WHITE PAPER ON REFORMING THE LEGAL AND POLICY FRAMEWORK GOVERNING TRADE SECRETS AND CONFIDENTIAL INFORMATION IN THE BIOPHARMACEUTICAL SECTOR OF TAU CETI

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I. BRIEF STATEMENT OF FACTS

Evolution of Tau Ceti's Pharmaceutical Patent Regime: The biopharmaceutical sector of the Republic of Tau Ceti finds itself at a critical point. The pharmaceutical sector of Tau Ceti developed through process-only patents and generic manufacturing, which allowed the production of inexpensive medicines. The transition to a TRIPS-compliant product patent regime in 1995 led to delays in generic entry and price increases.

Affordability Crisis: The situation is further aggravated by the demographic and economic profile of Tau Ceti. Medical costs remain a major issue for many people who cannot afford them. The legal monopoly on trade secrets, regulatory data, and manufacturing knowledge directly affects the accessibility of the therapy. The existing legal system governing such knowledge is fragmented and lacks mechanisms that integrate innovation incentives with public accountability.

Pandemic-Era Secrecy and Privatisation: During the Rhinovirus-19 pandemic, outcomes were privately controlled without enforceable public-interest conditions. Acme and Winston operated under undisclosed MoAs that concealed IP ownership, access, and benefit-sharing terms, and Acme filed patents in its own name despite public involvement.

Whistleblower Suppression: The Bjorn whistleblower incident revealed the drawbacks of unlimited data secrecy. Bjorn Pharma received regulatory approval for Xenotril, even though internal research did not support the safety claims. Mohit, an employee, leaked internal data because he could not tolerate the regulators' inaction and the public harm. The company retaliated through civil and criminal proceedings. The existing whistleblower protection laws were inapplicable to disclosures involving pharmaceutical safety and regulatory data.

Limits of Compulsory Licensing for Biologics: The Ontuzumab dispute highlighted the limits of compulsory licensing in biologics. Patients wanted access to an expensive gene therapy that was the only one able to save their lives. Local companies were ready to develop biosimilars but cited a lack of knowledge and documentation as the primary reason they couldn't proceed.

Systemic Failures in Trade Secret: Tau Ceti's framework permits trade secrets and regulatory data to remain exclusionary despite public funding and health interests, with delayed judicial intervention and no ex ante rules on disclosure, accounting, technology transfer, or whistleblower protection, undermining access, regulatory credibility, and emergency response.

II. REVIEW OF EXISTING JURISPRUDENCE, POLICY PROPOSALS, AND RECOMMENDATIONS

India's trade-secret protection has developed without a dedicated statutes. The Indian Contract Act, 1872,[1] supplies the foundational basis through non-disclosure agreements and confidentiality clauses, while common-law equity, crystallised in *John Richard Brady v.*

[1] Indian Contract Act 1872, ss 10–23.

Chemical Process Equipments,[2]recognises breach of confidence as an enforceable cause of action. India's accession to the TRIPS Agreement in 1995 entrenched the protection of undisclosed information through Article 39.[3] Statutory reinforcement is provided by the Information Technology Act, 2000, particularly Section 72, which address unauthorisedaccess to and misuse of data.[4] Criminal liability for the misappropriation of confidential business information is found in Bharatiya Nyaya Sanhita, 2023.[5] Judicial development has refined trade-secret protection through the four-fold test for confidentiality.[6] Policy-level assessments like the WIPO's overview of India's trade secret regime, consistently document the absence of a unified statute.[7]

Compulsory licensing in India has evolved exclusively in the patent context, with no statutory or judicial authority empowering courts or the executive to mandate disclosure of trade secrets, even during public-health emergencies. Responding to this, the Trade Secrets and Economic Espionage Bill[8] ("**Draft Bill**") adopts a narrowly tailored model that permits compulsory licences only in cases of "public health emergency, national security, etc." on government notification.[9]Licences are strictly non-exclusive and non-assignable, have confidentiality obligations, and terminate automatically once the emergency ends.[10]

Transparency in clinical trials, publicly funded biomedical research, and trade-secret claims remains fragmented and largely reactive. The Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019, regulate approvals but impose no obligation on the CDSCO to publish publicly funded clinical-trial protocols, Phase-III waiver data, etc. Disclosure therefore defaults to the Right to Information Act, 2005, where Section 8(1)(d) enables default secrecy with disclosure dependent on a delayed public-interest override. The Draft Bill, 2024, defines trade secrets broadly without carve-outs for publicly funded research, allowing state-supported innovation to remain confidential by default. While courts have recognised public interest as a limiting principle on confidentiality[11] these decisions articulate a balancing doctrine rather than a proactive disclosure mandate.

Whistleblowing protection in India is similarly limited. The principal mechanisms operate through Section 177 of the Companies Act, 2013[12] and the SEBI LODR Regulations, 2015[13], which mandate audit committees and whistleblowing policies for listed entities, supplemented

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[2]*John Richard Brady v Chemical Process Equipments*AIR 1987 Delhi 372.
[3] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (adopted 15 April 1994, entered into force 1 January 1995) art 39.
[4]*Information Technology Act 2000*, ss 43, 65, 66, 72, 72A.
[5]*Bharatiya Nyaya Sanhita 2023*, ss 303, 314, 316.
[6]*Burlington Home Shopping Pvt Ltd v Rajnish Chibber* (1996) 61 DLT 6; *American Express Bank Ltd v Priya Puri* 2006 SCC OnLine Del 638; *Zee Telefilms Ltd v Sundial Communications Pvt Ltd* (2003) 3 Mah LJ 695.
[7] World Intellectual Property Organization (WIPO), *Overview Of National And Regional Trade Secret Systems* <https://www.wipo.int/documents/d/trade-secrets/docs-overview-country-sheets-india-final.pdf > accessed 30 November 2025.
[8] Trade Secrets and Economic Espionage Bill 2024.
[9] Trade Secrets and Economic Espionage Bill 2024, cl 6.
[10] Trade Secrets and Economic Espionage Bill 2024, cl 6.
[11]*Petronet LNG Ltd v Indian Petro Group*2009 SCC OnLine Del 841; *Star India (P) Ltd v Laxmiraj Seetharam Nayak* 2003 SCC OnLine Bom 27.
[12] The Companies Act 2013, ss 177.
[13]Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations 2015.

by the Companies Order[14] requiring disclosure of whistleblower complaints to auditors. The Whistle Blowers Protection Act, 2014[15] remains unenforced and applies only to public servants. The Draft Bill[16] does not specifically mention the term 'Whistleblower'. However, Section 5[17] provides exceptions in which disclosure of a trade secret does not constitute misappropriation, including disclosure of "an unlawful act or professional or other misconduct", and the second is "in good faith to protect public interest".

III. OUTPUT DOCUMENT

1. EXECUTIVE SUMMARY

This Output Document proposes reforms to strengthen compulsory licensing of trade secrets, enhance transparency in publicly funded pharmaceutical innovation, and reinforce whistleblower protections, particularly during public health emergencies. It recommends a structured trade secret CL regime covering manufacturing know-how and tacit expertise, with clear scope, safeguards, compensation, and sunset clauses. The framework mandates technical assistance to ensure real manufacturing capacity, promotes transparency in public funding and regulatory decisions, and strengthens whistleblower protections through clearer public-interest standards and anti-retaliation safeguards.

2. ASSESSMENT OF ADEQUACY

2.1. Compulsory Licensing

2.1.1. Determination of the Scope and Extent of Compulsory Licensing

The Agreement on the Trade-Related Aspects of Intellectual Property Rights ("**TRIPS**") is silent on compulsory licensing ("**CL**")of trade secrets, but obligates member states to protect undisclosed information against "unfair commercial use"[18] and to protect undisclosed test data submitted for marketing approval.[19] However, TRIPS provides considerable flexibility for states to define the scope of protection.[20] Articles 7 and 8 of TRIPS[21] and the Doha Declaration[22] support public health measures and technology transfer, and there is no prohibition on CL of trade secrets in Article 39,[23] unlike Article 21,[24] which expressly prohibits compulsory licensing of trademarks. Trade secret law already accommodates public-interest

[14] The Companies (Auditor's Report) Order 2020.
[15] Whistle Blowers Protection Act2014.
[16] Trade Secrets and Economic Espionage Bill 2024.
[17] Trade Secrets and Economic Espionage Bill 2024, cl 5.
[18] Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299, art 39(2) (**'TRIPS'**).
[19] TRIPS, art 39(3).
[20] Biswajit Dhar, 'Article 39.3 of the TRIPS Agreement: Its Genesis and the Present Context' (Centre for WTO Studies, IIFT) <https://wtocentre.iift.ac.in/Papers/1.pdf> accessed 3 December 2025.
[21] TRIPS, arts 7–8.
[22] World Trade Organization, 'Declaration on the TRIPS Agreement and Public Health' (14 November 2001) WT/MIN(01)/DEC/2.
[23] TRIPS, art 39.
[24] TRIPS, art 21.

access routes in the US,[25] the EU,[26] the European Medicines Agency,[27]France,[28] and China.[29] Section 2(f) of the Bill defines "trade secrets," but the scope of mandated disclosure within this broad term under a CL needs greater clarity.[30]

2.1.2. Eligibility of Private Parties to Trigger Compulsory Licensing

The current framework does not allow private parties to apply for a CL. In the patent system, the only effective CL ever granted was *Bayer v. Natco*.[31] In contrast, Section 100 government-use powers have never been exercised,[32] and the absence of a compulsory licence during COVID-19 illustrates a broader hesitation to deploy compulsory licensing.[33]

2.1.3. Assessment of Government Responsibility for Loss of Secrecy

Clause 6(3) of the Bill identifies the parties' obligation to maintain confidentiality of the trade secret during and post termination of compulsory license explicitly, and by implication providing for a three-party order between the trade secret holder, the qualified licensee, and the Government.[34]Apart from statutory non-disclosure obligations, confidentiality maintenance requires government assurance onindependent monitoring with audit rights, site access,reporting duties, and penalties for leakage.[35] Since trade secrets lose all value once publicly disclosed, and secrecy cannot be restored after a breach,[36] the Bill must clearly allocate responsibility for security, accountability, and executive oversight.

2.1.4. Know-How Facilitation Under Compulsory Licensing

Written documentation is inadequate for complex biologics and vaccines as it depends on tacit knowledge, experienced personnel, and on-site coaching.[37] This raises questions about whether a CL can function like a mandatory injunction that forces the licensor's staff to travel, supervise plant setup, etc.[38] If country A issues a compulsory licence against a technology owner in

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[25] Defense Production Act of 1950, PL 81-774, 50 USC §§ 4501 et seq, s 303; *In re Mallinckrodt plc* Case No 20-12522-JTD (Bankr D Del 2020); *Detroit Medical Center v GEAC Computer Systems* Inc 103 F Supp 2d 1019 (ED Mich 2000).

[26] Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure [2016] OJ L157/1.

[27] Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents [2001] OJ L145/43; European Medicines Agency, 'Policy 0070 on Publication of Clinical Data for Medicinal Products for Human Use' (2014); Case C-178/18pageMSD *Animal Health Innovation GmbH and Intervet International BV v European Medicines Agency* (EMA) EU:C:2020:24.

[28] Code de la santé publique (Public Health Code), art L.3131-15 (France).

[29] Anti-Unfair Competition Law of the People's Republic of China (adopted 4 November 2017, amended 23 April 2019), arts 9, 17, 21, 31 and 32.

[30] Law Commission of India, *289th Report on Protection of Trade Secrets*, Draft Bill (2024), cl 2(f).

[31]*Bayer Corporation v Natco Pharma Limited* 2014(60) PTC 277 (BOM).

[32] Patents Act 1970 (India) ss 100.

[33] W Jon, 'Why countries will not use compulsory licensing – and how to fix it' (2025) 10 BMJ Global Health <https://gh.bmj.com/content/10/9/e020856> accessed 3 December 2025.

[34] Law Commission of India, 289th Report on Protection of Trade Secrets, Draft Bill (2024), cl 2(f).

[35] European Commission, *Study on Trade Secrets and Confidential Business Information* (2015) <https://ec.europa.eu/docsroom/documents/14838/attachments/1/translations/en/renditions/pdf> accessed 4 December 2025.

[36] World Intellectual Property Organization, *WIPO Guide to Trade Secrets and Innovation — Part III: Basics of trade secret protection* (Online) <https://www.wipo.int/web-publications/wipo-guide-to-trade-secrets-and-innovation/en/part-iii-basics-of-trade-secret-protection.html> accessed 4 December 2025.

[37] Policy Competition, Problem Statement,page 9.

[38] Olga Gurgula and Luke McDonagh, 'On Compulsory Licensing of Trade Secrets to Safeguard Public Health' (25 March 2024) forthcoming in The Cambridge Law Journal (2025) <http://dx.doi.org/10.2139/ssrn.4771745> accessed 3 December 2025.

country B and the licensor refuses in-person training, enforcement would rely on cross-border recognition which many jurisdictions do not grant.

2.1.5. Confidentiality Safeguards Governing Trade Secret Transfer

Once a trade secret enters the public domain, confidentiality must be preserved to ensure a compulsory transfer to one manufacturer does not lead to wider circulation.[39] The licensor loses control over choosing a trusted partner and must rely on the government's variable "best efforts" and limited indemnities. Employee mobility poses the greatest risk of leakage, yet many jurisdictions draw an uncertain line between protectable trade secrets and an employee's general skill and experience, making enforcement unpredictable.[40]

2.1.6. Prevention of Post-Transfer Confidentiality Breaches

Trade secrets have shifted from unfair-competition safeguards to patent substitutes, allowing firms to withhold key details, extend exclusivity, and avoid disclosure that enables cumulative research.[41] Compulsory licensing creates a paradox: once licensees access confidential know-how, they cannot later rely on reverse engineering or independent creation, leaving them "contaminated."[42]

2.1.7. Calculation of Compensation for Trade Secrets

Clause 6(2) of the proposed Bill mandates government-setremuneration reflecting the nature, value, and development/maintenance costs of a trade secret.[43] Since compulsory licensing overrides consent, royalty determinations must balance public health needs with fair compensation. TRIPS Article 31(h) offers no formula (only case-specific, market-based remuneration) and provides no guidance for trade secrets, leaving wide national discretion.[44] This creates uncertainty, risks retaliation (e.g., Abbott's withdrawal from Thailand after an HIV licence),[45] and assumes strong domestic capacity to manage proprietary know-how under Article 39.[46] Broad waivers may further weaken R&D incentives if firms anticipate loss of control over valuable information.[47]

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[39] *In re Mallinckrodt plc (Mallinckrodt ARD LLC*, formerly Questcor Pharmaceuticals, Inc) Case No 20-12522-JTD (Bankr D Del 2020).

[40] Camilla A. Hrdy, 'The General Knowledge, Skill, and Experience Exclusion' (2019) 60 Boston College Law Review 2409 <https://bclawreview.bc.edu/articles/323/files/63a925d2ca659.pdf> accessed 4 December 2025.

[41] European Commission, Study on Trade Secrets and Confidential Business Information in the Internal Market (Apr 2013) <https://ec.europa.eu/docsroom/documents/14838/attachments/1/translations/en/renditions/pdf> accessed 4 December 2025; World Intellectual Property Organization, WIPO Guide to Trade Secrets and Innovation (WIPO, 2022) <https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=621851>accessed 4 December 2025.

[42] Jerome H. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 37 *Journal of Law, Medicine & Ethics* 247-263; Andrea Contigiani and David H. Hsu, 'How Trade Secrets Hurt Innovation' (2019) Harvard Business Review (1 January 2019) <https://hbr.org/2019/01/how-trade-secrets-hurt-innovation> accessed 4 December 2025.

[43] Law Commission of India, 289th Report on Protection of Trade Secrets, Draft Bill (2024), cl 6(2).

[44] TRIPS, art 31(h).

[45] Doctors Without Borders/Médecins Sans Frontières (MSF), 'Thailand, Abbott, and the Second-Line AIDS Crisis' (25 April 2007) <www.doctorswithoutborders.org/latest/thailand-abbott-and-second-line-aids-crisis> accessed 4 December 2025.

[46] TRIPS, art 39.

[47] European Commission, Study on Trade Secrets and Confidential Business Information in the Internal Market (Apr 2013) <https://ec.europa.eu/docsroom/documents/14838/attachments/1/translations/en/renditions/pdf> accessed 4 December 2025; David Shore, 'Divergence and Convergence of Royalty Determinations between Compulsory Licensing under the TRIPS Agreement and Ongoing Royalties as an Equitable Remedy' (2020) 46 American Journal of Law & Medicine 55–88 <https://doi.org/10.1177/0098858820919553> accessed 4 December 2025.

2.1.8. Applicability of Article 31bis of TRIPS to Trade Secrets

Although Article 31 of the TRIPS Agreement is confined to patents and not trade secrets, the constraints in Article 31(h) regarding the predominant domestic-market supply requirement would not automatically extend to the compulsory licensing of trade secrets.[48] Article 31bis TRIPS was designed to overcome the limitations of Article 31(h) for patents, and Section 107A Patent Act 1970 domestically incorporates this principle for patented products.[49]

2.1.9. Data Exclusivity Protection for Trade Secrets

Data and marketing exclusivity restrict compulsory licensing by blocking access to the originator's clinical data. TRIPS Article 39.3 protects test data without mandating exclusivity, allowing suspension for health needs. Exclusivity delays vaccines and biosimilars that must prove similarity alone. Tau Ceti doesn't grant data exclusivity, however, upcoming FTAs demand such obligations increasingly.[50]

2.1.10. Structuring Wind-Down and Termination of Compulsory Licences

Clause 6(4) provides for automatic termination upon the end of the emergency;[51] however, it should statutorily specify the frequency of review rather than rely on the vague standard of "change in circumstances." Such ambiguity risks repeated review applications by licensors, hindering effective licence use, while also allowing a compulsory licence to continue despite non-working for over a year.

2.2. Transparency

2.2.1. Impact of Confidentiality in Emergency Clinical Trial Approvals on Regulatory Transparency

The clinical trial approvals' confidentiality regime restricts access to the main regulatory data. TCDSCO did not allow the disclosure of the Phase-III waiver data[52] and reviewer assessments of Acme's vaccine, and there is no obligation under the law to make trial protocols, CSR summaries, or regulatory rationale available to the public. Such non-disclosure in the course of emergency approval severely restricts independent scientific scrutiny.

2.2.2. Contractual and Funding Opacity in State-Funded Research

Although there was extensive public funding via TNMRO facilities, government-backed personnel, AMCs and research grants, Acme and Winston still considered MoAs, IP rights, trial results and participation logs as confidential.[53] The Draft Bill, 2024, characterizes trade secrets broadly and does not offer any exemptions for publicly funded research or related

[48] TRIPS art 31.
[49] TRIPS, art 31bis; Patents Act 1970 (India), ss 107A.
[50] 'India hasn't accepted UK "data exclusivity" demand in FTA to protect generic drug firms' (*The New Indian Express*, 12 May 2025) <https://www.newindianexpress.com/business/2025/May/12/india-hasn-t-accepted-uk-data-exclusivity-demand-in-fta-to-protect-generic-drug-firms> accessed 5 December 2025.
[51] Law Commission of India, 289th Report on Protection of Trade Secrets, Draft Bill (2024), cl 6(4).
[52] Policy Competition, Problem Statement,page6.
[53] Policy Competition, Problem Statement, page 5.

agreements while the current RTI law allows for the exemption[54] of such information on the basis of commercial confidentiality unless overriding public interest is established.

2.2.3. Effect of the RTI Act's Commercial Confidentiality Exemption on Disclosure of Publicly Funded R&D

Section 8(1)(d) of the RTI Act ensures that the information of a commercial nature is not disclosed unless the public interest is proven to be more significant. However, proving through appeals is a long process and thus the information often becomes available when it is too late.

2.2.4. Mandatory Accounting of Public Contributions to Innovation

Acme's vaccine was significantly supported by public laboratories, researchers, and fast-track regulatory support, but these were not disclosed and the ownership remained solely with the private company. The lack of a statutory accounting requirement permits public investment to continue being unrecorded and allows quiet private appropriation of publicly supported innovation.

2.2.5. Expedited Resolution of Disputes Affecting Vaccine Access

Winston's indigenous mRNA vaccine emerged after stalled technology-transfer talks with Bingo Pharma,[55] leading to litigation. The trial affected the vaccine's availability in the market. It has been clearly drawn that the necessity is for the public health emergencies to have the expedited, confidential hearing procedures so that such delays do not happen again.

2.2.6. Penal Consequences for Over-Classification of Public Records

Non-penalisation of over-classification enabled companies to hide their pricing discussions, IP ownerships and public contributions. The lack of criminal or administrative sanctions for wrongful secrecy claims, the Draft Bill's silence on penalties, and the RTI Act section 8(1)(d), which allows withholding of information marked as confidential or proprietary, all reinforce this opacity.

2.2.7. Absence of Institutional Powers to Verify Trade Secret Claims

Firms routinely overclaim trade-secret status to evade RTI disclosure and regulatory scrutiny.The Trade Secrets Bill, 2024 lacks explicit investigative or audit powers to verify or dispute trade secret claims, thus permitting confidentiality claims to go unnoticed by independent scrutiny, even though Clause 4 admits lawful acquisition through independent discovery, observation, or reverse engineering but does not provide a mechanism to examine or test such claims.

2.3. Whistleblowing

2.3.1. Definition of "Public Interest"

The term 'public interest' in the Bill has not been defined. The same would have to be interpreted by the courts while deciding whether a disclosure should be exempted or not.

[54] Right to Information Act 2005, ss 8(1)(d).
[55] Policy Competition, Problem Statement, page 6.

2.3.2. Threshold for Permissible Disclosure in Public Interest

A mere relation to the public issue of a trade secret does not always make the disclosure of such information to be in 'public interest'. Therefore, there needs to be a standard for sufficiency of public interest, and the information should be disclosed only to the extent necessary to unravel the wrongdoing.

2.3.3. Burden Imposed by the "Good Faith" Requirement

The term 'good faith' in Section 5 can impose excessive burden on the whistleblowers to disclose information about a wrongdoing only when they have sufficient evidence to conclusively prove that such wrongdoing has occurred, and the person did not have any ulterior motive behind disclosing it. The same can again demotivate people from revealing essential information due to the fear of not being able to prove good faith on his/her part.

2.3.4. Resolution of Conflicts Between the Draft Bill and Other Laws

Given the paucity of comprehensive whistleblower protections in India, situations may arise in which the provisions of the Draft Bill come into tension or even conflict with safeguards contained in other statutes.

2.3.5. Impact of Limited Awareness of Legal Protections

Many people in Tau Ceti live just above the poverty line,[56] which is bound to prevent them from properly exercising their rights. Whistleblowers might hesitate from disclosing information because of lack of knowledge about protection against retaliation.

2.3.6. Protection for Disclosures of Anticipated Wrongdoing

The scope of the Draft Bill leaves out cases where a whistleblower merely anticipates that misconduct may happen. This might create situations wherein the whistleblower might come into the knowledge that a wrongdoing is about to happen in terms of a trade secret, but cannot disclose the same until it has already occurred.

2.3.7. Adequacy of Existing Safeguards Against Retaliation

Whistleblowers are always at the threat of criminal prosecution, or other retaliations by their employers for disclosing confidential material. The same may include termination of employment, or discriminatory treatment.

3. ADDRESSING POLICY GAPS

In order to resolve the above-mentioned inadequacies, the following policy landscape followed internationally in various countries should be considered:-

3.1. <u>Compulsory Licensing</u>

1. **For scope of transfer,** Germany's Trade Secrets Act (GeschGehG) offers a workable approach by allowing the disclosure of trade secrets through statutory inspection powers,

[56] Policy Competition, Problem Statement,page1.

mandatory inventory disclosure upon designation of a licensee, and independent expert verification of completeness and necessity.[57] In the *Mallinckrodt* case, the company had to transfer ACTH-related patents under detailed requirements for documentation[58] In the 2007 FTC consent order,[59] voluntary and open COVID-19 technology-transfer models,[60]Corbevax's open licensing approach,[61] and the NIH's extensive know-how to Afrigen.[62]

2. **For private party-trigger of compulsory licensing,** most jurisdictions recognise national emergency, extreme urgency, unreasonable pricing, insufficient working and dependent technologies as valid grounds for CL (with the burden of proof on the applicant), also requiring prior attempts to negotiate a voluntary licence, while the rights holder must receive notice and an opportunity to be heard.[63]

3. **For "show-how" facilitation,** the United States Defense Production Act illustrates how a State can manage this higher secrecy burden.[64]***First***, the government must indemnify and compensate the rights holder for any loss arising from compelled access. ***Second***, compelled information is handled only within federally supervised contractor environments that comply with DFARS,[65] NIST,[66] and other federal information security standards. ***Third***, secrecy protection is monitored by independent federal bodies, now also being brought under improved accountability.[67] ***Fourth***, all compelled material is shielded under FOIA Exemption 4,[68] and any unauthorised disclosure attracts criminal penalties under 18 US Code Section 1905.[69]

[57] Trade Secrets Act (Geschäftsgeheimnisgesetz – GeschGehG 2019) (Germany) ss 2–4, 11, 14.
[58] In re Mallinckrodt plc (Mallinckrodt ARD LLC, formerly Questcor Pharmaceuticals, Inc) Case No 20-12522-JTD (Bankr D Del 2020).
[59] In the Matter of Hospira, Inc. and Mayne Pharma Limited, FTC Matter/File No 0710002, Docket No C-4182.
[60] World Health Organization, 'COVID-19 Technology Access Pool (C-TAP) and mRNA Technology Transfer Programme' <www.who.int/initiatives/covid-19-technology-access-pool> accessed 3 December 2025; The Open COVID Pledge <https://opencovidpledge.org> accessed 3 December 2025; Serum Institute of India and University of Oxford, 'Serum Institute of India and University of Oxford Strike Landmark Licensing Agreement for Meningitis-B Vaccine' (Oxford University Innovation, 16 April 2024) <https://innovation.ox.ac.uk/news/serum-institute-of-india-and-university-of-oxford-strike-landmark-licensing-agreement-for-meningitis-b-vaccine/> accessed 3 December 2025.
[61] '"Vaccine for World" Gets Emergency Use Authorization in India; Texas Children's Hospital Grants Non-Exclusive License to Biological E' (Health Policy Watch, 28 December 2021)<https://healthpolicy-watch.news/vaccine-for-world-gets-emergency-use-authorization-in-india-texas-childrens-hospital-grants-non-exclusive-license-to-biological-e/> accessed 3 December 2025.
[62] A Panagopoulos et al, 'A policy for enabling the licensing of mRNA vaccines' (2023) 22 *Human Vaccines &Immunotherapeutics* (online)<https://pmc.ncbi.nlm.nih.gov/articles/PMC10233741/> accessed 3 December 2025.
[63] Patents Act 1970 (India) ss 84, 92.
[64] Defense Production Act of 1950, PL 81-774, 50 USC §§ 4501 et seq, ss 303.
[65] Defense Federal Acquisition Regulation Supplement (DFARS) (USA) pts 204, 252.
[66] National Institute of Standards and Technology, *Framework for Improving Critical Infrastructure Cybersecurity* (Version 1.1, April 2018) <https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf> accessed 4 December 2025.
[67] The White House, *Ensuring Accountability for All Agencies* (The White House, 2025) <https://www.whitehouse.gov/presidential-actions/2025/02/ensuring-accountability-for-all-agencies/> accessed 4 December 2025.
[68] Freedom of Information Act 5 USC § 552(b)(4) (US).
[69] 18 USC § 1905 (US) – Disclosure of confidential information by officers or employees of the United States.

4. **For peri-transfer confidentiality,** scholarly proposals by O. Gurgula and L. McDonagh define the licensor's training obligations, specify where and how instruction is delivered, and recognise that on-site support is often essential.[70]

5. **For post-transfer confidentiality,** the EU Trade Secrets Directive[71] provides injunctions, damages, and confidentiality protections, while the US framework, through the UTSA,[72]DTSA,[73] and EEA,[74] offers strong civil and criminal remedies when evidentiary standards for independent creation and reverse engineering are not fulfilled.

6. **For compensation,** the 2001 UNDP Guidelines set a 4% baseline on the generic price, adjustable ±2%.[75] The 1998 Japanese Patent Office Guidelines set 2–4%, adjustable 0–6%, allowing a utilization ratio for multiple contributing inventions.[76] Canada's 2005 export rules use a sliding scale of 0.02–4% based on the recipient country's Human Development Index.[77] The Tiered Royalty Method bases royalties on high-income prices, adjusted for income or disease burden, supported by UNDP and WHO.[78] The Medical Innovation Prize Fund replaces royalties with national prize payments based on demonstrated health impact.[79]

7. **For data exclusivity,** in the EU, generics are delayed even with a patent licence because test data cannot be reused, and fresh trials are required.[80] The EU applies an eight-plus-two exclusivity model permitting filings but blocking marketing. Chile lifts exclusivity during emergencies or compulsory licences,[81] and Brazil[82] and China[83] provide public health

[70]Olga Gurgula and Luke McDonagh, 'On Compulsory Licensing of Trade Secrets to Safeguard Public Health' (25 March 2024) forthcoming in *The Cambridge Law Journal* (2025)<http://dx.doi.org/10.2139/ssrn.4771745> accessed 3 December 2025.
[71] Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure [2016] OJ L157/1, arts 7–9, 11–13.
[72] Uniform Trade Secrets Act 1985 (amended 1985, official text) §§ 1–8 (US).
[73] Defend Trade Secrets Act 2016, 18 USC § 1836(b)–(b)(3) (US).
[74] Economic Espionage Act 1996, 18 USC §§ 1831–1832 (US).
[75] United Nations Development Programme (UNDP), Human Development Report 2001: Making New Technologies Work for Human Development (UNDP, 2001), 108.
[76] Japan Patent Office, 'Guideline for Remuneration for Government-Owned Inventions on Behalf of the Entire Government (1998).
[77] Canada Gazette, *Notice Vol 138, No 40 — Use of Patented Products for International Humanitarian Purposes, Regulations, Regulatory Impact Analysis Statement* (2 October 2004).
[78] World Health Organization, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies* (WHO/TCM/2005.1, 2005).
[79]iMed Project, 'Medical Innovation Prize Fund (MIPF)' (iMed Project Proposals Database)<https://imedproject.org/proposals-database/mipf/> accessed 4 December 2025.
[80] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67; Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1.
[81] Law No 19.039 Establishing the Rules Applicable to Industrial Titles and the Protection of Industrial Property Rights, No 33.877 (25 January 1991).
[82] Federal Law No 12.527/2011 (Brazil) (Freedom of Information Act); Decree No 7.724/2012 (Brazil); Federal Law No 9.279/1996 (Brazil) (Industrial Property Law).
[83] National Medical Products Administration, *Implementation Measures for the Protection of Drug Trial Data* (Draft for Comments, 19 March 2025) arts 3–7, issued under the *Drug Administration Law of the People's Republic of China*.

routes. US FTAs with Peru,[84] Colombia,[85] and Panama[86] include health exceptions. The EU Export CL Regulation[87] and Medicines Patent Pool licences allow routine approval waivers.[88] The proposed EU Data Act would mandate access to data, including trade secrets, with confidentiality safeguards, functioning as compulsory access.[89]

8. **For compulsory licence wind-down,** Article 50 of Albania's Law on Industrial Property[90] and Article 32 of Bulgaria's Patent Law[91] impose one-year non-working caps absent in Sections 84 and 100 of the Indian Patents Act, 1970;[92] given the heightened sensitivity of trade secrets over patents, an express annual review-based wind-down mechanism should be incorporated rather than left solely to party application.

3.2. Transparency in Publicly Funded Clinical Research and Innovation

1. **For clinical trial regulatory transparency**, the EU Clinical Trials Regulation (CTR 536/2014)[93] and the Clinical Trials Information System (CTIS)[94] provide a transparency model. CTR requires public access to protocols, investigator brochures, result summaries, CSRs and regulatory communications, features absent from Tau Ceutian framework, and allows redaction only for commercial confidentiality, personal data or necessary public interest reasons. Recitals 67 and 68 identify transparency as essential for trust and innovation,[95] while Article 81 provides a legal enforcement pathway. In the United States, the FDA has adopted radical transparency by publishing Complete Response Letters for failed applications with trade-secret elements redacted.[96]

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[84] United States–Peru Trade Promotion Agreement (signed 12 April 2006, entered into force 1 February 2009) ch 16, arts 16.10(2)(a)–(c).
[85] United States–Colombia Trade Promotion Agreement (signed 22 November 2006, entered into force 15 May 2012) ch 16, art 16.10.1(a)–(c).
[86] United States–Panama Trade Promotion Agreement (signed 28 June 2007, entered into force 31 October 2012) ch 15, art 15.10.1–15.10.2.
[87] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public-health problems [2006] OJ L157/1; Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items [2021] OJ L206.
[88] Medicines Patent Pool, 'Agreements with Innovators — Licences' (Medicines Patent Pool)<https://medicinespatentpool.org/progress-achievements/licences> accessed 4 December 2025.
[89] Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act) [2023] OJ L 2854.
[90] Law on Industrial Property No 9977 (Albania, 7 July 2008) art 50.
[91] Patent Law No 27/1993 (Bulgaria, as amended by Law No 59/2007) art 32.
[92] Patents Act 1970 (India), ss 84, 100.
[93] Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use [2014] OJ L 158/1.
[94] European Medicines Agency, 'Clinical Trials Information System (CTIS)' (EMA, last updated 29 October 2025)<https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/clinical-trials-information-system> accessed 1 December 2025.
[95] Ż Zemła-Pacud and G Lenarczyk, 'Clinical Trial Data Transparency in the EU: Is the New Clinical Trials Regulation a Game-Changer?' (2023) 54 *IIC — International Review of Intellectual Property and Competition Law* 732, 732–763<https://doi.org/10.1007/s40319-023-01329-4> accessed 1 December 2025.
[96] US Food and Drug Administration, 'FDA Embraces Radical Transparency by Publishing Complete Response Letters' (News Release, 10 July 2025)<https://www.fda.gov/news-events/press-announcements/fda-embraces-radical-transparency-publishing-complete-response-letters> accessed 1 December 2025.

2. **For disclosure of publicly funded research arrangements**, the United States provides a useful openness model, i.e., under the Federal Technology Transfer[97] Act and FOIA,[98] CRADAs and funding arrangements must be disclosed, subject only to limited redaction under Exemption 4, and even then funding amounts, collaboration scope, public resource inputs, IP terms, and royalty-sharing arrangements remain public. Similarly, the EU Horizon 2020 / Horizon Europe frameworks mandate publication of grant agreements and State-funded R&D terms, creating a transparent record of public financial participation in innovation.[99] In Mersey Tunnel Users' Association v Information Commissioner,[100] the tribunal held that accountability for the use of public funds could outweigh confidentiality claims.

3. **For state oversight of publicly financed innovation**, the South African Government through the IPRs from Publicly Financed Research and Development Act, 2008[101] gives power to the State to intervene where innovation with public funds does not benefit the citizens, by mandating disclosure of IP to the National Intellectual Property Management Office.

4. **For post-grant oversight of publicly funded inventions**, the Bayh-Dole model, USA[102] establishes a disclosure and reporting duty for federally funded inventions and gives the state a mechanism to intervene when pricing or access diverges from public interest. This model ties public financing to transparent ownership records and post-grant oversight. WHO's R&D Blueprint[103] sets transparency expectations for publicly supported pandemic countermeasures.

5. **For expedited resolution of trade secret disputes**, while Section 9 of the bill offers important protective measures (i.e., in-camera (private) hearings) against public disclosure of trade secrets, it does not by itself create a mandatory, time-bound expedited hearing process akin to the U.S. ITC's 100-day[104] fast-track adjudication. Where important intellectual property is at stake, the ITC can put in place a "fast-track" initial determination on major points within 100 days. This compels a decision on the "illegal use of confidential

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[97] Federal Technology Transfer Act of 1986, 15 USC § 3710a(c)(5)(A) (public CRADA summaries); § 3710a(c)(5)(B) (limited withholding); § 3710(b)(2) (IP and royalty reporting); § 3710(f) (annual public reporting).
[98] Freedom of Information Act, 5 USC § 552(a) (general disclosure duty); § 552(b)(4) (trade secret and confidential commercial information exemption).
[99] Regulation (EU) No 1291/2013 establishing Horizon 2020, art 26 (grant agreement publication obligations); Regulation (EU) 2021/695 establishing Horizon Europe, arts 50-52 (disclosure of funding, grant terms, and public financial contributions).
[100] Mersey Tunnel Users' Association v Information Commissioner and Merseytravel (EA/2007/0052) [2008] UKFTT (Information Rights).
[101] Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008 (Republic of South Africa) <https://www.gov.za/documents/acts/intellectual-property-rights-publicly-financed-research-and-development-act-51-2008> accessed 3 December 2025.
[102] Bonnie W Nannenga-Combs and John M Covert, '2020 Patent Prosecution Tool Kit: Federally Funded Inventions and Compliance with the Bayh-Dole Act' (Sterne, Kessler, Goldstein & Fox, 7 July 2020) <https://www.sternekessler.com/news-insights/insights/federally-funded-inventions-and-compliance-bayh-dole-act/> accessed 3 December 2025.
[103] World Health Organization, 'An R&D Blueprint for Action to Prevent Epidemics: Plan of Action' (May 2016) <https://cdn.who.int/media/docs/default-source/blue-print/an-randd-blueprint-for-action-to-prevent-epidemics.pdf> accessed 3 December 2025.
[104] Gwendolyn Tawresey and Frank D Liu, 'Overview of a Section 337 Investigation at the ITC' (Troutman Pepper Locke, May 2025) <https://www.troutman.com/wp-content/uploads/2025/05/Overview-of-a-Section-337-Investigation-at-the-ITC-5-2025.pdf> accessed 5 December 2025.

information" issue, while standard civil trials take years, and the market is not disrupted for long.

6. **For limits on trade secret exemptions under access-to-information law**, the U.S. Freedom of Information Act (FOIA) Exemption 4 and the ruling in Argus Leader Media v. Department of Veterans Affairs[105] clarifies that trade secret or commercial information exemptions under FOIA cannot be used to conceal information that is no longer secret or does not cause substantial competitive harm, preventing over-classification and improper withholding of data funded by public resources.

3.3. Whistleblowing

1. **For public interest definition,** in the EU, the Directive allows an exception to trade secret protection when information is disclosed to expose misconduct, wrongdoing, or unlawful activity in order to safeguard the public interest.[106] It was held in Halet v Luxembourg[107] that the public's legitimate interest covers information about illegal acts. Further, in Detroit Med. Ctr. v. GEAC Computer Sys., Inc.,[108] the court acknowledged that public health concerns outweighed the claimed rights of the trade secret owner.[109]

2. **For the extent of disclosure,** in Germany, whistleblowers must also limit their disclosure of trade secrets to only what is needed to reveal the wrongdoing.[110]

3. **For good faith requirement,** in the US, a whistleblower can report not only direct proof of a crime but also information that simply creates a reasonable suspicion warranting an investigation into any potential offense.[111] In the EU Directive, the whistleblower only needs to have reasonable grounds to believe, the information they had, that the reported breach was genuine and covered by the directive. They are not required to prove the accuracy of the information they disclosed.[112] The CoE and the UN both stress that whistleblowers may not know the full picture and can be mistaken, but if they report issues based on a reasonable belief, they should still be protected from retaliation.

4. **For retaliation against whistleblowers,** the DTSA includes immunity provisions that safeguard whistleblowers from legal consequences for disclosing confidential material.[113] The EU Directive obliges Member States to protect whistleblowers from any form of retaliation or threat of retaliation.[114] The UK law on whistleblowing also protects

[105] *Argus Leader Media v USDA* 740 F.3d 1172.
[106] Council Directive 2016/1943/EC.
[107] *Halet v Luxemburg* App No 21884/18.
[108] *Detroit Medical Center v GEAC COMPUTER SYSTEMS* 103 F Supp 2d 1019 (ED Mich 2000).
[109] Swaraj Paul Barooah and Md Sabeeh Ahmad, 'Trade Secrets, Test Data, and Transparency in Indian Public Health' (2025) 19 NUALS Law Journal 191, 237.
[110] German Whistleblower Protection Act 2023, ss 6.
[111] Defend Trade Secrets Act 2016.
[112] Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure [2016] OJ L157/1.
[113] Defend Trade Secrets Act 2016.
[114] Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure [2016] OJ L157/1.

whistleblowers for discriminatory treatment from their employers after a disclosure has been made.[115]

4. RECOMMENDATIONS

4.1. Core Policy Recommendations

Compulsory Licensing

4.1.1. Identification Problem: Determining the Extent of Transfer

India must adopt a model for authorising limited-purpose access to undisclosed know-how and manufacturing processes under state supervision as well. A well-structured compulsory licence would define: (i) the scope of the transfer, (ii) confidentiality protections, (iii) restrictions on future use, (iv) compensation, and (v) enforcement and remedies.[116] On scope, the licence must specify the full set of information necessary to enable production.[117]

4.1.2. Enabling Private-Initiated Compulsory Licensing

A mechanism parallel to Section 84 of the Patents Act,[118] which allows private applications, would significantly increase the likelihood that CL for trade secrets is actually used. If private applications are allowed, additional safeguards must also apply, i.e., the applicant should demonstrate suitability and good faith through GMP-ready facilities, qualified personnel, established Quality Assurance & Quality Control, robust confidentiality policies, and strong trade secret controls, since designating an unfit licensee increases the risk of production failure and leakage of confidential information.[119]

4.1.3. Technical Assistance ("Show-How" Facilitation)

A statutory approach could mandate proportionate assistance, access, timelines, and independent oversight. This mirrors the model used in FTC antitrust consent orders that mandate technology transfer, personnel, and site access.[120] The UN mRNA Technology Transfer Hub at Afrigen demonstrates that supervised training can translate formal rights into

[115] Public Interest Disclosure Act 1998.

[116] In re Mallinckrodt plc (Mallinckrodt ARD LLC, formerly Questcor Pharmaceuticals, Inc) Case No 20-12522-JTD (Bankr D Del 2020).

[117] In re Mallinckrodt plc (Mallinckrodt ARD LLC, formerly Questcor Pharmaceuticals, Inc) Case No 20-12522-JTD (Bankr D Del 2020).

[118] Patents Act 1970 (India), s 84.

[119] World Intellectual Property Organization, WIPO Guide to Trade Secrets and Innovation – Part IV: Trade Secret Management (WIPO, 2022) <www.wipo.int/web-publications/wipo-guide-to-trade-secrets-and-innovation/en/part-iv-trade-secret-management.html>
accessed 4 December 2025.

[120] In the Matter of Carlyle Partners IV, L.P., PQ Corporation, INEOS Group Limited, and James Ratcliffe, Docket C-4233, FTC File No 071-0203; In the Matter of Baxter International, FTC Matter/File No 9710002.

real manufacturing capacity.[121] Singapore's biologics licensing framework[122] offers a concrete solution by mandating sequential validation milestones before scale-up.

4.1.4. Peri-Transfer Confidentiality

The Trade Secrets Bill[123] must be accompanied by Rules explicitly specifying the extent, scope, and responsibility of non-disclosure on the compulsory licensee and the government.

4.1.5. CompensationUncertainty

Trade secret compulsory licensing needs a statutory structure, including patent-style royalty bands (2-4% in health emergencies) adjusted for R&D, public funding, and secrecy costs. The law could mandate interim royalties at issuance with later true-up *via* independent valuation, secured through escrow and fixed timelines. Compensation should cover access to know-how and the licensor's technical assistance costs.

4.1.6. Review Duration, Wind-Down & License Termination Ambiguity

The Bill should incorporate a clearer statutory sunset clause aligned with the Patents Act model and require annual reviews to confirm continued necessity, limit the scope of the licence to what remains essential, and ensure automatic termination once the emergency or public need ends.

Transparency in Publicly Funded Clinical Research and Innovation

4.1.7. Regulatory Transparency in Clinical Trial Approvals

Tau Ceti should adopt CTR-style reporting for clinical trial decisions and EUA approvals, including publication of non-proprietary data, reviewer concerns and structured decision summaries. Regulatory approval should be linked to access conditions for publicly funded products, including affordable pricing, local manufacturing, mandatory know-how transfer, and disclosure of IP ownership terms.

4.1.8. Mandatory Public Disclosure of State-Funded Research, MoAs & R&D Cost Contributions

Introduce a statutory disclosure mandate requiring publication of all MoAs, AMCs, grant contracts, trial datasets, and IP-ownership terms involving public funds within thirty days all Memoranda of Agreement (MoAs), Agreements for Medical Care (AMCs), contracts for grants and clinical trial datasets as well as terms of intellectual property ownership that involve public funds, with tailored, independently reviewed redactions. All publicly financed R&D must be

[121] Herder M, Benavides X (2024) 'Our project, your problem?' A case study of the WHO's mRNA technology transfer programme in South Africa. PLOS Glob Public Health 4(9): e0003173. https://doi.org/10.1371/journal.pgph.0003173

[122] Health Sciences Authority, 'Guidance on Therapeutic Product Registration in Singapore' (2025) <www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/guidance-on-therapeutic-product-registration-in-singapore.pdf?sfvrsn=cd174383_52>.

[123] Law Commission of India, *289th Report on Protection of Trade Secrets*, Draft Bill (2019).

registered in a public portal and a standardized public contributions disclosure to be attached to the regulatory approval dossier.

4.1.9. Statutory Transparency and Benefit-Sharing in Public–Private Partnerships

Insert statutory provision that any research, development, or commercialisation activity receiving public funds, public infrastructure, or public personnel support shall, as a condition of such support, disclose IP ownership, funding inputs, and commercialisation plans to a designated public authority. Such disclosures shall be made ex ante and published subject only to strictly necessary, proportionate redactions.

4.1.10. Expedited and Confidential Adjudication During Public Health Emergencies

Establish a mandatory expedited confidential hearing procedure for compulsory licenses, completing the cycle within 30 days. Expert panels should oversee the process to protect trade secrets while ensuring swift resolution, preventing delays and enabling timely access to vital medicines during public health emergencies.

Whistleblowing

4.1.11. Amendment to the Definition of Public Interest

An indicative list should be added in the 'definitions' of the Bill, to provide indication of areas that would be covered under public interest. Once the law clarifies this, companies can no longer rely on broad claims of confidentiality. At the same time, whistleblowers gain a clearer legal basis to justify and protect their disclosures. It may be worded as " "Public interest" includes, but is not limited to, matters relating to public health or safety, regulatory integrity, misuse of public funds, fraud or corruption, and ethical misconduct."

4.1.12. Necessity of Legitimate Public Interest and Burden of Proof

The phrase "to the extent necessary to reveal the unlawful act or professional or other misconduct" be inserted after 'public interest' in Section 5, to act as a guiding factor for courts to determine the extent of public interest involved in the disclosure, and whether any additional information has been disclosed by the whistleblower. The same would also guide the whistleblowers before they reveal any information, and prevent unlawful disclosure of trade secrets.

4.1.13. Disclosure of Information with Sufficient Evidence- Good Faith

The term 'good faith' in Section 5 be substituted with 'in good faith, or if the person believed it to be in good faith'.

4.1.14. Retaliation by Employers

Insertion of provision providing the protective remedy of filing an interim relief application, through which the employer would be injuncted from terminating the whistleblower's employment until the complaint is resolved.

4.1.15. Disclosure of Threatened or Imminent Wrongdoing

Insertion of provision to allow a person to disclose the existence of such a threat of wrongdoing and not only completed acts. This must be allowed only before designated officials who can investigate the matter, and not anyone else.

4.2. General Policy Recommendations

Compulsory Licensing

4.2.1. Accounting for the Higher Monetary Obligation on the Government Against Secrecy Destruction

The relevant authority for trade secrets must be clarified in the Bill (be it a separate authority or the CGPDTM) and such authority must be strengthened administratively to adopt the four tasks illustrated under United States Defense Production Act, with the penal codes being strengthened to extend such protections.[124]

4.2.2. Post-Transfer Confidentiality (Avoiding Data Contamination / Taint)

Any post-compulsory license restrictionsbe time-boundand narrowly tailored rather than operating as perpetual bans.. A workable solution is a 'statutory clean room' pathway in which licensees must stop using or disclosing compelled secrets after termination, but are expressly permitted to pursue independent R&D using documented clean room procedures that demonstrate they did not rely on the compelled information. This is already addressed by Clause 4(1)(b) of the Bill.[125] Under the Rules as will be made under Clause 11 and 12,[126] clear evidentiary standards should be established for the competitors that didn't act as compulsory licensees so that they are able to retain full reverse engineering and independent creation defences.

4.2.3. Embibing the Spirit of Article 31bis TRIPS for Trade Secrets

Clause 6 of the Trade Secrets Bill[127] should expressly recognisethe possibility of export of compulsorily licensed trade secret-manufactured productsto prevent future ambiguity. It should explicitly adopt a framework that avoids thepredominant domestic market use under Article

[124]BharatiyaNagarikSurakshaSanhita 2023, ss 123–125; BharatiyaNyayaSanhita 2023, ss 210–215; BharatiyaSurakshaAdhiniyam 2023, ss 45–50.

[125]Law Commission of India, 289th Report on Protection of Trade Secrets, Draft Bill (2019), cl 4(1)(b).

[126]Law Commission of India, 289th Report on Protection of Trade Secrets, Draft Bill (2019), cl 11, 12.

[127]Law Commission of India, 289th Report on Protection of Trade Secrets, Draft Bill (2019), cl 6.

31(f) and any procedural burdens onexport under Article 31bis that complicate compulsory transfers.

4.2.4. Data Exclusivity

A statutory clause should allow regulators to override data exclusivity obligations for products made under a compulsory licence during a public health emergency, a national security threat, or extreme urgency. Tau Ceti should avoid these TRIPS-plus obligations for extended data exclusivity in domestic law, and should avoid trade agreements that impose them.

Transparency in Publicly Funded Clinical Research and Innovation

4.2.5. Statutory Accounting of Public Contributions to Pharmaceutical Innovation

Provide by law that every vaccine or drug project shall maintain and publish a standardised record of all public support received, including financial assistance, laboratory access, personnel time, regulatory facilitation, and purchase guarantees, excluding proprietary technical formulae. Require such record to be annexed to the regulatory approval process and made publicly accessible with an unique identification number.

4.2.6. Public Contribution Annex within Common Technical Document (CTD) Module 1

Append a Public Contribution Annex to the existing Common Technical Document (CTD) Module 1 (Administrative and Prescribing Information Section), without requiring disclosure of proprietary Chemistry, Manufacturing and Controls (CMC) data contained in Modules 3, making disclosure part of the approval process itself.

4.2.7. Criminal and Administrative Penalties for False "Trade Secret" Designations

Create a statutory penalty provision for false trade-secret designations, including monetary fines, individual officer liability and automatic disclosure orders where classification is abusive. Sanctions would prevent companies from using "confidentiality" as a shield.

4.2.8. Regulatory Review of Disputed Trade Secret Designations

Establish a regulator-embedded Confidentiality Review Panel, activated upon challenge in regulatory or court-referred proceedings, with limited authority to conduct secure in-camera technical assessment of disputed trade secret confidentiality claims.

4.2.9. Post-Approval Public-Interest Compliance Review for Publicly Funded Innovations

Provide by statute that inventions, products, or technologies developed with public funding shall remain subject to periodic public-interest compliance review post-approval, including assessment of pricing, access, availability, and use and if it still serves public interest..

Whistleblowing

4.2.10. Burden of proof on trade secrets holder

Through 4.1.8, Whistleblowers may worry that they will later be judged for disclosing more than what was strictly needed. The addition of this term might put additional burden on the whistleblowers to prove the extent of the necessity of disclosure of any information. Thus, an explanatory provision needs to be added, putting the burden on the trade secret holder to prove that an information was unlawfully disclosed without any necessary public interest.

4.2.11. Inconsistency with other Existing or Developing Legislations

A non-obstante clause should be added in Section 5 stating "notwithstanding any other provisions contained in any other act". This would ensure protection for whistleblowers of trade secrets without any ambiguity.

4.2.12. Enhanced Penalties for Failure to Provide Notice

Employment and confidentiality agreements must include information about provisions providing whistle-blower immunity, as provided in US' DTSA, 2016. However, under the DTSA, if an employer does not give this notice, they may lose the right to claim exemplary damages or attorney's fees in a lawsuit. The same is considered to be insufficient as such damages would be negligible. Thus, it is essential to impose huge costs in case of failure to comply with the same.

5. FEASIBILITY

Article 39 of the TRIPS Agreement does not mandate a standalone statute for trade secret protection, and therefore Tau Ceti is not obligated to replicate developed country models. Tau Ceti's growing socio economic importance has compelled the adoption of the Trade Secrets Act but it must do so in a manner consistent with its developing country status and the policy flexibilities preserved under TRIPS. This policy draws from both comparative and developed systems to understand both their safeguards and embedded flexibilities, and in also proposes to codify mechanisms that developed jurisdictions manage through practice rather than statute to secure the broadest flexibilities. Given Tau Ceti's developmental priorities, including accessibility, affordability and technological diffusion, the regime must balance protection with public interest rather than adopt stricter protection maximalist standards unsuitable to its context.