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SUBMISSION OF WORKING REPORT: A MANDATE REQUIREMENT FOR EVERY PATENTEE AND LICENSEE

By: Aayush Sharma

The mandate requirement of working statement for every patent granted in India has been very well defined in section 146 (2) the Patents Act, 1970. The working statement requirement can be fulfilled by submitting the prescribed Form 27 at the Patent Office, each year within 3 months from the end of the calendar year, i.e. by 31st March of the subsequent year.

The working statement is a declaration required from the patentee or the licensee, stating if the patent has been commercially exploited / implemented / worked in India to meet the reasonable requirements of the public at a reasonable cost in the last calendar year, along with other details and reasons, as applicable. Non-compliance to the working statement may increase the risk of compulsory license and revocation of the patent in India. Also, the patentee or the licensee shall be punishable with a fine which may extend to ten lakh rupees for non-submission of the working statement. Despite the risk of revocation and huge penalty, it seems that the compliance mandate requirement by the right-holders is not fulfilled at the Patent Office.

In 2015, a writ petition was filed in public interest, at the Delhi high Court, pointing out serious lapses in the filing of “patent working” documents by various patentees. Filings under Form 27 are meant to indicate how patentees have (or have not) worked the patent for the public benefit. Even those patentees who have filed the working statement, took it very lightly and

submitted only scanty information. At the time of filing petition, the petitioner examined over 150 filed Form 27s relating to life saving drugs, high technology inventions and public funded research units. Based on the study, the petitioner found that many patentees have failed to submit annual returns.

Amongst the submitted forms, a number of them were either incomplete, evasive or defective. The sample also included shocking instances where patentees cited ‘confidentiality’ and refused answers to particular queries in the Form. The petitioner pointed out several other instances where requirement of working statement had been taken very lightly and vague information was submitted. Government’s Annual Report too, shows that over 30 per cent of patentees did not submit Form 27s in 2013. The Patent office has issued 43920 patents during the year 2012-13, but returns as prescribed under Form-27 have been received only from 27946 patentees; and, shockingly, only 6201 patents have been disclosed as being worked by the patentees. No action was taken by Controller General (CG) under Section 122.

Sample Case Study:

NATCO Pharma, which was granted a compulsory license for an important anti-cancer drug, did not disclose as to how it was operating the license (and the quantum of drugs it was selling etc.). This despite the fact, that the Patents Act requires such reporting on working of patents even from licensees. Even the compulsory licensing order issued by Controller General had mandated that NATCO submit all information pertaining to quarterly sales.

The Petitioner also queried the CGPD TM regarding the action in case of M/s NATCO Pharma having failed to comply with the said requirements. In its response the petitioner has been informed that as per its records "no details are available".

Another shortcoming can be seen where Ericsson, in respect of Patent No. 203034 of August 24, 1999, mentioned against the column "the licenses and sub-licenses grant during the year" that *as all the license are confidential in nature, the details pertaining to the same shall be provided under specific direction from the Patent Office.*

The petitioner pointed that so far as the grant of patents is concerned, pertinent information is available on the website of the Patents Office. All that the patentees submitting Form-27 are required to submit, is the details of the licenses and sublicenses. This information cannot be termed "confidential" and therefore, the Patents Office must treat such suppression as failure to comply with the requirements of Section 146 of the Patents Act, 1970 and to take action against the patentees who do not furnish the required information.

The respondent, when came apprised about the above-mentioned facts, stated that concerns raised by the petitioner are valid and it is not adversarial litigation. The Respondent admitted that no action had been initiated under Section 122 so far. He also stated that Government was re-examining the form itself in view of the glaring defects pointed out in the petition.

After hearing the submissions, the Bench expressed disappointment with the state of affairs and directed the respondents to file

a status report before the next date of hearing on the extent of non-compliance and action taken. In particular, it asked the Government to state what steps were taken after filing the writ petition and the course of action planned to rectify the form.

MEMES AND COPYRIGHT: FAIR USE OR INFRINGEMENT?

By Shrabani Rout

In the year 1976, Richard Dawkins, an evolutionary biologist devised, the term 'meme' in his book "The Selfish Gene". In this book, Dawkins defines the meme as a unit of cultural meaning, such as a value or an idea, which is passed from one generation to another. Dawkins further illustrated that the meme is the cultural counterpart to the unit of physical heredity.

In recent times, the most popular understanding of memes would be illustrations, photos or movie excerpts which are superimposed with text with a humorous undertone, hence placed in a completely new funny context. These internet jokes (memes) spread like wildfire in the internet community, hence making the memes viral. The main issue here is whether these light-hearted memes which are mostly ironic and critical; functioning as a parody for the main content is infringing copyrights of the original artist?

A meme would fall under the ambit of 'artistic works' which is defined under the provision of section 2 (c) of the Copyright Act, 1957 which states that an artistic works include paintings, sculptures, drawings (including diagrams, maps, charts or plans), engravings, photographs, works of architecture and works of artistic craftsmanship. As mentioned earlier, an image/photograph in a meme is mostly copyrighted, thus sharing without an authorization will constitute an infringement. Any kind of reproduction by way of distribution and sharing of the meme, which has copyright wholly or partly, would come under the ambit of being an 'infringing copy' as stated in section 2 (m) (i) of the Copyright Act.

In order to successfully gain the fair use defense in India, a creator has to fulfill two conditions: (i) the intention to compete with the copyright holder must not be there; and (ii) improper usage of the original photograph/image/video, etc. must not be done. The first condition, also known as the market substitution test, can be easily won as the main purpose of a meme is taking a sardonic or comical take on something involving someone and does not seek to compete with the right holder. The second condition involves the term 'improper use', which is a very broad term and cannot be defined in a strait jacket definition rather it is open for interpretation and further deliberation. Since meme is for fun purposes, they hardly come under the purview of improper use unless they appear to be blatantly offensive to the right holder.

The 'fair use' doctrine is a legitimate defense in cases of copyright infringement. The Copyright Act enlists four different factors to determine the use of copyright work is fair or not, but none of these factors are determinative. The first factor is the purpose and the character of the use, second factor talks about the nature of the copyrighted work. The third factor talks about the amount and substantiality of the portion used in relation to the copyrighted work as a whole. The last factor talks about the effect of the use upon the potential market in regard to the copyrighted work¹.

The memes which weigh against fair use, for example a meme that an enterprise creates and distributes for sales and marketing purposes has a commercial element. These memes are different to the Internet memes created by fans, individuals, etc. If the nature of the copyrighted work is more factual and contemporary (for example, a picture of a historical figure), rather than something more creative (for example, a clip from a motion

¹ <https://techaeris.com/2015/09/05/blog-sued-by-getty-images-for-using-popular-socially-awkward-penguin-meme/>

picture), this will favor fair use. If the meme includes a short clip from a longer movie, then the amount and substantiality of the use factor will favor fair use; however, this may not be the same case when the meme consists of a single photograph/image.

Till date, India has not witnessed any memeology litigation. But in the USA, Warner Bros faced litigation under copyright infringement after they used the famous 'Nyan Cat' and 'Keyboard Cat' in their game Scribblenauts² and had to pay heavy compensation to the plaintiffs Charles Schmidt and Christopher Orlando Torres. AT&T President Aaron Slater faced \$100 million racial discrimination litigation after he shared an infamous racist meme³.

As it is stated above, memes have no commercial value and they usually fall under the ambit of fair use defense. But this defense won't work, when there is infringement in regard to right to privacy of an individual. The defense of right to speech and expression will not work when people/celebrities start using their publicity/privacy rights against 'mistaken' perpetrators. Copyright infringement comes into picture where there is non-obtainment of consent from the author/individual before using his/her image. Therefore, young and amateur creators must procure necessary licenses and approvals from the copyright holders to prevent any liability in the future.

² *Charles Schmidt & Christopher Orlando Torres v. Warner Bros Entertainment CV 13-02824*

³

<http://www.mondaq.com/india/x/417492/Copyright/Meme+vis+a+vis+Copyright+Law>

UNIVERSALITY TERRITORIALITY DOCTRINE REFERENCE WELL- KNOWN TRADEMARKS

By Shrabani Rout & Garima Raonta⁴

Introduction

The Indian Trade Mark Law bestows considerable protection on “well-known” trademarks. Well known trademarks have been defined under the Trade Marks Act, 1999 as a mark which is associated with a particular range of goods or services, by the public and if such mark is used on some other goods or services, it raises a presumption that there is a connection between the two.⁵ The concept of trans-border reputation and goodwill of a corporation was recognized by the Hon’ble Supreme Court of India, back in 1996, in the case of *N.R. Dongre & Ors. v Whirlpool Corporation & Anr.*⁶ But with the passage of time, the views of the Courts have changed regarding trans-border reputation. This article aims at explaining the concept of the universality and territoriality doctrine, and which doctrine shall take precedence over the other with reference to well known trademarks.

Territoriality Doctrine

The Territoriality principle stipulates that the intellectual property rights do not extend beyond the territory of the sovereign state which had granted the rights in the first place. It favors the notion that the reputation of a product or service is limited to the territory of the country in which that trademark was granted the status of a well known trademark.

The Indian courts have also recognized this doctrine. For instance, in the recent case of *Jones Investment Co v. Vishnupriya Hosiery Mills*,⁷ the Intellectual Property Appellate Board (IPAB) had ruled against the notion of preventing Indian companies from using trademarks even though the MNCs have no intention to introduce their product in Indian market.

Universality Doctrine

According to the Universality doctrine, once a trademark is recognized or registered in one country, it gains universal recognition. It favors trans-border reputation and is an exception to the Territoriality doctrine. This means that if a trademark enjoys the status of a well known trademark in the United States of America, it would enjoy the same status with regards to its goods or services in India as well, or any other country for that matter.

The Apex court has held the same in a plethora of cases. For instance, in the case of *Milmet Oftho Industries & Ors v. Allergan Inc*⁸ the Hon’ble Supreme Court, after establishing the trans-border reputation of the Respondents stated that “The mere fact that the Respondents have not been using the mark in India would be irrelevant if they were first in the world market.”

Rise of Territoriality over Universality

Both the doctrines have been recognized and upheld by the Indian courts. This gives rise to a significant moot point relating to well known trademarks that whether they should be

⁴ Legal Intern, 4th year Army Law School, Mohali

⁵ Section 2(1)(zg), The Trade Marks Act, 1999

⁶ (1996) PTC 415 (Del)

⁷ Order (No.24 of 2014) , OA/48/2010/TM/CH & MP NO. 260/2010 IN OA/48/2010/TM/CH

⁸ 2004 (28) PTC 585 SC

governed by the territoriality doctrine or the universality doctrine.

The judicial and academic opinion all over the globe is in favor of the territoriality principle as it protects the domestic traders against giant multinational corporations based in other countries. The favored notion is that the corporation claiming the status of a “well known” trademark in a territory should actually possess a reputation in that territory. For instance, the Apex Court of U.K in the case of *Starbucks vs. British Sky Broadcasting*⁹ held that, no trader can complain of passing-off as against him in any territory in which he has no customers and nobody who is in trade relation with him.

The contention supporting Universality doctrine is that recognition and reputation of a trade mark is not contingent upon the actual sale of goods in India bearing the mark in question. Advertisement and promotion of the mark through different forms of media is sufficient to establish reputation and goodwill within a particular geographical area. But this perspective is not in accordance with the principle of equality because if two things have to be compared, they must be equals in the first place. Therefore, if a corporation has not launched its product or does not have any consumers as well as reputation in a specific market then it cannot be compared with the corporation which has an existing product as well as a consumer base in that market. It must be proved that the reputation of a corporation has exceeded the boundaries of its home country and has extended to other nations.

The same question came before the Apex court of India in the recent case of *Toyota Jidosha Kabushiki Kaisha V. M/S Prius Auto*

*Industries Limited*¹⁰ and it was held that it must necessarily be determined if there has been a spillover of the reputation and goodwill of the mark used by the claimant who has brought the passing off action in the country in question. This decision of the Hon’ble Supreme Court sets a new benchmark for testing of evidence to claim trans-border reputation in India. It is therefore necessary that the trade mark is recognized and has a separate existence in each sovereign Country. The Supreme Court, after considering the jurisprudence in the U.K and Australia on trans-border reputation, came to the conclusion that the issue of trans-border reputation would be governed, in India, by the territoriality principle and not by the principle of universality. The legal position which stands now in India on trans-border reputation is that although the concept is recognized in India and the presence of actual business establishment is not a requirement for establishing trans-border reputation, the existence or non-existence of trans-border reputation is a question of fact. Evidence to support the contention must be explosive or ground breaking. The spillover of reputation can be through the internet, advertisement or through any means which provides the citizens of a country with sufficient knowledge regarding a brand and its products.

Reputation of a trademark implies to the knowledge and awareness of such trademark among the public and is the means by which a trademark is recognized. With globalization of trade and commerce, products are widely available in every nook and corner of the world irrespective of their place of origin. Adding to this, the knowledge about the products reach other countries long before the actual

⁹ [2015] UKSC 31

¹⁰ Civil Appeal Nos. 5375-5377 of 2017 (14-12-2017)

availability of the product through various modern mass communication technology like TV, internet, newspapers, magazines, cinemas, etc. And thus, the reputation of a trademark is not limited to the country of its origin, but surpasses the geographical frontiers and is spread all across the world.

The nature of goodwill as a legal property with no physical existence means that when a business is carried on in more than one country, there must be separate goodwill in each. Federal Court of Australia in *ConAgra vs. McCain Foods* 6 (1992) 23 IPR 193 observed that the test is whether the owner of the goods has established a 'sufficient reputation' with respect to his goods within the particular country in order to acquire a sufficient level of consumer knowledge of the product and attraction for it to provide customers, which if lost, is likely to result in damage to him.

Therefore, by virtue of the above stated facts and observations it can be rightly inferred that the Territoriality doctrine takes precedence over the Universality doctrine.

Conclusion

The modern day trade, i.e globalization, has brought in multi-channel modes of sale of goods in the market and therefore it is the Territoriality Doctrine that would hold the field. Prior use of the trade mark in one jurisdiction should not *ipso facto* entitle its owner or user to claim exclusive rights to the said mark in another dominion.

Prior to the introduction of the New Economic Policy in 1991 the foreign brand owners or corporations were incapable of doing business in India. But post 1991 the Indian courts

adopted an approach which aimed at developing a level playing field for foreign corporations. By virtue of which, the giant corporations ended up exploiting the small domestic traders and started wiping them out of business. But now since the Apex court of India has ruled in the favor of the territoriality doctrine, it would provide protection to the domestic traders and entrepreneurs against international or foreign corporate entities.

Territoriality doctrine is in accordance with the principle of equity, justice and good conscience as nobody should be allowed to take the benefit of someone else's hard work and reputation and hence it should take precedence over the universality doctrine.

The stance of the Hon'ble Supreme Court in the case of *Jidosha Kabushiki Kaisha V. M/S Prius Auto Industries Limited*¹¹ signifies the story of an advancing IP jurisprudence in India which not only redefines trans-border reputation but also shows that IP jurisprudence manifests in sync with the business environment, and the changing economic landscape of India.

¹¹ Civil Appeal Nos. 5375-5377 of 2017 (14-12-2017)

TRADITIONAL KNOWLEDGE AND SCOPE FOR PATENT PROTECTION

By Suchi Rai

Traditional Knowledge

Traditional Knowledge (TK) is the awareness, experience, expertise, knowledge and applications that are established, continued, performed and passed on from generation to generation within a region or community, often forming a part of its cultural, social or spiritual identity. TK can be attributed to in a wide variety of contexts, viz. agricultural, scientific, technical, ecological and medicinal knowledge as well as biodiversity-related knowledge.

TK is mostly undocumented and typically inherited via word of mouth.

Examples are as follows:

- Use of turmeric (*Curcuma longa*) for medicinal purposes.
- Use of ashwagandha (*Withania somnifera*) to treat heart related ailments.
- Traditional healing practices such as Yoga.

Defensive protection of TK¹²

Defensive protection refers to a set of strategies to ensure that third parties do not gain illegitimate or unfounded IP rights over TK. These measures include the amendment of the World Intellectual Property Organization

(WIPO)-administered patent systems (the International Patent Classification system and the Patent Cooperation Treaty (PCT) Minimum Documentation) The PCT minimum documentation is defined by WIPO as the minimum requirement for patent collections used to search for prior art documents for the purpose of assessing novelty and inventiveness. Some countries and communities are also developing TK databases that may be used as evidence of 'prior art' to defeat a claim to a patent on such TK. WIPO has developed a toolkit to provide practical assistance to TK holders on documenting TK.

Positive protection of TK¹³

Two aspects of positive protection of TK by IP rights are being explored:

- Preventing unauthorized use of TK, and
- Active exploitation of TK by the originating community itself.

¹⁴Negotiations on an international legal instrument are taking place within the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. In some countries, *sui generis* legislation has been developed specifically to address the positive protection of TK. In addition, providers and users may also enter into contractual agreements and/or use existing IP systems of protection.

Patentability of Traditional Knowledge:

Indian patent laws do not permit the protection of TK under section 3 (p) of the Indian Patent Act, 1970. An invention which in effect, is traditional knowledge or which is an

¹² <http://www.wipo.int/tk/en/tk/>

¹³ <http://www.wipo.int/tk/en/tk/>

¹⁴ <http://www.wipo.int/tk/en/tk/>

aggregation or duplication of known properties of traditionally known component or components is not an invention and cannot be patented.

However, if there is a substantial improvement in the existing TK which enables the invention to fulfill the criteria under the Indian IP law, IP protection can be sought.

The key issue in protecting TK is prior knowledge of the innovation as much of TK is already in public domain being passed on orally or through documentation through generations. This makes most TK ineligible for IP protection as majority of information is already part of "prior art" and therefore there is very little in terms of novelty which can be established for patent protection.

TK is an integral part of strength of local community knowledge. Attempts to exploit TK owned by local communities, for industrial or commercial benefit is a major issue as it is unfair exploitation of knowledge owned by local communities, as IP protection creates monopoly of patent owners. Governments the world-over including India have enacted laws to prevent such unfair exploitation of TK.

¹⁵Indian law has adequate provisions for the protection of TK. Traditional knowledge, by its very definition, is in the public domain and hence, any application for patent relating to TK does not qualify as an invention under section 2 (1) (j) of the Patents Act, 1970, which defines that "invention means a new product or process involving an inventive step and capable of industrial application". Further, under section 3(e) of the Patents Act "a substance obtained by a mere admixture resulting only in the

aggregation of the properties of the components thereof or process for producing such substances" is not an invention and hence, not patentable.

Applications for patents based on TK contravening the provisions of law can be refused under section 15 or in pre-grant opposition under clauses (d), (f) and (k) of Section 25 (1) and granted patents can be revoked in post-grant opposition under clauses (d), (f) and (k) of Section 25 (2) of the Patents Act, 1970.

It is required that all patent applications relating to Traditional Knowledge (TK) are correctly identified, screened and classified as "Traditional Knowledge" by RECS Section of Patent Office. The RECS in-charge is required to take due care that no case relating to TK is wrongly screened and classified. Additionally, the person in-charge of screening is required to accord appropriate IPC classification for such TK applications so that these applications can be properly routed for examination to the respective groups such as Chemistry, Pharmaceuticals, Agrochemicals, Biotechnology, Microbiology, Biochemistry, Food, Mechanical, etc. The screening of an application as "Traditional Knowledge" is an administrative process for facilitating the examination and to indicate that the subject-matter of the application is important and has relevance in the context of traditionally known substances, articles or processes for preparing them or their use.

In every case related to TK, the Examiner is required to carry out a thorough search for anticipation in TKDL and/or other databases.

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If any citation is made from TKDL database, then copy of the citation (English translated) is required to be sent along with the examination report.

When the subject-matter of claims relate to extracts of plant materials containing undefined active ingredients, such claims cannot be said to be novel if the use of such plants or plant materials is pre-known as a part of teaching of TK. However, if the claims relate to alkaloids and/or active principles obtained from the plant materials and structures of the said alkaloids and/or active principles are characterized, which do not form the part of the prior art, such claims cannot be said to involve an inventive step, since the use of said plant materials and their therapeutic effects are known from the teaching of TK. Thus, the prior art motivates the person skilled in the art to isolate the individual ingredients such as alkaloids, flavonoids, phytosteroids, etc.

TKDL:¹⁶

Traditional Knowledge Digital Library is a collaborative project of the Government of India through the Council of Scientific and Industrial Research (CSIR) and the Ministry of AYUSH, to collect information on traditional knowledge existing in India, in various languages and format as a single repository. TKDL serves as a reference of prior arts for patent examiners at International Patent Offices (IPOs).

Features of TKDL:

The two main features of TKDL are *Accessibility* and *Availability*. TKDL provides

accessibility in terms of *Language, Format and Classification*. The traditional Indian knowledge exists in local languages such as Sanskrit, Urdu, Arabic, Persian, Tamil, etc. TKDL translates such traditional knowledge into the native languages of the patent examiners, and in five global languages - English, French, Spanish, German and Japanese. The *format* of TKDL is also unique and is similar to the format of the patent application, making it easily understandable for the patent examiners. The full listing for each TK entity contains a bibliography of traditional Indian documents, which in turn contains links to scanned images of these documents in the original language. TKDL has created a new classification system for the traditional knowledge, known as the Traditional Knowledge Resource Classification (TKRC), which is based on the structure of International Patent Classification (IPC). Each listing in the TKDL includes both TKRC codes and IPC codes. Another main feature is the availability of TKDL. TKDL in complete form is available only at certain national patent offices for use by patent examiners. However, a representative version of the database is available at the TKDL website. This database has 1,200 representative listings.

TKRC:

Traditional Knowledge Resource Classification (TKRC) is an innovative classification system of TKDL. TKRC has structured and classified the Indian Traditional Medicine System in approximately 25,000 subgroups for Ayurveda, Unani, Siddha and Yoga. TKRC has enabled incorporation of

¹⁶

<http://www.tkdlib.res.in/tkdlib/langdefault/common/Abouttkdlib.asp?GL=Eng>

about 200 sub-groups under A61K 36/00 as defined in the International Patent Classification instead of few sub-groups earlier available on medicinal plants under A61K 35/00; thus, enhancing the quality of search and examination of prior-art with respect to patent applications in the area of traditional knowledge.

In 2011, an International Conference was organized by World Intellectual Property Organization (WIPO) in collaboration with CSIR on 'Utilization of Traditional Knowledge Digital Library as a Model for Protection of Traditional Knowledge', at New Delhi. Pursuant to this, WIPO in collaboration with CSIR and DIPP (Ministry of Commerce and Industry), organized an 'International Study Visit to TKDL' for 19 countries interested in replication of TKDL.

TKDL has proved to be a strong tool in protecting the unlawful rights over existing knowledge of TK and having exclusive IP rights over such TK. It also demonstrates the proactive action to protect such knowledge for the current and upcoming generations for years. The idea is not to restrict the use of traditional knowledge, rather to ensure that wrong Patent Rights are not granted due to lack of access to prior art for patent examiners.

SUPREME COURT ASKS DRUG TECHNICAL ADVISORY BOARD TO DECIDE FATE OF 349 BANNED FIXED DRUG COMBINATION (FDCS) MEDICINES

By Vijaylaxmi Rathore

The Supreme Court, in its judgment on December 15, 2017, on the matter of fixed drug combinations, has asked the Centre to make arrangement for experts to examine 349 fixed dose combination (FDC) medicines to first determine if there is any "therapeutic justification" to make these FDCs.

The Supreme Court bench of Justice Rohinton Fali Nariman and Justice Sanjay Kishan Kaul, was considering a special leave petition filed by the Union of India and the All India Drug Action Network, and a batch of transfer petitions, challenging an order of the Delhi High Court that quashed the ban of 344 FDCs in December 2016 on the ground of lack of mandatory consultations with the Drug Testing Advisory Board (DTAB) and the Drug Consultative Committee (DCC), statutory requirements under Section 26A.

The present appeals and transfer petitions relate to the interpretation of Section 26A of the Drugs and Cosmetics Act, 1940. By the impugned judgment of the learned single Judge of the Delhi High Court dated 1.12.2016, the learned Judge has held that the mandatory condition precedent for the exercise of the power by the Central Government under Section 26A of the Drugs Act is the prior consultation of the DTAB set up under Section 5 of the said Act.

Whereas, the FDCs, which contain two or more therapeutic ingredients, packed into a single dose, were banned on the recommendation of the government-appointed Kokate committee, which was set up to look

into safety and efficacy of FDCs that lacked regulatory approval from the Central Government. The Kokate committee had deemed these FDCs irrational; and accordingly, the Government notified a ban on them.

About Kokate committee:

The Kokate committee was an expert committee set up by the Ministry of Health and Family Welfare (MoHFW) for examining and listing in categories, the safety and efficacy of FDCs as per the following terms of reference:

- I. FDCs which are considered grossly irrational/unsafe based on pharmacokinetic and pharmacodynamic interaction, dosage compatibilities of FDCs vis-a-vis that of single ingredients present in the FDC and available literature/evidence.
- II. FDCs which the Committee may consider necessary for further deliberation by any of the 10 Expert Committees already constituted.
- III. FDCs which are considered as safe and effective based on pharmacokinetic and pharmacodynamics interaction, dosage compatibilities of FDCS vis-a-vis that of single ingredients present in the FDC, available literature/evidence, clinical experience and other data available.
- IV. FDCs which may be considered as rational, based on present data and knowledge available. However, data in post market scenario is required to be generated within a period of 1 to 2 years to confirm the same.

The Kokate committee had reviewed over 6300 fixed dose combination products and classified them in the four categories as described above: a) irrational, b) require further deliberations, c) rationale and d) require additional data generation.

The Supreme Court Verdict -

The Supreme Court, in its verdict, stated that for the exercise of powers under Section 26 (A) of the Drugs and Cosmetics Act, the DTAB need not be mandatorily consulted by the Government in order to be convinced of reasons for banning a medicine. The Court remarked that the Government could be justified in declaring a ban even if it finds that the drug has been banned in other countries.

Insofar as the 15 drugs that have been banned by Central Government notifications and which were manufactured before September 21, 1988 are set aside, as these cases were never meant to be referred to Kokate Committee. However, it will be open for the Central Government, if it so chooses, de novo, to carry out an inquiry as to whether such drugs should be the subject matter of a notification under Section 26A of the Drugs Act.

Insofar the cases of 349 FDCs that have been banned Including 5 FDCs that banned recently pursuant to the Kokate Committee report, by notifications of the Central Government under Section 26A of the Drugs Act, should be sent to the DTAB, constituted under Section 5 of the Drugs Act, so that it can examine each of these cases and ultimately send a report to the Central Government.

Supreme Court (SC) directions to DTAB:

In order that an analysis be made in greater depth, the DTAB and/or a Sub-Committee formed by the DTAB for the purpose of taking

a re-look into these cases, will not only hear the petitioners/appellants before SC, but they will also hear submissions from the All India Drugs Action Network.

The DTAB/Sub-Committee set up for this purpose will deliberate on the parameters set out in Section 26A of the Drugs Act, as follows.

1. First and foremost, in each case, the DTAB or the Sub-Committee appointed by it, must satisfy itself that the use of the Fixed Dose Combinations (FDC) in question is likely to involve any one of the aforesaid three things:
 - a. That they are likely to involve any risk to human beings or animals; or
 - b. That the said FDCs do not have the therapeutic value claimed or purported to be claimed for them; or
 - c. That such FDCs contain ingredients and in such quantity for which there is no therapeutic justification.
2. The DTAB/Sub-Committee must also apply its mind as to whether it is then necessary or expedient, in the larger public interest, to regulate, restrict or prohibit the manufacture, sale or distribution of such FDCs. In short, the DTAB/Sub-Committee must clearly indicate in its report:
 - a. As to why, according to it, any one of the three factors indicated above is attracted;
 - b. Post such satisfaction, that in the larger public interest, it is necessary or expedient to (i) regulate, (ii)

restrict, or (iii) prohibit the manufacture, sale or distribution of such FDCs.

3. The DTAB/Sub-Committee must also indicate in its report as to why, in case it prohibits a particular FDC, restriction or regulation is not sufficient to control the manufacture and use of the FDC¹⁷.

Note - The SC suggested to DTAB/Sub-Committee to be set up for this purpose to afford the necessary hearing to all concerned, and thereafter decide whether the manufacture and sale of these drugs should be regulated, restricted or outright banned, and submit a report with its recommendations to the government within six months from the date on which this judgment is received by the DTAB.

The SC also suggested that the Central Government, thereafter, must give due regard to the report of the DTAB and to any other relevant information, and ultimately apply its mind to the parameters contained in Section 26A of the Drugs Act and, accordingly, either maintain the notifications already issued, or modify/substitute them or withdraw them.

Conclusion: The Supreme Court judgment on the issue of Fixed Dose Combinations is a landmark judgment, as this now gives a clear direction to the government and regulator to look into this long- standing issue of fixed dose combination products in the country. The apex court has referred the issue of prohibition of 349 FDCs to the union health ministry's expert body on technical matters, the Drugs Technical Advisory Board (DTAB). The court has further asked the DTAB to submit a report with its recommendations to the government within 6-month.

Case Citation: Union of India Anr. (Appellants) vs Pfizer Limited and Ors. (Respondents), Supreme Court of India, Civil Appeal No. 22972 of 2017 (arising out of SLP (C) No. 7061 of 2017), D/d 15.12.2017.

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