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INDIAN LEGAL IMPETUS®

National List of Essential Medicine-2015

EDITORIAL

Manoj K. Singh
Founding Partner

Singh & Associates is thankful to all its readers who have always bestowed overwhelming support to us as a result of which we have been successful enough to bring new editions of our newsletter to enlighten the legal fraternity around the world by covering the latest legal developments in India.

The present edition has dwelled into some of the latest legal issues that have surfaced from the business law to that of the world of the IPR**.** The cover article of the current edition deals with the "**National List of Essential Medicines, 2015**" which focuses on the essential elements considered for the revision of NLEM, 2011 to control sale price of scheduled formulations. The next article is on "**Central Government's Scheme for Encouraging and Promoting Start-ups Intellectual Property Protection (SIPP)**"which aims to promote awareness and adoption of Intellectual Property Rights amongst start-ups companies. Further, the article "**Significance of Date of Grant of Patent: Under Indian Patent Act**" throws some light on the judicial understanding to consider which date the patent is deemed to be granted. The article, "**IPO Rejects Compulsory Licensing Application Against the Patent Drug SAXAGLIPTIN By Lee Pharma**", discusses about grant of compulsory license in India. Further article, "**Are Known Substances Really A Patentable Subject Matter In Light Of Indian Patents Act, 1970**" discuss on the issue of patentability of a new or subsequent medical use of a compound or composition wherein the first medical use of same is already known. Article, "**Ambit of Global Intellectual Rights Over Traditional Knowledge**" observes the deliberation over the elimination of indigenous or local knowledge forms from the global intellectual property system, and the Indian way to mitigation. Moreover, article "**The Duty To Deduct TDS With Regards An Expatriate Arises- Only When He Himself Furnished the Details Regards the Other Employer**" throws lights on the judicial understanding pertaining to tax deduction at source of an expatriate employee. Our last article, "**Companies (Incorporation) Amendment Rules, 2016**" highlights rules for considering company's name for incorporation of a company.

Lastly this issue also includes the latest developments in various fields of law which have been summarized in the Newsbytes Section of the Newsletter.

I hope that our esteemed readers find this information useful and it also enables them to understand and interpret the recent legal developments. I welcome all kinds of suggestions, opinion, queries or comments from all our readers. You can also send in your valuable insights and thoughts at newsletter@singhassociates.in.

Thank you.

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NATIONAL LIST OF ESSENTIAL MEDICINES, 2015- AN APPROACH TO CONTROL SALE PRICE

Rajdutt S Singh & Mansi Chaturvedi

INTRODUCTION

The Core-Committee (Committee) constituted by the Ministry of Health & Family Welfare (MOHFW), Government of India, reviewed and revised the National List of Essential Medicines(NLEM),2011 and formulated the criteria for inclusion and deletion of medicines in National List of Essential Medicines based upon the directions to look into the matter of coronary stents directed by Hon'ble High Court of Delhi in the Writ Petition No 1772 of 2015 wherein petitioner filed PIL seeking a direction to the respondents to include coronary stents in the National List of Essential Medicines (NLEM) thereby controlling the sale price of the same.

FINDINGS OF THE COMMITTEE

Upon the detailed examination, the Committee came to know that all the medicines are not listed in the National List of Essential Medicines (NLEM), 2011. The Committee opined that all medicines are essential and is taken only when it is needed by the patient and all these medicines, including life saving drugs, should be available in the market at affordable price. To keep this in view, the Committee recommended that the scope of price control needs to be enlarged to make all the drugs available, especially life saving drugs. Expressing concern over large sum of money spent on importing pharmaceutical products, the panel also called for incentivising domestic bulk drug industry and discourages Indian firms from buying from overseas. The report of the Committee addressed the topics pertaining to concept of essential medicines, criteria's considered for framing the NLEM and the necessity of revising the NLEM on a regular basis due to changing disease burden profile, emergence of antimicrobial resistance, development of newer and better medicines to preserve NLEM's relevance. NLEM has been revised twice the last being in 2011 and Committee recommended the revision of it at every three years.

SALIENT FEATURES OF NLEM 2015

There were 348 medicines listed in NLEM, 2011. A total of 106 medicines have been added, and 70 medicines have been deleted to prepare NLEM, 2015 which now contains a total of 376 medicines. Medicines in NLEM, 2015 are listed with reference to the levels of healthcare, namely, Primary (P), Secondary (S) and Tertiary (T) because the treatment facilities, training, experience and availability of health care personnel differ at these levels. There are 209 medicine formulations listed for all levels of health care (P, S, T),115 medicine formulations for secondary and tertiary levels (S, T) and 79 medicine formulations for the tertiary level (T). It is to be noted that formulations of certain medicines are listed at different levels but as item, they are counted as one. The total number of medicines remains 376. The essentiality of a medicine has been considered in terms of its dosage form and strength also. In general, medicines have been mentioned with respect to their active moieties, without mentioning the salts. The NLEM, 2015 has been prepared adhering to the basic principles of Efficacy, Safety, Cost-Effectiveness and considering of diseases as public health problems in India.

WHAT IS AN ESSENTIAL MEDICINE

As per the World Health Organization, Essential Medicines[1] are those that satisfy the priority health care needs of the population. The list is made with consideration to disease prevalence, efficacy, safety and comparative cost-effectiveness of the medicines. Such medicines are intended to be

1 *http://cdsco.nic.in/WriteReadData/NLEM-2015/Recommendations.pdf*

available in adequate amounts, in appropriate dosage forms and strengths with assured quality. They are available in the market such a way that an individual or community can afford. The concept of essential medicines revolves around addressing "priority health care needs" specific to a country. It is therefore important to take into consideration the 'burden' of diseases in that population. The burden of a disease may vary from country to country, so do the priority health care needs. For example, tuberculosis, malaria and diarrheal diseases are priority health care concerns in low- and middle- income countries, but it may not be so for high- income countries. On the same lines, trypanosomiasis may be a priority health care concern in the African region where it is endemic but not so in India.

CRITERIA CONSIDERED FOR INCLUSION OF A MEDICINE INTO NLEM, 2015

For inclusion of a medicine into NLEM, 2015, certain criteria were considered such as medicine to be licensed and approved in the country by Drugs Controller General (India); medicine to be useful in disease which is a public health problem in India; medicine have proven efficacy and safety profile based on valid scientific evidence; medicine to be comparatively cost effective; medicine aligned with the current treatment guidelines for the disease; medicine to be stable under the storage conditions in India[2]. In addition to these criterias, other criteria were also considered such as, when more than one medicine are available from the same therapeutic class, preferably one prototype, medically best suited medicine of that class to be included after due deliberation and careful evaluation of their relative safety, efficacy, cost-effectiveness; price of total treatment is considered and not the unit price of a medicine; Fixed Dose Combinations are not included unless the combination has unequivocally proven advantage over single compounds administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance; the medicine in NLEM, 2015 are based at primary/ secondary/tertiary level of health care according to treatment facilities and training, experience and availability of health care personnel at these levels.

CRITERIA CONSIDERED FOR DELETION OF A MEDICINE INTO NLEM, 2015

Deletion of any medicine from the NLEM is based on certain conditions like the medicine has been banned in India; existence of reports of concerns on the safety profile of a medicine; if medicine with better efficacy or favourable safety profile and better cost-effectiveness is available; the disease burden for which a medicine is indicated is no longer a national health concern; and in case of antimicrobials, if the resistance pattern has rendered a medicine ineffective etc.[3]

SPECIFIC ISSUES DELIBERATED DURING THE REVISION PROCESS

The specific dimensions were considered during the deliberation by the Core- Committee for revising the NLEM, 2015 such as, dosage forms/ formulations; strengths of medicines; salts of active moieties of medicines; isomers/ analogues/ derivatives etc. of medicines; medicines in national health programmes; pack size of formulations; incremental innovation; formulations of modified release/ sustained release/ extended release etc., and improved or novel drug delivery systems.

Enforceability of NLEM

NLEM is a list of medicines prepared by the Ministry of Health and Family Welfare based on essentiality and made part of the Drugs Price Control Orders (DPCO), 2013 (DPCO 2013) in the form of first Schedule of the DPCO 2013. DPCO 2013 is an order issued by the Central Government having power under section 3 of the Essential Commodity Act, 1955 which enables it to fix the prices of essential bulk drugs and their formulations mentioned under the NLEM. The formulations which are included in NLEM i.e. first Schedule of the DPCO 2013 whether referred by generic name or brand are known as

2 http://cdsco.nic.in/WriteReadData/NLEM-2015/Recommendations.pdf

3 http://cdsco.nic.in/WriteReadData/NLEM-2015/Recommendations.pdf

Scheduled Formulations. Any person acting in contravention of the DPCO 2013 is punishable under section 7 of the Essential Commodities Act, 1955, punishable with imprisonment for a term of not less than three months and may extend upto seven years. Where the person is convicted again the court may in addition to the penalty, direct the person to abstain from doing any business in essential commodities for a period not less than six months. Any company which is found acting in contravention of the DPCO 2013, the person responsible for the conduct of the business of such company shall be liable along with the company, for such contravention of the order.

CONCLUSION

Revision of NLEM in 2015 was based on the complex process in the light of fast changing concepts in medicines, treatment regimens, introduction of new technologies and incremental innovations in drug delivery systems and formulations, wide differences in medical practice pattern in the country, regional variations in health care system etc. NLEM has been made part of the DPCO 2013 which gives right to the Central Government to fix/regulate the prices of formulations listed therein.

CENTRAL GOVERNMENT'S SCHEME FOR ENCOURAGING AND PROMOTING START-UPS INTELLECTUAL PROPERTY PROTECTION (SIPP)

Vaibhavi Pandey

INTRODUCTION:-

The Intellectual Properties of any business entity are emerging as one of the greatest tools in the direction of strategically establishing itself on a competitive platform with the other units. With the Prime Minister's initiative of "Make in India" and increasing inclination towards the industrial sector by the majority of the youth, the number of Start-ups have been increasing considerably. As an initiative to encourage and facilitate such start–ups and newly launched ventures in India, the Government of India has initiated "The Scheme for Facilitating Start-ups Intellectual Property Protection (SIPP). This Scheme provides assistance to the Start-ups in various steps from filing till registration of Intellectual Properties like Trademarks, Patents and Designs.

"The Scheme of SIPP aims to promote awareness and adoption of Intellectual Property Rights amongst Start-Ups. Scheme is inclined to nurture and mentor innovative and emerging technologies among Start-ups and assist them in protecting and commercializing Intellectual Property Rights by providing them access to high-quality IP services and resources."[1]

The Scheme has been introduced as a Pilot and will be applicable for a period of 1 year. Under the Scheme, the government or the Facilitators as appointed by the government will not be entitled to claim any kind of ownership rights on the Intellectual Property of the Start-up and all the properties registered by them under this Scheme would be the exclusive property of the Start-up alone and no one else. The funds under the Scheme would be provided by the funds available with the Department.

ELIGIBILITY CRITERIA FOR GETTING BENEFITTED UNDER THE SIPP-

As the Scheme is aimed at benefitting the Start-ups and encouraging them to come up with new and creative ideas, the SIPP imposes an exclusive list of criteria which are to be qualified by an entity to gain advantage under this Scheme. The criteria for being considered as a Start-up under the SIPP are as mentioned below-

- The Start-up must be registered under the Start-up Certification Board as having an innovative business.
- The Start- up must not be incorporated or registered before a period of 5 years.
- The turn over of the Start-up must not have exceeded an amount of Rs. 25 crores in the preceding years.
- The Start-up must be working towards innovation, development, deployment or commercialization of new products, processes or services driven by technology or Intellectual Property.[2]

  Further, apart form the above mentioned criteria, the SIPP also imposes certain restrictions and narrows the ambit of an entity to be considered as a Start-up. Those restrictions are as mentioned below-

- The entity must not have come into existence after getting segregated or reconstructed from an existing entity.
- The entity will cease to be considered as a Start-up if its turn over exceeds the amount of Rs. 25 crores.

1 *http://www.ipindia.nic.in/iponew/facilating_StatupIndia_SIPP_18Janaury2016.pdf*

2 *http://www.ipindia.nic.in/iponew/facilating_StatupIndia_SIPP_18Janaury2016.pdf*

- The entity will cease to be considered as a Start-up if the date of its incorporation or registration exceeds a time period of 5 years.
- The Start-up can avail benefits under the SIPP only after it gets registered under the Start-up registration Board.

APPOINTMENT AND FUNCTIONS OF THE FACILITATORS-

For the purpose of facilitating the Start-ups and giving them assistance while getting their Intellectual Property registered in India, the Controller General of Patents, Design and Trademarks (CGPDTM) also appoints a panel of Facilitators. The panel shall contain Advocates (who qualify all the criteria of being an advocate implemented by the Advocates Act, 1961 and Bar Council of India and who are well versed with the provisions of the relevant Acts and Rules, and are actively involved in filing and disposal of applications for Patents, Trademarks and Designs), Patent Agents (registered with the CGPDTM), Trademark Agents (registered with the CGPDTM), Government Bodies like NRDC (National Rural Development Cooperation), DEITY (Department of Electronics & Information Technology) etc.

The Facilitators would perform the below mentioned functions-

- Providing general and basic advice to the Start-ups with respect to different Intellectual Properties.
- Providing information regarding protecting and promoting IPRs in different countries.
- Providing assistance and guidance in filing the applications for registration of Intellectual Properties like Trademarks, Patents and Designs and disposal of the same at the Indian Offices under the CGPDTM.
- Drafting Specifications, Claims, response to Examination Reports/Queries etc.
- Attending hearing on behalf of Start-ups.
- Contesting third-party Oppositions.
- Ensuring disposal of the IPR applications.

The Facilitators are not allowed to charge anything from the Start-ups for the services provided by them. Further, the Facilitators will be provided with a fixed amount of fee by the Central Government and it will not be entitled to charge any amount apart from that to the Entrepreneur. An exclusive table of fees applicable per application has been provided in the SIPP.[3]

CONCLUSION-

The Scheme is an appreciable and potentially effective step in the direction of providing guidance and a platform to prosper to the Start-ups. The idea of providing legal assistance is not alien to Indian Laws and it is even enshrined in the Constitution itself. As per the DPSP (Directive Principles of State Policy), the State is required to ensure that no one is deprived of legal assistance because of poverty or a social status and then only complete justice could be delivered. In today's era where the new entrepreneurs and Start-ups are creating history and entities like Facebook, Twitter globally and Paytm, Ola, Freecharge, Housing etc. in Indian market have emerged with innovation at its best and have also received huge acceptance and applaud from the customers at large. Keeping in view the level of success attained by these entities, such an encouraging and enthusiastic Scheme was the dire need of the day. The success and life of the Scheme will now depend on its effective implementation and working mechanism.

3 *http://www.ipindia.nic.in/iponew/facilating_StatupIndia_SIPP_18Janaury2016.pdf*

SIGNIFICANCE OF DATE OF GRANT OF PATENT : UNDER INDIAN PATENT ACT

Priyanka Rastogi

INTRODUCTION

What is the date of grant of patent or in other words on which date the patent is deemed to be granted. This seems to be a simple question with the simple answer, but that is not the case. In this regard, Hon'ble Delhi High Court heard a bunch of petitions where all of the petitions had this common question of ascertaining date of grant of patent. In general sense patent is said to be granted when it is approved by the Controller of Patents and no further objections are in its way. The said petitions raised the question of date of Patent in context to validity of a pre-grant opposition as introduced by the Patent Amendment Act, 2005.

FIRST SET OF PETITIONS[1], FACTS

In Dr. (Miss) Snehlata C. Gupte Vs. Union of India (UOI) and Ors[2]. J. Mitra & Company who was the respondent no. 5 in this writ petition filed two patent applications Nos. 590/Del/2000 and 593/Del/2000 on 14th June 2000 and the both were published on 20/11/2004 under section 11A of the Patents Act ("Act"). At that time as per pre-amended section 25 the time period for filing pre-grant opposition was 4 months from the date of publication of the Application.

Span Diagnostics Ltd. (hereinafter SDL) filed a pre-grant opposition against the grant of J. Mitra's applications and the same was rejected by the Controller on 23/08/2006. The order passed by the Controller reads as "In view of the above discussion and in consideration of the submissions of both the parties. I hereby order to grant [Patent No. 194639] on Patent Application No. 590/Del/2000". Thus as per respondent the date for the grant of patent was 23/08/2006 as per the Controller's order.

On the very next day i.e. 24/08/2006 Dr. Snehlata Gupte, the Petitioner in W.P. (C) No. 3516 of 2007, filed a pre-grant opposition to application filed by J. Mitra & Co stating that according to the amended Section 25 which is effected from 01/01/2005, the time period for filing pre grant opposition extends till grant of the patent. Further it was contended by Dr. Gupte that the patent was not considered as granted till such time it was sealed and entered in the Register of Patents. Further on 5/09/2006, Dr. Girish Rindani, who also was a Petitioner in Writ Petition (C) No. 5422 of 2007 filed a pre-grant opposition vis-à-vis same patent application. The Controller on 22/05/2007 passed an order of rejecting the pre grant oppositions of both the petitioners on the ground that the oppositions were time barred.

It was submitted by J. Mitra & Co. that the SDL, Dr. Gupte and Dr. Rindhani are connected to each other and the serial oppositions filed by these persons connected to SDL after the rejection of opposition by SDL itself is mala fide, and if such oppositions were entertained, then there will be no end to filing of such pre-grant oppositions. It was further submitted by J. Mitra & Co. that there

1 Writ Petition (C) Nos. 3516, 3517, 5422 and 5423 of 2007
2 W.P. (C) No. 3516 of 2007

shall be time limit for filing pre-grant oppositions and the same, in any case, cannot be beyond the date of the Controller's passing an order of grant of patent. J. Mitra & Co. contended that the sealing and entering into the register are not more than ministerial acts which make no difference to the date of the grant of the patent.

In response to above the petitioners submitted that the patents issued to J. Mitra & Co. were just imitations to patents obtained by an US Company EY Laboratories in 1991 and further the claims on which patent was issued were different form the published ones. Therefore it is duty of the Patent Office to publish those amended claims and not to grant patent within three months of the statutory period of appeal so that an aggrieved party could file an appeal. It was alleged that the entire process of grant of patent by the Patent Office was done in a quick and clandestine manner.

WRIT PETITION (C) NO. 1020 OF 2010, FACTS

In Tibotec Pharmaceuticals Vs. The Assistant Controller of Patents, Designs and Trade Marks and Ors[3]. the petitioner (hereinafter Tibotec) filed its application for grant of patent on 11th June 2004 which was published on 30th November 2007 in terms of Section 11A of the Act. After considering the petitioners reply to the First Examiner Report (FER) the Ld. Controller on 28/03/2008 issued a letter stating that the application for patent has been found in order for grant.

On 26th June 2008, Cipla Ltd. filed a pre-grant opposition against the grant. Tibotec opposed the pre-grant opposition pointing out that the same is time barred and prayed for the issuance of patent certificate in its favour while rejecting the pre grant opposition filed by Cipla Ltd. The Assistant Controller of Patents on pre-grant opposition heard both the parties and allowed the pre-grant opposition and rejected the patent on the grounds of lack of inventive steps. The order of the Controller was challenged by the Tibotec in this petition.

It was submitted by Tibotec that there was a difference between the "issuance" of a patent certificate under Rule 74 and the "grant" of patent for the purposes of Section 43. Referring to the Controller's order the petitioner submitted that it was observed that there is no impediment to the grant of patent and the letter patent shall be issued within seven days of six months i.e. 30/05/2008 from the date of publication of application. So for all practical purposes the date of grant shall be 30/05/2008 or the very next day.

Cipla Ltd. submitted that at the stage of examination of application the controller was the only fact finding authority. The intimation that the patent is in order is not by itself grant of patent, this is only an informal intimation to the applicant which is not required to be made in law. It is only a long standing practise of the Office but not a guarantee to the grant of the patent. Further it was submitted that the patent was not granted however good it is without completion of the procedure envisaged under Section 25(1) of the Act.

It was also submitted that the date of grant of the patent is the date on which the Controller of Patents pass the order of grant afterwards no matter when the letter of patents was issued or

3 Writ Petition (C) No. 1020 of 2010

notified or registered. Accordingly as on the date of filing of pre-grant opposition no grant of patent had taken place under the Act.

The Court citing several provisions of the Act stated that there are several hurdles to cross before the grant of patent is said to be final. The term for every patent is 20 years and according to Section 43 of the Act this term shall be counted from the date of filing of application for patent irrespective of the date of grant. In cases of pre-grant opposition there are larger chances that the patent holder is not able to work out his patent till the time the patent application remain challenged, or the grant is stayed, or when the patent holder is not confident enough to exploit it commercially till he attains the Letter Patent.

As there is this considerable loss of time in working of a Patent and given the limited life of patents, the time period for filing pre grant opposition under Section 25(1) cannot possibly be construed, notwithstanding that there is no specific time period mentioned, to be the farthest / outermost date in this process of grant.

The Court was of the view that the grant shall be deemed to have taken place (or the patent shall be deemed to be sealed) on the date on which the Controller pronounces his order stating that the Patent is granted.

The Court observes that when an application is found "to be in order for grant" under Section 43 of the Act includes the time during which application is published and followed by the examination. If the patent is not refused at that stage and no pre grant opposition is filed then the patent will proceed for grant. Where any pre grant opposition is filed then it has to be examined as per procedure outlined in Rule 55(1). After submission of documents from both the parties the Controller under rule 55(6) either refuse to grant a patent or require the complete specification to be amended before the patent is granted.

Rule: 55(6) After considering the representation and submission made during the hearing if so requested, the Controller shall proceed further simultaneously either rejecting the representation and granting the patent or accepting the representation and refusing the grant of patent on that application, ordinarily within one month from the completion of above proceedings.

The Court held that in terms of Rule 55(6) it is very clear that once the opposition is decided, the controller at the same time proceeds to either reject such opposition and grant the patent or accept the opposition and refuse the patent and that date shall be considered as the date of grant of patent. In case there are more than one pre grant oppositions, the Controller should bunch all of them together, hear them sequentially and express a final opinion on each of them as far as practicable, on the same date. It is like a Court hearing batch of petitions seeking similar relief.

The Court referring to Section 43 of the Act where the language used in that "a patent shall be granted as expeditiously as possible" stated that the patent has to be granted once it is found to be in order of grant and not refused in terms of Section 25(1). In other words the Controller should not delay the grant of the patent. The Court held that it is the date of grant of patent shall be the date on which the Controller decides the question and grants

the patent. The sealing and entry in the register follows the act of the Controller passing an order are intended to be ministerial acts evidencing the grant of patent.

CONCLUSION

The outcome of this case definitely clarifies the situation and answers very specifically as to what date shall be taken as date of grant of Patent. Determination of date of grant of patent will certainly cut down the volume of serial pre-grant oppositions filed with malicious intent. Also, the Court suggested to the Controller that all the notifications as of acceptance of application for the grant of patent shall be placed online (in public domain) at the date of decision itself.

http://www.doingbusiness.org/~/media/GIAWB/Doing%20Business/Documents/Annual-Reports/English/DB13-full-report.pdf

IPO REJECTS COMPULSORY LICENSING APPLICATION AGAINST THE PATENTED DRUG SAXAGLIPTIN BY LEE PHARMA

Saipriya Balasubramanian

INTRODUCTION

An application for Compulsory Licensing against 'SAXAGLIPTIN' drug was filed by Lee Pharma, a Hyderabad based Indian pharma company, dated 29.06.2015.'SAXAGLIPTIN' is protected by the patent IN 206543 entitled "***A Cyclopropyl-fused pyrrolidine-based compound***" granted to Bristol Myers Squibb (BMS) which was subsequently assigned to AstraZeneca by way of deed of assignment. An order issued by IPO on 12th August, 2015, rejecting the application under Rule 97(1) of the Patent Rules, 2003. The Applicant requested a further hearing which was granted on 15/12/2015 along with supplementary submissions on 29/12/2015. Subsequent to this hearing, the IPO passed an order[1] dated 19/01/2016 in which the Controller rejected the application for largely the same reasons as stated in its earlier order.

FACTS OF THE CASE:

SAXAGLIPTIN is a Dipeptidyl Peptidase-4 (DPP-4) inhibitor used in the treatment of Type II Diabetes Mellitus. The drug SAXAGLIPTIN is sold under the brand name '**ONGLYZA**' in dosages of 2.5 mg and 5 mg. SAXAGLIPTIN in combination with Metformin is sold under the brand name '**KOMBIGLYZE XR'** in dosage 5/500 mg and 5/1000 mg.

Grounds relied by the Applicant for making an application for Compulsory Licensing:

Section 84(1) (a): That the reasonable requirements of the public with respect to the patented invention have not been satisfied

The Applicant submitted that there are nearly 60 million people in India suffering from Type II DM and even if 1 million people were prescribed SAXAGLIPTIN then total number of tablets required for one million patients in one year would be 365,000,000 tablets per year. From Form-27 data submitted by the patentee , the Applicant mentioned the total number of ONGLYZA and KOMBIGLYZE imported for the whole year was 0.23% of the total number required for a year. Hence the Applicant submitted that there is more than 99% of shortage of SAXAGLIPTIN in the Indian market. Upon hearing the arguments of the Applicant, the Learned Controller insisted on authentic report for the data provided on increased diabetic population as well as the number of Type-II DM patients taking prescribed medicines in relation to other steps such as lifestyle change, dietary changes, exercise etc, but the Applicant could not provide authentic data.

Further, the Applicant did not provide any comparative data of SAXAGLIPTIN and other DPP-4 inhibitors such as Linagliptin, Sitagliptin and Vildagliptin which are also available in Indian market so that the reasonable requirements of the public in respect to SAXAGLIPTIN could be arrived. The learned Controller quoted the matter of '***Bayer Corporation Vs Union of India & Ors***' which held that in respect of medicines the adequate test has to be 100% i.e to the fullest extent.

Hence the Controller stated that it was unclear from the Applicant's submission whether one million patients need SAXAGLIPTIN despite other alternatives such as Linagliptin, Sitagliptin and Vildagliptin. In the absence of authentic data, there is no way to understand the exact requirements of SAXAGLIPTIN in Indian market to decide or not whether the patentee is meeting with the reasonable requirements of the public in respect to patented invention.

With regards to the above mentioned details, the Controller stated that a *prima facie* case has not been made out by the Applicant to the effect that the reasonable requirements of the public with respect to the patented invention are not being satisfied and therefore, no case is made out in terms of Clause (a) of section 84 of the Indian Patents Act.

Section 84(1)(b) – That the patented invention is not available to the public at a reasonably affordable price

The Applicant submitted that excessive high price of SAXAGLIPTIN is a barrier for the poor patients in India hence, it is unavailable to a general public at a

1 http://www.ipindia.gov.in/iponew/compulsoryLicense_Application_20January2016.pdf

reasonably affordable price. The Controller again quoted ***Bayer v. Union of India*** to hold that the Controller does not have any power of investigations to arrive at a reasonably affordable price, and that such a price must be arrived at on the basis of evidence led by the parties.

The Controller observed that the prices of other DPP-4 inhibitors available in the Indian market despite such large volumes and side effects are also in the same range (Rs.42 to 58) which are at par with the patentee's SAXAGLIPTIN (i.e Rs.41 to 49) based on the daily requirements. Based on the figures submitted by the patentee in Form-27 on 10/02/2014 the Applicant calculated the cost of importing one tablet of ONGLYZA and KOMBIGLYZE in India by the Patentee is only about Rs.0.80 and Rs.0.92 respectively. But the Applicant priced two medicines ONGLYZA and KOMBIGLYZE in the range of Rs.41 to 49 per tablet. Therefore, the Applicant alleged that the patentee remain a monopoly due to high pricing of the drugs despite the small amount of cost involved in manufacturing/importing a single tablet.

However, ironically the Applicant in its application for Compulsory Licensing initially proposed it selling price as Rs.27 to 32 per tablet but eventually revised its price during hearing held on 15/12/2015 in the range of Rs.11 to 16.

It was highlighted by the Controller that the Applicant in its submissions has not furnished the details of reasonable requirements of the public with respect to SAXAGLIPTIN, the comparative requirements of SAXAGLIPTIN and other DPP-4 inhibitors Lindagliptin, Sitagliptin and Vildagliptin or any authentic data or statistics on SAXAGLIPTIN prescription by the doctors over the other DPP-4 inhibitors. Hence in the absence of all the critical data above, the question of SAXAGLIPTIN'S availability and affordability can't be determined. Therefore the Applicant failed to *prima facie* show that the patented invention is not available to the public at a reasonably affordable price.

Section 84 (1) (c): That the patented invention is not worked in the territory of India

The Controller in this regard reasoned his findings from the judgment of Honorable Bombay High Court in the Bayer case, that to manufacture in India is not a necessary pre condition in all cases to establish patent's working in India. However, the onus is on the patent holder to establish the reasons which make it impossible to manufacture the patented drug in India, particularly when the Patentee has manufacturing facilities within the country. Hence the Controller stated that in the present application since the Applicant has failed to show the exact requirement of SAXAGLIPTIN in terms of the number of patients requiring it or whether it is in shortage, it is very difficult to conclude whether manufacturing in India is necessary or not.

CONCLUSION

In the above case, the Applicant has failed to provide evidence along with application or during hearing or supplementary submission. Further, the Applicant had failed to convince the Controller regarding any of the grounds specified under Section 84(1) of the Patents Act, therefore the Controller rejected the application for Compulsory License with a view that a *prima facie* case has not been made out under Section 84 of the Indian Patents Act.

ARE KNOWN SUBSTANCES REALLY A PATENTABLE SUBJECT MATTER IN LIGHT OF INDIAN PATENTS ACT, 1970.

Aayush Sharma

INTRODUCTION:

It is well stated in the Indian Patents Act, 1970 that grant of Product patent in India mainly in the areas of Pharmaceutical industry holds a relevance importance. In the last Patents (Amendment) Act, 2005 which is deemed to be revolutionized patent regime in India, amendment incorporated the provision of granting product patents in India. With the commencement of the amendment Act, patent protection in the fields of food, pharma, and drug products is now readily possible. The Indian patent practice relating to the patenting of food, medicine and drug products or biological material is relatively new and thus not so well established. Considering all patenting issues after the 2005 amendment, one of the major issue of this new regime is whether the **discovery of a new use of a known substance or pharmaceutical composition** would be entitled to a patent protection or not. Now with this article we discuss the issue of patentability of a new or subsequent medical use of a compound or composition wherein the first medical use of same is already known.

FROM THE INDIAN PERCEPTIVE:

With the execution of Indian Patents (Amendment) Act, 2005, it is now possible to obtain patent protection on a substance intended to be used or capable of being used as a medicine or drug. *According to section 3 (d) of the Act*, "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."[1]

Moreover, to obtain a patent for the second and subsequent use of a medicament the therapeutic efficacy must be enhanced or at least a new reactant must be employed in its manufacture. *Section 3(d)* clearly indicates that a substance or a composition must be novel, should involve an inventive step and should be capable of industrial application, whereas, swiss-type claim format deviates from the rule of absolute novelty. The discovery of previously unrecognized useful property of a drug is not considered novel in India and hence is not patentable. This section of the act makes it clear that swiss-type claims are not accepted for patent protection in India. An improvement made to a known substance does not qualify for patent protection in India.

The Act considers salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance to be the same substance, unless they differ significantly in properties with regard to efficacy. In India only a new chemical entity or a new molecule entity is granted protection. Formulations, such as, combinations of pharmaceuticals, changes in dosage form, new use of a known medicament, etc, are considered not patentable as there is lack of inventive step.

THE SCOPE OF PATENTABILITY OF NEW USE OF A KNOWN SUBSTANCE OR COMPOSITION- FROM US AND EPO PRECEPTIVE

There are different opinions regarding patentability of second and subsequent medical uses of known substances or pharmaceutical compositions. Under the Patent Laws of various countries, discovery of a new advantage of a known substance or pharmaceutical composition is considered as a new invention that qualifies to be patentable.

As per United States Patents Law US Code 101 *"whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."*[2] The claims addressed at the method of treatment are accepted in US, therefore it alleviates the need of swiss-type claim

1 http://ipindia.nic.in/ipr/patent/patent_2005.pdf

2 http://www.law.cornell.edu/uscode/text/35/101

format. However US patent and Trademark Office (USPTO) accepts swiss-type claims.

According to Section 4A (3) of the United Kingdom (UK) Patents Act 1977 (as amended), "in the case of an invention consisting of a substance or composition for use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art."[3] That is to say, the UK Patents Act regarded discovery of a new purpose of a known drug to be novel. The second and subsequent use of a known drug was not considered as lacking in novelty if the subsequent use did not form a part of the state-of-the-art. In Wyeth's Application [1985] RPC 545, one of the claims was drafted in the swiss-type format for patenting a new therapeutic use of a known drug which was refused by the examiner and later permitted by the UK Patents court on an appeal.

In a post G2/08 practice note issued by the UK Intellectual Property Office (IPO) the swiss-type claim format was prohibited from use in any UK patent application without any equivalent "grace period". Moreover, from the issuance of G2/08 the swiss-type claim format claiming second or subsequent medical use of a known drug was objected to by the UK IPO on the ground of lack of clarity.

USE OF SWISS TYPE CLAIM METHOD: -

Swiss type claims The origin of 'swiss-type claim format' is supported by the fact that the 'discovery of new use of a known drug' by a pharmaceutical company employs time, money and labor which makes the 'new use' equally worthy of patent protection as compared to the original research which established the first pharmaceutical use of that drug. To tackle the issue of establishing the 'Novelty of Purpose,' the European Patent Office and the Swiss Patent Office adopted the swiss-type claim format. The use of this form of claim format is derogation from the obligation for absolute novelty. Its format is *"Use of substance X in the preparation of a medicament for the treatment of disease Y."*

3 *http://www.ipo.gov.uk/patentsact1977.pdf*

THE REASONS FOR EXCLUSION

The basis for the exclusion of 'new use of already known chemical entity' from patentability is that it might lead to ever greening of that chemical entity. Through ever greening companies try to secure patents on large numbers of complex and often highly speculative patents through minor modifications, when the original patent over the active compound of a brand-name drug is due to expire. These subsequent patents cover different forms of the substance or minor variation and everything from aspects of the manufacturing process to tablet color, or even a chemical produced by the body when the drug is ingested and metabolized by the patient.

By ever greening the multinational pharmaceutical companies are retaining profits from their blockbuster drugs for long as possible. Pharmaceutical giants in countries like US adopt the swiss-type claim format as a monopolization strategy to evergreen their patented drugs.

CONCLUSION

It is clear from the Indian Patents Act, 1970, which mandates that for being patentable a substance or a composition must be novel, should involve an inventive step and should be capable of industrial application, whereas, swiss-type claim format deviates from the rule of absolute novelty. As per s. 3(d) of the Act, to obtain a patent for the second and subsequent use of a medicament, the therapeutic efficacy must be enhanced or at least a new reactant must be employed in its manufacture.

The stringent approach of Indian patent law towards the exclusion of swiss-type claim format has made the pharmaceutical industries reluctant towards further improvement of a known drug or discovery of new therapeutic use of a known substance. It is clear from the above paragraphs and discussions, that pharmaceutical research does not halt on patenting of one pharmaceutical activity mainly due to ongoing research the same drug may be found to have other beneficial properties which was previously unrecognized. Therefore, from the viewpoint of a pharma industry the exemption of swiss-type claim format in India is unwelcoming and would rather harm to the Industry.

AMBIT OF GLOBAL INTELLECTUAL RIGHTS OVER TRADITIONAL KNOWLEDGE

Monika Shailesh

Just like a cat is believed to have nine lives, the discussion of intellectual property rights over the local or traditional knowledge refuses to die. The moment it is believed to have ended it again resurrects. This editorial observes the deliberation over the elimination of indigenous or local knowledge forms from the global intellectual property system, and the Indian way to mitigation. Using the lens of cultural cosmopolitanism, the article highlights important trends in the contentions of developing countries engagement with intellectual property and other collateral knowledge protection systems. An amalgamation of aspects, such as economic globalization, advancement in genetic research for food, medicines, and agriculture, as well as the swelling occurrence of bio piracy[1] has made native and local group's incongruity concerning intellectual property an unkind ill affordable option.[2] These phenomenons indicates a one way transfer of native knowledge to the industrialized and developed western world leaving no or very little benefit to the place of originations. As a result the land of origination of this historical resource of traditional knowledge accumulated over a long period of time has resorted to the various mitigation plans.

Even though traditional knowledge is believed to be the source of medical relief for about eighty percent of the global population, traditional medicine and its associated knowledge are alleged as a form of local knowledge, in contrast to Western biomedicine. A number of aspects explain for the apparent local status of traditional medicine, and the cosmopolitan status of its Western counterpart. The most precarious factor is the colonial hierarchy of culture and power in which non-Western peoples and their knowledge systems are treated with disparagement and derogation.[3]

THE INDIAN ENTERPRISE

The Indian subcontinent has a gorgeous inheritance in traditional medicinal knowledge. This heritage originates from multiple medicinal traditions, including Ayurveda, homeopathy, naturopathy, Siddha, Unanani, and Yoga.[4] Even though the majority of this information has been passed down by verbal institution, noteworthy parts of it are described in diverse but usually inaccessible classical literature in different traditional or local dialects such as Hindi, Sanskrit, Urdu, Tamil, and others. It has become imperative to document this existing knowledge, available in public domain, on many traditional forms of medicine in order to protect the sovereignty of this traditional knowledge and to protect it from being misused in the form of intellectual property rights on prior art innovations. It has been observed that in modern times, various national as well as international pharmaceutical organizations and re-search institutions have been trying to exploit India's medicinal heritage through the intellectual property right system. Notable examples include the turmeric, basmati, and neem patents, the applications for which were the subject of controversy at the United States patent and Trademark Office (USPTO), the European patent Office (EPO), and elsewhere.[5] This experience became a cause of concern for India to address the nagging issue of the exploitation of its traditional medicinal heritage and the evil of biopiracy. India

1 *Generally, bio piracy is a slack mention to unidirectional adoption of biocultural knowledge and associated biological wealth of native and local communities by external interests or second comers.*

2 *See Chidi Oguamanam, Intellectual Property Rights in Plant Genetic Resources: Farmers' Rightsand Food Security of Indigenous and Local Communities, II DRAKE J. AGRIC. L. 273, 278 (2006)*

3 *See DUNCAN IVISON, POSTCOLONIAL LIBERALISM 35 (2002); Piracy, Biopiracy and Borrowing,supra note 18, at 33-37; Oguamanam,supra note 22.*

4 *See OGUAMANAM,supra note 14, at 120-21*

5 *See, e.g., Arewa, TRIPS and Traditional Knowledge, supra note 18, at 170-79*

fought successfully for the revocation of turmeric and basmati patents granted by United States Patent and Trademark Office (USPTO) and neem patent granted by European Patent Office (EPO). As a sequel to this, in 1999, the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy-(AYUSH), erstwhile Department of Indian System of Medicine and Homoeopathy (ISM&H) constituted an inter-disciplinary Task Force, for creating an approach paper on establishing a Traditional Knowledge Digital Library (TKDL).The project TKDL was initiated in the year 2001[6]. India's expertise is demonstrative of a universal trend in many developing countries with rich genetic resources and a traditional knowledge heritage.

According to Appu Rathinavelu, Executive Director, Rumbaugh Goodwin Institute for Cancer Research, Nova Southeastern University, U.S an awareness of the medicinal value of Indian plants goes up globally, more should be done by the Government to protect the nation's biodiversity[7]. Bakrudeen Ali Ahmed, visiting faculty, Institute of Biological Sciences, University of Malaya, Malaysia, who has specialized in researching the application of plant propagation, bio-active compound production via plant tissue culture methods and development of pharmaceutical products and pharmacological studies felt that it was important to explore and record the plant wealth of India. With a number claims of copyright over the various yoga asana and slokas have revealed the increase in anxiety of using intellectual property rights over the traditional knowledge. A rise in patent application related to yoga accessories like mats, devices and apparatus have been seen in many countries like RUSSIA, TAIWAN, CANADA, U.S.A, CHINA etc. and is clearly an indication towards the growing popularity of Indian traditional health practices. Discovery of Anti-Biotic was a major milestone in the medical world. However, since the failure of anti-biotics and rising cases of anti-biotic resistant disease causing agents the superbugs have diverted the attention of the researchers towards the age old traditional knowledge of Indian medicine to found out the plants and herbs that can prove to be very useful towards fighting this major issue. It has been estimated that about 2,000 patents relating to Indian medicinal systems were being erroneously granted by patent offices around the world.

India's rejoinder to the lush bio piracy was the formation of a defensive anti-adoption strategy, the TKDL(Traditional Knowledge Digital Library). For a patent to be granted, an applicant must satisfy the patent office that it is no prior art. As the Indian Traditional knowledge exist majorly in languages not understood by international patent offices across the world, there was no database for the patent officers to prove prior art. TKDL is an belligerent effort to create previously out-of-the-way but organized Indian traditional medicinal knowledge available in digital form, so that patent examiners will have them convenient as confirmation of prior art. The TKDL for India's systems of medicine is a massive government-sponsored interdisciplinary and inter departmental project. It deploys the nation's wealth of human resources in medicinal knowledge systems, information technology, science, research, and bureaucracy.[8] TKDL is intended to publish on customary knowledge from the prevailing texts related to Ayurveda, Unani and Siddha, in digitalized format in five global languages which are English, German, French, Japanese and Spanish.

In just under two years, in Europe alone, India has succeeded in bringing about the cancellation or withdrawal of 36 applications to patent traditionally known medicinal formulations. The key to this success has been its Traditional Knowledge Digital Library (TKDL), a database containing 34 million pages of formatted information on some 2,260,000 medicinal formulations in multiple languages.

6 *http://www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng*

7 *http://www.thehindu.com/news/cities/Tiruchirapalli/india-should-protect-patent-over-its-native-species/article7994968.ece*

8 *The collaborating institutions include the National Institute of Science Communication and Information Resources (NISCAIR), Council of Science and Industrial Research, Ministry of Science & Technology and the Department of Ayurveda, Yoga, Unani, Siddha and Homeopathy (AYUSH) and Ministry of Health and Family Welfare*

Designed as a tool to assist patent examiners of major intellectual property (IP) offices in carrying out prior art searches, the TKDL is a unique repository of India's traditional medical wisdom.[9]

CURRENT STATUS OF TKDL[10]

Current status of transcription of the traditional medicine formulation in the Traditional knowledge Digital Library is given in the following table :

Discipline	No. of texts (including volumes) used for transcription	Transcribed
Ayurveda	75 books	97,337
Unani	10 books	1,75,150
Siddha	50 books	23,016
Yoga	15 books	1,680
Total	150 books	2,92,662

CONCLUSION

The hard-edged lines of division and categorization between knowledge systems are no longer strictly sustainable, given the traffic across knowledge and cultural systems around the world. Both globalization and the dare of biopiracy have unlocked new prospects for logical initiatives to fissure and bridge the superficially impassable barrier between local knowledge and the intellectual property system. There is a distinguished progress in opening up local knowledge, especially traditional medicine, to that system. This is illustrated in the Indian-pioneered TKDL venture which is basically an anti-appropriation initiative. The TKDL has documented incredible accomplishment in augmenting traditional medicinal knowledge within the international patent process.

With the fact that many of the patents related to the Indian Traditional medicinal system have been granted wrongfully in U.S.A and Europe and several attempts being made to grip the Yoga under intellectual property rights it has become a matter of national concern. As the unidirectional flow of knowledge has brought no or a very little benefit to the people of India TKDL seems to be a great success. It has been estimated that over 0.22 million of patents were protected with the help of TKDL, otherwise opposing each patent around the world with a number of patent office would have been a time consuming costly matter for India.

9 *http://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html*

10 http://www.tkdl.res.in/tkdl/langdelaut/common/abouttkdl.asp?GL=Eng

THE DUTY TO DEDUCT TDS WITH REGARDS AN EXPATRIATE ARISES- ONLY WHEN HE HIMSELF FURNISHED THE DETAILS REGARDS THE OTHER EMPLOYER

Shipra Makkar Devgun

It has been recently held by the Hon'ble High Court of Delhi in the case of ***CIT v M/s AIR Liquide India Holdings*** *reported in 2015-TIOL-2808-HC-DEL-IT that no penalty under Section 271C of the Income Tax Act, 1961 can be levied against the Assesee and he cannot be held an Assesse in default when there was nothing brought on record by the Department to show that the Respondent had been intimated by the expatriate employees about the remuneration received by them from ALF.*

BRIEF FACTS OF THE CASE:

The fact leading to filing of the appeal by the revenue was that the Respondent was a wholly owned Indian subsidiary of Air Liquid France (ALF), a French multinational company. The Indian company has both Indian as well as expatriate employees on its pay rolls. A survey was conducted in the premises of the Respondent by the Department u/s 133A on a suspicion that multinational corporations were evading taxes on salary and allowances paid by them to the expatriate staff outside India. During the survey it was found that 2 employees were deputed by ALF to look after the Indian operations who were paid remuneration both by Indian company as well as ALF. TDS was deducted by the Respondents on the salaries paid by them to the said two persons, however no tax was deducted at source on the salaries paid to them by the parent company i/e ALF in terms of Section 192 read with S. 9 (1)(ii) of the Act. Accordingly, penalty proceedings u/s 271C were initiated against the Respondent.

The Additional Commissioner of Income Tax (TDS) and CIT (Appeals) dismissed the appeals filed by the respondent while rejecting the explanation offered by the respondent that it was unaware of the payment of salary by ALF to the expatriate employee and therefore, did not deduct tax.

However, the Hon'ble ITAT made a fact finding that there was no material on record to show that the respondent had been intimated by the expatriate employees about the remuneration being received by them from ALF. It noted that:

"Neither in the course of search under Section 133A nor subsequent thereto in evidence was found by the Department to this effect".

It was further noticed by the ITAT that after the search operation under Section 133A and discussion with the income tax authorities, the Respondent having become aware of the taxability of the remuneration received by the expatriate employees from ALF obtained the details and concurrence of ALF for the payment of tax dues. After completing necessary formalities and by arrangement with ALF, the Respondent commenced depositing not only the TDS but also the interest for the delay. Thus, both Sections 192(1) and 192(2) stood complied with by the Respondent even before penalty was levied under Section 271C of the Act by the order dated 17th November, 2000.

The Hon'ble ITAT observed that a duty to deduct tax at source from salary received by an expatriate employee from the 'other employer' could arise only when the employee himself furnishes the details in that regard to the company in India with which he was employed.

On appeal before the Hon'ble High Court, the Court in the light of the factual findings of the ITAT and relying on a similar case of CIT v Marubeni India (P) Ltd. reported in [2007] 294 ITR 157 (Del), accordingly dismissed the appeals filed by the revenue.

CONCLUSION:

The Duty to deduct TDS with regards an expatriate arises, only when he himself furnishes the details regards the other employer.

COMPANIES (INCORPORATION) AMENDMENT RULES, 2016

Arpita Karmakar

The Ministry of Corporate Affairs (MCA), vide notification dated January 22, 2016, issued the Companies (Incorporation) Amendment Rules, 2016, wherein rule 8, rule 9 and rule 36 of Companies (Incorporation) Rules, 2014 (hereinafter referred to as the principal rules), have been amended.

The changes in the principal rules have been briefed out as follows:

RULE 8-

i. Rule 8 of the principal rules provides for the names which are to be considered undesirable for incorporating a company. Vide this amendment notification, the government has omitted the following conditions from the list of undesirability:

a) The name which is not in consonance with the principal objects of the company as set out in the memorandum of association;

b) The proposed name is vague or an abbreviated name such as 'ABC limited' or '23K limited' or abbreviated name based on the name of the promoters;

c) The name which is intended or likely to produce a misleading impression regarding the scope or scale of its activities which would be beyond the resources at its disposal.

Accordingly, now application for name can be made in case the proposed name is in the manner mentioned above.

ii. Also, apart from the above, the government has further amended the principal rules wherein:

a) If any company has changed its activities, which are not reflected in its name, shall not be required to change its name in line with its activities.
Prior to this amendment, on change of its activities, the company was required to change its name within a period of six months from the change of activities and comply with all the provisions as applicable to change of name;

b) Prior to amendment, if the key word used in the name proposed was the name of a person other than the name(s) of the promoters or their close blood relatives, No objection from such other person(s) was required with the application for name. Also, in case the proposed name included the name of relatives, proof of relation was required to be furnished, along with the significance and proof thereof for use of coined words made out of the name of the promoters or their relatives.

Post this notification, the above clause has been omitted, thereby removing the obstructions of using the name of persons other than promoters or their close blood relatives. Neither there is any requirement of furnishing proof of relationship or the significance of proposing such words as the name of the company.

RULE 9:

As per the amended rule 9, an application for the reservation of a name shall be made in Form No. INC-1, which may be approved or rejected by the Registrar of Central Registration Centre (CRC). The CRC, having territorial jurisdiction all over India, has been established by the Central Government, to discharge and carry out the function of processing and disposal of application for reservation of names.

Prior to this amendment, the processing of application was done by the respective offices of Registrar of Companies (ROCs) according to the jurisdiction they have. It shall be noted that the processing and approval of name or names

proposed in e-form no. INC-29, shall continue to be done by the respective ROCs having jurisdiction over incorporation of companies under the Companies Act, 2013.

RULE 36:

Rule 36 was introduced vide Companies (Incorporation) Amendment Rules, 2015, for the purpose of simplifying the filing of forms for incorporation of a company in integrated process, via e-form INC-29, with effect from 01.05.2015.

According to sub-rule 12 of rule 36, the Registrar, on examining e-form INC-29, shall give intimation to the applicant to remove the defects and re-submit the e-form within fifteen days from the date of such intimation given by the Registrar. After the resubmission of the document, if the registrar still finds that the document is defective or incomplete in any respect, he shall give one more opportunity of fifteen days to remove such defects or deficiencies.

Based on the above sub-rule, this amended notification has inserted a new sub-clause wherein, after resubmission on second opportunity, if the registrar still finds that the document is defective or incomplete, he shall give third opportunity to remove such defects or deficiencies.

Therefore, only after giving three opportunities, if the Registrar is of the opinion that the document is defective or incomplete in any respect, he shall reject the e-form INC-29.

BRIEF FACTS OF THE CASE:

The fact leading to filing of the appeal by the revenue was that the Respondent was a wholly owned Indian subsidiary of Air Liquid France (ALF), a French multinational company. The Indian company has both Indian as well as expatriate employees on its pay rolls. A survey was conducted in the premises of the Respondent by the Department u/s 133A on a suspicion that multinational corporations were evading taxes on salary and allowances paid by them to the expatriate staff outside India. During the survey it was found that 2 employees were deputed by ALF to look after the Indian operations who were paid remuneration both by Indian company as well as ALF. TDS was deducted by the Respondents on the salaries paid by them to the said two persons, however no tax was deducted at source on the salaries paid to them by the parent company i/e ALF in terms of Section 192 read with S. 9 (1)(ii) of the Act. Accordingly, penalty proceedings u/s 271C were initiated against the Respondent.

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CONCLUSION:

The Duty to deduct TDS with regards an expatriate arises, only when he himself furnishes the details regards the other employer.

NEWSBYTES

DEEMED PUBLIC ISSUEC

The Securities and Exchange Board of India (SEBI) vide its press release dated 31 December 2015 has notified that any offer or allotment of securities shall be considered as public issue if the number of offerees / allottees exceeds 200 persons in a financial year under the Companies Act, 2013 as against the cap of 49 persons provided in the Companies Act, 1956. It further provide that in cases involving issuance of securities to more than 49 persons but up to 200 persons in a financial year, the companies may avoid penal action if they had provided the investors with an option to surrender the securities and get the refund amount at a price not less than the amount of subscription money paid along with 15% interest p.a.

PRIOR LAW

Prior to April 01, 2014, offers of securities - shares and debentures - by companies to more than 49 persons were deemed to be public offers. SEBI has initiated penal action on receipt of specific complaints against the companies offering such securities without complying with the relevant provisions of the Companies Act, 1956 and applicable SEBI Guidelines / Regulations governing a public issue. The companies making a public offer are required to issue a public offer document and an offer for sale in such scenario is allowed only if it is made to satisfy listing or continuous listing obligations.

DEEMED ISSUE

- Issuance of securities to more than 49 persons but up to 200 persons in a financial year would constitute a deemed public issue. The company/promoters can avoid penal action if they had provided the investors with an option to surrender the securities and get the refund amount at a price not less than the amount of subscription money paid along with 15% interest p.a. thereon. Therefore unlisted companies can now raise funds without issuing a public offer document
- The exit may be provided by the company itself or by the promoters or by such persons as arranged by the company / promoters.
- The refund shall be made through recognized banking channels.
- The companies will be allowed to adjust the amounts already paid to the allottees either as interest, dividend or otherwise from the amount of refund to be paid to investors.
- In case of transfer of securities by the original allottees, option for refund may be provided to the current holders of the securities.
- The refunds made by the company following the option for refund exercised by investors would be certified by independent practicing Chartered Accountants / practicing Company Secretaries / practicing Cost Accountants.

CONCLUSION

The Companies Act, 2013 provides for a higher cap with respect to private placement. The maximum number of allottees has been increased to 200 from 49 as provided in the Companies Act, 1956. If a company, whether listed or unlisted makes an offer to allot or invites subscription, or allots, or enters into an agreement to allot, securities to more than 200 persons, whether the payment for the securities has been received or not or whether the company intends to list its securities or not on any recognized stock exchange in or outside India, the same shall be deemed to be an offer to the public and shall accordingly be governed by the provisions of the Companies Act,1956. Therefore it was necessary to bring consistency between the provisions dealing with public offer and private placement.

The proposal has taken into account the interest of investors while recognising their right to stay invested in case they feel it is beneficial to them. By providing a guaranteed payment of subscription amount plus interest at 15 percent p.a, the investors interest has been secured shielding him from the volatility of the market. At the same time, the investors can continue to hold on to their if the proposition seems favorable to them thereby insuring them against potential risks.

FEW MAJOR DEVELOPMENTS IN DRUGS AND PHARMACEUTICAL INDUSTRY

No NOC for Pharmaceutical Exports to Developed Countries: The Central Drugs Standard Control Organisation (CDSCO) has relaxed the drug regulatory clearance for the pharmaceutical exporters of India to developed countries through wide No.DCGI/MISC/2015 (199) dated on December 11, 2015. It has been decided that the requirement of 'no-objection certificates' with respect to Shipping Bills from the port offices of the CDSCO for the export consignments to USA, Canada, Japan, Australia and European Union shall not be insisted with effect from January 1, 2016. This is being done in pursuit to bring ease in the drug regulatory practices in India related to export of drugs, medical devices and cosmetics. All the stakeholders are however required to comply with the regulatory requirements of the importing countries as per their specific need.

Regulation of e-Pharmacies: Circular issued by the Drugs Controller General of India (DGCI) dated December 30, 2015 does not impose any ban on e-pharmacies but only seeking strict adherence to the Drugs and Cosmetics Act and Rules. Online players based act as aggregators of both organised and unorganised retailers and should fully comply with all the rules stated by the Drugs and Cosmetics Act and should not allow any fulfillment of requirements without a proper prescription. The Drugs and Cosmetic Rules, 1945, under which the circular has been issued, regulates the sale and distribution of drugs in the country and does not distinguish between conventional and over-the-Internet sale of drugs. In the recent past, a few trade bodies of offline pharmacies have filed complaints stating that online medical stores are violating provisions under the Act. In this regard, the All India Drugs Control Officer's Confederation (AIDCOC) has in its letter to the sub-committee on e-pharmacy, suggested few amendments in Drugs and Cosmetics Rules, 1945, which include a separate part under Drugs and Cosmetic Rules, 1945 be incorporated to recognize online pharmacy including market place; market places should be required to register with the state licensing authority in which such market place (web platform) is located; market place should be subject to separate set of conditions of registration certificate which should include requirement of appointing registered pharmacist, ensuring that orders for Schedule H, Schedule H1 and X drugs are forwarded to the licensed pharmacy only if it is supported by valid prescription.

Proposed Cap on Sale Margins: With regard to the probe on "astronomical" price mark-ups on generic medicines that drug makers sell through distributors, as ordered by the Prime Minister's Office, a senior official in the Department of Pharmaceuticals (DoP) informed in mid January that a committee set up last year under the DoP has proposed a cap of 35% to check irrational margins on medicines. This margin is the margin which wholesales and retailers earn by selling the medicines. A total of 680 medicines are under the National List of Essential Medicines (NLEM) under the scheduled category of DPCO, 2013. The NPPA has already fixed the ceiling prices in respect of 530 medicines.

FORFEITURE OF PARTLY PAID UP SHARES - EXEMPTION FROM TAKEOVER REGULATIONS.

The Securities and Exchange Board of India (SEBI) vide its press release dated 30th November 2015 amended the SEBI (Substantial Acquisition of Shares and Takeovers) Regulations, 2011 for providing exemption from making an open offer for entities whose shareholding in a listed company increases due to forfeiture of shares.

The amendment was in line with the discussion paper issued by SEBI in August 2015 for seeking public comments on the issue. SEBI stated that

Increase in voting rights of any shareholder as a result of forfeiture of partly paid-up shares held by some shareholders is passive in nature as the process is initiated due to non-payment of call money by defaulting shareholders. Similarly, accrual of voting rights to the remaining shareholders, computed on pro rata basis, upon the expiry of call notice issued to the shareholders holding partly paid-up shares is also passive in nature.

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- As per SEBI's SAST regulations, any entity having over 25 per cent stake in a listed firm can hike the shareholding by up to 5 per cent in a financial year. If the limit is breached in a financial year, then that entity would have to make an open offer.
- Currently, there is no provision for exemptions under the Takeover Regulations in case of increase in the voting rights of a shareholder due to the expiry of call notice period and forfeiture of partly paid-up shares and an application has to be filed with SEBI for seeking exemption from the open offer obligations in this regard under regulation 11 of the SAST Regulations, 2011.
- If a member fails to pay any call, or installment of a call, on the day appointed for payment thereof,
    i. the Board may, at any time thereafter serve a notice on him requiring payment of so much of the call or installment as is unpaid, together with any interest which may have accrued.
    ii. The board or committee thereof shall pass a resolution authorizing the forfeiture of share and issue of notice for this purpose.
    iii. If the call money is not paid in response to such notice threatening forfeiture, the company may, at any time thereafter, before the payment required by the notice has been made, forfeit the shares by a resolution of the Board to that effect.

PASSIVE INCREASE IN VOTING RIGHTS

Any increase in voting right of a stakeholder due to unpaid dues of another shareholder should be considered passive in nature. This is because there is no effective increase in voting rights as voting rights on partly paid-up shares are considered to be in proportion to the actual amount paid for these shares and, under current rules, no individual can exercise any voting right in respect of any share on which any call or other sums are yet to be paid.

Any increase in voting rights on the expiry of call notice period may not be permanent and some shareholders may pay up the calls even after the expiry of call notice period. The shares are forfeited only after giving prior notice to the member on his failure to pay on the day specified for payment. The member can pay the call amount within the time period specified in the notice. The increase in voting rights becomes permanent only on forfeiture of shares but the same has also been exempted under the amendment.

Also, Increase in voting rights arising out of actions undertaken by the companies under the Companies Act, 2013 such as rights issues, buybacks and schemes of arrangement are exempt from the open offer obligations under regulation 10 of the SAST regulations. The aforementioned situations have the same impact on voting rights as in case of forfeiture as there is no positive act on the part of the acquirer with a view to gain control over the voting rights. The percentage increase in their voting rights was not by reason of any act of theirs but was incidental to the forfeiture of shares of other shareholders by the company.

Consequently, the increase in voting rights may not always be within the knowledge or control of the existing members and may lead to increased liability and resultant confusion. Therefore it is imperative that they be subjected to the same treatment and be exempted from making an Open offer.

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