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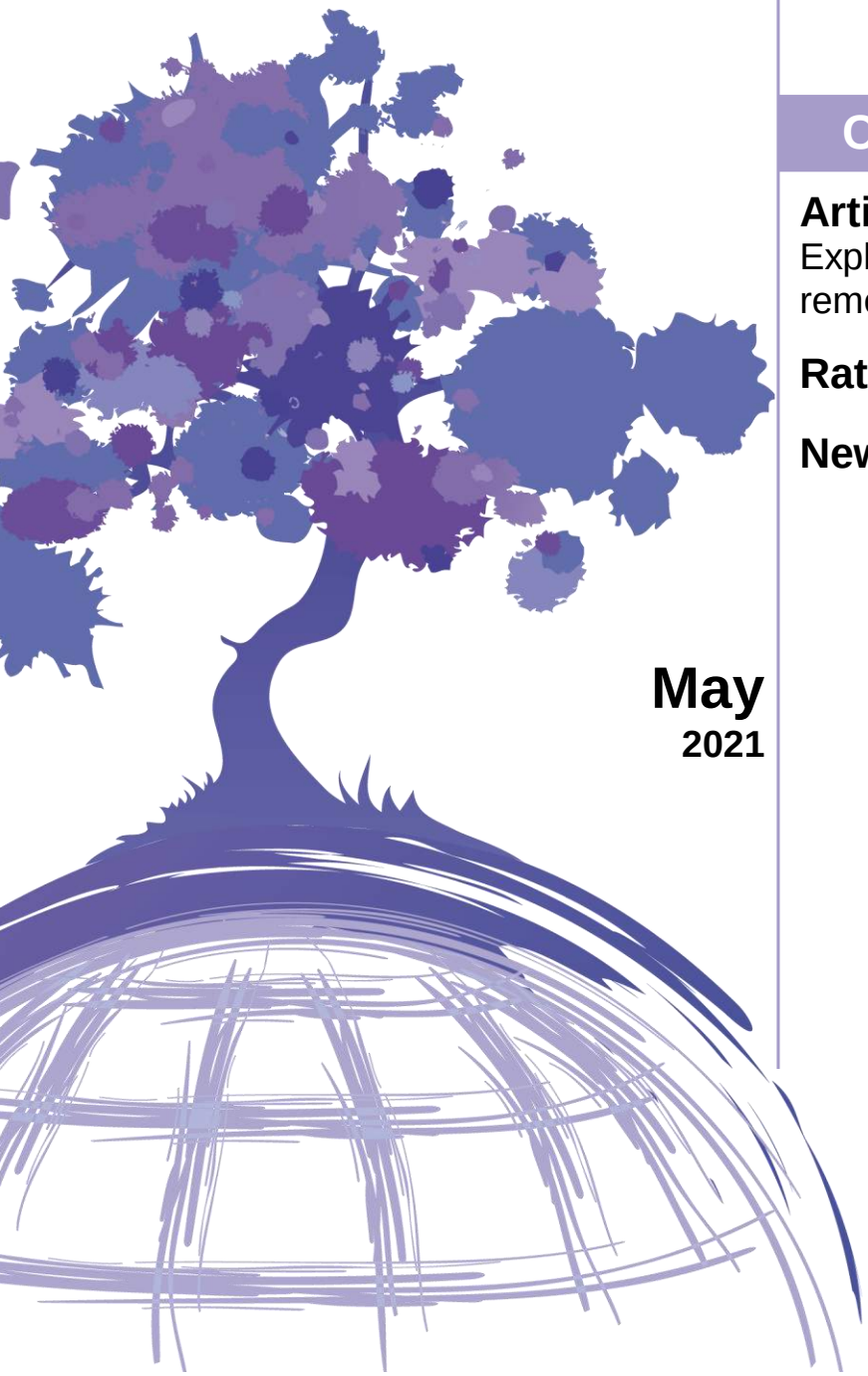

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Contents

Article

Exploring TRIPS Covid-19 waiver: Is the remedy effective?

By **Sutapa Jana and Sudarshan Shekhawat**

The unprecedented Covid-19 pandemic has wreaked havoc by not only taking countless lives but also by robbing the families of their means to livelihood. Countries across the world are grappling with both economic and social breakdown. While vaccinations have started in most countries, there is a glaring difference in accessibility and affordability of vaccines, drugs and other resources required to combat Covid-19 pandemic between the developed, developing and least developed countries. Also, if trends are any indicator, the poorest countries may not get vaccinated until at least the year 2024 and some countries may not even get there.[1] The situation of shortage of drugs and other resources is also worrying in many countries including India.

Considering the above scenario, a TRIPS waiver was jointly requested by India and South Africa. This has been applauded and supported by countries and various sections of the global community. The underlying presumption is that sooner or later the Intellectual Property Rights on these vaccines, drugs and other necessities may pose a barrier to public availability and affordability to the aforesaid tools required in the fight against Covid-19 pandemic. It needs to be examined if such a presumption is reasonable at all.

TRIPS waiver: What is it?

Covid-19 was declared as a global pandemic by WHO on 11 March 2020.[2] In this scenario of global emergency, termed as a revolutionary step, on 2 October 2020, India and South Africa made a joint submission, requesting the Council of TRIPS to recommend the General Council of WTO a limited temporary waiver from the implementation, application and enforcement of Sections 1 (Copyrights & Related Rights), 4 (Industrial Designs), 5 (Patents) and 7 (Protection of Undisclosed Information) of Part II of TRIPS Agreement in relation to prevention, containment or treatment of Covid-19, until vaccination is in place globally and majority of world's population develops immunity.[3]

What it seeks to achieve?

The request for waiver advocates that besides patents, other intellectual property may hinder access to affordable medical products and that many countries, primarily developing countries may face institutional or legal difficulties when using flexibilities provided under TRIPS Agreement.[4] The waiver proponents argue that it would give an option to all the TRIPS members irrespective of being a developed, developing or least developed country to neither grant nor

[1] https://www.theguardian.com/society/2021/jan/27/most-poor-nations-will-take-until-2024-to-achieve-mass-covid-19-immunisation

[2] https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020

[3] https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True

[4] *Ibid.*

enforce any patent or any other related IP pertaining to all Covid-19 drugs, vaccines, diagnostics, and other technologies, including masks and ventilators, for the duration as decided to combat this pandemic. This, it is argued, will provide space to all the countries to collaborate with all interested players, and not just IP holders, for research as well as scaling up and supplying necessary Covid-19 medicines, vaccines and other relief.[5]

Contradicting views related to waiver

Primary reason for seeking such a waiver has been the lack of access to vaccines and medicines to low-income countries. This is largely for the reason that manufacturers are unable to meet the demand and it is obvious that a handful of companies owning the technologies may not be able to amply provide vaccines for the entire global population.[6] Therefore, it has been advocated that such a waiver is needed, and exclusive rights and monopolies concentrated in the hands of a few is not an approach which can help us get through this pandemic. Numerous examples on IP acting as a barrier to access has been cited in the field of therapeutics, vaccines and other medicinal products.[7]

On the other hand, opponents of the waiver have argued that voluntary license agreements between innovator companies and other players are the way to ramp up the production, which these companies are already engaging into for scaling up the production.[8] To counter the same, it has been argued that pharmaceutical companies, like Gilead which owns patent for the API of Remdesivir in various jurisdictions, have entered into voluntary license agreements, *albeit* royalty free, with only a few of the manufacturers excluding half the world's population who might have to pay for the drugs at Gilead's own discretion.[9] Therefore, such restrictive license agreements can have an impact on the access and affordability to Covid-19 resources.[10]

Opponents of the waiver further argue that there are ample TRIPS flexibilities which are sufficient to combat the IP barriers during the Covid-19 pandemic. They advocate that voluntary efforts like COVAX with the objective to accelerate the development and manufacturing of Covid-19 vaccines, and to guarantee fair and equitable access for every country in the world have already been initiated.[11]

Contrarily, proponents of the waiver argue that the existing TRIPS flexibilities are not sufficient to counter this pandemic. The flexibilities are on a case to case basis and based on a country-specific approach whereas 'a global approach'[12] is the need of the hour. Moreover, on using TRIPS flexibilities, the countries face lot of limitations such as pressure from trading partners, lack of institutional capacities to scale up production of medical facilities and pharmaceutical products. One such example is that India has been put on watch-list by the US, for its section 3(d) and compulsory license schemes.[13] Further, it has been argued that this waiver will scale up global production without any threat of national or international IP disputes.[14] Further, parallel importation has its own limitations such as arduous contract negotiations,

[5] https://msfaccess.org/sites/default/files/2020-11/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf
[6] https://www.openaccessgovernment.org/trips-covid-19-waiver/103738/
[7] *Supra* Note 5.
[8] https://www.livemint.com/opinion/online-views/a-wto-waiver-on-patents-won-t-help-us-against-covid-11619625719625.html
[9] *Supra* Note 6.
[10] *Supra* Note 5.
[11] https://www.who.int/initiatives/act-accelerator/covax
[12] https://www.twn.my/title2/health.info/2021/hi210109.htm
[13] https://www.livemint.com/news/india/ustr-s-move-to-keep-india-on-ip-watch-list-could-hit-covid-drug-access-11588250898987.html, *Supra* Note 6.
[14] *Supra* Note 9.

rigorous regulatory requirements and approval being restricted to certain time and purpose only.

Another important point which has been argued by the proponents of TRIPS waiver is that none of the companies owning the patents have themselves made any big investments as most of them were funded by various governments and therefore, there cannot be any monopoly on such innovations. Therefore, the TRIPS incentive is not required in this case. Moreover, it has been also stated that there is enough competition between various governments to secure supply of vaccines, therefore the demand is huge and hence there is no such market failure that inhibits returns for these companies. Moreover, this waiver is not for existing or the continuing IP regime but a limited temporary waiver pertaining to Covid-19.

Present scenario of vaccines in India

Most experts believe that if India has to avoid a future carnage similar to the current wave, vaccination of population is critical. While the largest vaccination drive had been initiated in the country, reality is that there is a huge deficit of vaccines. As per Co-Win statistics, a total of more than 170 million doses have been administered and out of which a bit more than 36 million second doses have been administered.[15] At this rate, vaccination of more than 1.36 billion by next year would seems nearly impossible. While India is home to the largest manufacturer of vaccines in the world and was admired for its vaccination efforts for other countries, however, it is now being widely criticized for not being able to sufficiently provide vaccination to its own population. However, owing to the licensing arrangements with various vaccine manufacturers it is expected that the scarcity of vaccines might be overcome soon. Moreover, as per the CEO of Serum institute of India, scaling up the production is the formidable task which requires huge funding to the tune of 3000 crores.[16]

Is an IP waiver the answer to India's Covid-19 woes?

None of the arguments in favour of the waiver counter that the TRIPS protection is the very incentive which led to such rapid breakthroughs in the vaccine development for Covid-19. So, robbing these innovator or originator companies of their exclusivity incentive will not leave any impetus for these companies, researchers or scientists to provide such early breakthroughs.

As far as vaccines are concerned, it is not the IP which is acting as the sole barrier. There are problems relating to lack of raw materials, know-how transfer requirements and limited production capabilities because of the complexity of vaccines, that are the major hurdles for ramping up the production of vaccines.[17] Moreover, even without the waiver in place, almost all the vaccine companies have entered into voluntary licensing arrangements across the globe to facilitate the access of vaccines. These voluntary licensing arrangements ensure that the quality or standard of the product is maintained and the IP of the companies are also protected. Therefore, there is no necessity for enforcing such a blanket waiver for vaccines. Moreover, enforcing the waiver will not facilitate removal of hurdles like lack of institutional capacities and expertise and lead to ramping up of production of vaccines instantaneously. The major problems which are being encountered at least for vaccines are lack of raw materials and adequate production facilities. Various cumbersome regulatory regimes also act as an obstacle to

[15] https://dashboard.cowin.gov.in/

[16] https://scroll.in/latest/991581/covid-19-vaccine-production-very-stressed-need-rs-3000-crore-to-scale-up-serum-institute-chief

[17] *Supra* Note 8; https://www.statnews.com/2021/04/13/no-evidence-patents-slow-vaccine-access/

availability of the pharmaceutical drugs or vaccines or any other medical resources. Therefore, a TRIPS waiver cannot be the magic wand for increasing access and affordability of vaccines pertaining to Covid-19.

Many critical drugs being used in treatment of Covid-19 are biologics, which actually require a lot of exchange of additional information pertaining to the microbe being used, particular strain of that microbe, cell line being used, the standardized media and multiple other complexities in manufacturing. In such a scenario, patents alone may not be enough to obtain the final product. The know-how generated over a period of time to perfect the end result would also be equally important to arrive at the end product. Even if it is assumed that replicating the biologics by a competitor of an IP holder may not be difficult, the challenge of a regulatory approval for such an 'alternative/replica' within a short span of time would not be easy in addition to quality issues. So, in case of lack of biologics also, one cannot assume IP rights to be the sole culprit.

Lastly, considering purely chemical drugs, chemical reagents for test kits other tools including masks, PPE kits, tools used for oxygen cylinder, etc. which were in the market before Covid-19 pandemic and are now found to be effective for Covid-19, it can still be argued that know-how may not play such an important role and the same can be reverse-engineered or developed, if an IP waiver were in place covering the above items. However, it cannot still be completely denied that without the related know-how, it may be extremely difficult to arrive at the desired quality in the end products within a very short span of time. Therefore, even if it is assumed that TRIPS waiver may lead to easy access and affordable rates for these products, in absence of voluntary licensing arrangements, it seems to be a daunting task to successfully facilitate exchange of know-how to increase the production of such medicines and tools.

While Section 7 of Part II of the TRIPS Agreement relates to Protection of Undisclosed Information, and a waiver of the said Section may lead to forceful disclosure of know-how and confidential information which these companies have amassed over several of years to develop vaccines, biologics, therapeutics and other tools which are being used to put up a fight against this eerie pandemic. Know-how or trade secrets may be generally granted to the licensee along with the patent through execution of a Non-disclosure Agreement in addition to patent license agreement. Any forceful surrendering of these rights on account of waiver would be extremely disproportionate, may be counter-productive and can erode substantial value from these innovator companies which are part of a critical industry. Lastly, any such coercive measures will act as a deterrent to the companies to come up with inventions in the pharma space in addition to causing debilitating losses.

Even after getting an IP waiver, there are stringent regulatory laws in every country which pose a big challenge to such global production and supply approach, being claimed to be attainable through TRIPS waiver. In addition, most of the developing, and least developed countries suffer from infrastructure infirmities like effective storage and distribution facilities. As an example, the destruction caused by the second wave of Covid-19 in India cannot be solely attributed to lack of vaccines or medicines, but a major reason was lack of sufficient facilities, oxygen, ventilators etc. It was also admitted by the Government that there was adequate Oxygen in the country clearly showing that the centralized distribution was the issue.

Conclusion

It is imperative to vaccinate the larger share of world population at the earliest to limit the chances of mutation for the virus. Also, all countries need to have adequate supply of all tools required to put up a strong fight against any surge caused by Covid-19. Considering the current global scenario, it is not that the countries will be able to scale up the production rapidly as soon as a waiver is granted. Taking away the rights of the innovators or inventors would further deprive them of any incentive to keep up the scientific and technological breakthroughs.

Ripping off the IP rights may not create a harmony to attain this objective and on the contrary, it may lead to unwanted imbalances and adversely impact free transfer of technology across jurisdiction and international trade. These have the potential to do more harm than good in the long run. The governments must facilitate voluntary licensing arrangements and find ways to expedite the regulatory approvals or create certain efficient expedient regulatory regimes. Creation of joint ventures along with government funding can ensure that other challenges related to supply chains, industry infrastructure, storage and distribution channels are also tackled in a cohesive manner. Therefore, it is clear that mutual cooperation and collective efforts of various stakeholders including government, major pharma players, generics and scientific community is essential in combatting this pandemic and not the sole solution of TRIPS waiver.

[The authors are Principal Associate and Partner, respectively, in Intellectual Property Rights team at Lakshmikumaran & Sridharan Attorneys, New Delhi]

Ratio decidendi

Design – Compliance with standards when can lead to 'prior publication'

The Delhi High Court has rejected the contention that compliance with published standards can never be sufficient to constitute 'prior publication' of a design. The Court was of the view that this would have to be determined upon a consideration of the particular design and the published standards. Noting that the cited standards were in fact standards of the design itself, the Court held that where the novelty claimed by the owner of the registered design resides in the very element which is described in the standard with a reasonable degree of specificity, the design cannot be said to be novel or original. The Court also noted that the plaintiff itself asserted its compliance with the standards.

The dispute involved alleged infringement of the design of armature (construction) steel rods by the defendant. The defendant had relied upon

several international standards, including the British Standard B500C, the German Standard of 1984, the Polish Standard of 2006, International Standard 6935-2 of 2007, the Turkish Standard of 2010 and the Colombian Standard of 2012, to contend that the plaintiff's design was not original.

The Court noted that it was the surface pattern comprising of transverse and longitudinal ribs at an angle to each other that constituted the standard in question, and that these were not generic stipulations, but gave a detailed enumeration of the elements of the design. It noted that the product could be produced by reference to the design in question. It also observed that the situation would have been different if the standard had been of a characteristic which was not related to the design but to some other feature of the product, for example, the length of the rod, its weight, etc.

Plaintiff's plea of adoption of a particular combination of angles (48^0 and 65^0), was also rejected by the Court observing that benefit of the specific angles cannot be claimed in view of the definition of design in Section 2(d) of the Designs Act, 2000 and the prohibition contained in Section 4(c) thereof. It noted that the particular angles were not discernible by the eye alone, as required in Section 2(d) and were not significantly distinguishable from the published standard. The Court in this regard also noted that the design registration certificate did not refer to angles in question.

Noting that the plaintiff had no real prospect of success in the suit, the Court observed that the case was a fit one for summary judgement under Order XIII-A of the Civil Procedure Code. [*Kamdhenu Limited* v. *Aashiana Rolling Mills Ltd.* – Judgement dated 12 May 2021 in I.A. 647/2018 in CS (COMM) 90/2018, Delhi High Court]

'BharatPe' not confusingly or deseptively similar to 'PhonePe' – Suffix 'Pe' cannot be separated and prima facie has no secondary meaning

The Delhi High Court has rejected the application for grant of interim injunction in the case involving alleged infrigement of the plaintiff's mark 'PhonePe' by the defendant's mark 'BharatPe'.

In a case set up by the plaintiff essentially on the basis of the common 'Pe' suffix, the Court observed that both the marks were composite marks, which cannot be dissected. Drawing out the legal position from plethera of cited cases, the Court held that plaintiff cannot claim exclusivity solely over the 'Pe' suffix, as no infringement can be claimed on the basis of part of a registered trademark. Though it noted that there may be substance in the claim of the plaintiff that the 'Pe' suffix constitutes the dominant part or the essential feature of the 'PhonePe' and 'BharatPe' marks, and meant 'pay', it held that the expression was clearly descriptive of the services provided by the plaintiff and the defendants. Further, noting that if instead of 'Pe', the plaintiff had used the suffix 'Pay', it would not have been able to claim any exclusivity over the 'Pay' suffix, it held that by misspelling 'Pay' as 'Pe', the legal position cannot change. The Court also noted that at time of application for interim injunction, it was insufficient to conclude that the 'Pe' suffix was, in the public consciousness, indelibly associated with the plaintiff's services and had acquired any secondary meaning.

It also noted that barring the common 'Pe' suffix, it cannot be said that the marks were confusingly or deceptively similar. Further noting the

difference in the nature of services of the plaintiff and the defendant, the Court was of the view that consumers who deal with such applications may be expected, *prima facie*, to know the difference. It held that no *prima facie* case of passing off can be said to exist. [*Phonepe Private Limited* v. *Ezy Services* – Judgement dated 15 April 2021 in CS(COMM) 292/2019, Delhi High Court]

News Nuggets

Protection of intellectual property rights – India remains in USA's Priority Watch List

India has remained in the USA's Priority Watch List. As per USA's 2021 Special 301 Report released recently, India remains one of the world's most challenging major economies with respect to protection and enforcement of intellectual property rights. It states that the potential threat of patent revocations, lack of presumption of patent validity, and the narrow patentability criteria under the India Patents Act burden companies across different sectors, and patent applicants continue to confront costly and time-consuming pre- and post-grant oppositions, long waiting periods to receive patent approval, and excessive reporting requirements. The latest Report also states that the stakeholders continue to express concerns over vagueness in the interpretation of the India Patents Act. Further, Section 3(d) of the Indian Patent Act relating to restriction on patent-eligible subject matter is also a matter of concern for USA. According to the Report, India's overall IPR enforcement, despite progress made online, remains inadequate. It also notes that as per a recent study by OECD and EUIPO, India along with many countries are the leading sources of counterfeit medicines distributed globally. India also figures, along with many other countries, with high levels of online piracy and lack of effective enforcement. The Report also mentions that India do not effectively criminalizes unauthorised camcording in theaters and that it has slow opposition and cancellation proceedings in respect of trade mark protection. Argentina, Chile, China, Indonesia, Russia, Saudi Arabia, Ukraine and Venezuela are other countries in the 2021 Priority Watch List.

Use of trade mark in a published article when not violates Section 103

Merely because an online search for a word leads to some articles published in a news portal, it does not mean that the registered trade mark (involved in the searched word) has been falsely applied to the goods or services by the author of the articles. Observing so, the Bombay High Court has quashed the First Information Report (FIR) registered against the petitioner (author of the articles) for alleged violation of Section 103 of the Trade Marks Act, 1999. The case involved use of the official logos / trade mark of the 'Sakal Media Group' and 'Sakal Times' in few

alleged to be defamatory articles written by the petitioner. The High Court in *Prateek Chandragupt Goyal* v. *State of Maharashtra* [Judgement dated 20 April 2021] held that though the mark shown in the articles was the trade mark of Sakal Media Group under Section 2(z)(b) of the Trade Marks Act, considering Sections 101, 102 and 103 of the Act, the said mark cannot be said to be in the context of either 'goods' or 'services' as defined in Sections 2(j) and 2(z) of the Act.

Well-known mark of plaintiff – Defendant when cannot be restrained

Noting that the parties had earlier entered into a settlement, the Delhi High Court has modified its order granting *ad interim* injunction against use of the mark 'Siggnature' by the defendant. Plaintiff was using the mark 'Signature' in respect of alcoholic beverages while the defendant was using 'Siggnature' in respect of *pan masala* products. The Court though noted that the mark of the plaintiff was a well-known mark and there were many precedents stating that in respect of a well-known trade mark, a restraint order can be passed even in respect of different goods, it held that *prima facie* the judgements were not applicable. The High Court in *United Spirits Limited* v. *Som Fragrances Private Limited* [Order dated 28 April 2021] noted that in none of those decisions the parties had entered into a settlement as in the present case. According to the Court, the plaintiff was hence *prima facie* conscious that the use of this mark by the defendant does not create confusion or deception in the minds of the general public.

Copyrights in software coding – Copying of API code to reimplement user interface, a 'fair use'

The Supreme Court of the United States of America has held that Google's copying of the Java SE API (owned by Oracle) to reimplement a user interface, taking only what was needed to allow users to put their accrued talents to work in a new and transformative program, constituted a fair use of that material as a matter of law. Google had copied around 11,500 lines of code from the Java SE computer program. Noting that computer programs always serve a functional purpose, the Court observed that fair use has an important role to play for computer programs by providing a context-based check. The US Apex Court noted that as part of an interface, the copied lines were inherently bound together with uncopyrightable ideas and the creation of new creative expression (code independently written by Google). It noted that the code was very much different from the code that instructs the computer to execute a task and that Google's purpose was consistent with the creative progress that is the basic constitutional objective of copyright itself. The Court in the case *Google LLC* v. *Oracle America, Inc.* also found the 'substantiality' and 'market effect' factors in favour of fair use.

'Covishield' – No prima facie case of passing off by Serum Institute

The Bombay High Court has upheld the Order of the District Court rejecting the application for interim injunction to restrain the defendant from using the mark 'Covishield' for its vaccine for Covid-19. The Court for this purpose observed that while adequate material was not presented by the petitioner/appellant before

the Court regarding prior use and goodwill, there was convincing material available in respect of the defendant's prior use. Further, observing that the vaccine produced by the defendant was not available across the counter, and was sold to the government, the Court held that sale of appellant's disinfectant or sanitizer, sold over-the-counter, though related to same field of healthcare, cannot cause confusion. Plea of loss of future sale and potential injury were also rejected by the Court while declining to direct the defendant to maintain accounts. It observed that the argument that people may buy the product of the appellant thinking that they are protected against corona virus because of the use of the mark 'Covisheild', was self-destructive. Dismissing the appeal, the Court in *Cutis Biotech* v. *Serum Institute of India* [20 April 2021] also noted that an interim injunction directing the defendant to discontinue use of the mark will cause disruption in vaccine administration programme, having large scale remifications.

'Revital' a well-known mark – Delhi HC grants ex-parte injunction against 'Nuvital' for copyright in trade dress

Considering that the product in question was a health supplement, the Delhi High Court has passed an *ex-parte* injunction against use of the trade mark 'Nuvital' and the trade dress which is deceptively similar to that to of 'Revital'. The Court noted that the plaintiff was the owner of the copyright in the artistic work in the label / trade dress / carton packaging, including their overall colour combination, get up, placement of features, which constitute 'original artistic work' within the meaning of Section 2(c) of the Copyright Act, 1957. It may be noted that the Court in *Sun Pharmaceutical Industries Ltd.* v. *Nukind Healthcare P. Ltd.* [Order dated 28 April 2021] was of the view that there was infringement of trade mark and copyright and passing-off of the plaintiff's well-known mark 'REVITAL'.

LLP registration – Name already in use in different class, permissible

In a case where the registration of Limited Liability Partnership (LLP) in the name 'Reef Wellness and Excellence LLP' was denied by the Registrar of Companies as registration was already granted to 'REEFLEC', 'REEF', 'REEFIT FORTE', 'REEFER (HEMATANIC)', the Kerala High Court has directed the Registrar to incorporate the LLP without raising any dispute on the name proposed. The Court in this regard observed that earlier names were for products falling under Class 05 goods in Fourth Schedule to the Trade Marks Rules, 2002, while the petitioner/applicant had sought the name not for any product but for a service, which may further fall under Classes 44, 35 or 41 and not under Class 05. Supreme Court's decision in the case of *Nandhini Delux* v. *Karnataka Co-operative Milk Producers Federation Limited*, was relied upon by the Court in the dispute *Kunhi Muhammed Etayattil* v. *Asst. Registrar of Companies* [Judgement dated 7 April 2021].

'Mankind' – Prima facie confusion by 'Novakind'

Observing that *prima facie*, the suffix 'KIND', being common to all the products of the plaintiff, had attained distinctiveness within the meaning of Sections 17(2)(b) and 32 of the Trade Marks Act, 1999, the Delhi High Court has held that the use, by the defendant, of 'KIND', as the suffix for its pharmaceutical product, therefore, *prima facie*, infringes the plaintiffs' registered trademark. The Court was of the view that there was pernicious possibility of confusing or deceiving the public into believing that the products of the defendants

were those of the plaintiff. The Court in *Mankind Pharma Limited* v. *Novakind Bio Sciences Private Limited* also noted that the defendant was misrepresenting the registration of its trademark and the registered address, which was a serious matter justifying *ad interim* injunction, particularly because the products involved were pharmaceutical products.

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