Technological Capability and Innovations in Indian Biopharmaceutical Industry: Challenges Posed by Patent Cliff on Equity and Affordability

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INTRODUCTION

The present study has provided insights and suggestions on adequate regulatory policies and measures to overcome the failures in technological learning for improving technological and innovation capability of Indian biopharmaceutical firms to make health equitable and affordable for all. The study has contributed by formulating a 'regulatory policy framework for biosimilars'. It has analyzed secondary data, reports and relevant literature for the same. The study has formulated STI policy guidelines on biosimilars to assist the government and other actors in the health sector. This research work has reviewed and compared regulatory guidelines of biosimilars for India prepared by Department of Biotechnology (DBT) (Ministry of Science and Technology, Government of India) and Central Drugs Standard Control Organization (CDSCO) (Ministry of Health and Family Welfare, Government of India) with regulatory guidelines of European Medicines Agency (EMA); United States Food and Drug Administration (US FDA) and Ministry for Health Labor and Welfare and the Pharmaceuticals and Medical Devices Agency of Japan. It has attempted to streamline the regulatory structure of biosimilars and charted regulatory pathway for biopharmaceuticals for harmonizing its regulations.

OBJECTIVES

- To find the emerging challenges in the Indian biopharmaceutical industry with respect to patent cliff
- To analyze future perspectives of biopharmaceutical firms whether they will move towards inclusive innovation and bring equity and affordability in healthcare after patent cliff
- To explore whether the biosimilar firms could meet the regulatory requirements of safety, efficacy, and quality and whether they will meet global regulatory standards.

METHODOLOGY

The study has applied trend analysis methodology for analyzing biosimilar drugs approved for commercial use from 2000 to 2019. It has adopted Strength, Weakness, Opportunity, Threat (SWOT) methodology for examining strength and weaknesses of biosimilars market. It further applied extensive literature survey and secondary data analysis of biosimilars.

Defining Biosimilars

There is no standardized definition available for biosimilars. Biosimilars have been defined by different regulatory agencies across the world differently. Table 1 depicts the definitions of biosimilars provided by the European Union, USA, WHO and India. However, the definitions of biosimilars have some similarities in common, which are analyzed herewith.

i) Biosimilars are not generics
ii) They should have established comparability (similar copy) with reference product or original biologic product.
iii) They must hold similarities in safety, efficacy and quality with the approved biologic product (Agbogbo, et al. 2019).

Table 1: Biosimilars Defined Globally by Different Regulatory Agencies

S.N.	Regulatory Agencies	Term	Biosimilars Definitions
1.	European Medicines Agency (EMA), EU	Biosimilar	"A biosimilar is a biologic medicine, which is very similar to another already approved biologic medicine (the reference drug)".
2.	US Food and Drug Administration (US FDA), USA	Biosimilar	"A biosimilar is a biologic product, which is very similar to and has no clinically meaningful differences from an already FDA-approved reference product".
3.	Department of Biotechnology (DBT) and Central Drugs Standard Control Organization (CDSCO), India	Similar Biologic Product	"A similar biologic product is such a product that is similar in terms of safety, efficacy and quality to an already-approved reference biologic product based on comparability".
4.	World Health Organization (WHO)	Similar Biotherapeutic Product	"A biotherapeutic product that is similar in terms of safety, efficacy and quality to an already licensed reference product ".

Source: (EMA, 2017), (US FDA, 2017), (DBT and CDSCO, 2016), (WHO, 2013)

Growing Biosimilars Market

It is expected that the world's biosimilars market will grow upto $ 71.97 billion by 2027 at a CAGR of 32.1 percent from $ 5.95 billion in 2018 (Markets and markets, 2019). The commercialization of biosimilars began in Europe, where high treatment rates and dedicated regulatory pathways created a thriving market. By 2018, the European Union had approved more than 40 biosimilars, and many went on to be commercialized

successfully in Australia, Canada, Japan, and South Korea. In the United States, more than 15 biosimilars have been approved to date. Further, more than 70 such products are marketed in India, and more than 40 are marketed in China (Chen et al., 2019). As regulatory frameworks mature, the quality of these products is rapidly improving, making them more portable to other markets.

Moreover, with a high number of domestic approvals of biosimilars, expanding markets in highly regulated countries, the Indian biosimilar industry is growing at a rapid pace. It has an active pipeline of many biosimilar drugs for the Indian market as well as highly regulated markets. Table 2 provides the pipeline of biosimilar drugs of some of the leading firms in the market.

Table 2: Active Pipeline of Biosimilars for Indian and Global Markets

Firms Engaged in Biosimilars Production	Pipeline Information	Target Regulated Markets	Stage of Development
Biocon	Pegfilgrastim	USA, EU, Canada, Australia	Filing
	Adalimumab		Global Phase 3 completed
	Trastuzumab	USA, EU, Australia and Canada	Approved in the USA, Under review in the EU, Australia and Canada Filed/ Marketed in emerging countries markets
	Bevacizumab	Marketed in India	Global phase 3 trials
	Filgrastim	-	Early phase of development
	Etanercept	-	-
Intas Biologicals	5 Biosimilars in the pipeline for India and 5 biosimilars for regulated markets of EU and USA.		
Zydus Cadila	8 biosimilars in the pipeline for India and regulated markets.		

Dr Reddys	Pegfilgrastim	EU, USA	Studies initiated for approval
	Rituximab	EU, USA	
	Bevacizumab	EU, USA	
	2 new molecules entering the clinical phase of development in the coming future		
Reliance Life Sciences	14 biosimilars in global pipeline		
Wockhardt	4 biosimilars in the global pipeline		
Lupin Pharma	5 biosimilars in the global pipeline		

(Source: Adopted from Sharma, 2019)

It can be argued that the rising number of approved biosimilar products in the market with expected lower costs would broaden access to these drugs shortly. Though there is more focus on lifestyle diseases and high-income groups and exports, yet the manufacturers might try to make it more affordable and move towards neglected diseases. Even, some evidence is also available for producing biosimilars at quite lesser prices than estimated, by few analysts (Desai, 2016).

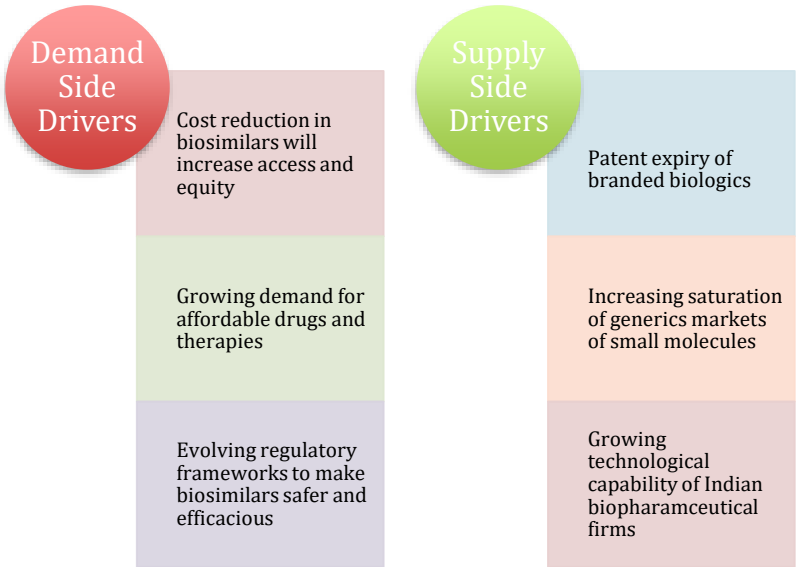
Drivers for Biosimilars

With the expansion of the biosimilars market and growing competition, biopharmaceutical firms involved in producing biosimilars are enhancing their technological capability to seize this opportunity. Figure 1 portrays several demands and supply-side drivers for the increasing growth of the biosimilars market in India.

Biosimilars involve lower investments and a reduced number of clinical trials; they tend to be cheaper as compared to reference products (Kanase et al., 2013). The cost of reference biologics is approximately $1 billion or more as compared to $100-$200 million costs of biosimilars (Agbogbo et al., 2019). Thus biosimilars are cost-effective, affordable and provide competitive pricing advantages as compared to reference products.

The regulatory approval pathway for biosimilars differs from original biologics, which affects the cost, requiring lesser time and investment for approval of biosimilars. Usually, the original biologics regulatory approval pathway takes 12 years from discovery to phase 3 involving safety and efficacy studies. However, biosimilars, may not require the discovery phase or initial efficacy phase (phase 2) and may progress from phase 1 to phase 3. Biosimilars thus have a shorter development path and regulatory path of approval of 8 years or maybe lesser, requiring lesser investments (Agbogbo et al., 2019). Nevertheless, the regulatory pathways for biosimilars are evolving in many developed and developing countries to make biosimilars much safer and efficacious.

Figure 1: Demand and Supply Side Drivers for Biosimilars



Source: Author's elaboration

Increased Access, Equity and Affordability due to Emergence of Biosimilars

With the patent expiry of most of the branded biopharmaceuticals, it is estimated that prices of biosimilars will be 20-30 percent lesser than biological. The reduction in prices of biosimilars will increase their accessibility and affordability. It can be argued that in India 'access' is a larger issue, which stirs intense policy debates, for instance, on questions related to intellectual property rights (IPRs), the wider inequality within the country and across various regions raises the debate on equity and affordability. The idea of equity and affordability is also significant since technology and gender divide are pre-dominantly evident. In this regard, it is worth pointing out that inclusive growth and social inclusion have gained wide importance in 12th Five Year Plan and the new 'Health Policy' also talks about inclusive innovation and commits health for all. Hence, equity, access and affordability are linked with inclusion. Access to benefits of advances in science, technology and innovation (STI) like in health sector and deriving the benefits of technological advances is important. Thus, access is an important value. Equity is a contested term but iniquitous distribution of benefits of advances of STI or bearing the disadvantages from developments in STI without deriving any benefits, indicates that STI policies might exacerbate persisting inequalities in the society and thereby contribute to widening disparities. Hence, with respect to this study 'Inclusive Innovation' holds a lot of significance, which pertains to providing the access of affordable health supply at the base of the pyramid population, reaching the poor. Even, institutions also play an important role in improving the health outcome by establishing linkages between biopharmaceutical innovations with public health and socioeconomic needs so as to attain more inclusive growth. Thus, with the expansion of the biosimilars market, it is expected that there will be enhanced access and affordability of biosimilar drugs to poor people, which were earlier unaffordable due to high costs involved.

CONCLUDING REMARKS

With the upcoming patent cliff, most of the large-scale biopharmaceutical firms are shifting towards producing biosimilars. These firms are adopting innovative technological approaches for producing biosimilars that may be affordable for the poor. Most of the biopharmaceutical firms are entering into international collaborations, technology transfer agreements, mergers and acquisitions for building their technological capability. There have been large-scale technology transfers and international collaborations for developing biosimilars (Kale, 2019). Many biopharmaceutical firms from developing countries have adopted technologies from developed countries for developing biosimilars. But developing biosimilars needs huge safety considerations and risk assessment. Hence, there is a need for stringent regulatory approval for biosimilars with adequate mechanisms for risk and safety assessment, labeling and interchangeability issues. The regulatory framework for biosimilars should have instant ADR reporting mechanisms. Thus, the study has attempted to evolve a stringent regulatory framework for biosimilars in India. It has suggested that India's biosimilars regulatory framework needs to become more robust and streamlined with globally harmonized regulations. It should ascertain safety and efficacy of biosimilars using the 'totality of evidence' approach.

STI Policy Recommendations

- The study has proposed for formulation of a 'biosimilars policy' for India with adequate provisions for accountability aspects and a strengthened 'risk management plan' to monitor and identify safety concerns if any. The risk assessment and management plan for biosimilars should encompass adequate pharmacovigilance plan, spontaneous ADR reporting system and provisions for extensive post marketing studies to maintain safety, efficacy and elimination of residual risk of biosimilars.
- The biosimilars policy should have clear regulatory guidelines regarding 'labeling, traceability and interchangeability' of biosimilars.
- It should address the issues of ethical considerations, risk perception, IPRs, and try to overcome the barriers related to the 'adoption' of biosimilars.
- Biosimilars manufacturers need to adopt transparent and innovative pricing models to increase access by reducing the affordability gap and expanding opportunities for patients.
- There should be a single window system for regulatory approval of biosimilars as per the recommendations of the 'Biotechnology Regulatory Authority of India' (BRAI) Bill (Chaturvedi, et al., 2012).
- Biosimilar manufacturers should focus on 'Good Manufacturing Practices' (GMP) and follow global standards to make the biosimilars safe and effective.

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Indo-ASEAN STI cooperation: Current status and future prospects

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INTRODUCTION

In the present globalized era, the role of science diplomacy has increased significantly in strategic relations between nations. It is thus expected that increased density of strategic relations in science, technology and innovation (STI) will help in providing a more favorable context for STI cooperation between India and ASEAN process. In this perspective, this study has acknowledged that there is a strategic shift in India's foreign policy from political and economic cooperation towards STI cooperation. It can be mentioned that STI cooperation helps in building innovation and technological capability amongst the nations. STI play a significant role in a country's prosperity and economic growth (Schuller, et al., 2008). The goal of India-ASEAN cooperation in STI is to achieve progress, peace and prosperity in both the regions. Thus, the study has focused on India-ASEAN STI cooperation and tried to find out the drivers for STI cooperation. It has attempted to seek future areas of STI cooperation of mutual interest between India and ASEAN countries. The research work has deliberated on the factors that may contribute to increased density of scientific and technological cooperation between India and ASEAN countries and has advocated possible measures and avenues that could take advantage of emerging opportunities in STI for mutual benefits.

OBJECTIVES

- To identify the current status of STI cooperation between India and ASEAN nations
- To ascertain different drivers of STI cooperation between India and ASEAN
- To identify the factors determining future STI cooperation between India and ASEAN

METHODOLOGY

The research work has applied scientometric analysis of patents and publications database, secondary data analysis of high technology trade data, GERD data, and foreign direct investment (FDI) data and involved extensive literature survey. Additionally, six telephonic interviews with subject matter specialists on science diplomacy were also conducted.

Strategic Shift from Look East Policy to Act East Policy

India's cultural influence on East and Southeast Asia has been eminent since ages. India provided a base to East Asian civilization and its culture has spread to other countries of

the East. Southeast Asia was occasionally referred as "Greater India", which reflected a sense of nationalist expansionism (Jaffrelot, 2003). During the inter-war period Asiatic identity strengthened and Asianism prevailed over western colonialism. Some political leaders expressed their desire for stronger ties between India, China and other Asian countries in lieu of common values, cultural affinity and as an opposition towards the western imperialism. Post-independence, some of the political leaders projected India as Asia's leader on the basis of cultural affinity. But after decolonization, the idea of Asianism soon started to loose its efficacy because of the divergence in the interests of the new nation states and due to the bilateral conflict between India and China post Sino-India war. China's influence in this zone started to rise and many Southeast Asian countries started to get inclined towards China. This inclination was clear in Bandung Conference in 1955, where Southeast Asian delegates rallied around China's leadership and ignored India. Besides, USA's interference also increased in Asia, which during that time, favoured Pakistan and signed a Mutual Defense Assistance Agreement in 1954 with Pakistan. It is well established in the literature how American, Soviet, Chinese and British interventions in Asia increased in the post war period (McGarr, 2013). India favoured non-alignment and expressed its resentment against Asian countries' strategic alliances with western camp like Southeast Asian Treaty Organisation (SEATO). Still some of the Southeast Asian countries like Singapore, Malaysia showed their inclination towards India in 1950s and 1960s.

ASEAN was formed in 1967, with five permanent members including Indonesia, Malaysia, the Philippines, Singapore and Thailand. Later on Brunei joined ASEAN in 1984, Vietnam in 1995, Lao PDR and Myanmar in 1997 and Cambodia in 1999 as permanent members. Initially when ASEAN was formed it desired India's friendship and expression of support but then India was disinterested. Thereafter, many of the Southeast Asian countries articulated their disagreement towards strengthening of ties between India and USSR in 1971. Yet some of the ASEAN members showed a positive approach towards India and Malaysia invited India twice in 1975 and 1980 for a dialogue, but India showed indifference and kept itself aloof from Southeast Asia for a decade due to geostrategic changes. Until late in 1980s and early 1990s after the collapse of the Soviet Union bloc and to gain economic liberalization, India began to rethink its foreign policy and started to look forward to East and Southeast Asia's success model. In order to establish economic and diplomatic ties, India started getting interested in joining ASEAN, for bringing economic reforms and trade facilitation (Pillai, 1995). Thus, with respect to deepen its economic and political ties with East Asian countries India enunciated its "Look East Policy" in 1991 (Mattoo, 2001).

Indian economy got liberalized and initiated economic reforms in 1991, which were favored by ASEAN countries. Thus, after the cold war was over India brought changes in its foreign policy and became closer to western countries too. It established its strategic and security ties with USA as well as with other nations of the West. Simultaneously, ASEAN countries established greater engagement with India to enhance its role in the world. In 1992 ASEAN provided "sectoral dialogue partner" status to India in commerce, investments, tourism and science and technology sectors. Thereafter, in 1995 during fifth summit, ASEAN granted "full dialogue partner" status to India along with China and Russia.

In a way, the grant of the full dialogue partnership was the culmination of India's Look East Policy. It can be noted that the Look East Policy focused on establishing synergetic, complementary relationship with its fast consolidating and progressive neighbourhood. The grant of full dialogue membership status to India was a geostrategic decision besides economic one. This was followed by India's membership with ASEAN Regional Forum (ARF) in 1996 for political, security and economic reasons. These two partnerships of India turned out to be constructive and fruitful (Asher et al, 2001).
Joint defense, naval exercises started with Southeast Asian nations of Malaysia, Indonesia and Singapore. Apart from intensifying diplomatic and strategic ties, India sought to strengthen its bilateral economic relations with ASEAN countries. For maintaining closer ties with East and South East Asian nations India's President, Prime Minister accompanied by a delegation of businessmen visited ASEAN; similarly, President and Prime Ministers of ASEAN nations visited India on a regular pace. These visits culminated in forming an "Asianist discourse" and a preference from India towards respecting "Asian Values", intensifying diplomatic relations and attracting benevolent attitude towards India in terms of investments (Jaffrelot, 2003).

India and ASEAN have joint cooperation and discussions under other forums like G-15 (Group of 15 developing nations including India, Indonesia and Malaysia); Indian Ocean Rim Association for Regional Cooperation (IOR-ARC) including members like Malaysia, Indonesia, Singapore and Thailand; Mekong-Ganga Cooperation (MGC), including India, Cambodia, Vietnam and Laos; and BIMSTEC including India, Thailand and Maynmar. India has also been active in maintaining bilateral relations with ASEAN countries especially with Myanmar, Indonesia, Singapore and Vietnam (Asher et al, 2001; PIB, 2015).

Recently, India unveiled its "Act East Policy" in 2014 during the 12th India-ASEAN Summit held in Nay Pyi Taw, Myanmar. It focuses on establishing ties with Asia Pacific region by way of strengthening regional, bilateral and multilateral engagements. The objective of Act East Policy (AEP) is to develop political, strategic and cultural initiatives along with economic one to establish institutional means for effective dialogue and cooperation. Act East Policy emphasizes on India-ASEAN cooperation on manufacturing, trade, infrastructure, skills, smart cities, urban renewal, Make in India, etc., initiatives (PIB, 2015). Thus, the Act East Policy heralded a new era of economic development, trade and industrialization.

Theoretical Contribution

Under the wide spectrum of Science Diplomacy, the study has contributed towards building theoretical foundation in the emerging area of Science Diplomacy and has proposed a new theory i.e. "Strategic Security Theory", which may be added to the theoretical framework of international STI cooperation theories. This theory relates to strategic security issues and the defense deals between the countries that are collaborating on defense agreements. The defense deals can be related to purchase of weapons, transfer of technology, joint defense exercises. In the present globalized economy, defense has emerged as one of the most important strategic issue of STI cooperation and entails a huge amount of budget flows and funding by the countries. This theory may be related to the recent defense deal between

Indian and France called as the "Rafale deal", in which India will have to pay 7.8 billion Euros to France for buying 36 off-the-shelf Dassault rafale twin-engine fighters. As per the provisions of this deal India will also receive spares and weaponry, Meteor missile, which is among the most advanced missile in the world. France will also invest 30 percent of the 7.8 billion Euros in India's military aeronautics related research programmes and 20 percent into local production of Rafale components. Reliance Defence Limited has become the French firm's Indian partner and the subsidiary of Reliance Defence Limited known as Reliance Aerostructure has signed a bilateral agreement and formed a joint venture with Dassault Aviation of France[1].

CONCLUDING REMARKS

India's STI cooperation with ASEAN has strengthened after 1990s and this trend is expected to grow in future as both the sides have increased their capacity and inclination to cooperate with each other and create institutions and mechanisms for broader and deeper linkages. This study has provided an empirical basis for analyzing the status of STI cooperation between these nations. So far, the relations between India and ASEAN countries have become stronger, but a lot needs to be explored in the future. The study has also contributed towards building a new theory i.e. 'Strategic Security Theory' and has contributed towards building 'International System of Innovation (ISI)' theory. It has elaborated on the knowledge base of ISI and its functions.

STI Policy Implications

- The study has deliberated that India and ASEAN STI cooperation strives for a mutually beneficial relationship for building technological and innovation capability, STI infrastructure, exchange of technologically skilled human resources, amongst the partnering nations.
- The process of technological change amongst ASEAN countries is more towards acquiring of knowledge and improving technological capability rather then innovating, except for few instances. International cooperation in STI between India and ASEAN countries with the help of effective STI policies may bridge this gap by generating innovation capabilities.
- India's cooperation in STI with ASEAN countries will facilitate knowledge transfer and assist in building technological capability amongst the ASEAN nations. Bilateral agreements between individual ASEAN countries and India involving areas such as mutual recognition of professional and technical qualifications, and flexibility in the movement of research professionals could help in further enlarging the scope of mutually beneficial cooperation.
- There is a need to remove trade barriers, improve labor laws, Intellectual Property Rights (IPR) law for enhanced STI cooperation between India and ASEAN countries.
- It is suggested that for strengthening STI cooperation, the gap between industry, academia, and government should be bridged. There should be increased participation of private sector in R&D and GERD ratio should be improved amongst India and ASEAN countries.

[1] https://www.ndtv.com/india-news/what-is-rafale-deal-controversy-all-you-need-to-know-1810706

- There are promising opportunities for cooperation between India and ASEAN countries in ICT, food, agriculture, biotechnology, space research areas, etc.

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Impact Assessment and Evaluation of 'Science Technology and Innovation (STI) Policy 2013

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INTRODUCTION

Science, Technology and Innovation (STI) play a vital role in nation building by advancing R&D and innovation for socio-economic development. STI has the power to transform the society by providing solutions for emerging global challenges. Government of India released the STI policy in 2013 to achieve sustainable and inclusive growth. STIP envisage "accelerating the pace of discovery and delivery of science led solutions for faster, sustainable and inclusive growth" (STIP 2013 Document). The STI policy lays greater emphasis on improving innovation and involves a framework to enable the integration of innovation with science and technology in identified priority areas to solve real-life problems of the society. STIP 2013 calls for integrating programmes of socio-economic sectors with the national R&D system. It also articulates upon the need for technological innovation and creation of a robust national innovation system. After the launch of the STI Policy, there have been several initiatives taken by the Government of India to strengthen the R&D and innovation ecosystem. In this regard, this study intends to review the STIP 2013 and evaluate its impact on the R&D ecosystem of India. It can be stated that STIP reviews helps to renew STI policy, provide inputs for framing new policy, highlights the importance of STI policies in national development strategy and enables the incorporation of STI activities in international cooperation strategies and plans.

OBJECTIVES

- To evaluate the STI policy 2013
- To identify the schemes and programmes of the R&D ministries and departments influencing the R&D ecosystem of India launched after STIP 2013
- To identify the indicators for policy evaluation
- To mainstream STI policy in national agenda

METHODOLOGY

The present study has applied questionnaire survey methodology and extensive literature review. In order to evaluate the STI Policy of 2013, a detailed questionnaire on "Mapping the Impact of Science, Technology and Innovation Policy 2013 on R&D Ecosystem of India" was prepared and was reviewed by eminent experts in STI policy area. Later on, the questionnaire was sent to all the R&D Ministries and Departments of Government of India.

A policy matrix has also been designed to evaluate the schemes and programmes of different R&D ministries.

ANALYTICAL FRAMEWORK

This study involves 'Transformative Innovation Policy' as its analytical framework (UNCTAD, 2019; Schot and Steinmueller, 2018). It seeks to internalize and accommodate social, economic and environmental dimensions of sustainable development, and take responsibility for social and environmental impacts of innovations and technologies it directly or indirectly enables or inhibits. The analytical framework of STIP review tries to align STI policy with the countries' development strategy and ensure that STI policies promote sustainable and inclusive development and assist achieving 'Sustainable Development Goals' (SDGs). STI policy aligned with the 2030 Agenda and the SDGs needs to focus on transformation. The 2030 Agenda and the SDGs can serve as a compass for STI policy to indicate the broad directions of transformative change to be supported by public intervention. This framework envisions for transformative STI policy making for achieving inclusive and sustainable development agenda.

The STIP review intends to involve broad range of actors emanating from R&D ministries of Government of India, academic institutions, universities, and civil societies. This participatory process tries to mobilize actors towards transformation by way of policy experimentation and learning.

STI Evaluation Framework

The STIP review process involves following steps:

i. Assessment of major STI capacities and gaps: It will involve desk research, mapping different kind of innovations like inclusive, grassroots, frugal, informal, social, technological innovations.

ii. Evaluation of national developmental goals and SDG challenges confronting the nation together with stakeholder's expectation on STIP review. It needs to be informed by preparatory mission and scoping interviews. Moreover, early deliberation with stakeholders will help in STIP review process.

iii. Charting out or mapping basic components of the STI system

- **Actors:** The actors in the innovation system involve R&D ministries, firms, entrepreneurs, research and education system, consumers, civil society. For achieving better benefits from STI, there is a need to recognize the roles and capabilities of all key actors in the innovation system.
- **Connections and linkages:** The connections and relationships between actors is a vital component of any innovation system. It involves network connections to enable organizations to translate new knowledge into innovations and enhanced productive capacity. Networking and connections needs to be undertaken for adoption of technology, learning, new technology development and knowledge absorption. Effective innovation systems encourage local,

national and international collaborations that cut across economic sectors, technology areas and scientific disciplines.

- **Framework conditions and enabling environment:** Effective innovation systems provide an enabling environment for actors, notably firms, to engage in innovation activities. The entrepreneurs are at the core of the systems, drawing upon the sources of knowledge and evolving in a more or less conducive context made of institutions, policies, and infrastructure. The building blocks of innovation systems include the following: policy and regulatory framework, institutional setting and governance, entrepreneurial eco-systems and access to finance, human capital, technical and R&D infrastructure.
- **STI Policy Mix:** STI policy for sustainable development draws from a wide range of policy instruments providing direct support to innovators and improving the enabling environment for innovation activities that contribute to sustainable development. Table 1 shows a suitable STI policy mix inclusive of several elements.

Table 1: STI Policy Mix

S.N.	Policy Instruments	Elements
1	Regulatory framework	Environmental and health protection regulations, product and industrial process standardization, consumer protection laws, IPRs, competition law
2	Economic and Fiscal instruments	R&D funding, innovation funding for companies, equity support to venture and seed capital, tariffs and subsidy schemes, tradable permit system (emissions trading), removal of subsidies for unsustainable activities. Tax incentive for R&D for companies, tax incentive for technology adopters, environmental taxation, removal of tax reliefs for unsustainable activities
4	Demand support	Sustainable public procurement, pre-commercial procurement, R&D and innovation procurement, support to private demand
5	Education and training	Adaption of formal education curricula to address the SDGs, placement schemes, staff mobility
6	Regional innovation strategy and networks	Clusters, industrial zones, S&T parks; technological platforms and networks; roadmaps and technology foresight
7	Trade policy	Trade tariffs
8	Capacity building and information provision	Business advisory services, local entrepreneurship and business incubation, technology transfer, capacity building for governments, market intelligence services.

9	Information and cultural instruments	Education and awareness training, network facilitation and enhancement, virtual and material infrastructure, events for innovation network building

Source: Adopted from UNCTAD, 2019 and Miedzinski et al., 2017

iv. Ascertain Directionality: To identify whether STI policy mix is oriented towards sustainable development and the SDGs and able to transform the system as required.
v. Policy Stringency: To determine whether policy protects marginalized sections of society and the natural environment.
vi. Policy Coherence: To identify whether STI policy mix is coordinated and internally coherent.
vii. Distributional Impacts: To examine whether STI policy has enhanced more equitable distribution of costs, benefits and risks, associated with innovation and with wider transformation, including from a gender perspective

CONCLUDING REMARKS

This study has contributed towards formulating the evaluation framework of STI review and developed new R&D indicators for the STIP assessment process. This research work has been functional in preparing a STI policy mix for the evaluation process. It has incorporated 'Transformative Innovation Policy' approach towards meeting Sustainable Development Goals.

References

Miedzinski, M., McDowal W., Turkeli S., Kemp R. (2017). "An Expert-based Participatory Evaluation of public Policies for Sustainability Transitions, Conference Paper Presented at EU-SPRI Conference, Vienna, 7-9 June 2017.

Schot, J. and Steinmueller, W.E. (2018) "Three Frames for Innovation Policy: R&D, Systems of Innovation and Transformative Change", Research Policy, 47: 1554-1567.

UNCTAD, 2019, A Framework for Science, Technology and Innovation Policy Reviews. Harnessing Innovation for Sustainable Development. United Nations, Geneva.

DETAILS OF SEMINARS/WORKSHOPS/CONFERENCES ATTENDED DURING THE ASSESSMENT YEAR:

i) Delivered oral presentation entitled "Evolving STI Policy: A Shift Towards Transformation and Sustainable Development" presented in National Conference on Environmental Sustainability: Innovations, Translational Dimensions and Way Forward, held between 10th – 12th February 2020, Babasaheb Bhimrao Ambedkar University, Lucknow.
ii) Organized National Workshop on "Building National STI Policy System and Governance for Effective R&D Ecosystem" conducted by DST-CPR, BBAU Lucknow, on 5-6 March 2019

iii) Attended a Summer School Training Programme on "Pathways to Sustainability" conducted by STEPS Centre, University of Sussex, IDS UK at Brighton, from 13-24 May 2019.

iv) Attended a five-day training programme on "Design and Evaluation of Innovation Policy", jointly organized by the DST-Centre for Policy Research at IISc, Bangalore and UNU-MERIT, during 25-29 March 2019

EVENTS











(Re) assembling knowledge on drought management policies for India: A learning from Israel, Australia, and China

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SUMMARY

Drought is one of the most disastrous phenomenons, which directly affects people more than any other natural hazards through economic, social and environmental losses in both developing and developed countries. Droughts have affected nearly 1,061 million people and killed 4.25 million people in India during 1900–2006 (Center for Research on Epidemiology of Disasters, 2006). Agriculture plays a vital role in India's economy. It is the sector that is heavily dependent on the monsoon and most impacted by drought. In 2009, India launched its National Policy on Disaster Management with a vision to build a safe and disaster resilient India. The policy aims to develop a holistic, proactive, multi-disaster oriented and technology-driven strategy through a culture of prevention, mitigation, preparedness and response. Some of the other major drought management programs by the Government of India (GoI) aims at mitigating the adverse impacts of drought and build the resilience of people by encouraging efficient water management practices, ensuring livelihoods, ensuring economic access to food and supplying fodder among other measures. However, despite these efforts, India still faces the brunt of drought every other year. In the present scenario, the regular increase in temperature and irregularities of monsoon thus increasing the area under drought shoves us towards bridging of gaps for the maximum utilization of drought policies under the government schemes. Analyzing and evaluating the best practices, from countries such as Israel, Australia and China, where water governance is consistently stronger compared with India could also be an important learning in the aspect of drought management.

OBJECTIVES

The proposed research aims to identify and evaluate technology-led policy approaches for sustainable drought management in India. The study would accomplish the following broad objective: To identify the key practices being followed for mitigating the drought risk in Israel, Australia, and China, which India can learn to reinforce its drought management approaches. The sub-–objectives are:

a. To review the drought management programmes in India and identify the key limitations
b. To identify the good practices for drought management in Israel, Australia, and China, in terms of technologies, laws, policies, and administration
c. To suggest measures for managing vulnerability to drought and enhancing resilience in India.

RESEARCH METHODOLOGY

The current study makes uses of qualitative research methodology. The synthesized facts are derived mainly from secondary sources, and which are qualitative in nature. The key findings are analyzed to reach to key findings.

A brief introduction of research work

Among many climatic incidents that affect the earth's environmental, drought is probably the most complex and least- understood of all. It is a natural hazard that results from the occurrence of deficit precipitation from normal, which is inadequate to meet the demands of human beings and the environment. Although lesser precipitation than expected may not be a disaster by itself, however, it becomes one depending upon its impact on the local community and environment. The implications of drought are many. People's vulnerabilities increases due to reduced water availability and crop productivity resulting in a decrease in resilience causing food insecurity, loss of livelihoods, and economic slowdown. Evidence suggests that accelerating global warming, rise in temperatures and enhanced dry conditions, are leading to an increase in number, frequency, extent, and severity of drought events. It is forecasted by The Intergovernmental Panel on Climate Change (IPCC) report of 2012, that the total area affected by drought in the world will expand by 15-44% till the end of the 21st century. Dryland regions in the world are more sensitive to droughts and their related impacts. An increase in drought events is found to be significant in the dryland regions of Africa, the Eastern Mediterranean region, Asia, and Southern Australia. South-Asian regions are amongst the recurrently drought-prone areas of the world. Afghanistan, Pakistan, India, and Sri Lanka have reported frequency of occurrence of droughts at least once every three years in the last five decades. Escalating menace of recurring drought has enforced many countries to develop and adopt novel technologies and strategies for drought management. Israel and Australia for instance, have become more resilient owing to notable success in drought risk rather than disaster management, achieved through incessant technological innovations, improvements in water use practices and development of long term water management plans. China is progressing rapidly in enhancing its preparedness against drought with its infrastructural advancement and recently imposed regulatory mechanisms such as 'Three Red Lines' water policy to limit water use. Apart from these, Canada, Spain, France, the United Kingdom, and Saudi Arabia are also doing incredible work in drought risk management.

Droughts are recurrent phenomena in India occurring almost every year in some Indian states. India had acknowledged drought as a challenge for a long time and introduced many policies, programs, and schemes targeting its mitigation. Somehow, these approaches have not performed impressively, as it is apparent from rising drought frequency and drought-prone regions in the country. Droughts continue to be inefficiently addressed in the country and the reason can be attributed to either one or combinations of the following factors - ineffectual policies and institutional framework, inappropriate planning and management, and inadequate implementation approaches at ground level. It is now a well-received fact that droughts will intensify risk to climate-sensitive economic sectors in India, especially agriculture on which about two-thirds of countries' population

depends. Thus, there is a need to be proactively prepared to manage this menace through better risk management strategies.

India can learn many lessons from countries that have pioneered in drought management, especially Israel and Australia, which, in spite of being severely drought-prone are forerunners in securing water resources. Drought management in these countries is based on the principles of self-reliance, proactive risk management, and an understanding that drought is an inherent feature of their environment. Not only Israel and Australia, but China also has made significant improvements in water management practices in the past two decades. Both India and China share many similarities, for instance - large population size to feed, a huge share of drought-prone area, small landholding size in agriculture, etc. but besides these resemblances, China's agriculture system has done far better than Indian agriculture on most parameters in the last few decades. China's success in this sector holds important learning for India, especially in water management in agriculture.

The objective of this review paper is to identify the key practices that are being followed for mitigating the drought risk in Israel, Australia, and China, which India can learn to reinforce its drought management approaches. The paper addresses the drought management strategies followed in India and the key limitations in the approaches. Major policies and measures adopted in Israel, Australia, and China are discussed. Key learnings from these countries that India should captivate in order to improve its drought risk management capabilities are conferred in detail.

KEY RECOMMENDATIONS

The study identifies following key learning for India in order to enhance its drought management approach: (1) consistent communication between drought monitoring agencies and state- level management committee that allows prompt dissemination of information and alert to government bodies and local communities; (2) enhanced impact assessment techniques, particularly in the agricultural sector, by the government to identify vulnerable regions as well as communities inhabiting it and periods of anomalous risk, and to trigger the quick release of assistance measures; (3) improved drought preparedness by employing multiple approaches, including supply-side (e.g. infrastructure and technology development, alternative water sources, efficient micro-irrigation technologies) and demand-side management strategies (e.g. water pricing, extraction levies, full cost recovery), public awareness, encouraging R& D, and involvement of PPP model in development and execution activities; (4) prompt and adequate supply of relief resources as short term measures in event of drought and resilience building of farmers by imparting skill development training for alternative livelihood choices as long term measure.

Governments in India generally respond to drought by crisis management rather than risk management. However, the recurring droughts in the country have proved that this process is grossly ineffective. A drought management policy for India must include approaches and measures that lessen risks, vulnerabilities, and effects of droughts. The

drought management will be effective if it religiously includes and executes the three components of drought risk reduction approach – monitoring and alert system, vulnerability assessment, and preparedness and mitigation measures, as practiced in Israel, Australia, and China. Learnings from these countries that are recommended for India may have a rationale for the concerned government departments, policy makers, and the stakeholders for consolidating the drought management policies at the national and sub-national levels.

Evaluating the technology barriers, policy support and quality assurance of biopesticides in India

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Introduction

India, the fourth-largest producer of pesticides in the world, with the market segmentation tilted mainly towards insecticides. Eight states consume more than 70% of the pesticides used in India. Paddy accounts for the maximum share of consumption (26-28%), followed by cotton (18-20%). 292 pesticides registered in the country, and it is estimated that there are around 104 pesticides that are continued to be produced/ used in India that have been banned in two or more countries in the world. Almost Rs 2,000-3,000 are being spent on pesticides by farmers per acre of the crop (mainly paddy and cotton).

In contrary to chemical pesticides, biopesticides emerged as a green tool in the era of sustainable agriculture. These are the most likely alternatives to some of the most problematic chemical pesticides currently in use. Biopesticides offer solutions to concerns such as pest resistance, public health issues and detrimental effects on the surrounding environment including humans. The overriding challenge for the biopesticide industry is to live up to the promises and expectations of the end-users or the market and public as a whole. Still, their percentage share is very less in comparison to chemical pesticides (Figure 1). There are unanswered questions and unexamined assumptions about these biological and eco-friendly alternatives (Figure 2). Challenges to biopesticides stem from questions about their efficacy, quality, safety, public and grower's confusion about the spectrum of biopesticide products registered and used in the market.



Figure 1. a. Global biopesticide use and

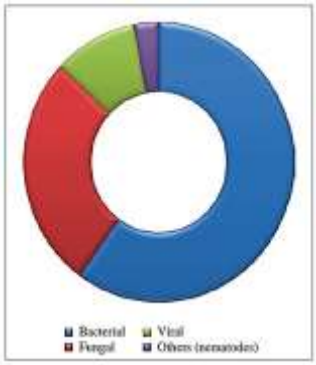

Figure 1. b. Market share of various types of biopesticide



Figure 1. c. Market share of biopesticide in various

CHALLENGES IN BIOPEPTIDES APPLICATION

Despite the scientific anticipation for developing biopesticide technologies, most remain untested in the marketplace. When it comes to using in agricultural applications, in the end, all that matter is what farmers think. For unenthusiastic farmers, who have internalized pest management with synthetics, switching over to biopesticides would be a major

challenge. They have to re-learn the entire process while risking their incomes. Earning their trust and proving efficacy has been a major challenge for biopesticides.

OBJECTIVES

1. Find out the technology barrios related to biopesticide production:
    - Types of active ingredients
    - Carriers used
    - Adjuvant used
    - Methods of production i.e.
        - Small-scale
        - Large-scale
2. Evaluating the policy support in the context of
    - Government schemes and impact
    - Validation of registrants
    - The eEntry of new ventures and stakeholders
    - Budget/fund release
3. Quality assurance of products
    - Shelf-life
    - Activity spectrum, i.e., Broad vs. narrow range
    - Feedback of farmers

METHODOLOGY

Objective 1. Find out the technology barrios related to biopesticide production

For this critical assessment of research already done in the field, biopesticide development were carried out whereas the evaluation of the technology for biocontrol product development was done by: -

- Literature search
- Patent granted or filed
- R&D lab visits
- Industry visits

Objective 2. Evaluating policy support in the context of:

- **Government schemes and impact**
- **Validation of registrants**
- **The entry of new ventures and stakeholders**
- **Budget/fund release**
- The objective was accomplished by:
    - Collecting data and information of registrants through various means such

as ministry website, blog/portal on organic agriculture

- Assessment of policy support for new ventures and stakeholders by analyzing the fund raised, and new schemes launched and awareness campaign.

Objective 3. Quality assurance of products for:

- **Shelf-life**
- **Activity spectrum, i.e., broad vs. narrow range**
- **Farmers feedback/expectations**

- Analysis of the field- data and its validation with the quality parameters of various biocontrol products registered under CIBC Act 9(3) and 3 B
- For Farmer's feedback on the reality vs. expectations of the biopesticide survey was planned (couldn't be completed) hence primary data were used.

OUTCOME

The present work highlighted the technology gaps that the biocontrol sector is facing. The finding of the work revealed that:

- Currently, more than 970 biocontrol products are registered and available for sale in the agrochemical market of India.

- However, a closer outlook of these products revealed that most of them don't follow the guidelines issued by the Directorate of Plant Protection, Quartile, and Storage (DPPQS).

- Similarly, more than 200 companies have granted the license of production, but amongst them, only a few are producing a quality product and satisfy the quality parameters such as carrier material used, the concentration of an active ingredient, CFU count and shelf-life, moisture content, packaging, delivery methods, etc.

- The active strains approved are one 13 and further fungal biopesticides are more in number in comparison to bacterial and rest of the other active ingredients.

- Currently, the Central Insecticides Board (CIB) and the Registration Committee (RC) under section 36 of the Insecticides Act, 1968 (46 of 1968), deals with biopesticide manufacture, grant of a license, expiry of the license, product labeling and packaging, data on the efficacy and safety of products and sale. However, this modal is completely based on pesticide which contains synthetic chemical compounds as an active ingredient.

- New opportunities can be created for small industries that are currently facing problems in the production of biopesticides. New policy or schemes on biopesticides can also restrict usage of conventional chemical that in turn help in organic India mission

RECOMMENDATIONS

* There is a need for significant conceptual frameworks, interpretational approaches, and new knowledge for biopesticides development.

* Currently, the high demand for biopesticides is being realized as a major tool for organic agriculture in India. There is a keen interest in the whole scientific community for organic agriculture. In such circumstances, biopesticide may prove an essential tool.

* Most of the research on biocontrol product development swivels around sate, and central agricultural universities and ICAR institutes, whereas the proportion and contribution of other R&D labs are very less. This is due to the lack of funds and administrative support. There have limited numbers of R&D projects that have been sanctioned in the last ten years in the field of biocontrol research. Whereas as already stated in the first recommendation, the process of converting biocontrol research into a marketable product is a major hurdle. Proceeding and requirement offered by CIBC are hectic, expensive and time-consuming which create disinterest in researchers and workers engaged in biocontrol research.

* Currently, User/consumer awareness issues and negative perceptions about biopesticides is the major hurdle. There is a lesser role of concerned authorities in promotion and development the biological products. Sale of spurious products and the substandard products is continuously discouraging to farmers. There is also an emergent need for a separate policy framework for biopesticides.

PUBLICATIONS

- Published a review paper on "Biopesticides in India: Technology and sustainability linkages in the journal 3Biotech (SCI=1.7)
- Prepared a policy draft paper on "Prerequisite of Biopesticide Policy in India"
- Published a review paper (in international collaboration) on Salt-Tolerant Plant Growth Promoting Rhizobacteria for Enhancing Crop Productivity of Saline Soils. Frontiers in Microbiology 10(2791) doi:10.3389/fmicb.2019.02791
- Published a review paper on Environmental sustainability: challenges and viable solutions. Environmental Sustainability 1(4), 309-340. doi: 10.1007/s42398-018-00038-w.
- Edited a book on Microbial Enzymes: Roles and Applications in Industries Springer-Nature (ISBN 978-981-15-1710-5).

EVENT ATTENDED/ORGANIZED

* Attended STI lecture series from February 2019 to March 2019. Lecture from ASTAR Singasingpore, NIPON, Japan were attended by video conferencing.

* Participated in on day seminar on "Science for people and the people for science" held on 28 February 2019 on the occasion of "National Science Day" in BBAU.

* Organized a one-day national workshop on "Building National STI Policy System and Governance for Effective R& D Ecosystem held on 5th March 2019 in BBAU.

* Attended one day workshop on "Environmenknetal hazards of electronic waste management" held on 13 March 2019 in BBAU.

* Attended a lecture by on 27 November

* Attended and given a talk on "Technology and sustainability linkages of biopeptides in India" on "International workshop on Technology-led innovations and sustainability" held on 26th February 2020 in BBAU.

* Attended Integrated Workshop on "Publication Ethics and Patenting and International Conference on "Environmental Sustainability: Innovations, Translational Dimensions and Way Forward" held on 10 to 12 February 2020 in BBAU.

* Joined national training workshop cum Faculty Development Program (FDP) on Environment, Biodiversity and Disaster Risk Management jointly organized by BBAU and NIDM, New Delhi from 02 to 06 March 2020 in BBAU.