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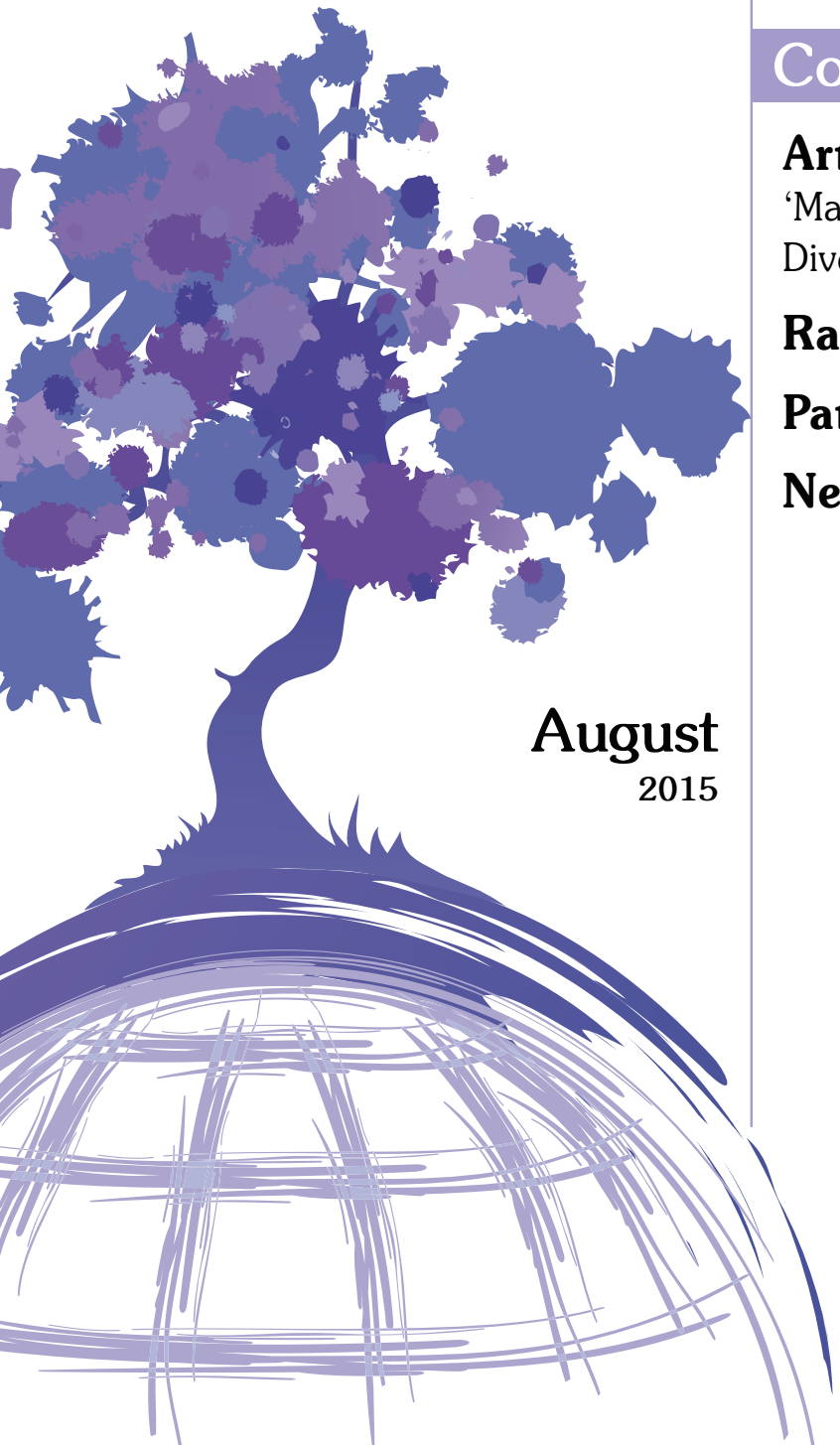

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'Make in India' meets the Biological Diversity Act

By **Dr. Amitavo Mitra**

'Make in India' is a flagship, nation-wide initiative of the Government of India launched in September 2014. Under this initiative, the government has identified 25 key sectors for attracting foreign investment in order to develop indigenous expertise, create jobs, and encourage intellectual ingenuity. Some of the key sectors identified under this initiative, and pertinent with regard to generation of intellectual property and applicability of the Biological Diversity Act, 2002 (referred to as "Act"), are biotechnology, food processing, pharmaceuticals and leather.

The biotechnology industry in India is the third biggest industry of its kind in the Asia-Pacific region, and is poised to grow more than 20 fold by 2025 to become a USD 100 billion industry, a staggering 30% growth for the next decade. Tax and customs incentives are being provided in the biotechnology arena to spur growth and innovation. In the pharmaceuticals sector, India is expected to be the third largest pharmaceutical market by 2020, the growth being driven by the burgeoning population, awareness and demand for access to better healthcare. India's manufacturing strength in generics is already well known.

In 2012, India was ranked number one in the world in production of perishable consumables such as mangoes, bananas, chickpea, ginger, goat milk, buffalo meat, and okra. It ranks second in production of sugarcane, wheat, and lentils among others. Given the increasing upward mobility of the middle class, India represents a unique opportunity for development of new plant varieties and modern science driven methods in food science.

The leather industry in India produces 2B sq. ft. of leather annually, accounting for 10% of world output. This is supported by a strong base for raw materials, wherein India is endowed with 21% of the world's cattle and buffalo population.

It is to be appreciated that a common denominator among the sectors under the 'Make in India' initiative is up to 100% FDI in the sectors via various routes, availability of a world-class talented work force, competitive R&D costs, investor friendly policies and the promise of bureaucratic efficiency that otherwise for long has plagued both private and public investment and growth in India.

India has a robust Intellectual Property Rights regime, evidenced by the fact that it is signatory to various international treaties such as Paris Convention Treaty, Madrid Protocol, Budapest Treaty, Berne Convention and Washington Treaty. In the past decade, the Indian Patent Office has seen a steady increase in number of patent filings. Though foreign entities dominate in terms of sheer numbers in the patent arena (about 4:1), it is encouraging to see that domestic inventors are slowly but surely realizing the importance of intellectual

property and its value proposition with regard to being globally relevant and competitive.

However, a potential elephant in the room is the Biological Diversity Act, 2002 (BDA). The BDA was enacted in 2002 by the Parliament of India to meet the obligations under the "Convention on Biological Diversity" (CBD), to which it is a signatory. As of 2012, State Biodiversity Boards (SBB) have been created in 26 States along with 32,918 Biological Management Committees across India. Out of the 26 SSBs, 15 have also notified state-wise rules.

The objective of the Act is not to deter or disincentivize use of the rich diversity in natural biological resources of India, but to ensure that such use is not exploitative in nature, detrimental to the socio-economic needs of country or to the people of the area from where the biological resource is accessed. The Act envisages benefit sharing in a multi-modal manner, namely (not limited to), joint ownership of IP rights, tech transfer, monetary compensation or non-monetary compensation.

The scope and extent of the ambit of the BDA can be appreciated by a mere perusal of the definitions section in the Act. Section 2(c) of the Act defines "biological resources" as *plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material,* while Section 2(d) defines "bio-survey and bio-utilization" as *survey or collection of species, sub-species, genes, components and extracts of biological resource for any purpose and includes characterization, inventorization and bioassay.* Further, Section 2(m) defines "research" as *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.*

In the field of biotechnology, food processing, pharmaceuticals, and leather, it is conceivable that any R&D activity with potential for generation of IPR would fall completely or partially under the scope of the BDA.

While individuals who are citizens of India or bodies registered in India (without non-Indian participation) need only "notify" SSBs for accessing any biological resource, or bio-survey and bio-utilization for commercial utilization (Section 7), anybody else, including a citizen of India who is a non-resident as defined in Section 2(30) of the Income-tax Act, 1961 is required to seek prior approval from the National Biodiversity Authority (Section 3). Interestingly, by design or otherwise, entities falling under Section 3 have to seek prior approval for both research and for commercial utilization.

The Act also restricts transfer of results of research to Individuals or entities covered by Section 3(2) of the Act and there are also restrictions on transferring further any biological resource or knowledge without prior approval of the National Biodiversity Authority (Sections 20, and 19).

While the Act has been in effect since 2004,

it is interesting to note that as of 2012 only 105 Benefit Sharing Agreements have been signed. These numbers though unusually low, could be due to a multitude of reasons, such as, delay in notifying various guideline, lack of enforcement, lack of awareness, etc.

It will be interesting to see, moving forward, how the various entities under the 'Make in India' campaign, designed to enhance inflow of FDI into Indian sectors, and further integrate India into the global economy, remain in compliance with the law of the land, in particular the Biological Diversity Act.

With regard to IPR, the Biological Diversity Act, under Section 6 envisages that no person shall apply for intellectual property right, in India or outside without obtaining the previous approval of the NBA for any invention based on any research or biological resource obtained in India. Some leeway is provided wherein, an application for patent made, may be allowed by the Indian Patent Office (IPO), but sealing of the patent will be deferred until approval is sought and provided by the NBA. India has traditionally been regarded as an agrarian economy and unsurprisingly, anyone seeking intellectual property protection of a plant variety under the Plant Variety Protection and Farmer's Rights Act, 2001 is exempt from Section 6 of the BDA. It is seen that the current patent practice at the IPO is to keep issuance of patents in abeyance until NBA approval is provided to the Patent Office.

With regard to IPR which includes research, and wherein the ultimate goal is commercial utilization and monetization of the IPR generated, it is of critical importance that there is harmonization among the workings of the NBA, SSBs, the IPO, and interested public and private parties in order to maximize the potential of the various sectors such as biotechnology and pharmaceuticals, while at the same time ensuring that the biological resources of India are not exploited for the profit of a few.

The BDA and 'Make in India' can truly complement each other to promote organic growth and improvement of the socio-economic status of its people, while at the same time contribute to the collective intellectual capital of the country, and maintain its rich biological diversity for future generations to enjoy.

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Ratio Decidendi

IPAB can receive additional documents even while exercising original jurisdiction

Dismissing the writ petition against the order of the IPAB which allowed miscellaneous petition seeking submission of additional pleadings and documents during revocation proceedings, the Madras High Court has held that IPAB is vested with powers to do so. The petitioner (patentee) argued that IPAB (Patent Procedure) Rules, 2010, which have been framed under Section 92 of the Trade Marks Act do not permit additional grounds to be

raised apart from the grounds initially raised in Form-1 of the Revocation Application. It stated that IPAB could receive additional documents only while exercising appellate jurisdiction in terms of Rule 14 of the Patent Procedure Rules. Observing that the petitioner could raise all defences based on proof and relevancy at time of hearing of the main revocation application, the High Court held that IPAB is vested with powers to regulate its own procedure like a Civil Court under Code of Civil Procedure, particularly for purpose of receiving evidence. The High Court refused to interfere with the impugned order of IPAB. [*Novartis AG* v. *UOI*, Judgement dated 28-7-2015 in W.P. No. 15736 of 2015, Madras High Court]

Appeal against order passed treating pre-grant opposition as review petition

Ruling on maintainability of appeal under Section 117A of the Patents Act, 1970, the IPAB has held that order passed pursuant to the directions given by High Court treating the pre-grant opposition as a review petition, was appealable. The argument against maintainability was that no appeal can be preferred against the order passed under Section 77 (f) - review of Controller's own decision and Section 77 (g) – setting aside *ex-parte* order. However observing that the order had been passed as a remedy to rectify procedural irregularity in processing the application, the IPAB held that the order was appealable. [*Abbvie Technology* v. *Controller of Patents*, Order No. 145 /2015 dated 7-7-2015, IPAB]

'Articles that infringe' covers post importation infringement by completing steps of method claim

Certain fingerprint scanning devices were imported along with software developer kits and after importation customised software to work the scanning machines was developed and the scanners were sold in the US. The imported products as such were not infringing at the point of importation. The United States International Trade Commission interpreted 'article that infringe' to mean those article which may be used to infringe IP rights post importation. The Federal Circuit upheld this interpretation, reasoning that the words of the statute do not expressly state so, there was ambiguity and the USITC could adopt an interpretation keeping in view the overall objective of preventing unfair practices. [*Supreme Inc.* v. *ITC*, Opinion 2012-1170 dated 10-8-2015, Court of Appeals for Federal Circuit]

Patent Office decisions

Composition when not a combination:

Indian Patent Office at Kolkata has refused to proceed with the application for grant of patent to a pharmaceutical composition containing a prodrug Fesoterodine as the active ingredient and xylitol/sorbitol/polydextrose as the stabilizer. The Patent Office was of the view that though improved properties (stability) of the claimed invention provide advantages over the prior art, they did not result in greater

therapeutic efficacy (as the appellant failed to demonstrate), and hence it failed to pass the test of Section 3(d) of the Patents Act, 1970. The applicant here had relied upon IPAB Order in the case of *Ajanta Pharma* v. *Allergan Inc.* to contend that the composition was combination of two different known substances, which ought not to be deemed to be new form of a known substance. Noting that the composition had one active pharmaceutical substance; that an active pharmaceutical substance will show different stability in different solvents is well known; and that it is matter of permutation/ combination to find out in which particular solvent it will be stable, the Patent Office was of the view that the claimed composition was not a combination of two different substances. [Patent Application No. 56/KOLNP/2009, decided on 21-4-2015]

Mixture of herbs - Section 3(j) not applicable: In a case involving patent for mixture of some herbs, the Indian Patent Offices, Kolkata has observed that since in the composition no direct plant has been used but a composition of powdered herb or extract have been used, it should not come under the mischief of Section 3(j) of the Patents Act, 1970. The applicant here had contended that operation of the said section is envisaged only when the process involves live-to-live products, and since no plant or plant part per-se is used for production of any known or new or old plant/s or new or old animal or anything alike, said provisions are not applicable. It was pointed out that in the claim, bone dry cum stone dead plant parts were used to make stone dead medicines. The patent however was not granted as invention lacked inventive step and its composition fell under the mischief of Section 3(e). [Patent Application No. 692/KOL/2008, decided on 21-7-2015]

Amendment in national phase application after international PCT application, not permissible: Observing that in the international application filed under the Patent Cooperation Treaty (PCT) designating India, the applicant had 21 claims and that in the application filed for entering national phase, the applicant had deleted the claims of international application and submitted new set of 19 claims, the Indian Patent Office has held the application as deemed to have not been filed. The Assistant Controller of Patents and Designs in this regard distinguished the IPAB Order No. 17 of 2013 in which changes were allowed in the interest of justice on different facts. Thus, Controller concluded that a patent applicant cannot amend *suo motu* any part of the specification at any interstice stage which goes unrecorded, and found the application to be in violation Section 59 Patents Act 1970, and Articles 3(4)(iv), 4(2), 19, 28(3) and Rule 52 of Articles and Rules of PCT. It was however taken note of that issuance of the First Examination Report in this case was an inadvertent error. The decision also discussed in length various perspectives as to why such amendments are restricted/ discouraged by the PCT and the Patents Act. [Patent Application No. 1772/KOLNP/2008, decided on 30-7-2015]

News Nuggets

Are electronically transmitted files goods?

The United States Court of Appeals for the Federal Circuit (CAFC) will shortly decide whether data sets transmitted electronically (which were later used to make goods by the process of 3D printing) are 'articles' that infringe. The 'importer' has argued that under US patent laws research data has been held as not being 'material' which infringes and in the strict sense, no importation takes place when data are uploaded on to a server. It has also contended that infringement attributed to the methods claims of the patentee which are allegedly carried out by it do not fall under the jurisdiction of USITC.

The dissenting opinion in the ITC order emphasises the scheme of 337 and states that legislature did not intend to regulate data transmissions through customs entry procedures and the trade law is not an extension of patent, trademark and copyright laws and other trade laws are also limited to tangible goods. Some of the other interesting arguments put forth are that unlike software recorded on discs which have been held to be 'articles' the digital data sets are not recorded on to a medium or sold.

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