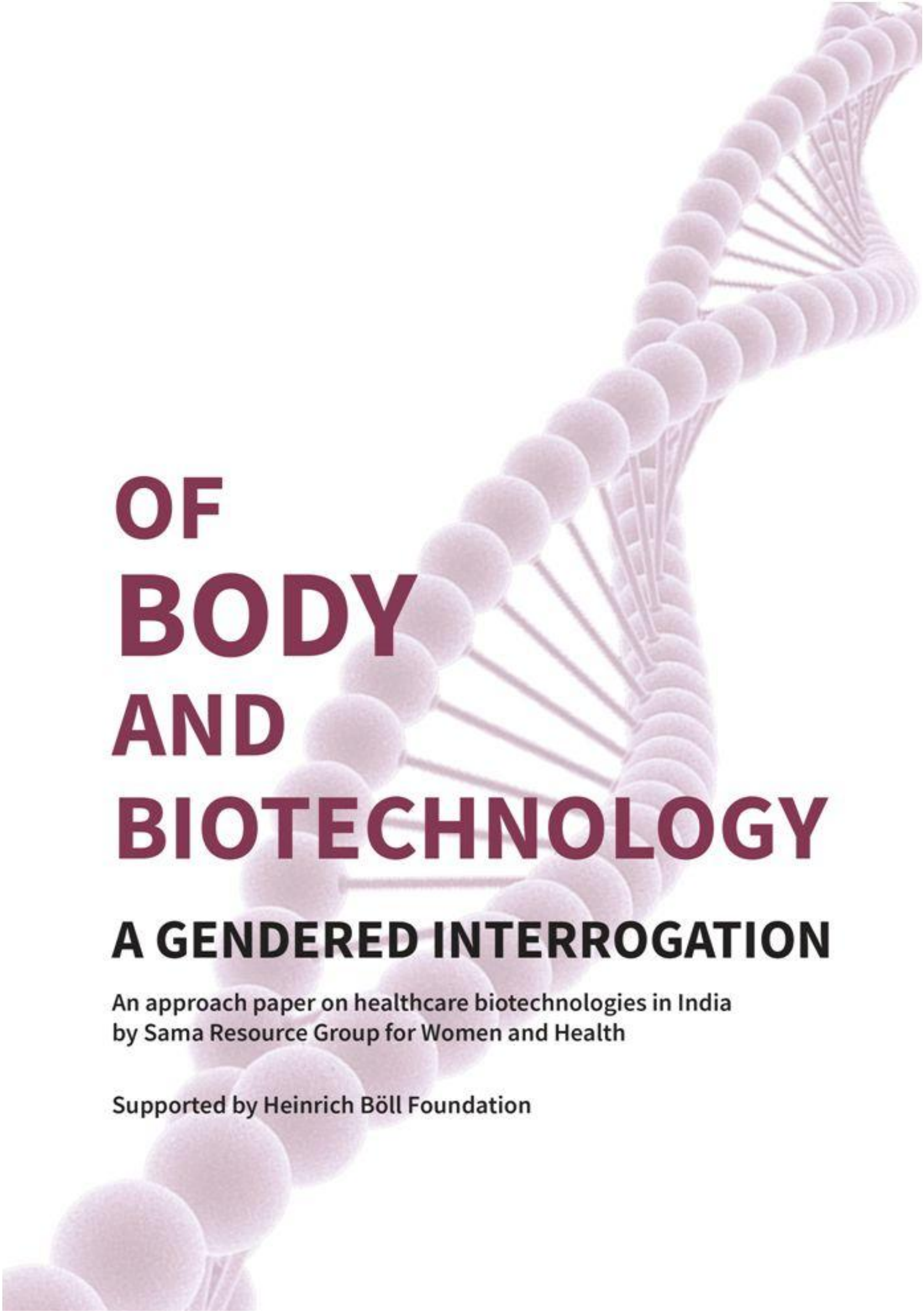

OF BODY AND BIOTECHNOLOGY

A GENDERED INTERROGATION

An approach paper on healthcare biotechnologies in India
by Sama Resource Group for Women and Health

Supported by Heinrich Böll Foundation

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Abbreviations

AIIMS: All India Institute of Medical Sciences

ANT: Actor Network Theory

ART: Assisted Reproductive Technology

BCIL: Biotechnology Consortium of India Limited

BIG: Biotechnology Ignition Grant

BIPP: Biotechnology Industry Partnership Programme

BIRAC: Biotechnology Industry Research Assistance Council

CAGR: Compound Annual Growth Rate

CBT: Center for Biochemical Technology

CCMB: Centre for Cellular and Molecular Biology

CDSCO: Central Drugs Standards Control Organization

CMC: Christian Medical College

CSIR: Council of Scientific and Industrial Research

CTRI: Clinical Trials Registry - India

DAE: Department of Atomic Energy

DBT: Department of Biotechnology

DCA: Drugs and Cosmetics Act

DCGI: Drug Controller General of India

DCR: Drugs and Cosmetics Rules

DNA: Deoxyribonucleic Acid

DOS: Department of Space

DST: Department of Science and Technology

ELISA: Enzyme-Linked Immunosorbent Assay

EPA: Environment Protection Act,1986

GOI: Government of India

HGP: Human Genome Project

ICAR: Indian Council of Agricultural Research

ICMR: Indian Council of Medical Research

IC-SCR: Institutional Committee for Stem Cell Research

IDBI: Industrial Development Bank of India

IGIB: Institute of Genomics and Integrative Biology

IGV: Indian Genome Variation

InStem: Institute for Stem Cell Biology and Regenerative Medicine

IP: Intellectual Property

IPR: Intellectual Property Rights

IVF: *Invitro* Fertilisation

LVPEI: L. V. Prasad Eye Institute

NAC-SCRT: National Apex Committee for Stem Cell Research and Therapy

NBDS: National Biotechnology Development Strategy

NBTB: National Biotechnology Board

NCRM: Nichi-In Centre for Regenerative Medicine

NII: National Institute of Immunology

OECD: Organisation for Economic Co-operation and Development

PGD: Pre-implantation Genetic Diagnosis

PPPs: Public–Private Partnerships

R&D: Research and Development

RLS: Reliance Life Sciences

SCNT: Somatic Cell Nuclear Transfer Technology

SCOT: Social Construction of Technology

SERC: Science and Engineering Research Council

USFDA: United States Food and Drug Administration

WTO: World Trade Organization

Preface

Following the rewiring of the Indian economy since the 1990s, one of the industries that received a major impetus and witnessed tremendous growth was biotechnology. It emerged as an independent market, largely informal and flowing into both organized and unorganized sectors. Within the biotech industry, there has been an accelerated development of technologies in the field of health, ranging from diagnostic equipment to therapeutic procedures in areas such as regenerative medicine, molecular diagnostics genetic and reproductive technologies. In India, the public as well as policy discourse on biotechnology reflects an uncritical optimism regarding its potential, where it is viewed as a tool for development. In the field of healthcare, biotechnology is viewed as important for improving overall health. However, evidence indicates that these technologies as well as the health system widely reflect the particular socio-cultural, economic, and political contexts in which they are embedded. Thus, when evaluating the biotechnologies, it is important to ask, who benefits from these technologies, who gets excluded from these benefits, what new forms of precarious labour are being produced or have been created, how are hierarchies being produced and reified between stakeholders in the market, and what are the socio-economic and ethical implications of these changes.

Indeed, despite the substantial growth of the biotechnology healthcare sector, the poor are systematically excluded from accessing these services. Recent critical appraisals also point to the fact that there are fundamental problems with the way the technology is developed with a 'discriminatory design', and also point to the fact that the adoption of exclusively technological approaches to addressing health leads to the neglect of more fundamental and imperative socio-economic factors that require immediate attention.

Historically, within patriarchal structures, women have been reduced to their bodies owing to their essentialization with regard to their reproductive capacities. In addition, women's position of subjugation within patriarchies has also ensured that control over their bodies, and hence their reproductive capacities, rests in patriarchal structures of domination, separate from notions of individual freedom and autonomy. This delicate relationship between body and identity, between body and control, has been an important experience of women historically. Reproductive biotechnologies, for instance, have demonstrated the need, indeed the compulsion, and the ability to pander to patriarchal demands through the provision of 'new' marketable techniques. These technologies thrive in a paradoxical situation, where technological innovations are touted as demand-driven, but where there is also evidence that the availability or supply of such technology fuels demand emanating from patriarchal societies (Sama, 2006).[1] Thus, gender is intrinsic to the biotechnological enterprise; gendered bodies are sources of biological material and gendered bodies are also the sites of

[1] Sama. (2006). *ARTs and women – assistance in reproduction or subjugation*? Sama –Resource Group for Women and Health.

the deployment of biotechnology. Particularly with regard to reproductive biotechnologies, feminists have consistently emphasized the fact that despite the promised emancipatory potential of such techniques, they have been employed instrumentally in furthering the patriarchal project of women's subjugation (Sama, 2012).[2] These critiques, since the late 1970s, have highlighted how women have encountered and experienced these technologies; however, the feminist positions examining the links between gender and reproductive technologies have expanded in scope, seeking to question the claims of gender neutrality and gender blindness of these technologies and technology-determined socioeconomic development.[3]

However, there is no systematic framework for a gendered analysis of biotechnology that examines the role of gender factors vis-à-vis various health-related issues or practices. This approach paper synthesizes and presents various feminist positions through which biotechnology has been examined. Further, it maps the ways in which gendered imprints are writ large on some emerging biotechnologies in India, employing the examples of genomics and stem cell technologies. Through these examples, we attempt to illustrate dilemmas related to commodification, labor, access and choice, concepts that have been at the core of feminist concerns. We present a critical review of the literature on biotechnologies, drawing from the life sciences, social sciences and gender studies. Feminist literature in this realm was a core focus of our review. Additionally, we also reviewed relevant articles on the market landscape of biotechnology, and analysed the relevant laws, guidelines, and other data sources.

[2] Sama. (2011). *Constructing Conception Mapping of Assisted Reproductive Technologies in India,* Sama – Resource Group for Women and Health.

[3] Srinivas, K. R., Hoareau, L., & Lebreton-Traoré, M. (2015) W*omen and Biotechnology Editorial Introduction*, Asian Biotechnology and Development Review, 17(1), pp. 1–6.

Chapter 1

Introduction

It is important to situate the emergence of biotechnology in the context of the history of modern science and technology in India and globally. In the newly independent India of the mid-twentieth century, science and technology were considered as modernizing, transformative agents of change that would serve to emancipate the country from backwardness, poverty, and superstition. This notion is enshrined in the idea of 'scientific temper', whose propagation is listed as a fundamental duty in Article 51 A of the Constitution.[4] The faith in science and technology as engines of progress led to substantial investment in scientific research and development (R&D) by the state.[5]Although the model of state-sponsored research in science and technology has been undergoing changes,[6] the faith in science and technology-based development continues to this day. This is evident in the national policies and programmes aimed at the development of science and technology that emphasize the need for India to emerge as a global leader in science and technology-based innovation.[7]

In the 1970s, during the global economic crisis, two important changes converged to give rise to the 'biotech revolution' in India and globally. First, profitable investment opportunities were dwindling in the leading economies, particularly in the United States, and rising inflation was jeopardizing the idle capital of financial institutions. Second, the biotech sector was yielding significant advances in molecular biology, genetics, bioengineering, etc. It was in this economic and social milieu that large pharmaceutical companies and venture capitalists looked to the emerging sector as a promising area for investment.[8]

The introduction of neoliberal policy reforms in India since 1991, however, has "radically altered the discourse on development, welfare and social justice" (p. 198)[9] with the state favouring the rapid commercialization of technology and research. The neoliberal paradigm "stipulates that the state ought to withdraw from productive activities and welfare measures, and allow the market to freely

4 Constitution of India, Article 51A, Subsection h; Fundamental duties: It shall be the duty of every citizen of India to develop the scientific temper, humanism and the spirit of inquiry and reform.

5 Raina, D. (2003). *Images and Contexts: The Historiography of Science and Modernity in India*.New Delhi: Oxford University Press.

6 Scoones, I. (2006). *Science, agriculture and the politics of policy: The case of biotechnology in India*. New Delhi: Orient Longman; Raina, D. (2003). *Images and Contexts: The Historiography of Science and Modernity in India*.New Delhi: Oxford University Press.

7 Kandhari, R. (2016), Stem Cell Research and Experimentation in India, in Sarah Hodges and Mohan Rao (Eds), *Public Wealth and Private Wealth: Stem Cells, Surrogates and Other Strategic Bodies*. New Delhi: Oxford University Press, 222–251.

8 Loeppky, R. (2005). History, technology, and the capitalist state: The comparative political economy of biotechnology and genomics, *Review of International Political Economy, 12*(2), 264–286, as cited in P. Ranjan, p.201.

9 Ranjan, P. (2016). 'Biotechnology in India: Catalyst for a knowledge era?', Sarah Hodges and Mohan Rao (Eds), *Public Wealth and Private Wealth: Stem Cells, Surrogates and Other Strategic Bodies*. New Delhi: Oxford University Press, pp.197–221,p. 198.

shape every aspect of the economy" (p.199).[10] This move has been accelerated by the state-supported privatization of the biotech industry, which has shifted power and capital away from the state and citizens towards the global market. India continues to promote foreign collaboration, moving away from developing internal social policies and focusing instead on the global market and pursuing profit for relevant stakeholders.

1.1. The Growth of Biotechnology in India

Before we turn to an examination of the structure and layout of the biotechnology industry, we will first briefly discuss what biotechnology means. From a common-sense point of view, the term biotechnology appears 'modern', yet the biological processes of microorganisms have been used for about 6,000 years to make food products such as curd, bread, and cheese and to preserve dairy products. In the twentieth century, the traditional use of biological processes was accelerated by the explosion of new technologies that occurred during this time. In the present day, biotechnology involves the application of various branches of science like physics, chemistry, engineering, mathematics, statistics, computer applications, and information technology.[11]There are thus several definitions of biotechnology,[12] many of which are rather technical or too narrow[13] for our purposes in this paper. Hence, we present a definition that serves our aim here: according to the Organization for Economic Co-operation and Development (OECD), biotechnology is "the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and service".[14]The Department of Biotechnology (DBT), Government of India (GOI), however, offers a broad and rather vague definition of biotechnology: "Biotechnology is an application of recombinant and non-recombinant technologies in biological resource utilization for product and process development aimed for commercialization."[15]

10 Ranjan, P. (2016)'Biotechnology in India: Catalyst for a knowledge era?', Sarah Hodges and Mohan Rao (Eds), *Public Wealth and Private Wealth: Stem Cells, Surrogates and Other Strategic Bodies*. New Delhi: Oxford University Press, pp.197–221, p.207

11 Nair, A. J. (2008). *Introduction to Biotechnology and Genetic Engineering* Infinity Science Press: New Delhi, p.34.

12 See, for instance, E. S. Grace (2006), *Biotechnology Unzipped:Promises and Realities* Washington, D.C.: Joseph Henry Press, p.2; Azaid et al., Glossary of biotechnology and genetic engineering, FAO Research and Technology Paper 7. Food and Agriculture Organization of the United Nations, p. iii, available at ftp://ftp.fao.org/docrep/fao/003/X3910E/X3910E00.pdf,accessed on 22/11/2017; Bhargava, P. M. (2009), Biotechnology in India: The beginnings,*Biotechnol. J.*, *4,* 313–318. DOI: 10.1002/biot.200800327, www.biotechnology-journal.com, accessed on 22/11/2017; Chaturvedi, S. (2003). Biotechnology: Need for reliable statistics. *Economic and Political Weekly, 38* (22), 2113–2114.

13 See the definition of biotechnology adopted by the Codex Alimentarius Commission (CAC), adapted from the Cartagena Protocol on Biosafety Section. See also the definition put forth by Food Safety Department, Modern food biotechnology, human health and development: An evidence-based study, World Health Organization, pp. 1–2 (2005), available at: http://www.who.int/foodsafety/ publications/biotech/biotech_en.pdf., accessed on 22/11/2017.

14 Brigitte van Beuzekom & Arundel, A. *OECD Biotechnology* Statistics 2009, p. 9, available at: http://www.oecd.org/dataoecd/4/23/42833898.pdf,accessed on 22/11/2017.

15 Chaturvedi, S. (2003). Biotechnology: Need for reliable statistics. *Economic and Political Weekly*, *38*(22), 2113–2114.

With regard to the biological sciences in India, although scientists in certain scientific institutions[16] conducted research in the biological sciences in specific departments, it was only in 1977 that the first institute dedicated to research in the biological sciences was set up. This was the Centre for Cellular and Molecular Biology (CCMB) in Hyderabad, established by the Council of Scientific and Industrial Research (CSIR). Following this, the National Institute of Immunology (NII) in New Delhi was set up by the Department of Science and Technology (DST).[17]Further, research in the biological sciences has been supported by governmental agencies or departments like the CSIR, Indian Council of Medical Research (ICMR), the Indian Council of Agricultural Research (ICAR), the Department of Atomic Energy (DAE), the Department of Space (DOS), and the DST, as well as the Science and Engineering Research Council (SERC), administered by the DST.[18] Consequently, India has a number of laboratories—many of which are institutions of excellence—engaged in research in the biological sciences.[19]The establishment of biotechnology as a discipline can be attributed to the persistent efforts of scientists who had also been a part of the administration in government ministries. In 1981–82, the Scientific Advisory Committee to the Cabinet engaged in extensive deliberation with the scientific community and consequently set up the National Biotechnology Board (NBTB) to provide a systematic impetus to the field of biotechnology and to look into scientific programmes in biotechnology requiring financial support.[20]

India's Sixth Five Year Plan (1980–1985) was the first policy document to cover the development of biotechnology in the country.[21] The plan proposed to strengthen and develop capabilities in areas like immunology, genetics, and communicable diseases. Thereafter, a number of pilot programmes were proposed in the Sixth and Seventh Five Year Plans as well. Finally, in 1986, the GOI decided to set up a separate Department of Biotechnology (DBT) to support R&D and technology validation, to establish centres of excellence, to build strong human resources, and to promote industry–academia interaction and technology transfer.[22] The DBT functions under the aegis of the Ministry of Science and Technology and is the only agency of the GOI that is completely devoted to R&D

16 For instance, the Indian Institute of Science in Bangalore, the National Chemical Laboratory in Pune, and the Department of Applied Chemistry at the University of Calcutta.

17 Bhargava, P. M. (2009). Biotechnology in India: The beginnings, *Biotechnol. J.*, *4,* 313–318. DOI 10.1002/biot.200800327, www.biotechnology-journal.com, accessed on 22/11/2017.

18 Bhargava, P. M. (2009). Biotechnology in India: The beginnings, *Biotechnol. J.,4*, 313–318. DOI 10.1002/biot.200800327, www.biotechnology-journal.com, accessed on 22/11/2017.

19 Such institutions include IISC and the National Centre of Biological Sciences in Bangalore; CCMB and the National Centre for Cell Sciences in Pune; the National Institute of Immunology and the International Centre for Genetic Engineering and Biotechnology in Delhi; the Indian Institute of Chemical Biology in Kolkata; and the Institute of Microbial Technology in Chandigarh.

20 Sharma, M.,& Swarup, R. (2003). The Way Ahead The New Technology in an Old Society, *Advances in Biochemical Engineering Biotechnology, 84*:1–48.

21 Government of India, Sixth Five Year Plan, 1980–85. New Delhi: Planning Commission, p. 326.

22 Sharma, M., & Swarup, R. (2003). The Way Ahead The New Technology in an Old Society, *Advances in Biochemical Engineering Biotechnology, 84*:1–48.

in biotechnology.[23]The main reason for this seems to have been a realization that the nature of biotechnology is interdisciplinary, requiring the integration of a variety of competencies in various scientific disciplines.[24]Public investment in the biotechnology sector has increased from INR 6,210 million in the Ninth Five Year Plan (1997–2002) to INR 65,000 million in the Eleventh Five Year Plan (2007–2012).

In the past decade, the DBT's major focus was on medical biotechnology. Out of a total of 1,225 projects implemented during the first four years (2002–2006) of the Tenth Five Year Plan (2002–2007), 39 per cent were in the field of agriculture biotechnology and only 20 per cent were in the field of medical biotechnology.[25]

It is important to note that the DBT was established at a time when India was being initiated into the idea of neoliberalism. Kandhari argues that globally as well as in India, the biotechnology industry developed in keeping with the deliberate policy decisions made in the 1980s when neoliberalism was gaining acceptance as a political ideology in many countries, including India.[26] Pushpa Bhargava observes that although the DBT was established initially with the primary objective of setting up indigenous and commercially oriented research, development, and production organizations—somewhat along the lines of corporations—it failed to achieve this goal.[27] However, the DBT has always been encouraging of the private sector, which has grown exponentially over the last 20 years.[28] This is not surprising given the aforementioned discussion on the close nexus between neoliberalism and biotechnology. Many of the DBT-supported institutions have developed and transferred technologies to the industry.

Further, in order to promote private investment in the field of biotechnology and to bridge the gap between industry and the public institutions, the GOI also established the Biotechnology Consortium of India, Limited (BCIL) as a public company in 1990.[29] It was set up jointly by the DBT (1993) and some government-sponsored financial institutions and industries to fulfil the same functions as those performed by venture capital companies in the United States, that is, to promote the creation of firms not only by providing venture capital but also to conduct techno-economic feasibility studies and monitoring the activities

23 Ramani, S. V. (2002). Who is interested in biotech? R&D strategies, knowledge base and market sales of Indian biopharmaceutical firms. *Research Policy*, *31*(3), 381–398.

24 Ramani, S. V. (2002). Who is interested in biotech? R&D strategies, knowledge base and market sales of Indian biopharmaceutical firms. *Research Policy*, *31*(3), 381–398.

25 Government of India, Ministry of Science and Technology, Department of Biotechnology, 'Report of the Working Group for the Eleventh Five Year Plan' (New Delhi 2006), available at www.dst.gov.in/sites/default/files/rep-dep-bio.pdf, accessed on 25/11/2017.

26 Kandhari, R. (2016), Stem Cell Research and Experimentation in India, in Sarah Hodges and Mohan Rao (Eds), *Public Wealth and Private Wealth: Stem Cells, Surrogates and Other Strategic Bodies*.New Delhi: Oxford University Press, pp. 222–251.

27 Bhargava, P. M. (2009). Biotechnology in India: The beginnings, *Biotechnol. J., 4*, 313–318. DOI 10.1002/biot.200800327, www.biotechnology-journal.com, accessed on 22/11/2017.

28 Bhargava, P. M. (2009). Biotechnology in India: The beginnings, *Biotechnol. J., 4*, 313–318. DOI 10.1002/biot.200800327, www.biotechnology-journal.com, accessed on 22/11/2017.

29 BCIL, http://bcil.nic.in/, accessed on 25/11/2017.

of start-ups or companies on behalf of financial institutions or investors.[30]The public–private formation of BCIL in 1990 marked the nascency of the neoliberal policy development, because its creation was meant to 'accelerate commercialization of biotechnology' by and through networking with industry stakeholders. This body is financed by pharmaceutical companies as well as financial institutions such as the Industrial Development Bank of India (IDBI). Under this partnership, programmes like the Biotechnology Industry Partnership Programme (BIPP) were created to promote enterprises and investment. This rapid commercialization of research and technology in India rests on a future-oriented rhetoric, aimed at leveraging the nation's scientific strength and at making manifest the DBT's projected growth from an industry worth$11.3 billion at present to a $25 billion industry by 2025[31] . By 2005, BCIL had facilitated about 60 technology transfers between the public and private sectors.[32]

In 2007, the GOI increased its funding to public–private partnerships (PPPs) in biopharmaceutical R&D by 30 per cent. It also approved the National Biotechnology Development Strategy (NBDS), 2015–2020, which aims to strengthen the industry's human resources and infrastructure while promoting growth and trade. The strategy proposed the establishment of a Biotechnology Industry Research Assistance Council (BIRAC) that would be responsible for promoting start-ups and ensuring the conversion of public–private funded and privately generated research sectors into viable and competitive enterprises.[33]BIPP is another initiative of the DBT that supports and funds PPPs, especially in the field of health biotechnology.[34]BIPP is a cost-sharing initiative and provides loans and grants for high-risk innovative projects in biotechnology. Under this programme, the government will bear a significant amount of risk, contributing about 30–50 per cent of the grant-in-aid, while intellectual property rights (IPR) would rest with the companies. The scientist in the public-funded institution would receive royalty on the patent.[35]

Encouragement of the private sector continues to be at the top of the national agenda even today, as seen in the NDA government's 'Make in India' initiative. The campaign slogan is 'a. Identify in India b. Invent with India c. Implement globally'. The campaign's mission is to promote foreign investment in India's

30 Kandhari, R. (2016), Stem Cell Research and Experimentation in India, in Sarah Hodges and Mohan Rao (Eds), *Public Wealth and Private Wealth: Stem Cells, Surrogates and Other Strategic Bodies*.New Delhi: Oxford University Press, pp. 222–251.

31 Indian Brand Equity Foundation (2017, June). 'Indian Biotechnology Industry Analysis.' Retrieved from: https://www.ibef.org/industry/biotechnology-presentation, accessed on 25/10/2017.

32 Kandhari, R. (2016), Stem Cell Research and Experimentation in India, in Sarah Hodges and Mohan Rao (Eds), *Public Wealth and Private Wealth: Stem Cells, Surrogates and Other Strategic Bodies*.New Delhi: Oxford University Press, pp. 222–251.

33 Government of India, Department of Biotechnology, The National Biotechnology Development Strategy 2015–2020 programme, www.dbtindia.nic.in/wp-content/uploads/DBT_book-29-december_2015.pdf, accessed on 01/12/2017.

34 Government of India, Department of Biotechnology, 'Biotechnology Industry Partnership Programme'. http://www.birac.nic.in/webcontent/BIPP_Scheme_Document_11_feb_15.pdf, accessed on 01/12/2017

35 Government of India, Department of Biotechnology, 'Biotechnology Industry Partnership Programme'. http://www.birac.nic.in/webcontent/BIPP_Scheme_Document_11_feb_15.pdf accessed on 01/12/2017

biotech industry. The marketing rhetoric pitches India as 'among the top 12 biotech destinations in the world' with a 'huge consumer base and large domestic market'. This programme is purported to support domestic skill development and entrepreneurship in biotechnology to achieve the long-cherished dream of increasing the net value of the biotechnology sector to $100 billion by 2025. To this end, a 'Make in India' Investor Facilitation Cell was set up in BIRAC to coordinate activities. The effects of a public–private hybridization are also seen in the area of regenerative medicine, which occupies an expansive scale in the biopharmaceutical sector, with BIRAC projecting that "stem cell banking has an expected growth from USD $95 million in 2014 to USD $473 million in 2019".[36] Similarly, with the globalization of the clinical trial industry and an increase in outsourcing contract manufacturing, India's bio-services sector is growing due to its supply of "large, genetically diverse patient-pool and treatment naive population" for clinical trials.[37]

Thus, commodities in the biotech industry are commercialized with minimal domestic co-development and collaboration, because the state's focus is to establish India as 'a world-class bio-manufacturing hub by 2020'. In this regard, in the 2017–2018 Union Budget, the DBT has allocated $2,222.11 crores, an increase of 22 per cent, to continue implementing the biotechnology strategy.

The scope of the biotech industry encompasses medicines, agriculture, industrial processing, and human resources. The five main sectors are biopharmaceuticals, bio-agriculture, bio-services, bioinformatics/IT, and bio-industrials. In the financial year 2016, more than 60 per cent of the biotech companies operated in the biopharmaceutical sector, followed by bio-services (18 per cent), bio-agriculture (14 per cent), and finally bio-industrial and bioinformatics (1 per cent).[38] The industry is expected to yield $11.6 billion revenue in 2017 and $100 billion by 2025, calculated by the CAGR of 20.33 per cent.[39]

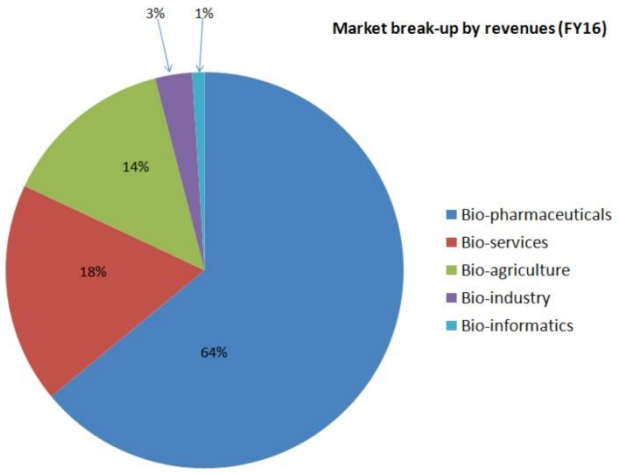


Figure 1: Market break-up. *Source: IBEF, June 2017*

36 BIRAC.(September 2016).Make in India for Biotech, the way forward.Retrieved from:http://birac.nic.in/mii/uploaded/MII-Report.pdf. p.14.Accesed on 30/10/2017.

37 BIRAC. (September 2016). Make in India for Biotech, the way forward.Retrieved from: http://birac.nic.in/mii/uploaded/MII-Report.pdf. p.19. Accessed on 30/10/2017.

38 IBEF, June 2017, www.ibef.com, accessed on 23/11/2017.

39 BIRAC.(September 2016). 'Make in India for Biotech, the way forward'. Retrieved from: http://www.birac.nic.in/mii/uploaded/MII-Report.pdf p.12, accessed on 30/10 2017.

1.2. The Biotech Market in India

The Indian biotech industry is purportedly among "the top 12 destinations in the world", ranking second in Asia after China.[40] Many developed markets in western countries are shifting their operations and activities to emerging markets like India due to low operational costs in these regions. India in particular became a major global destination for the biotechnology industry due to a combination of factors: highly skilled medical providers who are conversant with the hegemonic *lingua franca*; state-of-the-art technology and infrastructure, especially in the private healthcare sector; a large population of poor and needy people whose bodies are available as goods in the market; low-cost human resources; ambiguous or absent legal guidelines; and weak or absent juridical interventions.[41] The biotech industry has been witnessing robust growth for the last ten years, with an average growth rate of approximately 15 per cent, driven by a range of factors like growing demand, intensive R&D activities, and strong government initiatives.[42]

The Indian biotech industry is estimated to be worth $100 billion by 2025, assuming that it resumes its growth trajectory of CAGR (Compound Annual Growth Rate) of 25 to 30 per cent.[43] The top ten biotech companies collectively responsible for about 45 per cent of the total turnover of the industry are listed in Figure 2.[44]

Figure 2: Top ten biotech companies in India by revenue in 2015

Rank	**Company**	**Bioscience Revenue** (*Rs In Crores)*
1.	Serum Institute of India	3539
2.	Biocon	3143
3.	Nuziveedu Seeds	884
4.	Syngene International	843
5.	Kaveri Seeds	680
6.	Bharat Serum & Vaccines	565

[40] Mapping-BITP-Landscape.pdf, www.dbtindia.nic.in/wp-content/uploads/Mapping-BITP-Landscape.pdf, accessed on 25/11/2017.

[41] Nadimpally, Sarojini (2017), Ethical issues and Challenges in Research on Gender, Reproductive Technologies and Market, Unpublished article

[42] Mapping-BITP-Landscape.pdf, www.dbtindia.nic.in/wp-content/uploads/Mapping-BITP-Landscape.pdf, accessed on 25/11/2017.

[43] Mapping-BITP-Landscape.pdf, www.dbtindia.nic.in/wp-content/uploads/Mapping-BITP-Landscape.pdf, accessed on 25/11/2017.

[44] Mapping-BITP-Landscape.pdf, www.dbtindia.nic.in/wp-content/uploads/Mapping-BITP-Landscape.pdf, accessed on 25/11/2017.

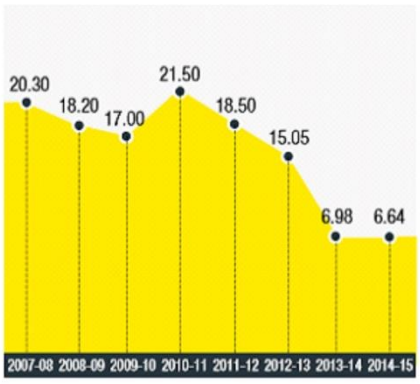
7.	Eli Lily	517
8.	Jubilant Life Sciences	483
9.	Indian Immunological	483
10.	Novozymes South Asia	469

Source: Biospectrum

However, the growth of the biotech sector in 2014–15 dipped to 6.64 per cent, which is the lowest growth rate registered during the last 12 years.[45] Figures 3 and 4 depict the trends in the growth of the biotech industry since 2007.[46] There was a slowdown in growth in 2013–14 and 2014–15 as well, which, according to a report, was due to delays in regulatory approvals. The process of regulatory approvals is expected to be streamlined shortly in order to revive the growth momentum of the biotech industry.[47]

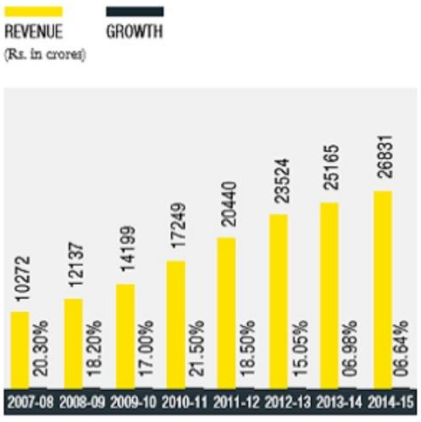
Figures 3 and 4

Growth of Biotech Industry since 2007(Fig.1)



Source: Biospectrum

Biotech Sector Revenue and Growth percent (Fig.2)



Source: Biospectrum

The biotechnology industry in India faced many hurdles in the initial stages because of the long research period and limited funding. Many investors stayed away from this industry for a long time.[48] The adoption of neoliberal policies

45 Mapping-BITP-Landscape.pdf, www.dbtindia.nic.in/wp-content/uploads/Mapping-BITP-Landscape.pdf, accessed on 25/11/2017.

46 Mapping-BITP-Landscape.pdf, www.dbtindia.nic.in/wp-content/uploads/Mapping-BITP-Landscape.pdf, accessed on 25/11/2017.

47 Mapping-BITP-Landscape.pdf, www.dbtindia.nic.in/wp-content/uploads/Mapping-BITP-Landscape.pdf, accessed on 25/11/2017.

48 Indian Biotech Industry Indian Mirror. Retrieved from:http://www.indianmirror.com/indian-industries/biotechnology.html. Accessed on 25/11/2017.

brought about a paradigm shift in the biotech industry as well. These reforms are notorious for encouraging the state's withdrawal from productive activities and social welfare measures, and for allowing the market to freely shape every aspect of the economy, with the state favouring the rapid commercialization of technology and research.[49] Thus, neoliberal policies have changed the discourse on development, welfare, and social justice in India. In the biotech industry, the impact of these policies is seen in state-supported privatization of biotechnology research and development, promotion of foreign collaboration and encouragement of private strategic alliances. The state has shifted away from developing and implementing welfare-oriented policies, focusing instead on the global market and on profit maximization for relevant industry stakeholders. Beneficiary stakeholders include the government, academic institutions, public–private entities, and private corporations. Thus, with regard to the biotechnological enterprise in India, the government has reconstituted and allocated power to the private sector, thereby dislocating the state as the central node of connectivity and as the regulator of the industry, resulting in the current emergence of poorly regulated biocommodities and technologies that favour economic growth and capital accumulation.

Further, the neoliberalization of India's economy has led to the privileging of 'knowledge-based sectors' and to the deregulation of the private sector. This trend is reflected in gaps in current international legal agreements on the global governance of biotechnology in relation to intellectual property (IP), ethics, and norms as responsible practices in the sector. The biotechnology industry has developed rapidly in the last 12 years. This growth has been made possible by the availability of alternative financial sources such as venture capital, private equity, and angel funds,[50] which prepared the ground for the establishment of BIRAC. Subsequently, the 2012 early-stage seed fund Biotechnology Ignition Grant (BIG) scheme[51] and the Start-up India campaign in 2016 [52]promoted investment in the sector, influencing the output and the direction of developed technologies for commercial profit. This state-sponsored corporatization of the industry has created a culture of overdetermined forecasting, serving to maximize returns for investors, and to secure and create future markets for developed products, while being built and serviced by the bodies of minority and disenfranchised populations in India.

49 Ranjan, P. (2016). 'Biotechnology in India: Catalyst for a knowledge era?', Hodges, S., & Rao, M. (eds) (2016). Public health and private wealth. Oxford University Press, New Delhi p.197-221, p.198

50 Planning Commission GOI (2013) 'Faster, more inclusive sustainable growth Vol 1 Twelfth Five-year plan', Retrieved from http://planningcommission.gov. p.112 accessed on 30 October 2017

51 Vignesh, J. (2017 February 17) 'How India's flagship Biotech Ignition Grant has made an impact on the biotechnology industry' Economic Times: Technology. Retrieved from: https://tech.economictimes.

52 Vignesh, J. (2017 February 17) 'How India's flagship Biotech Ignition Grant has made an impact on the biotechnology industry' Economic Times: Technology. Retrieved from: https://tech.economictimes.

1.3. Biotechnology Industry in Healthcare

In recent years, there has been an increasing and accelerated development of a range of biotechnologies in the field of health. A large part of the biotech industry comprises the healthcare sector. What gets termed "Healthcare biotechnology" would include biopharmaceuticals such as vaccines, diagnostic technologies, and therapeutics. These could include recombinant DNA or monoclonal antibody based products, DNA diagnostics and regenerative medicine which includes stem cell based therapeutics.

About 70 per cent of the biotech firms in India were established after 1980.[53] However, as is well known, health systems evolve in and reflect the particular social context in which they are embedded. Technologies too must similarly be situated in particular socio-economic, political, and cultural contexts in which they evolve. Vishalakshy (2008) observes that the growth of the Indian biotechnology industry was accelerated after the relevant research capabilities and infrastructure were developed.[54] The commercialization of the biotech industry took place in two phases. The first phase occurred in the late 1980s, with the founding of low-end biotechnology ventures specializing in tissue culture and ELISA (Enzyme-linked immune sorbent assay) or ventures in the field of vitro diagnostics. Most of the companies that were active in these areas slowly disappeared by the mid-1990s. Post ninetees, the companies, which were purely pharmaceutical companies, diversified their scope and expanded their operations in the area of biotechnology.[55]The new biotech start-up companies have a narrower focus on a couple of products. Some of the smaller companies are oriented towards providing services like basic research or other basic services or generating clinical data or bioinformatics.

Trends indicate that Indian biotech companies are using different strategies to expand their base, both domestically and globally. For instance, a number of Indian companies have entered into deals and strategic alliances with foreign biotech companies. These could be for contract research, manufacturing services, and technology transfer, or they could be joint R&D agreements in areas like regenerative medicine and other biomedical research.[56]Since 2009, Indian biotech companies have also been focusing on investing in foreign companies, especially those in western countries, to strengthen their research and manufacturing capabilities,to expand their markets and distribution networks, and also to develop a foothold in the US and European markets.[57] Many biotech firms,

53 BIRAC.(September 2016). 'Make in India for Biotech, the way forward'. Retrieved from: http://www.birac.nic.in/mii/uploaded/MII-Report.pdf, p.12, accessed on 30/10/2017.

54 S. Vishalakshy, 'Biotechnology', NISTADS, Department of Science and Technology, http://www.nistads.res.in/indiasnt2008/t4industry/t4ind15.htm, accessed on 25/11/2017.

55 S. Vishalakshy, 'Biotechnology', NISTADS, Department of Science and Technology, http://www.nistads.res.in/indiasnt2008/t4industry/t4ind15.htm

56 Ernst and Young. (2009). 'Beyond Borders: Global Biotechnology Report 2009', *Biotechnology Journal*, *4*,1108–1110. Retrieved from: http: //www.massey.ac.nz/~ychisti/E&Y09.pdf., p.114, accessed on 24/11/2017.

57 Ernst and Young. (2009). 'Beyond Borders: Global Biotechnology Report 2009', *Biotechnology Journal*, *4*,1108–1110. Retrieved from: http: //www.massey.ac.nz/~ychisti/E&Y09.pdf., p.114, accessed on 24/11/2017.

especially those involved in biopharmaceuticals (for example, Advinus, Bharat Bio-tech India, Panacea Biotech, Reliance Life Sciences, Shantha Biotechnics, and Wockhardt), are generating a pipeline of products, either by collaborating or entering into strategic partnership with foreign firms,or by engaging in contract research, clinical trials, and manufacturing services.[58]

1.4. Biopharmceuticals

The Biopharmaceuticals constitute the largest segment of the biotech industry in India and continue to account for the largest share of the total biotech industry revenues in 2016–17. Currently, India has a 2 per cent share in the global biopharmaceutical market, which is projected by the GOI to increase to 5 percent by 2020.[59] In 2016, the biopharmaceutical sector accounted for the largest revenue share, that is, 64 per cent, in the Indian biotech industry.[60]The biopharmaceutical industry in India is estimated to be worth $338 million; it has been growing at a CAGR of 30 per cent since 2008.

The large majority of biopharmaceutical products are biologics[61]derived from life forms and comprises vaccines, diagnostics, therapeutic drugs, insulin, animal biologics, and statins. Biologics are fast becoming the new top-selling drugs in the global market. For instance, Avastin,[62]an anti-cancer therapeutic protein, had $6.7 billion in sales in 2016.The global sales of three best-selling therapies for rheumatoid arthritis in 2016 are equally revealing: Humira[63]($16.078 billion), Remicade[64] ($6.97 billion), and Enbrel ($8.1 billion). However, the global sales figures in billions also indicate that biological drugs are extremely expensive. For example, the cost of one vial of Adalimumab (for the originator product Humira from AbbVie Inc.) costs about $1,000, almost equivalent to the average annual wage in a low-income country.[65] Even the non-originator products are unaffordable. Nevertheless, access to biological drugs is crucial for the treatment of many communicable and non-communicable diseases. There are three

58 Konde, V. (2009). Biotechnology business models: An Indian perspective. *Journal of Commercial Biotechnology*, *15*(3), 215–226.

59 IBEF (2017, June). Indian Biotechnology Industry. Retrieved from https://www.ibef.org/industry/biotechnology-presentation. Accessed on 01/12//2017.

60 IBEF. (2017, June). Indian Biotechnology Industry. Retrieved from:https://www.ibef.org/industry/biotechnology-presentation. Accessed on 01/12/2017.

61 Biological drugs are different because they are produced in the living cells through the biological process and by mimicking natural biological substances like hormones. Unlike chemical drugs, which are structurally well defined with low molecular weight, biopharmaceuticals are high molecular-weight compounds with complex three-dimensional structures. For example, the molecular weight of aspirin is 180 Da (Dalton) whereas that of interferon-β is 19,000 Da.

62 The FDA just approved the first direct competitor to a billion-dollar cancer drug. See :https://www.businessinsider.in/The-FDA-just-approved-the-first-direct-competitor-to-a-billion-dollar-cancer-drug/articleshow/60518377.cms

63 AbbVie's revenue from top product Humira from 2011 to 2016 (in million U.S. dollars). See: https://www.statista.com/statistics/318206/revenue-of-humira/

64 J&J confident of retaining Remicade rewards as biosimilar clouds gather, available at: https://www.biopharma-reporter.com/Article/2017/05/31/Janssen-At-least-5-more-years-of-multi-billion-dollar-Remicade-sales, accessed on 28/11/2017.

65 Average prices of Humira in selected countries in 2014 (in U.S. dollars): https://www.statista.com/statistics/312014/average-price-of-humira-by-country/

potential barriers to accessing affordable biopharmaceutical drugs, namely technology, IPR, and regulatory barriers.[66]Due to the high cost of these drugs, there is a great demand for generic versions of biological drugs.

1.5. Regulations and Regulatory Bodies

In the past, all regulatory requirements for biotechnology-based activities, including human healthcare, resided in India's Environment Protection Act, 1986 (EPA). Three provisions of EPA form the basis for the biosafety regulations which were formulated and formalized as the Biosafety Rules, 1989, which apply to the research, manufacture, use, import, and storage of microorganisms, gene technology products, and products made out of genetically engineered microorganisms.[67]

At present, parts of the healthcare biotechnology industry are regulated by a set of guidelines such as the revised National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, issued by the ICMR, and the National Guidelines for Stem Cell Research, 2017, issued by the ICMR and DBT. Regulatory control over drugs, including biologicals, in India is exercised through the Drugs and Cosmetics Act, 1940 (DCA) and the Drugs and Cosmetics Rules, 1945 (DCR).[68] Schedule Y of the DCR lays down the law governing clinical and pre-clinical testing of products. As per the DCR, vaccines and other biological products are considered to fall within the 'new drug' category and are thus governed by all rules and regulations applicable to new drugs.[69] The permission for conducting pre-clinical and clinical trials with recombinant drugs, their review and subsequent approval for release for human consumption, the reviewing of new drug applications, and the import of drugs are under the authority of a central agency, the DCGI.

A specific section in the ICMR revised guidelines, 2017 on biomedical and health research on human participants looks at the ethical issues related to human genetics testing and research, biological materials, biobanking, and datasets. The preamble to the section states:

> In no other area of biomedical and health research has there been a greater concern for ethical issues than in the field of human genetics. In recent years this concern has grown even further because of direct to consumer testing and the possibilities of embryo manipulations. While the recent DNA technology has provided one of the most powerful tools in the hands of mankind to unravel the 'mysteries' of the human genome

66 Submissions by Amit Sengupta and K. M. Gopakumar, on Bio-similar regulatory pathway, to UN Secretary General High-Level Panel on Access to Medicines: Advancing Health-Related SDGs through Policy Coherence, http://www.unsgaccessmeds.org/inbox/2016/2/28/yvtkspjtra6s965vwerl8mq67xfq4a

67 Reddy, K. I. (2009). Biotech regulations in India: Problems and promises. *Biotechnology Journal*, *4*(3), 306–309.

68 Government of India, Ministry of Health and Family Welfare. Central Drugs Standards Control Organization. Available from: http://www.cdsco.nic.in/,accessed on 06/12/2017.

69 Rule 122-E, Part X-A,Drugs and Cosmetics Rules,1945.

> and its manipulation, it has also led to a great deal of concern about scientists' ability to handle such information. There is also a very narrow gap between routine genetic testing and research [,] raising several ethical, legal and social issues, which warrant continuous and prompt monitoring and judicious response to the emerging ethical issues.[70]

The National Guidelines for Stem Cell Research, 2017 are looking at suspending the commercial banking of stem cells derived from biological materials such as cord tissue, placenta, tooth extract, and menstrual blood. The guidelines apply to various stakeholders, including individual researchers, sponsors, and oversight and regulatory committees associated with both basic and clinical research involving human stem cells. The guidelines emphasize the necessity of obtaining informed consent from the voluntary donor prior to the procurement of biological material for the isolation of stem cells. The guidelines also state that every other therapeutic use of stem cells shall be treated as investigational and shall be conducted only in the form of a clinical trial after obtaining the necessary regulatory approvals. The guidelines recognize that the IPR associated with the outcome of stem cell research may have commercial value. The option of sharing the IPR with the donor must be provided in the consent form which must be procured before initiating the research. Further, the guidelines expect that the benefits accruing from the commercializing of the research will be returned to the donor and to the public at large.[71]

The National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) currently monitors and oversees research activities at the national level. The Institutional Committee for Stem Cell Research (IC-SCR) approves and monitors stem cell research (both basic and clinical research) at the institutional level. These committees will ensure that the review, approval, and monitoring processes of all research projects related to stem cells are carried out in compliance with the national guidelines. In 2014, in addition to the publication of the revised guidelines mentioned above issued by the ICMR–DBT, the DCGI announced that it would modify the Drugs and Cosmetics Act, 1940 to treat "stem cells and cell-based products" as new drugs (CDSCO, 2014)[72].

With this announcement, it appears that the regulatory vacuum in the Indian stem cell sector is finally being addressed by statutory law. Jurisdictional ambiguities in the governance of stem cell therapy seem to have finally been resolved with the ICMR–DBT revising their guidelines and the DCGI extending

70 (2017). National Ethical Guidelines for Biomedical Research Involving Human Participants. Retrieved from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf. accessed on 01/12/2017.

71 Some major amendments include: mandatory registration of the Institutional Committee for Stem Cell Research (ICSCR) and the Institutional Ethics Committee (IEC), with the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) and CDSCO respectively; undertaking clinical trials only at institutes with registered IC-SCR, IEC, and only at Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) certified facilities; research undertaken by medical professionals registered with the Medical Council of India (MCI) and with an MCI-approved postgraduate qualification in the domain area of the specific trial.

72 CDSCO. (2014). "F.No.X-11026/65/13-BD: Directorate General of Health Services Central Drugs Standard Control Organization Biological Division." February 18.http://www.cdsco.nic.in/writereaddata/Guidance%20Document%20For%20Regulatory%20Approvals%20of%20Stem%20Cells%20and%20Cell%20Based%20Products.pdf. Accessed on 01/12/2017.

their statutory remit to stem cells in 2013–2014. Yet the question about instituting effective mechanisms for enforcement still remains to be addressed.

1.6. Conclusion

The notion that science and technology alone can bring about growth and development and reduce economic inequality is a widely held view among the scientific elite as well as the lay public alike. However, the positions on biotechnology in India, according to Visvanathan and Parmar (2002)[73] range from being uncritically optimistic to viewing it as anti-life. Further, they point out that:

> Biotechnology as a scientific venture in the populist and technocratic imagination is alive and well [,] but biotechnology as a part of the new democratic imagination committed to the rule of law and regulation, and governance sensitive to the ideas of risk is fragile (p. 2724).

As regards the regulation of biotechnologies, there is an industry-based argument that too many guidelines or laws would stifle technological growth. Thus, the regulatory guidelines prima facie accord significance to technological growth in building broader ecosystems for innovations, and stress the need for regulations to set standards for managing uncertainty.[74] All guidelines on biomedical innovation have formally acknowledged that research involving human beings as participants in drug research or regenerative medicines involving stem cells, gene therapy, and nanomaterials ought to follow the due process set out for informed consent and should also follow all the ethical standards. The regulatory guidelines have often been criticized for lacking any statutory power.[75] However, it remains to be seen whether statute scan regulate biotechnologies and simultaneously uphold a governance system premised on the feminist values of justice, dignity, equity, autonomy, and transparency.

73 Visvanathan, S., & Parmar, C. (2002). A biotechnology story: Notes from India. *Economic and Political Weekly, 37*(27), 2714–2724.

74 Borr´as, S., &Edquist, C. (2014). Institutions and regulations in innovation systems: Effects, problems and innovation policy design. https://charlesedquist.files.wordpress.com/2015/05/201412-cwp-institutions-and-regulations.pdf, accessed on 02/12/2017.

75 Tiwari, S. S., & Raman, S. (2014). Governing stem cell therapy in India: Regulatory vacuum or jurisdictional ambiguity? *New Genetics and Society*, *33*(4), 413–433. http://doi.org/10.1080/

Chapter 2

Gender and biotechnology: A conceptual framework

In the 1980s, in the climate of state restructuring and privatization then prevailing in India, priorities relating to health and healthcare shifted from protecting the public good to promoting the interests of industry, and creating the conditions for healthcare to be a site of corporate profit making (Mykitiuk, 2001).[76]According to Melinda Cooper (2011)[77], during this time, the countries of the global north also faced the neoliberal onslaught and simultaneously witnessed immense technological, epistemological and institutional creativity in the life sciences. As a result, the lines separating public-funded research in the life sciences, the market in new technologies, and financial capital began to blur, and the life sciences were perceived as being vital for economic reinvention and growth. Referring to the realms of biological reproduction and political economy, and the manner in which they have moved closer together over the last few decades, it is impossible to think of the life sciences today without employing concepts of political economy: the new biotechnologies are predicated on "the political economy of hope" (Novas, 2006).[78] They exploit the notion of a promissory future, of a life without illness and disease, and proclaim a new molecular knowledge that is invaluable. According to Sexton, "The larger market for genetic technologies—is not sick people, but healthy ones. [79]

Thus, the new biotechnologies have thrived and proliferated in the political economy of hope, promising future cures and capitalizing on the fears of the potentially ill. We place our analysis of the relationship between gender and biotechnologies in this context.

2.1. Gender and biotechnology: Feminist debates

Subramaniam (2015) writes, "Biotechnology [. . .] has often served the interests of the powerful" and that "the interests of women, feminist and democratic ideals have often been marginalized in the founding and governing visions of the field" (p. 22).[80]She illustrates this position by examining two cases: transnational surrogacy and the Indian Genome Variation (IGV) initiative.

76 Mykitiuk, R. (2001). Beyond conception: Legal determinations of filiation in the context of assisted reproductive technologies. *Osgoode Hall LJ*, *39*, 771, Retrieved from: http://works.bepress.com/roxanne_mykitiuk/13/, accessed on 06/12/2017

77 Cooper, M. E.(2011. *Life as surplus: Biotechnology and capitalism in the neoliberal era*. Seattle, WA: University of Washington Press.

78 Novas, C. (2006). The political economy of hope: Patients' organizations, science and biovalue. *BioSocieties*, *1*(3), 289–305.

80 Subramaniam, B. (2015). Colonial legacies, postcolonial biologies: Gender and the promises of biotechnology. *Asian Biotechnology and Development Review, 17*(1), 15–36.

Examining the case of commercial surrogacy, she argues that the womb is medicalized and commodified, and in the process, the language of mothering is replaced by a new language of clinical labour and commodification. Discussing the case of the IGV initiative, Subramaniam (2015) argues that examining biotechnology through a feminist lens requires placing and evaluating it within the larger sociopolitical context.[81]

In this analysis of gender and the new biotechnologies, we draw on the feminist theorizations that remain marginalized in mainstream technology studies. It is necessary to evaluate the new biotechnologies through a feminist lens recognizing that gender is a complex category intersected by other identity dimensions such as class, race, sexuality, geographical location, however, we believe that by virtue of their social and biological reproductive roles, the impact on women must be critically analysed further. Further, we also duly acknowledge that feminist positions overlap with other positions on biotechnologies and the life sciences.[82] Rather than adopt a polemical pro or anti technology position, we seek to examine biotechnologies particularly in healthcare and their relationship with gender in the context of the broader ethical, legal and social contexts.

In the debates on gender and technology, the rejection of technology as inherently patriarchal continues to be pitted against the strategy of enhancing women's access to and control over technology. For example, the proponents of the former line of thought may take the view that reproduction is a 'natural' process over which men (seek to) exert control through technological intervention (Corea, 1985),[83] while the proponents of the latter position may view reproductive technology as bearing the potential to liberate women by vesting in them the power to conquer their reproductive capacities, the lack of which has been the fundamental reason for women's relegation to the private, domestic sphere of the family (Firestone, 1971).[84]

One possible way of construing the relationship between gender and biotechnology would be place it within the feminist debates on gender and technology. Women are often invisible in the discourses on biotechnology and socio-economic development. At times, they are partly visible in some contexts, for instance, in studies that address the gender dimension of issues such as employment education and public perception of biotechnologies. This kind of a superficial treatment of gender when analyzing biotechnology is not unusual because often the value neutrality and gender neutrality of science and technology is taken as an axiom.

81 Subramaniam, B. (2015). Colonial legacies, postcolonial biologies: Gender and the promises of biotechnology. *Asian Biotechnology and Development Review, 17*(1), 15–36.

82 Rabinow, P., & Rose, N. (2006). Biopower today. *BioSocieties*, *1*(2), 195–218.

83 Corea, G. (1985), The Mother Machine: ReproductiveTechnologies from Artificial Insemination to ArtificialWombs.New York: Harper and Row.

84 Firestone, S. (1971) *The Dialectic of Sex: The Case for Feminist Revolution*.New York: Bantam Books.

Scholarship in the area of Technology studies broadly seeks to theorize the relationship between technology and society. Two major theoretical positions are the social construction of technology (SCOT), put forth by Trevor J. Pinch and Wiebe E. Bijker, and the actor–network theory (ANT), proposed by Bruno Latour, Michel Callon, John Law, and others (Wajcman, 2000).[85]SCOT emphasizes 'interpretative flexibility' in technological design, wherein, it is argued, a technology does not work merely because of its design, but also because social groups play a central role in making it function by participating in debates and negotiations pertaining to the technology. However, Wajcman (2000) argues that SCOT leaves women out of the scope of its analysis of relevant social groups.[86] ANT exposes the inadequacy of conceptualizing technology and society as distinct spheres. It advances the radical idea that neither technology nor society can be analysed in isolation and that both humans and non-humans are linked in a complex web of interactions. However, according to Wajcman, ANT also perceives the function of technology as being scripted in it by the inventor, foreclosing any possibilities of alternative interpretations of its function. This stance is rejected by feminist technology theorists who argue that those who are receivers or consumers are very much a part of interpreting and adapting a technology. They also critique ANT's focus on male scientist heroes and big science and technology networks, as opposed to areas where women are engaged, which involve manufacturing, sale, and end-use. Further, feminists also critique both ANT and SCOT for precluding from their analyses of technological design, development, and dissemination, the role of socially marginalized groups that are systematically excluded from participating in these processes.

It is feminist scholarship that has attempted to unravel the relationship between gender and technologies more specifically, pointing to masculinist biases within dominant theoretical positions wherein the relationship between technology and gender has not been explored. In the past few decades of feminist theorization, the understanding of what constitutes gender has undergone a radical transformation. The first change is a shift away from categorizing women as a homogeneous community and towards pointing to the differences that exist among women depending on their social positions based on race, religion, caste, class, and sexuality (Beoku-Betts, 2004; Sur, 2011)[87] and the recognition of the existence of multiple patriarchies. The second change is a shift in theorizing gender, arguing for the need to move beyond binary male–female categories (Fausto-Sterling, 2000).[88] Further, Wajcman (2000) points out that in contrast to earlier feminist theorizations on gender and technology, the newer feminist

85 Wajcman, J. (2000). Reflections on gender and technology studies: In what state is the art? *Social Studies of Science*, *30*(3), 447–464.

86 Wajcman, J. (2000). Reflections on gender and technology studies: In what state is the art? *Social Studies of Science*, *30*(3), 447–464.

87 Beoku-Betts, H. (2004). African women pursuing graduate studies in the sciences: Racism, gender bias, and Third World Marginality. *National Women's Studies Association Journal, 16*, 116–135: Sur, A. (2011). *Dispersed radiance: Caste, gender, and modern science in India*. Navayana.

88 Fausto-Sterling, A. (2000). *Sexing the body: Gender politics and the construction of sexuality*. New York: Basic Books.

technology studies do not treat gender and technology as unitary, *a priori* categories, but rather posit that the two mutually co-constitute each other. These approaches draw on the theoretical contributions of feminist scholars such as Judith Butler who argue for understanding gender as performance, where gender is viewed as being constructed and reconstituted in and through social interactions. Feminist technology studies scholars like Donna Haraway also argue for the continuity between the material and the cultural, which, in turn, is premised on postmodern views of technology where it is seen "as an object of consumption, as a text and as a communication medium" (Wajcman, 2000).[89] These newer approaches posit the necessity of viewing technology as enabling its users (women, in particular), whereby it becomes an aid to tinkering with representations of one's gender and of one's self. They eschew the technophobia inherent in traditional approaches that assume women to be receivers of technology, and reject the dichotomy assigned by these positions to the design and use aspects of technology. In other words, feminist scholarship examining gender and technology occupies the terrain between positions that try to understand technologies and their relationships with 'women' and those that try to conceptualize feminist technologies where technology and gender are not regarded as two distinct entities that are in a hierarchical relationship, but rather seen to be complexly intertwined with one another.

Feminists have also theorized, more specifically, the relationship between gender and biotechnologies. Banu Subramaniam (2015) describes two different ways of understanding the relationship between gender and biotechnology.[90] The first way, following the traditional approaches mentioned above, would be to cast the relationship as a question of the participation of women in biotechnology, asking whether they are fairly represented at different levels—in school and in higher education, as well as professionally in biotechnology-related areas. This may also involve understanding whether the presence of women impacts the nature of research undertaken in these areas. In this approach, both gender and biotechnology are treated as uncomplicated, pre-given, and mutually exclusive categories. The second way of conceptualizing the relationship between gender and biotechnology would be to explore the 'gendered dimensions of biotechnology', unravelling the gendered ideologies and assumptions that undergird these innovations, examining the constituencies they serve, analysing the social relations they nurture, and so on. Subramaniam (2015) argues that her position is not a pro- or anti-(bio)technology stance, but rather one that views technology as being "a site of knowledge and social action and (that attempts to understand) how it is connected to other forces and structures in society" (p. 19).

Agreeing with Subramaniam, at the outset we would stay away from moralistic reflections on whether these technologies are good or bad, or whether they are

89 Wajcman, J. (2000). Reflections on gender and technology studies: In what state is the art? *Social Studies of Science*, *30*(3), 447–464, at p. 457.

90 Subramaniam, B. (2015). Colonial legacies, postcolonial biologies: Gender and the promises of biotechnology. *Asian Biotechnology and Development Review*, *17*(1),15–36.

used for good and bad purposes, and thereby fall into the trap of rigid binary opposition of cof technophilia versus technophobia (Franklin, 2001).[91] It is, however, important to highlight that there are several factors that shape the development of biotechnology in ways that are not in women's interests. The first is the continuing, and indeed worsening, effects of global inequalities that are borne heavily by women. It remains a fact that access to adequate basic healthcare, remains limited and out of reach of the majority of women globally. This leads to high maternal and infant mortality due to preventable causes such as malnutrition and lack of potable water supply. Poor reproductive health also can be addressed by taking care of overall health, but instead technological solutions that are resource-intensive and privatized fertility care is promoted by the state and remain accessible ony to the affluent elite (not just in the global north but world-wide). The very epistemological premise on which these technologies work are predicated on is that of genetic determinism and essentialism wherein the causes of complex diseases are fallciously pinned down to faulty genes. . Inherently linked to the project of mapping the human genome is the urge to eliminate genetic pathology and to re-engineer it which in turn reflect eugenic agendas that the contemporary reproductive technologies have also been critiqued for furthering. Thus the feminist criticisms of reproductive technologies i have significant overlaps with the criticisms of biotechnology and genetic engineering (Franklin and Davis-Floyd, 2001).[92]

The concepts of identity, choice, agency, consent, labour, autonomy, and the body have been at the core of feminist theorization for about a century. These concepts have undergone profound transformations in meaning, both with evolving feminism(s) and with the advent of new reproductive technologies and biotechnologies. The latter have transformed the gendered body and the social relations within which it is embedded, further throwing up new challenges to feminist theorization. As Ettore, Rothman and Steinberg (2006) point out, some concepts that have been problematized by feminist theorization on biotechnologies are the "notions of risk, choice, the obligations and ownership of gendered bodies, discourses of reproductive 'fitness' balanced against the institutional powers of science and medicine" (p. 134).[93] For instance, with regard to the concept of 'choice' when discussing the surrogate mother's decision to participate in IVF arrangements, Christa Wichterich (2012) asks, "Is free choice not just an illusion and self-determination a fetish of modern capitalist societies?" (p.23).[94] She points out that labour as an analytical concept has been employed by feminists to describe women's agency in reproductive industries, referring to the concepts of emotional labour and regenerative labour

91 Franklin, S. (2001). Biologization Revisited: Kinship Theory in the Context of the New Biologies. In Franklin, S., McKinnon, S. (Eds.), Relative values: Reconfiguring kinship studies (pp. 302-325). Durham, NC: Duke University Press.

92 Franklin, S. and Davis-Floyd, R. (2001). Reproductive Technology. The Routledge International Encyclopedia of Women's Studies. Tara Montgomery, Editor. New York: Routledge.

93 Ettore, E., Rothman, D.,& Steinberg, D. L. (2006). Feminism confrontsthe genome: Introduction. *New Genetics and Society*,*25*(2), 133–142.

94 Wichterich, C.(2015).*Sexual and Reproductive Rights*. Heinrich Böll Foundation, p.23, https://www.boell.de/sites/default/files/sexual_and_reproductive_rights.pdf, accessed on 01/12/2017.

put forward by Hochschild (1983)[95] and by Waldby and Cooper (2010)[96] respectively.

In our review of the scholarship on gender and the biotechnologies, we discern positions that fall within two broad categories: One set of positions interrogate and analyze these technologies for their impact on the gendered body, which include issues related to commodification as well as the dilemmas that confront women as users of these technologies. The other set of positions attempt to analyze biotechnology from a feminist lens, situating it within the broader sociopolitical context. In the sections that follow, we detail these positions.

2.2. Biotechnology and the body: issues pertaining to commodification and choice

The last few decades have witnessed a trend of the commodification of the body and its parts in an unprecedented manner aided by innovations in the life sciences, which include biotechnologies and medicine. In other words, one outcome of the nexus between neoliberalism and the life sciences is the proliferation of biocommodities. These advancements in the life sciences are turning the vitality and regenerative capacity of our bodies, tissues, and cells into saleable commodities wherein developing countries like India have become inexpensive sources of biological material derived from human bodies. Although the commodification of the body is definitely not a new phenomenon (Sharp, 2000),[97] there has been, in recent times, an unprecedented burgeoning in the markets for human organs, tissues, and reproductive body parts. In contemporary society, the boundary between what can or cannot be bought and sold has been blurred. Even a cursory glance at the current markets for human organs, tissues, and reproductive body parts makes this clear. While the sale of organs is illegal in most countries, semen, ova, blood, and other body fluids and tissues fall outside the purview of legislation because of their regenerative quality (Gupta and Richters, 2008).[98]

Markets, being "indiscriminate [and] promiscuous . . . reduce everything, including human beings and their sexual and reproductive capacities [,] to the status of commodities, things [that] can be bought, sold, traded and stolen" (Soros, 1998, quoted in Scheper-Hughes, 2001, p. 43).[99] The fragmentation of the human body also extends the experience of vulnerability previously known only to women to other groups. As Donna Dickenson argues, "Women were much

95 Hochschild, A. R. (1983).*The Managed Heart: Commercialization of Human Feeling*. Berkeley: University of California Press.

96 Sexton Sarah (2010), Emerging Genetic Technologies and Research, pg 65, Making Babies, Birth Markets and Assisted Reproductive Technologies in India; Zubaan

97 Sharp, L. A. (2000). The commodification of the body and its parts. *Annual Review of Anthropology*, *29 (1)*, 287–328

98 Gupta, J. A., & Richters, A. (2008). Embodied subjects and fragmented objects: Women's bodies, assisted reproduction technologies and the right to self-determination. *Journal of Bioethical Inquiry*, *5*(4), 239–249.

99 Scheper-Hughes, N., & Wacquant, L. (Eds.). (2002). *Commodifying bodies*,Vol. 7, Nos. 2–3. Sage.

more likely than men to be treated as commodities in non-slave-owning systems" (p. 162). In marriage contracts, unlike other types of contracts, "the enforcement mechanism worked almost entirely in one party's favor: the husband's" (Dickenson, 2008, p. 164).[100]Dickenson sees an analogy between these traditional marriage arrangements and contemporary agreements on using biological tissues and cells for research: only one party benefits, and it is not the one who is in the more vulnerable situation. The patient waives any financial benefits that may arise after the use of his or her tissues in research. Extending this analogy, Dickenson argues that current biotechnological practices, especially the collection of human cells and tissues on a mass scale, have resulted in the feminization of the human body. Taken together, all these practices have resulted in the "fear of feminization of property in the body" (Dickenson, 2009, p. 165).

Historically, a woman was reduced to her body and lacked ownership over it and its reproductive capacities. This delicate relationship between body and identity, between body and control, has been a defining experience for women, and hence has been examined and challenged by feminist theory. In addition, feminists also emphasize that 'subjects' of scientific research should not be treated as 'objects' of research, but rather as collaborators in research endeavours (Etaugh and Worell, 2012).[101]

However, women are, in practice, treated as objects, where their bodies are seen as sources of biocommodities, and where their labour when participating in the process of donating their organs and tissues is not perceived as economically valuable. It is also women from less developed countries who are drawn into signing contacts under which they have to donate organs and tissues to earn a livelihood.

Besides the aforementioned commodification of the body, another issue that confronts women when they engage with the new biotechnologies is the fact that they have to shoulder the primary responsibility of making decisions or choices regarding these technologies. This is elaborated by Dickenson (2009) in an article where she categorizes feminist ethical perspectives that have been employed to understand the new reproductive technologies and human genetics.[102]Apart from the fact that it is women who have to undergo invasive procedures such as egg extraction or alpha protein testing for detecting conditions such as Down's syndrome, she argues that it is women who are made to bear the primary responsibility for the health of their foetuses, which is evident in cases where drug-addicted women have been imprisoned for causing harm to their foetuses. She further points out that the feminist ethical positions have also been

100 Dickenson, D. (2008).*Body Shopping: The Economy Fuelled by Flesh and Blood.* Oxford: Oneworld,p.162.

101 Etaugh, C., & Worell, J. (2012). Contemporary feminism for gender researchers: Not just "our bodies, our cells". *Psychology of Women Quarterly*, *36*(4), 419–422.

102 Dickenson, D. L. (2009). Feminist perspectives on human genetics and reproductive technologies. *Encyclopedia of Life Sciences (ELS*). Chichester: John Wiley and Sons Ltd, https://www.academia.edu/17948470/Feminist_Perspectives_on_Human_Genetics_and_Reproductive_Technologies, accessed on 01/12/2017.

concerned with the role of the family and of other institutions in the decision making of individuals involved in genetic testing. Proponents of feminist approaches contend that very often it is women who have to negotiate moral dilemmas and bear the brunt of decision making in the context of undergoing procedures such as pre-implantation genetic diagnosis (PGD), even when genetic material is shared with members of the extended family. Feminist approaches, according to Dickensen, also raise questions about the conventional view that 'genetic information is private', and argue instead that it is 'not owned but is, in a sense, only lent'. They also contend that abstract principles such as the 'duty to disclose genetic information' should be considered in the larger social context wherein the individual is being tested. Finally, Dickenson also discusses feminist positions that deal with questions around commodification and patenting. Pointing to the number of genes that have been patented to date, she argues, citing Waldby and Cooper (2008),[103] that biotechnology firms design their research studies around the issue of "which genes would be most profitable to patent and not necessarily which diseases most need treatment"(p.3).[104]Dickenson argues that monopoly patents have driven up the prices of drugs, particularly those that involve a patented gene, and very often it is women who have to bear the brunt of these policies and decisions.

2.3. Placing Biotechnology within the Sociopolitical Context

An integral aim of feminist technology studies is also to "trace the embeddedness of science in markets, capital and the economy" (Subramaniam, 2009, p.959).[105] Particularly with regard to the new biotechnologies, specific attention needs to be paid by feminist analysts to the marketing of drugs, the funding of science and technology, the adoption of regulatory and patenting policies, the role of international regulatory bodies like the World Trade Organization (WTO), and the role of social movements that resist these technologies. On the basis of her analysis of the Indian genome initiative, Subramaniam (2009) poses a pertinent question when she asks why a country like India—burdened by structural inequalities and poverty, where a large majority suffers from preventable, infectious diseases, and where most people lack access to basic health care—needs to invest in the new biotechnologies. She argues that biotechnology "gets heralded as the economic engine of the nation, even while its imagination continues to marginalize a large proportion of the population" (p. 30). She further notes, "What is often missing is a contextual understanding of biotechnology, locating it within its economic, political, cultural and national contexts."

103 Waldby, C.,& Cooper, M. (2008) The biopolitics of reproduction: post-Fordist biotechnology and women's reproductive labour. *Australian Feminist Studies* 23: 57–73.

104 Dickenson, D. L. (2009). Feminist perspectives on human genetics and reproductive technologies. *Encyclopedia of Life Sciences (ELS*). Chichester: John Wiley and Sons Ltd, https://www.academia.edu/17948470/Feminist_Perspectives_on_Human_Genetics_and_Reproductive_Technologies, accessed on 01/12/2017.

105 Subramaniam, B. (2009). Moored metamorphoses: A retrospective essay on feminist science studies. *Signs: Journal of Women in Culture and Society*, *34*(4), 951–980.

Etaugh and Worell (2012) argue that a feminist perspective on human genetics would challenge and visibilize the tension between individual and society, and between the personal and the political.[106] They lay down several feminist principles that could guide feminist scholars of biotechnology in their studies. One, of course, is the conflict between the biological and the social. Genetics research fails to problematize the social construction of concepts such as 'disability', 'disease', and 'normalcy'. Additionally, it tends to marginalize and downplay the economic, political, and social forces that impact the biological. As a result, resources that could be employed to remedy a disease condition through interventions at the social and political levels are diverted to research aimed at identifying the genes for that condition. Second, Etaugh and Worell (2012) draw attention to the diversity that characterizes the category of women and emphasize how blind human genetics research is to this diversity. They argue that mainstream genetics research tends to construe women as white, upper-middle-class, able-bodied, and heterosexual. They write that genetics research "appear(s) more interested in the diversity of genetic make-ups than in the diversity of whole individuals—acknowledging the importance of [the] genetic context on how genes are expressed, but not considering the context of women's lives"(p. 420).[107] and argue that feminists are critical of such ''context stripping'' (p. 420). They are also critical of what they refer to as the two-factor model of gender, pointing out that women of varying backgrounds and social locations—influenced by factors like race, class, ability, sexual orientation, ethnicity, and so forth—may differ from one another as much as a 'man' and a 'woman' may differ from one another.

In addition, Etaugh and Worell (2012) also draw attention to the fact that information on genetics and genetic testing services are both inaccessible to a large number of women from marginalized backgrounds, and that even if these testing services were accessible, the remedies would continue to remain expensive and hence out of reach. This situation leads to the increased prevalence of genetic diseases among groups who cannot afford testing services and treatments, furthering a certain form of eugenics. Citing an article by Meg Stacey(1996),[108] Etaugh and Worell (2012) suggest that genetic-screening programmes promote eugenics in another way, because "geneticists' promotion of screening programs for inherited disorders sends a clear message about the worth of those individuals who carry these disorders, as well as a strong societal mandate to abort impaired foetuses" (p. 420).[109]Feminist values that emphasize

106 Etaugh, C., & Worell, J. (2012). Contemporary feminism for gender researchers: Not just "our bodies, our cells". *Psychology of Women Quarterly*, *36*(4), 419–422.

107 Etaugh, C., & Worell, J. (2012). Contemporary feminism for gender researchers: Not just "our bodies, our cells". *Psychology of Women Quarterly*, *36*(4), 419–422.

108 Stacey, M. (1996). The new genetics: a feminist view. The troubled helix: Social and psychological implications of the new human genetics, 331–349.

109 Etaugh, C., & Worell, J. (2012). Contemporary feminism for gender researchers: Not just "our bodies, our cells". Psychology of Women Quarterly, 36(4), 419–422.

equity and diversity militate against the use of genetics to select individuals with socially valued traits.[110]

2.4. Conclusion

This review is not exhaustive, yet it is indicative of the multiple interpretations and analysis put forward by different scholars on the relationship between gender and biotechnologies. As we discussed, Wajcman (2000), proposes two broad ways of construing the relationship between gender and technology. One way is to view both technology and gender as *a priori* categories and to look at how technologies impact women. The other way is to look at both gender and technology as mutually constituting each other. This view offers a more nuanced understanding of the relationship between gender and technoscience, viewing the latter as a tool to tinker with one's self and one's gender. Besides these two ways, another position that is discernible in our review of the positions on biotechnology is one that attempts to look at biotechnology as an enterprise through a feminist lens (Subramanian, 2009).[111]It attempts to historicize and locate biotechnology in its sociopolitical context. It is interesting that most of the positions reviewed above (Subramanian, 2009; Dickenson, 2009; Etaugh and Worell, 2012) treat women and biotechnology as *a priori* categories, and attempt to discuss the relationship between them—whether they refer to the commoditization of body parts, the enrolment of marginalized women in the bioeconomy, the ethical dilemmas that confront women of the global north when they negotiate the biotechnologies, or the issues surrounding the accessibility and affordability of these technologies for women.

All these issues suggest that the relationship between biotechnologies and gender is asymmetrical and hierarchical. This is perhaps not surprising, given the tight embrace between neoliberalism and the life sciences, and the inequities that exist between the north and the south, that make it difficult for women to engage with the new biotechnologies in empowering ways.

If women's long-term interests are to be represented effectively in efforts aimed at determining the future direction of reproductive technology and biotechnology, women will need to participate collectively in shaping public policy. This principle should apply not just to women, but to all potential users of any technology. Unfortunately, there has been far too little involvement of users' opinions regarding the fundamental values at stake or the social goals that would best promote their well-being when developing any of these biotechnologies. In the midst of this, both private research efforts and the commercial marketing of biotechniques, including reproductive biotechnologies, continue to go forward with virtually no ethical constraints other than those that the researchers themselves choose to impose on themselves.

111 Subramaniam, B. (2009). Moored metamorphoses: A retrospective essay on feminist science studies. Signs: Journal of Women in Culture and Society, 34(4), 951–980.

Chapter 3
Human Genomics and Stem Cells

In this chapter, through a closer examination of two areas within biotechnology--genomics and stem cells, we explore how gender shapes and is shaped by biotechnology, and look at the larger ethical, social, and legal implications raised by new developments within the field of genomics and stem cell industry in India.

3.1. Genomics, personalized medicine, and gender

With the advent of the Human Genome Project (HGP), and with the proliferation of associated technologies that have enabled genome sequencing, it has now become possible to screen populations for disease-causing genes and to develop targeted therapies. According to Kaushik Sunder Rajan (2005), "Genomics is an articulation of experimental and informational science that has, to a significant extent, been technologically driven" (p. 19).[112] Technically, it involves the creation of genomic maps in which the positions of different fragments of DNA are determined with regard to each other. Once genome maps are created, the entire genome can be sequenced. This is then followed by the determination of gene function, which is referred to as functional genomics. The HGP was kick-started as a publicly funded initiative, but later Celera Genomics, a private corporation, entered the race and took over, marking, in Rajan's words, "the upstaging of state science by entrepreneurial corporate science" (p. 20).

One outcome of genome sequencing has been the emergence of personalized medicine, which involves treatment directed at, and based on, individual genetic profiles. This involves first establishing a genetic component of any disease, locating the gene(s) to the chromosome, and then, more specifically, identifying the gene. Once this is achieved, diagnostics can be developed to estimate the individual's predisposition to the disease. Diagnostic tests can be used to prescribe lifestyle changes for patients or to develop therapeutics on the basis of a more thorough understanding of the biological mechanism underlying the onset of the disease. Developing drugs that can be tailored to specific genetic profiles is also possible, an area known as pharmacogenomics. However, Rajan also notes that it is much easier to develop diagnostic tests than to develop therapeutics, as the nature of any disease is complex and multifactorial.[113]

Personalized medicine, of course, has significantly transformed the nature and meaning of what it means to be ill, as those who do not have any symptoms of an illness become marked at a molecular level for being 'at risk' for developing a

112 Rajan, K. S. (2005). Subjects of speculation: Emergent life sciences and market logics in the United States and India. *American Anthropologist*, *107*(1), 19–30.

113 Rajan, K. S. (2005). Subjects of speculation: Emergent life sciences and market logics in the United States and India. *American Anthropologist*, *107*(1), 19–30.

disease (Bell, 2013).[114]It is precisely this 'being at risk', or what Bell refers to as the "diseasification of risk", that the market exploits, promising to insure the individual against future illness (Rajan, 2005).[115]In this context, the erstwhile patient becomes a medical consumer who bares open her body for surveillance and engages in risk-minimizing behavior (Bell, 2013).[116]

3.1.1. Genomics in India

Although personalized medicine has gained popularity in the global north, it remains largely inaccessible to the developing world. India has its fair burden of genetic diseases, yet there are significant gaps in the data available on the rates of incidence of genetic diseases. Conservative estimates, however, indicate that haemoglobin disorders (including thalassaemia and sickle cell disease), chromosomal disorders like Down's syndrome, and metabolic disorders are rampant in the subcontinent (Kumar, 2012;[117]also see Verma, 2000).[118]Non-communicable diseases that have a genetic basis such as diabetes, cancer, and cardiovascular disorders, considered to be diseases of lifestyle, are also on the rise. The high rate of prevalence of genetic diseases has also to do with the practice of consanguinity within various communities (Kumar, 2012).

Genomics is an area of research that the Indian state has always wanted to promote, although India did not participate in the Human Genome Project (HGP), an international scientific research project. According to Rajan (2005),[119]genomics in India was seeded with the reinvention of the Center for Biochemical Technology (CBT) as the country's premier public sector genome laboratory, which then became the Institute of Genomics and Integrative Biology (IGIB) in 2002. However, soon afterwards, it sought a partnership with the private sector and since then the involvement of the private sector in genomics has grown.

In the recent past, the market for genetic testing technologies in India has expanded due to the increasing wealth of the urban middle classes, as well as the rising awareness of these technologies. As Vora (2017) notes, "Consumer direct testing companies [now] mushrooming in India offer several predictive genetic tests that clients, not patients, can buy online."[120]Vora (2017) and also

114 Bell, K. (2013). Biomarkers, the molecular gaze and the transformation of cancer survivorship. *BioSocieties*, *8*(2), 124–143.

115 Rajan, K. S. (2005). Subjects of speculation: Emergent life sciences and market logics in the United States and India. *American Anthropologist*, *107*(1), 19–30.

116 Bell, K. (2013). Biomarkers, the molecular gaze and the transformation of cancer survivorship. *BioSocieties*, *8*(2), 124–143.

117 Kumar, D. (Ed.). (2012). *Genetic disorders of the Indian subcontinent*. Springer Science & Business Media.

118 Verma, I. C. (2000). Burden of genetic disorders in India. *Indian Journal of Pediatrics*, *67*(12), 893–898.

119 Rajan, K. S. (2005). Subjects of speculation: Emergent life sciences and market logics in the United States and India. *American Anthropologist*, *107*(1), 19–30.

120 Vora,P. (2017,January,23). More Indians are taking home DNA tests but do they understand what their genes are telling them? Scroll [Online,at 2.30p.m.]. Retrieved fromhttps://scroll.in/pulse/827169/more-indians-are-taking-home-dna-tests-but-do-they-understand-what-their-genes-are-telling-them, accessed on 05/12/2017.

Thiagarajan (2017) note that there is a lack of data that profile the genetic information of various Indian population groups and that for this reason, such tests, fashioned on the basis of the genetic data of Caucasian populations, will not yield accurate predictions or results.[121]Furthermore, Vora notes that the tests cost between $60 and $2,000 in India, which is expensive for Indian clients. It is also disconcerting that for most of the diseases that are predicted through the tests, no cures are available, leading to the question of whether these tests would then be of any use in the first place. There are also ethical questions pertaining to what happens to the genetic information that is collected and whether it could be misused by insurance companies.

Where and how does gender figure in this analysis? Following the conceptual framework described at the outset of the concept note, one way of understanding gender in the context of genomics would be to look at how women are affected by this science, what moral quandaries are thrown up when they engage in genetic testing, and how we understand the role of the larger sociopolitical context in their decision making. Another way of conceptualizing the relationship between gender and biotechnologies would be to undertake a feminist analysis of genomics, which would not only look at women, but would also seek to understand how genomics as a field impacts and is impacted upon by the broader social and political environment. Employing these perspectives, we discuss the specific case of breast cancer.

3.1.2. Breast cancer genomics, genetic testing, and BRCA genes

Breast cancer is an interesting case to explore from the point of view of genomics and gender. In the following section, we discuss genetic screening involving BRCA genes as well as Herceptin, the breast cancer drug. Breast cancer is the most common cancer among women across the world, accounting for nearly a quarter (25 per cent) of all cancers, with an estimated 1.67 million new cases of cancer diagnosed in 2012. Breast cancer is ranked as the number one cancer among Indian women, with the age-adjusted rate being as high as 25.8 per 100,000 women and the mortality rate being 12.7 per 100,000 women. Younger women are showing an increased incidence of HER2+, a particularly aggressive form of breast cancer.[122] The ICMR has predicted that by 2020, there will be 17.3 lakh new cases of cancer and over 8.8 lakh deaths due to the disease.[123]According to a study (Viviana Rivera-Varas),[124] in 5 per cent of breast cancer cases, there is a

121 Thiagarajan,K.(2017,February 28).Taking the gene test. LiveMint[online at 11.20 a.m.]. Retrieved from http://www.livemint.com/Leisure/ksZOzf3gCOBo5Vz1a6xDfM/Taking-the-gene-test.html, accessed on 05/12/2017; http://www.livemint.com/Leisure/ksZOzf3gCOBo5Vz1a6xDfM/Taking-the-gene-test.html, accessed on 05/12/2017.

123 Narod, S. A., & Foulkes, W. D. (2004). BRCA1 and BRCA2: 1994 and beyond. *Nature Reviews Cancer*, *4*(9), 665–676.

[124] https://www.ndsu.edu/pubweb/~mcclean/plsc431/students98/rivera.htm accessed on 12 October 2017

strong inherited familial risk and genetic factors have been implicated in breast cancer. For example, mutations in the BRCA1 and BRCA2 genes. In India, the frequency of BRCA1 and 2 genetic mutations was reported in many studies to range from 2.9 per cent to 28.0 per cent among breast cancer patients.[125] In a normal cell, BRCA proteins 1 and 2 are involved in repairing DNA damage. A study by Marie-Claire King and her research group in 1990 linked early-onset breast cancer with mutations in the BRCA gene. Later, the gene was cloned by Myriad Genetics, based in Utah, USA (Narod and Foulkes, 2004).[126]Women in the global north routinely test for BRCA 1 and 2 mutations to ascertain the risk of developing breast and ovarian cancer. These tests have gained more popularity following the preventive mastectomy undergone by the Hollywood actress Angelina Jolie, an experience about which she wrote in the *New York Times*.[127] Women ascertained to be carriers of BRCA mutations, and hence at risk of developing breast cancer, are counselled to consider options such as prophylactic oophorectomy, mastectomy, or chemoprevention.

In India, the epidemiological evidence on breast cancer indicates an increase in incidence and mortality. The reasons for this have been attributed to rapid urbanization, industrialization, and other environmental factors. Several factors, including undernutrition, prolonged breastfeeding, low parity, obesity, lack of exercise, alcohol consumption, tobacco chewing, smoking, family history of cancer, as well as lack of awareness that could have prevented malignancy, have emerged as risk factors in various research studies in India. In addition, limitations related to the healthcare system—non-availability and lack of access to screening for breast cancer, paucity of diagnostic aids, medicines, and health information, apathy towards the health of women in patriarchal society—are significant contributors to the increasing incidence of breast cancer in the country. Thus, a majority of those with breast cancer receive a diagnosis and are able to access treatment at locally advanced and metastatic stages. Hence, reduction in the incidence of breast cancer and related mortality in Indian women necessitates a multipronged approach, including awareness-raising and screening programmes, availability of accessible and affordable treatment, and addressing the larger structural inequalities and social determinants of health.

A recent study conducted by Bengaluru-based Strand Life Sciences in collaboration with some other scientific institutes in India[124] reveals that the rate of BRCA-induced breast cancers may be higher than expected, although more studies may be needed to confirm this finding. The study also interestingly reveals that 20 per cent of the women who tested positive for the BRCA

125 Kim, H., & Choi, D. H. (2013). Distribution of *BRCA1* and *BRCA2* Mutations in Asian Patients with Breast Cancer. *Journal of Breast Cancer*, *16*(4), 357–365. http://doi.org/10.4048/jbc.2013.16.4.357

126 Bhattacharya,P.(2017,September 11). India is staring at a breast cancer epidemic. But do we have the awareness and tools to prevent one? Scroll (Online at 02.30pm). Retrieved from:https://scroll.in/pulse/850251/india-is-staring-at-a-breast-cancer-epidemic-but-to-we-have-the-awareness-and-tools-to-prevent-one, accessed on 06/12/2017.

127 Jolie,A.(2013,May 14).My Medical Choice.*NewYorkTimes*. Retrieved at http://www.nytimes.com/2013/05/14/opinion/my-medical-choice.html, accessed on 05/12/2017.

mutation had no family history of breast or ovarian cancer. However, genetic screening in India costs around $400 to $900, which is not affordable to most. Further, as Thiagarajan (2017)[128]notes, while preventive surgery is not yet the norm in India, there is more awareness about genetic testing among the urban middle classes. However, even if diseases are predicted, there are no ways to treat them. BRCA testing, however, comes with it's own set of dilemmas.

3.1.3. BRCA and ovarian cancer

BRCA mutations are also implicated in ovarian cancer. Patricia Kaufert (2000)[129]provides a fascinating account of the dilemmas that confront women who are diagnosed with BRCA mutations in Canada. In particular, she discusses how these women are often advised to go in for prophylactic oophorectomy (preventive removal of ovaries) and how this advice is provided in the context of minimal epidemiological evidence that supports its effectiveness. Further, she argues that advising prophylactic oophorectomy is a reminder that the "new" genetics comes into being in the context of "old" medical practice, which includes existing beliefs about heredity and danger, but also this very particular fear of the cancer-prone ovary. The very new contribution of the new genetics lies in being able to test closely related women and determine which ones are vulnerable and which not. The problem is, however, that this information is somewhat in advance of the technological capacity to determine when a predisposition turns into an actual cancer, leaving the prophylactic oophorectomy as still the primary response (p.22).

Ovarian cancer is also a fairly rare cancer, yet, on the ground, women are counseled to remove their ovaries even though epidemiological evidence of any benefits resulting from removal is tenuous. Another important issue that needs to be mentioned is the exorbitant cost of BRCA screening, which has been driven up due to the patenting of these genes. This has prompted feminists to ask if the patenting regime actually serves the interests of women.

3.1.4. Herceptin, the breast cancer 'wonder drug'

Yet another case that needs to be discussed in the context of breast cancer genetics is Herceptin. Herceptin is a monoclonal antibody-based drug used to treat breast cancer, in particular, the HER2 receptor positive breast cancer. Batt (2000)[130] provides an account of the development of the breast cancer drug and

128 Thiagarajan,K.(2017,February 28).Taking the gene test.Mint[online at 11.20 a.m.]. Retrieved from http://www.livemint.com/Leisure/ksZOzf3gCOBo5Vz1a6xDfM/Taking-the-gene-test.html, accessed on 05/12/2017.

129 Kaufert, P. (2000). Belling the cat: Learning to know (but not necessarily trust) the new genetics. *The Gender of Genetic Futures: The Canadian Biotechnology Strategy*, 18.

130 Batt, S. (2000). The new genetic therapies: The case of Herceptin for breast cancer. *The gender of genetic futures: The Canadian biotechnology strategy, women and health*, pp.9–17. Retrieved from http://www.cwhn.ca/sites/default/files/groups/biotech/availdocs/full-doc-2.pdf

its reception in North America, it's questionable efficacy, its side-effects, and its pricing. To begin with, it benefits only a small subset of women diagnosed with breast cancer who possess the particular cancerous gene. Second, its efficacy, even in these women, is not guaranteed, with only about 50 per cent of them responding to the treatment. Third, and most important, it has adverse effects on heart function. Even then, it is marketed in many countries worldwide. In India, for instance, in 2017, two biotech companies, Mylan and Biocon, after fighting a long legal battle with Roche, won the right to sell the biosimilars of the drug Herceptin from the time it was approved for marketing in 2014.[131]

In May 2000, when Genentech, the original developer of the drug, sent out an alert on the cardiac toxicity of Herceptin, cardiologists reacted with dismay, pointing to the irony that even a minor risk of carcinogenecity in a newly developed cardiac drug was reason enough to prevent it from being marketed. They asked: how did the US Food and Drug Administration (FDA) approve a cancer drug with 28 per cent cardiac toxicity (Batt, 2000).[132]

Finally, Batt (2000) discusses the issue of pricing. The cost of Herceptin continues to remain exorbitant and hence unaffordable to a large majority. In India younger women are showing an increased incidence of HER2+, a particularly aggressive form of breast cancer.[133].Even though a biosimilar of Herceptin has been made available this year (2017), at 25 per cent of the original price, Kresge and Gokhale (2014)[134]note that a course of treatment will probably cost at least INR7.12 lakh ($11,600), an amount that is unimaginable for a majority of women in India. According to Batt (2000), the nature of advocacy around drug pricing should be such that we oppose the clinical trials of drugs that are highly priced and "question the ethics of a system designed to spin enormous private profits from the genetic information provided by dying women praying for a few extra months of life" (p. 14).[135]

3.1.5. Postcolonial genomics and genomic sovereignty

The cases of BRCA testing as well as Herceptin drug show that global inequities exist in genomics, particularly with regard to the issues of access to testing and

131 Palmer, E. (2017, March 3). Mylan and Biocon finally win right to sell Herceptin biosim in India even as they have taken it to U.S. and EU.FiercePharma.(Online at 10.40 a.m.). Retrieved at https://www.fiercepharma.com/pharma/mylan-and-biocon-finally-win-right-to-sell-herceptin-biosim-india-even-as-they-have-taken-it

132 Batt, S. (2000). The new genetic therapies: The case of Herceptin for breast cancer. *The gender of genetic futures: The Canadian biotechnology strategy, women and health*, pp.9–17. Retrieved from http://www.cwhn.ca/sites/default/files/groups/biotech/availdocs/full-doc-2.pdf

133 Malvia, S., Bagadi, S. A., Dubey, U. S., & Saxena, S. (2017). Epidemiology of breast cancer in Indian women. *Asia-Pacific Journal of Clinical Oncology*, *13*(4), 289–295.

134 Kresge,N.Gokhale,K. [2014,January 21]. Biocon's copy of Roche breast cancer drug still expensive for India Livemint[Online at 9.15a.m.] Retrieved from: http://www.livemint.com/Companies/1dyS6yxQ7pKozrjCUwY3hN/Biocons-copy-of-Roche-breast-cancer-drug-still-ex pensive-fo.html, accessed on 05/12/2017.

135 Batt, S. (2000). The new genetic therapies: The case of Herceptin for breast cancer. *The gender of genetic futures: The Canadian biotechnology strategy, women and health*, p.14. Retrieved from http://www.cwhn.ca/sites/default/files/groups/biotech/availdocs/full-doc-2.pdf

drugs created by the monopoly of multinational biotechnology firms. The monopoly operates both at the level of sequencing as well as drug development, where genetic information pertaining to ethnic groups is often appropriated for drug research, and where these ethnic groups are never the beneficiaries of the drugs developed at their expense. This occurs either because of the non-availability of drugs that suit their genetic profiles or because of the high costs of the drugs owing to patents. As mentioned above in the discussion on the Indian scenario, many countries of the global south lack access to gene-sequencing technologies that can help map the genomic diversity of their populations. According to Benjamin (2009),[136]among the countries of the south, the perceived lack of genomic data and the monopoly over gene-testing technologies and biological drugs are causes of much anxiety. It is in this context that postcolonial genomics has emerged, whose proponents feel the need to harness genomics for economic development and for dealing with the health crises of citizens.

The concept of genomic sovereignty, taken from *A Room of One's Own*, the 1929 novel by Virginia Woolf, is used to describe the policies of countries outside the global power conglomerate of the countries of the north and the attempts of biotechnology firms to protect their genomic data. As Benjamin notes, "At once innovative and retrograde in its assertions [. . .] Diversity maps serve as a 'naturalizing' cartography of the nation that aims to account for the accumulated genetic inheritance of a people. They also act as social maps for contemporary anxieties about social fragmentation and future cohesion" (p.344). In India, for instance, there are plenty of projects that attempt to map caste and linguistic groups. Benjamin notes, "In all cases, there is a broader politics of difference at work in which genomics is being used to both unify and differentiate the population as part of a larger branding process—the nation as uniquely heterogeneous vis-à-vis other nations"(p.345).

The mapping of genetic diversity within these nations has been done with a view to developing health interventions that involve the generation or production of tailor-made drugs. However, opposition to such projects emanates from various quarters, including feminists who question the siphoning off of diminishing public health funds to projects that do not have any foreseeable benefits (Subramaniam, 2015). Projects on genomic diversity also rest on unquestioned assumptions about social groups that obviously have no biological basis. As Benjamin (2009) puts it, these projects rest on "under-analyzed starting assumptions about the association between ancestry, geography, 'folk' ethnoracial categories, and disease risk" (p.346).

3.1.6. Public health genomics

It is in this climate that a certain kind of politicized genomics, or what is called public health genomics, has emerged. Strong proponents of this idea are

136 Benjamin, R. (2009). A lab of their own: Genomic sovereignty as postcolonial science policy. *Policy and Society*, *28*(4), 341–355.

researchers from McLaughlin-Rotman Centre for Global Health in University of Toronto. According to Benjamin (2009):

> Within the field of public health genomics, 'withholding' genomic information from and failing to develop pharmacogenomic interventions for individuals and communities in poorer countries is conceived of as a ''new form of discrimination'' . . . They [proponents of public health genomics] argue that rather than focusing solely on the development of 'personalized medicine', genomics researchers should seek to 'carefully define' population differences with the stated goal of being able to tailor drugs to specific ethno racial groups in developing countries who are most in need of efficient treatment options therapies (pp. 246–347).

The proponents of public health genomics have also attempted to forge solidarities between the countries of the south. For example, the aforementioned researchers of McLaughlin-Rotman Centre for Global Health arranged a meeting between the officials of Pakistan's health ministry and the representatives of Hyderabad-based Shantha Biotechnics in India. However, despite the focus on poorer countries and the rhetoric of genomics as serving the larger good, the criticisms leveled against genomics from those who see it as an impractical investment in the context of limited public funds still stand. We also need to be wary of the emphasis on the role of private players in these projects. For instance, the proponents of public health genomics seek to expand the commercial platform of pharmaceutical development in their pursuit of public health advances, which may ultimately limit the affordability of health goods and services in the future.

What, then, is the road ahead? Genomic technologies pose huge challenges to people, specifically women in the countries of the global north, particularly because of the proliferation of genome-specific information on various diseases. The concomitant non-availability of cures makes decision making about the use of these technologies even more difficult, as discussed above in the case of BRCA testing. Can genomics ever play a positive role in countries plagued with huge disease burdens, where the public health infrastructure is abysmal, and where access to basic drugs, adequate nutrition, and sanitation is lacking? Given that genetic screening and biopharmaceutical drugs are expensive, and that patenting regimes have driven up the prices of these services and devices even further, issues related to the accessibility of these technologies pose challenges in developing countries like India. Further, the unique dilemmas that confront people, especially women in the global north who are pushed into making decisions regarding these technologies, do not as yet confront women of the global south.

The perceived limitations of genomics in addressing the needs of the global south have been recognized by advocates of genomic sovereignty as well as the proponents of public health genomics. Yet both these groups fail to place genomics in the larger context of the failing public health infrastructure and

public healthcare system in the countries of the global south, and they also fail to recognize the heavy investment required for projects that are futuristic in nature.

3.2. Stem cells: The 'new frontiers' of health

Regenerative medicine is an umbrella term used to refer to a field that brings together multiple disciplines within biomedicine and biotechnology. It focuses on treating conditions associated with damaged tissues, which include osteoporosis, cardiac disorders, spinal cord injury, and arthritis (Waldby, 2002).[137]As Waldby and Cooper (2010) explain, "The stem cell sciences aim to transform this generative capacity (of stem cells) into regenerative capacity – to divert this productivity away from the generation of new individuals and toward the regeneration of existing populations" (p.6). Stem cells can be found in other tissues, such as umbilical cord blood cells, foetal tissue, gonadal, mesenchymal, liver and neural tissue (Waldby and Cooper, 2012). The most versatile are the pluripotent embryonic stem cells, the sources of which are embryos.

In this section, we focus on a prominent area within regenerative medicine that involves research and therapy using stem cells, analysing it from a feminist lens. This includes, in line with the conceptual framework on gender and biotechnologies that we have proposed, a critical analysis of the industry in terms of the larger sociopolitical structures that have fostered its growth. Our analysis of the use of embryos for stem cell research and cord blood banking reflects this kind of an approach. We also discuss the stem cell industry and the issue of commodification of women's bodies, as embryos constitute one of the primary sources of stem cell tissue. This analysis would fall within the theme of biotechnology and its impact on women's bodies.

3.2.1. The stem cell industry in India

India aspires to be a leader in regenerative medicine, with several policy documents on science and technology emphasizing this goal (Kandhari, 2016;[138]Tiwari, 2013).[139] Tiwari (2013) observes that though considerable attention paid by international commentaries on embryonic stem cells in India, it is research and therapy on adult stem cells that mostly occur in clinical and research settings in India. The stem cell industry is the most recent and hence the youngest entrant into India's biomarket yet, its growth has been exemplary. The

137 Waldby, C., & Cooper, M. (2010). From reproductive work to regenerative labour: The female body and the stem cell industries. *Feminist Theory*, *11*(1), 3–22.

138 Kandhari, R. (2017), Stem Cell Research and Experimentation in India, in S. Hodges & M. Rao (Eds), *Public Wealth and Private Wealth: Stem Cells, Surrogates and Other Strategic Bodies*. , 222–251.

139 .Tiwari, S. S. (2013). *The ethics and governance of stem cell clinical research in India* (Doctoral dissertation, University of Nottingham).http://eprints.nottingham.ac.uk/14585/1/602957.pdf, accessed on 05/12/2017.

valuation of the industry in 2015 was more than INR 1,000 crore and it is expected to grow at 28 per cent through 2020.[140]

The potential of stem cells as cures for various disorders—ranging from neurodegenerative diseases to cardiac conditions and spinal cord injuries—has drawn the interest of various actors, including scientists, biotechnology firms, the media, and patients. Kandhari (2016) argues that "the state's scientific and economic aspirations are widening the nation's potential as a site for medical experimentation while overriding the health concerns of its people" (p. 225). She further notes, based on her empirical work, that the excessive optimism regarding the potential of stem cell research and the hope for various cures are moving clinicians and patients away from conventional therapies, which afford limited possibilities for cures for patients suffering from debilitating disorders.

The stem cell industry in India is flourishing in a context where infectious and non-communicable diseases are rampant, and where the population is 'treatment naïve' in the eyes of the pharmaceutical industry. Further, as elaborated below, it is notorious for its lack of proper regulation. Tiwari (2013) also notes that "expectations (on stem cell therapy) are configured on the basis [of the assumption] that stem cells have the potential *to:* solve the problem of organ shortage; help patients with ailments; provide affordable health care; and establish India as a global player" (p.3).

3.2.2. Stem cell research in India: The state of the art

According to Tiwari and Desai (2011),[141] about 40 institutions, including government laboratories and public and private hospitals, conduct research involving stem cells, and a large portion of these are government research laboratories. The DBT, for instance, is currently supporting 55 stem cell research programmes. Twenty private companies are also active in this field, although most are engaged in the area of cord blood banking, perhaps due to the less technical expertise required to do so (Tiwari and Desai, 2011). Notable among the government-funded institutes is the Institute for Stem Cell Biology and Regenerative Medicine (inStem) in Bengaluru, established by the Department of Biotechnology. It works in collaboration with the Centre for Stem Cell Research at Christian Medical College (CMC), Vellore, which has been involved in translational stem cell research. Other institutes active in this area are the National Centre for Biological Sciences, Bengaluru; the National Centre for Cell Science, Pune (bone marrow stem cells); the CCMB, Hyderabad; and the National Brain Research Centre, Manesar (neural stem cell). Notable among the private and public sector hospitals involved in research are the All India Institute of Medical Sciences (AIIMS), New Delhi, where 250 patients have been treated,

140 (2015, October 29). India Stem Cells Market to Grow at 28% Through 2020, Says Pharmaion. PRNewswire.(Online at 12.30 ET) Retrieved from:https://www.prnewswire.com/news-releases/india-stem-cells-market-to-grow-at-28-through-2020-says-pharmaion-538359641.htmlv, accessed on 05/11/2017.

141 Tiwari, S. S., & Desai, P. N. (2011). Stem cell innovation system in India: Emerging scenario and future challenges. *World Journal of Science, Technology and Sustainable Development*, *8*(1), 1–23.

and the L. V. Prasad Eye Institute (LVPEI), Hyderabad, where about 750 patients have received treatment (Tiwari and Desai, 2011). Nutech Mediworld, a private stem cell therapy clinic run by Dr Geeta Shroff in New Delhi, claims to have successfully treated about 850 patients employing embryonic stem cells for a range of disease conditions. Leading firms conducting stem cell research are Reliance Life Sciences Pvt. Ltd. (RLS), Mumbai; Stempeutics Research Pvt. Ltd., Bengaluru; and Nichi-In Centre for Regenerative Medicine (NCRM), Chennai, employing embryonic, adult, and cord blood stem cells (Tiwari and Desai, 2011; Tiwari, 2013). In January 2013, 60 stem cell trials were registered in the Clinical Trials Registry - India (CTRI) (Kandhari, 2016).

3.2.3. IVF and embryonic stem cell research

As mentioned, the link between technologies for assisted conception and stem cell research is most clearly evident in the field of embryonic stem cell research, that is, the use of spare and frozen embryos for research on stem cells. Fertility clinics have become a source of such embryos for further research. A large number of countries today permit human embryonic research on 'spare' embryos donated by couples undergoing IVF (*Invitro* Fertilzation). In addition to the use of stored embryos for stem cell research, there is also an effort on the part of scientists and doctors working in the field of stem cell research to gain access to fresh embryos rather than the stored ones in order to derive healthier stem cells.

The demand for embryos might also accelerate the growing commercialization of oocyte donation, where women consider selling oocytes for research in exchange for money. Waldby and Cooper observe that the oocyte donation industry premises itself on the language of "altruism and maternal qualities", a language that is starkly "absent from sperm bank recruitment"; this linguistic distinction reinforces the gendered nature of such transactions. In India, embryos and oocytes for stem cell research are largely obtained from couples who seek fertility treatment in IVF centres and very often they do so in return for free IVF cycles. According to Bharadwaj, "The situation in India, in a context of embryonic surplus, where embryos are transacted in "exchange for free IVF cycles" or on the basis of "sacrifice for the greater good", the quest for the source of the human embryonic form is absent" (Bharadwaj, 2009b, p.253; 2010b, p1140). Thus, the "sanctity of life" debate shrouds the ethical concerns around using embryos in countries of the global north, where Christianity is the dominant, state-backed religion. However, this debate does not manifest very strongly in Asian countries.

What is worrisome about these kinds of transactions is the kind of information provided to couples donating spare embryos for such research. In a country like India, a matter of even greater concern is the fact that couples accessing IVF procedures are hardly given complete or accurate information regarding the risks associated with these procedures, let alone regulate the number of oocytes

(Sama, 2006; 2012)[142] retrieved or the status of embryos that have not been implanted. Thus, financial concerns and misinformation about the research process override ethical concerns in the decisions by couples to donate embryos and oocytes for research. Although the ICMR-DBT Guidelines for Stem Cell research clearly state that proper informed consent should be obtained from the person regarding the status of the spare embryos, this injunction is often violated. This has important ethical implications and clearly points to the violation of the guidelines on the use and treatment of spare embryos.

Apart from stem cells derived from stored embryos, another field that is rapidly expanding is the storage of cord blood stem cells, which are derived from discarded tissue. This is yet another means of appropriating stem cells and the notion of futuristic cures for the purpose of financial gains. Although no direct linkages or connections should be, or can be, drawn between ARTs and cord blood stem cells banking, it is important to understand the parallels between the two,both of these being aggressively marketed and in turn being available as commercial 'products', which can be obtained by anyone having the required purchasing power. Promotion of technologies like ARTs and cord blood stem cell banking is clear evidence that life itself is treated as a saleable commodity or product in the open market resting on the notion of a promissory future free of illness.

3.2.4. Cord blood banking

The use of cord blood for therapies involves the collection and storage of cord blood from which the stem cells can be harvested. In this technique, umbilical cord blood, which is a rich source of stem cells, is stored for future use. There are two kinds of cord blood banking—public and private. While private banking requires the expectant parent to pay a sum of money to store one's cord blood in the hope of using it for one's own relatives in the future should the need arise; public banking is altruistic in nature. In India, the majority of foreign-origin stem cell firms are engaged in private cord blood banking. There are about 15 private cord blood banks in India. The market for private cord blood banking is predicted to be worth millions of dollars, given that India already witnesses 25 million births per year.[143] It seems that this potential market in India is a major attraction for multinational firms. However, Tiwari (2014)[144] notes that:

> the chances that a particular child will develop a condition requiring cord blood transplantation are very slim. It has been observed that 0.04 per cent (1/2,500) of cord blood units stored would ever be used for

142 Sama (2006). *ARTs and women: Assistance in reproduction or subjugation*?New Delhi: Sama – Resource Group for Women and Health.

143 Tiwari, S. S. (2013). *The ethics and governance of stem cell clinical research in India* (Doctoral dissertation, University of Nottingham).http://eprints.nottingham.ac.uk/14585/1/602957.pdf, accessed on 05/12/2017.

144 Tiwari,S.S. (2014, November 5). Cord blood banking: Ambiguous policy.*Deccan Herald*, Retrieved from: http://www.deccanherald.com/content/442320/cord-blood-banking-ambiguous-policy.html, accessed on 05/12/2017.

> autologous transplantation. The reason is that the occurrence of diseases currently treated with cord blood is small, and many patients would not be eligible for autologous cord blood, including those with genetic disorders and leukaemia.

It is also important to note that the National Guidelines for Stem Cell Research, 2013 included umbilical cord blood banking in the list of biological tissues that are prohibited (these include cord tissue, placenta, tooth extract, adipose tissue, dental pulp, menstrual blood, and olfactory ensheathing cells). The guidelines state that:

> ... advertisements are often misleading for the public and lack comprehensive and accurate information to the consumer. It may be mentioned that there is no scientific basis for [the] preservation of cord blood for future self-use and this practice is not recommended. On the other hand, parents should be encouraged for voluntary donation to public cord blood banks for allogeneic transplantation and research purposes (p. 21, Section 12.2.2, National Guidelines on Stem Cell Research, 2013).[145]

However, in 2014, in the interim union budget, the then finance minister Mr. P. Chidambaram, announced a tax exemption for cord blood banks, on the ground that they are also 'health care services'. Tiwari[146] adds, "With the contradictory statement of the former Finance Minister and the 2013 stem cell research guidelines, one can infer a serious policy conflict between biomedical agencies in India. This needs to be addressed soon as the proliferation of private cord blood banking leads to possible economic exploitation of expectant parents in the name of 'biological insurance'."[147]

It is interesting, however, that despite the fact that benefits of cord blood banking are unproven, the recent National Guidelines for Stem Cell Research (2017) exempts cord blood banking from the list of sources from where stem cells cannot be sourced and stored:

> At present[,] there is no scientific evidence to substantiate [the] clinical benefits with the use of stem cells derived from cord tissue, placenta, tooth extract, adipose tissue, dental pulp, menstrual blood and olfactory ensheathing cells[,] etc. Yet, procurement and banking of these biological sources is increasingly becoming a commercial activity. Hence, care

145 Department of Biotechnology, National Guidelines for Stem Cell Research, Section12.2.2,https://www.ncbs.res.in/sites/default/files/policies/NGSCR%202013.pdf,as cited in Tiwari, S. S. (2014, November 5). Cord blood banking: Ambiguous policy. Deccan Herald, Retrieved from: http://www.deccanherald.com/content/442320/cord-blood-banking-ambiguous-policy.html, accessed on 05/12/2017.

146 Tiwari, S. S. (2014, November 5). Cord blood banking: Ambiguous policy. *Deccan Herald*, Retrieved from: http://www.deccanherald.com/content/442320/cord-blood-banking-ambiguous-policy.html, accessed on 05/12/2017.

147 Tiwari,S. S. "Cord blood banking: Ambiguous policy",*Deccan Herald*, 5 November, 2014, http://www.deccanherald.com/content/442320/cord-blood-banking-ambiguous-policy.html, accessed on 05/12/2017.

> needs to be taken so that there is no exploitation and commoditization of the resources. As of now, only UCB banking is permitted and licensed by CDSCO. Accordingly, commercial banking of all other biological materials [is] not permitted until further notification (pp. 36–37).[148]

It is striking that the ICMR-DBT guidelines justifies its stand of exempting cord blood banking from the list of biological material banned from commercial banking citing that the CDSO has permitted it. This is particularly so because the CDSO only has a 'rubber-stamping' function and is expected to follow the ICMR-DBT guidelines (Tiwari, 2013).The only attempt at explaining why cord blood banking is exempted can be seen in the following statement in the 2017 guidelines: "Private storage of the cord blood HSCs is advisable when there is an elder child in the family with a condition treatable with these cells and the mother is expecting the next baby. In other situations, the parents should be educated about the limitations of banking at this point of time" (p. 37).[149]A framing of this kind gives leeway to companies to continue advertising cord blood banking.

A recent statement[150]issued by the managing director of LifeCell India, Mayur Abhaya, a leading provider of cord blood banking facilities, criticizes the new guidelines:

> The decision to recommend a ban on [the] banking of stem cells from cord tissue, menstrual blood and other biological sources is very unfortunate and totally overlooks the potential contribution of stem cells in research and development. Though today, applications of these are restricted, research and advanced clinical trials across the globe on these products have been demonstrating a significant progress. It is only a matter of time when these stem cells could become treatment solutions for many disorders that have very few other options for treatment.

Despite even the regulatory guidelines stating that there are no proven benefits that would emanate out of the storage of biological material, it is interesting that the managing director of LifeCell international states with certainty that there has been significant advancements in research on these products.

Thus, the aforementioned discussions on the debates around embryonic stem cells and cord blood banking illustrate how the stem cell industry has grown and thrived in the political economy of hope. The example of commercial banking of cord blood stem cells in India shows how the gaps in the regulatory frameworks and the oversight of the regulatory bodies have permitted the stem cell industry to flourish. The industry survives due to the ready supply of stem cells and

148 Department of Biotechnology, National Guidelines for Stem Cell Research,2017, http://icmr.nic.in/guidelines/Guidelines_for_stem_cell_research_2017.pdf, accessed on 04/12/2017.

149 Department of Biotechnology, National Guidelines for Stem Cell Research,2017, http://icmr.nic.in/guidelines/Guidelines_for_stem_cell_research_2017.pdf, accessed on 04/12/2017.

150 LifeCell respectfully challenges ICMR's recommendation to suspend commercial banking of stem cells from cord tissue, menstrual blood and few other biological materials. LifeCell. Retrieved from: https://www.lifecell.in/lifecell-respectfully-challenges-icmrs, accessed on 05/12/2017.

oocytes primarily from ART clinics that are sourced from women who partake in these transactions due to various pressures.

3.2.5. Stem cells, gender, and commodification

Any discussion of stem cell research and the stem cell industry also necessarily entails an examination of the role of women in sustaining these enterprises, as their bodies remain the primary sources of stem cell tissues like embryos, foetal tissue, cord blood, and oocytes. According to Waldby and Cooper (2010):

Such material is generally given for free in the advanced industrial democracies, constituted as a surplus ('spare' embryos) or waste (umbilical cord 'afterbirth', cadaveric foetuses, poor quality oöcytes) whose generative powers should not be withheld from others. At the same time, among impoverished female populations in developing nations, such biological material is now often procured through frankly transactional relations, where women undertake risky procedures for small fees. In each case, female bodily productivity is mobilized to support bioeconomic research, yet the economic value involved in these relations is largely unacknowledged (p.3).

If we employ the case of embryos as an example, as explained earlier, the dominant discourse renders them as both 'waste' and 'useful surplus' at the same time. This effectively erases the activity and role of the women involved in generating these tissues as non-economic, and hence as non-valuable. As mentioned, the women who donate embryos for research do so under the moral obligation to contribute to research for the larger good or to receive the benefits of free IVF cycles (Bharadwaj and Glasner, 2009).[151] Egg donation for research is a more complex issue, as it requires the donors to undergo invasive procedures like super-ovulation for the purpose of the extraction of oocytes. In the UK, the donation of oocytes for stem cell research occurs in exchange for lower fees for IVF cycles. In countries like the United States and India, the donation is transactional and unregulated (Waldby and Cooper, 2010; Gupta, 2012).[152][153]It is important to understand that the global market in oocytes flourishes in the context of the availability of a donor population that is impoverished and the existence of an affluent population who requires the generative capacities of the donor population for its own regeneration.

According to Nancy Scheper-hughes (2001), commodification encompasses "all capitalized economic relations between humans in which human bodies are the token of economic exchanges that are often masked as something else-- love,

151 Bharadwaj, A., &Glasner, P. E. (2009). Local cells, global science: The rise of embryonicstem cell research in India. London and New York: Routledge.

152 Waldby, C., & Cooper, M. (2010). From reproductive work to regenerative labour: The female body and the stem cell industries. Feminist Theory, 11(1), 3–22; Gupta, J. A. (2012). Reproductive biocrossings: Indian egg donors and surrogates in the globalized fertility market. IJFAB: International Journal of Feminist Approaches to Bioethics, 5(1), 25–51.

153 Gupta, J. A. (2012). Reproductive biocrossings: Indian egg donors and surrogates in the globalized fertility market. *IJFAB: International Journal of Feminist Approaches to Bioethics*, *5*(1), 25-51

altruism, pleasure, kindness." The stem cell industry represents a classic case which thrives on the commodification of female body parts. What is interesting is how patriarchal notions of altruism of sacrifice in the name of larger good or for the future of the family draw women into becoming willing subjects who make donations of their body parts. More importantly, class inequalities compel women of certain groups to sell their body parts and undertake risky procedures, in the hope of securing a future for their family. Given this fact and the futuristic nature of these technologies, it seems a distant possibility that an equitable relationship between women and stem cell technologies could exist.

Chapter 4

Conclusion and the Way Forward

The worlds described by Aldous Huxley in *Brave New World* (1932), Kazuo Ishiguro in *Never Let Me Go* (2005), and Jeanette Winterson in *The Stone Gods* (2007) are no longer confined to the written word and are instead today's reality, a reality where "cannibal markets" of human body parts flourish and wherein the integrity of the human body is being challenged and reconfigured by the new biotechnologies. These markets are fuelled by the growing global inequalities—social, economic, and cultural and offer improvements and advantages to certain, mostly privileged bodies, often at the cost of disadvantaging other marginalized human bodies.

This approach paper has employed a gendered lens to explore and analyse the relationship between gender and biotechnologies with a specific focus on health. The paper, in the course of the analysis, has also attempted to add to and strengthen the existing frameworks that analyse the relationship between gender and biotechnologies. The analysis foregrounds the tenacious and wide-ranging relationships between gender and biotechnology— from the need for these relationships, to their design, benefits and disadvantages, as well as the participation of women in the bioeconomy, among several other issues. We also interrogate concepts like commodification, labour, autonomy, and choice that have been the focal areas of feminist theorization, in relation to the biotechnologies especially in our analyses of the areas of genomics and stem cell technologies in India. Further, we have engaged in our analysis acknowledging that there is a need for critical reflection on the employment of biotechnology in reinforcing the essentialism of gender, largely bound by the normative binary, while potential (albeit frequently speculative) also exists for the (re) construction of gender.

Several ethical questions also arise related to the ways in which the health biotechnology market interacts with human bodies, especially marginalized bodies, which are located at the lowest rung in the global and gender power hierarchies, and invariably have compromised access to socio-economic and political determinants of health. What is more interesting is the manner in which these intersections are perceived as 'private', and the way in which they are framed in the context of privacy and individual freedom, raising fundamental questions about 'choice' and 'autonomy'. In such a context, 'choice' may need to be problematized. Can 'choice' with respect to biotechnologies, for example, be equated with the ideal of autonomy? Can the willingness of people (especially women) to purchase some form of biotechnological good or service or donate their biological material be perceived as evidence of the need for a belief in, and as proof of, the beneficence of biotechnology? Can it be argued that the benefits of novel biomedical technologies are largely gendered and inequitable, accruing mainly to the wealthier sections who are able to purchase them? We argue that this is indeed the predicament in developing countries, particularly in the

context of Assisted Reproductive Technologies (ARTs) and the stem cell industry where donors undergo serious risks when donating their biological material and only a small portion of the population can purchase these services.

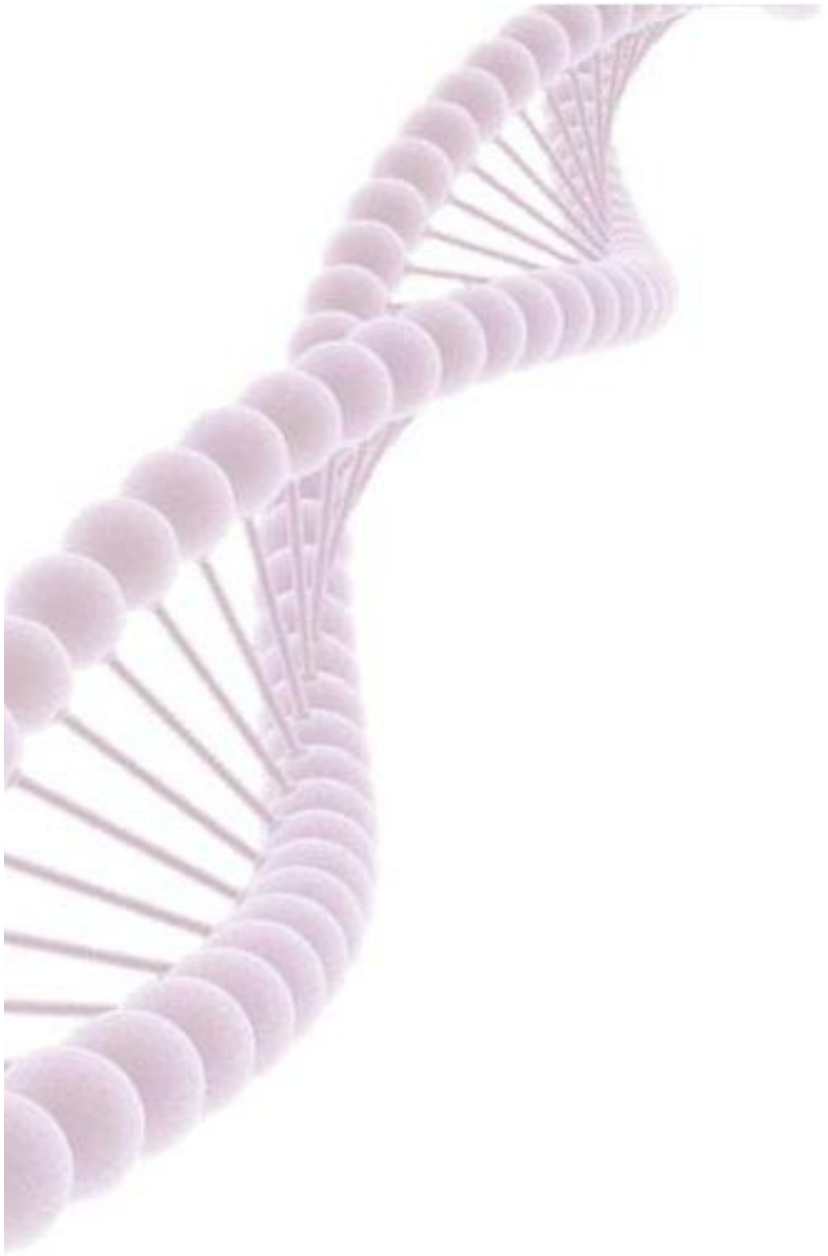
Further, ethical issues related to informed consent, transparency, and ownership abound in this context where human body parts are critical carriers of information about the body as a whole. Though there has been some gender-based analysis of some of these issues which have tried to look at the dilemmas that confront women when they engage in predictive testing, there has not been much done at the level of policy that would help women make informed choices. As discussed in the context of predictive testing of BRCA genes, there is no epidemiological evidence that has investigated the effects of procedures such as prophylactic oophorectomy that are advised to women when they are tested positive for BRCA genes. Further, in developing countries like India predictive genetic testing is only beginning to make inroads and it remains to be seen what dilemmas women are confronted when utilizing these services. Regulatory guidelines are only beginning to grapple with the ethical concerns posed by these technologies. In the midst of this, both private research efforts and the commercial marketing of biotechnology, including reproductive technology, continue to go forward with virtually no ethical constraints other than those researchers choose to self-impose. Individuals seeking to benefit from the outcomes of research are 'free' to negotiate, subject only to the constraints of private conscience and economic resources.

The analysis presented here finds resonance in existing scholarship which has raise concerns regarding the promissory nature of these technologies and their scepticism about claims about these technologies being best fixes or solutions to various health issues. In addition, given the global nature of these biotechnology markets, their pervasive commercialization has posed challenges to their equitable and non-exploitative employment as well as their regulation. The commodification and commercialization of these technologies have profound gender-based implications— both implicit and explicit. The positing of healthcare biotechnology as the answer to health issues especially in developing countries like India necessitates a critical analysis given that global and structural inequities, where the poor availability of and limited access to affordable healthcare, remain the core determinants of ill-health. The remedies for poverty, pollution, hunger, and discrimination, for example, do not lie in biotechnology. However, as we argue, trends indicate the increasing employment of the language of 'health promotion' to justify the increased investment in technology and pharmaceuticals, and also the generation of capital through their purchase, given that their location is largely in private spheres.

This situation demands thoughtful legislation and effective regulation. In the Indian context, as has been discussed in the case of stem cells specifically, the existence of multiple guidelines and authorities for the regulation of research and clinical practice pose independent challenges. Moreover, the guidelines are not adequate enough to address the ethical issues posed by many of these

emerging technologies. The fact that the regulatory guidelines lack any statutory power is also frequently misused, leading to widespread malpractices. Given this context, utmost vigilance is necessary to minimize exploitation of different stakeholders involved in transaction of biological material as well as transparency regarding data usage and data sharing, especially with regard to genomic information.

The paper reinforces the urgent need to engage with the various questions that arise in the journey of any biotechnology—from its conceptualization, development, and deployment to its ultimate effect on the health of citizens and the well-being of the larger society. Wider deliberations and multidisciplinary feminist dialogues on biotechnologies are critical to furthering the discourse on gender and biotechnologies towards evolving a well-informed and just approach for future research and advocacy. Such consultations should ensure that the hitherto unheard voices of the marginalized are heard and acknowledged and are actively engaged in these debates and dialogues on achieving transparent and accountable processes.



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