-sovereignty-zm0z14jjzchr.aspx#axzz31nH1toEp>

*free trade agreement, it is now possible and easy for farmers to obtain patents for any innovation or charge the corporate sectors for any genetic local crop races and other natural resources used for crop improvement. A new class of patents covers plants derived from conventional breeding. These patents even claim harvest and derived food products such as milk, butter, and bread. Such patents would become a major threat to food security, food sovereignty, and innovation, since the whole chain of seed, harvest, trade, and food production might be controlled by a few big international companies, leading to a monopoly via patent laws. These consequences would be reflected in genetic resources that would be subjected to seed patents and might increase food crises. Small farmers would be deprived of access to seeds, a productive resource essential for their livelihood, and the price of food could rise, making it less affordable for poor people.” (Emphasis added)<sup>89</sup>*

Such misguided, misinformed supposition is also apparent in another report, wherein the author presupposes that in the text of the Convention on Biological Diversity (CBD) that “*The Article 8(j) ... seems to affirm that the holders (subject to national legislation) have rights over their knowledge, innovations and practices, whether or not they are capable of being protected by IPRs.*”<sup>90</sup> However, said CBD Article neither explicitly nor implicitly refers to IPR: “*Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.*” This rather alludes to the necessity of establishing functional Access and Benefit Sharing systems in the developing countries, i.e., something that is in fact being coherently addressed in India.<sup>91</sup> Furthermore, the CBD provides templates as “*[m]odel ABS agreements and model contractual clauses can also play a key role in building capacity to negotiate mutually agreed terms and promoting equity and fairness in negotiations.*” These are in the form of materials transfer agreements (MTAs, i.e., bailment of a chattel pursuant to contractual obligations).<sup>92</sup> Rights are not inherent, but need to be established via contract; ergo, these two cases

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<sup>89</sup> Gahukar, *supra* note 11.

<sup>90</sup> Rachitta Priyanka. UPOV AND RIGHTS OF FARMERS - AN INDIAN PERSPECTIVE, *available at* <http://www.intelproplaw.com/>

<sup>91</sup> <https://www.cbd.int/countries/default.shtml?country=in>

<sup>92</sup> <https://www.cbd.int/abs/resources/contracts.shtml>; See Also Bennett AB, WD Streitz and RA Gacel. 2007. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A

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(confusion over patents and misinterpretation of the CBD) reiterates the need for capacity building in tech-transfer and IP management as they relate to agbiotech and food security.

However, progressive, informed and enlightened thinking and strategic discussions are entering the public agenda on food security in India. A recent report from the National Academy of Agricultural Research Management (NAARM) provides vision and encouragement.<sup>93</sup> Building on the concept of value-added agricultural innovation, the report identifies the inherent weakness of linkages in the Indian agricultural innovation system (The Indian National Agricultural Research System, NARS), including, but not necessarily limited to inadequate human resources, inadequate tech-transfer, inadequacies in management, monitoring and evaluation, weak inter-disciplinary and inter-institutional linkages, and insufficient focus on individual and institutional learning for change. However, the report does not end on this pessimistic note, but rather optimistically advocates for dynamic capacity building, i.e., what will be necessary to drive a Gene Revolution in India: *“Institutions of NARS will need to build capacities and identify appropriate policies and institutional mechanisms for integrating new sciences and emerging technologies into agricultural research and education, and strategic management of intellectual property. They will also need to institutionalize processes for valuing and licensing technologies, engaging in public-private partnerships for research and technology transfer, and informing policy makers, farmers and consumers of the risks, benefits and safety aspects of the new technologies and products.”* Furthermore, as part of the National Academy of Agricultural Research Management (NAARM), articulated strategy would also seek to *“enhance capacities for technology foresight and strategic management of intellectual property and commercialization of technologies.”*

The challenge, therefore for India, will be the proper, careful, thoughtful application of IP and tech-transfer to the agricultural innovation system, that is, appropriate for accelerating India's innovation base towards sustainable food security. In other words, what is needed is capacity in IP and tech-transfer, structured in such a way that it takes into account the developmental context of Indian agbiotech innovation. This will likely necessitate the ability to identify, import and adapt innovation

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Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at [www.ipHandbook.org](http://www.ipHandbook.org).

<sup>93</sup> National Academy of Agricultural Research Management, *supra* note 16.

as much as, if not more than, indigenous invention and innovation. Such a tailored approach is consistent with the observations of Ray and Saha, who have stated that:

*“Universities, institutes and laboratories, which are the pillars of public-funded research in India, do not uniformly perform in terms of the quality of research or human resource generation. Only a handful of premier institutes and universities can compare themselves with international standards. Such a skewed research performance may be linked to the concentration of good minds in the top-tier institutions only. Therefore, it remains to be seen how a uniform IP law can be tailored to suit every tier of the quality spectrum in India, if at all. Different constituencies are expected to respond differently to a new institutional framework triggered by a new law. It is here that one fears that a “one size fits all” approach could prove to be counter-productive. [What has] worked very well in some cases, the Silicon Valley around Stanford University and the Route 128 around MIT [might not be appropriate for developing countries]. [I]f we attempt to replicate these models in universities in India or elsewhere simply by institutionalizing IPRs for academic research, ignoring the realities of the differences in context, environment, culture and levels of scientific achievements, we may end up with misplaced priorities.”<sup>94</sup>*

A carefully structured strategy which takes into account India’s current agbiotech base and the likely need to identify, access, absorb and adapt agbiotech is conceptually consistent with the open-innovation paradigm. *“Open innovation stresses that organizations should use external as well as internal knowledge to drive innovation and advance technology towards commercialization”*.<sup>95</sup> Under the open-innovation concept, innovation moves in multiple directions as it flows through the global system. In rapidly emerging global knowledge-based economy, organizations must not rely solely on their own research efforts, but should instead buy or license patented processes or articles as inputs when necessary to accelerate their technological progress. Hence, a rapidly emerging technospace is increasingly driven by economic opportunities for development and new applications, leading to an omni-directional and global tech-transfer ecosystem, yielding spillovers of technologies from the developed countries to be absorbed by the developing countries.”<sup>96</sup> Recognizing this fundamental concept of the global technospace and open innovation, there are several models for building

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<sup>94</sup> Amit Shovon Ray and Sabyasachi Saha, *Patenting Public-Funded Research for Technology Transfer: A Conceptual-Empirical Synthesis of US Evidence and Lessons for India*, 14 THE J. OF WORLD INT. PROP. 1, 75 (2010).

<sup>95</sup>Hennessey et al., *supra* note 42.

<sup>96</sup>*id.*

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agbiotech innovation in India: “[T]hree possible avenues for public sector institutions in developing countries to gain access to transgenic technologies [could be]: (i) directly import private or public-sector transgenic varieties developed elsewhere, (ii) develop an independent capacity to develop and/or adapt transgenic varieties, and (iii) collaborate on a regional basis to develop and/or adapt transgenic varieties.”<sup>97</sup> This is particularly the case with advanced/appropriate agricultural innovations, e.g., Golden Rice, wherein multiple components and processes are assembled/embedded in order to develop a rice variety which can supplement vitamin A dietary requirements; appurtenant IP rights related thereto required careful management (e.g., via an efficient PPP that brought together an international group of both public and private stakeholders), which is precisely such a task the Agricultural Innovation Academy might have undertaken.<sup>98</sup>

Therefore, in India, food security in the coming century will depend on widespread improvements in national agricultural production systems, which, in turn will depend on how well India can connect to and function in the global innovation system. Perhaps it also should be mentioned that a...

*“system is a set of interdependent components forming an integrated whole, involving elements and relationships wherein there is movement and interaction. Agricultural innovations, e.g., agbiotech, increasingly exist in a global innovation system, said system including the developers, producers and owners of agbiotech; the various laws and treaties (including IP laws such as patent, PVP, trade secrets and germplasm) that regulate the protection, flow of, and access to agbiotech; and the elements (technological components and processes which comprise agbiotech) which includes crop varieties, germplasm resources, plant genetic resources, biodiversity and advanced agbiotech (e.g., genetic engineering inputs, and tools, such as genomics, gene maps and banks). The interconnectivity of these components forms a global innovation marketplace. The functioning of every component in this system determines its overall efficiency—the costs of transacting between the components is key. With adequate human resource capacity and capability, a developing country should itself be able to identify and access multiple pieces of agbiotech in this open innovation market.”<sup>99</sup>*

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<sup>97</sup> Pingali, *supra* note 83.

<sup>98</sup> Hennessey et al., *supra* note 42.

<sup>99</sup> *Id.*

The components comprising an Indian agricultural innovation system are present, more or less, in each category, e.g., laws and treaties related to IP, tech-transfer and crops are in place; nascent tech-transfer capacity and capability, as shown herein, has been established; an agricultural research and development infrastructure has been present for years. However, there is an imbalance and lack of connectivity among these systemic components, which impede efficient functioning of an agricultural innovation system in India, so sorely needed to address impending food security challenges. For example, in the public research and development sectors of India, much remains to be done with regard to tech-transfer capacity building:

Apart from elite scientific institutions that have institutionalized some policies and practices, only 5 percent of the research organizations have technology transfer offices like in Indian Institute of Technology (IITs). There are very few skilled people to handle technology transfer and licensing in India, and academic institutions do not have patent cells except a few academic institutions. According to the Department of Biotechnology (DBT) almost 60 percent of institutions do not have policy guidelines for patent cells.<sup>100</sup>

Whereas the government of India has, ostensibly, articulated the urgent priority of building a science, technology and innovation infrastructure and system in the country, it remains to be seen how this might be implemented in a coherent, sustainable manner:

The principal governmental body responsible for the development of science and technology and for promoting, organizing and coordinating science and technology activities in India is the Department of Science & Technology (DST). One of the principal responsibilities of DST is to formulate policy statements and guidelines on science and technology [e.g.] the Science and Technology Policy (2003). With respect to technology transfer, the policy states that “*every effort will be made to achieve synergy between industry and scientific research*” and that “*autonomous Technology Transfer Organizations will be created as associate organizations of universities and national laboratories to facilitate transfer of the know how generated to industry.*”<sup>101</sup> (Emphasis added)

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<sup>100</sup> Rajashree Sharma, *Public Funded Research in India – A Reckoner on Recent Legislative Actions*, 45 LESNOU 255 (2010).

<sup>101</sup> Siripurapu, *supra* note 58.



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Albeit “every effort will be made to achieve synergy” suggests aspirational sincerity at some level as well as a measured degree of comfort and assurance, it is totally insufficient for building an agricultural innovation system that will drive the Gene Revolution in India. To address the pressing national issue of food security in India, tangible and strategic actions are needed: An Agricultural Innovation Academy in India must be established, for example this could be hosted/situated at NAARM as part of implementation of its Vision 2050 strategy.

The general concept of an IP-focused Academy as a nationally-centralized, IP capacity-building, innovation-accelerator has been proposed, in one form or another, for decades. An Agricultural Innovation Academy in India could serve as an institutional platform which anchors IP/development activities and thereby fosters and facilitates sustainable progress; from a pragmatic operational perspective in India, NAARM is one possible location for an Agricultural Innovation Academy. As articulated by Hennessey et al., such capacity building organization can function as the hub from which IP and tech-transfer networks, capacity, capabilities and expertise radiate, i.e., spokes from the hub; however, resources need to be focused and strategically organized in order to achieve sustainable forward momentum. *“Pragmatically speaking, developing countries need personnel trained in tech-transfer, IP management and related business, technical and legal disciplines. These personnel need to be focused in institutional entities, whether called **ITECs**, **TTOs** or **TISCs** ...”*<sup>102</sup>

A supportive legal environment is necessary but not sufficient for... effective technology transfer ... must be supplemented by the establishment of an Innovation and Technology Entrepreneurship Center (ITEC) to handle ... spinning-in, adapting for local use, and spinning-out technology. This organization can either be a newly established entity or an existing unit within an established organization (Inclusive Innovation Center or university technology transfer centers), retrofitted to carry out new functions.

A framework to allow technology transfer to the public institutes of developing countries must be stimulated and developed. This has been addressed in some countries by the establishment of TTOs. TTOs are often located in a governmental unit associated with some aspect of agriculture. These offices work with researchers, allowing them to develop new crop varieties, and with government

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<sup>102</sup>Hennessey et al., *supra* note 42.

officials to develop appropriate laws and policies for intellectual property protection. They develop means for providing plant variety protection, biotechnology invention protection and intellectual property management. TTOs can play multiple roles in research and development (R&D) institutes, [including] protection of intellectual property ... revenues through licensing of intellectual property ... education and awareness, networking ... creation of new start-up companies ... institutional policies related to technology transfer [and] service to society.

Technology Innovation Support Centers (TISCs) act as service-oriented providers to: allow local users to benefit effectively from the increased accessibility of intellectual property information offered by internet searches through direct personal assistance; assist local users in creating, protecting, owning and managing their intellectual property rights; strengthen the local technological base by building up or reinforcing local know-how, and to increase technology transfer, e.g. by investigating the possibilities of licensing, joint ventures, etc. In short, TISCs are established so as to act as local drivers of innovation. The training of TISC so as to be able to assist local users and deliver these services is one of the most important elements ... and while initial training may be focused on searching patent and non-patent technology databases ... further training in other areas of intellectual property rights is considered particularly useful, as it not only continues to develop staff knowledge and their personal development, but also offers a one-stop-shop as regards other elements of intellectual property rights and of innovation support.

Another key component for an Agricultural Innovation Academy agenda would be to provide the tools, knowledge and motivation for fostering the formation of public-private partnerships (PPPs), collaborative endeavors to accelerate the development and deployment of crucial innovations in agbiotech. In PPPs, IP (as both an asset and tool) can function as a property-rights-system mechanism which operationalises transactions. This facilitates and accelerates the movement of technology and innovation across the globe, *i.e.*, both into and out of the Indian agricultural innovation system. IP will also enhance financial sustainability for agricultural innovation-driven development in India, via incentives for investment, licensing revenue and attracting venture capital for start-up companies, spin-off initiatives and related Small and Medium Enterprises (SMEs). Furthermore, in PPPs, SMEs need to become leaders in agricultural innovation development and commercialization in India, and hence need to become active participants in the IP and tech-transfer capacity building initiative that will flow from the Agricultural Innovation Academy.

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In summary, the concept of the Agricultural Innovation Academy seeks to build beyond the five percent of elite universities, where IP management and tech-transfer already (more or less) exist, to the other 95 percent, to foster the institutional infrastructure, networked human capital and capacity needed to address food security in India, towards the Gene Revolution. A commitment towards investing in building a core resource which advances food security in India, driving a Gene Revolution, would therefore be a grand gesture and a most auspicious occasion for the celebration of the 70<sup>th</sup> jubilee gala of India's independence. Indeed, the opening and launch of an Agricultural Innovation Academy at NAARM would signal to India and the world that strategic investment in and management of IP is a key factor in accelerating tech-transfer capacity building, and thereby access to, absorption, adaption and utilization of agbiotech for the benefit of all in India. How better to celebrate India's global leadership, as the assembled throng, singing the national anthem of India, paying homage to the national flag and standing together, confident in knowing that food security for all of India forms the unshakable foundation for the nation's continued development into a global innovation power.

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## A LEGAL-COMPARISON OF THE INDIA SOFTWARE LAW AND THE SOFTWARE LAW OF GERMANY

Thomas E. Soebbing\*

*India has emerged as one of the leading destinations for offshore outsourcing in the software industry and has attracted the attention of software industries of several countries including Germany. In order to sustain this outsourcing relationship, the legal frameworks of these countries play a very important role. In this article, the author conducts a comparative analysis of Indian and German laws that impact the software industry, mainly dealing with three fields: first, Copyright Law impacting the protection of intellectual rights over software; second, Contract Law specifically dealing with software contracts and nature of such transactions and, finally, the remedies available in both the countries under their civil, criminal and administrative law to ensure protection of software.*

### I. IT-ITES MARKET IN INDIA AND GERMANY

The Information Technology- / Information Technology Enabled Service industry (IT-ITES) and the business process outsourcing (BPO) sector are major parts of the economy of India. The growth in the service sector in India has been led by the IT-ITES/BPO sector, contributing substantially to an increase in GDP, employment, and exports. The sector has increased its contribution to India's GDP from 1.2% in FY1998 to 7.5% in FY2012. According to NASSCOM, the IT and BPO sector in India aggregated revenues of US\$100 billion in FY 2012, where export and domestic revenues stood at US\$69.1 billion and US\$31.7 billion respectively, growing by over 9%.<sup>1</sup> Export dominates the IT-ITES /BPO services, and constitutes about 77% of the total industry revenue.

In 2013, the German chamber of IT business (called 'Bitkom') estimated in its report in 2013 that the German market for information-technology and telecommunication (without the BPO – business) at a value of €153 billion (≈US\$203 billion or ≈ Rs.13.739 billion). The Top Five Indian IT

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<sup>1</sup> NASSCOM, *The IT-BPO Sector in India: Strategic Review 2012* (Retrieved 15 December 2012.)

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service providers<sup>2</sup> also find the German information technology and telecommunication market to be of great importance as well. The Germans like the know-how, quality and the costing of the Indian software engineers, and thus all of the Top Five Indian IT service providers have branches in Germany. The Germans call the IT business with India IT service providers: "Offshore or Offshoring."

Cost is definitely one of the main reasons for offshore outsourcing, but it is not the only reason. When a company decides to outsource developed software, it needs to factor in the initial investment needed in terms of infrastructure, recruitment, training etc. while the cost advantage is seen much later. Along with value addition, there are savings in offshore outsourcing, but outsourcers will realize the quality and value addition only after the outsourcing begins. Offshore outsourcing also leads to immense time saving, while maintaining quality and higher productivity. As reported by NASSCOM,<sup>3</sup> "India's great attraction as an outsourcing destination is its unbeatable value proposition and the PQR (Productivity, Quality and Rate) factor. Key drivers of global offshore outsourcing, along with India's strengths, are continuing to stoke the Indian ITES-BPO growth engine. India is at an advantageous position due to its active government support and stable political climate. According to a leading advocate of cyber laws, 'India is the 12th nation in the world that has cyber legislation apart from countries like the US, Singapore, France, Malaysia and Japan.'

The increase in offshore outsourcing is driven by a combination of the following factors:

*Firstly*, its visibility has encouraged more conservative companies to experiment with offshore outsourcing for competitive reasons.

*Secondly*, broadening of the IT services offered by offshore companies like Wipro and Infosys.

*Thirdly*, the establishment of captive offshore centres by user companies for their business processes.

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<sup>2</sup> The top five Indian IT services providers are Tata Consultancy Services, Infosys, Cognizant, Wipro and HCL Technologies. See <http://www.nasscom.in/industry-ranking> (Retrieved March 22, 2015).

<sup>3</sup> NASSCOM, *supra* note 1.

And *lastly*, Onshore IT and service vendors setting up shops in countries like India and China.

A great goal for the IT-ITES industry of India is the development of the new core-banking-system of Germany's largest bank: Deutsche Bank. Tata Consultancy Services won this project and designed new IT processes based on the SAP software. Approximately 1200 employees are expected to have worked on the mammoth project (called "Magellan").<sup>4</sup> In the end, the bank wants to save 250 million euros ( $\approx$ US\$331 million or  $\approx$  Rs. 21229 million) per year. Such projects of Deutsche Bank are great indicators for business-and IT trends in Germany.

## II. BASICS OF INDIA'S AND GERMANY'S SOFTWARE LAW

The Indian software law is based on the Indian Copyright Act. The Copyright Act, 1957(Act No. 14 of 1957) governs the laws & applicable rules related to the subject of copyrights in India. "Literary work" includes computer programmes (software), tables and compilations including computer databases (Sec. 2(o))<sup>5</sup>. Copyright Law in the country was governed by the Copyright Act of 1914, which was essentially an extension of the British Copyright Act, 1911 to India, and later borrowed extensively from the new Copyright Act of the United Kingdom of 1956. All copyright related laws are governed by the Copyright Act, 1957.<sup>6</sup>

The Copyright Act today is compliant with most international conventions and treaties in the field of copyrights. India is a member of the Berne Convention of 1886 (as modified at Paris in 1971), the Universal Copyright Convention of 1951 and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of 1995. Though India is not a member of the Rome Convention of 1961, WIPO Copyrights Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT), the Copyright Act is in compliant with it.

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<sup>4</sup> Christiane Putter, *Das Milliarden-SAP-Projekt der Deutschen Bank*, COMPUTERWOCHE (Published November 14, 2011; retrieved on March 22, 2015).

<sup>5</sup> Vermy in DER INTERNATIONALE SOFTWAREVERTRAG (THE INTERNATIONAL SOFTWARE AGREEMENT), 598 (2<sup>nd</sup> edn., 2006).

<sup>6</sup> THE INDIAN COPYRIGHT ACT, 1957.

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The German Copyright Law (which includes the Software Law) evolved to a certain extent from the European Union (EU). Most European Union directives<sup>7</sup> were transferred into the German Law, including the very important EU Software directive. Nearly 20 years ago the EU Commission decided to unify, the legal protection for software in the EU Member States. The Directive on the legal protection of computer programs (91/250/EEC) stipulates that, among other things, computer programs are protected by copyright as literary works. The Council Directive 91/250/EEC has formally been replaced by the Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs on May 25, 2009,<sup>8</sup> which consolidates the various minor amendments the original directive has received over the years.<sup>9</sup> The differences between the copyright laws of the European Union Member States are rather small. If one understands the German Copyright Law there is no big challenge to understand the Copyright Law of other Members of the European Union. The Germans call their Copyright Law as "*Urheberrechtsgesetz*" (the short form of which is "*UrbG*").

### III. PROTECTION OF SOFTWARE

The Indian Copyright Law 1957 defined computer programs (software) in Sec. 2 (ffc) as follows: "*Computer program means a set of instructions expressed in works, codes schemes or in any other form, including machine readable medium, capable of causing a computer to perform a particular task or achieve a particular result.*" Computer programs (software) includes many items like the programmed manuals and papers, computer printouts, punch cards containing information in a particular notation, magnetic tapes and

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<sup>7</sup> A directive is a legislative Act of the European Union, which requires member states to achieve a particular result without dictating the means of achieving that result. It can be distinguished from regulations which are self-executing and do not require any implementing measures. Directives normally leave member states with a certain amount of leeway as to the exact rules to be adopted. Directives can be adopted by means of a variety of legislative procedures depending on their subject matter. *See further:* Nanda, Ved P. (1996); Folsom, Ralph Haughwout; Lake, Ralph B. eds. *European Union law after Maastricht: a practical guide for lawyers outside the common market*, The Hague: Kluwer. p. 5. "The Union has two primary types of legislative acts, directives and regulations.

<sup>8</sup> Articles 10 and 11 of the Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs, L 111/16 EN, OFFICIAL JOURNAL OF THE EUROPEAN UNION (May 5, 2009).

<sup>9</sup> Jeremy Phillips, *Tuesday tiddlywinks*, IPKAT, (Published May 5, 2009.)

discs required for operation of computers. Computer databases are protectable under the copyright law in India as literary work<sup>10</sup> even when they only involve "sweat-of-the-brow" and may not involve any creativity or selections skill.<sup>11</sup> The Indian courts in numerous cases have attributed the same meaning to "originality" as under British law.<sup>12</sup> "Originality" for the purpose of copyright law relates to the expression of thought and is not concerned with the originality of ideas; and in the case of literary work, with the expression of thought in print or writing (in a concrete form). The degree of originality required for copyright protection is minimal; the emphasis is more on the labour, skill, judgement and capital expended in producing the work. To acquire a copyright, no formalities are required. It can be registered with the copyright office. But a copyright may exist in a work even if it is not registered and receives protection from the moment the work is being created. Registration will, however, be valuable in the enforcement of copyright.<sup>13</sup>

If software or an intellectual property wants protection by the German Copyright Act the threshold for the intellectual input required is high. In Germany and other States of European Union an IP must be higher than a special level of creativity (in German "Schöpfungshöhe") and it must be an intellectual work (German "werk"). The requirements for reaching the special creativity level as required under Sec. 2 UrhG are:<sup>14</sup>

There must be a personal creation of the author.

It must have an intellectual content.

It must have a tangible form.

There must be individuality of the author expressed therein.

This is not commonly important for a protection of software, but it is very important for the products around the software, such as documentation, business blue print, concepts and so on.

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<sup>10</sup>*Shyam Lal Paharia v. Gaya Prasad Gupta*, AIR 1971 All 182 (High Court of Allahabad).

<sup>11</sup>*Govindan v. Gopalakrishina*, AIR 1955 Mad 391 (High Court of Madras); *Burlington Home Shopping v. Rajnish Chibber*, 61 (1996) DLT 6 (High Court of Delhi).

<sup>12</sup> See e.g., *R.G. Anand v. Delux Films*, AIR 1978 SC 1613 (Supreme Court of India).

<sup>13</sup> Vermy in *DER INTERNATIONALE SOFTWAREVERTRAG (THE INTERNATIONAL SOFTWARE AGREEMENT)*, 601 (2<sup>nd</sup> edn., 2006).

<sup>14</sup>*Schricker/Loewenbeim*, URHEBERRECHT, 46-132 (2<sup>nd</sup> edn., 1999).



Generally these things are protected under Sec. 2 UrhG. For the protection of software the intellectual activity has to be very high. The special level of creativity for software is based on the "Theory of small coin" (German: "Lehre der kleinen Münze"). The Theory of small coin originates from the Latin Law and means all things for which one can pay with a small coin. In Germany and other States of the European Union, software is protected by the Copyright Act, if the software is not a "bagatelle" programming. A definition of bagatelle programming the term cannot be clearly defined. The courts decide case by case what a bagatelle programming is or what it is not. But it is not really a question in the legal practice in Germany or in the European Union.

#### IV. CONTRACT LAW

There is no specific law in India governing computer software like China. A computer software contract (called "*Software license agreement*") is governed by the common law principles as embodied in the Indian Contract Act 1872. If the software is classified as "goods", the Sale of Goods Act 1930 will also have relevance since it deals only with moveable goods and not with the tangible aspects of the goods.<sup>15</sup> The Sec. 2 (7) of the Sale of Goods Act defines "goods" as "*every kind of movable property other than actionable claims and money, and includes stocks and shares, growing crops, grass ...*" This definition is very wide and includes all types of movable properties, whether those properties are tangible or intangible. It would become a good provided it has the characteristics thereof having regard to (a) its utility; (b) capable of being bought and sold; and (c) capable of being transmitted, transferred, delivered, stored and possessed. If a software whether customized or non-customized satisfies these characteristics, the same would be goods.<sup>16</sup> In the judgement of *Commissioner of Sales Tax v. Pradesh Electricity Board*, electricity was considered as "goods" irrespective of its nature, or whether it was tangible or non-tangible, as it is capable of abstraction, consumption and use.<sup>17</sup> In case of *TCS v. State of Andhra Pradesh*, the Supreme Court of India considered computer software as "goods" and stated that

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<sup>15</sup> *TCS v. State of Andhra Pradesh*, 271 ITR 401 [2004] (Supreme Court of India).

<sup>16</sup> *TCS case, id.*

<sup>17</sup> *Commissioner of Sales Tax v. Madhya Pradesh Electricity Board* (1969) 1 SCC 200 (Supreme Court of India).

"even intellectual property, once it is put on to a media (e.g. Disk, CD or DVD)" would be treated as such.<sup>18</sup>

The law of India provides no specific form for software-contracts. But for valid software-contract it is important that there is an offer, an acceptance of that offer or proposal and consideration for that offer and acceptance. A software-contract based on Indian law must be covered by the licensing of computer software. The licensing gives the licensee a restricted right to use the software. The term of the license specifies the duties of the licensee of varying degrees. Thus it will be governed by the law of contract. In reference to Sec. 30 of the Copyright Act (India), "*the owner of the copyright in any existing work or the prospective owner of the copyright in any future work may grant any interest in the right by license in writing signed by him or by his duly authorized agent.*" An owner of the copyright may assign to anyone the copyright either wholly or partially and either generally or subject to limitations and either for the whole term of the copyright or and thereof. The assignment needs to be in writing to be valid. E.g. the licensing gives the licensee an exclusive or non-exclusive right to use the software.

It is not clear in the German jurisdiction whether software is classed as "goods".<sup>19</sup> The German Supreme court (called Bundesgerichtshof, short form BGH) means software is not a thing ("goods"), but is to be treated as thing/goods.<sup>20</sup> Thus it is very important to determine if software is a good or to be treated as things/goods under the German sales law (sec. 433 ff. BGB) and if other sections of the German civil code are applicable. The form of the right to use the software is based in the German Copyright Act (UrhG). The author may grant a right to another to use the work in a particular manner or in any manner (exploitation right).<sup>21</sup> An exploitation right may be granted as a non-exclusive right or as an exclusive right, and may be limited in respect of place, time or content.<sup>22</sup>

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<sup>18</sup> Vermy in DER INTERNATIONALE SOFTWAREVERTRAG (THE INTERNATIONAL SOFTWARE AGREEMENT), 778 (2<sup>nd</sup> edn., 2006).

<sup>19</sup> Sec. 90, BGB (German Civil Code): Goods in the sense of things.

<sup>20</sup> BGH, 04.11.1987 - III ZR 314/86 = BGHZ 102, 135; NJW 1988, 406; NJW-RR 1988, 312 (Ls.).

<sup>21</sup> Sec. 31 I S. 1 UrhG (German Copyright Act).

<sup>22</sup> Sec. 31 I S.2 UrhG (German Copyright Act).

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In a software-contract (license) the owner of copyright gives the exclusive or non-exclusive right to use the software.<sup>23</sup> The non-exclusive right of use entitles the right holder to use the work only as allowed by contractual terms and without exclusion of possible usage by a third party, Sec. 31 S.2 UrhG. For example, the author can grant a non-exclusive right of using a stage play to not just one but several theatre ensembles. The exclusive right of use entitles the right holder to use the work exclusively as allowed by contractual terms meaning no other person can be given the (exclusive) right of using a stage play to only one theatre ensemble. The right holder, however, can be given the right of independently granting non-exclusive rights of that work if the author agrees, as per Sec. 31 III 1 UrhG. German law does not discriminate between the grant of non-exclusive or exclusive use rights to the software, i.e. the Germans look at the content and purpose of the transferred IPRs, the Germans call it purpose of transmitting doctrine (in German “*Zweckübertragungslehre*”). The purpose of transmitting doctrine holds that copyright confers the rights in question only to the extent that it is necessarily required according to the contract purpose. This follows from Sec. 31 UrhG. The relevant paragraph reads: *"If upon the granting of usage rights not expressly designated uses individually so determined by the two partners of underlying purpose of the contract, on which types of use which it extends. The same applies to the question whether a right is granted to use, whether it be a simple or exclusive right of use is how far right of use and legal prohibition and restrictions subject to which the right of use."*<sup>2</sup>

The author of a work may freely decide about its use. To allow usage rights, what type and extent of the use, transfers to the appropriate legal or natural person have to be determined in a (oral or written) contract. This requires an agreement between the parties, which however is not bound to any form. If it cannot be discerned from the terms of the contract what rights should be transferred for use, then only the use rights necessary for the fulfilment of the contract are transferred (see Sec. 31 UrhG).

A contract which grants the rights for unknown or undecided types of use is required to be reduced into the written form (see Sec. 31a UrhG). Through this scheme, the contractor may be sure the work - in the context of usage to meet the contractually specified purpose - to use legitimate, even if no other arrangements are made in the contract. Therefore, the purpose for the transfer of teaching practice is of crucial importance.

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<sup>23</sup> Sec. 31 I S. 2 UrhG (German Copyright Act).

## V. PROTECTION OF SOFTWARE

The protection of software is very important in both India and Germany. In India there are three types of remedies provided under the Act against any infringement of copyright: civil, criminal and administrative.

In reference to Sec. 55 of the Copyright Act (India) the civil remedies under the Act include injunction, damages or account of profits, delivery-up of infringement copies and damages for conversion. In the case of innocent infringement, some of these remedies are not available.<sup>24</sup> A lawsuit or other civil proceeding relating to infringement of copyright is to be instituted in the concerned district court within the local limits of whose jurisdiction, at the time of the institution of the suit or other proceedings, the plaintiff resides or carries on business<sup>25</sup>. This is in contrast to the normal rule under the Civil Procedure Code, which dictates that a suit must be filed in the court in whose limits an action has arisen or where the defendant resides. For the purposes of remedies, "owner of copyright" includes an exclusive licensee also.<sup>26</sup>

For criminal remedies the Copyright Act (India) makes copyright infringement a cognizable offence and empowers the police to take action against pirates/infringers by seizing the infringing property and arresting the persons responsible. In reference to Sec. 63 of the Copyright Act (India) the offence of infringement is punishable with imprisonment, which shall not be less than six months but may be extended up to three years and a fine of Rs. 50,000 to Rs. 200,000. In reference to Sec. 63-A of the Copyright Act (India):

*"Whoever having already been convicted of an offence under Sec. 63 is again convicted of any such offence shall be punishable for the second and for every subsequent offence, with imprisonment for a term which shall not be less than one year but which may extend to three years and with a fine which shall not be less than one lakh rupees but which may extend to two lakh rupees: Provided that [where the infringement has not been made for gain in the course of trade or business] the court may, for adequate and special reasons to be mentioned in the judgment impose a sentence of imprisonment for a term of less than one year or a fine of less than one lakh rupees: Provided further that for the*

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<sup>24</sup> Ss. 55(1) and 58, INDIAN COPYRIGHT ACT, 1957.

<sup>25</sup> S. 62, INDIAN COPYRIGHT ACT, 1957.

<sup>26</sup> Vermy in DER INTERNATIONALE SOFTWAREVERTRAG (THE INTERNATIONAL SOFTWARE AGREEMENT), 778(2<sup>nd</sup> edn., 2006).

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*purposes of this Sec., no cognizance shall be taken of any conviction made before the commencement of the Copyright (Amendment) Act, 1984.]”*

For administrative remedies, the Registrar of Copyright, who or his authorized agent, on an application by owner of copyright or his duly authorized agent for banning the import of infringing copies into India may enter any ship, dock or premises where any such copies may be found and confiscate the infringing copies.

In Germany the copyright of software is also protected by civil law and criminal law. An administrative remedy in Germany is not possible, but in civil law it is a way for an injunction like an administrative remedy.

In the case of copyright infringement, the plaintiff may sue for injunctive relief under Sec. 1004 BGB (German civil code).

**Sec. 1004 Claim for removal and injunction:** (1) if the ownership is interfered with by means other than removal or retention of possession, the owner may require the disturber to remove the interference. If further interferences are to be feared, the owner may seek a propitiatory injunction. (2) The claim is excluded if the owner is obliged to tolerate the interference. ..

Furthermore, the plaintiff can claim damages if he has a contract with the injured from Sec. 280 BGB (the central Sec. for a breach of contract in German Civil Law).

**Sec. 280 Damages for breach of duty:** (1) If the obligor breaches a duty arising from the obligation, the obligee may demand damages for the damage caused thereby. This does not apply if the obligor is not responsible for the breach of duty...

Otherwise in tort law from Sec. 823 BGB Liability in damages, the central Sec. of tort law in German: “(1) *A person who, intentionally or negligently, unlawfully injures the life, body, health, freedom, property or another right of another person is liable to make compensation to the other party for the damage arising from this.* (2) *The same duty is held by a person who commits a breach of a statute that is intended to protect another person. If, according to the contents of the statute, it may also be breached without fault, then liability to compensation only exists in the case of fault.*”

Criminal copyright infringer can receive up to three years in prison. The Copyright Act states in Sec. 106 UrhG: “(1) *Whoever duplicated in other than the manner allowed by law without the consent of the person entitled to a work or an adaptation or transformation of a work, distributed or publicly reproducing, is punished with imprisonment up to three years or a fine. (2) The attempt is punishable.*”

## V. FINAL WORDS

The comparison of Indian software law and the German software law, shows that the software law in both countries is not so different. The protection of software is very important because manufacturing and marketing of software requires a lot of money. To protect the investment in software development, you always need a good legal system and enforcement of judgement.

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