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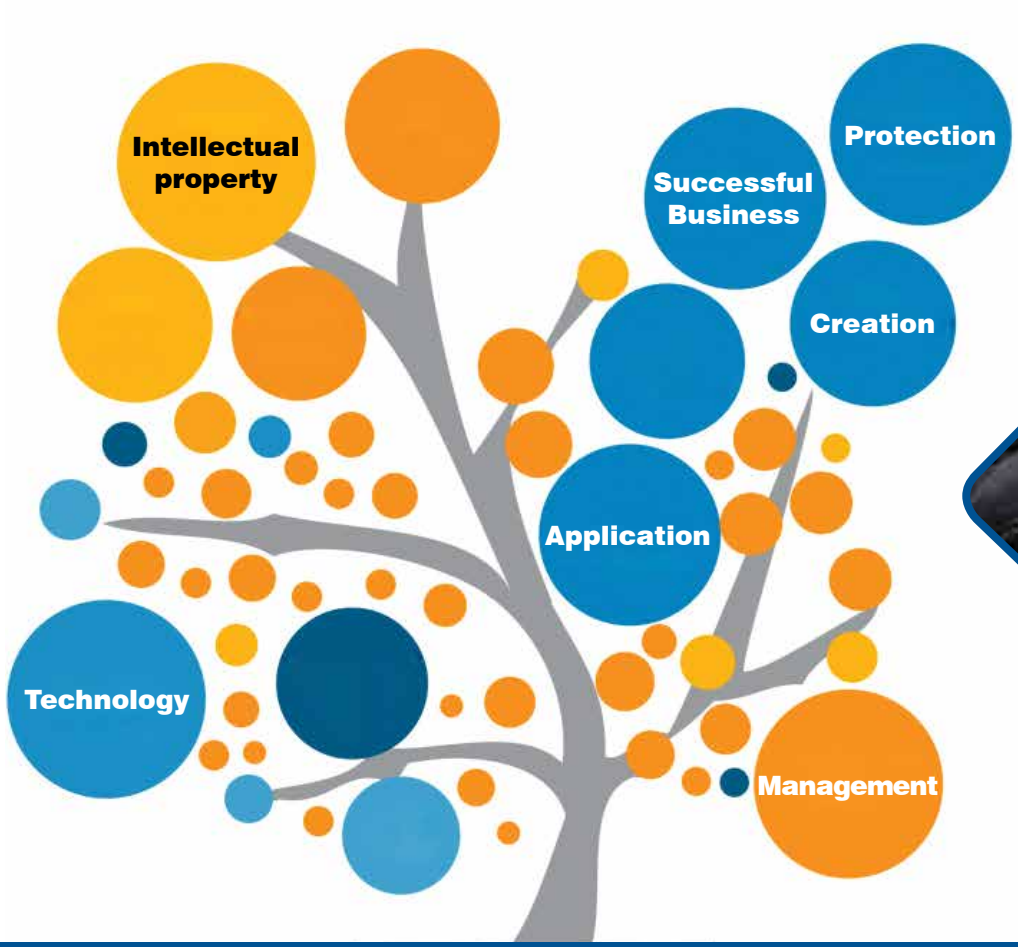

Intellectual Property and Technology Management

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Ignite Innovate Incubate
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chief editor's take

Intellectual property and technology management are the key strategic components for start-ups and SMEs to hold leadership position in a competitive bio-innovation ecosystem. The IP developed within India helps increase the innovation quotient of the country. In this regard, BIRAC extends support to start-ups and SMEs in providing a wide range of IP support through our various programmes including a focused program in providing assistance for filing national and global IP. BIRAC along with its regional centre, BIRAC Regional Innovation Centre (BRIC) extend help in FTO search and competitive analysis. Further, the IP division in BIRAC also helps to track the IP generated by BIRAC supported R&D projects and help formulate IP policies for academic and research Institutes. BIRAC also conducts IP workshops along with leading IP experts in the country in such that innovative enterprises become aware of the evolving IP issues nationally and globally.

BIRAC is aligned with the focused approach on IP issues with Government of India to boost innovations in start-ups and SMEs through programmes such as – SIIP (Start-ups Intellectual Property Protection) where BIRAC is a facilitator and others such as Make in India & Startup India.

One of the crucial elements in building an ecosystem is access to cutting edge platform technologies for Indian enterprises which can be leveraged in building globally competitive products. BIRAC continuously explores modalities to facilitate technology transfer in catalysing product development.

Over the four years, start-ups and entrepreneurs have generated 105 IP, commercialized 34 products/technologies and developed 31 early stage technologies through BIRAC's support.

The focused approach by BIRAC has helped in contributing to and boosting national programmes such as Make in India and Start up India. ■

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Prof. K. VijayRaghavan
Secretary, DBT, GoI & Chairman, BIRAC

Intellectual Property development & protection, technology transfer and its licensing play critical role in overall development of country's economy. Various programmes and schemes by Department of Biotechnology and BIRAC enable the innovators and start-ups protect their innovations and facilitate commercialization.

The Indian IP scenario has evolved rapidly over the last two decades and as a country we are now aligned with the WTO's IP regime which encourages innovation and protects innovators regarding ownership of their IP. The IP generated by BIRAC supported projects remains with the innovators. This sends a clear and a strong signal to the community of innovators regarding IP ownership issues.

There are two consistent trends that we have noticed, first increasing awareness in the Indian industry and academia regarding generation of new IP in India, the outcome of which is increased filing of IP from India thus highlighting the potential of Indian innovators, especially biotech innovators, in generating world class IP. Second, we notice increasing predisposition amongst academia and industry to collaborate in developing IP based technologies. These early visible trends have to be supported and amplified.

The Government of India has taken pro-active policy steps in encouraging Indian industry to focus on IP led R&D. The new Intellectual Property Rights policy has more clarity and uniformity about issues regarding Intellectual Property Right protection and technology transfer. The introduction of Patent Box is another positive step in the Indian IPR Policy that incentivizes IP focused R&D by reducing corporate tax on royalties from 30% to 10%. This has potential to transform the Indian S&T landscape.

DBT is aware of the need to boost several aspects of IP and technology transfer. It is with this intention that in our National Biotechnology Development Strategy (NBDS) 2015,we have explicitly stated an intent to establish new competent Technology Transfer Offices (TTOs) across the country as well as strengthen the existing TTOs. We are also cognisant of the fact that we need to train and build a cadre of technology transfer experts who are well versed in intricacies of IP, technology transfer, finance and negotiations.

BIRAC will play an important role in implementing many aspects of the NBDS 2015 strategy and we encourage interested stakeholders to explore partnership with us. ■

BIRAC Innovators Meet 2016

Innovating for a Better Tommorrow

BIRAC organized its 5th Innovators Meet at New Delhi (22nd-23rd September 2016).

The congregation witnessed the confluence of around 300 Scientists, Entrepreneurs, Industry Experts and Policy-makers.

Theme of the meet was *"Biotechnology Innovation Ecosystem: Strategizing for the Next Leap"*.

Inaugural Session

The innovators meet was kicked off with traditional lighting of the lamp. The dignitaries included – Dr. Harsh Vardhan, Hon'ble Minister of Science & Technology & Earth Sciences, GoI as Chief Guest; Shri Y.S. Chowdary, Minister of State for Science & Technology and Earth Sciences, GoI, as the Guest of Honor; Prof. K. VijayRaghavan, Secretary DBT & Chairman BIRAC; Ms. Yigal Erlich, YOZMA Group, Israel; Dr. Renu Swarup, Senior Adviser, DBT & MD, BIRAC; Mr. Sujay Shetty, PwC.

Dr. Renu Swarup welcomed the dignitaries and delegates. She highlighted BIRAC's role in providing an ecosystem to the innovators while emphasizing on the future strategies to nurture biotechnology ecosystem, eventually contributing to economy. She also outlined the role of national and global partnerships in nurturing this ecosystem across the nation.

Sh. Y. S. Chowdary spoke about the gap between industry and academia and highlighted the need for translational research to bridge this gap.

Dr. Harsh Vardhan, congratulated the innovators and underlined the various programmes initiated by Government of India to support passionate innovators with promising ideas. He cited the example of passion by story lining the polio eradication programme.

Mr. Sujay Shetty, PwC, gave a brief presentation on "Make In India for BIO-TECH The way Forward" report, prepared in collaboration with BIRAC.

Delivering the keynote lecture, Mr. Yigal Erlich, Founder, The Yozma Group, Israel spoke about the journey of Israel becoming a startup nation and his vision of accelerating start-ups and have maximum number of Entrepreneurs in every field. He elaborated about the funding scenario and success ingredients contributing to Israel Growth.

Prof. K. VijayRaghavan, in his theme address highlighted the need of regulations to be aligned with innovation ecosystem with great emphasis on Tax and Patent regime. He also underscored the example of Israel start-up ecosystem's key strategies which may help in developing India's Biotech Innovation Ecosystem.

As a first, the innovators meet included two new initiatives - a Conversation Session with Investors, and, Innovation Market Place.

Conversation with Investors

The Conversation with Investors session was an interaction between a group of high level investors having area specific expertise, and 20 startups. The investors included Ms. Padmaja Ruparel, IAN; Mr. Aditya Sharma, Unitus Seed Fund; Mr. Krishnan Neelkanthan, Ankur Capital; Mr. Ashwin Raghuraman, CIIE; Mr. Ramesh Byrapaneni, Endiya. Facilitated by Dr. Satya Prakash Dash, BIRAC and Dr. Taslimarif Saiyed, C-CAMP the interaction brought startups, entrepreneurs and investors at a common platform for innovators to discuss business models and understand investors' perspectives about their business plans.

Innovation Market Place

BIRAC has created "Innovation Market Place" to highlight the products/technologies developed through BIRAC support. 23 Innovators were selected to not only showcase their technologies/ prototype to investors but also to network with participants from Industry and academia. Dr. Shirshendu Mukherjee, PMU-BMGF, BIRAC, introduced the session to all the innovators, mentors and investors. Each innovator was invited to pitch for 1-2 minutes about their innovation to the audience. The investors torched upon the challenges faced generally in the early phase of establishing ventures, and suggested innovators to strategize their commercialization plans in advance to avoid the gap between product readinesses and launch. They urged innovators to do market analysis in advance, focusing on future perspective for their business plan.

Poster Session

In the poster session running parallel to the Innovation Market Place. 45 posters from BIRAC grantees from various schemes of BIRAC were presented. The posters were evaluated by a team of 4 Experts namely Dr. Amulya Panda (NII), Dr. CM Gupta (CDRI), Dr. Robin Mukhopadhyay (Former Scientist at ACTREC) and Dr. Rita Mulherkar (Former Scientist at ACTREC).

3D Prosthetic Technologies won the best poster award for "Developing and testing certain 3D printing technologies to produce innovative limbs at affordable costs for the disabled in India". Two appreciation awards were given to 'Saveer Biotech' and 'Windmill Technologies' respectively.

BIRAC INNOVATOR AWARDS

The innovators meet was also the occasion to present the prestigious BIRAC Innovator Awards. The awards were given broadly in three fields including Agriculture, Healthcare and Industrial Biotechnology. The awardees were:

- *Agriculture: Nirmal Seeds Pvt. Limited, Pachora, Jalgaon for "Development of nutritionally improved mustard (Brassica juncea) varieties/hybrids", in collaboration with The Energy and Resources Institute, New Delhi.*
- *Healthcare (Therapeutics): Serum Institute of India Pvt. Limited, Pune for "Development of Polysialylated Erythropoietin".*
- *Healthcare (Devices & Diagnostics): Panacea Medical Technologies Pvt. Limited, Bengaluru for "Development of Flat Panel Computed Tomography (FPCT) machine".*
- *Industrial Biotechnology (Technology Development): India Glycols Limited, Kashipur for "Validation of technology for production of 3000 Litre ethanol/day", in collaboration with DBT-ICT Centre for Energy Biosciences, Mumbai.*
- *Industrial Biotechnology (Product Development): Aumgene Biosciences Pvt. Limited, Surat for "Scale-up & commercialization of recombinant lipase enzyme".*

New Publications launched in the meet are:

BIRAC Innovators Compendium• Report on Make In India for Biotechnology-The Way Forward• Success stories of BIRAC Innovators• BIG booklet•

Panel Discussions

Innovators meet provided a platform for knowledgeable and thoughtful discussions on possible strategies and implementation plan. The panelists outlined possible ways to achieve next transition for the Indian biotechnology enterprise with support of industry, academia and government. In her opening remarks Dr. Swarup emphasized on BIRAC's role in mentoring and funding to a number of innovators across the nation. She envisioned having opportunity to extend BIRAC's support by means of partnerships to innovators across the nation and connect them globally. The factors involved in nurturing the ecosystem were discussed as highlighted below: Prof. K. VijayRaghavan emphasized on developing a unique model across the country suiting the Indian requirements, partnerships (global and national) and positive intervention by Government, providing the risk capital for technology development, infrastructure, facilitating tax incentives to promote and nourish innovation ecosystem and entrepreneurial development. Dr. Arun Chandavarkar, Biocon, talked about evolution of Biocon from a startup to a global company and strategies behind it. He said that there is requirement of identifying the areas in which Government can intervene such as healthcare and healthcare deliveries which needs immediate attention. Prof. Ashutosh Sharma, Secretary, DST, described the entrepreneurship development programmes by Government to support innovators of all ages and at all stages. He elaborated NIDHI (an initiative by DST) and its envisioned plan and need of quantum leap to create a turnaround number of 150, 000 start ups. Dr. Sarvajna Dwivedi, TiE Silicon Valley, suggested that Startups should consider swadeshi patients and swadeshi needs and focus on Swadeshi BioPharma. Dr. Arjun Surya, Curadev Pharma, pointed out that Regulatory ecosystem needs to be strengthened and BIRAC should work with the states in a synchronized and sustained manner to continuously promote biotech ecosystem. In conclusion, strengthening innovations through partnerships, Quality education along with government intervention for funding and support would be the key strategies to build strong Biotechnology Innovation Ecosystem.

Day 2

The second day kick started with a Plenary Talk by Dr. Sarvajna Dwivedi, TiE, Sillicon Valley and Chief Scientific Officer of Pearl Therapeutics. The esteemed guest in his plenary talk mentioned about his endeavor to establish Pearl Therapeutics and recent advancements of its existing products.

In closing remarks, Dr. Renu Swarup concluded the recommendations:

1. Focus on increasing Industry-academia interaction.
2. Government and all stakeholders should come forward to take risks for developing Biotech Innovation Ecosystem. ■

Panel I **Injecting capital for the Next Leap: Investor's Perspective**	The panel focused on identifying various source of funding at different stages of entrepreneurship and emerging landscape of private venture funding in the country especially in the life science arena. The panel recommended that Startups should have potential technology with focus on problem solving and it should strategize to raise funds from investors with sector expertise. **Panelists:** Ms. Padmaja Ruparel, Indian Angel Network (IAN); Mr. Siraj Dhanani, InnAccel; Mr. Krishanan Neelkanthan, Ankur Capital; Mr. Ashwin Raghuraman, CIIE **Moderator:** Mr. Ramesh Byrapaneni, Endiya Partner
Panel II **Boosting Technology Development and Translation from Academia-Bridging the gaps for Technology Transfer**	The panel discussed the existing gaps between industry and academia and suggested possible solutions for bridging the gap between them and strengthen technology transfer in India. The key outcomes were:1. Organize more networking events and government should intervene for making favorable IP Policies and establishing technology transfer offices to encourage and facilitate innovations and tech transfer processes. **Panelists:** Mr. Deepanwita Chattopadhyay, CEO, IKP, Hydrabad; Prof. P. Madhusudan Rao, IIT Delhi; Prof. Navkant Bhat, IISc **Moderator:** Prof. Jayesh Bellare, IIT Bombay
Panel III **Disruptive Technologies for the Next Leap- how will emerging technology influence Indian biotechnology growth?**	The panel comprised of brief presentations by key experts on disruptive technologies – Prof. Amaresh Chakrabarti, IISc presented on Internet of Things (IoT) followed by Dr. Jugnu Jain, Sapien Biosciences & Saarum Sciences on Personalised Medicine and Mr. Rajesh Urkude, TCS on Precision Agriculture. Mr. Rahul Prakash from Crop In, presented his company profile working on precision agriculture techniques and use of Smart Farm to estimate the yield per hectare area by analysing soil, weather and other farming conditions.

Personalized Medicine

Tailored Therapies

Vijay Chandru
Chairman & M.D
Strand Life Sciences

Vijay Chandru is an academic entrepreneur and co-founder of Strand life Sciences, which is one of the earliest spinouts from Indian Academia. He was recognized as a 'Technology Pioneer' by the World Economic Forum in 2006.

He trained in electrical engineering from BITS Pilani and holds a PhD from MIT USA. Following which, he held faculty positions at Purdue USA and then at IISc Bangalore. He is a Fellow of Indian Academy of Sciences (1996), and received MCIT Dewang Mehta Award for Innovation in IT (2001) as well as the President's Medal of INFORMS in 2006. He currently holds adjunct faculty position at IISc, Bangalore.

He was the Honorary President (2009-2012) of ABLE and also serves as an advisor to the Karnataka State Council on Science & Technology and on the Atal Innovation Mission (NITI Aayog).

How did the field of personalized medicine emerge? What were the early beginnings?

Vijay Chandru (VC) : Personalized medicine as a practice has been around since the time of Hippocrates, who said, "It's far more important to know what person the disease has than what disease the person has". The early beginnings of personalized medicine were probably influenced by the field of hematology for compatibility testing of blood transfusion between donors and patients. Around the 19th century, advances in the field of microbiology and biochemistry allowed us to understand the underlying cause of disease and its biology. More recently, the discovery of the DNA structure by Franklin, Watson & Crick helped us understand diseases at a genetic level, which has significantly contributed towards the emergence of personalized medicine.

What factors have shaped the emergence of personalized medicine?

VC : The development of Trastuzumab (Herceptin®) in 1998 for treating *HER2* positive breast cancers heralded the emergence of personalized medicine. Our understanding of cancer genetics helped develop a drug that could target a very specific population with a disease subtype. Later, the discovery and success of Imatinib to treat chronic myelogenous leukemia (CML) proved to be a turning point for developing targeted therapies.

An example of a blocking use of pharmacogenomics involves people infected with the human immunodeficiency virus (HIV). Before prescribing the antiviral drug abacavir (Ziagen), physicians now routinely test HIV-infected patients for a genetic variant that makes them more likely to have a bad reaction to the drug.

However, the most important factor for the emergence of personalized medicine and its present influence is due to the completion of the Human Genome Project in 2003, and the advent of Next-Generation Sequencing (NGS) which have created a downward spiraling effect on the cost of sequencing and a gradual abandonment of the "one shoe fits all" approach to treatment decisions.

The world of healthcare now has a choice on whether to continue to singularly focus on a very successful century of "curative medicine" or to blend in "prospective healthcare" which involves personalized, predictive, preventive and participative care.

How is the industry (of personalized medicine) playing out across the globe? especially the US, Europe, and Japan? What, if any, are the ethical, regulatory issues and financial-legal issues?

VC : The personalized medicine industry is an emerging space across the globe. The main players in this area are pharma companies that develop targeted therapies for oncology, or orphan drugs for rare inherited conditions, and genomic testing laboratories that provide genetic or pharmacogenomic testing. In the US for example, some of the early movers in genomic testing are Myriad Genetics, Foundation Medicine, and Invitae.

Perhaps, the US is one of the most matured markets for personalized medicine, because it has a supportive ecosystem. They have been able to create an end to end program or continuum for personalized medicine, starting with discovery in the laboratory, to the application of that discovery in the clinic (bench to bedside). The efforts in the US personalized medicine space are augmented by large government funding programs such as the President's Precision Medicine Initiative (PMI), which encourages research & discovery by academia or commercial enterprises. These discoveries can lead to the development of drugs and therapeutics by pharma. In the UK, similar efforts are underway through the government's program to sequence the genomes of people under the 100,000 Genomes Project.

Some of the issues that the industry faces across the globe are related to unclear regulations or non-availability of guidelines for the development and usage of laboratory developed tests (LDTs). This poses a challenge when it comes to proving the efficacy or clinical utility of genomic tests in the clinical care setting, and the corresponding health insurance coverage.

While countries such as the US and the UK have government supported programs, in addition to private players supporting precision medicine R&D and commercialization, globally, the industry has relied on exclusive funding by private players which has not accelerated the progress of precision medicine due to financial considerations.

Patient privacy and data protection is also a crucial area of debate across the globe. For example, Strand's technology platforms follow the best practices and are certified to be HIPAA compliant. If labs and diagnostic companies are regulated to follow the regimes of NABL, CAP, and ISO in a genuine way, these will automatically ensure security and ethical use of data. At Strand, we have an internal Institutional Ethics Review Board that oversees and clears all our processes as well as the specific tests that we launch.

It may be time for a global legislation along the lines of a "genomic information non-discrimination act" (GINA was passed in the US in 2009) that would protect citizens from misuse of their genetic data.

Has personalized medicine, especially in oncology, become the standard of care in the US? What policy initiatives are driving the growth of personalized medicine in the US & UK?

VC : Personalized medicine has had a major impact in US healthcare, especially oncology. The discovery and success of Trastuzumab and Imatinib allowed the adoption of personalized medicine for oncology. Targeted therapies coupled with companion diagnostics have become a standard of care for many of the cancers (lung, colon, melanoma), and sometimes offered as the first line of therapy for patients.

Another important policy reason for early adoption is the support of payers, both public payers like Medicare in the US and NHS in UK and private insurance companies that reimburse the pharma, laboratory, clinic or patient as the case may be for both testing and treatment involved in the practice of personalized medicine in these countries.

The success of such landmark events has encouraged the US and the UK to undertake policy initiatives driving the growth of personalized medicine. The major driver has been the government funding of genomics research and drug development. Programs such as the PMI, Cancer Moonshot, and 100,000 Genomes are aimed at accelerating the promise of personalized medicine.

Knowing that the effects of such large-scale projects would generate enormous amounts of information, the FDA has built up infrastructure to tackle such challenges. For instance, they have set up numerous task forces, committees, programs, specialized laboratories, and collaborative projects with industry to advance the knowledge in genomics, and accelerate drug development and approvals.

Laboratory regulations and standards such as CAP and CLIA have been set up to ensure that there are standardizations and adherence to quality across genetic testing laboratories.

Strand has been a pioneer in personalized medicine in India. What are your thoughts on the growth of this industry in India? What are the hurdles?

VC : Strand, with its history of excellence in innovative genomic research and solutions, pivoted into the genomic testing/ personalized medicine space in India about four years ago. During that time, there was neither market nor an understanding of genomic testing. We had to start the process of market development from scratch, by educating the medical community about genetic tests, and its benefits for effectively managing diseases such as cancer and inherited genetic disorders. Strand has had the opportunity to pioneer the complex field of genomic testing in India by offering robustly validated assays run in CAP/ISO certified environments. Along with us, there are few other players in the market offering genetic tests. We believe that we will continue to be the market leader in the space of complex multi-genic testing in India and will grow the market for the whole field. This is an emerging area of personalized and precision medicine which is happening now in India just as it unfolds in the West as well.

If you see the West, the treatment landscape is slowly but steadily shifting from a 'one-size-fits-all' approach to a personalized approach. Even in India, we see this trend taking shape in pockets. This approach will grow to become widely adopted mainly due to the genetic diversity in the Indian population. In oncology, for example, physicians have started adopting the personalized medicine approach to treating their patients. These indicators augur well for the growth of this industry.

However, a lot of work needs to be done to reach a stage where personalized medicine can become a mainstream approach in the clinic. Physicians mainly cite the lack of guidelines or published clinical utility data for them to adopt and follow while treating a patient. Moreover, most of the data that is published in the medical literature are based on Caucasian populations. We will need to design and carry out India-specific population studies in order to ensure that the genetic variants that are identified are relevant and targetable in terms of treatment or disease management. The good news is that Strand has already written clinical reports for over 5000 patients in India and several publications are out and in press that are beginning to shed light on the clinical genomics of South Asian ethnicities.

However, there is the universal challenge that we have only learned to interpret about 20% of the genes in human DNA. So there is a lot of signal from genetic testing that no body knows how to interpret. Knowledge is expanding rapidly and highly trained and large scale knowledge curation is required to address this challenge. Strand has a very special approach to this, our secret sauce, which has made us a global leader in interpretation.

From an affordability perspective, the cost and availability of targeted therapies in India put the promise of personalized medicine out of reach for a large section of the population. Unfortunately, the cost of genomic testing is also significantly on the higher side due to import duties that add to the cost of reagents that are required to run diagnostic assays. However, at Strand we are trying to reduce the cost burden for patients by innovating in both chemistry of reagents and in the use of advanced artificial intelligence (AI) based pipelines to make a huge impact on the affordability of our tests.

What elements should come together for greater adoption of personalized medicine? What role can Government, industry, and civil society play for this industry to grow in India?

VC : Strand is participating in bringing personalized and precision medicine to the Indian healthcare establishment in a responsible, ethical and scientifically validated manner. We are working with the medical establishment to define new guidelines for bringing this practice into the mainstream of medical practice, and are carrying out exceptional translational research with our partners in Mazumdar-Shaw Medical Center at Narayana Health which will put personalized and precision medicine in India on the global map. India has been a global leader in affordable medicines, affordable surgeries, and affordable hospital care. There is no reason we cannot be a global leader in affordable personalized and precision medicine.

In order to realize this vision, the government should play a major role in providing research grants or funding to undertake genetic studies based on the Indian population. The government should also set up India-specific guidelines for the development of diagnostic tests, accelerate drug development, and guide the industry appropriately.

The medical community should look at the advantages of moving towards a preventive healthcare model, rather than a reactive model. An example would be *BRCA* testing to identify if an individual is at risk of developing breast cancer over their lifetime. Knowing a person's risk in advance can help in preventing or managing the disease, which will not only help in the well-being of the patient but also avoid unnecessary costs with regard to treatment. The entire community should also come together and set up guidelines for the practice of personalized medicine in their respective specialties. At the medical education level, administrators should seriously consider incorporation of genetics as a curriculum in the undergraduate medical program. In the next few weeks, Strand will publish compilation of detailed case-studies which will be a great beginning in medical genomics pedagogy for Indian healthcare professionals.

The industry will have a responsible role to play in the advancement of the state of knowledge in this space by conducting novel research and extensive clinical validation studies. They will also have to work with the government and insurance providers to figure out an approach to ensure that these life changing tests and drugs are covered by insurance so that every citizen in the country can reap the benefits of advanced medical care. Lastly, the industry can play a significant role by educating the civil society by creating awareness about the benefits of personalized medicine.

How do you see the field evolve globally in the next 5-10 years?

VC : In personalized and precision medicine, genetic testing can help with choosing the right drug and the right dose for the individual patient. This has been effectively demonstrated in the care of many cancer patients. There are also great opportunities in preventive care of people whose risks for diseases can be estimated from genetic dispositions and appropriate preventive measures including many lifestyle changes, can be effectively brought to bear. Cardiac disease, Neurodegenerative, and Cardiovascular disease are particularly significant in adults and seniors.

Countries that have already adopted or adopting personalized medicine will see themselves in a very advanced position in the coming years. Their health outcomes and economics will be defined by the success of personalized medicine. In addition, global initiatives such as the PMI, 100,000 genomes, and other initiatives will culminate in the next 5-10 years, providing the much-needed validation and utility for the widespread clinical adoption of personalized medicine.

In the future, electronic health records will be linked to our personal genomic data from which insights can be derived for tailoring treatments and providing health advice. The field of personalized medicine will eventually evolve towards a point where our health is not just managed and treated by physical symptoms or broad molecular observation, but a combination of genomic, proteomic and epigenomic data points, coupled with medical imaging, minimally invasive methods such as liquid biopsies, and interventions such as gene therapies. ■

Implications of the Biological Diversity Act, 2002 on Seeking IP Registrations

Valuing Diversity

Malathi Lakshmikumaran

Malathi Lakshmikumaran has more than 30 years of experience in the field of Biochemistry and Molecular Biology with an expertise in Plant genomics, DNA fingerprinting, and Genetic Transformation. Prior to joining Lakshmikumaran and Sridharan attorneys, she served as the head, Centre for Bioresource & Biotechnology Division in The Energy and Resource Institute (TERI) for a period of 17 years. At present, she serves as a Director and heads the life sciences group at the IP division of the firm. She is a registered Patent Agent and has been actively engaged in preparing, filing, and prosecuting of patent applications, mainly in the area of Pharmaceutical, Chemical and Biotechnology. She is also active in the area of Biodiversity and Traditional Knowledge.

The Biological Diversity Act, 2002 (BDA) was enacted by the Indian Parliament in the year 2002 and came into force entirely in the year 2004. This legislation was enacted to give effect to the United Nations Convention on Biological Diversity (CBD), held at Rio De Janerio in 1992. India signed the CBD on 5th June 1992, ratified it on 18th February 1994 and became a party to the CBD on 19th May, 1994.

The Biological Diversity Act was introduced with the principal objects of conserving Indian biodiversity, regulating access to Indian biological resources[1] and ensuring that benefits arising from exploitation of Indian genetic resources are fairly and equitably shared. To that end, several regulatory approvals have been put in place in the legislation for Indian and foreign persons to access and use Indian biological resources and violations of these regulatory approvals are enforced through criminal sanctions. The approvals are to be sought from National Biodiversity Authority (hereinafter the NBA), a statutory body established under the Act at the national level. Several State Biodiversity Boards (SBB) and Biodiversity Management Committees (BMC) have also been established under the Act at the state level and local level, respectively.

One of the most important Notifications issued under the Act, is the Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014 ("ABS Regulations") that was notified on 21st November, 2014 by the NBA under the aegis of the Ministry of Environment, Forests and Climate Change. This notification was issued in pursuance to the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the Convention on Biological Diversity, which came into force on 12th October, 2014. The ABS Regulations contain an Annexure I to be used as a guide in assessing benefit sharing obligations. This Annexure contains the various types of monetary and non-monetary benefits that could be shared and are essentially adopted from the Annexure to the Nagoya Protocol. The benefit sharing obligations and approvals in general are implemented through a mutual agreement between the NBA and the applicant seeking approval. In granting such approvals there levant SBBs and BMCs recognized under the BDA are consulted. While the introduction of the ABS Regulations provided some important and much needed clarity on benefit sharing obligations under the Act and streamlined the procedures for seeking approval under the Act, to access and exploit Indian biological resources and associated traditional knowledge; there still exists some gaps to be filled. In particular, there exists need for clarity on the scope of the term 'conventional breeding' as stated in the exemption under Regulation 17(d) of the ABS Regulations which states that access of Indian biological resources for 'conventional breeding' or traditional practices in agriculture, poultry, dairy farming, animal husbandry or beekeeping do not require the approval of the NBA or the SBB. While the definitions provided under the Act make it clear that 'conventional breeding' does not amount to 'commercial utilization'[2]; however, it is still not clear as to whether 'conventional breeding' could amount to 'research'[3] or 'bio-survey and bio-utilisation'[4] which activities when undertaken in respect of Indian biological resources require the prior approval of the NBA or SBB, as the case may be.

IPR Implications under the Act

While Section 6 of the Act mandates that prior approval of the NBA is required before applying for an Intellectual Property Right in respect of any invention which is based on research or information on Indian biological resource, it also provides that in a scenario where a person has applied for a patent for such an invention without the previous approval of the NBA, the approval may be obtained after the acceptance of the patent but before the sealing of the patent by the concerned patent authority.

It is pertinent to note that there exists no corresponding provision under the Patents Act, 1970 that mandates a previous approval of the NBA for obtaining the registration of any patent claiming an invention based on Indian biological resources. The only reference that the Patent Act, 1970 makes in respect to seeking the approval or permission of any authority before the grant of a patent for an invention based on research or information on Indian biological resource, is in the form of a declaration[5] as part of Form 1 (the requisite form to be filled for applying for a patent application under the Patents Act, 1970) provided under the Second Schedule of the Patents Rules, 2003. Thus, there exists no basis for the Indian Patent Office under any substantive provision of the Patents Act, 1970 to direct applicants to obtain the necessary approval from the NBA, albeit a declaration which finds mention in a Schedule to the subordinate legislation (Patents Rules, 2003) framed under the Patents Act, 1970. It is observed as a matter of practice that the Indian Patent Office is strictly enforcing the mandate under Section 6 of the Act, such that patent applications claiming inventions

that are based on Indian biological resources do not proceed to grant until the requisite approval is obtained by the applicant from the NBA. Further, given the slow prosecution rate of Form III applications under Section 6 of the Act, by the NBA, many patent applications are stuck in limbo awaiting the NBA approval despite having complied with all the provisions of the Patents Act, 1970.

In order to overcome this logjam, there is a general consensus among patent attorneys that the two statutes, that is the Biological Diversity Act, 2002 and the Patents Act, 1970 need to be harmonized such that suitable amendments are made to the latter that allows for a formal procedure to be established where the authorities under both statutes meet at regular intervals to ensure that patent applications claiming inventions based on Indian biological resources proceed to timely grant subject to the payment of appropriate benefit sharing components under the ABS Regulations as determined by the NBA. ■

[1]Section 2(c) "biological resources" means plants, animals and micro-organisms or parts there of, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material; Section 2(p) "value added products" means products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form.

[2]Section 2(f): 'commercial utilization' means end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance,cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crop sand livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming,animal husbandry or bee keeping;

[3]Section 2(m): 'research' means study or systematic investigation of any biological resource or technological application, that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use;

[4]Section 2(d): bio-survey and bio-utilization' means survey or collection of species,subspecies, genes, components and extracts of biological resources for any purpose and includes characterization, inventorisation and bioassay;

[5]One of the Declarations in Form 1 under the Second Schedule to the Patents Rules, 2003; "I/We the applicant(s) hereby declare(s) that: - The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/us before the grant of patent to me/us."

IP Strategies for Start-ups

Ravi Bhola

Ravi Bhola chairs the patents practice in K&S firm. He has handled filing and prosecution of several patent applications in diverse areas such as biotechnology, bioinformatics, software, nanotechnology, pharmaceuticals and engineering. He is also active in patents and designs issues ranging from licensing, assignment, pre- and post-grant oppositions, freedom to operate, technology landscaping, due diligence etc.

Shreya Dave

Start-ups have often been recognised by their creative visions, out of the box thinking and bold strategies. It has been observed by industry experts, that start-ups are more likely to take a strategic market risks as compared to a well-established Fortune 500 company. Owing to this tendency, business model of start-ups tends to be more innovation centric.

Intellectual Property (IP) becomes a core asset for many of these start-ups and protection of the same takes paramount importance thus pleading the need for an efficient IP strategy and IP Management thereunder.

IP Strategy as depicted in Fig 1 is a step by step process starting with creation of IP, identification of the Portfolio, monetizing IP, valuation and IP Audit, structuring the IP assets bearing in mind the long-term targets of the organization as well as market dynamics.

It is prudent for start-ups to maintain and grow their IP portfolio post identification, protection and valuation of the same.

Speaking of the Indian patent scenario pertaining to start-ups, it becomes essential to refer to the criteria laid down by DIPP (Department of Industrial Policy & Promotion) for any entity to be qualified as a 'start-up':

1. more than five years have not lapsed from the date of its incorporation or registration;
2. the turnover for any of the financial years, out of the aforementioned five years, did not exceed rupees twenty-five crores; and
3. it is working towards innovation, development, deployment or commercialisation of new products, processes or services driven by technology or intellectual property.

There are however, certain limitations also placed on these criteria one of which being that if an enterprise/entity qualifying the aforementioned criteria is formed by restructuring or demerger of previously existing entities, the same would not qualify as a start-up. Under the amended Patent Rules 2016, several provisions have been introduced to encourage patent filings and in turn innovation by start-ups. Some of these are –

- **Discount in official fees:**
  Start-Ups are provided an 80% rebate in filing fees of patents vis-à-vis other companies.
- **Expedited examination:**
  Expedited examination can be requested by start-ups and entities for whom India is the International Search Authority. In expedited examination, it has been witnessed that after filing request for examination, applicants have received the First Examination Report just within a span of around three months. This in turn, accelerates the grant of patent and the right underlying thereunder.

Given that a lot of start-ups are focussed on innovation and technological advancement, it is advisable to file a provisional application in order to secure priority over the claimed inventions. In a scenario where there are multitude of competing technologies evolving every day, securing priority rights gives a considerable edge in the relevant market. It should be borne in mind that when the underlying invention relates to the field of life science or biotechnology, it is essential to showcase that the product or process invented is not a mere discovery. Emphasis must be put on the human intervention that led to such an invention.

In addition to filing an Indian provisional application, attempts can be made to secure patent rights in several jurisdictions, via either Conventional route or PCT (Patent Cooperation Treaty) route. It should be noted that start-ups, while opting for the PCT route, may consider selecting India as their International Search Authority (ISA) and International Preliminary Examination Authority (IPEA) owing to relatively lower official fees. Additionally, a start-up may look at filing regional application for cost-effective protection. For example- One single patent application for European Patent Organization (EPO) would render patent protection in more than 40 countries including major markets like United Kingdom, Germany, France, Italy, etc. Similarly, a single application made under African Regional Intellectual Property Organization (ARIPO) would secure protection in 19 counties in the same way as a single application under Gulf Cooperation Council (GCC) would in 6 countries.

However, before using any new technology for commercial use, it is essential that a thorough analysis of its freedom to operate (FTO) is undertaken. Freedom to Operate (FTO) is the ability to proceed with commercialization of a new product or process with a minimal risk of infringing the unlicensed intellectual property (IP) rights of third parties. FTO is usually used to determine whether commercialising a product can be done without infringing valid intellectual property rights of others. Since IP rights are specific to different jurisdictions, a "freedom to operate" analysis should relate to particular countries or regions where a start-up wants to operate.

It is further required to be aware of many regulatory compliance requirements with respect to Biological Diversity Act, 2002, Competition Act, 2002, etc. For example - Grant of patent in certain situations is subject to approval from National Biodiversity Authority or existence of certain restrictive conditions in a license agreement can be possible defences to infringement action. Compliance to these allied enactments is crucial as non-compliance in certain cases can lead to commercial loss.

Considering that for most of these start-ups, the major assets creation is that of intellectual property, carrying out thorough IP valuation would give an in-depth idea of the net worth of the technology created. IP Valuation is conducted using various methodologies including:

- **Quantitative Methodology**
  For Example – Cost based method, Market based method, Income based method, etc.
- **Qualitative methodology**
  Depending on life cycle of technology, geographical/ jurisdictional coverage, SWOT (Strength, Weakness, Opportunities, Threats) Analysis.

Further, it is a prudent idea to have multiple layers of IP protection. For example- For a novel device; the technology can be covered by patent protection, its aesthetic appearance can be covered by design protection, while its manufacturer can be recognized by trademark protection. It is pertinent to note here that with respect to software based inventions, copyright registration is usually not recommended owing to a requirement of disclosing the source code. However, existence of inherent copyright in certain works can be leveraged for enforcement in case of infringement.

An effective IP strategy would go a long way in increasing the valuation of an entity's IP assets. Higher the value of IP assets, higher is the bargaining power an entity would have in any acquisition or merger. There have been numerous IP strategic acquisitions in the recent past. It is hence advisable for start-ups to develop a certain critical set of patent portfolio for effective traction and valuation.

Further, one of the best modes of commercializing IP for start-ups is to license it out. The License-out business model has gained a lot of traction for many of these start-ups. In this kind of business model, an inventor obtains IP protection but then licenses it out and the licensee is required to carry out the commercialization activities. Hence, start-ups themselves need not engage in activities like production and distribution. In this manner, inventor enjoys royalty based on commercialization carried out by the licensee. It is however essential to be wary of certain crucial aspects that come tagged with this model, the most important one being clear title of the IP licensed out. Although seemingly an obvious aspect, various potential litigations can crop up in cases on unclear title.

Lastly, it should not be forgotten that if there ever was an age of innovation and intangible assets, it is this! ■

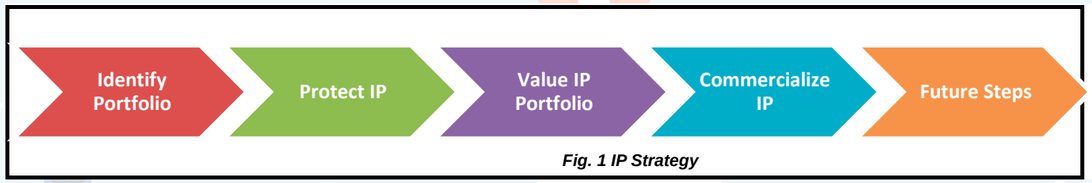

Fig. 1 IP Strategy

Grand Challenges India

Achieving Healthy Growth Through Agriculture and Nutrition

The Grand Challenges India (GCI) initiative is a mission-directed research approach collaboratively supported through a Memorandum of Understanding (MoU) between the Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India (GoI), Bill and Melinda Gates Foundation (BMGF) and United States Agency for International Development (USAID) to improve public health and beyond. Research efforts under this initiative cater to national and societal needs, and are aimed at accelerating progress and ensuring that advanced technologies should reach the developing countries that need them the most.

Program Management Unit at BIRAC

The Program Management Unit housed at BIRAC (PMU-BIRAC), was created in collaboration between the Department of Biotechnology (DBT) and the Bill and Melinda Gates Foundation (BMGF) to jointly administer the Grand Challenges India (GCI) framework. PMU-BIRAC works closely with strategic partners to identify and support scientific and technological opportunities with clearly articulated governance and implementation principles. This unit is also supported by USAID & Wellcome trust.

Since its inception, three calls have been launched under the GCI initiative.

The first initiative **'Achieving Healthy Growth through Agriculture and Nutrition',** launched under GCI framework funded a portfolio of five India-led pilot projects. These projects seek to target the relationship between agriculture, nutrition, and health to reduce high incidence of low birth weight, early

Savitri Dasaraman, a beneficiary from the wetland cluster

stunting and wasting among Indian infants through a variety of interventions. Three projects have been successfully completed and two are nearing completion.

One of the funded projects piloted an interesting alternative farming concept. Dr. Kathiresan intended to propel the adoption of Integrated Farming System (IFS) models in the Chidambaram region (Cuddalore district) in the state of Tamil Nadu by demonstrating the effectiveness of innovative integrated farming models that help improve agricultural productivity and create avenues for empowerment of women in agriculture in both lowland and upland agricultural fields.

The impact assessment report indicates that there had been significant improvement in the nutritional status of the beneficiary women farmers. For instance, the blood haemoglobin count of the beneficiary of wetland/upland cluster(s) increased significantly in comparison to the control group.

The IFS system of farming has led to economic gains, which in turn led to better hygiene & health. The addition of manure and the complimentary pest and weed control from animal components of the farming system also resulted in reduced agrochemical use, making the produce organic.

'Thankfully we are easily able to feed our children a good amount of fish and seasonal vegetables, this integrated approach has tackled our finances too" says Savitri Dasaraman, a beneficiary from the wetland cluster.

The **second initiative**, **"Reinvent the Toilet Challenge"** encouraged grantees to explore the research and development of low cost, eco-friendly and efficient 'next generation toilets'.

This call was also targeted specifically for the Indian context, where economic and social challenges require innovative solutions that are tailored for the people of the country.

The call resulted in five projects being fully funded, with both Indian and international collaborators. Each of the selected projects addressed different aspects of the waste collection and management process.

The PMU-BIRAC team conducted site visits in November 2016 to assess the progress of the five projects under this call, against their milestones. The team conducted site visits in projects located in Bangalore, Trivandrum, Mumbai and Goa between 14th and 21st November 2016.

One of the grantees under this scheme, Eram Scientific Solutions, Kerala in collaboration with the University of South Florida, USA aims to develop and demonstrate an innovative sanitation and resource recovery solution for the slum areas in India, through the project titled 'Field testing of off-grid,

self-sustained, modular, electronic toilet for slums, with solar energy for Indian weather and integrated with mixed waste processing unit, with water, energy/ fertilizer recovery'. The first objective of the Project is to design and implement a novel public sanitation platform that meets the specific needs of slums through new designs in Eram's eToilet. The second objective is to demonstrate closed-loop resource recovery by integrating the slum eToilet with a novel onsite wastewater treatment and recovery solution termed the NEWgenerator™. Combining an anaerobic membrane bioreactor (AnMBR) and solar (PV and thermal) technologies, the NEWgenerator™ allows for localized recovery of nutrients, energy and water from human wastes. This is accomplished by fully treating and recycling the flush water through the combined biological and membrane treatment system and by recovering energy in the form of biogas from anaerobic degradation. This off-grid and modular treatment system enables the combined e-toilet/ NEWgenerator™ system to be rapidly deployed to high-density urban areas as well as areas suffering from water scarcity and low-electrical grid connectivity, giving it great usability in high-density Indian settings.

The team has now set up a fully functional combined unit of the eToilet and the NEWgenerator ™ and is currently in the process of collecting data on the use and testing water quality of the NEWgenerator ™. The system has been set up in a school near Trivandrum, Kerala and the students from the school are very pleased with this new toilet system. The team intends to collect more data on the working of the system and work out some initial economic projections for building the NEWgenerator in India to reduce the cost of the entire system.

The '**All Children Thriving (ACT)**' launched as a **third call** under GCI framework intends to investigate novel cost-effective measurement tools and mechanisms to combat unhealthy birth, growth and development. The program aims to develop the best strategies that try to alleviate the burden of birth defects, adverse pregnancy, outcomes and developmental disabilities in children.

PMU-BIRAC team, visited Gurgaon General Hospital, Gurgaon (GGH) and Translational Health Science and Technology Institute (THSTI), Faridabad to review three of the current ACT projects:

- *Creation of a biorepository and imaging data bank for accelerating evidence generation to facilitate children to thrive (PI: Dr. Shinjini Bhatnagar).*
- *Stress outcomes on pregnancy, fetal growth and birth weight Development of methods to identify mothers at risk of preterm birth and intrauterine growth restriction resulting from maternal stress (PI: Dr. Arindam Maitra).*
- *The simple absolute neutrophil count as a measure of mucosal inflammation and as a predictor of linear growth in Indian infants (PI: Dr. Uma Chandra Mouli Natchu).*

The team visited GGH to get familiarized with the process of patient screening, taking consent, enrolment in the study and with the Standard Operating Procedures (SOPs) of sample collection, labelling (with unique ID code) and immediate processing.

In November, 2016, Jeff Murray, Deputy Director, Discovery and Translational Sciences (D&TS), BMGF along with Joe Torres, accompanied by PMU-BIRAC team, visited SAS to get insights on the Linear Growth Study, where the grantee familiarized the team on the formative research being done towards initiation of project activities in Q1, 2017.

Grand Challenges Explorations India (GCE-India)

A Mandate Definititon meeting for GCE-India Round 2 was held on 2nd Decemeber, 2016. Fifteen problem statements have been agreed upon for consideration, for the upcoming call to be launched on 15th January, 2017.

Knowledge Integration and Translational Platform

Knowledge Integration and Translational (KnIT) Platform has been devised to provide evidence and experience-based guidance on how to accelerate progress, equity, impact in maternal and child health & nutrition

The two Domain Centers identified for KnIT platform; the Society of Applied Studies (SAS), New Delhi, India (for nutrition issues) and International AIDS Vaccine Initiative (IAVI), India (for MCH issues) have signed agreements and the first tranche of funds have been disbursed. The centers have shared proposed name of members constituting the Center Core Committee (C3) and Interdisciplinary Standing Committee (ISC), as mandated by PMU-BIRAC for the due execution of the program.

A meeting on 2nd December was held with, PMU-BIRAC team, BMGF team and Dr. M. K. Bhan to devise a strategic plan for KnIT program implementation.

Dr. Bhan was of the view that for the KnIT platform, there is a need to synthesize small pieces of presentation that would articulate what needs to be done on the nutrition and maternal and child health (MCH) front in India. KnIT platform at both the domain centers should involve small cadre of young investigators, pediatricians, gynecologists, data modellers, community medicine experts, etc. The Center Core Committee (C3) will decide on pertinent issues in nutrition and MCH, and Interdisciplinary Standing Committee (ISC) will evaluate the available research and identify the gaps in these areas through formal meetings.

Healthy Birth, Growth & Development Knowledge integration India (HBGDki India)

With the aim of facilitating collaboration between researchers, quantitative experts, and policy makers in fields related to HBGD, focusing on reducing the global burden associated with three complex and interrelated outcomes: *Preterm birth, physical growth faltering and impaired neurocognitive development*. The goal is to enable broader impact of insights from past and ongoing studies by incorporating individual study data into a large pool data analysis. To transform data into insights, the Gates foundation is building a Global Health Analytics Platform (GHAP), a modeling, analysis, and interactive visualization suite. This platform will facilitate the process by which data scientists collect and connect insights, to construct an accurate representation of Global Health problems in order to accelerate learning and catalyze the generation of knowledge required to transform the lives of vulnerable populations. This platform will also aid in identifying evidence based gaps and into specific interventions to improve child health over generations.

In a meeting held on 2nd December, 2016 a detailed operational plan inclusive of the implementation strategy along with timelines, communication strategy and roll out strategy was discussed and agreed at the meeting.

PMU-BIRAC team is primarily responsible for governance which includes the execution of MoU, continuous involvement through the initiative, conducting workshops, answering data contributors' queries, contributing in getting more collaborators on board to building a stronger HBGDki India community, milestone-driven monitoring of the program, coordination between data contributors and local data management team among others.

Annual Grand Challenges Meeting, October 2016

The Annual Grand Challenges Meeting was held from October 23rd-26th 2016, at the Queen Elizabeth II Center in London, UK. Dr. Shirshendu Mukherjee, Mission Director, PMU-BIRAC facilitated interactions showcasing the achievements of the PMU to key stakeholders.

The Grand Challenges 'Healthy Birth, Growth, and Development – *knowledge integration*' (HBGD*ki*) initiative was also convened from October 26th -28th 2016, with the aim of connecting HBGD*ki* communities across globe. The HBGD*ki* convening catalyzed its Data, Discovery, Decisions (D3) Track meeting discussions on research and clinical sciences and the use of big data to promote knowledge-sharing between stakeholders and featured grantees and experts from HBGD*ki*-India, HBGD*ki*-Africa and HBGD*ki*-China.

Dr. Shirshendu Mukherjee, presented HBGD*ki*-India's progress report and led the 19 member delegation from India. ■

IGNITE Program

Nurturing Entrepreneurship

10th- 22nd July, 2016 - Judge Business school, Cambridge, UK.

Entrepreneurship development and enterprise building is critical component of BIRAC. Keeping this in view, BIRAC collaborated and signed a MoU with CfEL (Judge Business School) at University of Cambridge in 2013 for Ignite Programme.

Every Year BIRAC supports five BIG Grantees to attend an intensive, two week training programme at Cambridge, UK.

Ignite is one week training programe in which 70-80 entrepreneurs participate from all across the world every year.

From 2013 to 2016, twenty candidates have participated in Ignite. Considering the feedback obtained by Ignite fellows over the consecutive years, the programme has been evolved to have discussions and one to one meeting sessions.

The fellows have got the opportunity to meet various mentors, collaborators and investors. The fellows pursue expert advice on innovative business ideas by leading entrepreneurs and investors who also address important issues related to entrepreneurial development and product commercialization.

This programme is tailored to specific industry requirement specially focusing on individual and start-ups looking at developing internal business projects.

This year five BIG Grantees- Sudeshna Adak (OMIX), Aditya Kulkarni (Aten Porous), Tanuj Gigras (Nayam Innovation), Adarsh Natarajan (Aindra Systems) and Deepak Raj (DF3D) attended the Ignite Program. They got trained in various areas of entrepreneurship such as Value Proposition, Preparation of Business Models, Team Building, defining Marketing Strategy, Finance and Business Negotiations etc. A poster and panel presentation session was also held at the end of the first week to provide a platform to candidates to sell their ideas where delegates carefully listened to them and suggested on their shortcomings.

Second week comprised of site visits to companies established in UK such as AstraZeneca, Swift Molecular Diagnostics and HealX for open conversations. The fellows also visited Babraham Institute (University of Cambridge recognized postgraduate Institute) and met with Dr. David Brown, a renowned inventor in drug discovery with rich experience in Pharma industry.

The Ignite fellows also visited JA Kemp- one of the largest UK, European Patent and Trademark Attorney firm, - to get acquainted with trends of patent and trademark in Overseas Markets. ■

International Knowledge Millennium Conference

Boosting the Innovation Ecosystem

24th October 2016 - IKP, Hyderabad

IKP Knowledge Park conducted its flagship conference, IKMC - International Knowledge Millennium Conference themed "Accelerating Innovation". The conference brought together stakeholders and experts to deliberate on various aspects of funding & scaling innovations and their impact.

The conference kick-started with the inaugural session focusing on building innovation ecosystems. The plenary lectures were delivered by Dr. Balasubramanian of LV Prasad Eye Institute (LVPEI) and Dr. Balganesh of Gangagen Biotechnology Pvt. Ltd. (GBPL), who elaborated on evolution of biotech ecosystem over the last three decades and also highlighted the importance of mentoring for producing world class start-ups.

BIRAC Regional Innovation Centre (BRIC) at IKP Knowledge Park launched a Report on ***"Mapping Regional Innovation Ecosystems: A Study of four life sciences clusters in southern India"***. BRIC was established by BIRAC in partnership with IKP Knowledge Park in 2013 to gain a deeper understanding of India's Biotechnology sector, especially in South India. Dr. Satya Prakash Dash of BIRAC introduced the BRIC and the mandate behind mapping regional innovation systems.

The conference had about 60 technology showcases including Medical Devices, Drug Development. The valedictory session included presentation by the winners of the technology showcase and an inspiring speech by Mr. Sharad Sharma of iSPIRT (Indian Software Product Industries Round Table) on devising steps for nurturing next generation innovators and working towards creating a world class innovation ecosystem in India. ■

Workshop on Bio-entrepreneurship, Grant writing and IP Management

27th –28th September, 2016- IIT (BHU) Varanasi

Day I

A two day workshop on Bio-Entrepreneurship, Grant writing and IP management was jointly organized by BIRAC and IIT BHU, Varanasi. 78 participants registered for the workshop which included graduate, post graduate students, faculties as well as doctorates & post-doctorate researchers from various departments of IIT BHU.

The workshop was focused on disseminating info on "BIRAC's Role in creating Bio-Innovation ecosystem" elaborating BIRAC's key role in promoting Biotech Innovation Ecosystem through various schemes, technical mentoring and various partnerships. Specifically the role of CRS (Contract Research Scheme) in bridging the gap between academia and Industry for Translational Research was highlighted.

The speaker Mr. Pranav Chopra, Founder of Crimson Healthcare and also one of BIG Grantee shared his entrepreneurial journey.

Dr. Shirshendu Mukherjee, Mission Director, PMU-BIRAC explained key elements of effective grant writing and briefed the audience about the critical points that should be considered while submitting any proposal to any funding agency.

A Hands-on Exercise for Impactful Grant Writing was also conducted.

Prof. Pradeep Srivastava from School of Biochemical Engineering & Co-ordinator, TBI, IIT-BHU, narrated the status of innovation ecosystem in Varanasi/U.P.

Day II

The second day of the workshop was based on securing & exploiting Intellectual Property Rights in Bioscience sector. The focus of the session was to highlight various IP tools available for biotech sector and various patentable subject matters in Biotech sector.

The workshop kick-started by Prof. Rajeev Prakash by formally welcoming all the speakers. The key speakers for second day were Ms. Namrata Chadha (K & S Partners), Dr. Deepa Tiku (K & S Partners) and Ms. Amrita Majumdar (S. Majumdar & Co.).

Diversified areas of IP Management-Drafting Patent specifications, Patentable Subject Matters, Patent examination, PCT etc - were discussed by the Eminent speakers. ■

Accelerate Bio-entrepreneurship

Partnering with TiE-Delhi NCR

BIRAC (DBT) signed a wide ranging MoU with The Indus Entrepreneurs (TiE)-Delhi NCR, at the TiE Global Summit 2016 at New Delhi, to strengthen the biotech entrepreneurial ecosystem including healthcare and medical technology. Dr. Renu Swarup, Sr. Adviser, DBT and MD, BIRAC and Dr. Saurabh Srivastava, Chairman Emeritus, TiE-Delhi NCR signed the MoU, in the presence of Prof. K. VijayRaghavan, Secretary, DBT, and Chairman, BIRAC. BIRAC and TiE will leverage each other's strengths to mentor biotech startups as well as provide platform for BIRAC supported startups to interface with funders and investors. Commenting on the partnership Dr Renu Swarup said - "*We are very pleased to partner with TiE-Delhi NCR. BIRAC's vision is to foster and nurture the Indian biotech ecosystem and in this regard we look forward to our partnership with TiE and its global network of mentors.*

The partnership aims to establish a collaborative framework under which the organizations will carry out activities related to the exchange of best practices and setting up of coordinated support measures to foster technology and knowledge transfer and innovation cooperation between bio and health tech companies, organizations and institutions.

Integrated into the TiE Global Summit, BIRAC organized a session on – *The Next Leap for Indian Biotechnology: focus Medtech*. Prof. K VijayRaghavan gave his opening remarks by highlighting the importance of the new collaboration. The session was chaired by Dr. Renu Swarup and included panelists – Dr. Sarvajna Dwivedi, Co-Founder, Pearl Therapeutics; Ms. Padmaja Ruparel, President, Indian Angel Network; and Ms. Deepanwita Chattopadhyay, Chairman & CEO at IKP Knowledge Park. The Panelists talked about the bio-entrepreneurship and investment aspects involved in the biotechnology sector. Four BIRAC funded Ignition grantees – Dr Ulhas Kharul, NCL, Pune; Dr. Pawan Mehrotra, Entrepreneur; Mr. Chayan Chatterjee, Lattice Innovations; and Dr. Vivekanandan Perumal, IIT Delhi – also presented their innovations at the session. ■

About TiE

TiE is a non-profit Company incorporated under the provisions of Societies Registration Act XXI of 1860, with mission for nurturing startups by mentoring, networking, educating, incubating, and funding. TiE was founded in 1992 by a group of successful entrepreneurs and is currently the world's largest entrepreneurial organization out there. TiE Delhi–NCR is the largest and the most vibrant chapter across the vast TiE network in creating an increasingly positive ecosystem for the entrepreneurs and investors.

BIRAC PROGRAMMES

SITARE (Students Innovations for Advancement of Research Explorations)

BIRAC SRISTI GYTI AWARDS: Aimed at supporting the innovations and creativity at grassroot level among the university students, including individual innovators.

eYUVA (Encouraging Youth for Undertaking Innovative Research through Vibrant Acceleration)

- ***University Innovation Clusters (UIC):*** UIC initiative seeks to create an entrepreneurial culture in the Universities and help students to take their novel ideas to proof of concept.
- ***SIIP (Social Innovation Immersion Programme):*** A fellowship programme that builds the next generation of social entrepreneurs by helping them 'immerse' and interface with communities to identify gaps and then work on bridging the gaps through an innovative product or service offering.

Discovery, Early and Late Stage Funding

- ***BIG (Biotechnology Ignition Grant):*** Biotechnology ignition Grant (BIG) is available to scientists, entrepreneurs from research institutes, academia and startups, to stimulate commercialization of research discoveries by providing very early stage grants to help bridge the gap between discovery and invention.
- ***SPARSH (Social Innovation Programme for Products Affordable & Relevant to Societal Health):*** SPARSH combines social innovation and biotechnology for the well-being of the society by helping identify and support cutting edge innovations towards affordable product development with potentially significant social impact. SPARSH provides support in the form of impact funding and fellowships.
- ***SBIRI (Small Business Innovation Research Initiative):*** It is the early stage, innovation focussed PPP initiative to support incremental R&D in the area of Biotechnology to facilitate innovation and risk taking by SMEs.
- ***BIPP (Biotechnology Industry Partnership Programme):*** BIPP seeks to provide support for early to late stage high risk biotech R&D by industry and/or accelerate commercialization of new indigenous technologies.
- ***CRS (Contract Research Scheme):*** CRS scheme supports academic institutes to take forward research leads through a validation and translation cycle by the industry. Funding is in the form of grant given to both the academic as well as the industrial partner.

BIRAC BioNEST (BIRAC – Bioincubation: Nurturing Entrepreneurs for Scaling up Technology)

Birac's Flagship programme which has created 20 world-class bio-incubators to provide incubation space, mentor networks, instrumentation facilities, IP and technology management support.

Collaborative Funding

- ***Indo-French Centre for the Promotion of Advanced Research (CEFIPRA):*** Support high quality bilateral research, encourage and enable Indo-French collaboration between public, private research groups, industry, clinicians and end-users in the domain of red biotechnology.
- ***Wellcome Trust, UK:*** Support innovations in translational medicine in the domain of diagnostics for infectious diseases.
- ***Grand Challenges India (GCI):*** A consortium of DBT, Bill & Melinda Gates Foundation, Wellcome Trust, USAID, and BIRAC, focussing on supporting innovations in the areas of maternal and child health, agriculture and nutrition, sanitation and infectious diseases.
- ***USAID and IKP Knowledge Park:*** Support for new diagnostic tools for TB, with funding commitment of INR 5 crores for 3 years.
- ***Horticulture Innovation Australia (HIA):*** BIRAC-HIA Joint funding programme for supporting innovative technologies and solutions for sustainable and productive horticulture at a global level.
- ***NESTA, UK:*** BIRAC partnership with Nesta, a charity organization in UK, is aimed at supporting Discovery Awards Programme for innovators working for innovative diagnostics for anti-microbial resistance (AMR).
- ***Industry Innovation programme on Medical Electronics (IIPME):*** BIRAC in partnership with DeitY (Department of Electronics and Information technology) launched IIPME for supporting innovations in medical electronics and med devices sector.

Equity Funding

- ***SEED (Sustaining Enterprise and Entrepreneurship Development) Fund:*** Financial equity based support to start ups and enterprises through bio-incubators for scaling enterprises.
- ***AcE (Accelerating Enterprises) Fund***: A Fund of Funds to scale-up R&D and innovation in biotechnology domains of sectors such as healthcare, pharma, medical devices, agriculture, sanitation and many more.

FORTHCOMING CALL FOR PROPOSALS

BIG (1 January - 15 February) | BIIP & SBIRI (15 February - 31 March) | CRS (1 February - 15 march)

For further information please contact:
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