



Document prepared by Nerve Center of TFORD, Venture Center, Pune
Task Force on Repurposing of Drugs (TFORD) for COVID19
 S&T Core Group on COVID19 constituted by PSA to Gol

Assessment Framework #1

Ref: TFORD/AF/001

Date: 30 March 2020

About this document: This document suggests a framework for evaluating candidate drugs for their IP status and anticipating barriers to commercialization that may arise on the path to commercialization for the drug molecule.

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1. Information checklist

S. No.	Questions?
1.	Are there relevant patents active (filed or granted) in India?
2.	Who are the assignees of the patent?
3.	When is the patent expiring?
4.	What is the scope of coverage of the claims of the patent?
	○ Composition
	○ Process
	○ Product
	○ Equivalent of method of use
5.	Is the patent being worked?
6.	Is the patent under license for India? If yes, who owns the license right? What are the terms of the license?

2. Assessment Framework

S. No.	Questions?
1.	Is the patent holder willing and able to produce and supply the necessary quantities of drugs in India at a reasonable price?
2.	Is the patent holder willing to license the <u>technology and patent rights</u> to local manufacturers for the duration of this epidemic? (including via UN Medicines Patent Pool) Are there potential licensees available and interested?
3.	Is the patent holder willing to license the <u>patent rights</u> to local manufacturers for the course of this epidemic?

	Are there potential licensees who have knowhow already and are available and interested to be patent licensees?
4.	<p>Do we have Freedom to Operate (FTO) for a drug molecule in India?</p> <p>Is there any active patent application or valid patent granted in India that protects any aspect of the drug?</p> <ul style="list-style-type: none"> ○ Composition ○ Process ○ Product ○ Equivalent of method of use <p>If we have FTO, are there potential manufacturers who are able and interested?</p>
5.	<p>Do we have access to suppliers for all necessary raw materials needed without undue risk or cost? Is there any active patent application or valid patent granted in India that protects any aspect of the knowhow?</p> <p>If not, do we have FTO for producing the raw materials and other parts of the value chain?</p> <p>Are there potential manufacturers who are able and interested?</p> <p>If we do not have FTO, is the patent holder willing to provide a license to an interested manufacturer for the duration of the epidemic?</p> <p>Are there potential licensees available and interested?</p>

3. Decisions matrix

Questions?
If we do not have FTO, then how can we create freedom to operate during the crisis?
1. Use alternative molecules
2. Create a non-infringing route
3. Request/ negotiate/ press for a license
4. Request UN Medicines Patent Pool route for licensing (https://medicinespatentpool.org)
5. Government use – Section 100 (5)
6. Compulsory license - Section 84
7. Special provision of compulsory license - Section 92 (3)
8. Revocation for non-working of patent- Section 85
9. Revocation on any other grounds
10. Action in interest of Security of India – Section 157A

4. Extracts from IP Law

The following is a list of Sections of the Indian Patent Act that are relevant to creating a path for drug molecules to reach the market:

Section	Extract
Chapter 1: Preliminary; Section 2 91)(h)	(h) "Government undertaking" means any industrial undertaking carried on— (i) by a department of the Government, or (ii) by a corporation established by a Central, Provincial or State Act, which is owned or controlled by the Government, or (iii) by a Government company as defined in section 617 of the Companies Act, 1956 (1 of 1956), or (iv) by an institution wholly or substantially financed by the Government;
Chapter 3:	3. What are not inventions.—The following are not inventions within the meaning of this Act,— (d) 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 or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. (i) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products. (p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.
Chapter 5: Opposition proceedings to grant of patents	Provisions for Opposition <ul style="list-style-type: none"> • Pre-Grant Opposition • Post-Grant Opposition
Chapter 12: Section 66	Revocation of patent in public interest 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.
Chapter 16: Working of patents,	82. Definition of "patented articles" and "patentee".—In this Chapter, unless the context otherwise requires,— (a) "patented article" includes any article made by a patented process; and

<p>compulsory licenses and revocation</p>	<p>(b) "patentee" includes an exclusive licensee.</p> <p>83. General principles applicable to working of patented inventions.—Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely;—</p> <p>(a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;</p> <p>(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;</p> <p>(c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;</p> <p>(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;</p> <p>(e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;</p> <p>(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and</p> <p>(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.</p>
	<p>Section 84 Compulsory licences</p> <p>(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:—</p> <p>(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or</p> <p>(b) that the patented invention is not available to the public at a reasonably affordable price, or</p> <p>(c) that the patented invention is not worked in the territory of India.</p> <p>(2) An application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be estopped from alleging that the reasonable requirements of the</p>

public with respect to the patented invention are not satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.

(3) Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.

(4) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence upon such terms as he may deem fit.

(5) Where the Controller directs the patentee to grant a licence he may, as incidental thereto, exercise the powers set out in section 88.

(6) In considering the application filed under this section, the Controller shall take into account,—

(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

(ii) the ability of the applicant to work the invention to the public advantage;

(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit:

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee,

but shall not be required to take into account matters subsequent to the making of the application.

Explanation.—For the purposes of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months.

(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied—

(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,—

(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) a market for export of the patented article manufactured in India is not being supplied or developed; or

(iv) the establishment or development of commercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or

(c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing; or

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or

(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by—

(i) the patentee or persons claiming under him; or

(ii) persons directly or indirectly purchasing from him; or

(iii) other persons against whom the patentee is not taking or has not taken proceedings for

	infringement.
	<p>Section 85 Revocation of patents by the Controller for non-working</p> <p>(1) Where, in respect of a patent, a compulsory licence has been granted, the Central Government or any person interested may, after the expiration of two years from the date of the order granting the first compulsory licence, apply to the Controller for an order revoking the patent on the ground that the patented invention has not been worked in the territory of India or that reasonable requirements of the public with respect to the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonably affordable price.</p> <p>(2) Every application under sub-section (1) shall contain such particulars as may be prescribed, the facts upon which the application is based, and, in the case of an application other than by the Central Government, shall also set out the nature of the applicant's interest.</p> <p>(3) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that patented invention has not been worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may make an order revoking the patent.</p> <p>(4) Every application under sub-section (1) shall ordinarily be decided within one year of its being presented to the Controller.</p>
	<p>Section 89 General purposes for granting compulsory licences</p> <p>The powers of the Controller upon an application made under section 84 shall be exercised with a view to securing the following general purposes, that is to say,-</p> <p>(a) that patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable;</p> <p>(b) that the interests of any person for the time being working or developing an invention in the territory of India under the protection of a patent are not unfairly prejudiced.</p>
	<p>Section 90 Terms and conditions of compulsory licences</p> <p>(1) In settling the terms and conditions of a licence under section 84, the Controller shall endeavour to secure—</p>

(i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;

(ii) that the patented invention is worked to the fullest extent by the person to whom the licence is granted and with reasonable profit to him;

(iii) that the patented articles are made available to the public at reasonably affordable prices;

(iv) that the licence granted is a non-exclusive licence;

(v) that the right of the licensee is non-assignable;

(vi) that the licence is for the balance term of the patent unless a shorter term is consistent with public interest;

(vii) that the licence is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product, if need be in accordance with the provisions of sub-clause (iii) of clause (a) of sub-section (7) of section 84;

(viii) that in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use;

(ix) that in case the licence is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, the licensee shall be permitted to export the patented product, if need be.

(2) No licence granted by the Controller shall authorise the licensee to import the patented article or an article or substance made by a patented process from abroad where such importation would, but for such authorisation, constitute an infringement of the rights of the patentee.

(3) Notwithstanding anything contained in sub-section (2), the Central Government may, if in its opinion it is necessary so to do, in the public interest, direct the Controller at any time to authorise any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad (subject to such conditions as it considers necessary to impose relating among other matters to the royalty and other remuneration, if any, payable to the patentee, the quantum of import, the sale price of the imported article and the

	period of importation), and thereupon the Controller shall give effect to the directions.
	<p>Section 91 Licensing of related patents</p> <p>(1) Notwithstanding anything contained in the other provisions of this Chapter, at any time after the sealing of a patent, any person who has the right to work any other patented invention either as patentee or as licensee thereof, exclusive or otherwise, may apply to the Controller for the grant of a licence of the first mentioned patent on the ground that he is prevented or hindered without such licence from working the other invention efficiently or to the best advantage possible.</p> <p>(2) No order under sub-section (1) shall be made unless the Controller is satisfied—</p> <p style="padding-left: 40px;">(i) that the applicant is able and willing to grant, or procure the grant to the patentee and his licensees if they so desire, of a licence in respect of the other invention on reasonable terms; and</p> <p style="padding-left: 40px;">(ii) that the other invention has made a substantial contribution to the establishment or development of commercial or industrial activities in the territory of India.</p> <p>(3) When the Controller is satisfied that the conditions mentioned in sub- section (1) have been established by the applicant, he may make an order on such terms as he thinks fit granting a licence under the first mentioned patent and a similar order under the other patent if so requested by the proprietor of the first mentioned patent or his licensee: Provided that the licence granted by the Controller shall be non-assignable except with the assignment of the respective patents.</p> <p>(4) The provisions of sections 87, 88, 89 and 90 shall apply to licences granted under this section as they apply to licences granted under section 84.</p>
	<p>Section 92 Special provision for compulsory licences on notifications by Central Government</p> <p>(1) If the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licenses should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and thereupon the following provisions shall have effect, that is to say—</p>

	<p>(i) the Controller shall on application made at any time after the notification by any person interested, grant to the applicant a licence under the patent on such terms and conditions as he thinks fit;</p> <p>(ii) in settling the terms and conditions of a licence granted under this section, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.</p> <p>(2) The provisions of sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licences under this section as they apply in relation to the grant of licences under section 84.</p> <p>(3) Notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section (1) that it is necessary in—</p> <p>(i) a circumstance of national emergency; or</p> <p>(ii) a circumstance of extreme urgency; or</p> <p>(iii) a case of public non-commercial use,</p> <p>which may arise or is required, as the case may be, including public health crises, relating to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of licence under this section: Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87.</p>
	<p>Section 92A Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances</p> <p>(1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.</p> <p>(2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.</p>

	<p>(3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act. Explanation.—For the purposes of this section, 'pharmaceutical products' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.</p>
<p>Chapter 17: USE OF INVENTIONS FOR PURPOSES OF GOVERNMENT AND ACQUISITION OF INVENTIONS BY CENTRAL GOVERNMENT Section 99</p>	<p>Section 99 Meaning of use of invention for purposes of Government</p> <p>(1) For the purposes of this Chapter, an invention is said to be used for the purposes of Government if it is made, used, exercised or vended for the purposes of the Central Government, a State Government or a Government undertaking.</p> <p>(2) [omitted]</p> <p>(3) Nothing contained in this Chapter shall apply in respect of any such importation, making or using of any machine, apparatus or other article or of any such using of any process or of any such importation, using or distribution of any medicine or drug, as may be made by virtue of one or more of the conditions specified in section 47.</p>
	<p>Section 100 Power of Central Government to use inventions for purposes of Government</p> <p>(1) Notwithstanding anything contained in this Act, at any time after an application for a patent has been filed at the patent office or a patent has been granted, the Central Government and any person authorised in writing by it, may use the invention for the purposes of Government in accordance with the provisions of this Chapter.</p> <p>(2) Where an invention has, before the priority date of the relevant claim of the complete specification, been duly recorded in a document, or tested or tried, by or on behalf of the Government or a Government undertaking, otherwise than in consequence of the communication of the invention directly or indirectly by the patentee or by a person from whom he derives title, any use of the invention by the Central Government or any person authorised in writing by it for the purposes of Government may be made free of any royalty or other remuneration to the patentee.</p> <p>(3) If and so far as the invention has not been so recorded or tried or tested as aforesaid, any use of the invention made by the Central Government or any person authorised by it under sub-section (1), at any time after grant of the patent or in consequence of any such communication as aforesaid, shall be made upon terms as may be agreed upon either before or after the use, between the Central Government or any person authorised under sub-section (1) and the patentee, or, as may in default of agreement be determined by the High Court on a reference under section</p>

	<p>103: Provided that in case of any such use of any patent, the patentee shall be paid not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent.</p> <p>(4)The authorisation by the Central Government in respect of an invention may be given under this section, either before or after the patent is granted and either before or after the acts in respect of which such authorisation is given or done, and may be given to any person whether or not he is authorised directly or indirectly by the applicant or the patentee to make, use, exercise or vend the invention or import the machine, apparatus or other article or medicine or drug covered by such patent.</p> <p>(5) Where an invention has been used by or with the authority of the Central Government for the purposes of Government under this section, then, except in case of national emergency or other circumstances of extreme urgency or for non-commercial use, the Government shall notify the patentee as soon as practicable of the fact and furnish him with such information as to the extent of the use of the invention as he may, from time to time, reasonably require; and where the invention has been used for the purposes of a Government undertaking, the Central Government may call for such information as may be necessary for this purpose from such undertaking.</p> <p>(6)The right to make, use, exercise and vend an invention for the purposes of Government under sub-section (1) shall include the right to sell on non-commercial basis, the goods have been made in exercise of that right, and a purchaser of goods so sold, and a person claiming through him, shall have the power to deal with the goods as if the Central Government or the person authorised under sub-section (1) were the patentee of the invention.</p> <p>(7) Where in respect of a patent which has been the subject of an authorisation under this section, there is an exclusive licensee as is referred to in sub-section (3) of section 101, or where such patent has been assigned to the patentee in consideration of royalties or other benefits determined by reference to the use of the invention (including payments by way of minimum royalty), the notice directed to be given under sub-section (5) shall also be given to such exclusive licensee or assignor, as the case may be, and the reference to the patentee in sub-section (3) shall be deemed to include a reference to such assignor or exclusive licensee.</p>
	<p>Section 101 Rights of third parties in respect of use of invention for purposes of Government</p> <p>(1) In relation to any use of a patented invention, or an invention in respect of which an application for a patent is pending, made for the purposes of Government—</p> <p style="padding-left: 40px;">(a) by the Central Government or any person authorised by the Central Government under section 100; or</p>

	<p>(b) by the patentee or applicant for the patent to the order made by the Central Government, the provisions of any licence, assignment or agreement granted or made, between the patentee or applicant for the patent (or any person who derives title for him or from whom he derives title) and any person other than the Central Government shall be of no effect so far as those provisions—</p> <p>(i) restrict or regulate the use for the purposes of Government of the invention, or of any model document or information relating thereto, or</p> <p>(ii) provide for the making of payments in respect of any use of the invention or of the model, document or information relating thereto for the purposes of Government,</p> <p>and the reproduction or publication of any model or document in connection with the said use for the purposes of Government shall not be deemed to be an infringement of any copyright subsisting in the model or document.</p> <p>(2) Where the patent, or the right to apply for or obtain the patent, has been assigned to the patentee in consideration of royalties or other benefits determined by reference to the use of the invention then, in relation to any use of the invention made for the purposes of Government by the patentee to the order of the Central Government, sub-section (3) of section 100 shall have effect as if that use were made by virtue of an authority given under that section; and use of the invention for the purposes of Government by virtue of sub-section (3) of that section shall have effect as if the reference to the patentee included a reference to the assignor of the patent, and any sum payable by virtue of that sub-section shall be divided between the patentee and the assignor in such proportion as may be agreed upon between them or as may in default of agreement be determined by the High Court on a reference under section 103.</p> <p>(3) Where by virtue of sub-section (3) of section 100, payments are required to be made by the Central Government or persons authorised under sub-section (1) of that section in respect of the use of an invention for the purposes of Government and where in respect of such patent there is an exclusive licensee authorised under his licence to use the invention for the purposes of Government, such sum shall be shared by the patentee and such licensee in such proportions, if any, as may be agreed upon between them or as may in default of agreement be determined by the High Court on a reference under section 103 to be just, having regard to any expenditure incurred by the licensee—</p> <p>(a) in developing the said invention; or</p> <p>(b) in making payments to the patentees other than royalties or other benefits determined by reference to the use of the invention in consideration of the licence.</p>
	<p>Section 102</p>

	<p>Acquisition of inventions and patents by the Central Government</p> <p>(1) The Central Government may, if satisfied that it is necessary that an invention which is the subject of an application for a patent or a patent should be acquired from the applicant or the patentee for a public purpose, publish a notification to that effect in the Official Gazette, and thereupon the invention or patent and all rights in respect of the invention or patent shall, by force of this section, stand transferred to and be vested in the Central Government.</p> <p>(2) Notice of the acquisition shall be given to the applicant, and, where a patent has been granted, to the patentee and other persons, if any, appearing in the register as having an interest in the patent.</p> <p>(3) The Central Government shall pay to the applicant, or, as the case may be, the patentee and other persons appearing on the register as having an interest in the patent such compensation as may be agreed upon between the Central Government and the applicant, or the patentee and other persons; or, as may, in default of agreement, be determined by the High Court on a reference under section 103 to be just having regard to the expenditure incurred in connection with the invention and, in the case of a patent, the term thereof, the period during which and the manner in which it has already been worked (including the profits made during such period by the patentee or by his licensee whether exclusive or otherwise) and other relevant factors.</p>
<p>Chapter 23: Miscellaneous Section 156. Patent to bind Government</p>	<p>Section 156 Patent to bind Government</p> <p>Subject to the other provisions contained in this Act, a patent shall have to all intents the like effect as against Government as it has against any person.</p>
	<p>Section 157A Protection of security of India</p> <p>Notwithstanding anything contained in this Act, the Central Government shall:-</p> <p>(a) not disclose any information relating to any patentable invention or any application relating to the grant of patent under this Act, which it considers prejudicial to the interest of security of India;</p> <p>(b) take any action including the revocation of any patent which it considers necessary in the interest of the security of India by issue if a notification in the Official Gazette to that effect.</p> <p>Explanation.- For the purposes of this section, the expression "security of India" includes any action necessary for the</p>

<p>security of India which-</p> <ul style="list-style-type: none">(i) relates to fissionable materials or the materials from which they are derived; or(ii) relates to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment; or(iii) is taken in time of war or other emergency in international relations.

5. References

- Patents Act 1970 (including Amendments till 23 June 2017):
http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf

6. Background information

About TFORD-COVID19

The Principal Scientific Advisor to the GoI, Dr K VijayRaghavan, has constituted a S&T Core Group on COVID19. Under the aegis of the S&T Core Group on COVID19, a Task Force has been constituted focused on Repurposing of Drugs for COVID19 (in short "TFORD-COVID19"). The Task Force is being coordinated by Dr V Premnath, Head, NCL Innovations / Head, IP group at CSIR-NCL and Director, Venture Center and Dr Anurag Agarwal, Director, CSIR-IGIB. The Nerve Center for the Coordination is located be at Venture Center, Pune (located in the campus of CSIR-NCL).

Credits

Dr Premnath V, Dr Vidula Walimbe

Disclaimer

This Assessment Framework is a work-in-progress document meant to support structured and informed discussion. It is not meant to reflect the Government's position or that of any specific organization or individual.

Appendix: IP Assessment Questionnaire for Candidate Molecule

1. Information

S. No.	Questions?	
1.	What is the name of the lead molecule?	
2.	Are there relevant patents active (filed or granted) in India?	
3.	Who are the assignees of the patent?	
4.	When is the patent expiring?	
5.	What is the scope of coverage of the claims of the patent?	
6.	<ul style="list-style-type: none"> ○ Composition 	
7.	<ul style="list-style-type: none"> ○ Process 	
8.	<ul style="list-style-type: none"> ○ Product 	
9.	<ul style="list-style-type: none"> ○ Equivalent of method of use 	
10.	Is the patent being worked?	
11.	Is the patent under license for India? If yes, who owns the license right? What are the terms of the license?	

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2.	<p>Is the patent holder willing to license the <u>technology and patent rights</u> to local manufacturers for the duration of this epidemic?</p> <p>Are there potential licensees available and interested?</p>	
3.	<p>Is the patent holder willing to license the <u>patent rights</u> to local manufacturers for the course of this epidemic?</p> <p>Are there potential licensees who have knowhow already and are available and interested to be patent licensees?</p>	
4.	<p>Do we have Freedom to Operate (FTO) for a drug molecule in India?</p> <p>Is there any active patent application or valid patent granted in India that protects any aspect of the drug?</p> <ul style="list-style-type: none"> ○ Composition ○ Process ○ Product ○ Equivalent of method of use <p>If we have FTO, are there potential manufacturers who are able and interested?</p>	
5.	<p>Do we have access to suppliers for all necessary raw materials needed without undue risk or cost? Is there any active patent application or valid patent granted in India that protects any aspect of the knowhow?</p> <p>If not, do we have FTO for producing the raw</p>	

<p>materials and other parts of the value chain?</p> <p>Are there potential manufacturers who are able and interested?</p> <p>If we do not have FTO, is the patent holder willing to provide a license to an interested manufacturer for the duration of the epidemic?</p> <p>Are there potential licensees available and interested?</p>	
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3. Decisions matrix

	Questions?	
	If we do not have FTO, then how can we create freedom to operate during the crisis?	
	1. Use alternative molecules	
	1. Create a non-infringing route	
	2. Request/ negotiate/ press for a license	
	3. Consider UN Medicines Patent Pool route for licensing	
	4. Government use – Section 100 (5)	
	5. Compulsory license - Section 84	
	6. Special provision of compulsory license - Section 92 (3)	
	7. Revocation for non-working of patent- Section 85	
	8. Revocation on any other grounds	
	9. Action in interest of Security of India – Section 157A	