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Editorial Introduction

K. Ravi Srinivas*

Welcome to this issue of ABDR. In this issue also, we offer you a rich content which we hope will be of interest to you.

Although technology transfer may seem to be a simple process it is a complicated one. Developing innovations and making them available as affordable innovations is essential for innovations in health sector, particularly the ones based on biotechnologies so that the society derives the maximum benefit from them and from investments in R&D. The gap between innovation and successful adoption often becomes insurmountable and the idea of valley of death in innovations is too well known.[1] The path to be traversed from laboratory to user is not an easy one and there are many number of constraints that make the path harder and the journey more difficult. Tripta Dixit and her colleagues have addressed the issues in translating innovations in health care to affordable products and services. They have suggested significant changes in the current innovation landscape in health-related R&D and have given emphasis to technology transfer and realising the potential of the innovation. After an extensive study of the current innovation and regulatory landscape they have proposed that Department of Biomedical Technology (DBMT) be set up under the Ministry of Science and Technology. For enabling technology facilitation five regional centres, i.e. East, West, Central, North and South) are proposed to be set up. At the national level there will be a National Biomedical Technology Authority (NBMTA) with three management division and five core divisions. The five core divisions are Translational Division, Human Research Development, Liaising Division, Technology transfer Division and Entrepreneurial Support Division. The authors contend that this Matrix organisational structure is well suited for translational research and technology transfer. They suggest that Government may bring in an Act for supporting and expediting commercialisation of indigenous health

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technologies and services, giving emphasis to inclusive innovation. Prima facie, the proposed structure looks agile and can be an effective model in integrating various organisations and processes in innovation in health care technologies. But more than the structure and processes, the functioning of a system is influenced by many factors including the support from government, the quality of human resources and the enabling environment. In my view the proposed model deserves a serious consideration.

The role of Intellectual Property Rights (IPR) as an incentive and as a right over the innovation is often debated particularly in the context of access to medicines. With the harmonisation of the global IPR regime through the Trade Related Intellectual Property Rights (TRIPS) Agreement, the controversies have been recurring on the role of IPR and the need to regulate them so that a proper balance is struck between needs of the society and the incentivisation function and right over the innovation. Sabuj Kumar Chaudhuri in his article uses the lens of value pluralism to analyse the role of IPRs and the controversies over (mis)use of IPRs in innovations and suggests alternatives besides taking up two case studies to underscore the arguments he makes. In this long article he traverses among philosophy, public policy, case law and various Acts/Agreements. This article is a valuable addition to the literature as the author develops a holistic perspective without arguing that IPRs are irrelevant and by examining the available alternatives approaches for incentivising innovation in drug R&D.

Finally in the review article , two volumes are reviewed and the various views are briefly discussed. The two volumes deal with IPR in microbiology, and, in biotechnology.

Your comments, responses and ideas are welcomed

Endnote

[1] https://blogg.pwc.no/digital-transformasjon/bridging-the-technological-valley-of-death

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Translational Model of Healthcare Innovations in India

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Abstract: Inclusive innovation & indigenous development of affordable solutions is the much needed remedy for India's challenge of the low translational rate of healthcare technologies. A study is conducted to understand Indian Technology Transfer landscape and functional analysis of Technology Transfer entities, with qualitative dataset collected from six Indian Technology Transfer entities having different models of Technology Transfer for health technologies. The study provides comprehensive strength, weakness, opportunity, and threat (SWOT) analysis of current Indian Technology Transfer Entities. This has encouraged addressing an inevitable need of a robust translational healthcare model. The study proposes a translational model based on five major translational factors viz. Translational Activities, Human Resource Development, Liaising Activities, Technology Transfer, and Entrepreneurial Support. The model uses a matrix approach to have a focal authority (National Biomedical Technology Authority) with decentralized approach at its five regional facilitation centres (Regional Biomedical Technology Facilitation Centres) and a blue print towards regional development. Further, proposes a platform for sustenance and integrative approach for existing translational capacities.

Keywords: Healthcare Innovation, Translational model, Technology transfer, Policy

Introduction

The need for an efficient healthcare system is well acknowledged in view of the increased dual disease burden, out-of–pocket expenditure and public demand for quality healthcare services. (Bank, 2014), (Patel *et al.* 2015),

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(Kruk *et al.* 2016) and (Reddy *et al*. 2011). The inadequate availability and accessibility of affordable solutions, points to the possibilities of either insufficient research for the healthcare solutions or low translation rate. In quest of achieving universal health coverage (UHC) and the sustainable development goals in sight (Prinja and Verma 2011), approach of developing cost-effective health solutions in improving population health and health equity will be critical. The healthcare solutions in form of technology, serve as tool for socio-economic development, security, strength, international competitiveness, global recognition for a country. The translation phenomenon of healthcare solutions is most demanding and entails diligent involvement of various stakeholders such as academia, clinical researchers, healthcare industry, regulatory authorities and hospitals for its involvement of human health. It is rightly referred as 'Translation Continuum', to be supported by skilled technology transfer professionals to guide through the path since inception till commercialisation and public outreach (Drolet 2011). It is an acknowledged fact that US Bayh Dole Act 1980 (Franzoni, 2007) established the significance of utilising innovative capabilities for economic development, marking the onset of innovation and translation ecosystem. Followed by Lundvall (2007) and Freeman, outlining the translation ecosystem and coining the term National System of Innovation giving a definition to technological development of an idea and defining its journey till commercialisation along with complex set of actors in the system, such as enterprises, universities and government research institutes etc. Thereafter, in 1990's the Triple Helix Model of Innovation (Leydesdorff and Etzkowitz, 1998) was introduced. It refers to a set of interactions between academia, industry and government to foster economic and social developments. This triple helix model served an influential alternative to the National Innovation Ecosystem.

The transfer of knowledge and innovation from research organisations/ institutes for commercial application and public benefits requires delivery channels to support translational activities, manage IP protection, etc. These delivery channels are collectively referred as Technology Transfer Entities (TTEs) in Indian context as they are called differently and vary in mandates, nature of work as per their establishment, possess different team structure, etc. some are called Industry Liaison Patent Management Office, Knowledge Transfer Organisation, Industrial interface organisation,

etc. Various Technology Transfer (TT) models have been established at different intervals of time as per realisation of need and their mandates to support the commercialisation of conducted research for public use. All activities related to TT are managed by them despite their extent of the relationship, whether an arms-length relationship or being an in-house unit in an institution or a far located company.

Over the last decades, technology transfer has been seen as playing an increasingly significant role in stimulating innovation and economic development (Siegel 2003a). Traditional TT models can be broadly classified into (i) Linear and functional models; (ii) Qualitative and Quantitative models. The linear model defines sequential activities, interactions, and tasks whereas a functional model lists important activities and describes relationship amongst them. The qualitative and quantitative models objectify the activities, factors involved and effectiveness for measuring the success (Rosa, 2007 and Amadi-Echendu, 2011). Based on the influence of key factors/activities, there are: (i) Dissemination model (Rogers, 1983), (ii) Appropriability model (Gibson, 1991) , (iii) Knowledge utilisation model (Zacchea, 1992), (iv), Licensing model (Dorf, 1987), (v) Venture capital model (Dorf, 1987), (vi) Joint venture model (Dorf, 1987), (vii) Incubator-science park (Dorf, 1987).

On reviewing traditional TT models and scenario of technology transfer (Jervis, 1947; Creighton, 1972; Jasinski, 1974; Mock, 1974; Sharif, 1983; Lee, 1994; Mian, 1994; Goldsmith, 1995; Jain, 1997; Narayan, 1997; Jegathesan, 1997; Jolly, 1997; Joseph, 1999; Bozeman, 2000; Jones, 2002; Siegel 2003b,O'Shea, 2004; Kahn, 2004; Jelinek 2006; Alaedini, 2007; Cooper, 2008; Geuna, 2008; Lockett, 2008; Nelson, 2010; Mojaveri, 2011; Purushotham, 2013; Kaushik, 2014; Dixit 2018a; Dixit 2018b), following demerits/limitations were observed, which suggested attributes accountable for this such as (i) lack of resources and expertise or lack of collaborative activities with appropriate partner to scale up technologies at industrial level, (ii) inadequate professional education in TT, (iii) lack of vision: for instance, research agenda in organisations with primary focus on fundamental or basic research often gets diluted due to unreasonable expectations of commercialisation and vice versa (Sanhita, 2014), (iv) regulatory issues which hinder commercialisation of technologies, (v) inadequate funding support or inaccessible funding support.

Over decades the basic need, buying capacity, awareness and disease burden has undergone a paradigm shift, demanding quality care and affordable solutions (Dixit, 2018a). So the pressure on government to maintain economic growth and meet the needs of people has demanded academia to generate direct economic value to the society as a whole (Mian,1994). However, India didn't have a formal translational educational agenda nor invested significantly in translational medicine education until Science Technology & Innovation policy 2013 which pronounced science and technology led innovations as a driver for development, declaring period of 2012-20 as "decade of innovations" (Dixit, 2018a). With recent initiatives of the Ministry of Human Resource Development (MHRD)[1], Ministry of Health and Family Welfare (MoHFW) to develop the practice of translational research. The Ministry of Science and Technology realised that Biotechnology holds the potential to provide affordable solutions to emerging biomedical needs and allocated a budget US$ 369.15 million for year 2019-20. As per report of Institute of Competitiveness, 2019, it has grown exponentially in size to a $51 billion industry from a $1.1 billion in 2003 and contributes approximately three percent share in the global biotechnology industry. This has been achieved with increased research in generics, biosimilars, innovative biomedical devices which is helping millions of people around the world in battling life-threatening medical issues. Further strengthened by establishment of bio-incubators, bio-clusters, biotech parks, Biotechnology Industry Research Assistance Council (BIRAC)[2], Kalam Institute of Health Technology(KIHT)[3] and Biodesign program[4], has multiplied the output, revenue and employment generation in the industry. These efforts by Indian government recognise the fact that biotechnology can revolutionise healthcare by providing affordable biomedical solutions (Dixit, 2018b). And recently, National Biopharma Mission, BIRAC, DBT imparted training to technology transfer professionals for strengthening the translation ecosystem, envisaged under the National Biotechnology Development Strategy of government of India (DBT, 2015).

Other stakeholders have also stepped in to support healthcare translational ecosystem at their end such as the Department of Science & Technology (DST) initiated Biomedical Device and Technology Development in 2017[5]; NITI Aayog promoted public-private-partnership

(PPP) in healthcare (Dixit, 2018a); NPPA provided pricing capping for essential medicines with support from NITI Aayog (Natti, 2019); Central Drugs Standard Control Organisation (CDSCO) contributed in New medical Device Rules 2017 (IBEF, 2016) and also relaxed regulatory environment for innovative healthcare solutions (Natti, 2019; National Health Policy 2017[6] being implemented for achieving universal health coverage and aim of delivering quality health care services to all at affordable cost. Indian innovation ecosystem involves public and private Research & Development (R&D) labs, academic (medical & engineering research institutes) labs and individual inventors (folklore practitioners). Therefore, a strong need was felt to understand the existing TT landscape and gaps involved in the functioning of existing TT entities to identify the weaknesses/concerned skills/areas, for the appropriate strengthening of existing models. A total of 24 diverse Healthcare Technology Transfer Entities (TTE) have been reported (Dixit, 2018a) in our previous study. For this study three more TTE have been added to our previous data and broadly categorised them as University TTE, Organisation TTE and Programmes in PPP, depending upon various factors. Our analysis indicated that no single format could be used to map all 27 TTEs as depicted in Figure1 (see Annexure).

This paper is further to our previous studies where an extensive review of literature was performed to understand translational gaps, regional health needs, translational capacity, and prevailing Indian models (Dixit, 2018a and 2018b). A translational model of healthcare innovations has been prepared based on the existing need of the translational mechanism followed in the country.

Materials and Methods

The study has been performed in two phases, in first phase a functional analysis has been done to highlight strength, weakness, opportunity and threat, followed by devising a model with most significant parameters in Indian context.

To understand the TT landscape of existing TTEs a rational functional analysis of existing models was designed using a questionnaire(s) for a semi-structured interview of purposive sampling followed by a narrative analysis for responses. To find the factual issues a qualitative functional

analysis was planned for prominent ten TTEs related to the translation of health technologies. An in-depth, face to face semi-structured interview was conducted with each participant for an average of 30 minutes mostly at the premises of respondents. Prior to the start of the interview, the aim and background of the study were briefed for their understanding. Interviewees were first asked broad open-ended questions like 'what challenges do they face in technology transfer', enabling them to express their personal and subjective experiences as freely as possible, rather than handing over questionnaire. And gradually covering each component of the questionnaire as per the notion of the interview.

The targeted entities for data collection were 1) ICMR[7], 2) DRDO[8], 3) FITT[9], 4) IRCC[10] ,5) BCIL[11], 6) NRDC[12], 7) BIRAC[13], 8) IPTEL[14], 9) IC&SR[15], 10) SRIC[16], for their involvement in medical research or related research. Out of these, six responses were received from ICMR, DRDO, FITT, IRCC, BCIL and NRDC. Classified Indian medical related TTEs as per their mandate and establishment such as (i) Similar to internal Technology Transfer Office (TTO) (Organisational and University model (ii) Non-for profit, separate entity as society or section 8 company (contracted out either from university or organisation).

Further, the interview transcripts of the questionnaire were analysed to develop a structural description and to understand their functioning at each step of technology transfer. It was followed by segregation of the collected information in different attributes as mentioned in Table 1 (see Annexure). For every attribute, 2-3 parameters have been taken defining each activity and accordingly graded every attribute as low, moderate and strong.

A SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis was conducted for received responses of six TTEs in a conjoint manner for considering them as one entity. Taking into account the fact that they are (i) similar to internal TTO (Organisational and University model and (ii) not-for-profit, separate entity as society or Section 8 company (contracted out either from university or organisation), categorised their attributes, as LOW, MODERATE and STRONG. These were further classified as *internal attribute*, which can be directly controlled and *external attribute* which cannot be directly controlled as depicted in Figure 2 (see Annexure).

- Low attribute: columns with- two low, two moderate or more than two low
- Moderate attribute: columns with- two moderate, two strong or more than two moderate
- Strong attribute: columns with- More than two strong

The quadrants were divided based on the following:

- Internal (strength & weakness) - can be directly controlled
- External (opportunity & threat) - cannot be directly controlled have external influence
- Considering a sample size of six, it is likely to have a situation of overlapping possibilities eg. two low, two moderate and two strong, in such a case it will be considered as 'Low' over 'Moderate' as majority of the existing TTEs fall under category of similar to Internal TTOs which lack expertise.
- Proposed a translational model based on five components identified from SWOT of functional analysis, viz. Translational Activities, Human Resource Development, Liaising Activities, Technology Transfer and Entrepreneurial Support.

Results and Discussion

The performed functional analysis reflects influence of various organisational setup, available facilities and resources, on identified attributes, viz. Technology assessment, Technology validation, IP management, Technology valuation, Market assessment, Negotiations, TT implementation, Industry relations, Management support, Support Incubator/Science park, funding support, Mode of fund allocation for TTE (govt.)/self-sustaining, Regulatory support and Scientist involvement. The attributes have been categorised as low, moderate and strong based on available dataset illustrated in Table 2 (see Annexure). These six TTEs were evaluated on similar attributes to bring uniformity for SWOT analysis as below:

A. Organisational Analysis

ICMR has pioneered the translation and commercialisation of medical research in country. Since many years it has been providing solutions

for public health. However, the entity is evolving and holds strength in Intellectual Property Management, Negotiations and Management support for TT activities. It has great opportunity in technology validation, TT implementation and scientists' involvement. Whereas attributes like technology assessment, technology valuation, market assessment, Industry relations, support incubator/science park, funding support, mode of fund allocation for TTE (govt.) /self-sustaining, regulatory support, requires due attention and skill development.

DRDO has been confidentially translating and commercialising solutions as per defence needs. And with changing scenario they have recently taken the initiative of making their technologies available to civilians with their new TT policy. It reflects strength in IP management, negotiations, TT implementation and management support. It also holds great potential in IP Management and Scientists' involvement. Attributes such as technology assessment, technology valuation, market assessment, industry relations, support incubator/science Park, funding support, mode of fund allocation for TTE (govt.) /self-sustaining, regulatory support requires due attention and skill development.

FITT supports technologies of various disciplines of science generated from IIT Delhi. It is majorly strengthened by IP management, TT implementation, Management support, support incubator/science Park and Scientists' involvement. It is further supported by attributes like, technology assessment, technology validation, technology valuation, market assessment, negotiations, industry relations/communication, mode of fund allocation for TTE (govt.)/self-sustaining. Two attributes, viz. funding support and regulatory approvals need more strengthening and a new approach.

IRCC is one of the oldest entities and has gradually created innovation culture at IIT Bombay. It supports commercialisation of IIT Bombay technologies. The strength of entity lies in IP management, TT implementation, industry relations/communication, management support, support incubator/science park and scientists' involvement. Attributes such as technology assessment, technology validation, technology valuation, market assessment, negotiations, mode of fund allocation for TTE (govt.) /self-sustaining contributes to effective functioning. Two attributes, viz.

funding support and regulatory approvals need more strengthening and new approach.

BCIL has been established with the purpose of supporting commercialisation of biotechnology research in country. The entity demonstrates strength in most attributes and also supports functions such as technology validation and support incubator/science park. Two attributes, viz. funding support and regulatory approval have been graded low.

NRDC has been established with purpose of providing commercialisation services to various science and technology research organisations. The entity demonstrates strength in most attributes and also supports functions such as technology validation, support incubator/science parks and regulatory approvals. The funding support attribute has been graded low.

B. Attribute wise analysis

Tech assessment, tech valuation, market assessment, VC funding support, mode of fund allocation/self-sustenance, and understanding of regulatory framework are low attributes whereas tech validation and support incubators are moderate attributes. IP protection, negotiation**,** TT implementation, Management support, scientist involvement, industry relations are strong attributes of technology transfer ecosystem. Based on above classification, the attributes representing strength, weakness, opportunity and threat for health technology transfer model have been identified in Figure 3 (see Annexure).

C. Proposed Model

It is observed that as per existing infrastructure and available resources with each TTE, they have different set of challenges, opportunities, organisational set up, mandates, etc. This necessitates the establishment of a government supported facilitation body to connect existing models to share, utilise and benefit from each other's expertise. The facilitation body should aim at capacity building for technology transfer professionals, entrepreneurs, translational researchers involved in translation; collaborative activities such as project consultancy contract R&D, industry outreach; facilitate each stage of technology transfer; and entrepreneurship development and spin out formulation to support existing translation ecosystem. Therefore, an Indian

Healthcare Translational Model is proposed to strengthen weaknesses, mitigate risks, utilise opportunities and enhance strengths.

A model is devised with five translational components, viz. Translational Activities, Human Resource Development, Liaising Activities, Technology Transfer and Entrepreneurial Support for Indian healthcare sector to address existing translational challenges. It also proposed a blue print for each component, for central and regional functioning, further supported by a sustenance platform for the model. Lastly, to minimise the efforts of government in adoption of the model, a blue print is proposed for integration of existing capacities and their functional expertise under one umbrella.

The translational model is devised with objective of providing a single dedicated platform for accelerated translation of innovative, need based biomedical technologies for regional upliftment leading to country's socio-economic development.

Under the aegis of Ministry of Science & Technology, our model proposes a Department of Biomedical Technology which could be denoted as (DBMT). This department will govern a National Biomedical Technology Authority (NBMTA) which further has five Regional Biomedical Technology Facilitation Centres (East, West, Central, North South), as in Figure 4 (see Annexure). This model uses decentralised approach.[59] The National Biomedical Technology Authority will support human resource development, entrepreneurship, liaising, translation and technology transfer of indigenous biomedical technologies through its various divisions.

The National Biomedical Technology Authority (NBMTA) comprises of three management divisions and five core divisions as follows.

A. Management Divisions

- Administration Division: Responsible for handling all administrative matters, allocation of work among various divisions, etc.
- Finance Division: Manages the financial functions, transactions (inflow and outflow), budget allocation to each division, revenue generation, etc.
- Project Management Division: It works as mentoring body, performs evaluation of each department with their inputs and database entries, harmonises and solves challenges of each department and amongst departments to minimise time lag between coordinated activities. It also analyses global trends and submit monthly report to ministry.

B. Core Divisions

- Translational Division: Responsible for development and validation of a technology to attain an adequate TRL for effective translation into product.
- Human Research Development: Responsible for skill development of various stakeholders at different stages of translational process.
- Liaising Division: Responsible for collaborations, convergence, showcasing and database maintenance.
- Technology transfer Division: Responsible for transfer of technologies from labs to market place after conducting thorough evaluation of market, technology and regulatory needs, etc.
- Entrepreneurial Support Division: Responsible for mentoring and supporting new ventures, spin-offs, start-ups from introduction to sustenance in the market place.

The model adopts the matrix organisational structure (Miesing, 2018), which is most flexible and has a quick response to changing environment. It supports open communications which allows sharing of highly skilled resources between functional units and projects, which helps smooth flow of knowledge, collaborative activities to form an integrated, more dynamic organisation. It maintains close contact with the relevant authorities and combines centralisation and decentralisation approach. With increasing translation activities, technology transfer projects greater management complexities, therefore a matrix organisational structure is the right fit which will promote easy communication, experience sharing to achieve better performance.

Functioning at National Biomedical Technology Authority

I. Translational Division

It helps in augmenting institutional capacity by i) orienting research activities towards societal needs, national priorities; ii) enhance creation of IP , report IP to seek protection at earliest; and iii) generating new knowledge for regional economic growth by following activities:

- Identify Leads from on-going projects, complete projects etc and make entries in the database.
- Screen out patents or IP component- Immediate reporting of any

innovative or new or non-obvious component found in research, to the concerned division to examine patentability or any other form of IP for the technology.

- Assessment of Technology Readiness Level (TRL): Based on various templates access TRL level. Separate Technology readiness level for each segment as device, drugs, formulations, diagnostics, etc.
- Process for up-scaling and validation activities: Identify potential partners for conducting third party validation or for consultancy services and perform matchmaking with appropriate partners.
- Internalisation for up-scaling with co-working infrastructure: Efforts are made to create desired facility within their vicinity/laboratory/space for Up-scaling activities.
- Form multi facet teams: from interdisciplinary fields to offer varied expertise.

II. Human Resource and Development Division

1. Training and Development

i. Conducts training/workshop/seminars /courses for the following:

- Translational staff (for Researcher evaluation & TRL)
- Technology transfer employees (best practices in negotiation, licensing, market assessment, Technology valuation, IP practices, Regulatory guidelines)
- Entrepreneurs (entrepreneurial skills, elevator pitch)
- Engineering & Medical researchers (significance of commercialisation, best clinical and translational practice)

ii. Support sponsored degree courses for employees

2. Recruits appropriate professionals for various divisions

i. Define right qualifications as per advancing technologies, market needs, etc.

ii. Assessment of individual for their performance appraisals as per their domain such as project completed, technologies transferred, and negotiations performed, etc.

iii. Maintain other relevant information of employees.

3. Maintain and encourage healthy work environment

i. To organise intra-departmental activities and events for better cohesive environment.

ii. Award events for achievers and other perks for the employees.

(Figure 5 see Annexure)

III. Liaising Division: **It helps in collaboration, convergence and database maintenance**

1. Perform *Collaboration and Convergence* with industry, hospitals, clinical research organisations, academia, R&D laboratories/organisations, investor groups, funding agencies, regulatory bodies, various Medical technology associations, industry associations, etc. (Figure 6 see Annexure).

2. Create consortiums, exhibitions, shark tank sessions

i. Create showcasing and branding opportunities for products/ technologies.

ii. Arrange Innovation Market Place and other investor forums for technology /product commercialisation.

iii. Assess the portal for relevant information and draft material for liaising activities.

3. Maintain portal and database (depicted in Figure 7 see Annexure)

IV. Technology Transfer Division

It acts as most significant interface, in transferring knowledge and innovation from research organisations for commercial application and public benefits. These delivery channels support Technology assessment and valuation, market assessment, Intellectual Property Protection, regulatory approvals, post-transfer monitoring, enlarging business network and strengthening technology transfer implementation in righteous manner abiding by different techno-legal documents and enriching entrepreneurial environment as depicted in Figure 8.

V. Entrepreneurial Support Division

- Support start-ups/spin-offs and promote entrepreneurial culture.
- Assign a mentor to each one of them for dedicated development.
- If needed, connect start-ups/spin-offs to accelerators to achieve desired goals.

- Connect start-ups/spin-offs with appropriate incubator from database based on: facility required stage of development and region of business.
- Educate on entrepreneurship skills by organising seminars, inviting lectures such as investor pitching, risk and functional analysis, etc.
- Co-ordinate with appropriate department (translational research for improvement, IP, sub-licensing, business plan, etc.) to get approvals and support on fast track mode.
- Constant monitoring of progress and data entries in portal.
- Investor Pitching: i) assist in drafting elevator pitch, writing communication to the potential investors, and ii) preparing for shark tank sessions.

Literature has highlighted various challenges involved in matrix organisational structure.[57] The model has a Project Management Division as a mentoring body which plays a very crucial role in harmonising and solving challenges for each department and amongst other departments to minimise time lag between coordinated activities. It performs evaluation of each department with their inputs and database entries depicted in Figure 7 (see Annexure). It also analyses global trends and submit monthly report to ministry.

Functioning at Regional Biomedical Technology Facilitation Centre (RBTFC)

These divisions at NBMTA coordinate and work together in different phases such as phase I: Do It Right, Phase II: Review It Right, Phase III: Transfer It Wise at each RBTFC as illustrated in Figure 9 (see Annexure) and Table 3 (see Annexure).

A model is likely to fail in absence of ambient environment (Davis, 1978). Therefore proposed a society dedicated towards translation of biomedical technologies which can be set up along with government policies and guidelines for supporting translational ecosystem.

Association of Biomedical Translation Professionals

ABTP aspires to bring together researchers, entrepreneurs, governments, policy makers, investors, funding agencies, regulatory bodies and

Business world (Start-ups, Micro Small & Medium Enterprises (MSME), Multinational Companies (MNCs)) working in the field of biomedical technologies. It builds a synergistic environment for efficient translation and transfer of technologies. A non-profit organisation, aims to foster innovation culture, leadership, technology transfer management & commercialisation and strategic alliance as depicted in Figure 10 (see Annexure). It will act as a sensitisation forum for various stakeholders involved in translation of Biomedical Technologies.

The translation of ideas from basic research laboratories to commercial partners capable of transforming the inventions into beneficial products, services and solution powers the innovation economy by creating jobs, saving and enhancing lives, improving productivity and offering solutions to healthcare challenges. The ABTP will not only provide a platform but will build a network/nexus of enthusiastic stakeholders with a common objective of supporting translation to benefit public health, described in Table 4 (see Annexure). In future this could be converted into Association of Health Translation Professionals Accounting for translation of all segments of healthcare. Therefore, it is suggested that government should take a lead, provide necessary financial support, and use a membership-based approach to build technology transfer institution alliances.

Improve the Implementation of Technology Transfer Legislation: A common global approach to developing science and technology as an intermediary industry is to establish legislation, provide policy guidance, and promote and guide these intermediaries (TTEs) so they cooperate with firms, research institutes, and universities to accelerate technology transfer. This completes our efforts of devising a self-sustaining, globally competent translational mechanism for health sector that promotes handholding for indigenous technologies.

Integration of Existing Translational Capacities

For effective implementation of proposed model, efforts have been made to identify established capacities and their relevant programmes which can be considered for their services to be utilised by various divisions of proposed model illustrated in Figure 11 (see Annexure) and Table 5 (see Annexure).

Conclusion

India has made its mark as an emerging economy and efforts are being escalated by emphasising upon translational and entrepreneurial ecosystem. The healthcare sector demands attention on reported health disease burden and public health challenges. To support country's vision of health for all, the healthcare solutions should be made available and affordable for healthy and productive nation. With the hypothesised problem of low translation rate of healthcare technologies, this study explores the most suited model for effective translation of health technologies.

In view of India's diverse demographic needs and their economic strata, it necessitates developing an indigenous model which provides affordable solution for regional health challenges and strengthens country's stature globally. Government may consider introducing a national act to support and expedite commercialisation of indigenous health solutions with focus on inclusive innovation. The act should encourage entrepreneurship and collaborative translational activities to research on variety of problems of national importance and societal relevance to develop technology/product (up to Proof of Concept stage) of societal/ national importance and its subsequent up-scaling/validation. This should be further supported in creating a society or a database, common platform to submit, extract the information which could be later assessed to measure their performance. This may also serve the purpose of a good source for various translation activities, funding repository by various stakeholders (academia to contribute some part of their budget, industry to contribute their Corporate Social Responsibility budget and hospitals to contribute earnings made out of various campaigns, etc). And a space should be created for TT entities to realise their existence and significance, with right resources and a skilled team for effective delivery and desired results.

Thus, a matrix based system is proposed, named as National Biomedical Technology Authority (NBMTA), Department of Biomedical Technology (DBMT) under ministry of science & technology with designated divisions cordially working towards regional development in five Regional Biomedical Technology Facilitation Centres (RBTFC e/w/c/n/s) (East, West, Central, North, South), to strengthen existing weaknesses, mitigate threat, utilize opportunities and enhance strengths. For sustenance of this model a platform/society has been proposed, Association of Biomedical Translation

Professionals (ABTP), which aims to foster future of innovation, leadership management for various commercialisation and strategic alliance activities. Lastly, a workable blueprint is prepared in below image by utilising existing capacities to support each division for its effective implementation. Also, this will establish a link and bring all the biomedical translational activities under one umbrella.

The model envisages promoting accelerated, effective medical health translation. The model promotes capacity building of different professionals involved in translation, giving impetus to forming multifaceted teams for appropriate utilisation of resources, resulting in less incomplete or failed projects. Also, it will generate solution as per industry needs, end user needs and regulatory guidelines.

The proposed model will help in elimination of 3A anomaly and boost attainment of holistic goal of health for all and power India to become most productive and healthy economy. The model will strengthen the healthcare sector in a decentralised manner, thus resulting in strengthening of regional systems to handle outbreaks/ epidemic situations, and forming connections with regional stakeholders, regional growth together will impact the national growth socio economic development.

Endnotes

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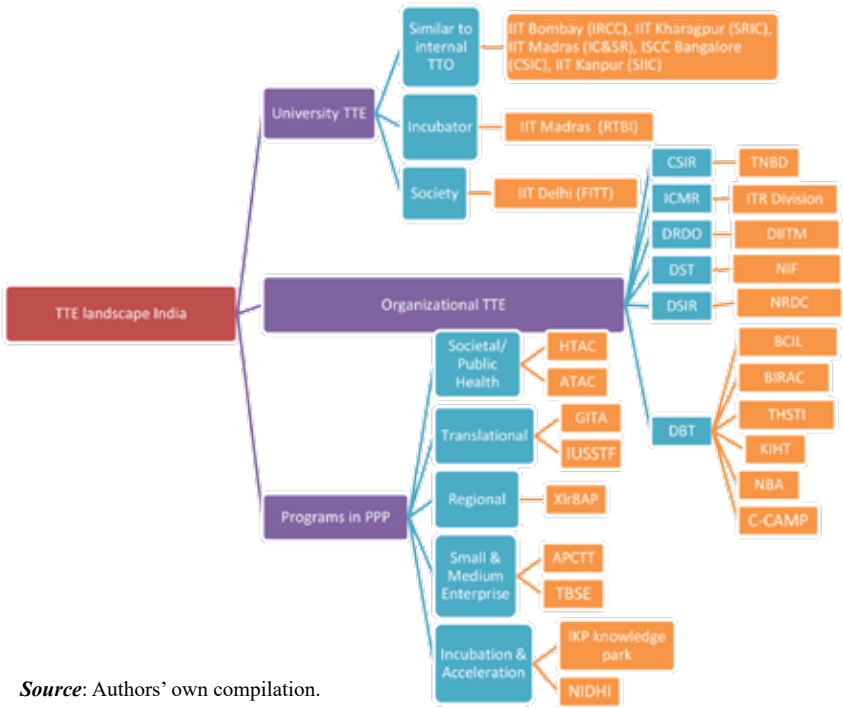
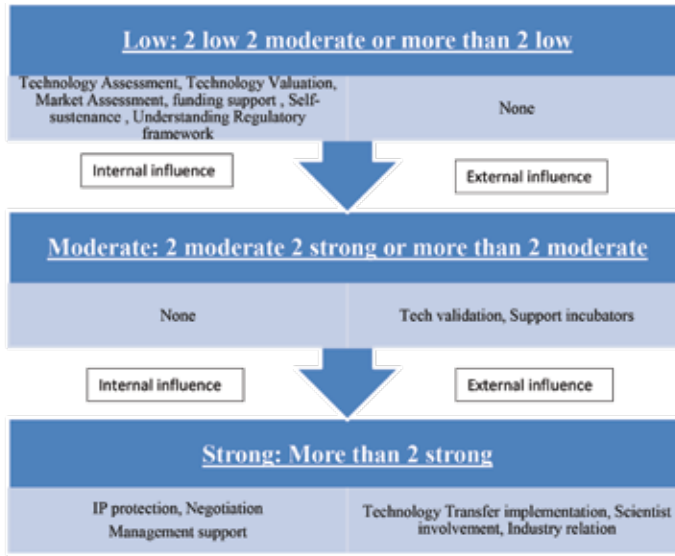
Annexure

Figure 1: Landscape of 27 Indian public Technology Transfer Entities in the healthcare sector(Industrial Research and Consultancy Centre[1]; Centre for Scientific and Industrial Consultancy[2]; Sponsored Research & Industrial Consultancy[3]; Industrial Consultancy & Sponsored Research[4]; SIDBI Innovation & Incubation Centre (SIIC)[5]; Rural Technology and Business Incubator[6]; Foundation for Innovation and Technology Transfer[7]; Innovation and Translation Research Division[8]; Directorate of Industry Interface & Technology Management[9] ;National Innovation Foundation[10] ;Translational Health Science and Technology Institute[11] ; Kalam Institute of Health Technology[12] ; National Biodesign Alliance[13]; Technology Networking & Business Development Division[14] ; Biotechnology Industry Research Assistance Council[15]; Biotechnology Consortium of India Limited[16], National Research & Development Corporation[17]; Health Technology Accelerated Commercialisation[18]; Accelerated Technology Assessment and Commercialisation[19]; Global Innovation and Technology Alliance[20] ;Indo-US Science and Technology Forum[21]; Xlr8AP[22]; Centre for Cellular and Molecular Platforms[23]; IKP Knowledge park[24]; National Initiative for Developing and Harnessing Innovation[25]; Asian and Pacific Centre for Transfer of Technology[26]; Technology Bureau of Small Enterprises[27])



Source: Authors' own compilation.

Figure 2 : Redefine Low, Moderate and Strong for conjoint SWOT analysis



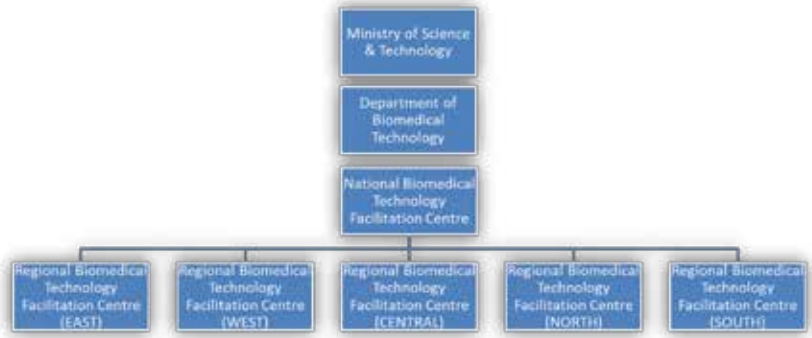
Source: Authors' own compilation.

Figure 3: Overview of Strength, Weakness, Opportunity and Threat analysis for Indian Healthcare TTEs

STRENGTHS- BUILD	**OPPORTUNITIES- INVEST**
Strength (factors supporting TTE functioning)	*Opportunity- Growth goals for TTE*
• Intellectual Property Management • Negotiation- domain specific expert committee do encourage commercialization of technologies to reach out to public (mention licenses) • Management support- organizational support to their TTO functioning (funding etc)	• Incubation • Technology Validation-weak technology • Industry Liaising- won't be understanding industry needs • Liaising with regulatory approvals
WEAKNESS/ AREA TO IMPROVE- SHORE UP	**THREATS- MONITOR**
Weakness (can control but can negatively impact) needs improvement	*Threat (due to their impact if not strengthened)- Adverse effects*
• Technology Assessment- need skill development • Technology Valuation- need skill development • Market Assessment- need skill development • VC funding support • Self-sustaining – less budget, won't be able to have a skilled TT team • Regulatory framework- lack proper understanding of process	• Scientist involvement- sensitize them and encourage them • TT implementation- else industry and academia will lose their trust (time bound & result oriented as per milestones, fair distribution of revenue)

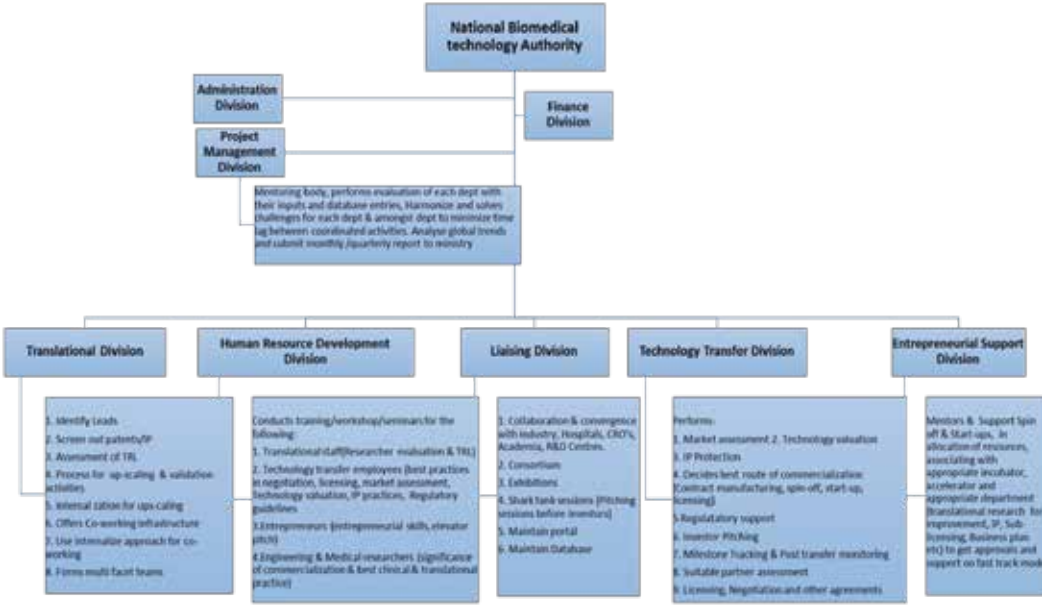
Source: Authors' own compilation.

Figure 4: An organisational chart outlining genesis of proposed model



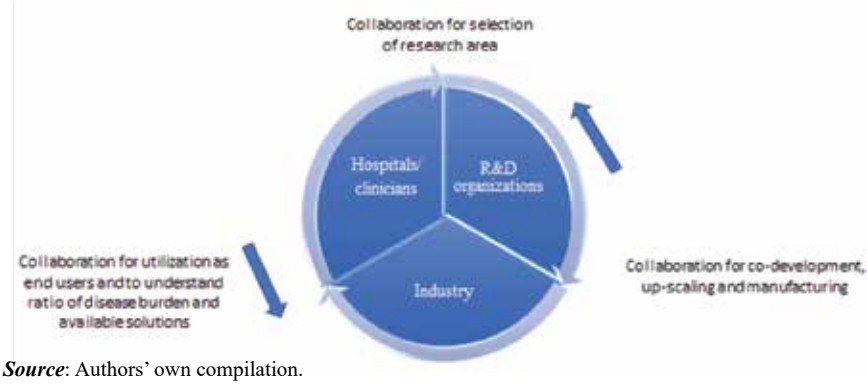
Source: Authors' own compilation.

Figure 5: The organisational profiles of various divisions of National Biomedical Technology Auth ority



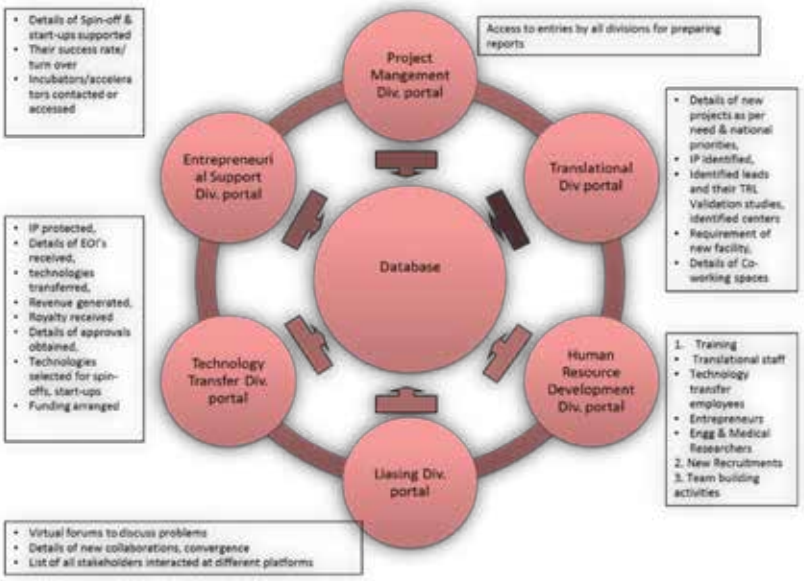
Source: Authors' own compilation.

Figure 6:Proposed collaborative cycle for translation of medical innovations for following activities- i) Create Medical Technology angel investor network and integrate with international investor forum, ii) Direct mapping of technologies in research organisations at national and international level, iii) Define open business problems to articulate technical needs and invite solutions



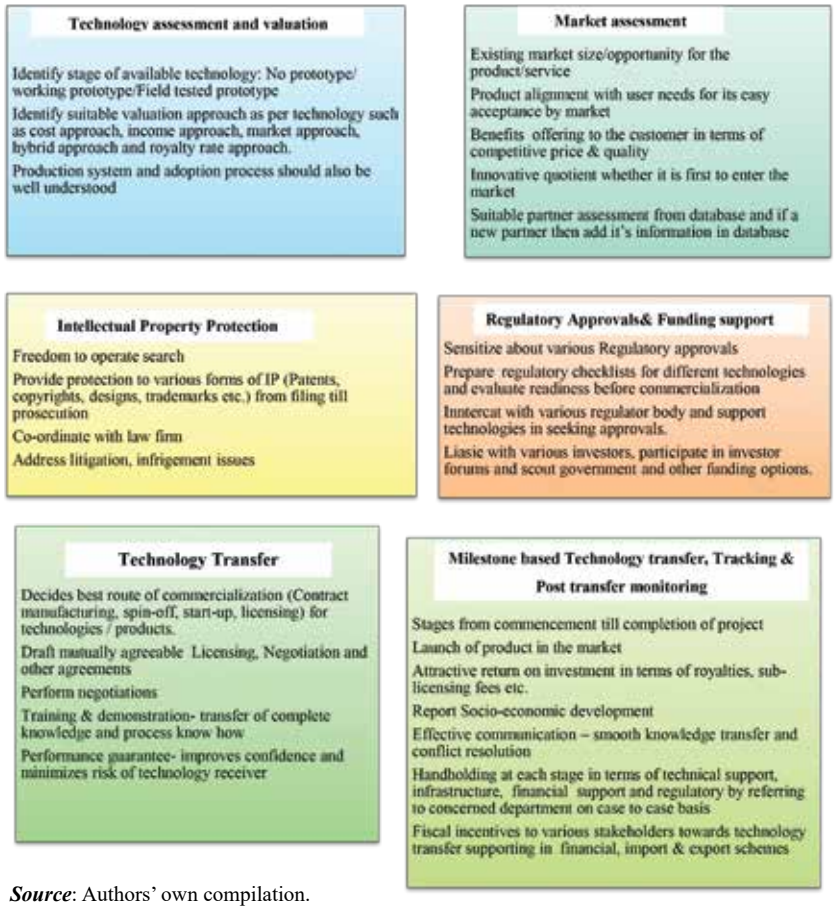
Source: Authors' own compilation.

Figure 7: Liaising division supports database maintenance for following activities- i) creates database of various stakeholders , ii) provides portals for each division for their respective activities, iii) proactive corporate branding, communication, exhibitors, iv) Identify & create opportunities to facilitate commercialisation, investment, scaling, private / government procurement, v) Coordinate with relevant division for seeking their participation in events.



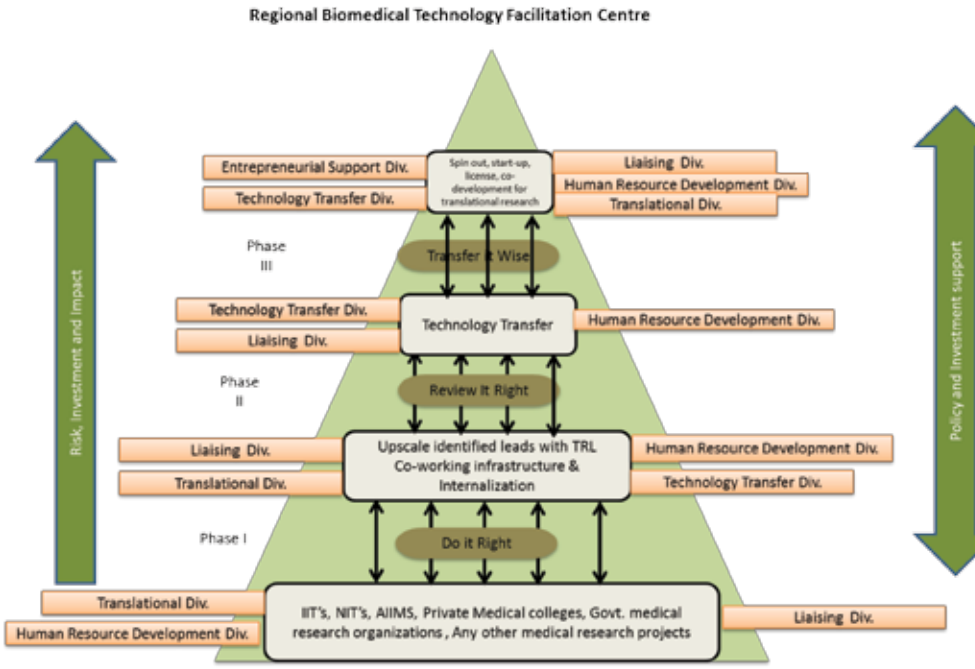
Source: Authors' own compilation.

Figure 8: Major activities undertaken by technology transfer division are technology evaluation & assessment, market assessment, intellectual property protection, regulatory approvals& funding support, technology transfer & commercialisation, post transfer monitoring.



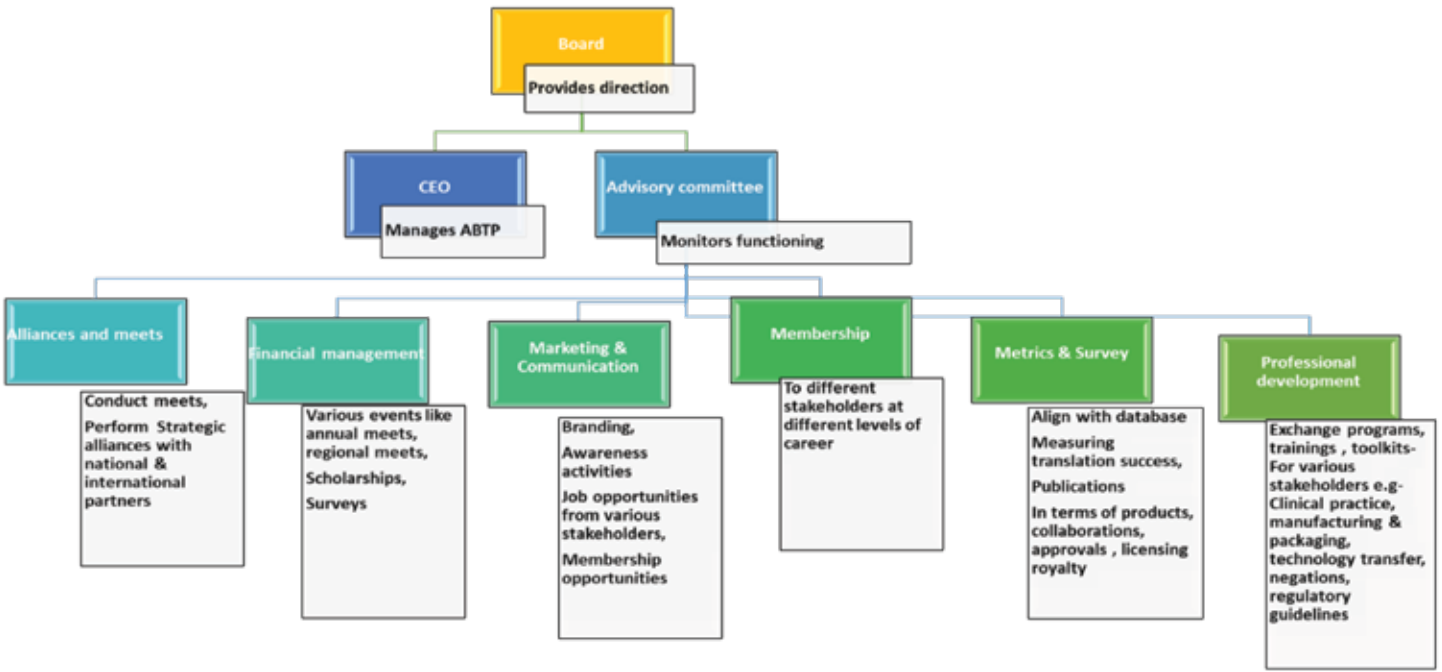
Source: Authors' own compilation.

Figure 9: Functional mechanism at each Regional Biomedical Technology Facilitation Centre



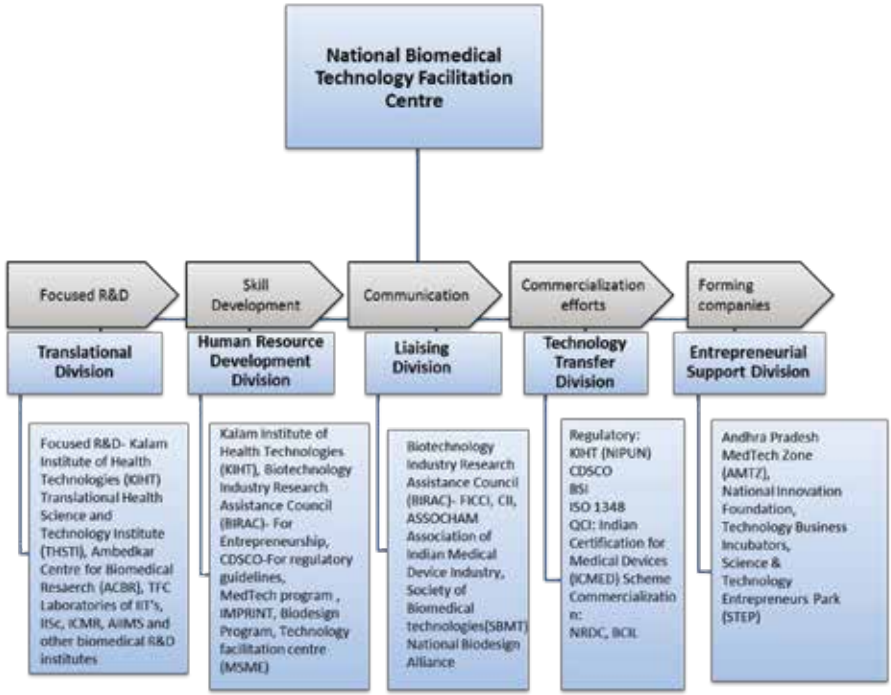
Source: Authors' own compilation.

Figure 10: The organisational structure of Association of Biomedical Translation Professionals



Source: Authors' own compilation.

Figure 11: Proposed integration of existing capacities for implementation of National Biomedical Technology Authority (NBMTA)



Source: Authors' own compilation.

Endnotes for above Figures

1 IRCC, Indian Institute of Technology, Bombay, Available from: https://rnd.iitb.ac.in/ Accessed on January 2019

2 CSIC, IISC Bangalore, Available from: http://www.csic.iisc.ernet.in/ , Accessed on March 2019

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6 RTBI, IIT Madras, Available from: http://www.rtbi.in/, Accessed on Accessed on January 2019

7 FITT, Indian Institute of Technology, Delhi, Available from: https://fitt-iitd.in/ Accessed on January 2019

8 ITR, Indian Council of Medical Research, Available from: https://www.icmr.nic.in/, Accessed on January 2019

9 DITTM, Defence Research and Development Organization Available from https://www.drdo.gov.in/drdo/English/index.jsp?pg=homebody.jsp Accessed on January 2019

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Table 1: Attributes of Indian TTE and their classification as Low, Moderate and Strong

S.No	Attributes	Strong	Moderate	Low
1	**Technology Assessment:** Evaluating the technology on parameters of technology readiness level and understanding the required prerequisites to reach the maturity level as per industry needs	Well defined format determining TRL and a dedicated skilled person who performs a necessary search like FTO etc	Anyone of them	None
2	**Technology Validation:** Planned activities performed to reconfirm the claims & reproduce the same results as claimed	Provide funds, monitor the program with a defined committee or skilled person regularly	support in finding a partner & arranging funds (refer to a related person)	None/ provide no support
3	**IP Management:** An established system with skilled professionals to perform activities like identification, protection of IP, IP portfolio management	Well defined division/unit with patent agents, patent analysts, attorneys, and good IP portfolio management	Outsource IP Management	None/ don't support
4	**Technology Valuation:** Activities performed for right positioning of the technology as per market needs like tech pricing as per its value, efforts invested, raw material/resources used etc. A team or individual that helps package it well to be presented before the market, a team that interacts with Industry & inventor. Have well-defined formats, competitive analysis	Skilled team & defined format	Only have defined format	Not defined activities/ use external support

Table 1 continued...

Table 1 continued...

5	**Market Assessment:** Assessing the market for the technology acceptance & competition with the following- skilled team, defined matrix, potential players & their requirements, market size	Skilled team & matrix	Only matrix	None/use external support
6	**Negotiations:** refer to the discussions in terms of financial and other terms & conditions before transferring the technology	Negotiations would comprise of these two parameters- Well-defined terms sheet evaluation mechanism and a person skilled at it	Anyone of them/ external support	None of them
7	**TT Implementation:** How effectively and timely each step is executed and milestones are achieved with a defined structured team	Dedicated monitoring of milestone with the team - assess how fast technology enters the market (only focus on TT and don't get distracted)	Lack dedicated monitoring and team	Unclear approach
8	**Industry Relations:** i) Have a dedicated window for regular interactions with industry in the form of seminars/ workshop/ discussion groups, form to exchange ideas/ challenges for effective collaboration. ii) The industry involved with industry in many other programs like incubators, research parks. iii)Just sends emails to industry/ web advertisement	i) The industry involved with industry in many other programs like incubators, research parks. ii) Have a dedicated window for regular interactions with industry in the form of seminars/ workshop/discussion groups, form to exchange ideas/ challenges for effective collaboration. iii) Just sends emails to industry/ web advertisement on their portal	Any two activities	Just sends emails to industry/ web advertisement on their portal Or Only the last activity
9	**Management Support:** It refers to the cooperation of university, organisation towards the functioning of TTE	The defined channel, easy approvals, regular interaction to discuss challenges if any	No regular interactions	No interactions at all

Table 1 continued...

Table 1 continued...

10	**Support Incubator/Science Parks:** Administration support, have incubator along with funding schemes to support, help in regulatory approvals, else provide assistance to incubators (in different activities- IP, etc.)	Administration support, have incubator along with funding schemes to support, help in regulatory approvals	Provide assistance to incubators (in different activities- IP, etc.)	No incubation activities
11	**Funding Support:** refers to the active involvement & support of TTE in arranging/providing funds for their spin-outs, start-ups, etc.	Those which have a successful history of producing start-ups with a dedicated person in their team for supporting this task	Those which have Incubatees and give referral support to these for arranging funds	Those which have Incubatees and provide all other support except this
12	**Mode of Fund Allocation for TTE (govt./self-sustaining):** Either govt. funds (regularly/ continuous) or from university/ annual funds based on income generated & also form its existing resources & operations or just from existing resources or & have to look for inventors	Govt. Funds (regularly/ continuous)	From university/ annual funds based on income generated & also form its existing resources & operations	Just from existing resources or & have to look for inventors
13	**Regulatory Support:** Handholding for seeking regulatory approvals and also bears the cost, may just guide the process (about regulatory authorities, process and fee structure) and provide support letter if required, else interfere or only on request	Handhold for seeking regulatory approvals also bears the cost	Guide the process (about regulatory authorities, process and fee structure), and provide support letter if required	Do not interfere or only on request
14.	**Scientists' Involvement:** In spinout formation, consultancy services, negotiations, in IP related activities, dossier formations	Spinout, consultancy, negotiations	In IP related activities, dossier formations	Don't involve much

Source: Authors' own compilation.

Table 2: Categorisation of different attributes for functional analysis of TTEs

Attributes Models	Technology assessment	Technology validation	IP management	Technology valuation	Market assessment	Negotiations	TT implementation	Industry relations/ communication	Management support	Support Incubator/ science park	Funding support	Mode of fund allocation for TTE (govt)/self-sustaining	Regulatory support	Scientist involvement
ICMR(2000, dedicated to Public health)	Low	Moderate	Strong	Low	Low	Strong	Moderate	Low	Strong	Low	Low	Low	Low	Moderate
DRDO(2009, dedicated to defence needs)	Low	Moderate	Strong	Low	Low	Strong	Strong	Low	Strong	Low	Low	Low	Low	Moderate
FITT (1992, for various disciplines of science)	Moderate	Moderate	Strong	Moderate	Moderate	Moderate	Strong	Moderate	Strong	Strong	Low	Moderate	Low	Strong
IRCC (1974, for various disciplines of science)	Moderate	Moderate	Strong	Moderate	Moderate	Moderate	Strong	Strong	Strong	Strong	Low	Moderate	Low	Strong
BCIL (1990, by DBT for Biotechnology research)	Strong	Moderate	Strong	Strong	Strong	Strong	Strong	Strong	Strong	Moderate	Low	Strong	Low	Strong
NRDC (1953, by DSIR)	Strong	Moderate	Strong	Strong	Strong	Strong	Strong	Strong	Strong	Moderate	Low	Strong	Moderate	Strong

Source: Authors' own compilation.

Table 3: Blueprint of Regional Biomedical Technology Facilitation Centre

Regional Biomedical Technology Facilitation Centre		
Phase I: Do it Right	**Phase II: Review it Right**	**Phase III: Transfer it Wise**
Translational team- **Identifies leads and assesses their TRL stage to process it further for Upscaling** *Liaising team*- **Identifies appropriate partner and centre for up-scaling in consultation with inventor** *Human Resource Development team*- **Skill development of scientists, medical students, engineers towards assessing commercial potential or health impact of their idea and then pursue it. Scientists are taught to take GO/ NO-GO decisions for their own research.**	The research laboratories can create co-working facility at their own institutes or else use various technology business incubators, Science &Technology Entrepreneurial Parks such as AMTZ etc or any other R&D centres: ***Technology transfer team-*** Undergo basic MOU or other agreement as per IP sensitivity **Translational team-** Offers co-working infrastructures or adopt internalising approach for up-scaling the technology ***Human Resource Development team*** – Makes best practices available for better performance ***Liaising team-*** Uses database to identify partner for developing co-infrastructure spaces and places for third party validation	***Technology transfer team-*** Performs the following for generated leads- • Market assessment • Technology Valuation • Intellectual Property Protection • Selects/decides best route of commercialisation (Contract manufacturing/co-development/spin-off/start-up/licensing) • Regulatory support • Investor pitching • Milestone tracking • Potential/Suitable industry partner assessment • Licensing , negotiations and other agreements ***Liaising team-*** • Provides platform for showcasing technologies • Exposes/introduces to number of potential partners through database • Update technology portal with number of Expression of interest received, processed, dropped and reason for each activity in order to improve it later. ***Human Resource Development team-*** Constant training of technology transfer team for better and improved skills with global best practices. ***Entrepreneurial team-*** • Mentors spin-offs/ start-ups • Refer to right department e.g tech transfer for patent filing, for sublicensing agreements, for using incubator/ accelerator spaces etc. to get work done on fast track mode. ***Translational team***- offers technical support or consultancy along with R&D labour & facility support to spin-offs and startups.

Source: Authors' own compilation.

Table 4: Overview of mission, goals and values of Association of Biomedical Translation Professionals

Mission Statement: **To support and advance translational activities** Values: **1. An interlinked community with common goal where members share knowledge** **2. Leadership nurtures accountability for respective field/task thus inculcated through professional development training.**	
Goal 1: Strengthen Innovation culture	• To organize annual meets, regional meetings and seminars to advocate various challenges and share available solutions. • To spread awareness among the stakeholders about aspects of entrepreneurship, Intellectual Property Laws, technology transfer practices and their impact. • To help academia, inventors and corporations in dealing with "real world" situations during translational journey and the possible ramifications involved.
Goal 2: Leadership development	i. Translation needs leaders to think differently to facilitate the complex process of converting idea into product. Leaders possess the zeal to fight odds for desired results. ii. Accountability of one's action need also needs a leadership quality , to enable a system of leaders where they assure their work thus leading to an error free translation • To promote best practices and take appropriate initiatives for capacity-building of different stakeholders. • To operate as a catalyst in professional development of translational professionals for the commercial benefits of innovations. • To offer a platform for translational professionals to facilitate their knowledge by peer interactions through membership tools, connections etc.
Goal 3: Technology Transfer Management and Commercialisation	• Increase understanding and support of the role of technology transfer among senior university administrators, policy makers, and the general public. • To support and advance technology managers capacity for effective management and commercialisation of solutions.
Goal 4: Strategic Alliance	• Create, grow and cultivate ABTP's Body of Knowledge. • Deliberately evolve ABTP products, tools, and services to ensure relevance to members and stakeholders by conducting regular surveys understanding their need and challenges • Execute a unified strategic communications plan for all stakeholders to ensure awareness and a positive brand image of ABTP. • Leverage relationships with stakeholder groups and other associations to create and improve the understanding of the societal benefit and for economic impact across the breadth of translational activities.

Source: Authors' own compilation.

Table 5: Overview of existing capacities and their suitability for various components of proposed model

Translational Division	Human Resource Development Division-	Existing networks can be utilized for establishing a common platform and database.	Following organisations offer Indigenous certification for healthcare and healthcare regulation	Entrepreneurial Support Division
• Kalam institute of Health Technology- It has separate cell for research & division, technology assessment, technology transfer and Market Intelligence & Trade. • Translational Health Science and Technology Institute- It performs solution based research in five thrust areas i) vaccines, ii) maternal and child health, iii) point-of-care diagnostics, iv) metabolic diseases and nutrition, and v) training in clinical and product development. It has skilled expertise and well equipped R&D laboratories. • Ambedkar Centre for Biomedical Research- basic and applied research in the field of human health and disease, • Technology Facilitation Centre- Gap assessment	• Kalam Institute of Health Technologies (KIHT), • Biotechnology Industry Research Assistance Council (BIRAC)- For Entrepreneurship, • CDSCO-For regulatory guidelines, • MedTech program , • IMPacting Research Innovation and Technology (IMPRINT), • Biodesign Program, • Technology facilitation centre (MSME)	• Biotechnology Industry Research Assistance Council (BIRAC)- Federation of Indian Chambers of Commerce and Industry (FICCI), Confederation of Indian Industry(CII), Associated Chambers of Commerce of India(ASSOCHAM) • Association of Indian Medical Device Industry, • Society of Biomedical technologies(SBMT), • National Biodesign Alliance	• Kalam Institute of Health Technologies (NIPUN)-Non-Regulatory Innovation Potential-Utility-Novelty certificate • Central Drugs Standard Control Organisation (CDSCO) • Bureau of Indian Standards (BSI) • International Organization for Standardization (ISO 1348) • QCI: Indian Certification for Medical Devices (ICMED) Scheme • For technology transfer • Biotechnology Consortium of India Limited, • National Research & Development Corporation	• Andhra Pradesh MedTech Zone (AMTZ)- provides in-house high investment scientific facilities to help manufacturers in reducing the cost of manufacturing • National Innovation Foundation strengthens the grass root technological innovations and outstanding traditional knowledge • Technology Business Incubators, • Science & Technology Entrepreneurship Park

Source: Authors' own compilation.

RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

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Patents on Medical Innovations and Value Pluralism in India: Paradoxes and Choices

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Abstract: Patent as a rewarding system to the inventor has been in vogue for more than six hundred years. This has resulted in major innovations that have revolutionised our lives besides saving millions of lives and eradicating deadly diseases. But over the years the corporations rather than scientists or technocrats have become the claimants and owners of patents. In the process the balance between incentivisation and patenting for control has been lost and this has resulted in major questions on the objectives and functioning of the intellectual property rights regimes, particularly in the case of drugs and pharmaceuticals. In this paper the idea of value pluralism is used to develop an alternative perspective and it is illustrated with two case studies. It is contended that this approach is suitable for countries like India. It is important to explore the alternatives like Prizes, Open Source Drug Discovery and other ideas that seek to overcome the problems with the patent law and practice. Since patents on medical innovations is also an issue of access and affordability to life saving drugs, devices and treatments, a narrow view on patents and innovation is not sufficient. This paper examines the values and choices before the society and calls for a rethinking in our approach to invention and incentivisation.

Key words: Patents, Value Pluralism, Evergreening, Ordre Public, Open Source

Introduction

A patent is a reward and an encouragement in the form of an exclusive right to the inventor given by the state or society for his creation in recognition of his creativity. In exchange of that inventor discloses his invention to the society so that it can be reproduced. As a result, both patentees and the society are benefitted. History of this rewarding system is not too old in comparison

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to our first invention of the wooden chopping device that was first invented possibly more than 2.6 million years back. Over the years, economists, legal pundits, philosophers, business organisations have justified patent rights as one of the most important forms of intellectual property rights (IPR). For about almost 600 years patent exists as a societal rewarding system to the inventors. More specifically precursor of the modern patenting system is here for 150 years only. In its journey, it has made mousetrap to mice -everything under the sun except the celestial bodies are patentable. Western intellectual property (IP) system promotes monopolisation of knowledge and profits for those who own the IP rights. All inventions are knowledge-based and the source of knowledge and access to knowledge play a pivotal role in creation. The kind of IP systems that has been extended by the Trade Related Intellectual Property Rights (TRIPS) under the World Trade Organisation (WTO) overlooked many such parameters and all inventions and innovations are country and context specific. Apparently one invention is good in a country may not be suitable in another country. The general principles of the WTO administered TRIPS have been implemented in the majority of developed countries first and then they force the remaining nations to change their laws and policies on IPR. It is an evidence of localized globalism where local context, values and wisdom of those nations were deliberately and strategically disregarded for aggressive promotion of trade across the globe. TRIPS has been spread across the globe considering every nation shares same value system throughout the world. Decades after World War II are often considered the "golden age" of medical innovation. Many of the tools of modern medicine were developed between 1940 and 1980, including antibiotics, the polio vaccine, heart procedures, chemotherapy, radiation, and medical devices such as joint replacements (Sampat, 2019). Few medical innovations no doubt have revolutionized the world we live like the first patent on life form was granted to Louis Pasteur on Yeast for manufacturing beer (US Patent No.-141072 dated July 22, 1873), patent on Aspirin on 6 March 1899 to Bayer & Co, patent on Penicillin on 25 May 1948 to A J Moyer , first patent on microorganism (pseudomonas bacteria) for splitting oil spill to Dr. Anadamohan Chakraborty (US Patent No. 4259444 dated 31 March 1981), the USPTO in 12 April 1988 granted a patent no. 4,736,866 to Harvard College claiming "a transgenic non-human mammal" – oncomouse and then the study of biology was radically

transformed by the discovery in 1953 of the structure of DNA, which is the genetic material of living organisms. But many a time medical innovations and inventions greatly influence various economic factors defying the socio-cultural factors and contexts of societal value systems. Value system had never been considered an important criterion neither while framing a relevant policy nor granting a patent on medical innovations. Any kind of medical innovations or an invented drugs impact human society directly and indirectly as well. The Global Innovation Index 2019 identifies while significant progress has been achieved across many dimensions over the last decades, significant gaps in access to quality healthcare for large parts of the global population remain (Cornell University, INSEAD, and WIPO, 2019). Impact, influence and long-term effect of these medical innovations on developing nations particularly in India in terms of the pluralistic value system is poorly studied which calls for a thorough study.

This paper seeks to study and understand value system conflict behind many medical innovations and its subsequent protection by patents. It seeks to find out a harmonised patent policy reform towards a tentative sustainable path in India. It argues, present monolithic rewarding system for invention through patents needs suitable alternatives based on value pluralism to make more just and more universal acceptance. The aim of this paper is not to define what value is rather contextualise the concept of value pluralism with patents in medical innovations.

Assumption

Present patenting system spread globally under the aegis of the Trade Related Aspects of Intellectual property Rights (TRIPS) of the World Trade Organisation (WTO) is unsustainable and biased that has ignored the value pluralism of our society.

Rationale of Patent and Drug Invention

A traditional feature of patents, similar to all types of intellectual property, is that they are territorially limited. Patents are awarded by individual nations and patent rights are generally only enforceable against infringements that occur within that nation. Moreover, a patent granted by one country does not guarantee that another country will grant a patent; this is a fundamental

principle that has been consistently recognised in international agreements governing patent protection.

One traditional exclusion from patentable subject matter for many countries was an exclusion of drug and drug components because the higher cost of patented drugs would limit access to affordable medicine. However, countries that barred patents on drugs often still permitted patents on the *methods* of making drugs.

Permitting only methods, but not products-such as an active ingredient of a drug-to be patented, has important consequences. When the drug or active ingredient is itself patented as product, no one else can make the identical compound, such that a patent can enable the manufacturer to charge a premium. On the other hand, a patent on only the process of making the drug does not block others from developing different methods of making the same drug. Moreover, if there are multiple manufacturers of the identical drug, such competition effectively lowers prices. Contrary to what the pharmaceutical industry often suggests, countries that provide patentability standards on drugs that are different from the United States are not all doing so simply because they fail to value innovation and intend to free-ride off of the United States. Rather, countries at all levels of development have barred patents on drugs because of the policy concern that patented drugs unduly impede access to affordable medicine. Some industrialised countries only began patenting drugs long after the United States and often as a result of external forces; Switzerland and Italy, for example, did so only in the late 1970s because of external pressure. In addition, even countries that granted drug patents sometimes had to allow patent owners to make the patented drug available at affordable prices under a *compulsory license*. An important issue is that although many countries now have to provide drug patents, there is not necessarily a broad consensus that good social policy is to do so. The idea of including the first international substantive patent protection norms was the brainchild of US companies, including the prior to the conclusion of the TRIPS, there were almost 50 countries that did not provide drug patents. These countries probably agreed to patent standards due to issues relating to non- patents, such as trade benefits but not as impetus to their innovation ecology.

Patent escalates the prices of branded prescription drugs and there is always a cheaper generic version of it. Patented drug calls for a premium

price because patents legally entitle their owner to exclude all others from making or selling the patented invention during the patent term. Drug companies often refer to development costs in justifying the high cost of patented drugs. In order to sell a drug, a company must provide substantial clinical data from both animals and humans to show that a new drug is safe and effective to a domestic regulatory agency, such as the Food and Drug Administration (FDA) in the United States. However, it may take years to identify any promising chemical compounds in the laboratory even before the multi-year clinical test can begin. Most initially promising chemicals fail before animal testing begins and many drugs tested in humans may fail to reach the market due to efficacy or safety problems. The industry suggests that only one in eight to ten thousand compounds tested in the laboratory finally reach the market. The companies, therefore, argue that the sale of commercial products must also cover the costs of investigating the many compounds that do not reach the market. A generic drug, on the other hand, has a shortcut alternative path to market for a small fraction of the time and costs. The time and costs for generic companies are significantly shortened not only because they do not need to invest in research, but also because regulatory agencies generally approve generic drugs based on an expedited procedure that requires a much more limited set of clinical data than is required for new drugs. The proposed general drug must only be tested to show that it is *bioequivalent* to the previously approved brand drug, allowing a regulatory agency to conclude that the earlier clinical safety and efficacy tests of the brand drug also apply to the generic drug. Besides, brand companies further argued that while they have to incur huge marketing costs, generics need not do marketing and they simply copy commercially successful drugs that have already been marketed by brand companies (Ho, 2015).

Patent and Value

Patents on various medical innovations, many a times contradict basic principles and philosophy of intellectual property rights. Many philosophers of science even argue that much focus on patenting as the resultant of scientific pursuit is detrimental to both scientific and as well as social progress (Biddle 2007; Brown 2008). The central question in traditional axiology is that what exactly constitutes good and what is of value. Any

good can only be understood in the terms of better. Good is always context dependent. Primary bearers of value are different goodness of stuff. Some philosophers debated that whether something is good or better should be determined by its value. Pluralists forwarded that there is more than one intrinsic value attached to any stuff but monists disagreed to it. Theorists did not argue over whether something is of value, but they contended over whether its value is intrinsic. Value can be intrinsic or instrumental. The value of knowledge sometimes is considered instrumental (Mill, 1861) but other logician favoured that knowledge is itself a value so it is intrinsic one (Moore, 1993). Patent is rewarded to the inventors to protect their knowledge worth of value. Every scientific invention emerges out from scientific ideals and backed by moral economy which is equally context dependent. The patent system does not exist in a moral vacuum. Patent protection of various medical innovations against public morality must be examined against moral pluralism which in fact value pluralism that varies from society to society and time to time. Moral decisions often require preference which does not call for rational basis always. On contrary, patent requires always a pseudo-logical premise that advocates monism. Pluralism accepts differences with values in plurality and protects human basic needs in different shades of life.

Emergence of Modern Patent System

The first patent was given to the Florentine architect Filippo Brunelleschi received a three-year patent for a barge with hoisting gear, that carried marble along the Arno River in 1421. Origin of the modern patent system can be traced back to the English Statute of Monopolis 1623. Subsequently it was amended in 1852 and became the foundation of the patent law in the US, New Zealand, Australia and elsewhere. Britain was the epicentre of the patenting movement from where it was spread to the rest of the world. Some thinkers claim that it was one of the most important stimuli of the industrial revolution of the eighteenth century. Some authors noted that the Statute of Monopolies as the Magna Charta of the rights of inventors, not because it originated patent protection for inventors, but chiefly because it laid down the principle that only a "true and first inventor" should be granted a monopoly patent (Machlup and Penrose, 1950). But where did this internalisation process start? In the late nineteenth century, countries chose to further their economic interests by having quite distinct intellectual property

laws, or even no laws. There were much mutual interest among business organisations, authors, artists, designers and traders in acquiring patents, industrial designs, copyrights and trademarks in those foreign countries where they sought to do businesses. It was resulted in two conventions, namely Paris Convention for industrial property in 1883 and the Bern Convention for copyright in 1886. Though the commercial importance of patent was started in the nineteenth century, it had accelerated since 1970. All these developments in intellectual property law which began in Europe or North America literally extended to the rest of the world through agreements as the World Trade Organization (WTO)-administered Trade Related Intellectual Property Rights (TRIPS). In ancient India there was no patent equivalent monopolistic right in Hindu jurisprudence over technological efforts. As a British colony, the first legislation in India relating to patents was the Act VI of 1856 but it was repealed in 1857 and re-enacted in 1859. This is based on the United Kingdom Act of 1952. In 1872, the Act of 1859 was consolidated to provide protection relating to designs. It was renamed as "The Patterns and Designs Protection Act" under the Act XIII of 1872. The Act of 1872 was further amended in 1883 (XVI of 1883). The Indian Patents and Designs Act, 1911, (Act II of 1911) replaced all the previous Acts. Then after many recommendations of various committees to make it suitable for independent India, the Patents Act, 1970 was passed. This Act repealed and replaced the 1911 Act so far as the patent law was concerned. India has already restructured various sections and articles of the Indian Patents Act, 1970.

Genesis of Inventorship from Individualisation to Corporatisation

In a broader sense, creation is putting the idea into action. Creativity is simply an act from ideation to realisation and IPR is the socio-legal expression to recognize these valuable ideas which are of economic and moral in nature or both. Creation has two perspectives one is subjective and other is objective. Subjective perspective refers to a deep impulse of creation from the creator to bring his ideas into realisation. On the other hand, objective perspective calls for distinct societal and market demand for a product or a process (Dutfield & Suthersanen, 2008). Every patentable invention has two phases in its journey -technical phase and social phase. Technical

phase understandably consists of steps required for an invention and the social phases refers to the application of this invention to in the society to satisfy human needs and obtain social results which will act as inspiration for future inventions (Franzosi,1997). Schumpeter noted that innovation stemmed from social interaction which involves both creators and other actors. He further pointed out that creation and ideas are always there, but it needs an 'economic leader' to amass it for rendering an invention practical and socially acceptable (Schumpeter, 1934). Dutfield and Suthersanen aptly noted that creativity concerns the production and application of information in the conception, development and use of scientific, industrial and cultural goods, irrespective of whether the information or goods technically qualify as an invention, a literary work or a mark. What is creative and protectable at the policy level is subject to constant review and debate and it is primarily a political and commercial decision driven by the market and rarely decided on the basis of genuine objectivity.

Since the late 1970s and early 1980s, there has been an dramatic increase on privatising and commercialising the results of scientific research, especially in the United States. The number of patents issued to US universities increased manifold from 434 in 1983 to 3,259 in 2003 (Walsh, Cohen, and Cho 2007). Patents on biotechnology granted escalated from 2,000 in 1985 to over 13,000 in 2000 (Walsh, Cohen, and Arora 2003). This was not inspired by the scientific community rather triggered by political and economic decisions, including the Bayh-Dole Act of 1980 and the US Supreme Court decision on historic Diamond v. Chakrabarty (1980) case. As a result, it has broken the barrier of 19th century boundaries of inventorship and brought all esoteric subjects as patentable gene, DNA, plant varieties, semiconductor topographies. Cornish reinforced the idea and illustrated that IPR may be extended to new subject matters by *accretion* or by *emulation* (Cornish, 1993). Accretion involves re-defining an existing right and emulation option leads to sui generis and new and distinct rights. The modern patent system for inventions has some distinction from its precursor system. *Firstly*, adopted the notion of patent as a bargain between the inventor and the society, *secondly* introduction of the specification in patent application to ensure it as a genuine invention and *thirdly* keeping patentable bar as low as possible to capture incremental inventions by corporations. In the post- World War II, in 1952, American pharmaceutical

companies successfully lobbied to change the 1952 US patent act for antibiotic prepared from natural products. Patent act with favourable and advantageous language protected the interest of corporations to ensure that antibiotics discovered through techniques of systematic screening can be patented. Merges traced out a very significant change regarding inventorship through historical data.In 1885, only 12 per cent of patents were issued to corporations. Slightly more than one hundred years later, the scenario had completely reversed: by 1998, only 12.5 per cent of patents were issued to independent inventors. These two statistics define the end more than any other single factor, drove changes past one hundred years. Twentieth century was more marked for large product development rather than of the lone workshop tinkerer.

The R&D not only brought more hands into the inventive made available large pools of concentrated capital, from the onerous task of constantly raising research. Altogether, the consequences of this on the society are deep, complex and long-standing. The rise of corporate inventorship spurred a rapid of patents during the early part of the century (Merges, 2000). Dutfield (2009) observed three radical changes began to emerge from 1960s to 1970s in intellectual property (IP) regimes of developed nations. *The First of these was the widening of patentable subjects and narrowing the exemptions and limitations. Second change was the creation of new rights under the aegis of IPR and third change was the progressive standardisation of the basic features of IPR. In the third changes, in addition to the standardisation of the three basic criteria of novelty, inventive steps and industrial application for patenting another most important change was occurred, and it was assigning rights to the first applicant rather than the first inventor* (Dutfield, 2009). This clearly attested what Merges identified that the shifting of inventorship from individual to the hands of corporate. In the course of time, so called inventors have become mere tools in the hands of the assignee or the big corporations who have financed the research rather promoted the research for their financial benefit.

Serendipity Vs Designed Drug Invention

In 1916 polio outbreak in the USA left 6000 dead and 27000 paralysed necessitated an immediate solution to control this lethal disease. Jonas Salk announced the polio vaccine in 1955 and saved the world from polio

forever. Yet despite its enormous success, the vaccine was not patented. He was ethically against of patenting of any medicine. In this context, Salk's famous response may be recorded to understand the importance of enlightened value and morality that sparks the invention. When asked who owned the patent, Salk answered: "*Well, the people, I would say. There is no patent. Could you patent the sun?*" (Johnston & Wasunna, 2007). Public health emergencies could take the form of a widespread epidemic which often requires the immediate resort to pharmaceuticals. The relationship between invention and commercial or industrial application is complex in nature. Commercial realisation may not be in the same path with inventor's thought and inspiration. For an example, Aspirin first sold in 1899, was one of the first patented medicines, a popular treatment for headaches and mild fevers ever since. Its precursor was known about thousands of years, yet its real mechanism of functioning was discovered in 1970s. It is the prime example, how an invention can be and the lesson was learned by the pharmaceutical industry. American Chemical Society stated in their website-*Traditionally the development of a new drug would often depend on the fortuitous discovery …The development of cimetidine was radically different: it was one of the first drugs to be designed logically from first principles…Using a step by step analysis of structural and physical properties* ….(ACS, 2015).Today this approach of rational drug design underpins the discovery programs of many major pharmaceutical companies. Nowadays, pharmaceutical companies are dependent for their well-being on the success of so-called block-buster drugs. Cimetidine, an anti - ulcerant is the world's first blockbuster drug. A few more such blockbuster drugs are 1970's Cimetidine (marketed as Tagamet), ranitidine (Zantac) and Omeprazole (Losec or Prilosec) marketed by AstraZeneca. Blockbuster drug can only be blockbusters if they are patented and for only as long as the patents remain in force. After the patents expire to keep the market, companies do adopt the process of *evergreening* of their products with a moderate and cosmetic change in their products. Corporate innovations and with the worryingly heightened level of protection through patents not only deleterious for consumers in terms of higher prices, but it may actually stifle far more innovation than it promotes. Reduced access to knowledge encouraged by the patenting system has tremendous impacts on the drug development in developing nations.

Regulatory Capture to Promote Business

Among the most innovative and commercially successful businesses in the world are those involved in human health particularly those which develop, deploy and trade in biological, chemical and genetic technologies, products and services. While megacorporations like Pfizer, Bayer, Novartis, GlaxoSmithKline, Syngenta and AstraZeneca have annual turnovers higher than the gross national products of many developing nations. It is highly established assumption is that individuals invent but the conflicting reality is corporate invention is inherently collective. Two most important changes that occurred in international arena to come to this feat were firstly, making rules for assign rights to the first applicant who are in fact these corporations primarily not the first inventor and secondly, rules relating to national treatment which refers to domestic treatment to all foreign corporations or citizens in terms of legal rights and remedies. National treatment was and continues the prime pillar of international IPR law.

Dutfield (2009) , called all international IPR related acts, rules, treaties, government agencies, courts and professional organisations, courts and professional people involved in interpretation, implementation and enforcements together as Public Policy regulatory institutions. Influencing these regulatory institutions by private interest groups like corporations has a strong mutual long term commercial interests have been identified in George Stigler's seminal work (1971) the Theory of Economic Regulation.

Stigler in his seminal work made a firm footing the concept of regulatory capture though the concept was chalked out earlier in 1950. Basic assumption of this concept is firms, like individuals (politicians and bureaucrats) are motivated by utility maximisation. Utility for civil servants or politicians could be non-monetary whereas for firms it means only profit. Given the unique power of states to prohibit or compel, to take or give money these firms or corporations can be expected to try to use the state to increase their profitability. To maximize this profitability corporation generally use four means like firstly , seeking monetary subsidies, Secondly, to control market entry of rival firms, thirdly, to restrict substitute products and services and finally, to fix prices in collusion with the state agencies. Regulations Stigler argued that it injures society more instead of providing protection and benefit to the majority of the public (Stigler, 1971). If we

dig deep we find that this process leads to information asymmetry between the regulated and less informed regulators. Three decades ago, Hardin advocated for overuse of common resources introducing the metaphor of *tragedy of the commons* (Hardin, 1968) but overlooked the possibility of overuse of rights over resources to exclude others. The expansion of IP rights upstream (i.e., over the consequences of essential research) makes a progression of snags to downstream (i.e., applied) research and product advancement; the outcome is that upstream licensing not just neglects to boost the improvement of innovations, it likewise discourages it-forwarded as *tragedy of the anticommons* (Heller & Eisenberg, 1998). Despite several criticisms, later studies have reaffirmed that patenting inhibits the sharing of information upstream at least in biomedical research (Biddle, 2012). These information asymmetries lead to information monopoly over the information associated with the patented drugs that are quite deleterious for poor developing nations.

Dutfield (2009) advocated that regulations are not achieving economic efficiency at all but about distributing income from some sectors of the economy to others. The winners are special interest groups (firms, regulators and politicians) and the losers are commoners or public. These special interest groups have been propagandising at least in three forms. First, it may masquerade as self-evident in the name of a proof. Second, it may intimidate about the punitive actions if the rights being demanded are not granted. Third, it may link IPR with positive and innovative ideas and denigrate less favourable linkages made by opponents .

Paradox of Patent as an Institution

Institutionalist scholars like Thomas Veblen (Veblen, 1923), Robert Hale (Hale, 1923) and John Commons (Commons, 1989) analyzed the property rights in an economic system. Peter Drahos pointed out that property rights that actually emerge in the market place are not necessarily efficient, simple reason is that those who have the capacity to shape, design the property rights will be more interested in rents than efficiency (Drahos, 1999). Patent holding firms believe: *We invented something useful. It did not exist until we brought it into being. It is not something from the intellectual commons that we have appropriated. Our exclusive rights to use and market the invention does not incur any cost on society or intrude on any legitimate interests of*

other inventors or rival firms. But on a close scrutiny a number of serious issues are unearthed which make patent as a paradoxical institution.

Paradox One - Invention Relay-race

Creatio ex nihilo-is a Latin phrase that means 'creation out of nothing'. No creation or no invention for our purpose can be done without prior knowledge or advancement on the subject of invention. An invention, in fact, is a collective result of the tireless efforts of a number of inventors worked for at least a few generations, including people who made a far larger contribution to the invention relay-race. But unlike the scientific article, patent application mentions only a very few inventors at the end who carried the baton the last few inches over the finishing line and ended up with the patent. Sally Hughes sought the logical explanation behind this irrational system (Hughes, 2001). George Basalla argued that a patent bestows societal recognition on an inventor and distorts the extent of the debt owed to the past by encouraging the concealment the network of ties that lead from earlier, related artefacts (Basalla, 1989).

Paradox Two - Unjustified Wider Claims

Claims of a patent are in fact are boundaries surrounding the patent in question. Ideally claims should be only to the invention, one has invented, but practically patent claims are written in such a manner so that any invention that may compete with the present invention is blocked.

Paradox Three - Blocking Rival Firms

Granstrand described six different patent strategies: a) ad-hoc blocking and inventing around, b) strategic patent searching, c) blanketing and flooding, d) fencing, e) surrounding and f) combination into patent networks (Granstrand, 1999).

Commercial organisation often opts for *Bracketing* and *Clustering* against a product as anti-competitive strategy against rival firms. Clustering refers to building a patent wall around a product (Rivette & Kline, 2000). Patent clusters sometimes are also known as patent thickets which actually are overlapping set of patent rights that requires innovators to reach licensing deals for multiple patents from multiple sources. Patent thickets obstruct

entry to some markets and so impede innovation (Hargreaves, 2011).

Paradox Four - Crafty innovations

The "incentive-to-disclose" theory of patent protection was often formulated as a social-contract theory. This use of the Rousseau conception was another part of the strategy of the French politicians to avoid interpretation of patents as privileges. The patent was represented not as a privilege granted by society, but as the result of a bargain between society and inventor, a contract in which the inventor agreed to disclose his secret and the state agreed, in exchange, to protect the inventor for a number of years against imitation of his idea(Machlup and Penrose, 1950).

Not only so, sometimes disclosure which is one of the essential components of a patent document is not exactly divulged and camouflaged so that others products are always lagging behind in terms of efficacy. It makes a patent non-reproducible in true sense.

Paradox Five - Evergreening

Big corporations, particularly drug companies resort to one strategic policy to block generic firms to come to market in order to delay price-reducing competition even when their patent is expired or going to expire after 20 years with their crafty innovations over the original invention. This is popularly known as Evergreening.

Paradox Six - Interpretive Culture

Alike all property rights, patent as an intellectual property right affects all non-rights holder. Every single person except the patent holder has a duty to observe the rights granted. If the patent holder charges a monopoly price, then many more members of the society is directly affected. Say for an example, if the price of a drug for cancer is too expensive to afford then it truly kills patients. If major patent holding entities advocate and lobby in favour of stronger patent rights then more people will be affected deeply particularly in developing nations. Drahos (1999) explained this can lead to interpretive custody or interpretive capture that refers to a situation where an interest group, or a collection of such groups acting together, has achieved acceptance in government and society as authoritative, definitive and exclusive explicators of a particular issue.

Paradox Seven - Hidden Cost-benefit

So far economists have been unsuccessful in offering and determining what should be an optimal patent system. In absence of it, with this fundamental uncertainty, institutionalists' arguments had always been in favour of stronger patenting system. A stronger patent system may involve cost and benefits. Eggertsson advocated vehemently that sometimes regulations are initiated by special interest groups and spread falsified information in favour of cost-benefit analysis of the regulatory measure (Eggertsson, 2003). The cost/benefit analysis of a patent system is complicated, however, by the fact that a system protects all inventions satisfying the requirements of the applicable patent statute. Patent statutes do not distinguish, and appear incapable of distinguishing , those inventions that are patent induced from those that are non-patent induced. Thus, the social benefits and costs of a patent system must be evaluated on the basis of protecting all inventions, not just those that are patent induced (Turner, 1969).

Paradox Eight - A Tool for Trade Sanction

Economist investigated the spread of the patenting system from developed to developing nations found a causal relationship which for primarily trade imbalances, trapped in debt as a defaulter, higher prices for import goods due to patent protected monopoly price and reciprocal technological protectionism(Oddi, 1987). Failing to provide protection may lead to trade sanctions that could be imposed on products sought to be imported from developed nations. This is why in spite of unsuitable economies, overwhelming numbers of foreign patents in developing nations are bound to join international treaties and agreements related patents.

Paradox Nine - Invention without Patents

Man does not need a property or a privilege as a stimulus to invent, contended by Victorian industrialist, scientist, engineer and technical innovator, William George Armstrong (1810-1990). He allegorizes- *the seeds of invention exist, as it were, in the air, ready to germinate whenever suitable conditions arise, and no legislative interference is needed to ensure their growth in proper seaso*n.

Petra Moser introduces a unique historical data set of more than 8,000 British and American innovations at world's fairs between 1851 and 1915 to explore the relationship between patents and innovations. The data indicate that the majority of innovations — 89 percent of British exhibit in 1851 — were not patented. Comparisons across British and U.S. data also show that patenting decisions were unresponsive to differences in patent laws (Moser, 2012). Cross-sectional evidence suggests that high-quality and urban exhibits were more likely to be patented. The most significant differences, however, occurred across industries: inventors were most likely to use patents in industries in which innovations are easy to reverse engineer and secrecy is ineffective relative to patents. In the late nineteenth century, scientific breakthroughs, including the publication of the periodic table, reduced the effectiveness of secrecy in the chemical industry.

Paradox Ten - Non-patent induced Invention

Undeniably many inventions that have revolutionised the society are the fruits of this patent system. Patent-induced inventions certainly argued in favour of patenting system. In contrary to that, there are innumerable inventions had been carried out irrespective of availability of patenting system. The aphorism that "necessity is the mother of invention" undoubtedly reflects reality. In addition, there are inherent incentives provided to the inventor outside of any patent system, such as the potential for secrecy, the competitive advantage of being first on the market, and the possibility of developing source recognition of the product (product differentiation) (Scherer, 1980). These non-patent incentives may well provide an adequate inducement for many types of inventions, which may be categorized as non-patent-induced inventions. John Barton suggested the "learning curve phenomenon." which has particular application in high technology areas, where one would expect revolutionary inventions to be created. According to Barton, as a consequence of this phenomenon suggests that being there first provides an economic protection that is the equivalent of patent protection (Barton, 1984).

Paradox Eleven - Socially Indifferent Institution

Dutfield (2009) classified four types of pro-IP organisations that actually

influence law and policy at the international and national level: a) multisector business associations for which IP is one of the several issues they work on; b) single or multisector business associations that are dedicated to promoting IP interests of the firms they represent; c) single sector business associations that are concerned with several issues including IPR; and d) Expert associations that give support to the IP system through advising policymakers, capacity building, training and propagandising.

Regulation involves four kinds of actions like:1) designing of general rules, 2) creation of institutions responsible for their implementation, 3) the clarification of the exact meaning of a general rule in a particular circumstance, and 4) the enforcement of the rule in those circumstances. So based on the empirical evidences of scholars like Drahos, Dutfield, Braithwaite and Sell following are clear that:1) national patent system reflects primarily the interest of big, influential interest groups, 2) stronger and more expansive rules are designed to make those groups more dominant, and 3) it greatly affects consumers and other groups.

All members of citizenry undoubtedly have a stake in the patenting system. But fact is, consumers even in the developed countries are hardly involved in shaping law or policy related with Intellectual Property Rights (IPR). Consumers are considered as weak, diffused and voiceless entity but in case of pharmaceuticals, government in many countries, particularly in developing ones take definitive roles to protect their citizens and it clearly reflects the significance of patents especially in areas of health and biotechnology.

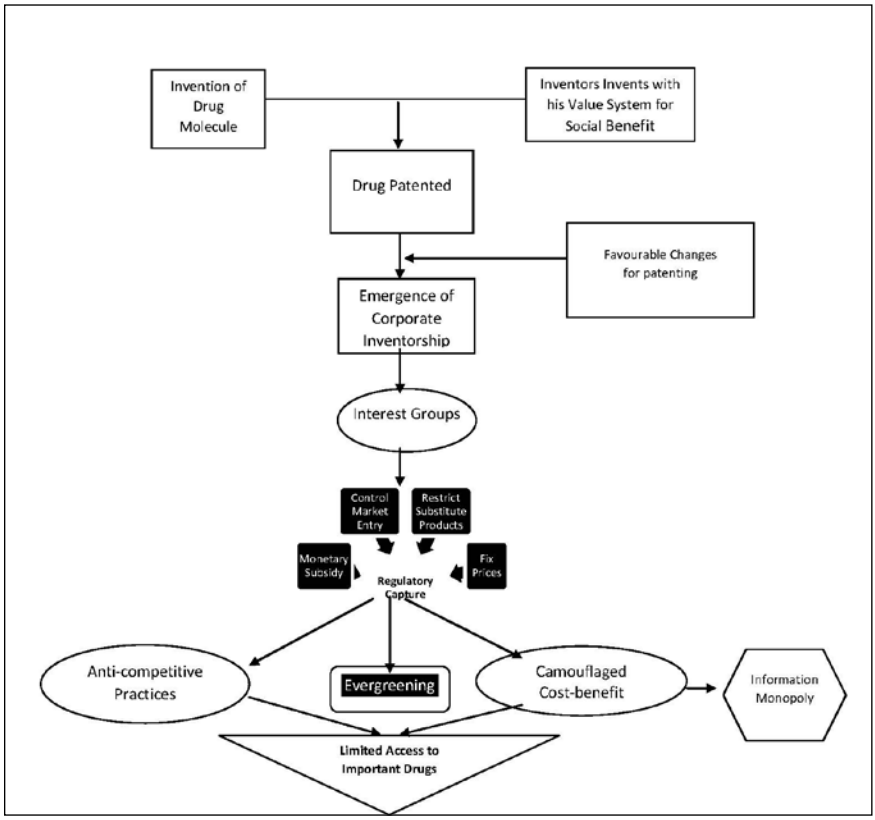
Paradox Twelve - Knowledge is Caged

Knowledge has always played a critical role to the organisation of human societies. The discourse about the rising centrality of knowledge to economic growth seems to imply a claim that human society — and more specifically, certain societies — are becoming more knowledgeable, leaving others behind. In the economic perspective, knowledge matters in its technological capacity, for its effect on productivity and growth. Karl Marx and Joseph Schumpeter early on posited that capitalism relies on technological dynamism, but the role of knowledge was not recognized in the neoclassical paradigm until the work of Robert Solow in the 1950s. Mainstream

economists soon began to contend that knowledge is not only important, but *increasingly* important to economic growth, positing that the world's most developed economies have been becoming more knowledge intensive. Manuel Castells refers to this as a transition to the "informational" mode of development. Castells defined knowledge as a *set of organized statements of facts or ideas, presenting a reasoned judgment or an experimental result, which is transmitted to others through some communication medium in some systematic form* (Castells, 1996). The rise of new forms of knowledge management and the application of sophisticated information-processing schemes to fields such as health means that our relationships to our very bodies–how we live–is more intimately governed by scientific and technical knowledge and information than ever before. Intellectual property rights are legal entitlements that give their holders the ability to prevent others from copying or deploying the covered information in specific ways. Patent, is one of the most familiar forms of intellectual property regulates information in a different way. Patent law regulates strategies of information production and the appropriation of value from information in the marketplace, which has become a central battleground in the struggles over the structure and spoils of the contemporary economy.

Adopted in 1995, TRIPS (Trade-Related Aspects of Intellectual Property Rights) was the brainchild of key players from the multinational information industries, that is, companies whose primary business is the production and processing of information and informational goods. CEOs from companies such as Pfizer, Merck, Monsanto, DuPont, General Motors, IBM, and Warner Communications, through a high-powered lobbying group known as the Intellectual Property Committee, persuaded the United States, Europe, and Japan that the agreement was needed to protect their national interests in strong intellectual property protection. This shift has been called a *second enclosure movement*, a metaphorical move that casts it as a modern-day analogue of the privatisation of common lands that occurred in stages in England from the fifteenth through the nineteenth centuries (Krikorian & Kapczynski, 2010). This has also inaugurated a new mode of *conquest* and *imperium* by the TRIPS as a binding obligation of all the World Trade Organization (WTO) members. Thus the critical knowledge is caged by the patent laws and acts and majority of the world population is greatly suffered for that (figure 1).

Figure 1: Multiple Regulations Restrict Access to Important Patented Drugs



Source: Author Compilation.

What is Value Pluralism?

Oxford philosopher and historian of ideas Isaiah Berlin is credited with being the first to popularize a substantial work describing the theory of value-pluralism, bringing it to the attention of academia. Value pluralism also known as ethical pluralism or moral pluralism is the idea that there are several values which may be equally correct and fundamental, and yet in conflict with each other. An example of value-pluralism is the idea that the moral life of a nun is incompatible with that of a mother, yet there is no purely rational measure of which is preferable. Hence, moral decisions

often require radical preferences with no rational calculus to determine which alternative is to be selected (Audiopedia, 2017). In addition, value-pluralism postulates that in many cases, such incompatible values may be incommensurable, in the sense that there is no objective ordering of them in terms of importance. Value pluralism is opposed to value monism. In his inaugural lecture in Oxford in 1958 Berlin propounded *Two Concepts of Liberty that* describes his philosophical position as follows: *If, as I believe, the ends of men are many, and not all of them are in principle compatible with each other, then the possibility of conflict and of tragedy—can never wholly be eliminated from human life, either personal or socia*l (Berlin, 1969). For Berlin *the ends of men are many*-is an acknowledgement of diversity and plurality in values and ends in both personal and social life. He also has a deep awareness that among these values and ends there can be conflict. Human beings are confronted with value conflicts in their lives. These conflicts occur not only between societies, but also within the same society, within groups with their different subcultures and even within the various roles individuals play in life. Already in 1956 Berlin wrote that: …

> *in life as normally lived the ideals of one society and culture clash with those of another, and at times come into conflict within the same society and, often enough, within the moral experience of a single individual;*

that such conflicts cannot always, even in principle, be wholly resolved. An example of a value conflict Berlin often uses is the conflict between justice and mercy: …

> *a world of perfect justice — and who can deny that this is one of the noblest of human values? — is not compatible with perfect mercy. I need not labour this point: either the law takes its toll, or men forgive, but the two values cannot both be realised*.

Berlin argued that there is no universal ranking of moral rights and duties. So when we are confronted with a situation where we have conflicting moral duties that cannot be put in a rank order of importance, we will inevitably have to choose which to fulfil and which to leave unfulfilled, but we will have no principled basis for our decision. Metaethical pluralism — the claim that at least some values inevitably conflict with each other, even under conditions of rationality, good will, and full information. John Gray's position might be called *bounded modus vivendi* and rests on the

claim that pluralism makes it impossible to show that any value system (such as liberalism) is morally preferable but that there are nonetheless some ways of life that are demonstrably immoral. Relativism — the claim that the fact of pluralism means that there is a large number of differing and incompatible value systems that cannot be put into any rank order at all. At least in this general version, relativism is distinct from nihilism — the claim that there are no true moral values, and thus, that differing moral systems cannot be ranked because they are equally meaningless. These three positions — *liberalism, bounded modus vivendi, and relativism* — reflect the logically possible positions with regard to pluralism. Moore pursued that value pluralism is in fact is the inability of ranking of values or value systems. He further argued that if two individuals, or two value-systems, conflict, it is possible that they may come to an agreement (Moore, 2009). Berlin used justice or equality or public order as obvious examples of values.

Rawls reinforced Justice is the first virtue of social institutions, as truth is of systems of thought. A theory however elegant and economical must be rejected or revised if it is untrue; likewise, laws and institutions no matter how efficient and well-arranged must be reformed or abolished if they are unjust (Rawls, 1971). It is a cliché that what is ethically allowed and not allowed change with the circumstances. In instances of need, for a lot of much conduct that would be generally unmerited, impermissible, or wrong turns out to be perfectly reasonable (Oberdiek, 2004). Value pluralism has a number of different forms, depending on its level of generality, but most basically it is the thesis that there are innumerable irreducibly distinct values that are (at least sometimes) incompatible (Larmore, 1994). On the other hand, context doesn't alter a right's content. The right's content remains unchanged and uninfluenced irrespective to circumstances. Circumstances, may oppose a right (justifiably) infringes or (wrongfully) violates the right. Thomson and Feinberg with Robert Nozick, called this as moral space of conception of rights. The paper argues that values are indeed plural and possible consequences (if any) of it on patents of medical innovations in India emerge from this plurality.

In 2005, the United Nations Education, Science and Cultural Organization (hereafter UNESCO) accepted the universal bioethical principle and human right of Article 12 of the Universal Declaration of Bioethics and Human Rights (hereafter UDBHR or 'Declaration'), which

reads as follows:

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope (UNESCO 2006).

***Recognising** that health does not depend solely on scientific and technological research developments but also on psychosocial and cultural factors,*

*Also **recognising** that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole.*

*Also **bearing in mind** that a person's identity includes biological, psychological, social, cultural and spiritual dimensions,*

***Convinced** that moral sensitivity and ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play a predominant role in the choices that need to be made concerning issues arising from such developments.*

It has to be kept in mind that the UDBHR describes itself as 'universal principles based on shared ethical values' in its *Foreword* (UNESCO 2006). These principles are also known as 'common morality'. Rawls acknowledged that pluralism is a permanent historical reality that cannot be ignored. He is convinced, however, that this reasonable pluralism does not wish to impose values upon others, but rather strives after shared values and is built on the viewpoint that diverse ethical traditions share minimum ethical values based on consensus.

Innovation and Plurality of Value System

Internalisation of research and development activities has been the core of economic dominance and monopoly of multinational pharmaceutical firms. Innovation is commonly understood as a process that realises creative ideas, i.e. turns them into practice. Innovation is the basis by which an entrepreneur either creates new wealth producing resources or endows existing resources with enhanced potential for creating wealth. These resources and capabilities

can lead to distinctive competencies and are expected to result in competitive advantages. Both local and global factors influence innovation. For example, increasingly sophisticated consumers, heightened domestic and foreign competition, and access to more advanced resources all create pressures on firms to innovate. At the national level, innovation is one of the most crucial dimensions of economic success (Allred & Swan, 2004).

To date, we have had only limited information on the nature of innovation activities in developing countries, on how countries develop the capacity to innovate, how it evolves over time, and what the potential barriers to innovation are. Most work on innovation has been done through the advanced country lens, and innovation is commonly seen as the work of highly educated labour in R&D-intensive companies with strong ties to the scientific community. It has, therefore, been largely perceived as a activity of advanced nations. The study reveals that innovation is a process that changes the value systems of both producers and adopters. The socio-cultural, economic situation greatly varies from developed to developing nations. Value systems are encapsulated in situations that are different for every agent.

The process that produces situations is called situatedness (Clancey 1997). Value systems using the function-behaviour-structure (FBS) and situations model using the idea of three interacting worlds has demonstrated the intricate relationship between value systems and innovations (Gero and Kannengiesser 2004). This model rightly depicts that situations are the carriers of value system as they produce expectations that lead to interpretations. It has propounded three interrelated worlds like *external*, *interpreted* and *expected world*. The *external world* contains symbolic or physically embodied value systems made available for interpretation. The *interpreted world* provides an environment for analytic and associative activities, related to current and previous value systems. The *expected world* forms goals through focussing on parts of the interpreted value systems, and predicts the effects of actions to modify the value systems in the external world. A situation in this model can be viewed as a snapshot of the interpreted and expected worlds at a particular point in time. The situation changes as a result of interactions between the three worlds. It is suggested that social ties, amplifiers and gatekeepers among both producers and adopters. Social ties refer to formal or informal groups of agents. Amplifiers

include agents or groups of agents with high visibility or reputation among their peers. Gatekeepers are agents or groups of agents with the normative authority to allow or reject specific designs to enter a society of producers or adopters (Gero and Kannengiesser 2009).This authority may be given explicitly by laws or regulations like certification authorities or implicitly by opinion leadership, e.g. trade magazines or market leaders.

Knowledge in Indian Value System

Vedas from which all knowledge of Hinduism sprung are also "Apaurusheya" that means the knowledge is eternal and divine and already present in the universe. Besides this the core teaching and purpose of the Veda's and Shastra's is to take care of all the creatures including nature, and to lead them towards moksha (the final emancipation of the soul) at the end. These scriptures were written from this point of view of Universal welfare and not to gain any personal fame, fortune and for any monetary gain.

In general way a patent is an exclusive right granted for an invention or knowledge the patent owner has the exclusive right to prevent or stop others from using invention or knowledge. In other words, patent protection means that the invention cannot be publically made, used, distributed, imported by others. The purpose of Hinduism scriptures is to ensure true welfare of all beings-both material and spiritual. The knowledge is being transmitted orally through *Guru-Shishya* tradition, for thousands of years and thus kept intact physical, mental, social and spiritual advancement of the people at large.

The vedas, puranas, upanishads and the other Hinduism texts are written with this point of view only. Because the ancient sages were knowing that material benefits are temporary and are perishable. That's why most traditions consider eternal *moksha* the ultimate goal.

So we can see the ultimate purpose of the scripture is to lead every one towards *Moksha*. The sages, saints and writers of Hinduism scriptures didn't claim any intellectual property rights on their writings or the knowledge they gained. Simply they did not want any material gain from doing this. Even some of them have not taken the credit by mentioning their name. (Vishwananda & Srinivasan 2017).

Indian Perspectives: Case Studies

To understand the issues discussed previously in a holistic manner I will illustrate two very important patented drugs that are used in India.

Case Study One: Sandostatin LAR

Active Ingredient: OCTREOTIDE ACETATE (Cleveland Clinic Cancer, n.a)

Generic Name: Octreotide

Molecular Formula: $C_{51}H_{70}N_{10}O_{12}S_2$

Other Trade Name: Sandostatin®

Dosage Form; Route of Administration: INJECTABLE; INJECTION

Approval Date by the FDA: Nov 25, 1998

Applicant Holder Full Name: Novartis Pharmaceuticals Corp, Switzerland

Marketing Status: Prescription

Four US Patents Granted to Novartis: US 4395403 , US 5538739 , US 5639480 & US 5688630 (USPTO database)

Patent Granted on – July 26, 1983, July 23, 1996, June 17, 1997 & November 18, 1997 respectively

Patent Expired on-January 13, 2017 (last patent with term extension)

Octreotide Acetate is the acetate salt of a synthetic long-acting cyclic octapeptide with pharmacologic properties mimicking those of the natural hormone somatostatin.

Octreotide is similar to a natural chemical called somatostatin. Somatostatin is produced in the body by the hypothalamus. One of its functions is to "switch off" the secretion of growth hormone by the pituitary gland. Somatostatin also decreases splanchnic blood flow and inhibits the release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin and pancreatic polypeptide. These actions are what help to control the symptoms of flushing and diarrhea in carcinoid tumors and Vasoactive Intestinal Peptide (VIP) secreting adenomas.

Somatostatin is chemically unstable and broken down by the body within minutes of its release. Octreotide, in contrast, is very stable and, therefore, much longer acting. It is for this reason that octreotide is preferred for

medicinal use (Pubchem). Sandostatin LAR is a hormone drug that is used to treat some types of cancer. This medication is classified as a somatostatin analog. This medicine is given to control symptoms such as diarrhea or flushing in patients with tumour.It generated global sales of $1.52bn for Novartis in 2012. Sandostatin was first launched in 1988 and is approved in more than 100 countries. Sandostatin LAR is approved in 47 countries for delaying tumour progression in patients with midgut carcinoid tumours.

Instead of having effective and cheap generic drug (bioequivalents) from Sun Pharma of India approved by the USFDA in 2007, yet market was not opened to it. Still it is imported and sold in India at an astronomically high prices and common Indian citizen are mercilessly exploited for their sufferings. In India it cost Rs. 65,499/ vial of 0.2mg/ml. This medication is generally given once every 4 weeks for 6-12 months. Prices are for cash paying customers only and are not valid with insurance plans. In this context, Drugs@FDA says Sandostatin LAR is what generics makers call "complex generics," which are complicated to produce and develop, so the bar for market entry is high (Sagonowsky, 2017).

The cost for Sandostatin LAR in international market, is around $2,964 . Novartis received the supplemental approval on July 1, 2014 from the FDA, US. Sharp contrastingly price of generic of Octreotide produced by Sun Pharmaceuticals Industries Ltd, India (Medindia, 2011) approved by the USFDA on August 18, 2007 which costs Rs. 255.00 Only ($3.91 / €3.18).

Very recently Sun Pharmaceuticals has got one US patent (number 10,342,850) *granted in* July 9, 2019 on *Octreotide* Acetate which will expire on May 15, 2038.

Case Study Two: Postinor

Chemical Name: Levonorgestrel (1.5mg) [LNG]

Molecular Formula: $C_{21}H_{28}O_2$

Route of Administration: Oral

Applicant Holder Full Name: Richter Gedeon, Ltd., Hungary

Marketing Status: Over the Counter (OTC)

Two Indian Patents Granted to Richter Gedeon , Ltd.

IN206098 (product)

IN202297 (process)

Patent Applied on: 26/11/2002

Patent Granted on 17/04/2007

In 2010, Indian Patent Office revoked Indian Patent Number IN202297 issued to Richter Gedon. Postinor containing the active ingredient levonorgestrel is an emergency hormonal contraception more commonly known as the "morning after pill". Levonorgestrel is a synthetic progestational hormone with actions similar to those of Progesterone.

The medication works by preventing the release of an egg from the ovary, fertilisation of the egg by sperm and changing the lining of the uterus (womb) to prevent development of a pregnancy. The tablets should only be used as an emergency contraceptive or backup in case regular birth control. On August 31, 2005, nonprescription, over-the-counter (OTC) access to levonorgestrel-only emergency contraception was approved by the Drug Controller of India.

Growing Concern of Emergency Contraceptive Pill (ECP)

Sale of ECP in last five years has increased almost four times from 4.9 million in 2008 to 16.4 million in 2013.The 18 large metro cities contribute 29 per cent of the total sales while Delhi NCR alone accounts for 8.6 per cent, followed by Mumbai and Kolkata. (Sharma, 2015).Other methods of contraceptive-usage declined 30-34 per cent in the same period. In 2007-08, no more than 8,958 emergency pills were sold in Haryana, the state with India's lowest sex ratio. Eight years later, the number had risen to 128,000, a 13-fold rise. The number of vasectomies, IUCD insertions and condoms sold in the state dipped 34 per cent, 30 per cent and 32 per cent, respectively, over the same period (Paul, 2017). Indian women are spending big on morning after pills.

According to recently released data from, India's market for emergency contraceptives jumped 88 per cent to $104.4 million (Rs. 667 crore) between 2009 and 2014, ranking the country third in the world after the US and China (Euromonitor International) (Thomas, 2015). Together, these three countries accounted for about 73 per cent of global emergency contraceptive sales.

The Emergency Contraceptive Pill, available over the counter, has triggered a sexual revolution of sorts in India. It may have its side effects, but that's no deterrent for young people keen to enjoy the sexual freedom it has to offer (Das, De, & Chakrabarti , 2013). Renowned Sociologist G.K. Karanth points out: "Growing promiscuity and a trend of premarital sex are fuelling the increasing use of emergency contraceptives."

Emergency contraceptives can change hormonal patterns and even lead to the development of polycystic ovary syndrome if used too frequently, which often happens in India. On top of this, the pills leave women vulnerable to sexually transmitted diseases (STDs).

It's also known that the ECP increases a woman's risk of breast and cervical cancer (Thomas, 2015). Prevalence PCOS (Polycystic Ovarian Syndrome) among adolescents has been increased from 9.13 per cent to 10.97 per cent. Prevalence of Polycystic Ovarian Syndrome in Indian Adolescents. In clinical trials, ECP efficacy was reduced in women weighing 75kg or more, and levonorgestrel was not effective in women who weighed more than 80kg. European Medicines Agency has started investigation whether increased weight and body mass index reduced their effectiveness (Daly, 2014).

Disturbing Facts related with Prevalent Cancers in India

- Every year new cancer patients registered over 0.7 million in India
- Cancer-related deaths 0.56 million (in the age group 30-69 years)
- Stomach, colorectal and hepatocellular carcinoma are the third most occurring cancer among both men and women in India. Sandostatin LAR discussed in the case study one is generally prescribed for these types of cancers.
- Breast and cervical cancer are the first and second most occurring cancer among women in India. Excessive ECP consumption also increases the risk of these cancers.
- Now, the global cancer death numbers have reached 8.8 million per year, out of which, India unfortunately is the largest contributor with the number of cancer deaths falling at 2.2 million per year.
- *(National Institute of Cancer prevention and research (NICPR) , the*

Indian Council of Medical Research (ICMR), Govt. of India) (NICPR, 2018)

Choices before Us

Every year new cancer patients registered over 7 lakh, cancer-related deaths 556,400 (in the age group 30-69 years) according to the data provided by the National Institute of Cancer prevention and research (NICPR, 2018) , the Indian Council of Medical Research (ICMR), Govt. of India. Out of this, stomach, colorectal and hepatocellular carcinoma are the third most occurring cancer among both men and women in India. Sandostatin LAR discussed in the case study One is generally prescribed for these cancers. The statistics also reveals that breast and cervical cancer are the first and second most occurring cancer among women in India. Now, the global cancer death numbers have reached 8.8 million, out of which, India has unfortunately is the largest contributor with the number of cancer deaths falling at 2.2 million per year.

On the other hand, treatment is either very costly or is out of the reach of the patients. India's per capita income (nominal) was $1670 in 2016, ranked at 112th out of 164 countries by the World Bank. Given the present context, we can think of judicious combinations of options to make the patenting system socially more acceptable and sustainable.

Choice One: Value and Ethical Judgement and Right Education for Pharmacists

Pharmacists are professionals that practice behind a standard code of ethics based on well-defined value system. Society relies on pharmacists to exercise their judgment and expertise when dispensing a medication. Pharmacists are not simply dispensing robots that must fill every prescription that they are presented with. There are many instances in which two drugs adversely interact with one another, and society expects that pharmacists will use their powers not to dispense in such a situation. The same can be argued when pharmacists are presented with a Plan B prescription. Besides they can also practice of dispensing ECP to the customers only on the production of prescription from registered practitioners.

Choice Two: Restrictive Price for ECP

Now ECP is available in OTC format. Its reckless consumption can be arrested to some extent if the price becomes restrictive. It may not solve the whole issue but can potentially curve the present consumption pattern.

Choice Three: Using Flexibility of Provision of *Ordre Public*

Ordre public basically is not a concept of international, but of domestic law. Protecting the basic values, *ordre public*, or 'public policy', as it is usually called, is an exceptional yet necessary device to avoid unacceptable results. These unacceptable results may be a consequence either of the application of a foreign law or of the recognition and enforcement of a foreign decision (Gebauer).

Article 27.2 of the TRIPs allows member countries to exclude form patentability such inventions which may offend the morality or public order of the society. Nothing has been clearly defined in the TRIPs with respect as to what comes under the morality. There is no *ordre public* and no public policy for all times and for all nations. Public policy is necessarily variable and dynamic. It changes with changing conditions and changing society. The *ordre public* is a function of time and place. We can exercise the discretion of value pluralism here to invoke *ordre public* for safeguarding public health.

The Indian Patents Act, 1970 provides a statutory provision regarding the public order or morality exclusion. Section 3(b) of the Indian Patents Act states that "*an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment*".

The exclusions of 'public order' or 'morality' from patentability vary from country to country as the scope of application of these exclusions largely depends upon local cultures and practices. What is considered as immoral in one country can be considered as normal practice and comes under public order. The terms 'public order' or 'morality' are full of ambiguity and vary according to the practices of the particular state. Looking into the issue that whether law is a reflection of morality or the same can be divorced from the former, the positivist school of law states that the law should be separated from morality and should be based on logic

and reasons. However the school of natural law argues that law reflects the morals and norms of the society and it cannot be based purely on rules of reason and logic.

Accordingly the positivist will argue that the patent shall be granted as long as the invention in novel, inventive and useful and morality should have no role to play in the grant of the patent. On the other hand, school of natural law will present opposite views that an invention which offends society's morals should not be granted patents reason being the natural schools fundamental principle that the law is a reflection of morals of the society and something which offends morality of society cannot be given a legal character. Indian patent office and finally by the Supreme Court of India rejected drug manufactured by Novartis for Chronic Myeloid Leukemia for two distinct reasons-a)Evergreening (sec. 3d) (modified version of Imatinib) b) Against *Ordre Public* (sec 3b).

Further the draft manual of Patents of Indian Patent Office also provides grounds for compulsory licensing; *Patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest especially in sectors of vital importance for socio-economic and technological development of India. Patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.*

Choice Four: Advocacy for Policy Reform in TRIPS for No Product Patents in Developing Nations

When the drug or active ingredient is itself patented, no one else can make the identical compound, such that a patent can enable the manufacturer to charge a premium price.

On the other hand, a patent on only the process of making the drug does not block others from developing different methods of making the same drug. Moreover, if there are multiple manufacturers of the identical drug, such competition effectively lowers prices.

Choice Five: Invention without Patent

Petra Moser examined a unique data set of more than 8,000 innovations at four world's fairs between 1851 and 1915. Most important, exhibition

data make it possible to systematically compare innovations with and without patents across industries, countries, levels of quality, levels of urbanisation, and over time. Exhibition data confirm a key result of modern surveys: patents are just one of many mechanisms that protect intellectual property and may, in fact, play a limited role in creating incentives to invent. In 1851, 89 percent of British exhibits at the Crystal Palace fair were not patented. Exhibition data indicate that 85 percent of U.S. exhibits in 1851 occurred outside the patent system, which suggests that the effects of the U.S. patent system may have been much smaller than traditional accounts suggest. Theoretical models predict that inventors use patents to protect small innovations but keep large innovations secret (Anton & Yao, 2004). In fact, patent laws may affect the direction of technical change if the necessity of patent protection varies across industries. Without patent laws, inventors focus on a small number of industries in which they can use alternative mechanisms to appropriate the returns from research and development. With patent laws, the center of innovative activity may shift to an entirely new set of industries, even as it fails to increase overall levels of innovation (Moser, 2012).

Choice Six: Prize System as an Alternative to Patenting System

Arrow (1972) narrated why some incentive scheme is useful, but not all scheme. Many schemes have been used in practice. In the seventeenth century, prize was first offered in France for developing a workable water turbine (Reynolds 1983). Similarly research and development works of scientists and innovators nowadays are sponsored to a large extent by government grants.

Fisher proposed a prize system as an alternative that may partially alleviate patent related drug prices. A prize system would work quite differently. Instead of authorising drug developers to exclude competitors, the government would pay successful developers. Other firms, including generic drug manufacturers, would be free to make and sell the drugs in question. The resultant competition would keep drug prices close to the modest costs of manufacturing them. The money necessary to run such a system would come, not from consumers (or their insurers), but from taxpayers (Stiglitz, 2006).

A prize system of the sort sketched briefly above has four potential benefits.

First, it would enable us to avoid the most serious of the drawbacks of the current patent system – namely, the social-welfare losses caused by the monopoly pricing of patented products. Second, a prize system can take advantage of the way in which knowledge concerning actual or potential pharmaceutical products is typically distributed (Fisher & Syed, 2006). The third and final potential benefit of a prize system is that it could reduce socially wasteful expenditures by pharmaceutical firms. The largest potential source of savings consists of marketing costs. Estimates of the magnitude of those costs under the current regime vary. Some scholars contend that pharmaceutical firms devote roughly one third of their revenues to marketing their products.

Choice Seven: Open Source Research

The Open Source Research programme aims to share all information, data and ideas in real time and openly with fellow researchers.

Open Source Drug Discovery (OSDD) contrasts with traditional drug discovery programmes which are typically implemented with defined teams, behind closed doors, releasing limited information into the public domain: Scientific teams compete to discover drugs with high commercial value, and feel more comfortable conducting research in secret. This is based on few principles (Todd, 2011):

- First law: All data are open and all ideas are shared
- Second Law: Anyone can take part at any level of the project
- Third Law: There will be no patents
- Fourth Law: Suggestions are the best form of criticism
- Fifth Law: Public discussion is much more valuable than private email
- Sixth Law: The project is bigger than, and is not owned by, any given lab. The aim is to find a good drug for malaria, by whatever means, as quickly as possible.

Open Source Drug Discovery (OSDD) is a CSIR led team India Consortium with global partnership with a vision to provide affordable healthcare to the developing world by providing a global platform where the best minds can collaborate & collectively endeavor to solve the complex problems associated with discovering novel therapies for neglected tropical diseases like Tuberculosis, Malaria, Leishmaniasis etc (CSIR, 2008).

Choice Eight: Inclusive Business Model

An 'inclusive' business model is one that explicitly aims to include people living on very low incomes in its customer base in order to improve access to specific medicines or other health products. These models can be either cost-neutral or, ideally, commercially sustainable. 'Inclusive' business models see poorer populations as part of a sustainable market for medicines and health products. Such models can have a particular impact on access in emerging and frontier markets, which often have weaker health systems. These business models (Table. 1) go beyond pricing, licensing and donations initiatives, recognising that conditions and circumstances in low-and middle-income country markets can be vastly different. Five companies are expanding commercial opportunities through different six innovative and inclusive business models (Access to Medicine Foundation, 2018).

Table 1: Innovative and Inclusive Business Models

Company	Innovative and Inclusive Business Models
Eli Lilly	*Lilly Expanding Access for People (LEAP)* Lilly Expanding Access for People (LEAP) aims to improve training for physicians to manage diabetes and strengthen links between communities and hospitals in China.
GSK	*Live Well social enterprise* Live Well social enterprise builds and supports local distributor networks in Zambia by training community health entrepreneurs to become lastmile distribution agents.
Merck KGaA	*Curafa™ programme* The Curafa™ programme establishes primary healthcare centers in five counties in Kenya.
Novartis	*ComHIP program* ComHIP program enables patients with hypertension to access diagnosis and care at community level in three districts in Ghana.

Novartis	*Novartis Access* Novartis Access markets 15 generic and on-patent products for non-communicable diseases to national governments, NGOs, etc., for USD 1 per treatment per month in Ethiopia, Kenya, Rwanda and Uganda.
Roche	*Global Access Programme* The Global Access Programme provides better access to diagnostic testing for HIV/AIDS in sub-Saharan Africa including Ethiopia, Nigeria and Rwanda.

Source: Access to Medicine Foundation, 2018

The Tres Cantos Open Lab Foundation (TCOLF) of *GSK*, a specialist research centre in Spain, created in 2010, allows independent researchers to access GSK facilities, resources and expertise to help them advance their own research into diseases of the developing world. A second initiative, Trust in Science, aims to build R&D capacity. A third initiative is the global health R&D catalyst unit, which oversees GSK's Africa NCD Open Lab and its maternal and neonatal health R&D unit.

Johnson & Johnson's extensive financial and on-site resources to enable groups behind early-stage projects to overcome limitations associated with development.

In 2017, Merck KGaA launched Merck Global Health Institute, as part of its new corporate affairs function. The overall mission of this institute is to develop health solutions – through R&D, capacity building and access planning – focused on controlling and eliminating infectious diseases that severely impact children, and to contribute to the United Nations Sustainable Development Goals. It focuses on developing, producing and distributing new products to address malaria, schistosomiasis and bacterial infections, including antimicrobial-resistant bacteria, in low- and middle-income countries. To accelerate innovation in R&D, the institute seeks to establish partnerships with a range of public and private partners, such as universities, access-oriented organisations and major funding bodies around the world, including those in low- and middle-income countries. Since April 2017, it has established more than 30 partnerships to develop projects for target diseases.

*Merck Glo*bal Health Institute partners up to accelerate R&D for bacterial infections, schistosomiasis and malaria GLOBAL Institute setting

up R&D partnerships to develop projects to target bacterial infections, schistosomiasis and malaria in low- and middle-income countries(Access to Medicine Index 2018;Open Lab, 2014).

Choice Nine: Quick Publications of Research Findings Hasten innovation

Instead of keeping research results secrets for patent application, Government may encourage scientists and researchers to publish their research output as early as possible so that the development quickly spreads across the global citizens. Governmental research funding can only be available with the declaration from the project investigators to that effect.

Choice Ten: Change in National Innovation Ecology and Creative Culture

India's expenditure on education 3.8 per cent of Gross Domestic Product (GDP), 0.6 per cent of the GDP for R & D placed India in 52 ranking by the Global Innovation Index (GII) 2019 which is understandably neither adequate nor very conducive for generating a creative ambience and of course cannot solve acute crisis of drug development and access to medicines. Most innovative nations strikingly invest much more in R&D to develop a creative ecology like both Switzerland and Sweden spend 3.4 per cent of GDP (Rank 1 & 2 in GII, 2019), the United States of America spends 2.8 per cent of GDP(Rank 3 in GII, 2019), the United Kingdom spends 1.7 per cent (Rank 5 in GII, 2019), Singapore Spends 2.2 per cent of GDP (Rank 8 in GII, 2019), Germany spends 3 per cent of GDP (Rank 9 in GII, 2019), and China spends 2.1 of GDP (Rank 14 in GII, 2019). Experts opine that it should be at least in the order of 3 per cent of the GDP to develop a competitive innovation ecology and creative culture in the society in terms of S&T infrastructure development and manpower development etc.

Conclusion

It is probably safe to conclude that the current unsustainable patent system can survive only on the condition of widespread infringement (Biddle, 2012). If multiple value system can be equally well justified, then it is suggested that the decision making process should not only be based on epistemological or evidence and reasoning, instead we should expect it to involve compromise and collaboration, open-mindness and a tolerance for complex processes and imperfect outcomes (Marino, 2017). The problems raised by innovative solutions are not just technical issues, but bigger issues that need intensive dialogue and consensus that lies at the heart of ethics. Decision-making structures must be developed to encapsulate the far-reaching impacts on societal values. Similarly, as costs for new technologies increase exponentially, the potential for further challenges — to equity or access — may grow (Mossialos, 2018).

Monistic approach fails to resolve the moral dilemma and bring practical rationality in existing patenting system. IP is probably the best screening mechanism for projects where the sponsor cannot observe value and costs, since the private value of IP reflects social value, and companies automatically compare some measure of value with innovation costs. IP regime is based on length, breadth and standard for the protection (Gallini & Scotchmer, 2001). Analogous concept of fair use in copyright may be introduced in the patenting system as the present patent regime premised on 'one size fits all' is not rational enough as the optimal length of the present patenting system may not fit all member nations of TRIPS. Innovation should be protected for the long term societal benefit but rewarding system should be adequately flexible so that harmonisation of patent is not driven by economic interests only and social value of the participating members are respected.

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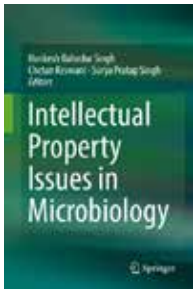

Intellectual Property Issues in Microbiology (2019)

Harikesh Bahadur Singh, Chetan Keswani and Surya Pratap Singh ((Eds.) Singapore: Springer, Pp 402 , ISBN 978-981-13-7465-4 ISBN 978-981-13-7466-1 (eBook) https://doi.org/10.1007/978-981-13-7466-1

Intellectual Property Issues In Biotechnology (2016)

Harikesh Bahadur Singh, Alok Jha, and Chetan Keswani (Eds.) Wallingford: CABI, Pp 278, Hardback, ISBN 9781780646534

The two volumes reviewed here address Intellectual Property (IP) issues in biotechnology and microbiology and have comprehensively covered the developments. This review article highlights the relevance of these volumes for debates on IP as a tool for incentivisation and how IP can positively or negatively affect, inter alia, access to drugs, food sovereignty and access and benefit sharing.

Intellectual Property Issues In Microbiology

The volume begins with Chapter 1 which examines the patentability of subject matter in the United States, and discusses, the state of the patent system where boundaries are not clearly defined. Mireles cites important precedents of cases in the United States Patent and Trade Mark Office (USPTO), and analyzes the patent eligibility subject matter and acknowledges the key

role of the court decisions in framing guidelines. Chapter 2 focusses on the emerging field of synthetic biology and role of intellectual property rights in that field. Lucchi examines the issues in finding the right mode of protection in synthetic biology and suggests copyright protection for engineered sequences. In Chapter 3, Sharma discusses patents related to microbiology, particularly patenting of genetically modified organisms. . The author also discusses *Dimminaco AG v Controller of Patents* wherein the Calcutta High Court, India held that patenting of on genetically modified microorganism is permissible.

Chapter 4 gives an overview of IP rights in the areas of Microbiology and authors Yadav, *et al.* describe the customary practices of storing the microbial samples in designated and recognized repositories and discuss how this is relevant to meet disclosure of origin norms, if they were to be made part of regulation. In Chapter 5, Akansha *et al.* discuss patenting of microorganisms in India. In Chapter 6 Kumar give nuances on intellectual property protection in the areas of Bioinformatics, a field that is coupled with the use of computational tools thus relying on protection in the form of trademarks, trade secrets, Database protection. The author concludes the need for an extended IP protection in the field of Bioinformatics involving crafted legislation that demands complete disclosure of information. Kireeva, in Chapter 7 emphasizes on the link between microbiological research and IPR. Chapter 8 gives an overview of patents of bacterial species *Bacillus* through a patent landscape study, and Sansinenea examines patents related to Bt cotton. In Chapter 9 Blakeney, contextualizes the governance and regulation of genetic resources and cites examples of Azadirachtin from Neem tree seeds[1] and Basmati rice lines and grains[2] related patents, and discusses patenting of DNA.

Al-Ani provides a patent landscape activity in Chapter 10 on the status of *Trichoderma* related patents (2007-2017). *Trichoderma* is a biocontrol agent, and is widely used in agriculture. In Chapter 11 Srivastava and Adholeya review the patent landscape in biofertilizers. The patent landscape study (2007-2017) of biofertilizers combined with text mining exercise on patent families indicates the need for bioprospecting of novel microbes and development of next generation biofertilisers to support sustainable agriculture,

In Chapter 12, Al-Ani, provides an excellent analysis of the role of Entomopathogenic fungi as an alternative to chemical pesticides and the innovation and patent landscape in Entomopathogenic fungi. It is shown that inventors have come up with innovations that have made Entomopathogenic fungi more useful and relevant. Azmat and Moin in Chapter 13 introduce the prospective process of sequestering the CO2 through microbial synthesis; and give a list of patents being cited for the microbial production of biomass and bioenergy, and, this Chapter discusses how microbial engineering can be used to meet the challenges of Climate Change. In Chapter 14, Al-Ani discusses the emerging innovation and patent landscape in Endophytic Fungi. An endophytic fungus is a microbe that can grow in any part of a plant and survive through symbiosis. The Chapter shows that patents indicate the development of novel isolates and underscores the potential of the fungi in enhancing resistance to diseases in plants and human beings.

In Chapter 15, Finston *et al.* discuss the idea of patent as a social contract and illustrate that with laws such as Hatch-Waxman Act, Biologics Price Competition and Innovation Act and court cases. In the context of pharmaceutical patents and innovation they call for a balance between patent system and needs of society in terms of innovations. In Chapter 16, Lee and Sohn discuss patents on treatments for Malaria in USA and China. They point out that although the disease was common, in China, related technological fields as reflected in patents were different. In China patents on treating Malaria using natural compounds were claimed whereas in USA the focus was more on chemical compounds/products and processes. Using the analysis of patent claims they argue that although the objective was the same, there is a distinct evolution in technological fields as evident from patent claims in both countries. In Chapter 17, Shriti *et al.* discuss evergreening of patents in pharmaceuticals and provide a discussion based on TRIPS Agreement and case law in India (*Novartis AG v Union of India)* and the role of compulsory licensing. In Chapter 18 Possas *et al.* review patent landscaping activity of Vaccines associated with Arboviral disease. The analysis reveals the potential of designing a patent pool to facilitate access to medicines. The authors highlight the use of patent documents as information resources. In Chapter 19, Raj and Shah discuss the increasing resistance to antimicrobiasls and patenting activity related to this. They suggest increased participation of public health groups and civil societies and

collaborations in developing antimicrobials and emphasising on responsible use. In Chapter 20, Agarwal gives a perspective on flexibilities under the Indian Patents Act for pharmaceutical related inventions, and, address inter alia, ever greening, compulsory licensing and Section 107A of Indian Patent Act and related judgments. In Chapter 21, Kalita and Ram presents a survey of patents related to bacterium called *Pseudomonas fluorescens*, and the microorganism is known to have an extensive application in agriculture and bioremediation.

Intellectual Property Issues in Biotechnology

In Chapter 1 Singh *et al.* give a brief understanding of important branches of Biotechnology such as Agriculture, Industrial and Pharmaceutical. Authors have suggested synchronisation of international policy frameworks when it comes to guidelines for patenting of life. Chapter 2 covers inter alia relevant international framework on biotechnology and biosafety and Cadillo Chandler also provides an overview of laws relating to patenting, biotechnology and biodiversity in China and India.

In Chapter 3, Chakrabarty gives an extensive analysis patenting in biotechnology, ranging from microorganisms to stem cells and examines the position in India and in Europe. He justifies the need for stronger patent protection in biotechnology. Laws providing for pre-grant and post-grant of patents are essential to examine grant of patents and to ensure quality in patents granted. In Chapter 4 Prakash and Singh make a critical analysis on sections of the Indian Patents (Amendment) Act, 2005 particularly Sections 3 and 4. Bas in Chapter 5 contextualizes the university-industry relationships, and highlights the role of star scientists in the research where local factors influence entrepreneurial activities the need for collaborations and issues in translation of research from bench to markets.

Part 2 comprising of six chapters deals with Agricultural Biotechnology; discussing inter alia the concept of protection of plant varieties and farmers' rights under the intellectual property regime. In Chapter 6 Alandete-Saez, Jefferson and Bennett introduce concepts like Patent Thickets and Freedom to Operate (FTO) which are quiet contemporary in knowing the IP landscape. The authors discuss the emergence of Agbiogenerics[3] and challenges in navigating the technological landscape in agriculture, and call

for balanced perspective on innovation and intellectual property protection and an equitable access to the proprietary technologies.

Srivastava Chauhan and Misra in Chapter 7 give insights in the areas of crop productivity and the importance of microbial diversity that constitutes the soil health. The authors see decline in patent application being filed from 2010 onwards, and emphasize the need for advancing research on microbial inoculants.

Canada regulates GM crops through the concept of 'Plants with Novel Traits', and does not differentiate between genetic modification, and, traditional breeding practices in regulatory assessment as long as the product is the same. In Chapter 8, Abergele, analyzes the potential for commercial introduction of new 'improved' plant varieties., based on the regulatory norms in Canada. In Chapter 9, Hefferon analyzes the development and use of Agrobacterium-mediated transformations, one of the principal methods of generating a transgenic plant, and the role of public funded research institutions in this and how this played a key role in enhancing productivity of genetically engineered plants. Open Innovation and development of clusters in specific technologies has been studied in literature. Linking these two, Mitkova and Wang, in Chapter 10, examine innovation systems in China and describe how knowledge sharing models are used in clusters in China in translational research. In Chapter 11 Srivastava, and, Yadav, discuss the interface between plant variety protection and agricultural biotechnology in India, highlighting the features of , Protection of Plant Varieties and Farmers Rights (PPVFR) Act 2001 and the *sui generis* model incorporated in it. In Chapter 12, Blakeney examines the patent law relating to DNA and how the law and practice has evolved and the social and ethical questions that have arisen on account of this.

In Chapter 13, Lin, Hung and Fan highlight the issues on the patentability of genes in China and Taiwan and point out that in both countries further clarity on legal concepts used in patentability is necessary. Prakash and Pansare in Chapter 14 discuss bioprospecting and the Nagoya Protocol on Access and Benefit. Sharing. In Chapter 15, Bisen Keswani *et al.* provide an in depth analysis of patent cases on CRISPR technology, particularly the cases between Broad Institute and University of California. In Chapter 16, Dutfield examines Personalized Medicine and public health and the

impact of patenting in Personalized Medicine. The cases involving stem cell patents are well known examples of controversies over patentability and in the decisions in USA and Europe were different. Jang Li provides an extensive discussion on the stem cell patents owned by The Wisconsin Alumni Research Foundation (WARF) and the cases on such patents. Li discusses the patent landscape for stem cell patents in Europe and USA and points out how morality was invoked in Europe to deny grant of patents on stem cells. In Chapter 18 Possas *et al.* provide a Brazilian perspective on vaccines and biotechnology and explain the patent landscape in vaccine. They suggest creation of patent pools to accelerate development of vaccines and propose incentives to facilitate this. Satyanarayana and Sadhna Srivastava in Chapter 19 analyze the trends in innovation in biosimilars and the regulatory framework and the Intellectual Property regime in India. They point out the dangers in evergreening of patents and challenges in providing Data Protection for clinical trials data. In Chapter 20 Chowdhury, Borchetia and Bandyopadhyay discuss the status of drug discovery in India and the Intellectual Property Dimension and call for boosting the R&D ecosystem in India so that drug discovery process is accelerated. Raj and Arivazhahan in Chapter 21 explore biotechnology and drug development and contextualize this in terms of international treaties and national regulations and managing patents in biotechnology. In the final Chapter Borah, Basak and Jana address an important but often overlooked subject, Neglected Tropical Diseases, taking Leishmania as a case study and discuss the status of drug development for Leishmania, highlighting the need for more investments in R&D and the case for new drugs that are innovations in terms of efficacy.

A reading of both the volumes, gives an integrated perspective on industrial and socio-legal implications of developments in intellectual property regime. The chapters have been on inter alia, agricultural biotechnology, biopesticides, Genetically Modified Organisms, Biosimilars, Vaccine, Drug Development and IP issues and patent thickets. The author(s) have used different approaches to analyze the issues using inter alia, patent landscaping to identify the gaps and discuss the state-of-art of innovations, and, obviously have discussed the relevant cases. The authors have examined the issues with traditional views on patents as incentives and have cautioned against patent thickets, enclosures through patents and

'anticommons' and have suggested alternative approaches like patent pools, Open Source Drug Discovery and Open Innovation.

Both will be of relevance and be useful to scholars, students and policy makers working on intellectual property rights and biotechnology.

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Endnotes

1 US patent US 5411736 A

2 US patent US 5663484

3 Jefferson, *et al.* (2015)

Reference

Jefferson, D.J., Graff, G.D., Chi-Ham, C.L. and Bennett, A.B. 2015. The emergence of agbiogenerics. *Nature Biotechnology*, 33(8), Pp.819-823

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Guidelines for Contributors

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(b) Edited volumes:

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Lakshman, W. D. 1989. "Lineages of Dependent Development: From State Control to the Open Economy in Sri Lanka" in Ponna Wignaraja and Akmal Hussain (eds) *The Challenge in South Asia: Development, Democracy and Regional Cooperation*, pp. 105-63. New Delhi: Sage.

(d) Articles from Journals:

Rao, M.G., K. P. Kalirajan and R. T. Shand. 1999. "Convergence of Income across Indian States: A Divergent View". *Economic and Political Weekly,* 34(13): pp. 769-78.

(e) Unpublished Work:

Sandee, H. 1995. "Innovations in Production". Unpublished Ph.D thesis. Amsterdam: Free University.

(f) Online Reference:

World Health Organisation. 2000. "Development of National Policy on Traditional Medicine". Retrieved on March 31, 2011 from http://www.wpro.who.int/sites/trm/documents/Development+of+National+Policy+on+Traditional+Medicine.htm

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This issue carries two articles and a review article. While the first article proposes a mechanism to incentivize translational research and research in health biotechnology for innovation and technology transfer, the second article examines the merits and shortcomings of the patent regime and examines the intellectual property rights regime from a value pluralism perspective and with two case studies, and discusses the options available. The review article discusses two books, on intellectual property rights in microbiology and on intellectual property rights in biotechnology.

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