

ISSN: 2582-2942



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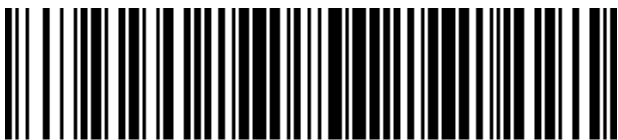
Legal Journal

Vol-II Issue- I

October, 2020

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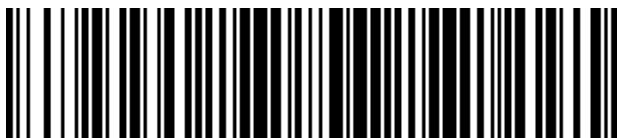
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**Licensing In and Out**

Sayali Joshi

## ABSTRACT

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*The drive to create something new and useful could be appealing and the dream of many business enterprises but could not be achieved in reality due to various reasons. One option that has gained popularity in the recent years is the 'licensing in and licensing out' model. It may often happen that the company has a well-established business in a specific arena but does not have the adequate amount of resources to carry out the research and develop and expand its business or enter new markets. This can normally be witnessed in the pharmaceutical sectors where a company either large or small has an established business but does not have the adequate resources to carry out researches or market their products and hence, enters into a licensing agreement with another company which has made an invention which is of some importance to the that company. However, this may not be the primary intention of many business companies and the innovators to enter into a licensing agreement. This paper will deal with whether the 'licensing in and out' model is indeed the best method of commercializing intellectual property and enter the global markets or does it attract more complications than benefits.*

## INTRODUCTION

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Intellectual property rights (IPRs) can be defined in economic terms as the rights to use and sell or dispose of the "creations of the mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce".<sup>1</sup> From the point of view of the owners of the intellectual property these form the part of their intangible assets. But mere possession of these assets is of no use to the innovator or the company owning such intellectual property rights. Thus, commercialisation of such IPR's is essential in order to earn returns. Commercialisation in simple terms means the process whereby ideas are turned into assets. According to the World Intellectual Property Organisation, commercialisation of an IP means selling one's idea which, if not exploited would bring no rewards to the innovator nor would find recognition in the global market.<sup>2</sup> Thus, one of the best means the world economy has developed to commercialise their inventions is to license it in-return for the payment to be received in the form of royalties.

As we are all aware of the fact that intellectual property rights are per se negative rights. That is to say it protects the owner of the intellectual property and his rights from being used by anyone without his permission. Hence, one of the best ways to access this permission is by means of taking a license to use it. If we study the demands of the global markets, we may come across the urge of creating something new or inventing something novel by many business enterprises. However, this seems like a farfetched dream of many business companies. Due to various factors and short comings some are in a position to achieve it while some are not. It may often happen that the company has a well-established business in a specific arena but does not have the adequate amount of resources to carry out the research and develop and expand its business or enter new markets. This can normally be witnessed in the pharmaceutical sectors where a company either large or small has an established business but does not have the adequate resources to carry out researches or market their products and hence, enters into a licensing agreement with another company which has made an invention which is of some importance to the that company. Similarly, it may also be the case that the individual innovator has invented a piece of technology but lacks the knowledge as how to exploit it or gain profits by commercializing it. Hence, licensing is one of the most effective method for the individual innovators to capitalize their innovation in return for payments

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<sup>1</sup> World intellectual property definition(<http://www.wipo.int/about-ip/en>)

<sup>2</sup> Gary Keller, 'Guide on Intellectual Property Commercialization', (2015), World Intellectual Property Organization, <[http://www.wipo.int/edocs/mdocs/mdocs/en/cdip\\_16/cdip\\_16\\_inf\\_4.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_16/cdip_16_inf_4.pdf) > accessed on 14 December 2017



and also an expeditious way in which the companies can gain out of these inventions without actually taking the trouble of re-inventing.

## LICENSING AND ITS TYPES

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A license on an intellectual property essentially means a grant of a permission by the owner or the licensor of the intellectual property to use the intellectual property which otherwise would amount to infringement. In other words, absence of such grant of permission would render the acts carried out by the any person other than the owner of the intellectual property as infringing the rights of the owner of the intellectual property. The grant of permission to use the intellectual property (license) does not involve any transfer of ownership, it's a mere permission to use the intellectual property with the consent of the owner. Usually the owner of the IP (intellectual property) who enters into a licensing agreement is termed as the "Licensor", whereas the person who obtains such a license is termed as "licensee". It is highly recommended that the licensing agreement should be written which creates a formal legal relationship between the licensor and the licensee. Also, the licensing agreement should clearly define the scope and the rights of the licensee thereby making efforts to avoid future disputes.

As we are well aware of the fact that the intellectual property in practicality means the rights over the ideas and creation of mind which are put down, intellectual property thus can take various forms. It may be the artistic work of an artisan, or the literary works of an author, or the inventions of a patent owner<sup>3</sup>. Thus, depending upon the type of property involved the licensing of such intellectual property differs. As for instance if the property to be licensed is a technological invention or a know-how license, then the licensing of such a property is often referred to as "patent licensing". Similarly, if the property to be licensed is a software then such licensing is coined as software licensing. In the same manner if the licensee obtains a license for the using the brand name or the trademark of another company, which has a well-established brand image then the act of doing so is called as "trade mark licensing".<sup>4</sup> Patent and trademark licensing are dealt by the author in the following segment.

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<sup>3</sup> < <http://www.gandb.com/wp-content/uploads/2017/03/Ch-2-Licensing-Basics.pdf> > accessed on 6 January 2018

<sup>4</sup> Sec. N.3

## PATENT LICENSING

Patent as we all know is the grant of monopoly by the government over an invention which is novel and new and is capable of industrial application. With the advancement and the advent of technology many new ideas keep emerging and patent applications are filed to protect these ideas in the relevant national patent offices. Now-a-days, the academic institutions are very active with their researches and we come across many cases whereby they assign or license their R&D in order to earn revenues. Licensing such technologies benefits the owner of the IP to geographically exploit its invention by opening the doors of new global markets. Even though licensing in all forms of intellectual property is very rampant these days the most common of all is the patent licensing, as it has benefits of its own.<sup>5</sup>

The university of Campinas, popularly known as the Unicamp is amongst the top ten universities of Brazil and Latin America<sup>6</sup>. With the help of its technology transfer office – Inova, this Brazilian university has been able to achieve great deals for its inventions in the short span of seven years. Where the university had started from scratch as a small research-based center in 1962 the university is now globally renowned for its researches. Unicamp has managed to coin many technologies and is well known for entering into 128 licensing agreements in the span of just two and a half years. The Brazilian university ‘Unicamp’ had licensed out ‘Biphor’ to an agricultural company named ‘Bunge’.<sup>7</sup> “Biphor is a white pigment based on aluminum phosphate nanoparticles”<sup>8</sup> used mainly in the field of nanotechnology. According to the terms of the agreement, Unicamp has managed to receive royalties at the rate of 1.5% for the span of twenty years along with royalties amounting to 33% to be paid to the inventors.

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<sup>5</sup> Foray D, Technology transfer in the TRIPS age: The need for new types of partnerships between the least developed and most advanced economies, report for The International Centre for Trade and Sustainable Development, 2008; Gupta V K, Insight into firm's strategy for leveraging technological competences in Asia, *Journal of Intellectual Property Rights*, 15 (1) (2010) 130-137.

<sup>6</sup> Di Giorgio R C in Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices edited by A Krattiger et al. (MIHR, Oxford, UK), 2007.

<sup>7</sup> Patent Licensing: Global Perspective and Analysis of Case Studies, *Journal of Intellectual Property Rights* Vol 15, November 2010, pp 442

<sup>8</sup> Rosana Ceron Di Giorgio, ‘From Univesity to industry: Technology Transfer At Unicamp in Brazil’, (2006) Handbook of Best Practices <<http://www.iphandbook.org/handbook/chPDFs/ch17/ipHandbook-Ch%2017%2016%20Di%20Giorgio%20UNICAMP%20Brazil.pdf>> accessed on 26 December 2017

Another interesting example is of the Ohio University, which had patented a drug named “Somarvet” to treat acromegaly, that is a drug to deal with the disorder of overproduction of body hormones. After spending 15 long years on the research and the development of the drug the university was successful in obtaining a patent protection from the US Food and Drug Administration in the year 2003. It was in the year 2010 that Pfizer obtained a license to market this drug from the university, and by the virtue of this licensing agreement the University of Ohio has managed to earned royalties amounting to \$8 million. Since then there has been a gradual increase in the amount of royalties received by the university and currently the university is receiving more than \$30 million from this licensing deal.<sup>9</sup>

### **TRADEMARK LICENSING:**

Licensing out could be an effective method for the licensor to commercialise his IP. Also, if the licensor has licensed the Trademark of his company along with the other IP, then in such a case the licensor’s image and goodwill is benefited from the marketing skills of the licensee and as far as the question of quality control is concerned the licensor has the liberty to expressly state that in the licensing agreement. Brand licensing or “merchandising” is a classic example of this. Also for the licensee, trade mark licensing provides an access to the consumer market captured by the licensor, and an impetus for dealing with the new channels of distribution and also helps in dealing with the competition.<sup>10</sup> Merchandising and licensing are one of the techniques that has gained popularity in the recent times. One of the best impacts of these techniques is the increased sales and creation of a brand- image, thus this explains why ‘The Coca-Cola Company’ is not only amongst the top three leading beverage companies in the world<sup>11</sup> but also amongst the top global licensors.<sup>12</sup> The Coca-Cola company has managed to capture the market with more than 300 licensors across the globe<sup>13</sup> distributing more

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<sup>9</sup> Forbes investing newsletters: In Pictures: Top Patent-Revenue-Generating Universities, Sept 12<sup>th</sup>, 2008., <<https://www.ohio.edu/research/communications/news>> accessed on 15 December 2017

<sup>10</sup> Herzgeld O and Bergovoy R on *Trade Mark Licensing Made Easy.* (2007) Managing Intell Prop 34

<sup>11</sup> Maggie McGrath, ‘World’s Largest Food and Beverage Companies 2017’ (24 May 2017), <<https://www.forbes.com/sites/maggiemcgrath/2017/05.24/worlds-largest-food-and-beverage-companies-2017-nestle-pepsi-and-coca-cola-dominate-the-landscape/#6d66e4603a69>> accessed 27 December 2017

<sup>12</sup> License Global, ‘The top 150 global licensors’ (1 May 2016) <<http://www.licensemag.com/license-global/top-150-global-licensors-2>> accessed on 21<sup>st</sup> December 2017

<sup>13</sup> See. N.3

than 500 beverages including Sprite, Fanta, Coca-Cola Zero, Minute-Maid and along with that drinkware and bar accessories like bottle openers and so on. According, to a survey conducted by LIMA of the licensing industry in 2017, the apparel industry has managed to be the top licensed product of the year followed by the toys industry and fashion accessories.<sup>14</sup> The Coca-Cola Company has thus managed to penetrate into the fashion and beauty products market as well with designer 'Tommy Hilfiger' designing rugby t-shirts with the Coca-Cola logo on it<sup>15</sup>. The company manages to earn around \$70 million royalties every year which amounts to only 0.3% of their total revenues.<sup>16</sup>

However, where the goods in question are not ordinary commodities but luxurious goods there always exists a fear in the minds of the licensors that the licensee's action may act detrimental to the reputation of the trademark or may cause serious injuries to the goodwill of the company. Well under such circumstances the licensors always expressly mention the scope and field of use and distribution of the goods and any actions in contravention to the provisions of the licensing agreement leaves the licensor with the option of opposing the resale of such goods by the licensee if such a resale is detrimental to the reputation of the mark.<sup>17</sup>

Thus, earlier where the property would majorly refer to tangible objects, in the modern times with the advent of intangible property rights and their related protection the awareness for the protection and commercialization of intangible property has gain importance. Depending upon property involved and the related intellectual property rights the licensing agreement differs and the terms of such agreement vary accordingly.

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<sup>14</sup> <<https://www.licensing.org/news/lima-annual-global-survey-of-licensing-industry-now-available/>> accessed on 27 December 2017

<sup>15</sup> Amy Ingoldsby, 'The Apparel and accessories account for 65% of Coca-Cola's licensing business', (July 7), <<<https://www.linkedin.com/pulse/20140707142105-35455432-apparel-and-accessories-account-for-65-of-coca-cola-s-licensing-business>>>accessed 1 January 2018.

<sup>16</sup> See.N.3

<sup>17</sup> Copad SA v Christian Dior Couture SA and Others.' 2009 ECR I-3421

## **STRATEGISING BUSINESS VIA LICENSING:**

Let's consider an example. Suppose there is a research-based company A, which own a considerable number of patents in the field of technology. However, being a small -scale company does not possess the adequate resources to exploit its inventions and also does not have the required knowledge to enter new markets or does not possess the required machinery to manufacture and distribute the invention in the global markets. Thus, licensing is an effective tool at the disposal of such companies or innovators who wish to market their inventions but lack the resources to do so.

“Licensing is a strategy for business development both for the licensor and for the licensee”<sup>18</sup>  
The author wants to convey that licensing is indeed a win -win situation for both the licensor and the licensee as well. From the point of view of the licensor who is the owner of the intellectual property this is an easy way to market his product. And from the point of view of the later licensing is a tool that enables him to capture the markets with the innovations of someone else. That is to say it helps him expand and develop his business without actually engaging his resources in developing the inventions

### **LICENSOR'S POINT OF VIEW**

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...As discussed earlier licensing is a way for the innovators to jump the local barriers and globalise their inventions. When a licensor enters into a licensing agreement with a foreign company or a multi-national enterprise the doors of the global market automatically open. It may so happen that as per the terms of the licensing agreement the manufacturing, production and sales of the technology may happen in more than just one country. And as a standard practice in licensing, since the risks of manufacturing and selling the technology are largely taken up by the licensee coupled with the huge amount of investments made by him, this creates a favourable environment for the licensor to enter into licensing agreement. And to add on to this the licensor even receives remuneration for his efforts by the way of royalties paid to him either on lump sum basis or by providing a share in the profit.<sup>19</sup>

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<sup>18</sup> Micheal brooke and John Sklilbeck: Licensing- the international sale of patents and know *how*', (Gower, 1994

<sup>19</sup> <<http://www.referenceforbusiness.com/management/Int-Loc/Licensing-and-Licensing-Agreements>> accessed on 21 December 2017

For instance, the famous apparel and perfume brand ‘Calvin Klein’ has captured the economy by launching 40 international and regional licensees in the global market thereby accelerating its sales and profitability. This licensing deal has covered a wide ranged of products including household commodities and managed generate a revenue of nearly \$3 billion only in the retail sales which is just half of its global sales.<sup>20</sup> Phillips and Van Heusen has captured the world market and sustained their expansion by introducing Arrow, Izod and Van Heusen to contemporary economies like the middle east, India, Mexico and so on. Arrow has managed conquered the Indian markets and is the most purchased men’s apparel brand in the country, thereby launching 18 stores and anticipates on opening 20 more.<sup>21</sup>

Also, another advantage of licensing is it provides an impetus to the companies or institutions to overcome the problem of shortage of resources to market their inventions. These types of problem of shortage of resources to commercialise the invention can specifically be seen with the academic or research institutions. Licensing is an advisable channel through which these institutions can bring their inventions to the store shelves.<sup>22</sup> However, it is to be kept in mind that such does not necessarily restrict only to academic institutions who does not possess the adequate means to market and sell their innovations but also to companies irrespective of their size and even to technologically enriched firms.

Licensing also at the same time enables the licensor to enter new branches of market other than the principle line of the product. Often product merchandising or brand licensing is adopted to expand the business of the enterprise in the areas which are relatively foreign to the principle specialization of the business. Thus, the Cartoon Network Enterprise a subsidiary of Turner Broadcasting System which is televisions most loved network among the kids. With the launch of its blockbuster series pf cartons like ‘The Powerpuff Girls, Dexter’s Laboratory, Jonny Bravo, Ricky and Morty, Ben 10

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<sup>20</sup> License Global, ‘The top 100 licensors’ (1 April,2008) <<http://www.licensemag.com/license-global/top-100-licensors>> accessed on 6 January 2018

<sup>21</sup> See. N.19

<sup>22</sup> See.N.18

and so on, the Cartoon network enterprise was in a position to create a global image and expand its business in the sector of apparels, accessories, toys, publishing, games and more.<sup>23</sup> With the re-launch of Ben 10 in Europe and Asia and the Powerpuff girls, the Cartoon Networks's global team has managed to capture over 100 licensors worldwide out of which 30 being only in the US. The company has managed to secure licensees in wide range of departments. For instance, where Funko will develop and market the cutlery and other accessories Jewelboots will launch interactive friendship bracelets featuring the cast, whereas Galarie will launch sweaters. Not only this but the company will also make an entry in the electronics sector. Likewise, for Ben 10 Playmate toys will be the global toy partners.<sup>24</sup>

Other advantages of licensing are the minimum amount investment to be made by the licensor. Usually, as a general trend of licensing when the licensor licenses his product or invention to the third party the risk of investment is usually taken up by the licensee. Also, if the country's economic policies suggest a complex structure to market the invention, then such a scenario licensing is a preferred option. Licensing is also a medium to launch the products in different countries when the launch in a certain country is negated due to the government policy of that specific country. Thus, the location where the licensor had initially thought of launching the product but could not launch it in reality due to some encumbrances, the licensor can market his products using a license. Thus, earlier in the past due to government regulations the use of plastic-pipes in the residential and housing sector was banned. The companies in the USA then took resort to licensing and licensed their products to other territories.<sup>25</sup>

Even not always, but a licensing agreement can bring benefits to the licensor if the licensee develops or brings any improvements to the product/invention. That is to say it

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<sup>23</sup> License Global, 'The top 150 global licensors' (1 May 2016) <<http://www.licensemag.com/license-global/top-150-global-licensors-2>> accessed on 21<sup>st</sup> December 2017

<sup>24</sup> 'Cartoon network enterprises unveils expanding portfolio at licensing....' <<https://www.prnewswire.com/.../cartoon-network-enterprises-unveils-expanding-portf.>>

<sup>25</sup> Homer Blair on *Overview of licensing and technology transfer*, N.C.J.Int'lL & Com, (1982), Vol.8, pg no.179

is indeed a way by which the licensor can get an access to the rights in the improvements that maybe be developed by the licensee during the tenure of his contract.<sup>26</sup>

Licensing can be termed as the gate-pass to enter foreign markets. While it may not be feasible for the licensee to manufacture and market the product at the same time, licensing is an effective way out. Along with this it also helps in eliminating the barriers that may arise due to lack of transportation facilities and helps the licensor penetrate into foreign markets using the skills and expertise of the licensee.<sup>27</sup>

Lastly, another benefit of licensing from the licensor's point of view is that it is one way in which the licensor can retain his ownership over his invention or product or brand but simultaneously earn royalties over it. As it is a well- established fact that unlike assignment in licensing there is no transfer of ownership in the favour of the licensee, licensing creates a favourable environment for the licensor whereby he is benefited with retaining the ownership of his IP along with receiving royalties for the same.

## LICENSEE'S POINT OF VIEW

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In the earlier segment, we had taken a look at the licensing deal from the licensor's point of view. Now we shall consider the other side of the coin. Every business enterprise either large or small, has the dream of entering and capturing the global markets by coming up with ideas that are never thought before. However, only few business entities are in a position to achieve their dream and bring it to reality. Others often cannot make it to the global markets even though have the rush to reach. Thus, licensing deals here act as medium through which the licensees can get an access to the brands and technologies and expertise which are pre-established. For instance, the United Bottlers have successfully acquired the license to manufacture coke from the Coca-Cola Company in

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<sup>26</sup> 'Licensing Advantages and disadvantages', World Intellectual Property organization, <<http://www.wipo.int/export/sites/www/sme/en/documents/pdf/licensing.pdf>> accessed on 29 December 2017

<sup>27</sup> Sec. N. 24



Zimbabwe.<sup>28</sup> This makes it easier for the licensee to reach and enter the global markets and gain a position in the market in their competitive era.<sup>29</sup>

In addition to that, the licensee may be a well-established company in the global market but however due to some short-comings does not possess the latest technological advancement or the modifications to the existing technologies. Licensing thus, serves as a medium to access such technological advancements and a means to protect the status of the company from being jeopardized. Licensing is one of the convenient and the quickest way to fill in this lacuna/ to bridge the gap.

Specifically, in trademark licensing a huge amount is spent by the licensors in advertising his brand to create a brand image. Licensee are thus in a position to gain out this advertisement without taking the trouble of advertising the product or having the burden of creating a reputation in the consumer market.<sup>30</sup>

Also, if we take the look at the small-scale industry, then we may come across the fact that often such small companies do not possess the adequate resources or financial assistance to develop a product. Licensing thus provides the licensee to gain access to such technological expertise and resources which would otherwise be inaccessible to them.

Other reason why licensing is preferred by licensees is because the licensing deal may help a company pair up with a rival company and establish a new product- which could possess the qualities of the “next blockbuster product” in the market. And as opposed to mergers and acquisitions or joint ventures, licensing involves less formalities, also is pocket friendly in comparison to the others.

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<sup>28</sup> Steve Carter: ‘Global Agricultural Marketing Management’, Food and agricultural organisation of United Nations, 1994

<sup>29</sup> Sec. N. 25

<sup>30</sup> Song N, 'The Legal Aspects of Licensing Agreements Involved in the Flow of Technology to Developing Countries (Particularly Singapore).' (1970) 2 Sing L Rev 66

The licensee as seen above can be benefitted from the licensing agreement, but that's not the end to it. The licensee must simultaneously possess a great bargaining power to negotiate the contract. The costs of acquiring a technology or a product should be reasonable and beneficial to the licensee. as a matter of fact there have been instances where the licensees have managed to get monetary gains by curtailing the profit-sharing ratios.<sup>31</sup>

## LICENSING IN THE DRUG INDUSTRY

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The drug industry is indeed one of the most dynamic industries which involves great amount of research and investments. However, the manner in which any pharmaceutical company or research institution can earn out of their inventions is a matter of how effectively their IP rights are exploited and their business is strategized.<sup>32</sup> Patent rights are those branches of intellectual property which enables an innovator to gain monopoly over the product or the process for a definite period of time. As patent rights being territorial in nature, it provides protection to the owner of the IP only in those jurisdictions where the patent protection over the invention is granted. The famous case of GlaxoSmithKline and Novartis over the generic reproduction of “Augmentin” in the United States of America(USA) is a classic example of this. This dates back to May,2003 when on the notice that the US legal system has rejected the patent claim of GSK over “Augmentin”, Novartis had launched the generic version of the drug. The US Court of Appeals for the Federal Circuit had held in this case that the Swiss Pharmaceutical company –Novartis was indeed not infringing any patent rights GlaxoSmithKline(GSK)<sup>33</sup>. Thus, were GlaxoSmithKline had the patent protection over “Augmentin” in the UK, the same could not acquire patent protection over the same drug in a different legal system. It is an undisputed fact that the patent protection has help in the expansion of the pharmaceutical sectors and has developed as an effective tool to expand the company's business and retain exclusivity over the invention.<sup>34</sup>

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<sup>31</sup> See. N.21

<sup>32</sup> Rakesh Mishra and Sesha Kumar on *How Pharma Companies can leverage their IP Rights-managing intellectual property*, (2008), pg no.57

<sup>33</sup> <[www.telegraph.co.uk](http://www.telegraph.co.uk)> Finance accessed 18 December 2017

<sup>34</sup> See. N.31

Also, the pharmaceutical sector combined with the chemical industry has often resulted in the best venture to earn the highest amount of royalties to the licensors.<sup>35</sup> In today's competitive era of drug development, it is quite conventional for the pharmaceutical companies to take resort of biotechnological companies in order to restore their position in the market and also their pipeline, which is considered as the "life-blood" of the pharmaceutical industry. The biotechnology companies in return count upon the pharmaceutical companies to market their products and also finance their inventions.<sup>36</sup> The scholars from the past had made an assumption that by the end of the millennium year the pharmaceutical industry would be in a position to have doubled the number of molecular inventions. And not only this but would have reduced the time to be invested upon launching a new drug in the market. However, these anticipations/goals could not be achieved in reality and the pharma industry was on the other hand the victim of heavy costs to be spent on the research and the development of a drug.<sup>37</sup> According to a recent study conducted by the Tufts Center for the Study of Drug Development the estimated expenses for launching a fully developed drug in the market is \$2.558 million.<sup>38</sup> Thus, even for the biotechnological companies sustaining the inflation and surviving in this emerging sector is not easy. Developing a new drug not only involves huge amounts of investments but also has to undergo various stages which include- the initial research, the pre-clinical trials followed by the clinical trials and so on. Only if the drug manages to successfully pass through all the stages and get an approval from the concerned national authority, then the drug reaches the market. Accordingly, the estimated time from the initial development of the drug up to the final stage where it is launched in the market ranges between seven to fourteen years roughly. Not only does it consume a lot of time but the risks involved in the development of a drug are also high. It is usually stated about half of the drug candidates cannot make it to the global markets as they cannot pass the clinical testing and also as a matter of practice inferences of any negative results during tests ultimately leads to the scrapping of the entire process.<sup>39</sup> Thus, where the biotechnological companies have the researches and skills to develop a drug the pharmaceuticals industry has the means and channels to market and

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<sup>35</sup> Micheal D. and Rostoker on *IDEA: The Journal of Law and Technology*, Vol. 24, Issue 2 (1983), pg.69

<sup>36</sup> Kharabi D, 'A Real Options Analysis of Pharmaceutical-Biotechnology Licensing.' (2006) 11(2) *Stan JL Bus & Fin* 201

<sup>37</sup> Myers, S., & Baker on '*A Drug discovery--an operating model for a new era*', (2001), Vol.19, pp.727-30.

<sup>38</sup> Tufts Center for the study of Drug Development, <[http://csdd.tufts.edu/news/complete\\_story/tufts\\_csdd\\_rd\\_cost\\_study\\_now\\_published](http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published)>, accessed 18 Dec 2017

<sup>39</sup> Philip and Pater on *Patents for chemicals, pharmaceuticals, and biotechnology-fundamentals of global law, practice, and strategy*, Fifth edition, pg no.425

commercialise the drug. Hence, both the industries often collaborate using licensing whereby the pharm companies are benefitted with the new inventions and the have access to the next “block-buster drug” and the biotechnological on the other hand gain royalties or assistance for further study and research.<sup>40</sup>

Recently in December 2016, SunPharma the India’s largest pharmaceutical company and Israel based- Moebius Medical had announced of collaborating through an exclusive licensing deal to develop a drug named “MM-II” to be used for the treatment of osteoarthritis.<sup>41</sup> Moebius Medical had developed the technology with the assistance of the professors of three respected research institutions namely- Hebrew University of Jerusalem, Technion Israel Institute of Technology and Hadassah Medical Centre. According to the terms of the licensing agreement, Moebius Medical will receive an upfront payment along with royalties to be paid post sales. The development of the drug in the pre-clinical stages will be conducted by Moebius Medical whereas Sun-Pharma will carry on with the development of the drug post phase-II. Not only this but SunPharma will acquire an exclusive license to globally commercialise and market the drug.<sup>42</sup>

However, licensing in the drug industry is not a cake walk. For many years the pharmaceutical industry has the played the villain. The industry is cursed for the growing rates of the medicines and the vaccines and the media had also contributed in developing this global image. Unfortunately, this is not the exact case. It took nearly forty-two years for the development of the first cancer drug.<sup>43</sup> The research and the innovation in the biotechnology and the pharmaceutical sector is relatively expensive and time consuming, the end result of which being the increased price of the drugs.

The governments of many countries to tackle this situation had come up with the idea of ‘compulsory licensing’. The remarkable decision of the Intellectual Property Appellate

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<sup>40</sup> Sec.N.36

<sup>41</sup> Press trust of India, ‘*The Hindu-Business Line*’ (Mumbai, 12 December 2016) <<http://www.thehindubusinessline.com/.../sun-pharma-moebius-tieup-to.../article9423796.ece>> accessed 20 December 2017

<sup>42</sup> BioMedReports: Sun pharma moebius medical sign exclusive global licensing deal to develop novel liposoma, (2016). Chatham: Newstex. Retrieved from <<https://search-proquest-com.ezproxy.library.qmul.ac.uk/docview/1847841513?accountid=1337>>, accessed on 20 December 2017

<sup>43</sup> ‘Cancer research and development and the drug development process’, (2007), Vol.8, Supp.3, Annals of Oncology.

Board<sup>44</sup> on the 4<sup>th</sup> of March 2013, granting compulsory license to Natco Pharmaceuticals created a history in the pharmaceutical patent licensing. M/s Bayer Corporation was the owner of the drug “Nexavarán” used in the treatment of kidney and liver cancer granted to it by the Indian Patent Office in 2008. Natco Pharma Ltd.– Pharmaceutical company of Indian origin had approached Bayer for obtaining a voluntary licensee, and on denial from Bayer had filed an application to the Controller of Patents in India for the grant of compulsory license.<sup>45</sup> Natco pharma had then applied for a compulsory license of the drug under Sec.84(1) of the Indian Patent Acts,1970<sup>46</sup> on the ground that Bayer was not making the drug accessible to the public at large.<sup>47</sup> On the 9<sup>th</sup> of march 2017, the Controller granted the license to Natco Pharma and an appeal was filed by Bayer with the IPAB. The IPAB taking the view of the public health at large and in the light of Art.21 – Right to life, of the Constitution of India stuck by the decision of the controller<sup>48</sup> which was later on upheld by the Bombay High court.

The larger picture of this being that this decision has now opened the doors for the competitors to secure compulsory licenses. Even though the decision sounds legally correct it has created a great amount of insecurities in the pharmaceutical sectors. A fear of using compulsory licensing as a tool to cope up with the competition is now prevalent in the global economy. Scholars have remarked that this decision will not only impact the investments in the pharma industry but will also hamper the expenditure occurring in the R&D of a new drug.<sup>49</sup> The growing threat for the pharma industry is the increasing number of compulsory licensing. Compulsory licensing as opposed to voluntary licensing does not give scope of negotiations

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<sup>44</sup>hereinafter referred to as IPAB.

<sup>45</sup> <[www.academia.edu/.../Natco\\_vs.\\_Bayer\\_Controller\\_of\\_Patents\\_2012\\_Case\\_Analysis](http://www.academia.edu/.../Natco_vs._Bayer_Controller_of_Patents_2012_Case_Analysis)> accessed 21December 2017

<sup>46</sup> Sec 84(1): Compulsory licences:

1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:<sup>[1]</sup>(a) that the reasonable requirements of the public with respect to the patented invention have

not been satisfied, or<sup>[1]</sup>

(b) that the patented invention is not available to the public at a reasonably affordable price,

or<sup>[1]</sup>

(c) that the patented invention is not worked in the territory of India.

<sup>47</sup> Sudhi Bagri and Nishtha Tiwari, ‘Compulsory Licensing in Relation to Pharmaceutical Sector in India’ (2017), Voil.8, Issue.1, IJIPR,

< [https://www.iaeme.com/MasterAdmin/uploadfolder/IJIPR.../IJIPR\\_08\\_01\\_001.pdf](https://www.iaeme.com/MasterAdmin/uploadfolder/IJIPR.../IJIPR_08_01_001.pdf) > accessed on 25 December,2017

<sup>48</sup> Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), <<http://www.ipab.tn.nic.in/045-2013.htm>> accessed on 30 December 2017.

<sup>49</sup> Sood M, 'Nato Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India.' (2013) 6(1) NUJS L Rev 9

and stalking the licensor. On the other hand, it jeopardises the position of the patent owner. Voluntary licensing as opposed to compulsory licensing offers the licensor the opportunity to choose its licensee and on agreed terms. In the above- mentioned case Bayer corporation had the patent over the drug but could not commercialize its invention as it failed the negotiations stage. Voluntary licensing can thus be adopted by companies to tackle the issue of compulsory licensing and commercialising their invention on their term as opposed to the agreement made in the threat of compulsion. Gilead for example, has entered into contracts with eleven companies to sell its drug for the treatment for ‘hepatitis C’<sup>50</sup>. As per the terms of the contract Gilead receives royalties at the rate of 7% on the total amount of profits earned also it has expressly permitted the distribution of drugs to ninety-one developing countries.<sup>51</sup>

At present voluntary licensing is the way out that the business has development to release themselves from the traps of compulsory licensing. Voluntary licensing either in or out, is not only beneficial in the drug industry but can be employed in the industries where the controversies over the inventions are yet to arise.<sup>52</sup>

## LICENSING IN GLOBAL MARKETS

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According to a survey conducted by LIMA on the licensed products in 2017, USA and Canada are the top global licensing merchandising markets generating a total revenue of \$152.3 billion followed by the Western Europe particularly France, Germany and UK. Northern Asia and China have also joined the league with total revenues amounting to \$24.5 billion.<sup>53</sup> In this world market scenario, the goal and aim of every country is to be equipped with the latest technology to sustain in the competitive market. However, if we conduct market analysis we come across a striking difference in the approach the developing and the developed nations have towards technology. Where majority of the developed nations have already developed the

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<sup>50</sup> Gilead-‘Gilead announces generic licensing agreements to increase access to Hepatitis C treatments in developing countries’<<http://www.gilead.com/.../gilead-announces-generic-licensing-agreements-to-increase-access>> accessed on 26 December 2017

<sup>51</sup> Kim DD, 'Voluntary Licensing of Pharmaceuticals: The Strategy against Compulsory Licensing.' (2016) 8(1) *Intell Prop Brief* 63,

<sup>52</sup> See.N.51

<sup>53</sup> ‘LIMA Annual Global Survey of Licensing Industry Now Available’<<https://www.licensing.org/news/lima-annual-global-survey-of-licensing-industry-now-available/>>, accessed on 27 December 2017

recent means of technology the developing nations are still striving to acquire that piece of technology. Hence, in order to enter the unfamiliar -markets it is essential to conduct a global market survey before licensing any technology or product. What may be useful and effective in a certain market or geographic condition may not have utility in a certain place. If we take the examples of woollen apparels and trench coats, where they are a necessity in colder regions such may not have any or less utility in tropical or temperate zones.

It is of utmost importance for the licensor as well as the licensee to conduct a market survey and analysis before entering an unfamiliar market. Adhering to the demands of the foreign market play a crucial rule before entering into the foreign markets. If the technology to be licensed has no utility in the market it is proposed to be licensed then such a deal would not yield fruitful results for the either party. At a point in time when Egypt had developed this urge for nationalism, it had come up with the practice of maintaining the national records in the Arabic text. As a matter of knowledge Arabic text is written and read from right to left as contrary to English text. Modifications to the English-language recording machine were felt to cope up the requirements of the Arabic language which was then used to maintain the national records.<sup>54</sup> Thus, is very essential that the technology is updated and fulfils the demands of the market for the licensee to earn best results out of the transactions.

The next step after the market analysis come the stage where the licensors needs to stalk the potential licensee. Finding the appropriate licensee in very crucial for the long-term development of the company. There exists a large of companies and individuals as well willing to offer their services, all that is needed is to locate the one best suited for your product. Licensing expos can be useful in reducing the burden and making the task easier. The financial stability, the marketing resources and strategies, the market reputation, the past records, the familiarity with the proposed markets and so on are the matters to be considered while selecting the licensee.<sup>55</sup> Along with that his excellence in the research and development, managerial skills and affiliations also play an important factor.<sup>56</sup>

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<sup>54</sup> Behrman JJ, 'Foreign Licensing.' (1957) 1(2) Pat Trademark & Copy J Res & Ed 220

<sup>55</sup> See. N. 21

<sup>56</sup> Porter PR, 'Common Mistakes in Licensing.' (1960) 42(2) J Pat Off Soc'y 92

Next comes the negotiation. Negotiations also play a very important for two reasons- one for arriving at an agreement that is best suited for both and second is to evaluate and examine the capabilities of the licensee.<sup>57</sup> Often it happens that the when the negotiations are not accurately in leads to undefined objectives and ambiguous scope and field of use.<sup>58</sup> Future securing a great deal on agreed terms depends upon the bargaining power of the parties. The basic idea of entering into negotiations is thus to grab the best deal possible while entering an unknown market and at the same time specifying the use and purpose of the technology or product licensed so as to put it to the desired appropriate use.

As a general rule of thumb, before entering any market a risk analysis should be conducted. Licensing is indeed a medium making the foreign markets accessible and brings the world closer, should be taken for granted as always being the best possible solution. The anticipation of market risks is very essential before entering any foreign market. The competition in the foreign market, the possible governmental regulations, the costs that are expected to be incurred for setting up the technology and so on should be considered.<sup>59</sup> For instance as per the regulations of the Indian Government on licensing technology in India, using of foreign brand names is prohibited for sales within the country. Even though export sales are permitted only under the condition that the product should be imprinted with the name of the manufacturing company in whose collaboration the technology is launched in the country with the view to secure brand name identity.<sup>60</sup>

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<sup>57</sup> Landau, Henry, Editor. *Doing Business Abroad*. New York, Practising Law Institute.

<sup>58</sup> Sec.N.54

<sup>59</sup> Sec. N. 21

<sup>60</sup> Fjetland M, 'Licensing Technology in India.' (1983) 11(11) Int'l Bus Law 33



## CONCLUSION

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Licensing is definitely an effective way that the business had developed, as it has helped the companies with limited resources cross that barrier and enter the global market. It is a vital form of intellectual property exploitation helping in strategizing business and opening new branches providing an access to the new economies. Indeed, it is crucial to analyse if licensing is certainly the best solution that can be embraced.<sup>61</sup>

Entering into a licensing agreement is not a cake walk and involves a complex structure. It completely depends upon how efficiently the agreement is drafted. A poorly drafted agreement paves the way for further disputes and complications. It is very essential that the rights and liabilities of both the parties are well defined, the scope and field of use is clearly set out along with the express mention about the licensee's right regarding improvisations. Where for the licensee the agreement is a prompt and rapid means of reaching the markets, the licensor on the other hand may not be that depended upon the agreement and be concerned only with the royalties.<sup>62</sup>

Also, to deal with the competition and fair payment to the licensee the governments of various countries have developed rules and regulations to monitor licensing agreements. Even though the provisions may differ from nation to nation the underlining fact remains that the limitations often restrict the exploitation of the technology or inventions.<sup>63</sup> Specially in the developing economies, the fear of colonization had instigated the governments to stricken the access to their economies despite being detrimental to their foreign policy and thus jeopardizing the positions of the licensors and the licensee.<sup>64</sup>

With the urge to enter the new markets and accelerate the process of establishing a global name it often happens that the competitors are turned into prospective licensees. There exists a threat that the licensee may develop the technology on its own without further assistance. Once the

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<sup>61</sup> 'Licensing of intellectual property assets: advantages and disadvantages'- WIPO <<http://www.wipo.int/export/sites/www/sme/en/documents/pdf/licensing.pdf> >, accessed on 31 December 2017

<sup>62</sup> See.N.21

<sup>63</sup> Ladas SP, 'Problems of Licensing Abroad.' (1966) 56(7) Trademark Rep 484

<sup>64</sup> Behrman JJ, 'Licensing Abroad under Patents, Trademarks, and Know-How by U.S. Companies.' (1958) 2(2) Pat Trademark & Copy J Res & Ed 181

competitor acquires the technology it is hazardous to the growth and global standing of the licensor. The best way to tackle this situation is by engaging the licensee with the developments of the technology and occupying him and ensuring his dependency.<sup>65</sup> Even though licensing is the best way to access technologies which are pre-established it should be dealt with caution.

In the current global scenario with advancement of technology and the means of exploitation of IPR there exists a lacuna in the economic and legislative policies of the developing economies to deal with such complexities. Where the developed economies have already established means of exploitation of the intellectual property in various manner, the developing economies are still striving to come with policies to govern such exploitations. Thus, bearing this in mind it is essential for the upcoming economies to focus on strategizing the business policies and form a nexus between strong marketing policies to target the size of the audience, their purchasing capacities and launch the products accordingly.<sup>66</sup>

However, despite shortcomings license still manages to be the optimum solution a business can develop to enhance and multiply its global standing and explore new branches. It would not be wrong to say that licensing has more benefits than drawbacks, however in all cases all the people entering into a licensing agreement must conduct a prior market study, negotiate the deal critically, anticipate the future risks and then decide if the agreement is beneficial or not. Licensing encourages the owner of the Intellectual property to retain the ownership and gain rewards for his efforts, also it enables the co-operating parties to gain out of the deal<sup>67</sup>. Along with that it encourages further research and development, foreign investment and helps in maintaining the goodwill. It acts as a medium to develop a market image and accelerates the acquisition of the newest technology without the trouble of inventing it. The author would like to state that licensing is a method of obtaining the best rewards at minimal costs. Where the other process of collaborations like entering into a joint-venture, or merging with a company are all time consuming, licensing offers the best deals in an expeditious manner.

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<sup>65</sup> See. N. 21

<sup>66</sup> Kanikaram Satyanarayana, 'In-Licensing Strategies by Public-Sector Institutions in Developing Countries', [2007] Handbook of Best Practices, <<http://www.iphandbook.org/handbook/chPDFs/ch11/ipHandbook-Ch%2011%2010%20Satyanarayana%20In-Licensing.pdf>> accessed on 31 December 2017

<sup>67</sup> See.N.51