भारत सरकार
विज्ञान और प्रौद्योगिकी मंत्रालय
जैव प्रौद्योगिकी विभाग
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

सत्यमेव जयते

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PID-14011/1/2022-MED-DBT **Dated: 06.09.2023**

OFFICE MEMORANDUM

Sub: DBT Intellectual Property Guidelines, 2023

The Department of Biotechnology hereby notifies "DBT Intellectual Property Guidelines 2023." The Guidelines provide for ownership, transfer/commercializing of IP arising from DBT funded research outcomes. The Guidelines shall be applicable to all DBT funded extra-mural and intra-mural research organisations.

The details of publications and patents emanating from DBT-funded research may be reported by investigators at link https://dashboard.dbtindia.gov.in/sbt/publication/ and https://dashboard.dbtindia.gov.in/sbt/patents/ respectively. DBT will showcase such reported outcomes to the Government and Public regularly and hence all investigators are encouraged to report outcomes from ongoing and completed projects.

(Dr. Kalaivani Ganesan)
Scientist F, DBT

DBT INTELLECTUAL PROPERTY GUIDELINES

DEPARTMENT OF BIOTECHNOLOGY
MINISTRY OF SCIENCE & TECHNOLOGY

2023

DBT INTELLECTUAL PROPERTY GUIDELINES

1.0. Introduction

1.1. Every effort should be made by the institutes funded through public support to disseminate knowledge arising out of their research to the society for achieving public good. It could be in the form of peer-reviewed publication and development of a process or product for deployment on a scale through IP protection and transfer. The appropriate approach must be decided by the host institutions depending on the findings of the research work whether it has novelty, inventiveness and applicability or is deciphering of new concepts, understanding and theoretical frameworks.

1.2. These guidelines have been framed to enable seamless transfer of IP at academic institutes/research laboratories towards commercialization into technologies/products for larger societal impact.

1.3. IP arising out of public-funded research is a huge asset and must be appropriately harnessed for maximizing socio-economic impact and achieving public good.

1.4. The means and modes of IP transfer should be decided by the scientists based on their Institutional committees with external expert members. A suitable committee

comprising of external experts, including from the scientific, legal, finance and other relevant fields may advise the Director/Head of institute. The committee may review IP filing, granted status, as well their transfer or licensing. IP piling up for long periods without transfer or licensing should be avoided.

2.0 Background

2.1. For IP from academic/public funded research labs to be realized as a product and be deployed for the public good, focused up-scaling and other development is needed and this requires significant investments. The technologies developed at academia are generally not market-ready and up-scaling with persistent efforts is required to realize their value and potential.

2.2. The capacity and ecosystem to convert promising research leads into technology and products for the masses lies in the industrial/Start-up ecosystem. Hence transfer of research outcomes from publicly-funded research labs to SMEs/Start-ups is important

2.3. At present, as per DBT grant MoA, the IPs developed with DBT grant support can be transferred to industry only on a non-exclusive basis. This means that the Government can also provide the same IP to another interested industry. This has become a deterrent to technology and product development, as industries are not willing to invest significant time and finances into furthering technologies which may also be taken up by others.

2.4. The same issue arises where IP has been jointly developed by publicly funded academic institutes/research laboratories along with Industry, as this requires substantial commitment of time and finances by Industry. Similar issues arise for IP that arises from research that is jointly funded by multiple agencies both national and international.

2.5 DBT held discussion meetings with PMO, PSA and organized inter-ministerial brainstorming meetings.

2.6. Many deliberations were held with scientists, IP experts, academicians, policy-makers, Government officials and it has been recommended that grant MoA should be amended to provide options for all forms of licensing. The mechanism of licensing will be decided on a case-to-case basis by the inventor and the host institute through the institutional IP committees and informed to the Government.

2.7. DBT thereafter constituted a Working Group to draft a Report and recommendations.

2.8. The recommendations were shared with DPIIT and their recommendations obtained.

2.9. DBT committee under the Chairmanship of Additional Secretary & Financial Advisor, was constituted to suitably draft the Policy and implementation modalities of the WG recommendations.

3.0 IP ownership of DBT funded research outcomes

3.1. IP obtained through DBT intra-mural funding may be owned by the DBT institutions and commercialized using the principles outlined at Para 5.0 below.

3.2. IP obtained through extra-mural competitive grant funding to DBT and other public/private institutions may be owned by the institutions and commercialized using the principles outlined at Para 5 below.

3.3. In case more than two public/private institutions are partnering in the research program, they may enter into IP sharing agreement mutually amongst them.

4.0 Reporting of research outcomes - Publications/IP

4.1. It is important for Government to know the outcomes of its public-funded research. This will encourage Government's enhanced participation in public research and also to leverage evidence for future policy initiatives and suitable reforms. Accordingly, following to be adopted:

4.1.1. All investigators and host institutions to undertake in grant MoA for reporting the research outcomes from their DBT-funded research. Both publications and IP granted (if commercialized, the mechanism of tech transfer) be mandatorily reported to DBT.

4.1.2. All investigators and host institutions to undertake in grant MoA for acknowledging the support of DBT in their publications and products.

5.0 Principles on IP commercialization modality

Following are broad principles that may be considered in deciding on IP commercialization modalities.

5.a. The mechanism of licensing is to be decided on a case-to-case basis by the host institute through the institutional IP committees and informed to the Government. Transparent mechanisms should be built-in by the institutes to ensure that IP is transferred to the right industry with potential capability and competence to scale-up the innovation especially for exclusive licensing.

5.b. Following licensing, the host institution should report details to DBT.

5.c. In exclusive licensing, for products/technologies that are intended for large scale public deployment, agreements should include a clause of affordability in Indian markets.

5.d. The public-interest issues in exclusive licensing will be protected appropriately and all Indian patents are secured by the GoI through March-in Rights including the option of compulsory license under our patent law, if there will be any exigency arising for that technology/patent.

5.e. IP Assignment requests, if any, needs to be referred to DBT by the host institutions and will be taken up separately on a case to case basis with approval of Secretary, DBT to encourage spin-outs and start-ups formation.

5.1. Non-exclusive licensing

5.1.a. For research leads in higher TRLS, non-exclusive licensing may be the preferred modality with licensing fees decided on a case to case basis.

5.1.b. Competition to be encouraged so as to bring out high-quality, affordable products in the market.

5.1.c. Timelines on commercialization should be clearly defined in licensing agreements.

5.1.d. Preference to Biotech SMEs and for manufacturing in India.

5.2. Exclusive licensing

5.2.a. For research leads in lower TRLs, exclusive licensing may be considered.

5.2.b. Public interest should be protected with clauses on availability of the final product in Indian markets at affordable rates, especially for products with potential for mass deployment.

5.2.c. Timelines on commercialization should be clearly defined in licensing agreement.

5.2.d. Preference to Biotech SMEs and manufacturing in India.

5.2.e. Preferred purchase arrangements for start-ups for products developed under Government funded programs.

5.2.f. A standard licensing agreement framework may be developed by the public institution that would ensure a share of the revenue earned by the licensee to be given to the partnering public institutions for a limited timeframe.

5.2.g. The license shall be subject to the irrevocable, royalty-free right of the Government of the India to practice or to require the licensee to grant sublicenses to responsible applicants, on reasonable terms, when necessary to fulfill health or safety or security needs of the country.

Annexures

REPORT ON
COMMERCIALIZING INTELLECTUAL PROPERTY FROM PUBLIC FUNDED RESEARCH

सत्यमेव जयते
Goverment Of India

DEPARTMENT OF BIOTECHNOLOGY
MINISTRY OF SCIENCE & TECHNOLOGY

2022

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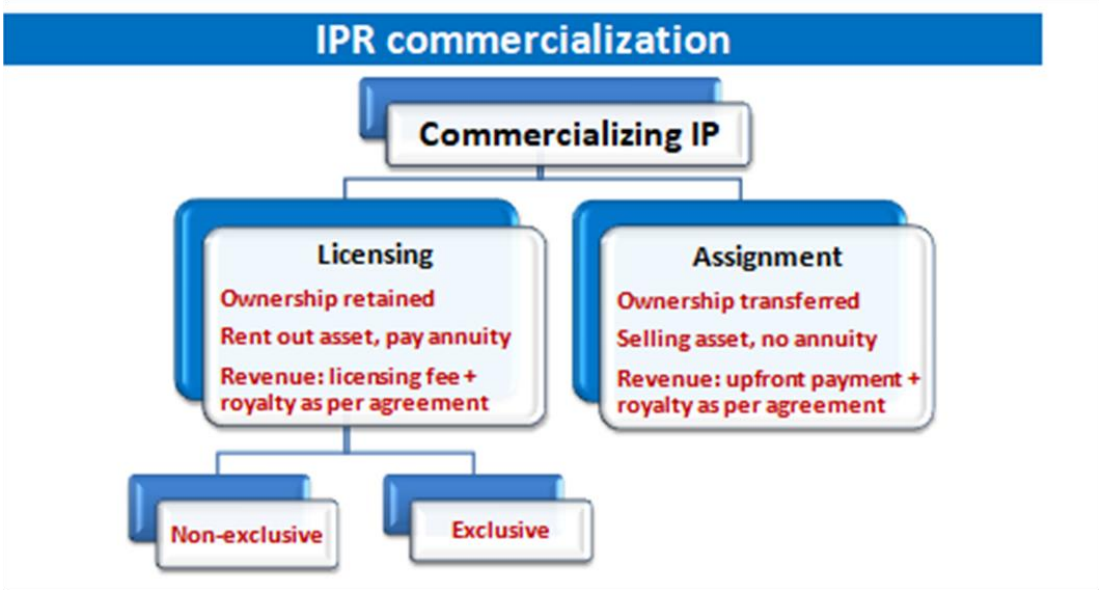
CHAPTER – 1

INTRODUCTION

Scientific Ministries and Departments like the Department of Biotechnology (DBT) are promoting Research and development in the country through competitive grant-in-aid schemes supporting research efforts across a wide spectrum of public and private academic institutions, clinical research centers and industry. The outcome of this research is publication of knowledge generated and also intellectual property, mostly as patents and in some instances as industrial designs.

IPR commercialization mechanisms



There are two major mechanisms for transferring IP for commercialization as shown above: Exclusive and non-exclusive. In Exclusive, rights for commercialization are

transferred to one party and in non-exclusive, to more than one party. IPs can also be sold, which is called IP assignment and this is in limited practice in academic settings. Currently, very few patents from Indian academic research are progressing to commercialization. The main deterrent is the "non-exclusive licensing clause" prescribed in the grant MoA guidelines.

Non-exclusive licensing

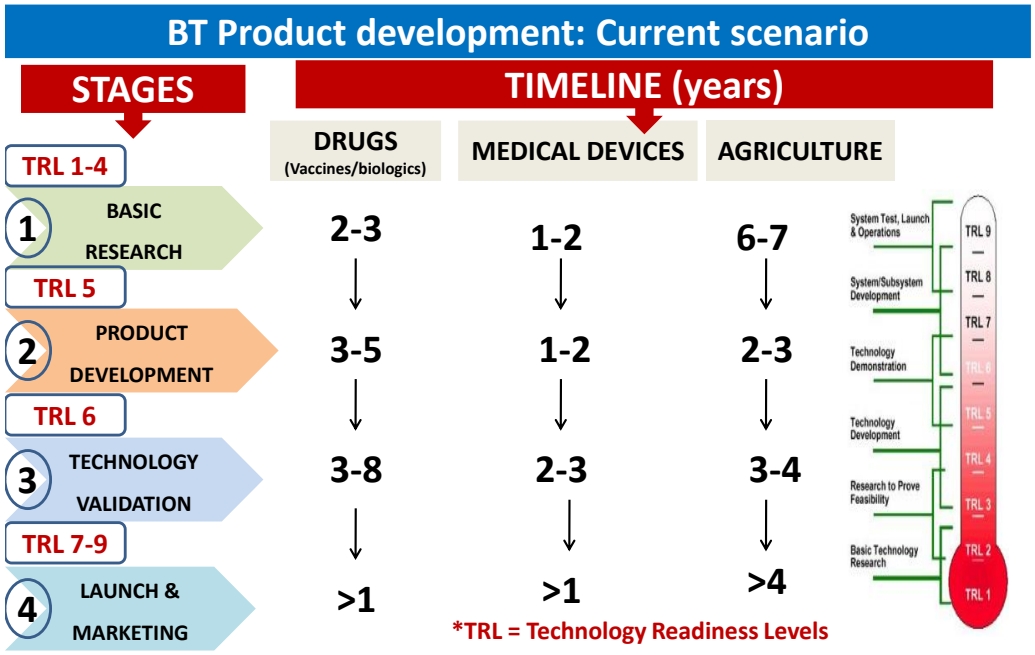
In Non-exclusive licensing, the rights for commercialization are granted to more than one person/organization. This was originally preferred by the Government to: encourage competition, avoid monopoly and get more refined products into market. This has however become a deterrent in commercialization of public by funded research in the country for the following reasons:

- Technologies from academia are not market-ready; require development and investments to commercialize research leads
- Maximum academic, publicly funded research in India is in biotechnology, healthcare, agri-tech etc where industries are limited
- Currently even though a large number of techno start-ups are emerging, these are in the early stage and unwilling to license non-exclusive IP as they will be incurring substantial developmental costs.

- There is a need for start-ups or even spin-outs (emerging out of the technologies) to participate in commercializing research leads

- Time for commercialization in Biotech Sector can take decades

The chart below demonstrates the Product development timelines in Biotechnology research:



As can be seen from the above, biotechnology product development timelines are long and require huge investments and efforts. Hence protection on investment is essential to entice industries into product development.

Exclusive licensing

In exclusive licensing, the rights for commercialization are granted to one person/organization generally for a limited duration or geography. Exclusive licensing should also be considered as the main option for licensing academic research leads for the reasons discussed in the previous section:

Exclusive licensing will protect investments and are more easily enforceable. The public interest issues underlying the arguments in favor of non-exclusive licensing may be addressed in the Exclusive Licensing Agreements with a clause that "exclusive licensing for products/technologies that are intended for large scale public deployment, agreements should include a clause of affordability in Indian markets".

Why is reform requested?

IP has accumulated in our institutes without commercialization/societal utility. Public Institutes incur huge costs to maintain patents and are unable to pay costs for international filings. Therefore exclusive licensing and IP assignment options (especially for incremental innovation/spinouts) to be considered favorably. This will save costs on IP maintenance incurred by public institutions, allow IP to be globally protected, and enhance its utility. As per IP laws, the Government will have March-in Rights; in case of an emergency to make the technology available for its people. India does not have

many industries to compete for a non-exclusive licensing, especially in the biotech sector. Opening up commercialization options will help in the following ways:

- Start-ups will benefit from access to assets created with many years of hard-core research in institutions with one-of their kind ecosystems and infrastructure.

- Government achieves its public good by translating the publicly-funded academic research into societal benefit.

CHAPTER 2

GLOBAL LICENSING PRACTICES

The purpose of the chapter is to study the models/guidelines offered by global funding agencies in the developed world namely US Federal Agencies such as NIH, NSF, Horizon Europe for the European Nations, and the Global Access Policy implemented by the Gates Foundation.

USA:

- The Bayh-Dole Act applies to all the National Institute of Health (NIH), National Science Foundation (NSF) research and development funding granted to all universities, non-profit entities as well as to commercial organizations irrespective of their size.
- To retain rights and title to the inventions, the fund recipients must comply with the Bayh-Dole statute which ensures that the invention will be brought to practical application while protecting certain rights of the federal government.
- Inventions made under NIH, NSF extramural grants and contracts are generally owned by the funded institutions. The NIH, NSF practices a selective licensing policy by providing different types of licensing options such as Non-exclusive license, Exclusive license, Commercial Evaluation license or an internal commercial use license.

- Further, the University provides the Federal Government with a non-exclusive, non-transferable, irrevocable, paid-up license to practice/use the invention.

Horizon Europe (HE)

- Horizon Europe is the EU's key funding programme for research and innovation with a budget of €95.5 billion which facilitates collaboration and strengthens the impact of research and innovation in developing, supporting and implementing EU policies.
- To understand the modalities associated with the ownership of intellectual property rights and transfer of research results, the Horizon Europe Model Grant Agreement was studied.
- The Article 16 of Model Grant Agreement of HE discusses the Intellectual Property Rights which includes Background and Results-Access Rights and Rights of Use. It highlights that the results are owned by the beneficiaries that generate them; however, two or more beneficiaries may jointly own the results in case of a project submitted by consortium. However, in case of joint ownership, all joint owners must agree on the allocation and terms of exercise of their joint ownership.
- The granting authority does not take ownership of the results produced under the action (Action is defined as Project which is being funded in the context of the agreement).

- However, the granting authority has the right to use non-sensitive information for policy, information, communication, dissemination and publicity purposes, and is granted in the form of a royalty-free, non-exclusive and irrevocable license for the whole duration of intellectual property rights (if it is protected through intellectual property rights).
- The beneficiaries may transfer ownership of their results and may grant licenses to their results on an exclusive basis as well as on a non-exclusive basis.
- Further, it is important to note that granting authority has a right to object to transfers or licensing based on the call conditions announced by Horizon Europe.
- The beneficiaries need to obtain permission from the granting authority to transfer ownership or grant an exclusive license.

Bill and Melinda Gate Foundation: "Global Access: The Foundation's approach to managing innovations"

- The Global Access Policy of the foundation does acknowledge the protection of intellectual property rights for the technologies/information arising from the Funded Developments, provided these intellectual property rights are managed to implement the Global Access commitments by the Fund recipients.
- In addition to this, the fund recipients need to check the rights held by third parties to ensure that these rights do not interfere with the objective of ensuring

the availability and accessibility of the Funded Developments to serve the beneficiaries, including in terms of cost, quantity, supply and delivery.

- It is clear from the policy that the foundation does not take ownership of IP Rights, with limited exceptions such as ownership of the copyright in reports or a white paper or in a study. Hence, Fund recipients may file and own patents and other intellectual property rights on Funded Developments and it is up to the grantees to manage the intellectual property arising from the funded developments. The foundation expects that fund recipients must manage the intellectual property rights consistent with the humanitarian license (see below) and the Global Access commitments.
- Further, to achieve the purpose of Global Access, fund recipients grant the foundation a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license (Humanitarian license) to make, use, sell, offer to sell, import, distribute, copy, create derivative works, publicly perform and display.
- The Humanitarian License does not restrict the fund recipient to use or license-out the funded developments as long as it does not limit the scope of the humanitarian license or limit the Global Access commitments. However, if the fund recipient demonstrates to the satisfaction of the Foundation that Global Access can best be achieved without this license, the Foundation and fund recipient may modify or terminate this license.

- In India, it has been noticed that different funding organizations have different policies for implementing the ownership of research results/IPR and transfer of these research results/IPR. Organizations like CSIR and ICAR have highlighted the provisions for granting both exclusive as well as non-exclusive licenses. On the other hand, DBT currently follows only non-exclusive licensing provisions in case of transfer of technology. However, the general practice is to grant license on non-exclusive basis and exclusive license will be given on case to case basis.
- To highlight a few case studies, ICAR-Indian Veterinary Research Institute (ICAR-IVRI), Izatnagar through a Network project on Brucellosis supported by DBT developed S 19 delta per mutant vaccine in which a gene was knocked out from *Brucella abortus* S19 strain. This technology was transferred to the industry on non-exclusive basis for the territory of India where preclinical and immunogenicity safety studies and field trials would be carried out. It can be noted that initially the industry was interested to have an exclusive world-wide license for the development and production of vaccines. Since, DBT had a provision only to grant non-exclusive license, DBT and ICAR as a general practice agreed to grant a non-exclusive license to the industry.
- Three White Rust Resistant Oilseed Mustard *(Brassica juncea*) lines namely Varuna-WRR2, Pusa bold-WRR2 and Rohini-WRR2 were developed by University of Delhi South Campus (UDSC) supported by Department of Biotechnology (DBT). This is

another example where a non-exclusive license was given to the industries for further development and commercialization with an aim to provide benefit to the farmers in India and the country at large for its effective utilization. However these lines were the starting points for further development by companies to incorporate and develop into proprietary lines for commercialization.

- Covaxin, India's indigenous Covid19 vaccine was developed in collaboration with ICMR-National Institute of Virology (NIV). ICMR-NIV transferred strains to the company on a non-exclusive basis to Bharat Biotech to develop the inactivated vaccine and its manufacturing and commercialization. Around 309 Million doses of Covaxin have been administered so far.

Observations:

- Based on the policies/guidelines available globally, two important points were noticed:

    a. Ownership of research results/information and/or IP right - Ownership of research results/information/IPR lie with the University/Institute. Funding Organizations/Federal Agency and Gates Foundation do not take stake in the ownership of IPRs, though these organizations all have the right to use the research results/IPR by way of a non-exclusive license.

b. Transfer of research results by way of licensing- US Federal Agencies and Horizon Europe have given provisions for both exclusive and non-exclusive license for further development and commercialization.

c. The Gates Foundation also as such does not restrict the transfer to a non-exclusive basis. Fund recipients may transfer the results on an exclusive basis as long as they comply with the commitment of implementing Global Policy Practices.

d. It is also important to note that for obtaining the exclusive rights or in case of transfer/assignment of ownership, the Government needs to give their consent and approval.

- The Federal Agencies of USA follows the provisions of Bayh-Dole Act, wherein the Universities/Institutes are permitted to have ownership on the research results/IPR. These Universities/Institutes generally do not give up the ownership of IPR (even for spin-off creation) though it can be licensed-out to the industry on an exclusive basis.
- With the above quoted cases, it can be seen that in India, general practice is to grant non-exclusive license to the industries though a few of the organizations do have provisions to transfer the technology on exclusive basis also.

Comments:

- In view of the above, it is hereby proposed that the agreement/policy document of DBT must have provisions to provide different types of licensing options such as exclusive, non-exclusive, commercial evaluation license, sole license.
- Modality to decide the type of license (whether exclusive, non-exclusive, Commercial evaluation, sole license) shall be the purview of the funded Institution. This may be based on the nature of the technology, Technology Readiness level, market, risk assessment, investment requirement and how much development a technology requires by the industry to take it to the market.
- However, the Institutions/Universities need altogether different capacity in terms of domain experts to assess the technologies and access to information to assess the type of license to be granted to the industry based on the above-mentioned parameters. There is a dire need to create domain expertise that can evaluate the technologies, negotiate with the industries, identify the value of the technology and can liaison with the industries for commercializing the innovations.
- One possibility could be to deploy 2-3 domain experts in the University/Institute to evaluate the technologies for IPR protection as well as for technology marketing to the industry.
- Further, Indian funding organizations may revisit their policy on owning IPR as a co-applicant/applicant to ease the process of commercialization with a flexibility to

grant different types of licenses as per the need of the technology. Globally, NIH, NSF, BMGF, Horizon Europe etc. as a Federal Agency do not take any ownership in the IPR except copyright, the funding organizations in India may also think about leaving the ownership in the IPR and allow the funded Institute to own IPR.

- However, for monitoring as well as for tracking the innovations for IPR filing and their commercialization, funding Organizations may devise a structured online reporting mechanism/database to report the inventions, patents and licensing information generated by Funded Institutions/Universities. In the United States, several funding organizations use iEdison (Interagency Edison) database, which is an online relational database designed around the reporting requirements of the Bayh-Dole Act and its implementing regulations. As a country, we can also look for such databases for monitoring the IPR filing and commercialization reports to track the progress of the projects.
- These efforts should result in more translatable research, and industry-academia linkages to bring products to the market, which would help us to achieve the initiatives of "Make in India" and AatmaNirbhar Bharat Abhiyan.

CHAPTER 3

CASE STUDIES OF SUCCESSFUL EXCLUSIVE LICENSING AROUND THE WORLD

COVISHIELD

Covishield, the most widely used SARS-CoV-2 vaccine, was developed initially in Oxford University and then last stage development was done in partnership with AstraZeneca in 2020. It was given an emergency use authorization (conditional approval) for active immunization of individuals aged 18 years and older for the prevention of coronavirus disease 2019 (COVID-19).

For the Covishield Vaccine candidate, early proof-of-concept has been developed by Oxford university in the UK and territory-based exclusive license for manufacturing and commercialization was given to AstraZeneca in UK and Serum Institute of India (SII) in India. The vaccine has since been approved by a number of non-EU countries, including Vietnam, Argentina, Bangladesh, Brazil, the Dominican Republic, Salvador, India, Israel, Malaysia, Mexico, Nepal, Pakistan, the Philippines, Sri Lanka, and Taiwan, South Korea. Approval was given to AstraZeneca for manufacturing in partnership with local distributors. Australia and Canada also followed in early 2021.

CISPLASTIN

Cisplatin is a chemotherapy medication used to treat a number of cancers. These include testicular cancer, ovarian cancer, cervical cancer, breast cancer, bladder cancer,

head and neck cancer, esophageal cancer, lung cancer, mesothelioma, brain tumors and neuroblastoma. It is given by injection into a vein.

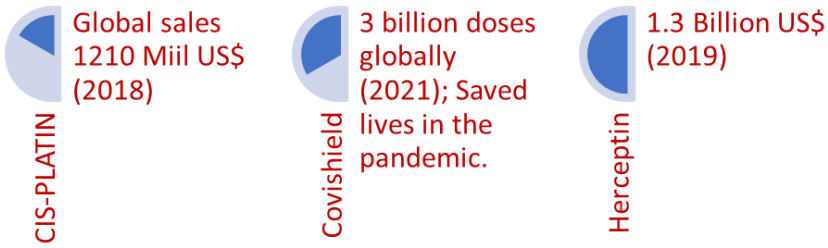
The discovery of cisplatin in 1965, by Dr. Barnett Rosenberg, was done at Michigan State University (MSU), funded by NCI (National cancer institute). Also, the clinical efficacy studies were done by Dr. Lawrence Einhorn of Indiana University, funded by NCI. The successful results of these trials led to Food and Drug Administration (FDA) approval of cisplatin in 1978 for testicular cancer treatment.

The patent for cisplatin was licensed on an exclusive basis to Bristol -Myers Squibb for five years. In 1983, the US federal government gave approval for a seven year extension of the exclusive license to manufacture cisplatin, which was then the leading cancer drug in the United States. Till now, for the majority of cancers, Cisplatin remains the drug of choice for clinicians, making it the most successful cancer chemotherapy till date.

Herceptin

The drug was first developed and IP was generated by scientists including Dr. Axel Ullrich and Dr. H. Michael Shepard at Genentech, Inc. Early leads for this drug development originated in academic labs in the Harvard Medical School, Massachusetts Institute of Technology, Whitehead Institute of Biomedical Research, Rockefeller University and University of Pennsylvania School of Medicine. Earlier discovery in these

academic research organizations contributed to the establishment of HER2 targeted therapies. Genentech developed trastuzumab jointly with UCLA, beginning the first clinical trial with 15 women in 1992. As an obvious outcome, Genentech Inc. is the IP assignee of the resultant drug candidate Trastuzumab. This may be considered as an early stage transfer of IP and co-development of the molecule in partnership with the industry.



Typhoid conjugate vaccine (Vi-DT)

International Vaccine Institute in Seoul, South Korea, a nonprofit international research organization established in 1997 as an initiative of the United Nations Development Programme (UNDP), is funded by governments of member states and a few philanthropic funding agencies, as well as through CSR of a few large industries. IVI has completed development of a typhoid conjugate which consists of the Vi polysaccharide purified from Salmonella Typhi, chemically conjugated to diphtheria toxoid (DT). They have compared this vaccine candidate with Vi typhoid vaccines, for infants under two years of age, young children, and adults.

IVI has transferred the technology for production and quality control of Vi-DT to three manufacturing partners exclusively for specific geographies and is working with them to complete the clinical development aimed at local licensure and WHO prequalification. The products from two partner manufacturers (SK Chemicals in South Korea and Biofarma in Indonesia) have completed phase I clinical trials, and phase II clinical trials will soon be underway. As with all of IVI's vaccine technology transfer partnerships, global access agreements have been signed to ensure high quality, affordable vaccines for use in public-sector markets.

Humira (Adalimumab)

Adalimumab was discovered as a result of a collaboration between BASF Bioresearch Corporation and Cambridge Antibody Technology, U.K., itself a collaboration of the government-funded Medical Research Council and three academics, which began in 1993.

Initially named D2E7, it was then further manufactured at BASF Bioresearch Corporation, developed by BASF Knoll (BASF Pharma), and ultimately manufactured and marketed by Abbott Laboratories after Abbott's acquisition of BASF Pharma. This is another example of a blockbuster drug where the initial lead was from academia industry collaboration, funded majorly by government sources, then co-developed and commercialized by the industry partner. The IP ownership rests with the industry, since the molecule was co-developed and industry investment was significant.

Overall trend

Overall trends for successful product commercialization in the field of life sciences provides us a picture which is complex and involves many layers of evolution and is also geography specific.

Rockefeller University, Emory University, Yale University, Harvard Medical School, Massachusetts General Hospital, etc. have mostly been involved in early stage development of target and molecule, but later brought in an industry co-developer. By this strategy, the specific industry automatically becomes an IP assignee. On the contrary, MIT has engaged in an insightful strategy of exclusive licensing of its IP to innovator start-ups and small companies (limited to time period, geography and indication/usage). A significant number of these start-ups and small companies eventually have gone through M&A after advanced stage development resulting in many successful products. MIT also has non-exclusive licensees, mostly in the case of large companies. Presently most of the premier academic research organizations, with established track record of producing lead to successful life science products, have engaged in both non-exclusive and exclusive licensing strategies, following a few general principles:

- Exclusive licensing being given to small companies and start-ups with no adjunct sponsorship from the academic organization
- Exclusive licensing given for limited time period, geography and usage

- Exclusive licensing agreement essentially mentions a clause of commitment to affordable global access.
- The academic organization retains rights to the IP for exploiting it for non-commercial purposes.

CHAPTER 4

INTELLECTUAL PROPERTY (IP) COMMERCIALIZATION STRATEGIES

Purpose

This chapter intends to discuss the different forms of intellectual property (IP) licensing for promotion of IP commercialization and their impact on follow-up product development and commercialization. This chapter aims to:

- List the potential modes of IP licensing with their advantages or disadvantages to promote, encourage and aid IP commercialization in DBT funded organizations;
- Facilitate research activities and technology-based relationships with third parties;
- Outline institutional procedures for IP licensing-out

Factors deriving choice of licensing type

The choice of licensing type typically depends upon the below given factors:

- **Market potential**: if the technology developed has huge market potential, the licensor may be interested to opt for non-exclusive licensing. However, the potential licensee will show interest only based on the risk-associate and investment required for further development of the technology for its commercialization.
- **Technology readiness level (TRL) of the innovation**: The technologies that are close to be commercialized and at higher side of TRL (*i.e.*, ≥TRL-7) might have required

significant investments (intellectual inputs and infrastructure) during its development and may not involve significant risk and investment for its further development and commercialization. Therefore, these technologies may be considered for non-exclusive licensing by the licensor. However, the licensee may be more interested to get these IP on exclusive basis to project their commercial interest. Whereas, the technologies that are at the lower side of TRL (*i.e.*, ≤TRL-6), might have required comparatively lower level of investments (intellectual inputs and infrastructure) during its development and may involve significant risk and investment for its further development and commercialization. Therefore, the licensor may consider them to license-out on an exclusive basis to encourage the licensee. However, there may be a lower number of entities showing interest in the technologies that are at the lower side of TRLs.

- **Nature and capacity of the IP**: if the IP as standalone has limited/no commercial value and can only be commercially viable in conjunction with other IPs, the potential licensee may have restrictions to opt for it.
- **Required investment for maturation of the technology:** If the inventions require significant amounts of investment for their further development for commercialization, the potential licensee typically considers it for exclusive licensing.

Most commonly used terms of licensing

The licensing terms typically depend upon the nature and potential use and are discussed and defined by the licensor and licensee, mutually. However, in practice, only a few terms are commonly observed, with or without royalty and/or conditional (for a defined product/domain/period)/unconditional use. These may be as given below

- A non-exclusive, royalty-free license for any internal research and development purposes
- A non-exclusive, royalty-free license without the right to grant sublicenses
- A non-exclusive, royalty-bearing license with the right to grant sublicenses
- An exclusive, royalty-bearing license to use IP for conditional use (for a defined product/domain/period) with the right of sublicensing
- An exclusive, royalty-bearing license with the right of sublicensing
- An exclusive, royalty-free license with the right of sublicensing

Assignment of IP rights by academic institutions is a rarely seen activity.

Impact of mode of licensing for commercialization on different stakeholders

The mode of licensing out the IP matters a lot to different stakeholders and hence can significantly impact the fate of IP for its commercialization. Therefore, it is extremely important to understand the interest(s) and functioning of different stakeholders opting for IP licensing.

- Non-exclusive licensing: Since the IP has been generated using public funds (tax-payers money), extending its socio-economic benefit to the maximum number of people becomes the priority to the DBT or its institutions. Since non-exclusive licensing enables licensing of the technology to any number of licensees and encourages competitive commercialization of the product, in terms of cost and availability, it is the priority choice to the DBT or its institutions. Whereas, exclusive-licensing/IP-assignment may empower licensees to regulate the cost and availability of the product and hence minimize the impact of the innovation at society-level.
- The start-ups and companies show limited interest in non-exclusive licensing of the IP. The start-ups, including faculty start-ups, have limited resources but humongous challenges to survive in the market. They consist of energetic and risk-taker individuals who typically take license of technologies at ≤TRL-6 and invest their time and resources to further develop and commercialize the technology. However, attracting investors with non-exclusive technology licensing is comparatively much more difficult than exclusively-licensed/IP-assigned technology. This ultimately causes delay or failure in development and commercialization of products. Whereas, established companies typically opt for low-risk investments and hence gamble for technologies ≥TRL-7. Entering into non-exclusive licensing of technology poses a risk of market competition and risk

ofthe investment and hence engaging via non-exclusive licensing is not the preferred mode for them. However, in certain cases (such as huge market size spread over vast geography), established companies may also come forward for non-exclusive licensing, but such cases with DBT or its institutions are extremely low.

- **Exclusive licensing**: Exclusive licensing is the preferred mode of engagement of the start-ups and established companies with publicly funded organizations, including DBT and its institutions as it protects the commercial interest of the companies by reducing the avoidable market-competition in the domain. Exclusive licensing favors the successful maturation of the technology to bring it into the market and serves the purpose of helping people via science.

  Whereas, DBT or its institution prefer non-exclusive licensing primarily because they have the responsibility of protecting societal interest. It is learned over time that the start-ups, due to resource limitation, may delay or fail in further development and commercialization of technology, limiting potential of the technology. The established companies may also delay/shelve the product development and its commercialization, after obtaining the exclusive license or IP-assignment, to protect the commercial interest of the company if they have any similar product in the domain or unforeseen changed priorities over time. In such

situations, exclusive licensing limits the licensor to grant this technology to other potential licensees to explore, if they can develop it further and commercialize.

- **IP Assignments**: Assignments are considered for technologies in which the licensor is not willing to make investments for its further development due to its limited commercial value as per their valuation but an entity (potential licensee) foresees its commercial value and has willingness. These technologies may be considered for assigning the IP by the creator to the entity. Besides, there may be a scenario, where the licensor and licensee both foresee significant commercial value and hence the licensee is interested in getting the IP assigned to them on a mutual agreement basis.

Technology transfer examples: Non-exclusive, Exclusive, IP Assignments

- **Non-exclusive licensing:** In 2015, National Institute of Immunology transferred a technology 'High Cell Density Fermentation' technology to IMGENEX India Pvt. Ltd on non-exclusive basis, for a period of 10 years from the date of signing the agreement. This technology can be used by a number of industries without impacting the business of other industries and this kind of technology requires no further investment for validation and clinical trials. These kinds of technologies are ready to use and can be sold to industries ranging from small to big pharmaceuticals for growing the bacterial strains for expression of desired proteins in large quantities.

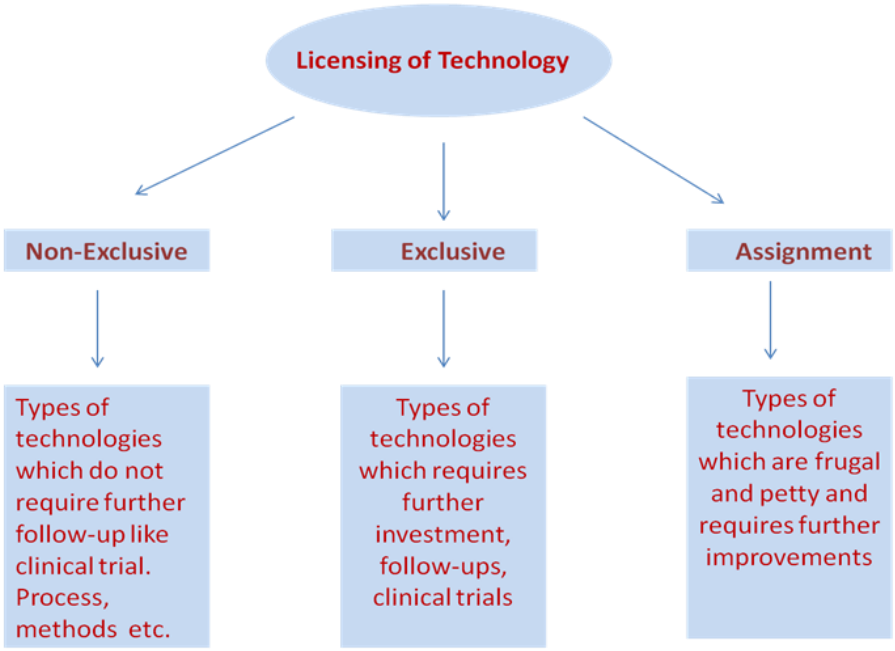
- CSIR-IGIB had developed a rapid testing kit named "FELUDA" which utilizes an indigenously CRISPR Cas9 technology that is used to recognize COVID-19 sequence in a sample. The technology uses a sample of CRISPR biology and paper-strip chemistry which leads to a visible readout on a paper strip that can be used to confirm the validity of the viral infection in the sample. The CSIR-IGIB has transferred this technology to Tata Sons for further research and market commercialization. The testing kit claims to have certain advantages associated with it such as being a reasonable testing kit that is easy to use and thus reduces the dependence on expensive testing kits. The FELUDA technology for CoV2 detection has been licensed non-exclusively to TATA Medical and Diagnostics. This is another example where 'KIT' kind of technologies can be sold on non-exclusive basis to a number of industries which further ensures a level playing field in the diagnostic market.

Exclusive licensing: Technologies which seem promising to generate good revenue in terms of royalty to the university can be considered for exclusive transfer and one such technology related to fuel additive was licensed to M/s AbhitechEnergycon Limited, Mumbai, a company started by an IIT Bombay alumnus in May 2006. This technology has been used to develop chemical formulation and marketed as 'thermal and thermact technology', widely used in the chemical and petroleum industry. Initially this technology was licensed with

exclusive rights for five years with an annual lump sum payment. After a successful venture for five years, the license for this technology was renewed to the same company for another five years with an increased license and royalty money.

Technologies which require further validation and clinical trials are generally transferred on an exclusive basis. One such technology transfer belongs to National Institute of Immunology which transferred insulin release technology on exclusive basis to 'Extended Delivery Pharmaceuticals', USA (previously NLSP) in 2009. This widely acclaimed innovation popularly referred to as 'SIRF' which releases biologically active insulin monomers into the blood upon subcutaneous injection, maintaining normal level of glucose for 90 days. This technology was meant for further validation and clinical trials before its commercialization to the market.

- **IP Assignments:** Simple technologies such as "Process for the preparation of a highly interconnected porous shaped gelatin matrix" which are based on filed or granted patents can be transferred to industry on assignment basis wherein patent(s) can be transferred in the name of industry. One such example belongs to National Institute of Immunology which assigned a patent to M/s Excel Matrix Biological Devices P. Ltd., Hyderabad in 2006. Developing this kind of simple technology does not require much investment and can be developed in a short time.



Different options for licensing from academia to industry.

Conclusions

Since exclusive licensing protects commercial interest of licensees favoring further maturation of the innovation and its commercialization which is also the ultimate aims of DBT and its institution, it should be promoted and preferred based on the nature of innovation (such as methods that can be applied universally may be a fit for non-exclusive licensing but the product-specific innovation or require investment of significant resources may be good fit for exclusive licensing) and request from licensee. However, other terms & conditions (such as product/domain/geography/time bound exclusive licensing) that give enough flexibility along with a sense of responsibility and binding for successful development and commercialization of technology may be

negotiated and mutually agreed upon by the licensor and licensee. Moreover, IP assignments to industry partners shall depend on the type of invention. For example, minor technological advancements or frugal innovations can be assigned to industry partners, however, innovations which may bring the name and fame to the DBT or its institution shall only be assigned to industry after careful evaluation to protect the interest of the public. Furthermore, technology transfer to stats-ups, specifically faculty start-up, require flexibility in guidelines on technology transfer as success rate is very low for commercialization and here non-exclusivity may seem appropriate for technology transfer. In cases where industry/ startups have been involved from inception/ early stage including where IP is jointly created in the academic-industry collaboration, assignment may be considered.

CHAPTER 5

INDIA AND BAYH DOLE

THE BAYH DOLE ACT

The Bayh-Dole Act, 1980 Act of the United States enables universities, nonprofit research institutions and small businesses to own, patent and commercialize inventions developed under Government-funded research programs within their institutions. In 1980, before the enactment of this Act, there were some 28,000 patents granted to various universities and research centers, developed using government funds. These were owned by the government and less than five percent of these patents were licensed to companies for developing them into successful products or applications. This law was implemented to enable robust technology transfer from academic research efforts. It ultimately has motivated more and more universities to become actively involved in the transfer of technology from the lab to market.

As per the provisions in the law:

- University is allowed to retain ownership and commercialize IP arising out of publicly-funded research.
- Universities must actively attempt to develop and commercialize the invention. If not, the Government may take control of the invention.

- When commercializing the invention, universities give preference to small businesses.
- Government may also take ownership of the invention, in case of National priorities referred to as March-in rights.
- Exclusive licenses may be granted by the University ensuring that the invention will be "manufactured substantially" in the United States.
- University must share a portion of the royalties with the inventor(s).

PROTECTION AND UTILIZATION OF PUBLIC FUNDED INTELLECTUAL PROPERTY (BILL 2008)

As per its statement of objects and reasons, this Bill sought to promote creativity and innovation to enable India "to compete globally and for the public good" by ensuring the protection of all intellectual property (meaning copyright, patent, trade mark, design, plant variety, etc.) that is the outcome of government-funded research.

- Ensure access to innovation by all stakeholders for public good
- Develop framework for protection and utilization of IP in public-funded research institutes
- Promote creativity & innovation through incentives (upto 30% royalty can be shared with the inventors)

It also included other clauses for promoting manufacturing in India, March-in Rights for Government etc as in the Bayh Dole Act.Though the overall mandate of the

Bill was to maximize impact from public-funded research outcomes, there were certain clauses which finally resulted in the withdrawal from the Cabinet.

The broader vision of the Bill was built on achieving self-reliance at public institutions by generating funds from licensing and commercializing IP thereby minimizing dependency on Government.Following the Bayh Dole, this Bill was also framed to vest patent ownership with inventors and host institutes.

- The penalty clauses for failure to inform were found to be harsh, and imposing compulsory patenting aspects was found to be against the interest of science and discovery. The Bill required the scientist who creates an intellectual property to immediately inform the research institution. The institution shall disclose this information to the government within 60 days. The institution is required to inform the government of the countries in which it proposes to retain the title. The title in all other countries will vest in the government.
- Failure of the scientist to intimate the institution and of the institution to inform the government carries penalties, which include fines and recovery of the grant funds.

- Intimation to Government at each step was seen as more bureaucratic

- The Bill also aimed to encourage innovation in small and medium enterprises and promote collaboration between government, private enterprises and non-government organizations but no mechanisms were detailed to achieve these.
- The provisions for royalty sharing in the Bill are already in place in many institutions and GoI has no objections to that.

CONCLUSIONS

Now and then, there are suggestions that India should enact a Bayh Dole like Act to maximize impact from public-funded research outcomes. As may be seen from the above, this may not be required. Only certain policy-level reforms and guidelines are needed to enable this as a smooth transition.

In India IP is owned by inventor and host institute, Government is only a co-applicant

All rights to commercialize (in case of DBT) has been provided to the host institute as per the institute's norms. However, the grant agreement mandates non-exclusive licensing. Instead this may be decided on a case-to-case basis with provisions for exclusive licensing and IP assignment options for spin-offs and start-up ventures emerging out of the IP or actively involved in its development.

Revenue and royalty sharing may continue as per institutional mechanisms.

Many institutes like IITs and Universities have provisions for incentivizing spin-out creation and sharing equities or royalties with inventors. As per Cabinet approval, GoI has also notified detailed rules and regulations in scientific ministries for "Encouraging development and commercialization of inventions and innovations" which permits scientists to establish spin-outs/start-ups while being in service among other such enabling provisions.

Promoting Science, Technology and Innovations is an indispensable role of the Government for building a strong Nation. Therefore public academic and research institutes should not be seen to be largely or solely revenue generators, though every attempt has to be made to maximize research outcomes for socio-economic impact and achieving public good.

CHAPTER 6

RECOMMENDATIONS

- IP arising out of public-funded research is a huge asset and must be appropriately harnessed for maximizing socio-economic impact and achieving public good.
- For IP from academic/public funded research labs to be realized as a product and be deployed for the public good, focused up-scaling and other development is needed and this requires significant investments. The technologies developed at academia are generally not market-ready and up-scaling with persistent efforts is required to realize their value and potential.
- The capacity and ecosystem to convert promising research leads into technology and products for the masses lies in the industrial/Start-up ecosystem. Hence transfer of research outcomes from publicly-funded research labs to SMEs/Start-ups is important
- At present, as per DBT grant MoA, the IPs developed with DBT grant support can be transferred to industry only on a non-exclusive basis. This means that the Government can also provide the same IP to another interested industry. This has become a deterrent to technology and product development, as industries are

not willing to invest significant time and finances into furthering technologies which may also be taken up by others.

- The same issue arises where IP has been jointly developed by publicly funded research laboratories along with Industry, as this requires substantial commitment of time and finances by Industry. Similar issues arise for IP that arises from research that is jointly funded by multiple agencies both national and international. In such cases, IP related policies may be decided by mutual discussion between the funders, taking into consideration the quantum of funding provided by each party.
- DBT held discussion meetings with PMO, PSA and organized inter-ministerial brainstorming meetings.
- DPIIT, the Department in-charge of Patent laws, has clearly clarified that there are no specific guidelines/rules/laws deterring exclusive licensing. This had arisen more of a practice than law due to the conventional view of avoiding monopoly in public interest. Further, there are other Government funding agencies which do not insist on either IP licensing or IP ownership.
- Many deliberations were held with scientists, IP experts, academicians, policy-makers, Government officials and it has been recommended that grant MoA should be amended to provide options for all forms of licensing - Non-exclusive, exclusive, or even IP assignment (if there will be spin-out/start-up emerging out

of the technology or if the IP is jointly developed with Industry). The mechanism of licensing and/or assignment will be decided on a case-to-case basis by the inventor and the host institute through the institutional IP committees and informed to the Government. If IP assignment is recommended by the IP committee, all owners of the IP must communicate their approval or otherwise within a period of thirty days. If no communication is received, it will be assumed that the owners have granted approval for the assignment. In general, it is recommended that ownership or assignment should only be given to co-developers whose contributions have been essential to development of IP which is not majorly funded by the Government of India.

- Following licensing, the host institution should report details to DBT
- For exclusive licensing and IP assignment, for products/technologies that are intended for large scale public deployment, agreements should include a clause of affordability in Indian markets.
- The public-interest issues in exclusive licensing and Assignments will be protected appropriately and all Indian patents are secured by the GoI through March-in Rights including the option of compulsory license under our patent law, if there will be any exigency arising for that technology/patent.
- This is expected to push the transfer of IP at institutes towards commercialization into technologies/products for larger societal impact.

REFERENCE GUIDLINES FOR HOST INSTITUTES FOR DECIDING ON THE IP COMMERCIALIZATION MODALITY

Every effort should be made by the institutes funded through public support to disseminate know-how and transfer the IP emanating from research for the larger public good. Institutional committees with external expert members as required may be constituted to review IP filing, granted status, as well their transfer or licensing. IP piling up for long periods without further transfer or licensing should be avoided. Following are broad principles that may be considered in deciding on IP commercialization modalities.

Non-exclusive licensing

- For research leads in higher TRLS, (TRL-6 and above), non-exclusive licensing may be the preferred modality with licensing fees decided on a case to case basis.
- Competition to be encouraged so as to bring out high-quality, affordable products in the market.
- Timelines on commercialization should be clearly defined in licensing agreements.
- Preference to Biotech SMEs and for manufacturing in India.

Exclusive licensing

- For research leads in lower TRLs (TRL-5 and below), exclusive licensing may be considered.

- Public interest should be protected with clauses on availability of the final product in Indian markets at affordable rates,especially for products with potential for mass deployment.
- Timelines on commercialization should be clearly defined in licensing agreement.
- Preference to Biotech SMEs and manufacturing in India.
- Preferred purchase arrangements for start-ups for products developed under Government funded programs.
- A standard licensing agreement framework may be developed by the public institution that would ensure a share of the revenue (1-2% of the revenue) earned by the licensee to be given to the partnering public institutions for a limited timeframe.
- The license shall be subject to the irrevocable, royalty-free right of the Government of the India to practice or to require the licensee to grant sublicenses to responsible applicants, on reasonable terms, when necessary to fulfill health or safety or security needs of the country.

IP Assignment

IP assignments for IP arising from publicly funded research to be considered preferably for spinouts and start-ups that contributed to the IP generation, with a clause on commercialization timelines.

- Timelines on commercialization should be clearly defined in licensing agreement.
- Public interests should be protected with clauses on availability of the final product in Indian markets at affordable rates, especially for products with potential for mass deployment.
- Preference to spin-outs or startups that contributed to the IP generation, or creation of techno start-ups in India using the assigned technology.
- The license shall be subject to the irrevocable, royalty-free right of the Government of the India to practice or to require the licensee to grant sublicenses to responsible applicants, on reasonable terms, when necessary to fulfill health, safety or security needs of the country.

LIST OF WORKING GROUP MEMBERS

1. Prof Raghavan Varadarajan, Indian Institute of Science (IISc), Bangalore (Chair)
2. Prof. Chandrabhas Narayana, Director, Rajiv Gandhi Centre for Biotechnology (RGCB), Thiruvananthapuram
3. Dr. Alka Sharma, Senior Advisor/Scientist 'H', Department of Biotechnology (DBT), New Delhi
4. Dr. Shirshendu Mukherjee, Mission Director, Biotechnology Innovation Research Assistant Council (BIRAC), New Delhi
5. Dr. Vinita Jindal, Chief Manager IP & Technology, Biotechnology Innovation Research Assistant Council (BIRAC), New Delhi
6. Dr. Susmita Chaudhuri, Assistant Professor, Translational Health Science and Technology Institute (THSTI), Faridabad
7. Dr. Niraj Kumar, Assistant Professor, Translational Health Science and Technology Institute (THSTI), Faridabad
8. Dr. Anil Kumar, Staff Scientist-IV, National Institute of Immunology (NII), New Delhi
9. Dr. Kalaivani Ganesan, Scientist 'F', Department of Biotechnology (DBT), New Delhi (Convenor)

Committee for reviewing Department for Promotion of Industry and Internal Trade (DPIIT) and Department of Expenditure (DoE) comments on DBT IP Guidelines

1. Shri. Vishvajit Sahay, AS & FA, DBT (Chair)

2. Dr. Alka Sharma, Scientist 'H'/Senior Advisor, DBT

3. Dr. Malathi Lakshmikumaran, IP Attorney, Executive Director and Practice Head, Lakshmikumaran & Sridharan Attorneys and Former Professor, TERI, New Delhi

4. Dr. Taslimarif Saiyed, CEO and Director, C-CAMP, Bangalore

5. Shri. Chaitanya Murti, Joint Secretary (Admin), DBT

6. Dr. Sundeep Sarin, Scientist 'G', DBT

7. Dr. Anamika Gambhir, Scientist 'G', DBT

8. Dr. Nitin Kumar Jain, Scientist 'F', DBT

9. Dr. Kalaivani Ganesan, Scientist 'F', DBT (Member Secretary)

Annexure - C

Series of meetings held for framing DBT IP Guidelines

S.No.	Events	Date
1.	Cabinet Secretary Meeting on "Patent practices and IPR issues for AYUSH academia and industry" – Presentation by Secretary, DBT	01st August, 2022
2.	Letter sent to Secretary, DPIIT on the existing practice and suitable reforms required	03rd August, 2022
3.	Discussion meeting with PMO	16th August, 2022
4.	Discussion meeting with PSA	23rd August, 2022
5.	Inter-ministerial Brainstorming meeting on IP, licensing and commercialization of public funded research	24th August, 2022
6.	Meeting with International Experts	29th August, 2022
7.	Constitution of Working Group and meetings	16th September, 2022; 03rd October, 2022 and 11th October, 2022
8.	Report of Working Group	27th October, 2022
9.	DPIIT Observations	01st February, 2023
10.	Committee to review DPIIT and DoE comments	7th March, 2023; 16th March, 2023; 19th April, 2023; 16th May, 2023; 03rd August, 2023
11	DBT IP guidelines approved by Hon'ble Minister	17th Aug, 2023

(MODEL FORMAT FOR MEMORANDUM OF AGREEMENT)

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this [Date of signing the MoA] day of Two thousand and twenty-three BY AND BETWEEN President of India, acting through Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or repugnant to the subject shall mean and include its successor-in-office and assigns) of the ONE PART;

AND

[Full Institution name], having its registered office in/at [Address of the institution] hereinafter referred to as [institution's acronym] (Which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

WHEREAS DBT being desirous of "[Title of the Project]" decided to support a project submitted by [Institution's acronym] along with "[acronym of institution 1, Institution 2, Institution 3…]" for the attainment of the objectives hereinafter described in the **Annexure I** and milestones & deliverables described in the **Annexure III**;

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the "[Title of the Project]"

NOW THE PARTIES HERETO AGREE AS FOLLOWS: -

1.0. ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of [sanctioned amount (in lakhs)] over a period of ..... years from the date of sanction of the project, to [Institution's acronym] for undertaking activities as detailed in Annexure I & Annexure III. Details of the funds to be provided are given in Annexure II.

2.0. ROLE OF [Institution's acronym] (Institute/NGO)

2.1. To provide their contribution of [NIL] for ..... years from date of sanction of the project as detailed in Annexure – II. *(if a jointly supported project)*

2.2. To provide existing facilities as mentioned in the project document.

2.3. To be responsible for accomplishing objectives identified and activities listed.

2.4. To recruit all scientific and non-scientific staff as sanctioned by DBT.

2.5. To prepare and submit all periodical reports and other documents that would be required by DBT.

2.6. To maintain a separate audit head of account for the grants received from DBT for the project.

2.7. To submit an annual audited statement of expenditure incurred under the project.

2.8. To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

2.9. The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such that the contract for engagement of the manpower shall run concurrently with the said project period only.

3.0 DURATION OF PROJECT

3.1 Duration of project shall be ___ years from the date the Project has been sanctioned by DBT.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 Every effort should be made by the institutes to disseminate know-how and transfer the IP emanating from public-funded research for the larger public good. All institutes should mandatorily report the details of their scientific outcomes - published articles, patents granted, technologies commercialized to DBT as per the formats provided for both completed and on-going projects. The outcomes are to be reported at the following links - https://dashboard.dbtindia.gov.in/sbt/publication/ & https://dashboard.dbtindia.gov.in/sbt/patents/

4.2 The Intellectual property generated from DBT-funded on-going and completed project by [Institution's acronym] will be the owned by the institution [Institution's acronym]. It shall be the responsibility of [Institution's acronym] to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copyrights, industrial designs, etc. The Intellectual property developed may be transferred by the institutions through review by their scientific advisory committees adhering to DBT IP Guidelines. The equipment acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned.

4.3 It shall be the responsibility of [Institution's acronym] to ensure that support of DBT is suitably acknowledged in the publications (papers, reports, etc.), products, technologies and the catalogues arising out of the PROJECT.

5. MONITORING

5.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

5.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

5.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of [Institution's acronym] for the grants received from DBT for this project.

5.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, [Institution's acronym] shall hand over all documents including technical details and equipment purchased related to the project.

6.0 DURATION OF MEMORANDUM OF AGREEMENT

6.1 This MoA will remain inforce for the duration of the project and until all claims are settled between DBT and [Institution's acronym]

7.0 ARBITRATION

7.1 In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice, and Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made there under shall be final and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be

deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

8.0. GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

IN WITNESS WHEREOF the parties hereto have signed, sealed and delivered this Agreement on the day, month and year first above written in presence of:

(To be signed by DBT officials)

Witnesses:

Signed by.....

1. Name and Official Seal

2.

for and on behalf of The President of India

(To be signed by Head of the Organization and Project Investigator)

Witnesses:

Signed by.....

1. Name and Official Seal

2.

for and on behalf of (Head of the Department/Division/Organization)

Annexure - I

Project Objectives

Annexure - II

Details of the Funds

Annexure – III

Quarter Wise Milestone Title(s) and Deliverable Title(s)