# 1NC Yale R2

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#### The distinction between the noumenal and the phenomenal world is not an uncrossable bridge – this implies that freedom can be won via legal and socially recognized rights, Schroeder 05:

Schroeder, Jeanne L. "Unnatural rights: Hegel and intellectual property." U. Miami L. Rev. 60 (2005): 453.

In this section I will address three common mis-readings of Hegel's personality theory that might lead to the incorrect conclusion that logic dictates that society recognize intellectual property. First, I show that Hegel believes that there are no natural rights of any sort, let alone natu- ral property rights. Second, I address the closely related point that Hegel rejects a first-occupation justification of property rights. Third, I show that intellectual property has no privileged place in personality theory. For simplicity, I stated that Hegel started his analysis by contin- gently adopting the notion of the free individual in the state of nature. I now more carefully explain my terminology as we consider Hegel's the- ory of the relationship between freedom and nature. Hegel thought that the freedom of the autonomous individual in the "state of nature" was only potential. Hegel argued not merely that the individual must leave the state of nature and go out into the real world if he is to make his freedom actual as a matter of fact. He also believed that the individual is driven by a passionate desire to do so. A complete discussion as to why the individual would desire to leave this uterine state of ignorant bliss is beyond the scope of this Arti- cle. Suffice it to say, it relates to one of the fundamental points of Hegel's idealism and theism. Hegel's idealism should not be confused with a vulgar neo-Platonic concept of an ideal world "out there" beyond the imperfect physical world. Such a notion is more reminiscent of the Kantian notion of an unknowable, intellectual, necessary, eternal, and transcendent world of essences called the noumenon or "thing-in-itself' beyond the contingent, empirical, temporary, and immanent world of appearance that can be known by experience (the phenomena). Hegel's metaphysics is an extended critique of Kant's. **Hegel rejects all concepts of transcendence**. 9 8 **There is no essence beyond appearance.** 99 Essence only exists insofar as it appears. 1" Or more rad- ically, essence is nothing but appearance properly understood. Hegel's is a radically materialistic philosophy, 01 but not an atheistic one. None- theless, Hegel's God, or Spirit, is not transcendent, but immanent in the material world. Why this is significant for our purposes is that **it follows from Hegel's rejection of transcendence that there can be no potentiality with- out actuality-what claims to be potential must become actual or reveal itself a liar**. Actually, the theory is even more radical than this. As I have argued elsewhere,102 Hegel's logic is retroactive, not prospective. **Potentiality is only retroactively revealed after something becomes actual.** **Consequently, if the autonomous individual in the state of nature claims to be free, and if this radically negative freedom is only potential, then the individual's claims to freedom can only be retroactively tested after he leaves the state of nature and makes his freedom affirmative and actual**. 103 Another way of saying this is that the liberal "state of nature" is not natural at all. Rather, it is a logically "necessary" hypothesis that is retroactively posited by the fact that we occasionally observe actualized freedom in modern constitutional states. As such, the "state of nature" is actually created by human thought. To Hegel, like Kant, real "nature" is the empirical, mechanical world governed by the causal laws of neces- sity where there is no freedom. Any freedoms and rights derived from the liberal conception of the hypothetical "state of nature" by definition cannot literally be natural. 2. NATURE AND RIGHTS Hegel sharply distinguishes between natural and positive law, and locates rights within the latter. He states, "[t]here are two kinds of laws, laws of nature and laws of right: the laws of nature are simply there and are valid as they stand ....The laws of right are something laiddown, something derivedfrom human beings."'" The liberal "state of nature" is, in fact, the hypothesis that autonomous individuality is a necessary, albeit inadequate, moment of human personality that we retroactively posit to understand political freedom. If so, what is the status of "nature" and its relationship to rights and freedom? Once again, I do not pretend to give a comprehensive account of Hegel's philosophy of nature, but will point out one aspect relevant to this Article. The first thing to note is to reiterate the simple point that there can be no "rights" in the hypothetical state of nature because the "state of nature" is defined as autonomy. Rights are necessarily interrelational. Hegel's point is more subtle and powerful than this, however. More specifically, there is no freedom in the empirical natural world. This can probably best be explained by going back to Kant's famous analysis of antinornies presented in his CritiqueofPureReason."5 An antimony is a logical paradox, or two statements that seem to be equally logically required yet are in contradiction. To say they are in contradiction means not merely that they are mutually inconsistent, but that they are the only logically possible alternatives. This suggests not merely that if one statement is true then the other must be false, but also that if one statement is proven to be false, the other is proven to be true. 0 6 For reasons that do not concern us here, Kant identifies four antinomies that he divides into two dyads: two "mathematical" antino- mies and two "dynamical" antinomies. He claims to solve the two mathematical antinomies by showing that neither statement is true because there is a heretofore unrealized third alternative that may be true. 10 7 He claims to solve the two dynamic antinomies by arguing that both statements are true, but that their contradiction is merely apparent so that, in fact, they can be reconciled.108 It is Kant's third antinomy of freedom and nature that concerns us. The thesis of Kant's first antinomy is that freedom can exist in the world.10 9 Kant is referring to negative freedom as the uncaused cause- the potential for pure spontaneity, action beyond necessity. Like all of Kant's theses, this is a dogmatic proposition posited by reason alone. 1 0 Its antithesis is that everything is subjected to the causal laws of nature-there are no uncaused causes and, therefore, no freedom.' Like all of Kant's antitheses, this is an empirical proposition reached by applying logic to our experience of the world.1 1 2 As this is a dynamic antinomy, Kant must solve this paradox by arguing that the contradiction between the two propositions is only apparent. If they are properly understood, then they can be reconciled. Kant argues that both propositions are true, but about different aspects of the world. Kant relies on his distinction between the phenomenal, or empirical, contingent, changing world of appearance that we can know from experience, and the noumenal, or transcendental, necessary, eternal world of essences, or the "thing-in-itself' which we do not know directly, but can infer through logic.113 **It is true, Kant states, that the entire phenomenal world is natural and therefore subject to the laws of nature-i.e., everything empirical is caused.1 14 It is also true, however, that freedom exists in the transcendental, non-empirical world of the noumena.15 Indeed, these conclusions follow from his definitions of phenomena and noumena. 11 6 If a "noumenon" were caused by some- thing else, then it would be contingent on that other thing and, therefore, not a noumenon. Conversely, if a "phenomenon" were free of an exter- nal cause, then it would not be a mere phenomenon, but a noumenon. The question that this analysis proposes is, if freedom is noumenal, can it manifest itself in the phenomenal world, or is merely a theoretical construct?**1 7 To put this in Kant's idiosyncratic terminology, is free- dom "practical?" ' 1 8 By extension, one might ask, since each individual human being is embodied and, therefore, phenomenal,119 can man achieve freedom? In the Critique of Pure Reason, **Kant claims to show that freedom is at least theoretically possible in the phenomenal world. He argues that although all phenomena are caused by something else, the cause need not itself be phenomenal.** A phenomenon can be caused by a nou- menon. 2 ° **Because noumena are free (uncaused), their free acts can appear in the world through the phenomena they cause. Although each individual human being is phenomenal, man's essence (his spirit or soul, his status as the liberal, autonomous individual) is noumenal and there- fore free.**12' This implies that it is at least theoretically possible that the noumenal aspect of man can actualize his freedom by causing his phe- nomenal self to act. In the Critiqueof PracticalReason, Kant tries to prove not merely that practical reason is theoretically possible but that we have good reason to think it exists. There are as many problems raised in this analysis as are solved. Even ardent Kantians are somewhat embarrassed by it.'2 2 Hegel called Kant's argument "a whole nest... of faulty procedure." 123 My simpli- fied account is not an attempt to develop a comprehensive critique of Kant. My limited point is that, as I have argued elsewhere, 24 much of Hegel's speculative logical method can be seen as being inspired by Kant's idea of antinomy. I characterize **Hegel's complaint against Kant as an accusation that Kant does not have the courage of his own convictions and is afraid to follow his insights to their logical extremes.** Hegel, in effect, criticizes Kant for thinking that there were only four antinomies. Rather, Hegel's entire universe is constituted by a fundamental, essential contradic- tion.125 Further, Hegel criticizes Kant for thinking that contradiction is a problem that must be "solved." Contradiction "is not to be taken merely as an abnormality which only occurs here and there, but is rather the negative as determined in the sphere of essence, the principle of all self- movement . "..."126 In other words, **contradiction is a universal fact about the world. It is correct that contradictions are unstable and must be resolved, but each resolution is temporary and leads to a new contra- diction ad infinitum. Far from being frightening or disturbing, this merely means that the universe is dynamic, not static. Contradiction is the engine of change.** This means that Hegel rejects the Kantian noume- nal-phenomenal distinction. **To Hegel, there can be no necessary, perma- nent, unchanging essence (noumenon) behind the contingent, temporary, empirical world of appearances that is in a constant state of flux.** To Hegel, it is appearance all the way down. Finally Hegel's sublative logic can be seen as a rejection of Kant's specific claims to have solved his four antinomies by assuming that he had to show either that both sides were true, but not in contradiction, or that both the thesis and antithesis were false because there is a third alternative. In contrast, through sublation (the standard but poor English translation of Hegel's term for the logical method of resolving contradic- tion) one realizes that both sides are simultaneously equally true and false, thereby generating a third alternative that simultaneously negates 127 Regardless of these differences between Hegel and Kant, I believe that the Philosophy of Right can be seen as Hegel's struggle to come to grips with the specific contradiction that Kant identifies in the third antinomy: freedom v. causality. In his analysis, **Hegel accepts Kant's proposition drawn from experience that all nature is subject to natural laws of causation.** This means that nature is fundamentally unfree and implies that actual (practical) freedom must be unnatural by definition. **Yet on the other hand, Hegel also begins his analysis by contingently accepting Kant's presupposition that the most basic notion of human personality is self-consciousness as free will.** Hegel seeks to prove this presupposition (that freedom is possible) by finding that freedom actu- ally exists in the phenomenal world. Because Hegel rejected transcendence, he could not adopt Kant's proposed answer to this problem: freedom is noumenal, but noumena can cause phenomena. To Hegel, Kant's proposal answered nothing. According to Kant's own theory, we can know nothing about the nou- menon. Consequently, Kant's proposition is equivalent to saying that we can know nothing about freedom. Hegel was, in effect, responding to Kant: "You are being inconsistent. Your philosophical writings show that you know a lot about freedom. By your definitions, therefore, free- dom must be actual." Hegel's counterproposal was that **actual freedom is not natural but artificial: a human creation, created out of natural materials. Legal sub- jectivity (as well as higher stages of personhood) is, therefore, not a natural state but a hard-won achievement.** The story of the development of human consciousness, to Hegel, was the struggle of man to free him- self from and overcome his natural limitations. "Hence the personality of the will stands in opposition to nature as subjective.... Personality is that which acts to overcome [] this limitation and to give itself reality .... "128 **Abstract rights are, therefore, the first most primitive step in man's attempt to actualize his freedom, understood as the overcoming of nature**. The basis [] of right is the realm of spirit in general and its precise location and point of departure is the will; the will is free, so that freedom constitutes its substance and destiny [] and the system of right is the realm of actualized freedom, the world of spirit produced 1 29 **Rights are, therefore, not merely unnatural in the sense of artificial (man made), they are a means by which man distinguishes himself from nature. 130**

#### Property and legal contracts are the only medium of recognition and intersubjectivity, Schroeder 2:

\*bracketed for gendered language\* Schroeder, Jeanne L. "Unnatural rights: Hegel and intellectual property." *U. Miami L. Rev.* 60 (2005): 453.

Contract solves this problem. To reiterate, Hegel believes that **subjectivity is created not by possession per se, but by intersubjective recognition by other subjects. Property is only a medium for this purpose. This regime of recognition is abstract right-the rule of law. Subjectiv- ity is the capacity to bear legal rights and duties recognized by, and enforceable against, other subjects**. To concentrate on the specific object of property is to conflate subject with object-the opposite of recognizing the person's unique subjectivity. This is in sharp contradis- tinction to Radin's proposition that the merging of owner with her per- sonal property furthers human flourishing. Hegel, looking forward to psychoanalysis, considers such a relationship to be destructive-an addiction, or more technically, fetishism. **In contract, each party remains identifiable as a rights-bearing sub- ject through object relations because the object [t]he[y] gives up in contract is simultaneously replaced by a new object. That is, the contracting parties recognize each other as rights-bearing subjects, or persons having the capacity not only to own property, but to respect the property rights of others, and to live up to his contractual obligations.** In Hegel's words: [Contract] contains the implication that each party, in accordance with his own and the other party's will, *ceases* to be an owner of property, *remains*one, and *becomes* one. This is the mediation of the will to give up a property (an individual property) and the will to accept such a property (and hence the property of someone else). The context of this mediation is one of identity, in that the one voli- tion comes to a decision only in so far as the other volition is present.74 Hegel went so far as to assert that "[tihe whole issue can also be viewed in such a way that alienation is regarded as a true mode of taking posses- sion. 75 That is, **possession is the recognition by others that a specific object belongs to a specific subject. Paradoxically, this recognition only *expressly* occurs *retroactively* when the owner contracts to sell that object to another person. In other words, the identification of subject to object in possession is only *effectively* recognized at the moment when another subject pays the first subject to release the object from her possession.** Once again, one must remember Hegel's radical definition of objects as anything that is not the individual herself. This includes not only intangibles, but also an individual's own labor is an object separate from her personhood. Consequently, service contracts, whereby the individual alienates part of her productive capacity in exchange for wages is, to the Hegelian analysis, a contract for the exchange of prop- erty. In fact, the service contract is an excellent example of the logic of Hegel's dialectic of recognition. In our modem capitalistic society, a primary way we recognize each other is through our occupations. **The mutual intersubjectivity of contract is necessary because**, according to Hegel, **one becomes a subject** (eine Person)**only when one is recognized as such by another subject. Subjectivity (the capacity to bear legal rights and duties) exists only insofar as rights are enforceable.** **Since all persons logically begin as abstract individuals (not subjects), in order to achieve subjectivity, each individual must first make other indi- viduals into subjects by recognizing them as such. This means that it is impossible to create rights by unilaterally claiming them for oneself.** Since rights are intersubjective they can only be created intersubjec- tively. This is one reason why the Lockean attempt to justify claims of property through first-appropriation fails. The conundrum should be obvious. How does anyone become a subject recognized by other subjects when there are no subjects in the state of nature? Where does thefirst subject come from? The Hegelian answer is that **multiple subjects must come into existence simultaneously**. This is the alchemy that Lacan calls "love"-the relationship in which each lover sees in his beloved more than she has, that empowers the beloved to live up to the lover's expectations and become more than she once was.76 Contract is the most primitive form of eroticism-albeit a pathetic, and unromantic one. **Each individual,by admitting that another individ- ual has legal rights** (i.e., the right to possess and contract to exchange the object to be acquired), **makes that individual into more than she once was-she is no longer an individual, but a subject**. 3. FORMALITY AND RECOGNITION The Hegelian logic of alienation confuses many commentators because they do not recognize the purely formal nature of subjectivity and abstractright. Here, **object relations are purely instrumental and subordinate to the goal of recognition.** Hegel, like Kant, defines a free individual as an end in and for her self, and not the means to the end of another. In contrast, an object is something that is the means to the ends of something else. **In abstract right, each individual paradoxically wants both-that other individuals help him reach his end of becoming a subject, and that other individuals remain an end in and to themselves rather than merely a means to the first person's ends. Subjectivity is only created through recognition as such by a person that one recognizes as another subject. To treat another person as one's means, rather than as his own ends, is to fail to recognize him as an individual or a subject. The question then becomes, how can one accomplish one's own ends (which requires action by another person) without impinging on the ends of that other person or treating her like a means (an object)?** The Hegelian answer is that subjects can mediate their relationship through objects. **Both subjects mutually exploit the objects of exchange as means of recognizing each other-each fulfills her own ends (becom- ing a subject) while respecting the ends of the other (also to become a subject). The two subjects are united in a common will, in the sense that each wills his own ends, but these potentially competing ends tempora- rily coincide in the meeting of minds known as contract.** This means that, as a logical matter, one does not enter into object relations for the sake of the object itself or for the "natural" or other concrete functions they might serve. The specific characteristics of any object of a property claim is irrelevant and should be a matter of indifference to the subjects, from a logical standpoint. Right is something utterly sacre dfor the simple reason that it is the existence [ ] of the absolute concept, of self-conscious freedom. But the formalism of right-and also of duty-arises out of the dif- ferent stages in the development of the concept of freedom. In oppo- sition to the more formal, i.e. more abstractand hence more limited kind of right, that the sphere and stage of the spirit in which the spirit has determined and actualized within itself the further moments con- tained in its Idea possesses a higher right, for it is the more concrete sphere, richer within itself and more truly universal. Each stage in the development of the Idea of freedom has its distinctive right, because it is the existence of freedom in one of its own determinations. When we speak of the opposition between morality or ethics and right, the right in question is merely the initial and formal right of abstract personality. Morality, ethics, and the interest of the state-each of these is a distinct variety of right, because each of them gives determinate shape and existence to freedom.77 In other words, a full concrete personality requires the entire regime that Hegel calls Recht, which includes not only abstract right (property and contract), but morality and ethics. Abstract right is the most primitive form of right that only creates the form necessary for freedom-the empty vessel of legal subjectivity understood as the mere ability to accept legal rights and duties imposed by others. The content of person- ality will be added by morality and ethics. Consequently, Hegel states with respect to the legal subject: Since particularity, in the person [i.e. what I am calling the subject], is not yet present as freedom, everything which depends on particu- larity is here a matter of indifference. If someone is interested only in his formal right, this may be pure stubbornness, such as is often encountered in emotionally limited people; for uncultured people insist most strongly on their rights, whereas those of nobler mind seek to discover what other aspects there are to the matter in ques- tion. Thus abstract right is initially a mere possibility, and in that respect is formal in character as compared with the whole extent of the relationship. Consequently, a determination of right gives me a warrant, but it is not absolutely necessary that I should pursue my rights, because this is only one aspect of the whole relationship. For possibility is being, which also has the significance of not being. 78 Indeed, it is precisely the function of the element of alienation to make this irrelevance and indifference manifest. Nevertheless, even as subtle an analyst as Hughes, who expressly recognizes that the fact that object relations can also serve natural functions (food and shelter) is irrelevant to a Hegelian analysis, 79 misses this point. Hughes finds alienation "incoherent"80 because the subject loses the object that supposedly makes the subject recognizable.8' He finds this particularly problematic in Hegel's discussion of copyright, because the objects of copyright, being the author's creations, seem intrinsically linked to the author's personality.82 Consequently, he infers that the objects of copyright uniquely serve the goal of differentiating and identifying the author and concludes that complete alienation of artistic works might defeat the goal of the creation of personality. Consequently, he sees the Hegelian analysis of property as supporting certain restraints on alienation of copyrightable material, such as in the droit morale under which an artist retains some control over her creations after sale.83 But this critique is based on the misimpression that, to Hegel, the legal right of property relates to the creation of the full complex per- sonhood of empirical human beings situated in relations of family, civil society, and state.84 But **legal relationships relate only to the creation of legal subjects-persons capable of bearing rights and duties. The legal subjectivity mutually constituted with abstract right is, therefore, equally abstract and formal. Moreover, it is precisely abstractness and formality that enable abstract right and legal subjectivity to serve as the substra- tum for the concrete freedom of citizenship.** Above, I mentioned in passing an analysis that I have developed extensively elsewhere: Hegel's property jurisprudence is essentially erotic because contract is a primitive type of "love."8 5 My goal in doing so was to break down the dichotomy between rationality and passion that implicitly underlies both utilitarianism and romanticism. To Hegel's jurisprudence, rationality and passion are two sides of the same coin.86 **Reason tells the autonomous individual that he must actualize his freedom and to do so requires recognition by other subjects. Conse- quently, the free individual rationally decides that he must give way to the desire for others. Because abstract right is created in order to enable the interrelationship of mutual recognition to occur, it is erotic.** The "love" and desire that exist at the level of abstract right are only a pale shadow of the passions we feel towards our family, lovers, and friends. Consequently, I have argued vociferously that although utilitarians like Posner are right in seeing a parallel between economic activity and sexuality, they are wrong in trying to reduce the latter to a form of the former.87 Rather, from the Hegelian position, the former (economics) is merely a step that makes the latter (eroticism) possible. That is, contract establishes the form of love, not its content. Conversely, Hughes and Radin are equally mistaken in trying to argue that property can perform a direct function in the creation of the full, loving artistic personality. Although Hegel was a great defender of legalism and capitalistic markets, he also insisted that they be limited to their appropriate sphere. To analyze more complex interrelationships in terms of abstract right (property) is not merely erroneous. Never one to mince words, Hegel called it "crude" and shameful.88 Consequently, only the most base persons stand on their rights.8 9 The noble person accords rights to others. This is why Hegel condemns the classical lib- eral concept of government as social contract-citizenship is Hegel's most highly developed level of personality, and therefore, unlike the subject, cannot be comprised solely by legal categories. A corollary of this is that it is equally incorrect, indeed shameful, to adopt the romantic position towards copyright that conflates the legal relationship of property with the flowering of personality in artistic expression. From a Lacanian point of view, to do so is literally per- verse. Specifically it is fetishistic-the identification of objects with subjects.90 The specific content of objects of copyright has nothing to do with their status as a legal concept. To Hegel, saying copyright is "property" is not to say that society must or should establish a copyright regime. This decision can only be made by pragmatic reasoning. In this sense, Hegel's theory has a surprising utilitarian twist. Society's desire to further creativity may, however, be a good pragmatic argument in favor of such a regime.

#### Thus, the standard is consistency with abstract right, or legal rights instantiated in a community.

#### I negate –

#### 1] Personality Theory – IP is uniquely an extension of reason and sensibility through personal investment – Priya 08:

Priya, Kanu. "Intellectual Property and Hegelian Justification." NUJS Law Review, vol. 2008, no. 2, 2008, p. 359-366. HeinOnline. // LHP PS

**Many proponents of intellectual property law seek refuge in a personality theory of property associated with GW.F. Hegel.** This theory seems to protect intellectual property from potential attacks by a utilitarian analysis that would recognizes property only contingently insofar as it furthers society's goals of utility or wealth maximization. **Personality theory, in contrast, supposedly offers a principled argument that intellectual property right must be recognized by a just state, regardless of efficiency considerations**. Personality theory **also seems to protect intellectual property from assault by critics who maintain that it is not a form of "true" property at all.** Finally, **the theory has also been used to** support **an argument for heightened protection of intellectual property beyond that given to other forms of property - the Continental "moral" right of artists in their creations is an example**! **Hegel's view of property, with its foundation on the notion of the individual and the formation of self-identity, "is perhaps most directly applicable to the narrower notion of intellectual property."** Also characterized as the "personality theory" of property, **Hegel's rationale suggests that the inventor has imbued the invention with his personality or will, making the process of creation an intensely individualistic one.** **Hegel postulates that property and ownership are important milestones in the journey toward self-development, and are essential to survival as well.** **These are ideas that should make sense to emerging countries seeking to justify their protection of intellectual property rights.** However, this view may not successfully justify intellectual property rights in cultural systems that are less centered on the individual and more focused on the identity of the community and on the protection of community property. The individualistic underpinnings of patent law, expounded by philosophers such as Hegel, may be difficult to incorporate into more community-oriented societies.9 It has long been argued that intellectual property is justified on a number of alternative bases. Economic, labour and spiritual theories have been advanced to justify propertising intellectual creations. **Intellectual property theorists**, following Hegel's and Kant's thoughts on the subject, **contend that the personhood theory of property is especially true when the property is a work of art. They argue that works of art are created through a person's mental labor and thus embody more of her individual essence of being than works created through routine physical labor.** **Since artistic works are part of an artist's very identity, she never should be completely separated from the work. The personhood theory of intellectual property thus supports not only the idea of copyright in artistic products, but also the idea of moral rights**. The debate surrounding the correct theory about why intellectual property exists is not purely academic. It can play a decisive role in the outcome of copyright cases. For example, in Sony v. Universal City Studios (The Betamax Case) 1, the Supreme Court held the videotaping of televised programs for purposes of "time-shifting" could be considered fair use. The discussion of reputation and values shows that open-source software can embody and express personality, but it assumes a capacity for software to express personality similar to that of other copyright subject matter. This assumption requires examination, because software has unique attributes as copyrightable subject matter. Despite the differences, in terms of personality expressing capacity, the similarity is sufficiently close to conclude that the opensource approach carries and expresses personality equivalently to moral rights, even if traditional closed software does not, or perhaps cannot, because the source code is not available to be viewed. The other moral rights also fit the personality theory. The author or artist needs to control the first publication or disclosure of the work in order to ensure that when the work leaves the author's domain, it embodies the personalityview desired. Once released, the right of attribution ensures that the original author or artist retains the degree of association with the work under which the author released it. This is often done by name, but could also be under a pseudonym, or be anonymous. The right to withdraw the work upon remuneration also fits the personality theory. If the artist changes the genre or reworks the image, it may be fitting, from a moral rights perspective, for the artist to withdraw from circulation works that clash with a prior era in the artist's development. The justifications advanced for intellectual property law have been many and varied. It has been suggested that intellectual property is analogous to tangible property and justifications used to support the propertisation of physical creations can be advanced for intellectual ones as well. A common assertion used tojustify propertising **intellectual works is that intangible creations require property protection because they are economically valuable works worthy of protection in their own .** This is essentially an economic justification, one premised upon overcoming market failure and market imperfections. **Economic justification for propertising creative work is premised on the very foundation that without proper protection authors would have insufficient incentives to write new works unless they are compensated with property rights.**

#### 2] The affs international imposition of trade policies violates the legal sovereignty of states to develop trade policy. Herrmann-Pillath,

Herrmann-Pillath, Carsten. “Leadership, Deliberative Trade Policy, and Civil Society: The Hegelian Approach”

Hegel had argued against Kant’s formal foundation of ethics in stating that real-world commitments to universal values can only emerge in a historical process that links those values to specific commitments in particular societies (Hicks 2012). His position reveals some deep affinities with the economist’s viewpoint as one reason for this insufficiency of purely abstract and rational principles is that there would be no incentivization for acting accordingly ithin particularistic contexts. Hegel’s distinctiveness and similarity with Sen is also obvious from his conceptualization of ‘freedom’, which he regards as the most pivotal ethical value, but does not conceive merely as an abstract human right. According to Hegel, **freedom is nothing what exists as a ‘natural’ claim, but what is constituted by concrete historically evolved institutions out of which the abstract conception of values emerges, and in which individuals are enabled to realize their freedom in communities of ethical life** (Neuhouser 2008). This clearly resonates with Sen’s ideas about positive freedoms in his theory of capabilities (Boldyrev and Herrmann-Pillath 2013). **Hegel was the founding father of the idea of ‘civil society’** (for an assessment of this concept in the context of international relations, see Stillman 2012). **By this he referred to a historically emergent structure of institutions that are geared towards the division of labour and market relations, embedded into generalized notions of cooperation and shared commitments to values. Apart from the rule of law, this structure includes a web of associational relationships, mostly organized along professional and occupational lines, and a representational setting in the context of the state (which he conceived as a constitutional monarchy). The state is the primordial unit that encompasses all these structures and stands in a higher-order relationship with other states. Citizenship as defined by states is a core criterion for individual identities beyond their associational ascriptions.** Hence, on first sight Hegel perceived international relations in what today are called ‘realist’ terms, with an apparently Hobbesian flavour. Thus, we might conclude that Hegel’s approach fits nicely into the standard view underlying hegemonial theory. Hegemonial theory clearly puts states and their relative power positions at the centre, and explains institutions as reflecting those international structures. A leader is a country that assumes as pivotal role in these power structures and can therefore incentivize other countries in taking actions. However, as the recent discussion of the Hegelian theory of international relations has shown, this view would be overly narrow (Vincent 1983; Buchwalter 2012). Matching with these contributions, I propose a Hegelian framework for deliberative trade policy that differs from these simplistic realist interpretations. At the same time, this Hegelian view also differs from current institutionalist approaches (which are mainly inspired by the ‘New Institutional Economics’) and ties up with the recent revival of ‘ideational’ studies in political science. In ddition, the Hegelian approach is congenial to game theoretic analyses of international relations which have shown that realism and institutionalism can be reconciled if incentive structures, communication patterns and information flows are properly detailed (for a seminal approach, see Snidal 1993). In order to make the essentials of a Hegelian approach clear, it is necessary to reflect upon the most basic notion of ‘freedom’ and to apply this on the notion of ‘free trade’ (Neuhouser 2008; Buchwalter 2012: 214f). Neuhouser distinguishes between ‘personal freedom’, ‘moral freedom’ and ‘social freedom’: Personal freedom refers to the autonomy of the will, moral freedom means the autonomy to commit oneself to moral constraints on one’s own actions, and social freedom means to have the necessary capacities to realize the other freedoms in the context of a concrete community. I argue that these three dimensions also apply on the notion of ‘freedom’ in international trade. **Hegel’s concept of personal freedom as applied on individuals means autonomy and self-determination, clearly building on Kant. Now, in the very first place this means autonomy from natural urges to action, that is, refers to one’s own nature, and only secondarily freedom relative to others. To be free means to be able to reflect upon one’s desires, and to determine actions based on autonomous decisions of will.** Basically, this idea of freedom, firstly unfolded in the Phenomenology, also underlies the notion of sovereignty of the state, deployed in the Philosophy of Right (as embodied in Hegel’s figure of the monarch). Now, consider **the typical structure of economic theories of trade policy, including hegemonial theories. They share one important property with ‘naturalistic’ theories of the individual in being mechanistic theories. That means they identify a causal structure by which observed actions of governments result into certain institutions**. For example, there are political support functions that directly translate into certain institutions; given certain assumptions about the generic incentive structure of governments (such as aiming at reelection) (classical approaches are Grossman and Helpman 1994, 1996). That corresponds to the simple picture of ‘natural desires’ driving the actions of the individuals, given certain goal functions, if we approach both on an abstract level as ‘mechanistic’ theories of action, individual or political. **Hence, we can make a rather surprising Hegelian point about trade policy, namely that, in the first place, ‘freedom’ means autonomy of governments in setting trade policies: ‘autonomy’ is manifest in the capacity to act independently from any domestic or international pressures to take a particular action in trade policy** (this idea is also familiar from political science approaches to the role of domestic constraints on international relations, see Deese 2008: 32ff.). In the Hegelian view, ‘**free trade’ therefore needs to be based on the idea of sovereignty of governments in terms of trade policies. This implies that trade policy cannot be justified by imposing certain external norms of ‘free trade’ on countries.** Indeed, although today most people would agree that high tariffs are bad, the issues at stake in the GMO controversy seem much more contentious. In this context, **the first Hegelian principle implies that countries should be free in determining the institutional setting of their trade policy.** It is important to notice that this principle guided the old GATT, but has been partly weakened as a result of the Uruguay round, leading to the current stalemate of the Doha round. For example, whereas under the old GATT countries actually negotiated about mutually valued rights to market access, **the ‘single undertaking’ approach of the WTO partly imposes the same institutions on all member countries, such as in the TRIPS agreement, if they want to enjoy the benefits of other parts of the agreement** (Finger and Nogués 2002). In transferring the logic of Hegel’s reasoning from the individual to entire countries, we follow his own approach in equating the sovereignty of the state with the free will of the monarch, but there is also another, more systematic rationale. **Why are countries the ultimate actors in trade policy, and not individuals,** as in the Kantian constitutional view? **This is because in the absence of a unified international law and hence, world government, individual freedom to trade can only be enshrined in rights that are contained in national laws, such that in the international domain, this freedom can only be established in coordinating those national laws. This coordination cannot be achieved on the individual level, but always needs to involve the governments as representatives of the individuals qua citizens of their nations, and as being the only institutions that have the right to enforce legal norms (monopoly of violence). Therefore, even if one adopts the view that freedom to trade is an individual right, this right cannot come into existence but by means of coordinated actions by governments, both in their role as representatives and enforcers.** This argument can be supported by further considerations, such as considering the use of domestic public goods in conducting international trade, which I leave out for reasons of space (see Herrmann-Pillath 2009). This view is also bolstered by an argument in the standard theory of trade policy which builds on the terms-of-trade effects of tariffs (Bagwell and Staiger 2002). The argument can be easily related with Hegel’s notion of individual freedom, because the sovereign freedom of governments to impose tariffs on international trade does not only affect their own citizens, but may also cause ToT externalities on citizens of other countries if the country imposing tariffs has market power (which is often the case if one considers specific industries and products). These externalities work via the international price system and therefore directly affect individual welfare, hence curtail the sphere of personal freedom in the international marketplace: In fact, it means that the government does not only tax its own citizens, but also citizens of other countries, who have no channel of political influence, however (a tax without representation). So, these ToT externalities cannot be countervailed by individual actions directly: Therefore, only an international agreement among governments can result into institutions that also safeguard individual freedom. It is important to notice that the ToT argument, though disputed in the literature (see e.g. Ethier 2004), is sufficiently powerful to explain a number of specific features of the current multilateral trading systems, such as the Most Favoured Nation principle. Now, one most interesting Hegelian turn results to be the insight that the autonomy of states also applies to domestic politics: **Sovereignty as freedom means that states can overcome the mechanisms of domestic political economy as scrutinized by the economic approaches.** This linkage, following seminal approaches such as Putnam’s ‘two-level games’, has also been recently explored by many political science contributions (for an overview, see Snidal and Thompson 2004).

#### 3] WTO rulings are not consistent with Hegelian construction of law – it’s coercive and absolutely influence rather than accounts for a countries sovereignty.

Trejo-Mathys, Jonathan (2013). *Towards a Critical Theory of the World Trade Organization: Thinking with Rawls beyond Rawls. Constellations, 20(3), 459–482.*doi:10.1111/1467-8675.12051

In the second place, there is a more systemic or functional question that touches upon the way **the political authority of the WTO impacts the normative environment of actors within the domestic legal systems of states**, i.e., firms and individuals. There is a clear process, familiar from the evolution of the EU, of ‘spillover.’ It can be visualized using the metaphor of peeling an artichoke: **Since the GATT was written, deeper layers of trade barriers have indeed been exposed, creating dozens of newer functions for the GATT/WTO system to perform.** In the 1960s and 1970s, demand grew for more elaborate rules to discipline antidumping and countervailing duty actions, voluntary restraint agreements, and government procurement. In the 1980s and 1990s, demand emerged to address many “new” issues, such as trade in services, intellectual property protection and internal investment measures. Since the Uruguay Round, the WTO has also begun addressing issues relating to environmental protection and competition policy. **In short, spillovers have increasingly generated “trade” topics that historically have been treated as internal regulatory measures** . . . from 1947 to 1979, we peeled off the outer leaves [of the artichoke], and we have now arrived at the heart of the matter— differences in national regulatory systems that have been reserved traditionally for sovereign control.72 **This implies as well that the WTO rules are moving closer to the everyday legal and political environment of local actors, whether firms or individuals, and not simply actors operating internationally on a regular basis. As this process has advanced, it seems clear that the impact of WTO rules on states and on domestic actors has increased greatly.** The ‘disciplining’ of trade policies of states cannot fail to entail transformations in the way those states, and now forces beyond them, ‘discipline’ their citizens and residents.73 **This means that insofar as compliance with these rules can be morally justified, the WTO directly impacts the genuine political obligations of actors; insofar as such compliance is not morally justified, WTO rulings impact the merely imputed or positive legal obligations of actors that are sanctioned by the authorization of economic retaliation** (i.e., through political-economic power). In either case it is of immediate critical concern for the informed and reflective judgment of political actors at all levels. C) Resistance to TRIPS as an Empirical Indication of the Appropriateness of this Extension **Over the last decade or so, developing nations such as Thailand, South Africa, and Brazil have responded to TRIPS by issuing (or threatening to issue) compulsory licenses allowing domestic producers to make generic versions of anti-AIDS drugs, which are copyrightprotected under TRIPS law. That these actions did not result in widespread retaliation by the governments of developed Western nations on behalf of their powerful domestic pharmaceutical interests must be in part explained by the fact that global public opinion viewed such measures as an analogue to traditional forms of civil disobedience.74 There is evidence that the various actors involved in such resistance, including both activist networks, NGOs, and national states themselves, understood their actions in this way.75 This reading is supported by an aspect of the resistance that is crucial to the practice of civil disobedience in domestic or national contexts according to the classic interpretation of it given by Martin Luther King and further developed by Rawls: namely, the rejection of a specific norm or institution against the background of a (sometimes tacit) acceptance of the legitimacy of the wider system of norms or institutions as a whole. The countries that have resisted TRIPS clearly do not intend to reject the system tout court.** Rather they (and also non-state actors that share their aims) seek to change a seriously unjust part of the system through targeted strategies of resistance and political ‘hardball’ (e.g., threatening to issue compulsory licenses as a way of getting multinational pharmaceutical firms to come to the bargaining table to negotiate lower prices). From a theoretical point of view, the most striking and ‘revolutionary’ aspect of this example is the fact that here national states are adopting the role of actors engaged in civil disobedience with respect to a supra-statal legal and political system. **This indicates that use of the traditional political concepts of authority, obligation, and civil disobedience is increasingly at home in an emerging ‘global imaginary.**’76 We will return to this point when we critically discuss the global trading system from a ‘constitutional’ perspective below (§5.c-d).

## Case

### Topicality

#### The India/South Africa plan is extra-T – the TRIPs waiver includes things other than medicines, like manufacturing or protective equipment.

<https://www.crowell.com/NewsEvents/AlertsNewsletters/all/Three-Takeaways-From-the-May-21-Revised-TRIPS-Waiver-Proposal>

***Second***, **paragraph 1 of the revised proposal, in contrast to same paragraph in the original proposal, provides additional clarity as to the scope of the proposed waiver.** Specifically, the scope **encompasses “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19**.” As in the original proposal, the scope of the revised waiver likewise **applies to the implementation, application, and enforcement of TRIPS provisions regarding copyright and related rights** (Part II, section 1), industrial designs (section 4), patents (section 5), and the protection of undisclosed information (section 7). The scope of potential “health products and technologies” remains unclear, not least because the specified list does not appear to be exhaustive. What is certain, however, is that **the scope of the revised proposal remains broad including, among others, COVID-19 vaccines and diagnostic tests, as well as underlying manufacturing technologies, and covering various types of intellectual property**. Whether, during subsequent negotiations, the scope of the waiver is reduced, such as limiting the health products and technologies or applicable TRIPS provisions, will be critical for stakeholders. Notably, Ambassador Tai’s statement earlier this month specifically reflects the Biden-Harris Administration’s support for a temporary waiver for COVID-19 vaccines only, not other health products or technologies.

#### AND Merriam Webster -- medicines are

https://www.merriam-webster.com/dictionary/medicine

**a substance or preparation used in treating disease**

### Trade Secrets

#### turns case, Moore 18:

Adam D. Moore, Intellectual Property and the Prisoner’s Dilemma: A Game Theory Justification of Copyrights, Patents, and Trade Secrets, 28 Fordham Intell. Prop. Media & Ent. L.J. 831 (2018). Available at: <https://ir.lawnet.fordham.edu/iplj/vol28/iss4/3> //LHP AV

First, one could argue that there can be no tragedy of the commons when considering intellectual property. Given that intellectual property cannot be destroyed and can be concurrently used by many individuals, there can be no ruin of the commons. Upon closer examination, this assertion does not hold true. To begin, ask, “**What is the tragedy in the typical case?”** Generally, it is the destruction of some land or other object and the cause of the destruction is scarcity and common access. **But the tragedy cannot actually be the destruction** of land or some physical object because, as we all well know, matter is neither created nor destroyed.47 **The tragedy is the loss of value**, potential value, or opportunities. Where there was once a green field capable of supporting life for years to come, there is now a plot of mud, a barren wasteland, or a polluted stream. **If access to valuable resources is not restricted, the tragedy will keep occurring**.48 The tragedy in this, and other such cases, is not only the loss of current value, but of future value. **Unless access is restricted in such a way that promotes the preservation or augmentation of value, a tragedy will likely result**.49 Now, **suppose that intellectual works were not protected—that if they “got out” anyone would be able to profit from them**. In such cases, **individuals and companies would seek to protect their intellectual efforts by keeping them a secret**. As noted below, secrecy was the predominant form of protection used by guilds in the Middle Ages.50 **The result of this secrecy can be described as a tragedy or a loss of potential value. If authors and inventors can be assured that their intellectual efforts will be protected, then the information can be disseminated, and licenses can be granted, so that others may build upon the information and create new intellectual works.** **The tragedy of a “no-protection rule” is secrecy, restricted markets, and lost opportunities.**51 This view is echoed by Professors Roger Meiners and Robert Staaf: The same story has been told about patents**. If inventions lost their exclusivity and became part of the commons, then in the short run there would be over-grazing.** **The inventor could not exclude others, and products that embody previously patentable ideas would now yield a lower rate of return**. **There would be lower returns to the activity of inventing, so that innovative minds would become less innovative**. In the case of open ranges, common rights destroy what nature endows, and in the long run keeps the land barren because no one will invest to make the land fertile. Similarly, **common rights would make the intellectual field of innovations less productive relative to a private property right system**.52 It should be obvious that **such considerations would inevitably lead content creators to deploy their efforts in less risky pursuits**. **53 If would-be innovators know that they would likely end up playing out prisoner’s dilemma games with each other numerous times, and with countless other players, each would pick a different profession. The incentives to create intellectual property content would be severely undermined.**

### Innovation

#### Pharma innovation is strong now – patent incentives are key to maintaining progress, Austin and Hayford 21:

David Austin, [an Analyst in CBO’s Microeconomics Studies Division] and Tamara Hayford, [a principal analyst in the Health, Retirement, and Long-Term Analysis Division, Congressional Budget Office] prepared the report with guidance from Joseph Kile, Lyle Nelson, and Julie Topoleski. Christopher Adams, Pranav Bhandarkar, and David Wylie (formerly of CBO) contributed to the analysis., April 2021, “Research and Development in the Pharmaceutical Industry” <https://www.cbo.gov/publication/57126> //LHP AV DOA: 9/8/21

At a Glance This report examines research and development (R&D) by the pharmaceutical industry. Spending on R&D and Its Results. **Spending on R&D and the introduction of new drugs have both increased in the past two decades.** In 2019, the **pharma**ceutical industry **spent $83 billion dollars on R&D.** Adjusted for inflation, **that** **amount is about 10 times what the industry spent per year in the 1980s**. Between 2010 and 2019, the number of **new drugs approved** for **sale increased by 60 percent** compared with the previous decade, with a peak of 59 new drugs approved in 2018. Factors Influencing R&D Spending. **The amount of money that drug companies devote to R&D is determined by** the amount of **revenue** they expect to earn from a new drug, the expected **cost** of developing that drug, **and** **policies** that influence the supply of and demand for drugs. The **expected** **lifetime global revenues of a new drug depends on the prices that companies expect to charge** for the drug in different markets around the world, the volume of sales they anticipate at those prices, and the likelihood the drug-development effort will succeed. **The expected cost** to develop a new drug—**including capital costs and expenditures on drugs that fail to reach the market**—**has been estimated to range from less than $1 billion to more than $2 billion**. The federal government influences the amount of private spending on R&D through programs (such as Medicare) that increase the demand for prescription drugs, through policies (such as spending for basic research and regulations on what must be demonstrated in clinical trials) that affect the supply of new drugs, and through policies (such as recommendations for vaccines) that affect both supply and demand. Notes Research and Development in the Pharmaceutical Industry Summary Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered **policies** **that** would **lower** drug **prices** and reduce federal drug expenditures. Such policies would probably **reduce the industry’s incentive to develop new drugs**. In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation. **The share of revenues that drug companies devote to R&D has also grown**: On **average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses in 2019, which is almost twice as large a share of revenues as they spent in 2000**. That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On average, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), which are costly to develop, hard to imitate, and frequently have high prices. Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. What Factors Influence Spending for R&D? Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, Expected costs to develop a new drug, and Policies and programs that influence the supply of and demand for prescription drugs. **Various considerations inform companies’ expectations** about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The **prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments**. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA.** In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug. **Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA**. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and **during that time the company does not receive a financial return on its investment in developing that drug.** The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatments of uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, **the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D.** Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. In particular, **spending on drug R&D increased by nearly 50 percent between 2015 and 2019**. Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, **the trend is broadly representative of R&D spending by the industry as a whole**.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3

#### Intellectual property protections are key to pharmaceutical innovation – laundry of list of studies – that solves access better, Ezeli and Cory 19:

Stephen Ezell, [vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He focuses on science and technology policy, international competitiveness, trade, manufacturing, and services issues.] and Nigel Cory, [an associate director covering trade policy at the Information Technology and Innovation Foundation. He focuses on cross-border data flows, data governance, intellectual property, and how they each relate to digital trade and the broader digital economy. Cory has provided in-person testimony and written submissions and has published reports and op-eds relating to these issues in the United States, the European Union, Australia, China, India, and New Zealand, among other countries and regions, and he has completed research projects for international bodies such as the Asia Pacific Economic Cooperation and the World Trade Organization.] “The Way Forward for Intellectual Property Internationally” April 25, 2019, <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally> //LHP AV

INTELLECTUAL PROPERTY UNDERPINS INNOVATION AND GROWTH Intellectual property rights arrangements are well recognized, going back to the Middle Ages, as enabling innovators to earn the returns necessary to continue to innovate and promote the availability of leading-edge technologies. **Nobel laureate economist Douglas North**, one of the foremost scholars of economic history, **argues that the introduction of intellectual property rights had one of the most profound impacts on spurring economic growth in human history**. North points out that average global economic growth rates for about one and a half millennia prior to the Industrial Revolution were essentially zero. Eighteenth-century elites in England had practically the same per capita income as their counterparts in third-century Rome.21 North has shown that the inflection point toward greater economic growth was the widespread development of patent systems in the 19th century.22 Gregory Clark, in his seminal book, Farewell to Alms: A Brief Economic History of the World, reached a similar conclusion that the introduction of **IPRs was catalytic to turbo-charging global economic growth**.23 **Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks**. By raising the private rate of return closer to the social rate of return, in**tellectual property rights address the knowledge-asset incentive problem, allowing inventors to realize economic gain from their inventions, thereby catalyzing investment in knowledge creation.** If innovators know that most of the benefits from their innovations would go to others without compensation, **they would be much less likely and capable of engaging in future innovations**. In addition, as they capture a larger portion of the benefits of their innovative activity, **innovating companies obtain the resources to pursue the next generation of innovative activities.** **IP thus produces a number of positive benefits, including: 1) creating powerful incentives for domestic innovation; 2) inducing knowledge spillovers that help others to innovate; 3) ensuring** a country’s **companies can focus on operating productively and innovating**, instead of having to devote an undue amount of their time and resources to protecting their IP in an environment where it’s at risk; **4) promoting the international diffusion of technology, innovation, and knowhow; and 5) boosting a country’s levels of research and development, inbound foreign direct investment (FDI), and exports of goods and services**.24 Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks. The **evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike.** As the definitive 2010 OECD review of the effects of intellectual property rights protections on developing countries, “Policy Complements to the Strengthening of IPRs in Developing Countries” found, “The results point to a tendency for IPR reform to deliver positive economic results.”25 The OECD study found that **developing-country IPR reforms concerning patent protection have tended to deliver the most substantial results**, although the results for copyright reform and trademark reform are also positive and significant. But to have the greatest impact on economic growth, IPR reforms must occur concomitantly with other positive complements, particularly ones regarding inputs for innovative and productive processes and the ability to conduct business. These include policies that influence the macro-environment for firms as well as the availability of resources (e.g., related to education), a country’s legal and institutional conditions, and fiscal incentives.26 The evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike. The following section details the broad swath of academic literature reviewing the relationships between IPR strengthening and trade, FDI, and technology transfer; IPR reform and innovation and R&D; and IPR reform and exports and industry growth, revealing the benefits of stronger IPR protections for developed and developing countries alike. IPRs Strengthen Trade, FDI, and Technology Transfer A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Strengthening IPR protection has been shown to correlate with increased trade.27 For instance, Fink and Primo Braga found that IPR protection is positively associated with international trade flows, in particular of manufactured, non-fuel imports.28 Other studies have found a positive association between IPR protection and trade flows in high-technology products.29 Likewise, strengthening of IPR protection has also been connected with increased inflows of FDI. Cavazos Cepeda et al. found that a 1 percent increase in the protection of IPRs as measured by the Patent Rights Index (a measure of the strength of countries’ IPR regimes) is associated with a 2.8 percent increase in the inflow of FDI.30 Similarly, a 1 percent increase in trademark protection levels is associated with a 3.8 percent increase in incoming FDI; and a 1 percent increase in copyright protection yields a 6.8 percent increase in FDI.31 Moreover, the researchers identified a virtuous cycle between FDI and protection of IP, whereby improvements in the IPR environment are associated with improved economic performance—in particular with respect to FDI—and, in turn, further improvements in the IPR environment. Park and Lippoldt showed that stronger IPRs in developing countries are associated with an increase of technology-intensive FDI, while Awokuse and Yin provided a concrete example concerning the relationship of IPR protection in China to FDI inflows, concluding that IPR reforms in China have had a positive and significant effect on inbound FDI.32 There is also evidence that countries with similar levels of intellectual property protection trade more with one another.33 Academic research also signals a strong correlation between IPR and technology transfer. Lippoldt showed that IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment.34 Research has revealed that a country’s level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.35 That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.36 For instance, foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of countries.37 The research on this matter is clear and consistent. For example, a 1986 United Nations Conference on Trade and Development (UNCTAD) study found that direct investment in new technology areas such as computer software, semiconductors, and biotechnology is supported by stronger intellectual property rights policy regimes.38 (However, as this report later clarifies, subsequent UNCTAD reports have lamentably taken a more skeptical view toward IP.) A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IP rights reduce computer software direct investment; and a 1990 study by UNCTC found that weak IP rights reduce pharmaceutical investment.39 Mansfield conducted firm-level surveys and found that perceptions of strong IP rights abroad have a positive effect on incentives to transfer technologies abroad. Likewise, survey research by the World Bank’s International Finance Corporation found that, with variations by sector, country, and technology, at least 25 percent of American and Japanese high-tech firms refuse to directly invest, or enter into a joint venture, in developing countries with weak intellectual property rights; and a later study confirmed those survey findings with actual foreign direct investment data.40 And an Institute for International Economics study of World Bank data concluded that weak intellectual property rights reduce flows of all these commercial activities, regardless of nations’ levels of economic development.41 A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Studies have also shown how the benefits of intellectual property extend to developing countries. Diwan and Rodrik demonstrated that stronger patent rights in developing countries give enterprises from developed countries a greater incentive to research and introduce technologies appropriate to developing countries.42 Similarly, Taylor showed that weak patent rights in developing countries lead enterprises from developed countries to introduce less-than-best-practice technologies to developing countries.43 Interestingly, the relationship goes in both directions. Branstetter and Saggi showed that strengthened IPR protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original innovation.44 They concluded that IPR reform in the “global South” (e.g., developing countries) may be associated with FDI increases in the “global North” (e.g., developed countries). As northern firms shift their production to southern affiliates, this FDI accelerates southern industrial development, creating a cyclical feedback mechanism that also benefits the North. Another study by Liao and Wong, which focused on firm-level analysis, highlights the inter-relationship of IPR reform in developed and developing countries. Their study concluded that developing countries can entice technology transfer from the North by providing IPR protection for incoming products (although they note there is a need for redoubled R&D efforts in developed countries to spur needed innovations).45 **IPRs Strengthen Innovation** Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that **counties with stronger IP protection have more creative outputs** (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), **even at varying levels of development**.46 **IPR reforms also introduce strong incentives for domestic innovation**. **Sherwood**, using case studies from 18 developing countries, **concluded that poor provision of intellectual property rights deters local innovation and risk-taking**.47 In contrast, **IPR reform has been associated with increased innovative activity, as measured by domestic patent filings**, albeit with some variation across countries and sectors.48 For example, **Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets**.49 **Park** **and Lippoldt also observed that** the provision of adequate protection for **IPRs can help to stimulate local innovation**, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, **local innovators are introduced to technologies** first **through** the technology transfer that takes place in an environment wherein **protection** of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development. The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that **R&D to GDP ratios are positively related to the strength of patent rights**, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56 BOX 1: INNOVATE FOR HEALTH: IP IS NOT THE PROBLEM, BUT PART OF THE SOLUTION **Many opponents of robust IPR rights view them as antithetical to the interests of developing countries in terms of access to medicines or the provision of national health care services**. Yet the reality is that **stronger IPR rights in developing nations actually unleash the power of developing-country innovators to contribute to solving health challenges both in their own nations and across the global economy**. First, opponents of IP fail to recognize **that intellectual property rights matter for health care innovation in emerging economies.** **A**n Information Technology and Innovation Foundation (ITIF) and George Mason University Center for Intellectual Property Protection **report**, “How Innovators Are Solving Global Health Challenges,” **provides 25 case studies that show innovators in developing countries relying on IP to invent and bring solutions to market**.57 The 25 case studies revealed a number of key themes, including that there is opportunity in adapting health care interventions for developing-country environments where resources and infrastructure are scarce, and that local innovation and **IP can contribute substantially toward providing both affordable and robust tests for diagnosing diseases and affordable interventions to meet basic needs in challenging environments.** Second, **opponents of IP tend to ignore broader systemic issues that contribute to poor health care outcomes in developing countries.** **While cost is a central factor for policymakers in all countries, given resource scarcity, these trade-offs are not unique to health**. **The greater the resource scarcity, the greater the need for innovation**. One of the biggest challenges policymakers and innovators in developing countries confront again and again is scarcity—in access to trained professionals, in transportation, and in other infrastructure. For example, reports estimate that as many as 1 billion people lack access to essential health care because of a shortage of trained health professionals.58 A 2014 World Health Organization study estimated a shortage of 7 million public health care workers, with that number expected to rise to 13 million by 2035.59 More than 80 countries currently fail to meet the basic threshold of 23 skilled health professionals per 10,000 citizens.60 The challenge is even more daunting when it comes to specialists. For instance, Cameroon has fewer than 50 cardiologists supporting a population of over 23 million citizens.61 And Ethiopia, a country of some 90 million residents, is served by a single radiation-treatment center located in the capital of Addis Ababa.62 In other instances, individuals lack access to essential medicines, with cost being a relatively small part of the problem. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, on average, essential medicines are available in public-sector facilities in developing countries only 40 percent of the time.63 Again, **the cost of medicines is far from the most serious problem in the provision of health care services in developing nations**. Indeed, **the vast majority of drugs—at least 95 percent—on the World Health Organization’s Essential Medicines list are off-patent, and thus potentially available in generic versions**.64 **The problem, in much larger part, stems from countries’ underdeveloped health systems and the fact that many people live in rural areas far from care.** **Stronger IP rights create an environment wherein entrepreneurs can innovate to meet health challenges in their own nations, the benefits thereof spilling over to benefit the entire international community.** IPRs Strengthen Exports and Industry Growth Academic research has also found that **stronger IPR protections support exports from developing countries and faster growth rates of certain industries.** Yang and Kuo argue that stronger IPR protection improves the export performance of firms benefitting from technology transfer. And in their research, Cavazos Cepeda et al. found that trademark protection has a statistically significant association in relation to the export turnover, sales, and total assets of firms studied. They also found a significant association between copyrights and export turnover. Moreover, they found “a positive influence of patent right protection on export turnover (e.g., sales) under certain specifications with respect to complementary policies.”65 In cross-country studies, researchers have found that stronger patent rights are associated with faster company growth in IP-intensive industries such as pharmaceuticals. In fact, during the early 1990s, a one-standard-deviation increase in patent rights was associated with an increase in firm growth of 0.69 percent (an advantage amounting to nearly one-fifth of the average industry growth rate of 3.7 percent).66 Consequences of Countries Not Enacting Robust IPR Protections and Enforcement **Nations** **that** have not implemented—or **do not enforce**—**robust intellectual property rights protections end up harming their economic development in at least three principle ways. First, they deter future innovative activity. Second, they discourage trade** and foreign direct investment, which only hurts their own consumers and businesses, by both limiting their choices and inhibiting their enterprises’ ability to access best-of-breed technologies that are vital to boosting domestic productivity. **Third, in countries with weak IP protections, firms are forced to invest undue amounts of resources in protection rather than invention**. Ironically, **developing countries’ own economic development opportunities** and intellectual property development potential **are inhibited by their own weak intellectual property protections.** For instance, the lack of effective protection for intellectual property rights in China has limited the introduction of advanced technology and innovation investments by foreign companies, thereby reducing potential benefits to local innovation capacity.67 As Cavazos Cepeda et al. found in a case study of IPR protections in that economy, “China has made progress in strengthening the protection of intellectual property over the past two decades, as attested to by indicators such as the Patent Rights Index…. However, uncertainty around the protection of intellectual property [remains] an important deterrent for foreign as well as domestic firms engaging in R&D-related activities.”68 Ironically, developing countries’ own economic development opportunities and intellectual property development potential are inhibited by their own weak intellectual property protections.

### AT Evergreening

#### First, “incremental” innovations are a key aspect of R&D, Jones 6

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

As already mentioned, **the costs and time necessary to bring a drug to the market are considerable**. While the initial patents covering the basic chemical or protein entity are important to encourage the further investment to bring the drug to the market, **the length of time afforded protection** by such patents ‐ due to the considerable amount of time necessary to develop a suitable formulation and presentation of the drug, and the time to conduct clinical trials ‐ **usually does not provide sufficient protection to balance the overall financial investment.** Further, **many inventions** made during the develop‐ ment of the drug formulation or presentation, while possibly **viewed as ’incremental inventions’ by some, are actually critical to bringing the drug to the market**. Indeed, as a proportion of all patents granted worldwide, very few relate to what may be termed “breakthroughs”. **The vast majority cover innovations which build on inventions of others, with the benefit of full disclosure of those inventions in patent specifications**. That is what the patent system was designed to encourage. **By its very nature**, there‐ fore**, it encourages inventors to adapt and modify the developments** patented by others **incrementally** or in any other way. It would therefore, in ICC’s view, be wholly in‐ appropriate not to allow patents for such forms of innovation; and any such change would adversely affect the ability to finance future drug research. **The innovation process in the pharmaceutical sector, as for all other scientific sectors, is one of evolution**. The criteria for patentability are clear. Patents are available for any invention, whether product or process, in any field of technology, provided it is new, involves an inventive step and is capable of industrial application. **If an invention meets these criteria, it is entitled to patent protection. If it does not, it is not patentable. Of these criteria, the most relevant here is inventive step**. The invention must not have been obvious to a person skilled in the relevant art at the time the application for a patent was first filed, taking into account the state of the art at that time. There is no common understand‐ 192 7 Negative Evidence ing around the world on how this criterion should be applied and TRIPS provides no guidance. The precise manner in which it is applied differs from country to country. It even differs over time within the same country. Significant progress has, however, been made in harmonizing the standard, particularly in the US, Japan and Europe. This harmonized standard should, in ICC’s view, in time become the “gold standard” for patents globally. In the meantime, it may be necessary and appropriate, to encourage investment in local research and manufacturing, for developing countries to adopt a lower threshold to provide easy access to patents for local entrepreneurs. But in ICC’s view, it cannot be right to require such countries to adopt a higher standard of inventive step. In any event, neither the inventive step requirement, nor the other basic criteria, make any distinction between different types of innovation œ for example between “in‐ cremental” and “discrete”, or between “me too” and “breakthrough” innovations. As with any innovation, all of these have to be judged against the same basic rules, and that, in ICC’s view, is entirely appropriate. To the extent that genuine concerns about patent quality exist, they relate to the whole range of patents**. They are not specific to patents for healthcare products, nor to patents for so‐called incremental innovations. If such inventions fail to meet the fundamental criteria set out above, patents should not be granted for them; and where patents have wrongly been granted, courts should (and have) corrected those errors** œ all as part of the international efforts referred to above to ensure that an appropriate balance is achieved between all entities affected by patents. **However, the fact that there have been some examples of patent‐granting authorities ap‐ plying the criteria incorrectly does not justify fundamental change to those underlying principles.**

#### Second, evergreening only proves flaws in the application process, not the legitimacy of patents themselves, Jones 6

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

In the context of pharmaceuticals, it has been suggested that patent protection should not be given to inventions comprising different salts, esters or other derivatives of known drugs, different dosage forms or means of administration of existing products, combinations of known products (including fixed dose combinations), nor “mere” new uses of known compounds, (all of which might qualify for the misnomer “incrementally modified drugs”); nor for modifications to medical devices (such as a single‐, rather than multiple‐dose, syringe). These suggestions are, in ICC’s view, misconceived. As stated above, if any such inventions do not satisfy the basic patentability criteria, patents should not be granted for them; and if patents are found wrongly to have been granted, courts and patents offices should correct those errors, just as they should for patents in any field and for any category of innovation. This approach should address, and is addressing, concerns about illegitimate extension of patent term, or “evergreening”. There is no need for separate, or new, legislation to deal with this issue. Further, the suggestion that such inventions do not benefit society is wrong. These types of so‐called “incremental” innovation generally result in better health outcomes2, for example by increasing efficacy, reducing side effects and/or making administration easier, resulting in improved compliance and greater effectiveness

### Solvency/Turns

#### [1] The proposed waiver won’t solve because of how complicated it would be to mandate disclosure and transfer of trade secrets—the plan is insufficient to trigger the advantages, Donahoe

<https://www.natlawreview.com/article/waiver-ip-protections-covid-19-vaccines-still-under-consideration-wto>, 24 Aug 2021, Donahoe, Casey D.

While the proposed waiver extends to several areas of IP, most agree that patents and undisclosed information, in particular, form the crux of the debate. Katherine Tai, the U.S. Trade Representative, has not publicly committed to any position beyond waiving patent protections in particular. [Karpan 2021-07-01] Moderna has temporarily waived its COVID-19 vaccine patent rights, but the vaccine is still protected, at least in the U.S. and EU by regulatory marketing exclusivity. [Collins 2021-06-11] **With respect to patents, existing TRIPS flexibilities already allow for countries to issue compulsory licenses for domestic production in the face of public health crises and, under additional criteria, compulsory licenses for export.** But proponents of the waiver argue that the existing processes, which can require country-by-country and case-by-case negotiations and litigation with the vaccine developers and may be limited to public uses, are too time-consuming and inconvenient to mount an effective response, particularly where thickets of IP protection cover single vaccines. [Labonte 2021-01-09, The Conversation]; [Public Citizen, tradewatch.org] In fact, compulsory licensing to exporting manufacturers under Article 31b is has only been successfully used once in the past twenty years, [Public Citizen, tradewatch.org] when Canada issued a compulsory license authorizing the manufacture and export of an AIDS medication to Rwanda. [WTO 2007-10-04] Additionally, multiple countries may be involved in the pipeline for manufacturing a single packaged vaccine to be distributed in a country in need. Further, one key advantage to a unanimously agreed-upon waiver over attempting to utilize existing TRIPS flexibilities, would be that countries could more comfortably exploit the waiver without the threat of trade complaints or sanctions from other nations. [Lopez 2021-05-07] Proponents of the waiver point to alleged U.S. and European retaliatory trade measures against nations that have attempted to use existing TRIPS flexibilities to skirt IP protections. [Public Citizen, tradewatch.org] While the proposed waiver extends to several areas of IP, most agree that patents and undisclosed information, in particular, form the crux of the debate. **However, even if patent protection were not an issue, manufacturing and distribution of the vaccines would remain a substantial obstacle to achieving global immunity.** [Paton 2021-05-07 Bloomberg] **Aspects of vaccine manufacturing and regulation raise further issues of what TRIPS calls “undisclosed information,” encompassing trade secrets and know-how. Such undisclosed information may be particularly crucial in scaling up manufacture in a commercially viable fashion**. [Garrison 2020-12-16]. Article 39 of TRIPS requires members to protect the confidentiality of undisclosed information, including data submitted to regulatory agencies for marketing approval of pharmaceuticals. **As related to vaccines, undisclosed information could include clinical data** (e.g., related to effectivity, including negative results), **manufacturing processes, medical formulas, cell lines, genomic information, technical designs and specifications, instruction manuals, process controls and monitoring, quality control procedures, technical training, working practices, etc.** [Garrison 2020-12-16]; [Levine 2020-07-10]; [Eakin 2021-05-25 Law360] **The Pfizer and Moderna vaccines,** in particular, are expected to be **extremely difficult to replicate** given **they rely on new mRNA technology.** The WTO touts the COVID-19 Clinical Research Coalition, which aims to provide a platform for voluntary data-sharing, and the WHO-backed COVID-19 Technology Access Pool (C-TAP), which provides a platform for technology developers to bundle intellectual property rights, knowledge, and data into non-exclusive licenses with each other and with multiple quality-assured manufacturers, as examples of voluntary efforts to fill-in the know-how gap. [WTO Report 2020-10-15] In general, the voluntary transfer of know-how between two parties is highly contractually stipulated, usually allowing the licensor strict control over the dissemination of its know-how and protecting rights to improvements and developments that may derive from the collaboration, some of which might be patentable in themselves. [Bracho 2021-05-24 Bloomberg]. **The proposed waiver**, though, **wades into relatively unchartered territory of compulsory transfers of undisclosed information. Likely the biggest threat felt by vaccine manufacturers is that the compulsory transfer of undisclosed information will not simply diminish their return on investments in COVID19 vaccines, but would jeopardize entire proprietary technological platforms that support a wide range of potential products.** Such giveaways would likely impact small-to-medium sized enterprises especially, which account for approximately 75% of US COVID-19 treatments, and particularly small university spin-outs, which are highly depend on IP for valuation. [Balfour 2021-06-30] As details of a waiver have not yet been hammered out, it remains unclear exactly who might have access to such undisclosed information (e.g., the general public or only generic manufacturers) and the mechanisms by which such transfers would be achieved. Even with a waiver in place, individual countries would likely need to enact legislation or emergency executive actions to execute the transfer of information. [Labonte 2021-01-09, The Conversation**] The most obvious means would be for regulatory agencies to disclose data and manufacturing protocols submitted by vaccine manufacturers that they are ordinarily required to keep confidential.** In fact, the issue of data confidentiality has already been raised in the U.S. as an obstacle to developing a competitive generic biologics market, with some pointing to the Federal Pesticide Act (FPA) as a successful model which allows more free dissipation of regulatory data by the EPA. [Heled 2019] There are some exemptions to confidentiality of data supplied to regulatory drug agencies implemented in the U.S. and Europe, particularly where public funding helped finance the underlying research. For example, for research funded by the U.S. government, the Bayh-Dole Act provides some additional licensing provisions to the government which could potentially extend to some know-how; however, these provisions are largely untested and may be contractually restricted. [Collins 2021-06-11]. **But there is no precedent for compulsory transfer of confidential information**

**in general**. [Levine 2020-07-10] **Even with a waiver in place, individual countries would likely need to enact legislation or emergency executive actions to execute the transfer of information. Additionally, knowledge holders may be located outside the jurisdiction of a member state desiring to compel transfer,** [Garrison 2020-12-16] **and waiving an obligation for member states to protect undisclosed information does not necessarily compel other member states to do so.  Notably, India, one of the waiver proponents that actually has substantial pharmaceutical manufacturing capacity, does not even presently require submission of test data for marketing approval.**  [Haugen 2020-12-01]  **Compulsory disclosure of undisclosed information is further complicated by the fact that the knowledge holders for manufacturing a single vaccine may be dispersed across multiple entities and/or even multiple jurisdictions, particularly where a supply chain of highly technical components is utilized or certain processes are outsourced to contractor entities.**  [Garrison 2020-12-16]  **The legislative levers that might be needed to fully enforce compulsory disclosure of undisclosed information or that could be pulled to halt executive branch action, as well as the lawsuits that might be filed would seem likely to stall any grand gestures of governmental action related to undisclosed information.** [Eakin 2021-05-25 Law360]  **For instance, compulsory disclosures would likely spurn allegations of violating the Takings Clause of the Fifth Amendment**, although the Supreme Court had found previously in *Ruckelshaus v. Monsanto Co*. that the FPA had not done so [Heled 2019].  Still, compulsory disclosure facilitated by regulatory agencies may not be sufficient to fill the knowledge gap for the successful manufacture of the vaccines, leaving room for countries to consider other creative avenues.  Brazil, for instance, has proposed one of a kind legislation which would tie patent rights to the compulsory disclosure of all information needed to make COVID-19 vaccines.  [Eakin 2021-05-25 Law360] Opponents argue that **bottlenecks in manufacturing capacity and supplies would stymie the effect of the waiver, despite the transfer of undisclosed information, and that even with full technology transfer, it would take months or years for factories to come up to speed on vaccine production.**  [Leonard 2021-05-06, Bloomberg]; [Paton 2021-05-07 Bloomberg]  **Manufacturing capacity is particularly limited for mRNA-based vaccines and there’s not even necessarily a sufficient population of people with expertise capable of manufacturing them.**  [Karpan 2021-05-11 Law360]  **Some also warn that redistributing crucial supplies to manufacturers without existing capabilities to manufacture the high-quality vaccines with regulatory approval would actually hinder vaccine distribution efforts.**  [Karpan 2021-05-11 Law360]; [Lima 2021-05-08 Bloomberg]; [Paton 2021-05-07 Bloomberg]  Even manufacturing facilities with access to all IP rights are experiencing production delays from regulatory reviews.  [Baschuck 2021-05-06]  Opponents also resound that such efforts to undermine IP rights will only discourage future innovation, including research that targets new variants of the coronavirus.  [Bacchus 2020-12-16 Cato Institute];  [Paton 2021-05-07 Bloomberg] The large divide between fervid proponents of the waiver and even those who have expressed some mild support suggests any significant compromise may be some time coming.  Many view the waiver controversy any way as less of a problem-driven exercise and more of an opportunity for the usual players to debate both the power of big pharma in the U.S.  [Collins 2021-06-11] and the stifling effects IP protections can have on the least developed nations around the world.  Also, the angst amongst some proponents of the waiver, some believe, may stem more from policies of vaccine nationalism than of TRIP impediments. [Clarke 2021-04-22 Lexology] Regardless, the decisions reached at the WTO during this crisis are likely to shape future policy discussions for years to come.

#### [2] Waivers won’t solve the actual problem. Supply will be a non-issue by years end. The TRIPS waiver is a theatrical gesture aiming to let rich economies off the hook for actually solving the problem, Adler

<https://foreignpolicy.com/2021/07/20/wto-trips-waiver-vaccine-equity-distribution-covid-pandemic/>, July 20, 2021

These rollout problems found in the United States are amplified many times when it comes to global rollout. The Biden administration discovered this first hand when it attempted to donate 80 million doses from domestic U.S. supply to the rest of the world in June but fell well short of this target. **White House press secretary Jen Psaki** [**said**](https://www.whitehouse.gov/briefing-room/press-briefings/2021/06/21/press-briefing-by-press-secretary-jen-psaki-june-21-2021/)**, “what we found to be the biggest challenge is not actually the supply—we have plenty of doses to share with the world—but this is a herculean logistical challenge.** And we’ve seen that as we’ve begun to implement.” She pointed to the distributional challenges associated with storing vaccines at the proper temperature as well as the need for needles and syringes. **The TRIPS waiver can be seen as essentially a political or even theatrical gesture.** As Psaki’s comments show, there is more to vaccinating the world than just increasing supply. **Even if there are vaccine shortages at this moment, limited vaccine supply may not be a binding constraint by year end**. Serum Institute of India, the world’s largest vaccine manufacturer, has announced **it will begin** [**exporting later this year**](https://www.reuters.com/world/india/indias-serum-institute-start-export-covid-19-vaccine-by-year-end-2021-05-18/)**, implying India should have adequate vaccine supply by then.** **Pfizer/BioNTech has** [**pledged to deliver**](https://www.voanews.com/covid-19-pandemic/pfizer-biontech-pledge-2-billion-vaccine-doses-poor-nations) **2 billion doses to low- and middle-income countries**. **AstraZeneca is continuing to scale up production.** Nonetheless, the Biden administration’s signature international COVID-19 policy, the [**TRIPS waiver**](https://crsreports.congress.gov/product/pdf/IN/IN11662)**, is a supply side move—but one unlikely to lead to any actual increase in supply**. This waves intellectual property protections for COVID-19 vaccines to further foreign production. The [U.K.](https://www.gov.uk/government/news/wto-trips-council-june-2021-uk-statements) and [German](https://www.dw.com/en/germany-rejects-us-push-to-waive-covid-vaccine-patents/a-57453453) governments have viewed it skeptically and can block it. Also, as has been widely noted, manufacturing involves trade secrets and supply chain issues that go well beyond intellectual property (IP) rights. Less widely noted is the fact that the Johnson & Johnson, AstraZeneca, and Novavax vaccines have already been [licensed to Indian manufacturers](https://www.statnews.com/2021/05/05/india-vaccine-heist-shoddy-regulatory-oversight-imperil-global-vaccine-access/), so it is not clear to what degree IP rights are really hindering additional foreign production. Therefore, the TRIPS waiver can be seen as essentially a political or even theatrical gesture, well removed from the messy world of vaccine distribution and administration. It appealed to a domestic audience hostile to Big Pharma and an international audience of countries like India and South Africa whose industrial policies have long called for limitations on IP rights. The Biden administration’s policies keep [evolving](https://foreignpolicy.com/2021/07/16/biden-africa-covid-19-ship-millions-vaccines/), and newer proposals are likely to show more immediate results. The United States has [pledged](https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/10/fact-sheet-president-biden-announces-historic-vaccine-donation-half-a-billion-pfizer-vaccines-to-the-worlds-lowest-income-nations/) to buy 500 million U.S. produced doses of the Pfizer/BioNTech vaccine over the next year and donate them to low-income countries. Many [financing initiatives](https://www.npr.org/2021/02/18/969145224/biden-to-announce-4-billion-for-global-covid-19-vaccine-effort) have been announced. But U.S. plans of how to tackle the critical last mile and get the vaccines into people’s arms have not been as clearly fleshed out, with the United States mostly taking a hands-off approach. Administering vaccines requires a global rollout plan. After all, as the truism goes, a global pandemic demands a global response. However, this phrase is open to interpretation, with vaccine nationalism typically cloaked in globalist rhetoric. Many in the United States are deeply uncomfortable with a U.S.-led pandemic effort and hear the statement to mean that globalist institutions should take the lead. In other countries, the phrase can mean something very different. For instance, when European Commission President Ursula von der Leyen floated the idea of a “[vaccine export transparency mechanism](https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_221)” to block vaccine exports from the EU to the U.K., she said it was for the “global common good.” These various meanings are somehow aligned in discouraging any U.S. unilateralism and pose challenges to a more active U.S. involvement in a global rollout. The primary global initiative to ensure all countries have access to COVID-19 vaccines is [COVAX](https://www.gavi.org/covax-facility?gclid=Cj0KCQjwub-HBhCyARIsAPctr7wD6lbQwpflk8lliN12KxEUIUL9NkbdH7NgZ3UTkYqdsLWgG380utMaAqtvEALw_wcB), co-convened by the Coalition for Epidemic Preparedness Innovations, the vaccine alliance Gavi, and the World Health Organization. Gavi oversees procurement but does not have an [on-the-ground presence](https://www.gavi.org/our-alliance/operating-model) for administering vaccines. This is left up to the health ministries of developing countries and other partners. The coalition’s key partner responsible for delivering vaccines is UNICEF. UNICEF is a [children’s agency](https://www.unicef.org/) whose mission is helping every child thrive all over the world. However, it is the elderly who are most at risk for COVID-19. Ultimately, COVAX has rollout capabilities but limited bandwidth and resources when it comes to vaccine administration. The United States has these resources, including deep expertise in both vaccine distribution and administration. Operation Warp Speed showed the Defense Department can manage the complex ultra-cold logistics required for mRNA vaccine distribution. The Centers for Disease Control and Prevention (CDC) and the U.S. Agency for International Development (USAID) have knowledge of vaccine administration—although addressing a global pandemic would be a “stretch goal.” The United States could use its personnel and expertise to help solve the global rollout problem, either on its own or in a partnership with multilateral institutions, such as COVAX. This is not to imply the United States, with its declining life expectancy, necessarily has a better health system than other afflicted countries—only that it has rollout knowledge it learned the hard way. The key lesson is the last mile is the hardest part to roll out. Rather than having vaccine supplies arrive and only then start training, it is better to have mass vaccination sites up and running and already fully staffed. The United States could offer technical guidance and materials necessary for rollouts, including refrigeration, ancillary kits, and having enough needles on hand. USAID could offer advice on how a country could improve its vaccine readiness plan. Addressing vaccine hesitancy is also critical to a successful rollout. The reasons behind vaccine hesitancy are complex and vary by country and population. Hence, responses need to be country specific but will typically require a massive communications effort. Where is the global effort? Where is the global planning for this effort? Tackling these global, last-mile challenges faces huge domestic roadblocks in the United States. It would require making global rollout a top U.S. foreign-policy priority, necessitating the planning, financing, and personnel of something akin to the Marshall Plan. It would be expensive. It involves industrial planning, which still has negative overtones in the United States. Which agency in the U.S. government should coordinate such a plan? The State Department? The Defense Department? The National Institute of Health? The CDC? The White House COVID-19 Response Team? Perhaps the most divisive question is if the United States should lead such an effort or follow the WHO’s directives. But none of this is relevant because there is no domestic political pressure for pursuing such an approach, unlike the TRIPS waiver. This is because nonprofit activism is still primarily focused on [supply](https://www.amnesty.org/en/latest/news/2021/06/g7-support-for-pharma-monopolies-putting-millions-of-lives-at-risk/) and [eliminating vaccine hoarding](https://www.oxfamamerica.org/press/cnn-rich-countries-are-hoarding-covid-19-vaccines-and-leaving-developing-world-behind-peoples-vaccine-alliance-warns/) by rich countries. True global vaccine equity requires a broader definition and effort beyond just manufacturing more supply, namely creating a global rollout plan and deploying the health resources necessary to get shots into people’s arms. The end result is the United States is hesitant to find more concrete ways to get involved with a global rollout beyond just pledging more vaccine supplies or money. It is hesitant to directly intervene to help the worst afflicted poor countries distribute and administer vaccines. And vaccine hesitancy, in whichever form it takes, can be deadly.

#### Turns case – enables rich countries to politically justify not putting additional effort into int. COVID vaccinations.

#### [3] Turn- Waiving patents can’t resolve drug access issues but instead create a more dangerous scenario for developing countries – Garde 21

Damian Garde (national biotech reporter for STAT), Helen Branswell (senior writer at STAT covering infectious diseases and global health; former CDC Knight Fellow and Nieman Global Health Fellow at Harvard; recipient of the 2020 George Polk Award for coverage of the Covid pandemic), and Matthew Herper (senior writer at STAT covering medicine). “Waiver of patent rights on Covid‐19 vaccines, in near term, may be more symbolic than substantive.” Stat News. 6 May 2021. JDN. https://www.statnews.com/2021/05/06/waiver‐of‐patent‐rights‐on‐covid‐19‐vaccines‐ in‐near‐term‐may‐be‐more‐symbolic‐than‐substantive/

In October, **Moderna vowed not to enforce its Covid‐19‐related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines**. “There are currently no generic vaccines primarily because there are hundreds of pro‐ cess steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, **but the transfer of skills is not that simple,” said Norman Baylor,** who formerly **headed the F**ood and **D**rug **A**dministration**’s Office of Vaccines Research and Review**, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — **using messenger RNA technology** — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. **There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instanc**e, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in‐demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry‐wide ... looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly **all of the peo‐ ple who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing**.”  As Michelle McMurry‐Heath, CEO of the trade group BIO, put it in a statement, “**hand‐ ing needy countries a recipe book without the ingredients, safeguards, and sizable work‐ force needed will not help people waiting for the vaccine.”**

#### [4] A vaccine waiver greenlights counterfeit medicine – independently turns Case.

**Conrad 5-18** John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

#### [5] Lack of access is not a result of IP – rather IP is key to ensure high quality vaccines that pass regulatory hurdles, which means the plan actually reduces access

Stevens, Philip, and Mark Schultz 1/14. “Why Intellectual Property Rights Matter for COVID-19 - Geneva Network - Intellectual Property Rights and Covid-19.” Geneva Network, 14 Jan. 2021, geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/. Philip Stevens in the Founder and Executive Director of Geneva Network. He is also a Senior Fellow at the Institute for Democracy and Economic Affairs, Malaysia.; Professor Mark F. Schultz is the Goodyear Tire & Rubber Company Endowed Chair in Intellectual Property Law, the Director of the Intellectual Property and Technology Law Program at the University of Akron School of Law. He was a professor at Southern Illinois University School of Law for 16 years and was co-founder and a leader of the Center for Protection of Intellectual Property (CPIP) at George Mason University in Washington, D.C., where he remains a non-resident Senior Scholar. He also serves as a Senior Fellow of the Geneva Network. //sid

IP has underpinned the research and development that has led to the arrival of several game-changing vaccines. But the challenge does not end there. Perhaps the biggest hurdle is manufacturing billions of doses or new antibody treatments while maintaining the highest quality standards.

There’s more to it than starting a global manufacturing free for all by overriding or ignoring patents. A spokesperson for Regeneron, a manufacturer of a novel COVID-19 antibody treatment explained to [The Lancet](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext): “Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months, as well as significant resources and skill. Unfortunately, it is not as simple as putting a recipe on the internet and committing to not sue other companies during the pandemic”.

[John-Arne Røttingen](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext), chair of the WHO COVID-19 Solidarity trial, explains that technology transfer will be crucial to scaling up production, but voluntary mechanisms are better: “If you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological samples, cell lines, or bacteria” to be able to document to regulatory agencies that you have an identical product, he explains.