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INTELLECTUAL PROPERTY AND TECHNOLOGY LAW UPDATES

S&A IP-Tech

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REVOCATION OF ANTI-COVID19 DRUG REMDESIVIR

NEHA GARG

In April 2020, the Cancer Patients Aids Association wrote to the Ministry of Health for revocation of patent on Remdesivir granted to Gilead in February 2020.

Importance or Remdesivir - The drug Remdesivir is known for treating infections caused by Filoviruses that belong to virus family called filoviridae and are known to cause haemorrhagic fever in humans and nonhuman primates. The drug was primarily produced as a possible treatment of *Ebola* virus epidemic but the clinical trials did not show very promising results. Later, the drug was modified and a patent application was filed for the modified version in India in 2015 which was granted in February 2020, and is under clinical trial stage.

With the worldwide outbreak of coronavirus pandemic, and the coronavirus being a filovirus, the drug Remdesivir was named as a promising drug by the World Health Organization. The drug Remdesivir is used along with chloroquine and hydroxychloroquine in combination with two anti-HIV drugs Lopinavir and Ritonavir. Currently, Remdesivir is being considered as a potential drug for cancer or diabetes also and has gained lot of importance in the pharmaceutical market.

Why CPAA wrote for patent revocation - CPAA after perceiving the importance of Remdesivir, approached the Ministry of Health for revocation of patent and to produce generic alternatives to ensure the availability of drug at affordable price for socio-economically underprivileged patients. CPAA has filed a representation for revocation of patent in public interest under Section 66 of the Patents Act and Section 64 on the grounds of non-patentability of the drug.

The criteria of the patentability in India is defined in Section 2(j) of the Patents Act, 1970, which states that 'invention' means a '*new product or process*' (i.e. the invention should be novel), '*involves an inventive step*' (i.e. should not be obvious to a person skilled in the art) and 'capable of industrial application' (i.e. capable of being made or used in an industry). Further, Section 3 provides the list of inventions that are not patentable under the Patents Act, 1970.

The CPAA has made the representation on two major grounds of contentions for the granted patent. It states that the patent granted for Remdesivir is non-patentable under Section 3(d) of the Patents Act, 1970. The Section 3(d) states that the '*mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance*' is not an invention under the Act. CPAA further claims that the granted patent is mere modification of compound Remdesivir already disclosed in previously filed PCT applications and hence lack novelty and inventive step in view of the prior art documents.

Novelty and Inventive Step: Nothing New Here?

The representation of CPAA's plea is largely based on the argument under Section 66 keeping public interest in focus, whereas the review of the representation elaborates that the invention is not patentable under the Patents Act, 1970. Hence, the CPAA has filed a revocation of the patent under Section 64(1)(d), (e), (f) and (k) of the Act. Section 64 provides for the provision to allow petition for revocation of patents granted by the Indian Patent Office.

Section 64(1): Revocation can be granted on the following grounds:

'(1)(d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;

(e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in section 13;

(f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim;

(k) that the subject of any claim of the complete specification is not patentable under this Act;'

CPAA claims that Applications (WO 2012/012776, PCT/US2011/045102 and PCT/US2015/057933) previously filed by Gilead Sciences are proof of the prior art available for the current Patent Number: 332280. However, the letter is not supported by the expert evidence which is required while filing revocation petitions claiming revocation for novelty, obviousness and Section 3(d) argument. Remdesivir's patentability contention can be regarded as a post-grant opposition as per Section 25(2) or a revocation petition as per Section 64 in the IPAB.

Public Interest and Patents

CPAA has exercised Section 66 for the revocation of Remdesivir's patent which can be forcefully correct if the drug shows positive results for the treatment of COVID-19 cases. This shall further be supported by Article 21 of the Indian Constitution which provides for the Right to Health and therefore, the CPAA is pushing for the availability of drug at affordable prices along with the production of generic variants of the drug.

Section 66 of the Patents Act states that '*Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked'*

Article 21 of the Indian Constitution states that '*No person shall be deprived of his life or personal liberty except according to procedure established by law.'*

Since the formulation of the patent law, public interest has been used only twice as a ground for revocation of patents, once in the year 1994 and another in 2012. A patent granted to a US Company Agracetus was revoked in year 1994 to prevent any negative impact on Indian economy and to preserve farmers' right. The patent was granted for the process of producing cotton cells resistant to Lepidoptera pests, such as bollworms. An Avesthagen patent was revoked in year 2012, the patent was granted for treatment of diabetes.

The above two precedence do not strongly support the revocation of Remdesivir's patent on the grounds of public interest. However, in case of current scenario, many appeals are being filed across the globe for amendments in the working of patent law and for the grant of compulsory license for possible treatments of COVID-19 which may provide support to CPAA's representation.

Further, if the Central Government is exercising the power under Section 66 of the Act, then there are significant chances of possible resentment from the Pharmaceutical companies which might treat it as the last option to conduct their businesses in India.
Finally, India is the largest provider of generic alternatives globally and enjoys an important position in the global pharmaceutical sector. The granted patents may be an obstacle for the creation of cheaper and affordable treatments. Dr. Reddy's Laboratories has denied the creation of generic version of Remdesivir, the reason may be avoiding a possible patent infringement suit. Hence, it can be concluded that there is an urgent need to address the possible barriers posed by the patent law with due forethought to the consequences of policy changes.

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ARTIFICIAL INTELLIGENCE AND INTELLECTUAL PROPERTY RIGHT

GEETA

Artificial Intelligence (AI) has raised some very interesting questions and debate in the world of Intellectual Property. AI related inventions generally use techniques like machine learning, deep learning, and neural networks. Patent applications have been filed in the fields of telecommunications, transportation and life and medical sciences with activity mainly in computer vision, natural language processing and speech processing. Robotics and control methods are the fastest growing AI functional applications, and aerospace/avionics and smart cities are the fastest growing application fields.

An AI related invention is not a single invention but a combination of several, for example it can be a computational or a mathematical method or an algorithm or a combination of both. It is questionable if it is even possible to capture these combinations in a claim or if that will reduce the scope of protection. Further, the foundation of AI lies in its algorithms or mathematical models and this is not eligible for patent protection. In India, we have an absolute ban on the patentability of algorithms and computer programs unless it produces a technical effect or technical contribution which will be difficult to establish in an AI related invention. According to section 3 (k) of the Indian Patent Act, mathematical and business methods, computer programmes per se or algorithms are categorized as non-patentable subject matter. Even if one manages to obtain patent protection, it may be redundant in light of the fact that the algorithms will be constantly revised and updated, and with this new inventions will be created and will require protection.

AI Patentability in IPR

There are challenges with patenting AI systems and platforms. An example of an AI mimicking the human task is Microsoft's Inner Eye project which is an AI system helping oncologists target cancer treatment in a shorter time. It manages to accomplish this task by using machine-learning techniques in the analysis of magnetic resonance imaging scans of patients and delineate tumours from surrounding healthy tissue and bone. The oncologist himself previously accomplished this task by drawing by hands contours on 3D images. In case a patent application is submitted for this task done by the machine, it would be rejected because one of the fundamental requirements of patentability, which describes how the invention works, is not met in this case.

Even in the case of disclosing a patent application which claims the source code or description of how an AI system works, patent would be rejected. This may constitute an impediment to patenting because a patent is not granted for a mathematical method or any other method for accomplishing a mental act including methods of teaching and reading according to the section 3 (k) of the Indian Patent Act.

IP and Patentable Subject Matter

Having a patent would grant you exclusive right over your product or process for a period of time and

duration of protection may vary from one legislation to another. This is an important factor that asks for a patent product or process to be of non-obvious nature. Here it is important to mention that obviousness is to be looked at in context of what is obvious, the product or the process should be a technical advancement over existing knowledge and not just an obvious advancement. This test is taken in relation to the person for whom that knowledge is obvious (Thorne & Priestley, 2012). An example of an invention in the field of physics would be obvious to a person of a certain level of knowledge in the field of physics. In the same way it would be non-obvious for that same person if that knowledge does not exist before the point of reference. Most of the laws all over the world require this test and consider this as an important factor that determines whether something could be patented or not.

Most of the times in a patent, novelty plays a major role, any claim made by the creator for a patent must be novel. First, for such a novel idea or product or process the elements are the ones that cannot be found in a single prior art reference. Here is where the AI can help; given the computer power and enough input of data certain references can be created for a very large inventory of processes or products. Arguably there could be a very little chance for the artificial intelligence to go wrong on finding the right reference or the novelty in an item. The artificial intelligence in such a case would be a wonderful tool to do novelty assessment or analysis. It would also be a wonderful tool to do a single prior art reference test. The current laws are also silent on the use of AI for the assessment of novelty. There is, however, no legal bar on use of such technology for such kind of assessment. The right to challenge a certain assessment could be built in the system. Once challenged by the originator or creator of the IP, the AI can change the parameters of the information available to test the novelty of an item.

There is the human bias, which is called hindsight bias; human mind belies invention as it seems obvious every time somebody invents a product or process. Similar hindsight bias could exist in artificial intelligence as well, remember the data fed into the artificial intelligence is the data that usually is going to come out of it. If at a certain point artificial intelligence starts thinking on its own that bias and possibly many other biases can possibly exist in the machine learning. This is the point where we need human supervision to manage the machine.

However, among the advantages that AI has, one can assert that AI has a major strength, which is held in the repeatability of results due to the strict rules (algorithms) it follows. In fact, AI should provide the same results based on the same inputs. Physical exhaustion or lack of experience does not affect the performance of AI.

One could argue that copyright laws would indirectly protect the algorithm once incorporated into the code but since copyright law does not protect the inventive concept behind the expression, the AI related invention cannot fully be protected under copyright law.

Another problematic issue is the non-obvious rule connected to patentability of an idea. Patent law requires that an inventive concept be non-obvious to a person skilled in the art of that concept. In the world of AI and its capacity to process higher levels

of intelligence and predictability, there is the likelihood that all inventive concepts could be considered obvious to an AI and if so, will that eliminate the stipulation for patent protection entirely?

It is obvious there is a massive gap between ground reality and existing regulations with too many challenges brought on by AI. Today, IBM has the largest portfolio of AI related patent applications with 8,290 patent applications in the world, followed by Microsoft with 5,930 patent applications. With this increasing popularity of AI related inventions and the sheer volume of AI related patent applications being filed, it will be up to the patent offices and regulators to revise existing patent and IP laws and create new molds to fit the emerging technology.

Conclusion

The current IP laws need severe upgrading to come at par with the artificial intelligence that is continuously growing. If they are not upgraded the artificial intelligence would keep on becoming smarter to such a point where the current laws would not be able to serve human needs. Using smart mixed AI and human models like the one mentioned above, could solve the fear that human beings have and could also serve in making the process of achieving intellectual property rights more smooth, transparent and effective. The approach to completely convert the IP process to algorithmic decision-making lacks for the time being legal infrastructure and human experiences.

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REVOCATION OF IBRUTINIB PATENT

TUSHAR KOHLI

Recently, IPAB issued an order maintaining the interim stay over the revocation of an anti-cancer drug patent. The timings of the order clashed with the attempt of US-based Biopharma company AbbVie to build a patent wall around Imbruvica (Ibrutinib's market brand), having secured 88 patents out of 165 applications filed.

Three-factor test and Public Interest

Many questions were raised regarding court's lack of discussion of the three-pronged test while granting injunctions and interim orders. The order in the Ibrutinib case begins by emphasizing the necessity to make out those factors - a prima facie case, balance of convenience and irreparable injury. It goes on to devote a long discussion to whether a prima facie case exists and concludes in the affirmative. However, balance of convenience and irreparable injury are barely touched upon. For the latter, IPAB has reasoned that the interim order must continue for the parallel continuation of the infringement suits against Laurus Labs and third parties.

Public interest – which becomes relevant due to Ibrutinib being an anti-cancer drug – has not been discussed at all. In *Roche v. Cipla*, despite the fact that Roche had a valid patent, the price differential between the patented drug and the generic ones had been taken into consideration on account of restriction of public's access to affordable medicine. Given that the patent in question is a revoked one and there is no question of presumption of validity, it was surprising that such an important consideration did not even merit a discussion.

Reason for sustaining revocation

Before the scheduled hearing on 25th September 2019, the opponent had filed additional documents which prompted Pharmacyclics to approach Delhi High Court (DHC) against their admittance. Pharmacyclics also decided to file rebuttal evidence of its own. The court, in an order dated 6th November 2019, stressed upon the importance of following the timelines laid down in the Act and the Patent Rules 2003 and directed all of the evidence to be sent to the Opposition Board. However, the Joint Controller did not send the evidence and moreover, two members of the Board remained absent from the hearing. The patent was then revoked after placing great emphasis on Laurus's additional evidence and disregarding the Opposition Board's report which favoured Pharmacyclics. The stay order of 12th June was passed in light of the above facts.

Clarification on Rules for filing Additional Evidence

The IPAB considered at length the Rules 60 and 62 of the Patent Rules 2003, which deal with the filing of further evidence and the hearing, respectively. Rule 60 holds that further evidence can only be filed with the Controller's permission and is only possible before the hearing has been fixed under Rule 62. Relying on the DHC order of 6th November, IPAB observed that once the Opposition Board is constituted, no evidence ought to be permitted. However, in case any new evidence comes to light, one last opportunity to file the same may be availed under Rule 60 – but this has to be done prior to the fixing of the hearing. Post that, Rule 60 cannot be

invoked and no further evidence can be filed. The permission under Rule 62(4) to 'rely on any publication' refers only to publicly available documents and is to be exercised with five days' notice.

It has been often emphasized that Rule 60 is an exception and cannot be invoked as a rule. The DHC order had explained that the purpose behind the strictness in setting timelines was the enormous sanctity placed on the two-stage decision-making process in a post-grant opposition. This is because by this time, the patent application has already undergone rigorous examination along with possible pre-grant oppositions. This clarification on the purpose and operation of Rules 60 and 62(4) would be quite helpful as just about a month back, the IPAB had stayed another revocation in case of Novartis's Ceritinib drug owing to the Controller's oversight regarding acceptance of additional evidence post the fixing of hearing.

Though the DHC gave direction, the Joint Controller did not forward the newly filed evidence to the Opposition Board citing the reason as shortage of time. He stated that forwarding the evidence to Members of Opposition Board was not necessary and insisted that presence of all members of the Board at the time of final hearing is not mandatory either. Interestingly, regardless of the Board not being sent the evidence, each of their reports rules in favour of Pharmacyclics. The Joint Controller though, in the revocation order, has relied strongly on the opponent's additional evidence.

The DHC's order had stated that Board members have to be present during hearing because they would not have had the opportunity to look at the documents submitted under Rule 62(4). This raised the question – if the members' presence is important to peruse publications that are notified late, how can they be kept in the dark about a complete set of evidences which the Joint Controller himself goes to rely strongly on?

The IPAB did not concur on the above facts and noted that failure to forward the evidence was against the DHC's order. Moreover, no reason was given to explain the absence of the Board members during the hearing. Rule 62(5) mandates that the Joint Controller shall take into consideration recommendations of Opposition Board while deciding the opposition. IPAB relied on the Supreme Court's decision in *Cipla v. Union of India* which held that the 'Opposition Board has got considerable relevance' and the Board's report is '*crucial in the decision making process while passing order by the Controller under Section 25(4)*'.

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DISRUPTIVE INNOVATION

SHIKHA SRIVASTAVA

Disruption, in general, is a negative term which implies disturbance or problems or interruption in normal process. But the term is now increasingly being used in businesses for a process in which a company having few resources is in a position to displace a well-established company. Well-established businesses (Incumbents) tend to cater to the demands of their existing customers i.e. their focus is on improving or upgrading existing product or services to satisfy the customers' future needs, thereby, ignoring their current needs. Also, incumbent businesses focus on the needs of their biggest customers. As a result they tend to overlook smaller customers. New business entities or Entrants cater to those overlooked segments of customers. They gain foothold by providing same or better product or services at a lower price[1]. Due to this, new businesses start making a place for themselves in the market and disruption takes place.

The term disruptive innovation was coined by Harvard Business School professor Clayton Christensen. Disruptive innovation means a product, concept or service that creates a new market by disrupting an already existing market.

What is disruptive innovation and what is not?

Netflix was launched in 1997; its initial service did not appeal to most of Blockbuster's customers, who rented movies by going to store. Netflix had an exclusively online interface and a large inventory of movies, but it was a US mail order rental company. Blockbuster didn't anticipate the threat until Netflix tapped into streaming services. By then it was too late. Today, Netflix is worth billions of dollars and Blockbuster is bankrupt.[2]

Let's consider example of Uber. Founded in 2009, the company has enjoyed fantastic growth. It has reported tremendous financial success. Uber is clearly transforming the taxi business. But is it *disruptive innovation?* The answer is no, according to Christensen's theory. Uber launched in San Francisco, its customers were already using taxis, so it didn't exactly target non consumers. And Uber wasn't a low-end alternative to a complicated, costly, inaccessible service. It actually originated in a mainstream market first, and then increased overall demand and appealed to lower-end segments later.[3] Other example of successful disruptive innovation is Mini steel mills that affected the business of US steel mills.

Disruptors take time to establish themselves in the market. It is due to this fact that incumbents don't consider them as threat.

Importance of Disruptive Innovation

Disruptive innovation delivers massive growth opportunities to companies adapting new trends. It can benefit both competition and consumers by providing better and cheaper products and more accessible services. Through disruptive innovations,

1 https://hbr.org/2015/12/what-is-disruptive-innovation

2 https://www.tonyrobbins.com/career-business/what-disruption-really-means/

3 https://openviewpartners.com/blog/11-disruptive-innovation-examples-and-why-uber-and-tesla-dont-make the cut #.X7_3atIzbIU

smaller companies and startups compete with big corporates by establishing and growing new market segments of their own[4].

Disruptive innovations are important for customers as they tend to provide better service or product at a lower price. For established businesses, it is important to have the knowledge of how disruptive innovations work in their domain which will help them anticipate any threat to their business.

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4 https://channels.theinnovationenterprise.com/articles/how-disruptive-innovation-benefits-the marketplace

ACCESS TO A QUICK & COST-EFFECTIVE PATENT APPLICATION –PATENTAMENDMENT RULES, 2020

SAIPRIYA BALASUBRAMANIAN

The Department for Promotion of Industry and Internal Trade (DPIIT) issued a notification[5] on October 19, 2020, which has published the Patents (Amendment) Rules, 2020 (that amend the Patent Rules 2003). A skim through the notification evinces that the Amendment Rules 2020 are focused on revision in **timeline and format of Statement of Working (Form-27) for granted patents** and submission of **Priority documents and their translations for PCT national phase applications in India.**

The key highlights of the Patent Amendment Rules 2020, are elaborately set out as follows:

Priority Documents

Rule	Amendment	Explanation
21 (1)	*"(1) Where the applicant in respect of an international application designating India has not complied with the requirements of paragraphs (a), (b) or (b-bis) of rule 17.1 of the regulations under the Patent Cooperation Treaty, and subject to paragraph (d) of the said rule 17.1 of regulations under the Treaty, the applicant shall file the priority document referred to in that rule before the expiration of the time limit referred to in sub-rule (4) of rule 20 in the Patent Office"*	According to sub-rule(1), the applicant must file the priority document before the expiration of the time limit referred in sub-rule (4) of Rule 20, if the international application has not complied in accordance with paragraphs (a), (b) or (b-bis) of rule 17.1 of the regulations under the Patent Cooperation Treaty (PCT).
21(2)	*"(2) Where sub-paragraph (i) or sub-paragraph (ii) of paragraph (e) of rule 51bis.1 of the regulations under the Patent Cooperation Treaty is applicable, an English translation thereof duly verified by the applicant or the person duly authorised by him shall be filed within the time limit specified in sub-rule (4) of rule 20".*	According to sub-rule (2), an English translation of the application duly verified by the applicant or a person authorized by him must be filed within the time limit under sub-rule (4) of Rule 20, in cases where sub-paragraph (i) and (ii) of paragraph (e) Rule 5 of the PCT Regulations are applicable.
21(3)	*"(3) Where the applicant does not comply with the requirements of sub-rule (1) or sub-rule (2), the Patent Office shall invite the applicant to file the priority document or the translation thereof, as the case may be, within three months from the date of such invitation, and if the applicant fails to do so, the claim of the applicant for the priority shall be disregarded for the purposes of the Act."*	According to sub-rule (3), if the international applicants do not comply with Sub-rule (1) & (2), the Indian Patent Office will invite the applicant to submit the priority document or the English translations within three months from the date of the invitation. If the applicant fails to comply with the invitation, the Patent Office will not take the claimed priority into consideration.

Filing of Priority Documents

In case of PCT National phase applications, priority is claimed by an applicant through submission of priority documents either with World Intellectual Property Organization (WIPO) or the Indian Patent Office (IPO). WIPO - Digital Access Service (DAS) is an electronic digital library which allows applicants, filing application across multiple countries, to request the Office of first filing to deposit or register the priority application in DAS. Once the document is available via DAS, the applicant can ask the office of second filing to retrieve a copy electronically from DAS. This

5 http://www.ipindia.nic.in/writereaddata/Portal/Images/pdf/patents_amendment_rules_2020.pdf

process of exchange of priority of documents can be carried out across multiple IP offices.

The access of priority documents by Indian Patent Office through WIPO DAS is officially formalized by the Patent Amendment Rules 2020. Therefore, with reference to **amended Rule 21(1)** an applicant can claim priority if the priority document is registered and made available in WIPO DAS in accordance with paragraphs (a), (b) or (b-bis) of rule 17.1 of the regulations under the Patent Cooperation Treaty (PCT).

Requirement of Translated Documents

The amended rule 21(2) provides that verified English translation of the priority documents are required to be submitted where PCT Rule 51*bis*.1 (e) (i) or (ii) are applicable, viz in the first case, where the validity of the priority claim is relevant to the determination of whether the invention concerned is patentable; in the second case, wherein the filed international application is incomplete with regards to a missing element or part and the applicant claims that the missing element or part is completely contained in the priority document filed.

The amended Rule 21 (3) provides that in cases where the applicant has not complied with the requirement of filing the priority documents or the English translations thereof within the prescribed time, which is 31 months of the priority date, then he shall be invited to submit the said documents. The applicant must submit the priority documents or their verified translations within 3 months from the date of invitation from the Controller.

Working Statements- Format & Timeline

Rule	Amendment	Explanation
131(2)	*"(2) The statements referred to in sub-rule (1) shall be furnished once in respect of every financial year, starting from the financial year commencing immediately after the financial year in which the patent was granted, and shall be furnished within six months from the expiry of each such financial year."*	According to amended sub-rule 2 of Rule 131, the statement of working of patent is to be filed by the patentee or licensee once every financial year, within **six months** from the expiry of such financial year which is **30th of September of each year**.

Contents of the Revised Form-27

1. Revised form requires the statement of working to be submitted once in every **financial year** which is from 1st April of a year to 31st March of next year. Therefore, the due date of filing of annual statement of working is 30th September of each year.
2. One working statement can be filed in respect of multiple related patents, wherein the approximate value/value accrued from a particular patented invention cannot be derived separately from the approximate revenue/value accrued from related patents, and all such patents are granted to the same patentee(s).
3. In case of multiple related patents, the patentee shall list all the patent numbers for which the statement of working is being filed and individually specify whether each patent is worked or not worked.
4. Revised form **does not** require the applicant to provide the details of licenses and sub-licensees issued in any given financial year.

5. The statement requiring the applicant to provide whether 'the reasonable requirement of the public' in India has been met partly/ adequately/ to the fullest extent at a reasonable price **has been removed** from the revised form.

6. Details of importation (country-wise details) as well as the quantum of product manufactured and/or imported to India has been done away with. The applicant is required to provide only the approximate value/s accrued by working the patent in India/importing into India.

7. Co-owners of a patent can file a single joint working statement for one or more related patents; however, each licensee is required to file working statements separately which means every patentee and every licensee (exclusive or otherwise) is required to file working statement.

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FREQUENTLY ASKED QUESTIONS W.R.T. WORKING STATEMENTS FOR THE FINANCIAL YEAR 2020-2021

HEENA LAMBA

What amendments have been brought about in the Patent Rules w.r.t. Filing of Working Statements?

1.1. **Rule 131(2)**, which specifies the furnishing of statements of working has been amended as marked below:

"*The statements referred to in sub-rule (1) shall be furnished once in respect of every calendar* ***financial*** *year, starting from the financial year commencing immediately after the financial year in which the patent was granted, and shall be furnished* ***within six months from the expiry of each such financial year.*** *within three months of the end of each year.*"

1.2. **Form 27** for submitting the statement of working of patented invention on a commercial scale in India has been substituted. New Form 27 is annexed herewith – *Annexure A.*

What is the due date to file working statement?

Working statement on Form 27 with respect to previous financial year shall be filed within six months from the expiry of such financial year, i.e., Form 27 shall be filed by 30th September. For example, for the financial year 2020-21, Form 27 shall be filed by 30th September 2021.

What is the duration of financial year in India?

A financial year in India is the period staring 01st April to 31st March of the following year. Accordingly, financial year 2020-2021 ranges from 01st April 2020 to 31st March 2021.

Can a single Form 27 be filed for multiple patents?

Yes, after the said Amendment, single Form 27 can be filed for multiple "related patents".

What information/data is to be provided on new Form 27?

Now the Patentee(s) and Licensee(s) shall provide below listed information while furnishing statement of commercial working of patent in India on Form 27:

i. Name(s) of the Patentee(s) / Licensee(s)

ii. Patent No.

iii. Worked / Not Worked [Yes / No]

iv. Approximate revenue / value accrued in India to the Patentee(s) or Licensee furnishing the statement from Patent No(s) where the working is through:

   a) Manufacturing in India (in INR)

   b) Importing into India (in INR)

v. Brief in respect of approximate revenue / value accrued in India or the Working of the Patent at the commercial scale in India –*Brief may include countries from which patented articles are imported, name of licensee(s), sub-licensee(s), how multiple patents (if on single Form 27)*

are related, how approximate value was derived or any other information which the Patentee/Licensee deem appropriate while filing Form 27.

vi. If not worked, reasons for not working of the Patented invention and steps being taken for working of the invention

Are any documents required to be enclosed with the working statement on Form 27?

Apart from the above stated information to prepare Form 27, we would require a Power of Authority (if not provided already) from the Applicant(s)/ Licensee(s) authorizing S&A to file statement of working of patent(s) at the Patent Office.

Which Patents are eligible for filing Working Statements for financial year 2020-21?

For financial year 2020-21, working statements should be filed for all patents granted on or before 31st March 2021 and are active/ subsisting on Patents Register for part or whole of the financial year 2020-21.

Do all Patentees and Licensees need to file the Working Statements?

Yes, all Patentees and Licensees shall file working statement. While co-Patentees over a patent can collectively file single Form 27, the Licensees are required to file Form 27 separately.

When can the Patentee/ Licensee/ In-House Attorney provide instruction with information for preparing and filing working statements?

Required information for preparing and filing of working statement on Form 27 can be provided any time before 30th September of the year. However, to avoid the last week's rush to file working statements in thousands of subsisting patents in India and to reasonably correct/clarify on the information, the Client should preferably give instructions with relevant information for Form 27 by July 2021.

Guidance on what is meant by "related patents" and how related they have to be to each other.

i. How Patents will be classified as 'related patents'?

Phrase "related patents" includes all patents relating to the same product or are interlinked such that approximate value for a particular patent or each patent cannot be derived separately. Further, it should be kept in mind that the Patentee or Licensee making the Statement is the same for all patents included on the single Form 27.

ii. Are patents only allowed to be considered as "related" if the approximate revenue / value accrued from a particular patented invention cannot be derived separately from the approximate revenue/ value accrued from related patents?

To use single Form 27 for multiple patents, it is assumed that the Patentee/Licensee cannot derive value for a particular or each patent separately from the said group of "related patents".

iii. Does it have to be stated how the patents are related?

While the Form 27 does not particularly asks for "how the patents are related", it is advisable to put information with respect to the same in column *4(b) Brief in respect of (a) above.* One may also include how total approximate revenue/value was derived.

iv. Will it be assumed that all the pat-

ents mentioned on the same form 27 are related?

Yes.

v. In case the patents are not related, is a separate form 27 needed?

Yes.

What options are available if the due date for filing the Statement of Working is missed?

In case the working statement (Form 27) is not filed by 30th September, the same can be filed along with petition under Rule 137/138 giving detailed reasons for such delayed submission. The acceptance of such petition and delayed Form 27 will be at the discretion of the Controller.

Will the new Form 27 information still be submitted online?

Yes.

With respect to imports, does the patentee/licensee need to specify country of origin?

The revised Form does not particularly require "country of origin" for imported items. Further, the old version of Form 27 is still showing and revised Form 27 is not yet updated on the IPO's e-Filing portal. In the given scenario, while "country of origin" is not required as per revised Form 27, the Patentee/Licensee may choose to provide "country of origin" and we can include the same in Col. 4(b) of revised Form 27. *Further, we will keep a watch on revised Form 27 over e-Filing portal and will inform our clients in case there is any clarity in this regard.*

What sort of information is required for the brief about working statements (4b)?

As on date, there is no prescription from the Patent Office as to what can be included in Col. 4(b) *Brief in respect of (a) Approximate Value*…. The Patentee/ Licensee may choose to include "how patents are related" in case of multiple patents, "how approximate value was derived" and/or "country of origin" in case of value by importing in India or any other information that the Patentee/Licensee deem appropriate while providing statement of working of patent(s) in India.

i. Does the brief only relate to the information in 4a?

Yes.

ii. Can the brief be omitted entirely, or be blank/empty?

We will be able to answer "*whether 4(b) is mandatory while e-Filing of Form 27 or not*" once the e-Filling portal is updated with revised Form 27.

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FORM 27

THE PATENTS ACT, 1970

(39 of 1970) AND THE PATENTS RULES, 2003

No Fee

STATEMENT REGARDING THE WORKING OF PATENTED INVENTION(S) ON A COMMERCIAL SCALE IN INDIA

[*See* section 146(2) and rule 131(1)]

1. Insert name, address, nationality, patent number(s).	I/ We, the Patentee(s)/ Licensee ……, in respect of patent number(s) ……, furnish this statement, (Explanation: One form may be filed in respect of multiple patents, provided all of them are related patents, wherein the approximate revenue / value accrued from a particular patented invention cannot be derived separately from the approximate revenue/value accrued from related patents, and all such patents are granted to the same patentee(s)).		
2. State the financial year to which the statement relates.	in respect of the financial year ……		
3. Worked / not worked. Please state whether each patent in respect of which this form is being filed is worked or not worked.	Patent Number(s)	Worked [Tick (✓) if applicable]	Not worked [Tick (✓) if applicable]
	(more lines can be added to include multiple related patents)		
4. If worked.	(a) Approximate revenue / value accrued in India to the patentee(s)/ licensee furnishing the statement from patent number(s) where the working is through:		
	(1) Manufacturing in India …… (in INR)	(2) Importing into India ……. (in INR)	
	(b) Brief in respect of (a) above **(maximum 500 words)**		
5. If not worked.	Reasons for not working the patented invention(s) and steps being taken for working of the invention(s).**(maximum 500 words)**		
	The facts and matters stated above are true to the best of my/ our knowledge, information and belief. Dated this ..... day of 20.....		
6. To be signed by Patentee(s) / Licensee / Authorised Agent furnishing the statement.	Signature(s)..... To The Controller of Patents, The Patent Office, at ……		

Note: Every patentee and every licensee (exclusive or otherwise) is required to file this Form; where a patent is granted to two or more persons, all such patentees may file this Form jointly; however, each licensee shall file this Form individually. ".