

## FRAND VIS-À-VIS ESSENTIALITY: DETERMINATION OF SEP FOR NOVEL VIRUS' CURES

**Author- Lolita Delma crasta**

### **Abstract**

*In the constantly changing and evolving fields of technology and medicine, patents are sought actively by the inventors to safeguard their right over their ideas. When such inventions form the basis of a uniformity, a special Standard Essential Patent (SEP) is granted to the technology. This technology, centric on the customer's interest, needs to be declared a standard essential and determined by Standard Setting Organization (SSO)<sup>1</sup> through a detailed comparison with existing alternatives. However, when a novel technology is taken under this lens that has no other competitors to set a standard, questions arise on the competency of methods employed by an SSO. This paper delves into such stances in light of the cures discovered for the novel coronavirus, and examines the granting of standard essentiality. The position taken by Indian Judiciary in landmark cases including *Micromax v. Ericsson*; and *Philips N.V. & Anr. v. Rajesh Bansal* are analysed. In furtherance of the same, a SEP patent caters to the advantage of both the holder and the licensee, as it allows a licensee to use the technology upon payment of royalty as per FRAND principles. On the split side, however, this payment of royalty might increase commodity price, deferring competition laws and bringing the same into the light of a technology that is essential in the public interest, exempli gratia the vaccinal cure for the novel coronavirus. This paper analyses the ambit of justification for the rise in prices of 'need of the hour' technology. The paper aims to answer the dilemma whether FRAND principles can be exercised for deviating from fair competition for a necessary drug.*

**Keywords:** COVID-19, Intellectual Property Rights, Standard Essential Patent, FRAND principles.

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<sup>1</sup> Herein referred as SSO.

## I. INTRODUCTION

A Standard Settings Organization (SSO) is the regulatory body responsible for declaring and granting Standard Essential Patents (SEP). The body in India responsible for this function is the Bureau of Indian Standards (BIS).<sup>2</sup> This body employs the methodology of declaring standards formulated through specialist technical committees namely, Sectional Committees in various fields including Medical Equipment and Hospital Planning, Electronics and Information Technology. These standards are reviewed periodically to keep up with the regular advancements and are subject to alterations.

An inventor can claim protection upon his rights through a patent, valid across borders owing to the WTO agreement. This protection empowers only the inventor's and the applicant's rights over the production of the technology. An SEP is similar to a patent, in being valid across borders, however manufacturers other than the applicants can also indulge in its production. This is due to the fact that the technology protected under an SEP has an essential make that is necessary to be used by all the products in the field to aid the consumers. This statement can be better explained by an example. The 3-pin socket used by the electrical appliances in the country is widely availed to establish uniformity and ease. This aids the consumers to universally use the sockets and pin-based appliances. Thus, all electric board have a similar make.

Another example of this could be the medical composition and ingredients of drugs used in Indian medical system. It is necessary to maintain standard in medical realm, since only certain medical compositions suits certain groups like people belonging to one geographical area. Concerning this standard and essentiality, it becomes imperative for the technology to be used widely. However, allowing other manufacturers will diminish the rights of the inventor which leads to Fair, Reasonable and Non-Discriminatory licensing (FRAND) being formulated. Through the FRAND principles, the manufacturers pay a royalty percent to the patent holder to compensate for using their rights.

This principle has been utilised for various technological advancements. Still, a question arises as to its rationality when a thoroughly novel product arises. Taking into account the novel

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<sup>2</sup> Bureau of Indian Standards, The National Standards Body of India, via BIS Act 2016 (July 15, 2021, 16:54), <https://bis.gov.in/index.php/standards-overview/>.

SARS-COV-2, a cure for this will also be accounted as a novel entity despite the constituents in it. Despite being a necessity, this cure couldn't be declared a standard for the lack of alternatives. Recently, in WTO India and South Africa proposed a relaxation in norms of the TRIPS agreement to ensure quick and affordable access to vaccines and medicines.<sup>3</sup> This initiative was supported by 120 countries, and is yet to be set in concrete. A grant of patent usually takes about two to four years, and there are a few medi-cares pending a patent.

## II. LITERATURE REVIEW

### A. Srividhya Ragavan, *The Significance of The Data Exclusivity Debate and Its Impact on Generic Drugs*, JIPS Volume 1 Issue 1 (April 2017).

TRIPS Agreement establishes minimum standards for the availability, scope, and use of seven forms of intellectual property. Article 39 of the TRIPS Agreement throws light on data exclusivity and trade secrets. It protects disclosure of information against unfair competition as incorporated by the World Trade Organization after the Paris Convention. The members are obliged to protect any information that the owner deems a secret from unlawful disclosure and seeks to ensure honesty in commercial transactions. The submission of data to federal agencies, for instance as part of clinical trials, refers to data exclusivity which is transferred in confidence and kept inaccessible to third party. Similar to patents, the Indian Drugs and Cosmetics Act 1940, u/s 122E, provides for data exclusivity for a "new drug" for a total period of 4 years from the date of approval.<sup>4</sup>

### B. Hanns Ullrich, *Frاند Access to Open Standards And The Patent Exclusivity: Restating The Principles*, Max Planck Institute For Innovation And Competition Research Paper No. 17-04 (2021).

There is a controversy regarding licensing of the technology as per fair, reasonable and, non-discriminatory (FRAND) agreement and principles and the patentee's right to seek injunctive relief. The standardization policy by a Standard Setting Organization giving access to technology under the FRAND principles takes away from the protection sought by the inventor

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<sup>3</sup> Patent waiver in WTO to enable timely availability of Covid vaccines: Govt, [https://www.business-standard.com/article/economy-policy/patent-waiver-in-wto-to-enable-timely-availability-of-covid-vaccines-govt-121050601254\\_1.html](https://www.business-standard.com/article/economy-policy/patent-waiver-in-wto-to-enable-timely-availability-of-covid-vaccines-govt-121050601254_1.html)

<sup>4</sup> Srividhya Ragavan, *The Significance of The Data Exclusivity Debate and Its Impact on Generic Drugs*, JIPS Volume 1 Issue 1 (April 2017).

of the technology through a patent.<sup>5</sup> The common ground was deduced by the European Court of Justice in the case of Huawei Technologies v. ZTE.<sup>6</sup> This jurisprudence is coherent in the competition laws since the patent determine the available rewards as a result of competition on the merits of the inventor and of her/his invention by acting on monopolistic market.

**C. Chryssoula Pentheroudakis, Justus A. Baron, Licensing Terms of Standard Essential Patents: A Comprehensive Analysis Of Cases, JRC Science For Policy Report ISSN 1831-9424 (2017).**

This paper details out the fair, reasonable and non-discriminatory (FRAND) principles and the various comprehensive framework and commitment centred around it. FRAND is a bilateral negotiation process defining ex – ante considerations and benchmark. While considering the legitimacy of injunctive relief and the concept of the “willing licensee”, it is very essential to take into account the parties’ conduct. The principles and economic guideposts underlying these decisions are finding their way into the strategic and tactical decisions of SEP holders.<sup>7</sup>

**D. Yann Ménière, Fair, Reasonable and Non-Discriminatory (Frاند) Licensing Terms: Research Analysis of A Controversial Concept, JRC Science For Policy Report ISBN 978-92-79-49280-8 (2015).**

The tension created by complex standards in Information and Communication Technology (ICT) between the need to incentivise and provide benefits to the owners of Standard Essential Patents (SEPs) and make these technologies a standard. Various factors aid in weighing in rewards that may cover standard specifications and the need to make standards available to all for public use. The agreement between a patent holder and licensee needs to accommodate the parties' respective market positions, patent portfolios, and business models. An ex – ante approach comes in handy to incentivise flexibility between the parties.<sup>8</sup>

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<sup>5</sup> Hanns Ullrich, Frاند Access to Open Standards and The Patent Exclusivity: Restating the Principles, Max Planck Institute for Innovation and Competition Research Paper No. 17-04 (2021).

<sup>6</sup> In Case C-170/13.

<sup>7</sup> Chryssoula Pentheroudakis, Justus A. Baron, Licensing Terms of Standard Essential Patents: A Comprehensive Analysis of Cases, JRC Science for Policy Report ISSN 1831-9424 (2017).

<sup>8</sup> Yann Ménière, Fair, Reasonable and Non-Discriminatory (Frاند) Licensing Terms: Research Analysis of A Controversial Concept, JRC Science for Policy Report ISBN 978-92-79-49280-8 (2015).

**E. Harold G. Fox, A Study of The History and Future of The Patent Monopoly, Monopolies and Patents University of Toronto Press (1947).**

There have been questions raised on the validity of patents granted to various technologies. The determination of these questions by the judiciary around the globe, in countries of Canada, the United States of America, and the United Kingdom, have been relatively uncertain. This results from the bench deciding these cases without a fixed standard to compare against, thus leading to arbitrariness. The survey of English cases shows Courts have arbitrarily decided whether patents are valid or based on subject matter. Even though there has been consistency in the House of Lords, various judgements have reversed on validity. In the Supreme Court of Canada, the patentee was successful in thirteen out of 43 cases.<sup>9</sup>

**F. Raghavi Viswanath, Demystifying the Indian Frand Regime: The Interplay Of Competition And Intellectual Property, Journal Of Intellectual Property Rights Vol 21 Pp. 89-95, (March 2016).**

The various FRAND related litigation has developed India into one of the essential forums for dispute resolution. The growing appeal of this IPR seat has been proven due to the various foreign manufacturers approaching the Indian dispute resolution forums. This is proof that the framework of Indian intellectual property rights framework is desirable due to the accessibility. Nevertheless, there are pressing considerations that need to be evaluated. The judiciary has a predisposition regarding the public policy element in most patent suits. However, the same may not bode well with a majority of the SEP – holders.<sup>10</sup>

**G. Richard S. Taffet, Smartphone Patent Litigation and Standard Essential Patents, 8 Landslide 50 (2016).**

The Smartphone war or the dispute regarding establishment of standard technology amongst the competitors raises chaos in the patent system. This was also identified by Judge Posner in the case of *Apple v. Motorola*.<sup>11</sup> Standards on the communication technology have been altering rapidly that lead to further innovations in the field. Evidence and jurisprudence suggested to be otherwise, however through assertion of Standard Essential Patents, such litigation has

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<sup>9</sup> Harold G. Fox, A Study of The History and Future Of The Patent Monopoly, Monopolies And Patents University Of Toronto Press (1947).

<sup>10</sup> Raghavi Viswanath, Demystifying the Indian Frand Regime: The Interplay of Competition And Intellectual Property, Journal Of Intellectual Property Rights Vol 21 Pp. 89-95, (March 2016).

<sup>11</sup> *Apple v. Motorola Inc.*, No. 12-1548 (Fed. Cir. 2014).

benefitted. An analysis into the risks and theoretical harms would further immensely benefit policy considerations.<sup>12</sup>

**H. Andreea Tigau, Standard-Essential Patent - Frand Licensing, 2016 Rom. J. Intell. Prop. L. 268 (2016).**

An inventor can claim protection upon his rights through a patent, valid across borders owing to the WTO agreement. This protection enables only the inventor's and the applicant's rights over the production of the technology. An SEP is similar to a patent, in being valid across borders, however manufacturers other than the applicants can also indulge in its production. This is so since the technology protected under an SEP has an essential make that is necessary to be used by all the products in the field to aid the consumers. This statement can be better explained by an example. Therefore, the 3-pin socket used by the electrical appliances in the country is widely availed to establish uniformity and ease.<sup>13</sup>

**I. Kassandra Maldonado, Breaching RAND and Reaching for Reasonable: Microsoft V. Motorola And Standard-Essential Patent Litigation, 29 Berkeley Tech. L.J. 419 (2014).**

The accepted Letter of Assurance (LOA) is a factor creating a contract between an SEP holder and a licensee. This contract is in accordance to RAND principles and a consequence of negotiations between the mentioned parties. The accepted Letter of Assurance (LOA) acts as a unilateral offer for the purpose of application of reasonable and non – discriminatory principles. The provision of a standard established by an SSO organization ensures that the licensee cannot choose an alternative. It depends upon the SSO and the bargaining power of the SEP holder to manipulate the market into becoming a monopoly. This however is in contravention to the reasonable and non – discriminatory principles (RAND).<sup>14</sup>

**J. Jianmin Dai, Competition and Antitrust Enforcement Against Standard Essential Patent in Asia: Introduction and Overview, 62 Antitrust Bull 443, (2017).**

The Competition Commission of India holds significant authority over India's antitrust enforcement over SEPs. In the case of Philips N.V. &Anr. v. Rajesh Bansal<sup>15</sup> the Competition

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<sup>12</sup> Richard S. Taffet, Smartphone Patent Litigation and Standard Essential Patents, 8 *Landslide* 50 (2016).

<sup>13</sup> Andreea Tigau, Standard-Essential Patent - Frand Licensing, 2016 *Rom. J. Intell. Prop. L.* 268 (2016).

<sup>14</sup> Kassandra Maldonado, Breaching Rand and Reaching for Reasonable: Microsoft V. Motorola And Standard-Essential Patent Litigation, 29 *Berkeley Tech. L.J.* 419 (2014).

<sup>15</sup> CS (COMM) 24 of 2016.

Commission of India's acceptance of the standard essentiality of the technology without enquiring into the same on its own accord. In this case, one of the issues framed by the judiciary was the determination of the patent as SEP. Thus, whether an SSO had taken the specific technology into its cognizance did not have an impact. The influence of international exchange and communication, either academic or practical, strives for cooperation and experience in the arena.<sup>16</sup>

### III. Extent of Criteria of Effectiveness Accounting to Standard Essentiality

The Indian Bureau of Standards determines the essentiality of a technology for it to be a standard. Nevertheless, essentiality of a patent isn't determined by just an SSO declaration. The Indian Judiciary has accepted other facets to establish so, either through submitted facts or recognition of the standard by another country. In the case of *Micromax v. Ericsson*<sup>17</sup>, the Competition Commission of India determined the essentiality of the patent through *suo motu* investigation. The Bench pronounced the technology to be a standard despite not being declared SEP by the Bureau of Indian Standards. The important conditions with respect to adoption of SEPs are:

- a) Before adopting a standard, the members must disclose Intellectual Property Rights that would be essential to the implementation of a proposed standard; and
- b) The members must commit to license their SEPs to third parties at FRAND rates.<sup>18</sup>

In the case of *Philips N.V. &Anr. v. Rajesh Bansal*<sup>19</sup> the Competition Commission of India accepted essentiality of a technology based on allegations without enquiring into the same on its own accord. In this case, one of the issues framed by the judiciary was the determination of the patent as SEP. Thus, the fact of whether an SSO had taken the specific technology into its cognizance did not have an impact. It was argued by the plaintiff that not considering the provision of an SSO, the primary factum making a patent essential is that it would be technically impossible to manufacture, sell, lease, etc., the equipment which complies with such standards without using the patented technology. "*Widespread adoption of standard essential technology is not entirely indicative of the added usefulness of an innovation over the*

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<sup>16</sup> Jianmin Dai, Competition And Antitrust Enforcement Against Standard Essential Patent In Asia: Introduction And Overview, 62 Antitrust Bull 443, (2017).

<sup>17</sup> Competition Commission of India, Case No. 50 / 2013; Intex v. Ericsson [Competition Commission of India, Case No. 76 / 2013]; iBall v. Ericsson [Competition Commission of India, Case No. 04 / 2015].

<sup>18</sup> Supra.

<sup>19</sup> Philips N.V. &Anr. v. Rajesh Bansal CS (COMM) 24 of 2016.

*prior art*".<sup>20</sup> The judiciary differentiated between essentiality and standard here, wherein an SSO is vital for declaring a standard.<sup>21</sup> However, essentiality could be determined by various facets like necessity, effectiveness etc. This is because despite the drug's effectiveness, being a first does not provide enough grounds for it to be declared a standard. With time, better-suited combinations may evolve. A necessity factor would need the drug to be synthesised on a larger scale, and a patent would hurdle it even if it's worked out on a FRAND-encumbered agreement.

#### **IV. Competency of SSO to Declare a Standard in a Field**

The second criterion employed by SSO to declare a technology as an essential in a particular field is based on its comparison with alternatives. When the technology proves superior to its competitors, it's declared a standard to be uniformly utilized in all the technologies. In the case of *Microsoft v. Motorola*,<sup>22</sup> the Court defined a given patent to be essential to a standard if use of the standard requires infringement of the patent, even if acceptable alternatives of that patent could have been written into the standard. During the development of standards, SSOs are typically presented with a range of competing technology solutions that can potentially achieve the same result.<sup>23</sup>

For such standards, FRAND principles have to be followed for licensing i.e., terms and conditions that are "Fair, Reasonable and Non-Discriminatory" (FRAND). This aids the inventors of the technology in gaining revenue out of the invention, while at the same time ensuring that the novelty is protected upon IPR policies. Since the pandemic of 2020, a number of treatment methodologies and cures have been developed. The time span of getting a patent of these technologies is six (6) months minimum. For employing FRAND principles upon a licensed standard patent a voluntary contract needs to be underwent between the SSO and the SEP holder. This contract solely lays out the 'fair' terms of licensing. Licensing a technology on the fair and equitable principles of FRAND is determined by a voluntary contract between an SEP holder and an SSO.

In cases where the same technology, when unregistered, is used unauthorised by a third party, disputes arise. No applicant of the patented drug or any of the inventors were SEP holders. In addition, neither of the mentioned persons had a valid voluntary contract with an SSO in

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<sup>20</sup> Id at 17.

<sup>21</sup> Koninklijke Philips N.V. &Anr. v. Rajesh Bansal, CS (COMM) 24 of 2016; Koninklijke Philips N.V. &Anr. v. Bhagirathi Electronics, CS (COMM) 436 of 2017.

<sup>22</sup> Microsoft Corp. v Motorola Inc., 696 F.3d 872 (9th Cir. 2012).

<sup>23</sup> Apple Inc. v Motorola Inc., 869F, Supp.2d, 901,913 (N.D Ill.2012).



existence. In granting relief, the judiciary then considers the aspect of necessity with the underlining principle behind granting an injunction: a party must suffer irreparable damage if the same is not granted.

#### V. Licensing on FRAND principles affects Competition

Licensing of patented technology aids creates an artificial monopoly in the market with one source gaining all revenue. The agreement on FRAND terms involves royalty rates that is guided purely by negotiations between the parties. Due to the royalty payable, a common trend amongst the licensees is to hike the prices of the commodities to meet their quota safely. This results in deviation from the competition laws. In the case of *Commonwealth Scientific and Industrial Research Organisations vs. CISCO Systems, Inc.*,<sup>24</sup> the Competition Commission reiterated this fact, hinting at warrant action by the competition authorities.

In the pharmacy sector, changes in prices can lead to drastic effects, which interest public policy. Hence, policy regulation in this arena showcases the changes that was made by the competition authorities in prior times to make healthcare affordable. This is in furtherance to the fact that royalty amount to huge rises in the price structure affecting consumers negatively. The same was emphasised upon by the judiciary in the cases of *Micromax v. Ericsson*,<sup>25</sup> *Intex v. Ericsson*<sup>26</sup> and *iBall v. Ericsson*<sup>27</sup>. The Competition Commission of India stressed on the consumer interest and held that a monopoly created by such license is a matter of grave invalidity. The Delhi High Court stated that 'patent laws define the contours of certain rights, and the anti-trust laws are essentially to prevent abuse of rights.' The court also added that these two legislations should be considered harmoniously.<sup>28</sup>

#### VI. Legal Framework and Policy Development

The Department of Industrial Policy and Promotion (DIPP) in March 2016 published a discussion paper that aimed to push the need and importance of SEPs and FRAND terms to the public so that feedback could help generate appropriate policy.<sup>29</sup> This paper was critiqued to the fact that there was no need of legislations and stakeholders could do without more

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<sup>24</sup> Commonwealth Scientific and Industrial Research Organisations vs. CISCO Systems, Inc.

<sup>25</sup> Micromax v. Ericsson Competition Commission of India, Case No. 50 / 2013.

<sup>26</sup> Intex v. Ericsson Competition Commission of India, Case No. 76 / 2013.

<sup>27</sup> iBall v. Ericsson Competition Commission of India, Case No. 04 / 2015

<sup>28</sup> *Ibid.*

<sup>29</sup> Discussion Paper on Standard Essential Patents and Their Availability on FRAND Terms, Government of India Department of Industrial Policy and Promotion Ministry of Commerce & Industry, March 01, 2016.

confusion. it was also recommended as a response to the paper that there was a need to develop Intellectual Property Rights (IPR) policies.<sup>30</sup> The government should offer suggestions for the working of SSOs to avoid a future chaos of disputes.<sup>31</sup> Recommendations for fixing royalties and FRAND terms on a component and not device level was also made, considering that mobile phones in India can average around 4,000 patents. Subsequently, DIPP launched the Centre for IPR Promotion and Management (CIPAM) to publish content and generate awareness. This was targeted to assist the public, as well as, promote commercialization to benefit Indian businesses.<sup>32</sup>

In the country, the Competition Law Review Committee published its report<sup>33</sup> dated July 2019. This was followed by the introduction of the Draft (Competition) Amendment Bill 2020.<sup>34</sup> This bill proposed an amendment of insertion of Section 4A<sup>35</sup> that provided to extend the protection to IP holders against to abuse of dominance (AoD) litigation. This was previously provided under Section 3(5) on anti-competitive agreements.<sup>36</sup> A bare reading of the provision clarifies that it isn't an absolute protection but is a declaration that the IP right does have an important role in its intersection with competition law. At the same time, there are discussions regarding that the implementation of such a provision under AoD could be challenging as dominant market players could disguise their action and position of dominance using IP protection.<sup>37</sup>

## VII. Conclusion

In recent times, Standard Essential Patents have been a subject matter of several debates and great significance. There are matters of dispute regarding the policies of Standard Setting Organizations on the global level. India's choice to deal with these disputes goes a long way in

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<sup>30</sup> Wong-Ervin et al, Comment of the Global Antitrust Institute, George Mason University School of Law, on the India Department of Industrial Policy and Promotion's Discussion Paper on Standard Essential Patents; George Mason Law & Economics Research Paper No. 16-15, March 31, 2016.

<sup>31</sup> Ashish Bharadwaj and Tohru Yoshioka-Kobayashi, *Regulating Standard Essential Patents in Implementer-Oriented Countries: Insights from India and Japan*, 2018.

<sup>32</sup> Anubha Sinha, Nehaa Chaudhari & Rohini Lakshane, *Comments on Department of Industrial Policy and Promotion Discussion Paper on Standard Essential Patents and their Availability on FRAND Terms*, May 01, 2016.

<sup>33</sup> Report of the Competition Law Review Committee, Government of India, Ministry of Corporate Affairs, July 2019.

<sup>34</sup> The Competition Amendment Bill, 2020.

<sup>35</sup> "Section 4A- Nothing contained in section 3 or section 4 shall restrict the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his (IP) rights."

<sup>36</sup> Karan Chandhiok & Deeksha Manchanda, *A Look At The Draft (Competition) Amendment Bill, 2020 – Clarity, Transparency, Robustness, And Bit More To Be Desired*, March 01, 2020.

<sup>37</sup> Draft Competition (Amendment) Bill Proposes Extension of Protection to IPR Holders in Abuse of Dominance Cases, March 03, 2020.

the government's efforts to reshape and develop the country in the global IPR technology. From the litigator's perspective, the complexity of the disputes in this arena poses a tough question to the litigators to maintain a balance between 'right' and 'business efficiency'. The transparency of FRAND royalty and publishing the same on public domain establishes trust amongst the consumers in the process of creating a brand value.

The pandemic has created a dire need for synthesising medicines in the pharmaceutical sector. Setting patents on these drugs will create further chaos due to lack of availability or high prices resulting from FRAND royalty. Thus, it becomes necessary to culminate particular criteria through the legislature to make its availability feasible and affordable.

