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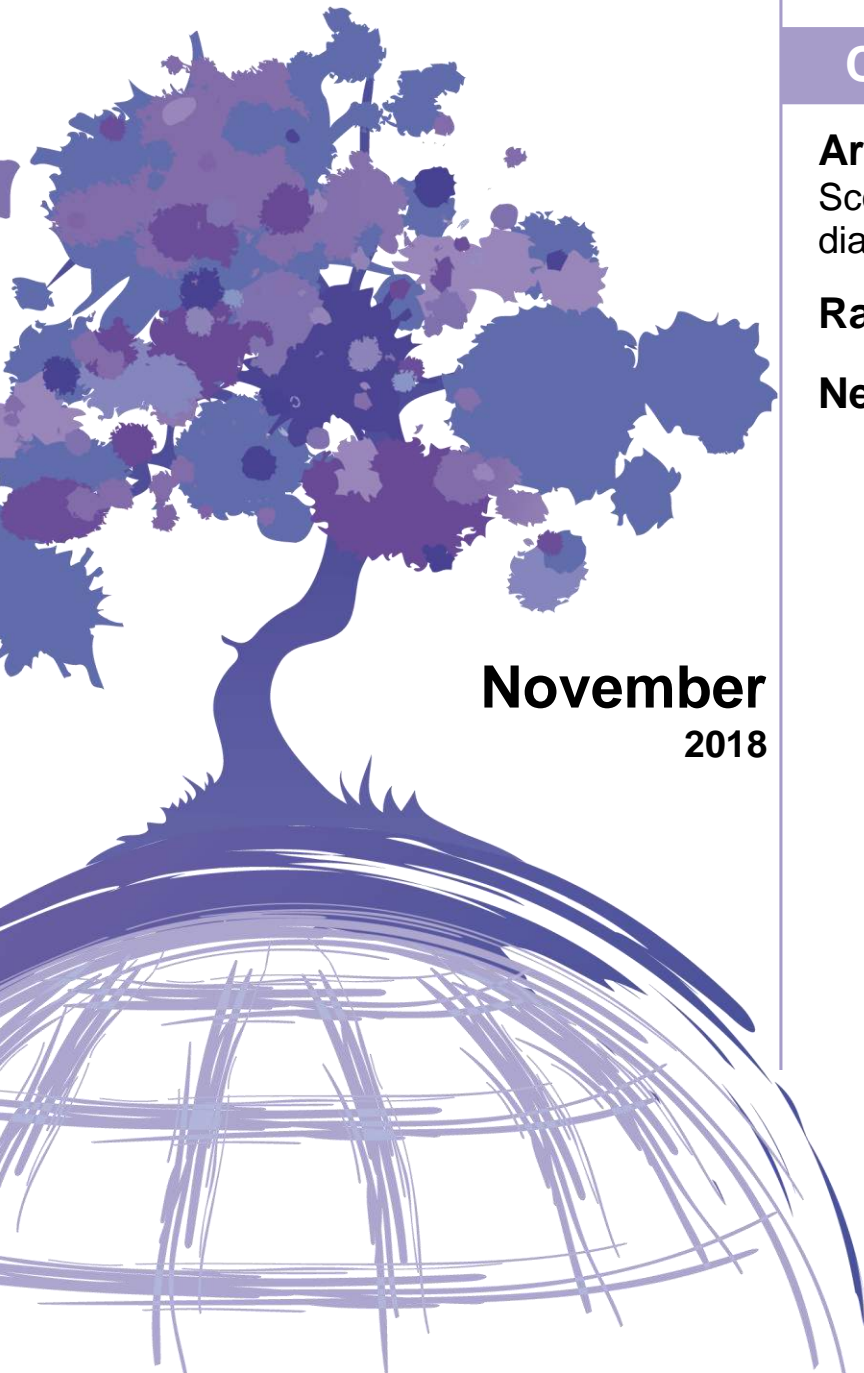
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## Article

### Scope of Section 3(i): An analysis on diagnostic methods of treatment

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#### *TRIPS and methods of treatment*

Patentability of methods of treatment is a contested subject matter worldwide. Article 27 of the World Trade Organisation's Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement, provides flexibility to its Member States by giving them liberty to decide whether patents may be granted to "*diagnostic, therapeutic and surgical methods for the treatment of humans or animals.*" The USA, Australia and New Zealand are the only TRIPS members that allow patenting of such matter.

Utilizing the flexibility provided by TRIPS, India has opted to categorise said methods and related subject matter under the ambit of non-patentable inventions. Accordingly, in India, Section 3(i) of the Patents Act, 1970 ('Act'), as amended, excludes from patentability "*any process for the medicinal, surgical, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals [\*\*\*] to render them free of disease or to increase their economic value or that of their products*"<sup>1</sup>.

The European Patent Office (EPO), under Article 53(c) of the European Patent Convention (EPC), excludes only "*methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods*".

Therefore, the method of treatment by surgery or therapy and diagnostic methods practised on human or animal body are excluded, while methods outside the body and products for medical use are allowable subject matter under Article 53; and subsequent medical use of known products is also allowable under Article 54 of the EPC<sup>234</sup>.

#### *Indian Position*

The Indian Patent Office (IPO) has held the following inventions to be non-patentable:

1. Inventions claiming surgical methods: 447/KOL/2007 (relating to a surgical method of joining tissues); 1395/CHENP/2012 (relating to isolation of bone marrow, adipose tissue, skin from human through surgery).
2. Inventions claiming therapeutic methods: 2770/MUMNP/2010 (relating to use claims and method of treatment claims using Lanosta-8,24-dien-3-ols); 4773/DELNP/2006 (relating to multiphasic medicament and dosage as recited); 5040/DELNP/2008 (relating to combination vaccination regime and administration regime to pig); 2609/DELNP/2011 (relating to claimed invention being performed on human body with administration of curcumin followed by *in vivo* retinal imaging); 3112/DELNP/2006 (relating to composition for a single administration formulation and dosage form

<sup>2</sup> <https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html>

<sup>3</sup> *General Hospital Corp/Hair removal method T 383/03 (2005) OJEOPO 159*

<sup>4</sup> EP Board of Appeals T0144/83

<sup>1</sup> [http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1\\_38\\_1\\_4-biotech-guidelines.pdf](http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf)

given *in vivo* against ionizing radiation exposure).

3. Inventions claiming diagnostic methods: 1086/MUMNP/2011 (relating to ‘a method of diagnosing liver fibrosis in a human subject, obtaining a blood sample from a human subject suspected of having liver fibrosis...’); 6616/DELNP/2010 (relating to biomarkers for COPD diagnosis to determine course of treatment).

### *Diagnosis versus Detection methods*

As defined in Manual of Patent Office Practice and Procedure, “*Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general physical state of an individual (e.g. a fitness test) is considered to be diagnostic,*”<sup>5</sup> which is distinct from an assay to assess (i.e., determining a value indicative of presence or amount in a sample with no bearing on disease) an analyte. Therefore, diagnostic methods are intended to ascertain the presence (or absence) of a disease; and are decisive for treatment decisions in otherwise symptomatic patients.

Further, as recited, Section 3(i) of the Act does not encompass detection tests, e.g., a screening test, wherein the primary purpose is early detection or risk factors of a disease which may never lead to a disease and are merely susceptibility markers in otherwise healthy individuals as well as prediction methods for progression rather than diagnosis in already diagnosed diseased individuals, since it has no bearing on developing methods for further course in therapy. Hence, detection tests, e.g. for screening, and prognostic methods for

assessment of disease progression are fundamentally different from diagnostic methods of treatment.

### *Interpretation and practice*

The interpretation and scope of Section 3(i) of the Act has not been judicially tested and the practice varies in the IPO. An assay method for detecting an analyte in a biological sample removed from a body may be interpreted, if supported by the specification of the application for a patent, as an *in vitro* detection method as opposed to a diagnostic method of treatment. In the absence of judicial interpretation and guidance, there have been instances of various applications being granted and, also rejected by the IPO.

Successful applications like 363/DELNP/2009, Patent No. 278579, where addition of a disclaimer, “*wherein the assay is not a method of diagnosis of an ailment associated with a human being and/or animal,*” led to grant; 731/DELNP/2010, Patent No. 298259, where explanation that it is “*a method of determining a value indicative of...viral infection in an untreated whole blood sample,*” led to grant; 843/DEL/2006, Patent No. 299791, where deletion of the phrase “*by a method as claimed in claim 1,*” led to grant; 853/MUM/2012, Patent No. 285429, where recitation as an *in vitro* method for analysing a sample {in the body fluids of a patient (i.e. human being)} for the presence of *Bacillus anthracis*, led to grant; 1974/MUMNP/2011, Patent No. 298524, where deletion of the word ‘diagnostic’ and the phrase ‘providing a sample of a bodily fluid from said subject suffering from a primary non-infectious disease’, led to grant.

In contrast, some applications were rejected for being excludable subject-matter under Section 3(i) of the Act, e.g., 52/DELNP/2010, relating to *determining the correlation between HBP levels and prediction of severe sepsis*, was interpreted as a method of diagnosis, since the

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[http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1\\_28\\_1\\_manual-of-patent-office-practice\\_and-procedure.pdf](http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_28_1_manual-of-patent-office-practice_and-procedure.pdf)

claims were directed at using a composition for diagnosis rather than the composition itself and amendment thereof was prohibited under Section 57 read with Section 59 of the Act.

Another application, 1492/CHENP/2010, relating to a method of detecting the presence or absence of a Chikungunya virus (CHIK) strain in a biological sample, was also refused under Section 3(i) of the Act. In that case, a fair reading of the specification implied that the detection method of invention stops at presence or absence of an immune complex, but nowhere does it recite the presence of the immune complex confirms or diagnoses a person as having been affected by CHIK. Further, during prosecution, an argument that it is not a diagnostic method of treatment to render humans free of disease was made, but a possible future use by a doctor for diagnosis was admitted. It was further argued that reading the provision under Section 3(i) of the Act should be done in its entirety and not choosing the ‘*diagnostic...method of treatment...*’ selectively, while disregarding the qualifier ‘*to render them free of disease or increase their economic value or that of their products*’. Equating the ambit of Section 3(i) of the Act to Article 53(c) of the EPC, and an argument that Section 3(i) of the Act concerns only to methods that are performed directly on human or animal body, was not accepted by the IPO and ultimately led to the refusal of this application.

Further, in application 4981/DELNP/2008, the invention was found to be novel, inventive and otherwise patentable, but was refused under Section 3(i) of the Act. The invention relating to an *in vitro* method for detecting fragmentation of an adiponectin receptor, where the presence or absence of certain soluble fragments of the adiponectin receptor in bodily fluids was interpreted as predictive of disease and hence categorised as a diagnostic method of treatment. However, no definition was provided for the

diseased state and neither anything related to the same was claimed as such in the application. The IPO refused the grant of the application by stating that Section 3(i) of the Act makes no distinction between *in vitro* and *in vivo* methods.

### *Ambit of Section 3(i)*

In view of the exemplary cases above, in contrast to the EPO provision applying Article 27 of TRIPS, by reciting additional methods of treatment and ending with a non-limiting recitation of “*or other treatment*,” the IPO, under Section 3(i) of the Act, makes for a blanket exclusion on any methods of treatment, but no direction is given for screening methods, probability methods, i.e., prognosis, or assay of analytes without any bearing on diagnosis or treatment. Further, no distinction is made between diagnostic methods performed ‘*in vivo*’ versus ‘*in vitro*’, and it is interpreted differentially. The recitation, “*render them free of disease or to increase their economic value or that of their products*” under Section 3(i) of the Act is sometimes interpreted as implied without any basis for the same being present in the claims or specification of an application and it further adds to the ambiguous interpretation.

It appears beneficial to provide arguments and basis from the specification of an application for a patent to support that the claimed methods and compositions relate to detection rather than diagnosis or treatment of a disease. Also helpful is establishing and exemplifying that the claimed invention relates to routinely performed assays in laboratories with an aim to provide support to medical research, to improvise on currently used detection methods and to study the comparative results of two or more methods involved in detection of similar type of biomolecule in a sample.

### *Conclusion and looking forward*

In the light of the above, a foundational and formidable jurisprudence and interpretation in the



courts of law is required to reduce the ambiguity and discrepancy in interpretation of Section 3(i) of the Act. Simultaneously, with the global environment heading towards dynamic biotechnological and medical innovation supported by incentives to the innovators in terms of patenting, Indian patent law needs to find a balance between public health, socio-economic growth of the country, along with support to medical technological innovation to be competent and survive at the global scale.

While there is a need for reprimanding and discouraging exclusivity over the commercial use and exploitation of inventions at the interface with human and animal life and health, there is a need

to drive medical innovation to combat the ever-changing and challenging landscape of virulent pathogens, lifestyle changes and environmental exposures underlying maladies. Indian patent law provides conditional allowance in this sphere of innovation, strongly discouraging claiming of mostly any method of treatment. The realm of what as a method may be patentable in the field of medical technology and pharmaceuticals seems highly ambiguous and is unlikely to be settled in the near future.

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## Ratio decidendi

### Trademark – Confusion, especially in education, to be avoided

Rejecting the plea of prior use, Delhi High Court has held that use of the name “AMITY SCHOOL, Bharuch” since 1986 cannot protect the defendants to justify adoption of name “AMITY INTERNATIONAL SCHOOL” in 2014, the name being identical to the Plaintiff’s school established in 1991. The Court also observed that chances of mistaken identity was very high and especially in the educational field, such confusion ought to be avoided. It was of the view that the use of identical names for two schools, completely disconnected from each other, would result in enormous confusion and could also result in having a damaging effect on the careers of children.

The Plaintiff had contended that the use of word ‘AMITY’, especially in relation to education, would constitute violation of their rights and that ‘AMITY’ is a well-known mark under Section 2(l)(zg).

Injunction applications were however restricted to the relief *qua* ‘AMITY INTERNATIONAL SCHOOL’ and the Trust running it.

Defendant’s plea of absence of territorial jurisdiction of the court was also rejected observing that defendant’s website is accessible across the country, the school is taking part in several activities across the country and has also applied for a registered trademark without any territorial restriction. Court was of the view that the activities of school were not restricted to a location. [*Ritnand Balved Education Foundation v. Ranchhod M Shah* – Judgement dated 16-10-2018 in CS (COMM) 236/2016, Delhi High Court]

### Trademark – Use of same word in names of similar services in same locality, fatal

In a case involving use of the word ‘orchid’ in the names of contending schools, the Bombay High Court has upheld the District Court’s Order granting temporary injunction against use of the mark SPRING ORCHID SCHOOL. Plaintiff-

Respondent had a registered mark ORCHID SCHOOL having registration and user much prior to the registration and user of the Appellant. The Court noted that since the nature of services offered (education and training to students) was same, there was possibility of likelihood of enhancing confusion. The fact that schools were more or less in the same locality was also considered by the court for this purpose.

Pleas of following different syllabus, and the submission that addition of the word 'spring' is sufficient to indicate different trade origin and to distinguish both schools, were also rejected. Further, the contention that the word 'orchid' is generic was rejected by the court, distinguishing the Supreme Court decision in the case of *Skyline Education Institute (India) Pvt. Ltd.* The court observed that respondent's trade name was already registered and that it was not a case of passing off simplicitor but a case of infringement. It was also held that delay on the part of the respondent will not affect relief of injunction in infringement. [*Sipra Education Society v. Pradnya Niketan Education Society* – Judgement dated 17-10-2018 in Appeal from Order No. 64 of 2017, Bombay High Court]

### No copyright in compilation of list of customers when identity of author not disclosed - Every database of customer list is not 'trade secret'

The Delhi High Court has held that employer (plaintiff) cannot restrain its employees from using compiled list of customers after the end of their employment, as there can be no copyright of the employer in the list. Noticing that there was no averment in the plaint of the technique/criteria in compiling the list of customers, and that the plaintiff had not disclosed the name of the author (of such list) who was employed with the plaintiff, it was held that plaintiff, which is a company, cannot be the author of such a list. The Court was of the view that it was essential for the

plaintiff to disclose identity of the author, to claim ownership of the copyright.

The High Court also held that it is not possible to claim trade secret on every customer list unless the confidentiality around such a list is of economic /business /commercial value. It observed that names and contact addresses of businesses are easily available in public domain, and that any competitor of the plaintiff worth its salt would also know of such businesses/industry and be free to market his services to them, even if presently employing the service of the plaintiff.

The Employment Contract under which the defendants had agreed not to compete with the plaintiff for a period of one year after leaving the employment of the plaintiff either by carrying on the same business themselves or by joining employment of any competitor of the plaintiff, was also held as violating Section 27 of the Contract Act. [*Navigators Logistics Ltd. v. Kashif Qureshi* - CS(COMM) 735/2016, decided on 17-9-2018, Delhi High Court]

### Trans-border reputation of trademark "Burger King"

The Delhi High Court has confirmed the earlier injunction granted against use of mark BURGER KING by the defendants. It observed that the trademark is a known mark across the world through a franchisee network and that there was complete imitation of the plaintiff's mark and logo by the defendant. The court noted that though there was no documentary evidence placed on record by the plaintiff, the list of outlets of Burger King in several international airports across the world shows that travellers would be aware of the restaurant chain by the name of Burger King, and that was important. Genuineness of documents produced by defendants was found to be nebulous, until the documents were proved in trial.

Observing the uncanny resemblance between the two logos, and the fact that defendants were not able to show prior use of the logo, the Plaintiff was held to be the prior user of the logo. The Court also observed that the way the defendants were soliciting enquiries and wanted to give franchisees under the name poses a clear and imminent threat for extreme dilution of the mark. The Court however did not bar defendants from using the mark Burger Emperor. [*Burger King v. Rajan Gupta* – Order dated 24-9-2018 in CS (COMM) 229/2018, Delhi High Court]

### Trademark – Injunction for use of mark MYSOAP infringing mark MYSOP

The Madras High Court has confirmed the interim injunction in a case involving infringement of mark MYSOP by the mark MYSOAP. Applying

the ‘Parle principle’ laid down by the Supreme Court in *Parle Products (P) Ltd. v. J.P. and Co.*, the court observed that the man of average intelligence with ordinary prudence and imperfect recollection, while seeing the offending mark be lulled into belief that he is seeing the registered mark of the plaintiff.

The Court also noted that the products involved were the same and were purchased from the same channel of marketing. The Defendants plea of *publici juris* was rejected by the Court observing that the defendant itself had applied for registering the mark MYSOAP. [*Pradeep Cholayil v. Karnataka Soaps and Detergent Ltd.* – O.A. No. 329 and 330 of 2018 decided on 4-10-2018, Madras High Court]



## News Nuggets

### Devin, a name of Bulgarian town, can be registered as EU trademark

EU’s General Court has annulled EUIPO decision which had declared the mark ‘Devin’ as invalid. EUIPO had observed that the town was known in Bulgaria and to significant consumers in neighbouring countries as renowned spa town and that it was linked with mineral waters. The Court in *Devin AD v. EUIPO* observed that the average consumer of mineral water in EU does not have a high degree of specialisation in geography or tourism and that there is no specific evidence to establish that such a consumer perceives the word as a geographical place in Bulgaria.

### EU Trademark on pharmaceuticals – Dominance of word mark

European Union’s General Court has upheld the decision of Board of Appeal that the word element ‘salospir’ constituted dominant and distinctive element of the mark applied for, while the white tablet depicted was a mere illustration of pharmaceuticals at issue. It was also held that the use of white and green colour and waved lines were common graphic elements, being merely decorative. The Court in *Bayer AG v. EUIPO* observed that purchaser, as a rule, for pharmaceuticals issued without prescription, will say their name, and hence word element of the mark must be held to be dominant.

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