## 1

#### Interp: Precluding a future increase is not a reduction

Melinda **Harmon 12**, Judge, United States District Court for the Southern District of Texas, Houston Division, 3/6/12, Zieche v. Burlington Res., Inc., 2012 U.S. Dist. LEXIS 30134, p. lexis

Zieche contends that the Court erred when it concluded that "there was no reduction in Zieche's salary or bonus percentage" that would constitute "good reason" for his resignation. Doc. 70 at 8, 9. The Court relied on the fact that Zieche received "his full 2006 performance bonus" after he began working at ConocoPhillips and that the bonus percentage increased from 30% in 2005 to 40% in 2006 as proof that Zieche did not suffer a reduction in salary.

Zieche contends that an increase in his bonus is irrelevant to a determination of whether his salary was reduced because a "bonus is not part of the salary," but is instead [\*12] "something in addition to what is expected or strictly due." Doc. 72 at 4. Additionally, Zieche alleges that "the [C]ourt's analysis ignores the specific provisions of the retention agreement," which defines "good reason" to include "any reduction from your annual rate of base salary." Id.

Initially, although Zieche alleges that ConocoPhillips reduced his salary, he introduced no summary judgment **ev**idence to support this contention. In his Response to ConocoPhillip's Motion for Summary Judgment, Zeiche repeatedly asserts that, in his new position at ConocoPhillips, he would "**not be eligible for annual merit salary *increases***" as he had previously received at Burlington. Doc. 54 at 4 (emph. added). The summary judgment evidence before the Court included Zieche's deposition, in which he admitted that his salary "remained the same . . . up to the time [he] resigned from ConocoPhillips." Doc. 48-1 at 50 (emph. added). Nevertheless, Zieche argues that the Court unnaturally should read the word "reduce" in the retention agreement to mean "**not increase**," rather than interpreting the word according to its plain meaning. **The Court does not agree with this reasoning**, and Zieche has introduced [\*13] no evidence to convince the Court otherwise.

#### Violation: they preclude patent extensions

#### 1] Limits and ground—they allow the aff to monopolize prep by precluding a future increase anytime from now allowing affs to no link from uniqueness scenarios, delay CPs, etc which kills engageability—leads to unpredictable affs that skew the debate away from whether IP is good/bad to when a reduction should occur.

#### 2] TVA – defend the advantage to a whole rez timeframe. We don’t prevent new FWs, mechanisms, or advantages. PICs don’t solve – our model allows you to specify countries and medicines.

#### Fairness – debate is a competitive activity that requires fairness for objective evaluation. Outweighs because it’s the only intrinsic part of debate – all other rules can be debated over but rely on some conception of fairness to be justified.

#### 1NC theory is DTD – a) T indicts the whole aff so DTA is DTD b) abuse is supercharged with the 7-6 rebutal time skew c) deters future abuse

#### Competing interps – [a] reasonability is arbitrary and encourages judge intervention since there’s no clear norm, [b] it creates a race to the top where we create the best possible norms for debate.

#### No RVIs – a] illogical, you don’t win for proving that you meet the burden of being fair, logic outweighs since it’s a prerequisite for evaluating any other argument, b] RVIs incentivize baiting theory and prepping it out which leads to maximally abusive practices c] Forcing the 1NC to go all in on the shell kills substance education and neg strat which outweighs on urgency

## 2

#### The subject emerges through alienation from the attempt to articulate one’s desires through language, which always has a communicability gap that restricts expression. Thus, the ROB is to traverse the fantasy – that means exposing drives.

McGowan 13 Todd McGowan, 2013, “Enjoying What We Don’t Have: The Political Project of Psychoanalysis,” University of Nebraska Press/Lincoln and London, SJBE

The subject as such emerges through the experience of loss. It is the loss of a part of the subject — an initial act of sacrifice — that creates both subject and object, the object emerging through this act as what the subject has lost of itself. The subject takes an interest in the object world because it forms this world around its lost object. As Jacques Lacan notes, “Never, in our concrete experience of analytic theory, do we do without the notion of Obviously, no one literally creates objects through an initial act of sacrifice of an actual body part. This would be too much to ask. But the psychical act of sacrifice allows for a distinction to develop where none existed before and simultaneously directs the subject’s desire toward the object world. In his breakthrough essay “Negation,” Freud describes this process as follows: “The antithesis between subjective and objective does not exist from the first. It only comes into being from the fact that thinking possesses the capacity to bring before the mind once more something that has once been perceived, by reproducing it as a presentation without the external object having still to be there. The first and immediate aim, therefore, of reality-testing is, not to find an object in real perception which corresponds to the one presented, but to refind such an object, to convince oneself that it is still there.”6 Though Freud doesn’t use terms from linguistics, it is clear that he is making refer- ence to the subject’s alienation in language and that he sees this alienation as the key to the emergence of both the subject and the object. When the subject submits to the imperatives of language, it enters into an indirect relation with the object world. The speaking being does not relate to books, pencils, and paper but to “books,” “pencils,” and “paper.” The signifier intervenes between the subject and the object that the subject perceives. The subject’s alienation into language deprives it of immediate contact with the object world. And yet, in the above passage from “Negation,” Freud conceives of the subject’s entrance into language — its “capacity to bring before the mind once more something that has once been perceived, by reproducing it as a presentation without the external object having still to be there” — as the event that produces the very distinction between subject and object. This means that the indirectness or mediation introduced by language deprives the subject of a direct relation to the object world that it never had. Prior to its immersion in the mediation of language, the subject had no object at all — not a privileged relation to objects but a complete absence of relationality as such due to its autoeroticism. In this sense, the subject’s willingness to accede to its alienation in language is the first creative act, a sacrifice that produces the objects that the subject cannot directly access. Language is important not for its own sake but because it is the site of our founding sacrifice. We know that the subject has performed this act of sacrifice when we witness the subject functioning as a being of language, but the sacrifice is not an act that the subject takes up on its own. Others always impose the entry into language on the subject. Their exhortations and incentives to speak prompt the emergence of the speaking subject. But the subject’s openness to alienation in language, its willingness to sacrifice a part of itself in order to become a speaking subject, suggests a lack in being itself prior to the entry into language. That is, the act through which the subject cedes the privileged object and becomes a subject coin- cides with language but is irreducible to it. The subject engages in the act of sacrifice because it does not find its initial autoeroticism perfectly sat- isfying — the unity of the autoerotic being is not perfect — and this lack of complete satisfaction produces the opening through which language and society grab onto the subject through its alienating process. If the initial autoerotic state of the human animal were perfectly satisfying, no one would begin to speak, and subjectivity would never form. Speaking as such testifies to an initial wound in our animal being and in being itself. But subjectivity emerges only out of a self-wounding. Even though others encourage the infant to abandon its autoerotic state through a multitude of inducements, the initial loss that constitutes subjectivity is always and neces- sarily self-inflicted. Subjectivity has a fundamentally masochistic form, and it continually repeats the masochistic act that founds it. The act of sacrifice opens the door to the promise of a satisfaction that autoerotic isolation forecloses, which is why the incipient subject abandons the autoerotic state and accedes to the call of sociality. But the term “sacrifice” is misleading insofar as it suggests that the subject has given up a wholeness (with itself or with its parent) that exists prior to being lost. In the act of sacrifice, the incipient subject gives up something that it doesn’t have. The initial loss that founds subjectivity is not at all substan- tial; it is the ceding of nothing. Through this defining gesture, the subject sacrifices its lost object into being. But if the subject cedes nothing, this initial act of sacrifice seems profoundly unnecessary. Why can’t the subject emerge without it? Why is the experience of loss necessary for the subject to constitute itself qua subject? The answer lies in the difference between need and desire. While the needs of the human animal are not dependent on the experience of loss, the subject’s desires are. It is the initial act of sacrifice that gives birth to desire: the subject sacri- fices nothing in order to create a lost object around which it can organize its desire. As Richard Boothby puts it in his unequaled explanation of the psychoanalytic conception of the emergence of desire, “The destruction and loss of the object . . . opens up a symbolic dimension in which what was lost might be recovered in a new form.”7 He adds: “Sacrifice serves to constitute the very matrix of desire. The essential function of sacrifice is less do ut des, I give so that you might give, than do ut desidero: I give in order that I might desire.”8 The subject’s desire is oriented around this lost object, but the object is nothing as a positive entity and only exists insofar as it is lost. This is why one can never attain the lost object or the object that causes one to desire.9 The coming-into-being of this object originates the subject of desire, but, having no substance, the object can never become an empirical object of desire. We may see an object of desire as embodying the lost object, but whenever we obtain this object, we discover its emptiness. The lost object is constitutively rather than empirically lost. Eating Nothing In this light, we can see the anorexic as the model for all desiring subjectivity. Most cultural critics justifiably see anorexia as the product of oppressive definitions of femininity that abound in contemporary society and force women to starve themselves in order to fit the ideals of feminine beauty. According to Naomi Wolf ’s classic popular account in The Beauty Myth, the ideal of thinness became a way of controlling women — disciplining their bodies — after the idea of natural female inferiority began to evanesce.10 The anorexic embodies female victimization: she has internalized a patriarchal ideal and does violence to her own body in order to live up to this ideal. But the problem with this analysis is that the anorexic doesn’t just try to embody the ideal of feminine beauty.11 She goes too far in her pursuit of thinness and comes to inhabit a body far from the ideal. Even when everyone tells her that she no longer looks good, that she is too thin, the anorexic continues to lose weight. It is for this reason that many feminists have seen her as a subversive figure. As Elizabeth Grosz puts it, “Neither a ‘disorder’ of the ego nor, as popular opinion has it, a ‘dieting disease’ gone out of control, anorexia can, like the phantom limb, be a kind of mourning for a pre-Oedipal (i.e., pre-castrated) body and a corporeal connection to the mother that women in patriarchy are required to abandon. Anorexia is a form of protest at the social meaning of the female body.”12 Grosz accounts for the excessiveness of anorexia by aligning it with feminist resistance to patriarchy rather than obsequious submission to it. But she aligns the anorexic with wholeness and the maternal bond rather than with the lost object. In this sense, she misses the true radicality of the anorexic, a radical- ity that stems from the power of the anorexic’s desire. The anorexic doesn’t simply refuse to eat but eats nothing, the nothing that is the lost object. While all positive forms of food fail to address the subject’s lack, nothing does speak to the subject’s desire and allows that desire to sustain itself. The anorexic starves not because she can’t find, in the mode of Kafka’s hunger artist, any food that would satisfy her but because she has found a satisfying food, a food that nourishes the desiring subject rather than the living being. The logic of anorexia lays bare the hidden work- ings of desire that operate within every subject. Subjects believe that they pursue various objects of desire (a new car, a new house, a new romantic partner, and so on) and that these objects have an intrinsic attraction, but the real engine for their desire resides in the nothing that the subject has given up and that every object tries and fails to represent. Objects of desire are desirable only insofar as they attempt to represent the impossible lost object, which is what the anorexic reveals. Still, the anorexic is exceptional; most nonanorexic subjects imagine that their lost object can be found in something rather than nothing. Despite its resonances with the structure of desire, anorexia cannot be dissociated from the imposition of the ideal of thinness as a mode of control- ling female subjectivity. Though this ideal distorts the anorexic’s relationship to her own body, it also renders the nature of desire itself apparent. The impossible ideal of perfect thinness allows the anorexic subject to avow, albeit unconsciously, the structural impossibility of desire itself. Unlike male subjects (or other female subjects who manage to distance themselves from the ideal), the anorexic cannot avoid confronting the impossibility of her object. The oppressive ideal of perfect thinness allows the anorexic to bear witness with her body to the truth of desire.13 Understanding the impossible nature of the lost object — what the anorexic makes clear — allows us to rethink the nature of the political act. Rather than being the successful achievement of some object, the accomplishment of some social good, the political act involves insisting on one’s desire in the face of its impossibility, which is precisely what occurs in the death drive. The key to a politics of the death drive is grasping, in the fashion of the anorexic, the nothingness of the object and thereby finding satisfaction in the drive itself. But the subject’s relationship to its object inherently creates an illusion that makes this possibility almost impossible. Though the lost object that initiates subjectivity has no substance, its status for the subject belies its nothingness. For the subject, the originary lost object is the object that seems to hold the key to the subject’s very ability to enjoy. Subjects invest the lost object with the idea of their own completion: the loss of the object retroactively causes a prior state of comple- tion to arise — a state of completion that never actually existed — and the object itself bears the promise of inaugurating a return to this imaginary prior state.14 In short, it promises to fill in the subject’s lack and answer its desire. As a result of this investment on the part of the subject, the initial lost object becomes the engine for all the subject’s subsequent desiring. Without the initial act of sacrifice, the would-be subject neither desires nor enjoys but instead suffocates in a world of self-presence, a self-presence in which one has no freedom whatsoever. Through the loss of the privileged object, one frees oneself from the complete domination of (parental or social) authority by creating a lack that no authority can fill. Ceding the object is thus the founding act of subjectivity and the first free act. Every subsequent effort by authority to give the subject what it lacks will come up short — or, more correctly, will go too far, because only nothing can fill the gap within the subject. For this reason, dissatisfaction and disappointment are correlative with freedom: when we experience the authority’s failure to give us what we want, at that moment we also experience our distance from the authority and our radical freedom as subjects.

#### Debate is structured by agential fantasy and is futile – only saying NO to the affirmative can solve

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“Ego,” then,names the economy of compensatory subjectivization driven by the repetition and refusal of demands. The nascent subject presents wants and needs in the form of the demand, but the role of the demand is not the simple fulfillment of these wants and needs. The demand and its refusal are the fulcrum on which the identity and insularity of the subject are produced: an unformed amalgam of needs and articulated demands is transformed into a subject that negotiates the vicissitudes of life with others. Put in the meta- phor of developmental psychology, an infant lodges the instinctual demands of the id on others but these demands cannot be, and for the sake of develop- ment, must not be fulfilled. Thus, pop psychology observations that the in- cessant demands of children for impermissible objects (“may i have a fourth helping of dessert”) or meanings that culminate in ungroundable authori- tative pronouncements (the game of asking never ending “whys”) are less about satisfaction of a request than the identity-producing effects of the pa- rental “no.” in “The Question of Lay Analysis,” freud argues that “if . . . demands meet with no satisfaction, intolerable conditions arise . . . [and] . . . the ego begins to function. . . . [T]he driving force that sets the vehicle in mo- tion is derived from the id, the ego . . . undertakes the steering. . . . The task of the ego [is] . . . to mediate between the claims of the id and the objections of the external world.”31 Later, in Group Psychology and the Analysis of the Ego, and Civilization and Its Discontents, freud relocates the site of the ego’s genesis beyond the parent/child relationship and in the broader social relationships that animate it. Life with others inevitably produces blockages in the indi- vidual’s attempts to fulfill certain desires, since some demands for the fulfill- ment of desires must be frustrated. This blockage produces feelings of guilt, which in turn are sublimated as a general social morality. The frustration of demand is both productive in that it authorizes social moral codes and, by ex- tension, civilization writ large, although it does so at the cost of imposing a contested relationship between desire and social mores.32 Confronted by student calls to join the movement of 1968 Lacan famously quipped: “as hysterics you demand a new master: you will get it!” under- standing the meaning of his response requires a treatment of Lacan’s theory of the demand and its relationship to hysteria as an enabling and constraining political subject position. Lacan’s theory of the demand picks up at freud’s movement outward from the paradigmatic relationships between the parent/ child and individual/civilization toward a more general account of the sub- ject, sociality, and signification. The infrastructure supporting this theoreti- cal movement transposes freud’s comparatively natural and genetic account of development to a set of metaphors for dealing with the subject’s entry into signification. As already noted, the Lacanian aphorism that “the signifier represents a subject for another signifier inverts the conventional wisdom that a pre-given subject uses language as an instrument to communicate its subjective inten- tions.”33 The paradoxical implication of this reversal is that the subject is si- multaneously produced and disfigured by its unavoidable insertion into the space of the Symbolic. An Es assumes an identity as a subject as a way of ac- commodating to the Symbolic’s demands and as a node for producing de- mands on its others or of being recognized as a subject.34 As i have already argued, the demand demonstrates that the enjoyment of one’s own subjec- tivity is useless surplus produced in the gap between the Es (or it) and the ideal i. As a result, there is excess jouissance that remains even after its reduc- tion to hegemony. This remainder may even be logically prior to hegemony, in that it is a useless but ritually repeated retroactive act of naming the self that produces the subject and therefore conditions possibility for investment in an identitarian configuration. The site of this excess, where the subject negotiates the terms of a non- relationship with the Symbolic, is also the primary site differentiating need, demand, and desire. need approximates the position of the freudian id, in that it is a precursor to demand. Demand is the filtering of the need through signification, but as Sheridan notes, “there is no adequation between need and demand.”35 The same type of split that inheres in the freudian demand inheres in the Lacanian demand, although in Lacan’s case it is crucial to no- tice that the split does not derive from the empirical impossibility of ful- filling demands as much as it stems from the impossibility of articulating needs to or receiving a satisfactory response from the other. Thus, the speci- ficity of the demand becomes less relevant than the structural fact that de- mand presupposes the ability of the addressee to fulfill the demand.This im- possibility points to the paradoxical nature of demand: the demand is less a way of addressing need to the other than a call for love and recognition by it. “in this way,” writes Lacan, “demand annuls the particularity of everything that can be granted by transmuting it into a proof of love, and the very sat- isfactions that it obtains for need are reduced to the level of being no more than the crushing of the demand for love.”36 The other cannot, by definition, ever give this gift: the starting presupposition of the mirror stage is the con- stitutive impossibility of comfortably inhabiting the Symbolic. The struc- tural impossibility of fulfilling demands resonates with the freudian de- mand in that the frustration of demand produces the articulation of desire. Thus, Lacan argues that “desire is neither the appetite for satisfaction, nor the demand for love, but the difference that results from the subtraction of the first from the second.”37 This sentiment animates the crucial Lacanian claim for the impossibility of the other giving a gift that it does not have, namely the gift of love: “all demand implies . . . a request for love. . . . Desire begins to take shape in the margin in which demand becomes separated from need: this margin being that which is opened up by demand, the appeal of which can be unconditional only in regards to the other . . . having no universal satisfaction. . . . it is this whim that introduces the phantom of omnipotence, not of the subject, but of the other in which his demand is installed.”38 This framing of demand reverses the classically liberal presupposition regarding demand and agency. Contemporary and classical liberal democratic theories presume that the demand is a way of exerting agency and, further, that the more firmly the demand is lodged, the greater the production of an agential effect. The Lacanian framing of the demand sees the relationship as exactly the opposite: the more firmly one lodges a demand, the more desperately one clings to the legitimate ability of an institution to fulfill it. Hypothetically, demands ought reach a kind of breaking point where the inability of an in- stitution or order to proffer a response should produce a reevaluation of the economy of demand and desire. in analytic terms, this is the moment of sub- traction, where the manifest content of the demand is stripped away and the desire that underwrites it is laid bare. The result of this “subtraction” is that the subject is in a position to relate to its desire, not as a set of deferrals, avoid- ances, or transposition but rather as an owned political disposition. As Lacan frames it, demanding subjects are either learning to reassert the centrality of their demand or coming to terms with the impotence of the other as a satisfier of demands: “But it is in the dialectic of the demand for love and the test of desire that development is ordered. . . . [T]his test of the desire of the other is decisive not in the sense that the subject learns by it whether or not he has a phallus, but in the sense that he learns that the mother does not have it.”39 The point of this disposition is to bring the subject to a point where they might “recognize and name” their own desire and, as a re- sult, become a political subject in the sense of being able to truly argue for something without being dependent on the other as a support for or orga- nizing principle for political identity. Thus, desire has both a general status and a specific status for each subject. it is not just the mirror that produces the subject and its investments but the desire and sets of proxy objects that cover over this original gap. As Easthope puts it: “Lacan is sure that everyone’s de- sire is somehow different and their own—lack is nevertheless my lack. How can this be if each of us is just lost in language . . . passing through demand into desire, something from the Real, from the individual’s being before lan- guage, is retained as a trace enough to determine that i desire here and there, not anywhere and everywhere. Lacan terms this objet petit a . . . petit a is dif- ferent for everyone; and it can never be in substitutes for it in which i try to refind it.”40 Though individuated, this naming is not about discovering a latently held but hidden interiority, rather it is about naming a practice of thinking the uniqueness of individual subjects as a product of discourses that produce them. Thus, this is an account of political subjectivization that is not solely oriented toward or determined by the locus of the demand but that is also determined by the contingent sets of coping strategies that orient a sub- ject toward others and a political order and serve as the condition of possi- bility for demands.As Lacan argues,this is the point where a subject becomes a kind of new presence or a new political possibility:“That the subject should come to recognize and to name his desire; that is the efficacious action of analysis. But it isn’t a question of recognizing something which would be en- tirely given. . . . in naming it, the subject creates, brings forth, a new presence in the world.”41 Alternatively, subjects can stay fixated on the demand, but in doing so they forfeit their desire, or as fink argues, “an analysis . . . that . . . does not go far enough in constituting the subject as desire leaves him or her stranded at the level of demand . . . unable to truly desire.”42 A politics defined by and exhausted in demands is by definition a hysterical politics. The hysteric is defined by incessant demands on the other at the ex- pense of ever articulating a desire that is theirs. in the Ethics of Psychoanaly- sis, Lacan argues that the hysteric’s demand that the other produce an object is the support of an aversion toward one’s desire: “the behavior of the hys- teric, for example, has as its aim to recreate a state centered on the object, in- sofar as this object . . . is . . . the support of an aversion.”43 This economy of aversion explains the ambivalent relationship between hysterics and their de- mands. on one hand, the hysteric asserts their agency, even authority, over the other.yet, what appears as unfettered agency from the perspective of a discourse of authority is also simultaneously a surrender of desire by enjoy- ing the act of figuring the other as the one with the exclusive capability to satisfy the demand. Thus, “as hysterics you demand a new master: you will get it!” At the register of manifest content, demands are claims for action and seemingly powerful, but at the level of the rhetorical form of the demand or in the reg- ister of enjoyment, demand is a kind of surrender. As a relation of address the hysterical demand is more a demand for recognition and love from an os- tensibly repressive order than a claim for change. The limitation of the stu- dents’ call on Lacan does not lie in the end they sought but in the fact that the hysterical address never quite breaks free from its framing of the master. The fundamental problem of democracy is not articulating resistance over and against hegemony but rather the practices of enjoyment that sustain an addiction to mastery and a deferral of desire. Hysteria is a politically effective subject position in some ways, but it is politically constraining from the perspective of organized political dissent. if not a unidirectional practice of resistance, hysteria is at best a politics of interruption. imagine a world where the state was the perfect and complete embodiment of a hegemonic order, without interruption or remainder, and the discursive system was hermetically closed. Politics would be an impos- sibility: with no site for contest or reappropriation, politics would simply be the automatic extension of structure. Hysteria is a site of interruption, in that hysteria represents a challenge to our hypothetical system, refusing straight- forward incorporation by its symbolic logic. But, stepping outside this hy- pothetical non-polity, on balance, hysteria is politically constraining because the form of the demand, as a way of organizing the field of political enjoy- ment, requires that the system continue to act in certain ways to sustain its logic. Though on the surface it is an act of symbolic dissent, hysteria rep- resents an affirmation of a hegemonic order and is therefore a particularly fraught form of political subjectivization.

#### They destroy the possibility for politics, ethics, and the value of life, and their defense will prove my point— controls the internal link to all other impacts

Ruti ‘14 (mari, English, Toronto, Psychoanalysis, Culture & Society (2014) 19, 297–314) SJBE, recut from Harvard BoSu

On the other hand, Lacan – again like Marcuse – recognizes that the symbolic order is repressive beyond the demands of subject formation, that it includes forms of violence that exceed the ubiquitous violence of the signifier. Indeed, even the violence of the signifier is not equally distributed, so that some of us are much more vulnerable to its injurious effects than others (consider, for instance, hate speech). Lacan does not necessarily talk about the unequal distribution of resources in the manner Marcuse does, but there is no doubt that his analysis of symbolic law as the Law of the Father elucidates a historically specific, deeply heteropatriarchal and hierarchical organization of social life. In point of fact, one reason I have taken a detour through Marcuse is to illustrate the obvious ways in which Lacan’s portraiture of the symbolic mirrors that of Marcuse’s explicitly historical account: what Marcuse calls “the performance principle,” Lacan calls the “service of goods.” Both thinkers identify the underpinnings of a social order dominated by the ideal of productivity – an ideal that is, moreover, placed in direct opposition to the pleasure principle. Both emphasize that the dominant morality of this symbolic – what Lacan calls “the morality of the master” – measures the merit of lives based on largely pragmatic criteria. And both acknowledge that the model citizen of this symbolic is a subject who shows up at work reliably every morning, performs its duties with a degree of diligence, does not let its desires get the better of its productivity, and seeks satisfaction (“enjoys”) in moderate, socially sanctioned ways. “Part of the world has resolutely turned in the directions of the service of goods,” Lacan writes, “thereby rejecting everything that has to do with the relationship of man to desire” (318). This, he adds, “is what is known as the postrevolutionary perspective” (318). In other words, the service of goods reflects the mindset of the levelheaded utilitarian subject who has deemed revolutionary change to be unrealistic. Lacan is here referring to the kind of depoliticization that is arguably the hallmark of Western subjectivity under capitalism. Lacan’s point is by no means, as critics such as Butler have suggested, that a different kind of symbolic is intrinsically impossible but rather that the configuration of subjectivity that Western modernity has produced – a subjectivity that has been subjected to a particular form of surplus-repression (the performance principle, the service of goods) – makes it virtually impossible for us to entertain the idea that the symbolic could be organized differently, that it could be centered around a different version of the reality principle. As Marcuse remarks, one reason the performance principle is so powerful is that it has managed to convince us that all alternatives to it are either utopian or otherwise unpalatable. Yet, for Marcuse, the fact that this principle has been so successful also points to the possibility of transcending it. As he states, “The very progress of civilization under the performance principle has attained a level of productivity at which the social demands upon instinctual energy to be spent in alienated labor could be considerably reduced. Consequently, the continued repressive organization of the instincts seems to be necessitated less by the ‘struggle for existence’ than by the interest in prolonging this struggle – by the interest in domination” (pp. 129–130). This is to say that there is really nothing besides social power that keeps us invested in the notion that our welfare demands relentless toil. The performance principle has outlived its usefulness in the sense that our collective productivity these days surpasses what is necessary for the provision of food, clothing, housing, and other basic amenities. The fact that these amenities have not yet reached all corners of the world, or even all corners of our own society (the homeless, innercity dwellers, etc.), is a function of domination (the unequal distribution of resources) rather than of any deficiencies of productivity. As a result, in Marcuse’s view, all we would need to do to bring about a more “non-repressive civilization” (p. 134) would be to refuse the parameters of the current symbolic; even something as simple as reducing the length of the working day would immediately realign our priorities, perhaps even impacting the very organization of our psychic lives. Our standard of living might drop somewhat, but we might also learn to assess the value of our lives according to other, less performance-oriented, measurements. Psychoanalysis, particularly Lacanian analysis, does not have a normative goal; it does not seek to tell us how we should desire but merely to explore the idiosyncratic contours of our desire. But this does not change the fact that Lacan, at least as a theorist, was exasperated by people’s inability to make their way out of the maze of the master’s morality, including its performance principle; he was frustrated by individuals who were so out of touch with the truth of their desire that they were willing to sacrifice this desire for the sake of social conformity and that they were, furthermore, willing to do so to the point of self-betrayal. As he explains, “What I call ‘giving ground relative to one’s desire’ is always accompanied in the destiny of the subject by some betrayal – you will observe it in every case and should note its importance. Either the subject betrays his own way, betrays himself, and the result is significant for him, or, more simply, he tolerates the fact that someone with whom he has more or less vowed to do something betrays his hope and doesn’t do for him what their pact entailed” (p. 321). Such a betrayal invariably results in the reassertion of the status quo, sending the subject back to the service of goods, what Lacan in this context calls “the common path” (p. 321). And given that desire, for Lacan, is “the metonymy of our being” (p. 321), betraying it in this way leads to the kind of psychic death that extinguishes the subject’s sense of agency. To use Lacan’s wording, “Doing things in the name of the good, and even more in the name of the good of the other, is something that is far from protecting us not only from guilt but also from all kinds of inner catastrophes” (p. 319). It is precisely such inner catastrophes that Lacanian clinical practice was designed to counter, though it may be Julia Kristeva – rather than Lacan himself – who has most clearly developed this interpretation of analytic work. Kristeva depicts psychoanalysis as a means of restoring the subject’s psychic aliveness, as an explicit revolt against the numbing impact of what she calls “the society of the spectacle” (2002, p. 4). This society of the spectacle – of technology, image, and speed – shares many parallels with Adorno’s “culture industry”: a flattened surface of the life world, a constriction of psychic space, a death of critical thought, the worship of efficiency over intellectual curiosity, and the incapacity to revolt. Against this backdrop, psychoanalysis – along with art, writing, and some forms of religious experience – offers, for Kristeva, a gateway to revolt, a way of resurrecting “the life of the mind” (a phrase Kristeva borrows from Hannah Arendt) through ongoing questioning, interrogation, and psychic recreation. “Freud founded psychoanalysis as an invitation to anamnesis in the goal of a rebirth, that is, a psychical restructuring,” Kristeva writes: “Through a narrative of free association and in the regenerative revolt against the old law (familial taboos, superego, ideals, oedipal or narcissistic limits, etc.) comes the singular autonomy of each, as well as a renewed link with the other” (2002, p. 8). In the context of my overall argument in this essay, it is worth stressing that it is “the desire of the subject” that, in Kristeva’s view, reserves a place “for initiative, autonomy” (2002, p. 11). This is in part because the “Freudian journey into the night of desire was followed by attention to the capacity to think: never one without the other” (2010, p. 41). In other words, the exploration of desire, in psychoanalysis, is akin to the critical (or at least curious) movement of thought – the very movement that Arendt also saw as vital to the life of the mind. This is why psychoanalysis has, Kristeva asserts, “the (unique?) privilege today of accompanying the emergence of new capacities of thinking/representing/thinking, beyond the frequent and increasingly noticeable disasters of psychosomatic space – capacities that are so many new bodies and new lives” (2010, pp. 41–42). Kristeva therefore draws the same link between desire and autonomy (in this instance, the capacity for critical thought) as Lacan does. Furthermore, to translate Kristeva’s point into Marcuse’s terminology, one might say that psychoanalysis, at least the kind of analysis that refuses to uphold social adaptation as a therapeutic goal, presents the possibility of sidestepping, or at the very least diminishing, the effects of surplus-repression. This, in turn, creates space for the truth of the subject’s desire in the Lacanian sense. This does not mean that repression as such is defeated. Quite the contrary, as we will see shortly, the truth of the subject’s desire is inextricable from the primary (constitutive) repression that accompanies subject formation. But as I have already suggested, the lifting of surplus-repression renders the imprint of primary repression more clearly discernable, for when surplus-repression is removed, what remains are the always highly singular outlines of primary repression. And if Lacan – like Marcuse – sought to remove surplus-repression, it was because he understood that it was on the level of primary repression (fundamental fantasies) that one could find the most basic building blocks of the subject’s psychic destiny; primary repression was the layer of psychic life that expressed something essential about the distinctive ways in which the pleasure principle, in the subject’s life, had become bound up with the repetition compulsion. This is why Lacan states, “If analysis has a meaning, desire is nothing other than that which supports an unconscious theme, the very articulation of that which roots us in a particular destiny, and that destiny demands insistently that the debt be paid, and desire keeps coming back, keeps returning, and situates us once again in a given track, the track of something that is specifically our business” (p. 319).According to Lacan, analysis aims to enable us to understand something about the eccentric specificity (or truth) of our most fundamental desire as well as about the track of destiny that this desire carves out for us (and that is therefore “specifically our business”). If it is indeed the case, as I have conceded, that most of us tend to be alienated from our desire, Lacanian analysis strives to undo this alienation by familiarizing us with the truth of this desire. This process entails, among other things, recognizing that the destiny we owe to this desire can never be definitively overcome, that the debt of desire can never be fully redeemed (for how are we to compensate the signifier for having brought us into being as subjects of desire?). Our destiny – which might initially coincide quite seamlessly with our repetition compulsion – consists of recurring efforts to pay off this debt, which is why it keeps ushering us to the same track of desire, the same nexus of psychic conundrums, our unconscious hope being that if we wear out the track of our desire by incessant reiteration, one day we might be able to absolve ourselves of our debt. But since we cannot, the only thing to be done is to “own” our destiny even as we might seek to mitigate its more painful dimensions. That is, the only way to arrive at the kind of psychic rebirth Kristeva is talking about is to take full responsibility for our (unconsciously generated) destiny. In the ethical act, our impulse is to embrace this destiny wholesale regardless of consequences (this is one way to understand what it means to plunge into the jouissance of the real). In analysis, the exploration of our destiny is more gradual, more self-reflexive. But in both cases, the point is not to obliterate our foundational destiny (or fundamental fantasies) but merely to elaborate it in more satisfying directions, away from the incapacitating effects of the repetition compulsion and toward the rewards of subjective autonomy. And, if we are to achieve this goal, nothing is more important than staying faithful to the truth of desire that, on the most elementary level, determines our destiny.

#### Vote negative to embrace the lack – this requires being open to the anxiety that occurs from an encounter with the real of the other and breaks down fantasy and drives.

McGowan 3 Todd McGowan, 2013, “Enjoying What We Don’t Have: The Political Project of Psychoanalysis,” University of Nebraska Press/Lincoln and London, SJBE

The alternative — the ethical path that psychoanalysis identifies — demands an embrace of the anxiety that stems from the encounter with the enjoying other. If there is a certain ethical dimension to anxiety, it lies in the rela- tionship that exists between anxiety and enjoyment. Contra Heidegger, the ethics of anxiety does not stem from anxiety’s relation to absence but from its relation to presence — to the overwhelming presence of the other’s enjoyment. In some sense, the encounter with absence or nothing is easier than the encounter with presence. Even though it traumatizes us, absence allows us to constitute ourselves as desiring subjects. Rather than producing anxiety, absence leads the subject out of anxiety into desire. Confronted with the lost object as a structuring absence, the subject is able to embark on the pursuit of the enjoyment embodied by this object, and this pursuit provides the subject with a clear sense of direction and even meaning. This is precisely what the subject lacks when it does not encounter a lack in the symbolic structure. When the subject encounters enjoyment at the point where it should encounter the absence of enjoyment, anxiety overwhelms the subject. In this situation, the subject cannot constitute itself along the path of desire. It lacks the lack — the absence — that would provide the space through which desire could develop. Consequently, this subject confronts the enjoying other and experiences anxiety. Unlike the subject of desire — or the subject of Heideggerean anxiety — the subject who suffers this sort of anxiety actually experiences the other in its real dimension.¶ The real other is the other caught up in its obscene enjoyment, caught up in this enjoyment in a way that intrudes on the subject. There is no safe distance from this enjoyment, and one cannot simply avoid it. There is nowhere in the contemporary world to hide from it. As a result, the contem- porary subject is necessarily a subject haunted by anxiety triggered by the omnipresent enjoyment of the other. And yet, this enjoyment offers us an ethical possibility. As Slavoj Žižek puts it, “It is this excessive and intrusive jouissance that we should learn to tolerate.”27 When we tolerate the other’s “excessive and intrusive jouissance” and when we endure the anxiety that it produces, we acknowledge and sustain the other in its real dimension.¶ Tolerance is the ethical watchword of our epoch. However, the problem with contemporary tolerance is its insistence on tolerating the other only insofar as the other cedes its enjoyment and accepts the prevailing symbolic structure. That is to say, we readily tolerate the other in its symbolic dimen- sion, the other that plays by the rules of our game. This type of tolerance allows the subject to feel good about itself and to sustain its symbolic identity. The problem is that, at the same time, it destroys what is in the other more than the other — the particular way that the other enjoys.¶ It is only the encounter with the other in its real dimension — the encounter that produces anxiety in the subject — that sustains that which defines the other as such. Authentic tolerance tolerates the real other, not simply the other as mediated through a symbolic structure. In this sense, it involves the experience of anxiety on the part of the subject. This is a difficult posi- tion to sustain, as it involves enduring the “whole opaque weight of alien enjoyment on your chest.”The obscene enjoyment of the other bombards the authentically tolerant subject, but this subject does not retreat from the anxiety that this enjoyment produces. If the embrace of the anxiety that accompanies the other’s proximate enjoyment represents the ethical position today, this does not necessarily provide us with an incentive for occupying it. Who wants to be ethical when it involves enduring anxiety rather than finding a way — a drug, a new authority, or something — to alleviate it? What good does it do to sustain oneself in anxiety? In fact, anxiety does the subject no good at all, which is why it offers the subject the possibility of enjoyment. When the subject encounters the other’s enjoyment, this is the form that its own enjoyment takes as well. To endure the anxiety caused by the other’s enjoyment is to experience one’s own simultaneously. As Lacan points out, when it comes to the enjoyment of the other and my own enjoyment, “nothing indicates they are distinct.” Thus, not only is anxiety an ethical position, it is also the key to embracing the experience of enjoyment. To reject the experience of anxiety is to flee one’s own enjoyment.¶ The notion that the other’s enjoyment is also our own enjoyment seems at first glance difficult to accept. Few people enjoy themselves when they hear someone else screaming profanities in the workplace or when they see a couple passionately kissing in public, to take just two examples. In these instances, we tend to recoil at the inappropriateness of the activity rather than enjoy it, and this reaction seems completely justified. The public display of enjoyment violates the social pact with its intrusiveness; it doesn’t let us alone but assaults our senses. It violates the implicit agreement of the public sphere constituted as an enjoyment-free zone. And yet, recoiling from the other’s enjoyment deprives us of our own.¶ How we comport ourselves in relation to the other’s enjoyment indi- cates our relationship to our own. What bothers us about the other — the disturbance that the other’s enjoyment creates in our existence — is our own mode of enjoying. If we did not derive enjoyment from the other’s enjoyment, witnessing it would not bother us psychically. We would sim- ply be indifferent to it and focused on our own concerns. Of course, we might ask an offending car radio listener to turn the radio down so that we wouldn’t have to hear the unwanted music, but we would not experience the mere exhibition of alien enjoyment through the playing of that music as an affront. The very fact that the other’s enjoyment captures our attention demonstrates our intimate — or extimate — relation to it. This relation becomes even clearer when we consider the epistemo- logical status of the enjoying other. Because the real or enjoying other is irreducible to any observable identity, we have no way of knowing whether or not the other really is enjoying. A stream of profanity may be the result of someone hurting a toe. The person playing the car radio too loud while sitting at the traffic light may have simply forgotten to turn down the radio after driving on the highway. Or the person may have difficulty hearing. The couple’s amorous behavior in public may reflect an absence of enjoyment in their relationship that they are trying to hide from both themselves and the public.¶ Considering the enjoyment of the other, we never know whether it is there or not. If we experience it, we do so through the lens of our own fantasy. We fantasize that the person blasting the radio is caught up in the enjoyment of the music to the exclusion of everything else; we fantasize that the public kisses of the couple suggest an enjoyment that has no concern for the outside world. Without the fantasy frame, the enjoying other would never appear within our experience.¶ The role of the fantasy frame for accessing the enjoying other becomes apparent within Fascist ideology. Fascism posits an internal enemy — the figure of the Jew or some analogue — that enjoys illicitly at the expense of the social body as a whole. By attempting to eliminate the enjoying other, Fascism hopes to create a pure social body bereft of any stain of enjoy- ment. This purity would allow for the ultimate enjoyment, but it would be completely licit. This hope for a future society free of any stain is not where Fascism’s true enjoyment lies, however. Fascists experience their own enjoyment through the enjoying other that they persecute. The enjoy- ment that the figure of the Jew embodies is the Fascists’ own enjoyment, though they cannot avow it as their own. More than any other social form, Fascism is founded on the disavowal of enjoyment — the attempt to enjoy while keeping enjoyment at arm’s length. But this effort is not confined to Fascism; it predominates everywhere, because no subjects anywhere can simply feel comfortable with their own mode of enjoying.¶ The very structure of enjoyment is such that we cannot experience it directly: when we experience enjoyment, we don’t have it; it has us. We experience our own enjoyment as an assault coming from the outside that dominates our conscious intentions. This is why we must fantasize our own enjoyment through the enjoying other. Compelled by our enjoyment, we can’t do otherwise; we act against our self-interest and against our own good. Enjoyment overwhelms the subject, even though the subject’s mode of enjoying marks what is most singular about the subject.¶ Even though the encounter with the enjoying other apprehends the real other through the apparatus of fantasy, this encounter is nonetheless genuine and has an ethical status. Unlike the experience of the nonexistent symbolic identity, which closes down the space in which the real other might appear, the fantasized encounter with the enjoying other leaves this space open. By allowing itself to be disturbed by the other on the level of fantasy

## 3

#### CP text: The member nations of the world trade organization should add more stringent requirements for filing secondary patents by requiring secondary patent filers to demonstrate increased efficacy as compared to the original. Solves all your offense by reducing purely strategic patents while permitting R and D for genuine improvements.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

The current framework for evaluating a patent application, particularly the requirements of utility and nonobviousness, is insufficient for evaluating whether a secondary patent should be issued for a drug. Given that courts are tied to the low bar for utility and inconsistent with their application of nonobviousness,1 04 it is necessary to pass legislation creating a new utility requirement tailored to secondary pharmaceutical patents. This Note's Author proposes legislation language as follows: 35 U.S.C. § 106: Patentable Pharmaceutical Inventions (a) Utility requirement for secondary patent: In the case of a pharmaceutical invention claiming an improvement on a patented invention, the applicant shall demonstrate through clear and convincing evidence in the written description that such invention has increased efficacy as compared to the original. (b) Increased efficacy defined: As used in part (a), "increased efficacy" refers to a proven improvement in the mechanism of action, as disclosed in the patent claims. 0 5 (c) Mechanism of action defined: As used in part (b), "mechanism of action" refers to the process by which a drug functions to produce a therapeutic effect, as disclosed in the patent claims. 06 Under this legislation, the USPTO could grant a secondary patent only if the new formula's mechanism of action, or production of the intended pharmacological effect, in fact improves upon the patented drug's mechanism of action. For example, because VidaDrug is a chemotherapy drug, the new formula must include a change in the mechanism of action which causes an improvement in the efficacy of the drug's tumor-shrinking abilities to be eligible for a secondary patent. A formula tweak that reduces side effects is insufficient, because the underlying purpose of the drug - to treat cancer - remains unaffected. Lowell provides some precedent for creating a higher utility standard. 07 This new standard would focus on a drug's overall improved efficacy, rather than a minor tweak in the formula that would mitigate or resolve a previously caused side effect. This standard would require holding the pharmaceutical industry to a higher standard than other industries, which could potentially conflict with the United States' TRIPS Agreement obligations with the WTO.

#### Solves best

Newsome 2, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

Pharmaceutical patents are inherently different from software or manufacturing patents. 144 Pharmaceutical companies create life-saving drugs that carry a very serious benefit for a vulnerable group of consumers - patients. Because of this, the pharmaceutical industry should be held to a higher standard if its companies seek to prohibit affordable generic drugs from coming to the marketplace. An Efficacy-Focused Standard Will Motivate Pharmaceutical Companies to Channel Resources to Creating Real Innovation Pharmaceutical companies argue that patent-life-cycle-management strategies (their preferred name for those tactics described herein as evergreening) are essential to ensuring they recoup R&D costs. 145 However, creation of a standard such as the one proposed here would ensure that pharmaceutical companies are properly incentivized to channel R&D resources to creating measurable change in the drugs, rather than creating minor changes that prolong the time they can profit off of monopolies at the expense of patients. For those industries in which R&D is more productive, like the pharmaceutical industry, "patent procedures should be refined to tighten the relationship between patents and the underlying inventions."14 6 A Higher Standard for Secondary Pharmaceutical Patents Will Increase Competition & Lead to Lower Prices The patent system enables pharmaceutical companies to retain market exclusivity for their drugs, allowing them to set high prices without an eye toward competition.1 47 The companies cite the need to recoup R&D costs as the driving factor for their pricing decisions,148 but critics say their main motivation is making a profit.'49 While the pharmaceutical companies' argument may hold weight, high prices for drugs have a negative impact on those patients who need those drugs, but cannot afford them.150 Tightening patent laws to prevent pharmaceutical companies from retaining patent protection for minor changes in their patented drugs will allow other companies to enter the marketplace sooner and drive prices down through competition. 5

## Case

### TL

#### [1] No solvency, no evidence that the aff spurns innovation.

#### [2] If second companies can repurpose that means a. they don’t solve innovation since companies will just direct r and d towards repurposing research instead of developing new drugs. B. plan gets circumvented. Companies can just acquire smaller companies to get their patents.

#### The WTO can’t enforce the aff- causes circumvention.

Lamp 19 [Nicholas; Assistant Professor of Law at Queen’s University; “What Just Happened at the WTO? Everything You Need to Know, Brink News,” 12/16/19; <https://www.brinknews.com/what-just-happened-at-the-wto-everything-you-need-to-know/>] Justin

Nicolas Lamp: For the first time since the establishment of the WTO in 1995, the Appellate Body cannot accept any new appeals, and that has knock-on effects on the whole global trade dispute settlement system. When a member appeals a WTO panel report, it goes to the Appellate Body, but if there is no Appellate Body, it means that that panel report will not become binding and will not attain legal force.

The absence of the Appellate Body means that members can now effectively block the dispute settlement proceedings by what has been called appealing panel reports “into the void.”

The WTO panels will continue to function as normal. When a panel issues a report, it will normally be automatically adopted — unless it is appealed. And so, even though the panel is working, the respondent in a dispute now has the option of blocking the adoption of the panel’s report. It can, thereby, shield itself from the legal consequences of a report that finds that the member has acted inconsistently with its WTO obligations.

### 1NC – Exclusitivites Defecit

#### THE AFF ONLY IMPACTS PATENTS AND NOT NON-PATENT EXCLUSIVITIES. THEY ARE DISTINCT WHICH MEANS THE AFF DOESN’T SOLVE SINCE COMPANIES STILL HAVE ACCESS TO EXCLUSIVITY MEASURES

FDA 20 (FDA, 2/5/2020, Frequently Asked Questions on Patents and Exclusivity, https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What\_is\_the\_difference\_between\_patents\_a)

[1. What is the difference between patents and exclusivity?](https://www.fda.gov/drugs/development-approval-process-drugs/null)  
Patents and exclusivity work in a similar fashion but are distinct from one another and governed by different statutes. Patents are a property right granted by the United States Patent and Trademark Office anytime during the development of a drug and can encompass a wide range of claims.  Exclusivity refers to certain delays and prohibitions on approval of competitor drugs available under the statute that attach upon approval of a drug or of certain supplements.  A new drug application (NDA) or abbreviated new drug application (ANDA) holder is eligible for exclusivity if statutory requirements are met.  See 21 C.F.R. 314.108, 316.31, 316.34 and sections 505A, 505E, and 505(j)(5)(B)(iv) of the FD&C Act.  Periods of exclusivity and patent terms may or may not run concurrently. Exclusivity was designed to promote a balance between new drug innovation and greater public access to drugs that result from generic drug competition.

#### YOUR OWN AUTHOR SAYS EXCLUSIVITIES ARE KEY PART OF EVERGREENING

**Feldman 2** (Robin Feldman 18, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, <https://doi.org/10.1093/jlb/lsy022> Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation (Study Notes: Presenting the first comprehensive study of evergreening, this article examines the extent to which evergreening behavior—which can be defined as artificially extending the protection cliff—may contribute to the problem. The author analyses all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity.)

Anecdotal evidence has identified strategic behaviors various companies have deployed to great effect. One such practice is ‘evergreening’, which can be defined as artificially extending the life of a patent or other exclusivity by obtaining additional protections to extend the monopoly period.[30](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn30) Scholarly work, including our own, has documented these behaviors as examples have emerged in individual cases and in press reports.[31](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn31) What has been missing from the literature, however, is a comprehensive empirical view.[32](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn32) Just how pervasive are such behaviors? Is it simply a matter of certain bad actors, to whom everyone points repeatedly, or is the problem endemic to the industry? Only by answering this question can we contemplate the extent to which reforms are needed, as well as the extent to which strategic behavior to block generic competition may be contributing to rising drug prices. This study answers the questions. Providing a robust empirical analysis was no easy task. Transparency is not in the industry's interests, and companies have been known to go to great lengths to camouflage strategic behavior.[33](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn33) After all, a pharmaceutical company would be loath to let regulators and legislators know what it is up to, let alone competitors who might mimic the clever strategies. To accomplish our study, we turned to government sources, analysing more than a decade of data published by the US Food and Drug Administration (FDA). This involved extracting and analysing detailed information on as many as 11 different aspects of roughly 1800 drugs. The task would have been sufficiently challenging if the information were readily available. It was not. The project required teasing information painstakingly out of each monthly and annual publication, many of which are no longer available from the government in any form. Moreover, the complexities of pharmaceutical regulation and approval require intricate analysis of the information disclosed by the government, when that information is disclosed at all. In all, our work required assembling and analysing over 160,000 individual cells of data, all entered by hand. The results, however, were striking, and they show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. The data demonstrate that throughout the industry, companies create serial barriers to hold off the type of competitive entry that is fundamental to our innovative system. Key results from our 2005 to 2015 study include the following: Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, 78% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% had their protection extended at least once, with almost 50% having the protection cliff extended more than once. Looking at the full group, almost 40% of all drugs available on the market created additional market barriers by having patents or exclusivities added on to them. Once a company starts down this road, there is a tendency to keep returning to the well. Eighty per cent of those who added protections added more than one. Among those adding more than one barrier, some were serial offenders, with almost half adding 4 or more protections and some adding more than 20. The problem is growing across time. The number of drugs that had a patent added on to them almost doubled during the time period. The addition of certain other types of barriers increased at an even greater rate, with some tripling.[34](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn34) These results may easily understate the landscape. In designing the methodology, we repeatedly adopted a conservative approach, following the path that would point away from suggesting a competitive barrier. In addition, the pharmaceutical industry has developed techniques for erecting competitive barriers that do not involve obtaining additional patents and exclusivities, techniques that would not be captured by our analysis.[35](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn35) Finally, we could only quantify those behaviors of which we are aware. Much behavior in the pharmaceutical industry remains obscured, and we cannot measure what we cannot see.[36](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/#fn36)

### 1NC – AT: Innovation

#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**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? T**he 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 averace, 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 treatmentscof 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 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### The affs wholesale attack on secondary patents ruins innovation---prefer contingencies that solve evergreening.

Holman 18 [Christopher; 9/21/18; Professor at the University of Missouri-Kansas City School of Law, where his primary research focus lies at the intersection of intellectual property and biotechnology; “*Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection*,” Intellectual property watch, <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/>] Justin

Why Protect Follow-On Innovation? The attack on secondary pharmaceutical patents is based in part on the flawed premise that follow-on innovation is of marginal value at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, follow-on innovation can play a critical role in transforming an interesting drug candidate into a safe and effective treatment option for patients. A good example can be seen in the case of AZT (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT began its life as a failed attempt at a cancer drug, and it was only years later that its potential application in the fight against AIDS was realized. Follow-on research resulted in a method-of-use patent directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate. Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include Evista (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), Zyprexa (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime. Pharmaceutical development is prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself. The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation. Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day. Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate). “Evergreening” – an Incoherent Concept Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation. Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs. Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself. For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself.

#### Strong IP protection are the only incentive for drug innovation.

Stevens and Ezell 20 Philip Stevens and Stephen Ezell 2-3-2020 "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" <https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work> (Philip founded Geneva Network in 2015. His main research interests are the intersection of intellectual property, trade, and health policy. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division on a range of IP and health issues. Prior to his time with WIPO, Philip worked as director of policy for International Policy Network, a UK-based think tank, as well as holding research positions with the Adam Smith Institute and Reform, both in London. He has also worked as a political risk consultant and a management consultant. He is a regular columnist in a wide range of international newspapers and has published a number of academic studies. He holds degrees from the London School of Economics and Durham University (UK).)//Elmer

The **Current System** Has **Produced a Tremendous Amount of Life-Sciences Innovation** The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.24 And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that **noncommunicable** diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities **in developing countries**.25 Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.26 Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.27 To develop treatments or cures for these conditions, novel biomedical innovation **will be needed from everywhere**. Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over **$1.36 trillion in R&D** in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, **943 new active substances have been introduced** globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than **500 new medicines since 2000** alone. And these medicines are getting to more individuals: Global medicine use **in 2020 will reach 4.5 trillion doses**, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the **world’s most intractable diseases**, **including cancer and Alzheimer’s**.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved **41 new medicines** (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through **enhanced clinical efficacy** (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, **or better treatment** for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures. For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients’ liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.36 “If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the Financial Times. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”37 Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.38 As Geoffrey Dusheiko and Charles Gore write in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”39 As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because … without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”40 Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary **to induce companies to invest** in researching new chemical entities.”41 This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical **companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investment**s.42 Indeed, **it’s the ability to recoup fixed costs, not just marginal** costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, **there would be no new drugs developed**, just as there would be no new products developed in any industry. Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.43 A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to $2.8 billion.44 Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of $1.7 billion to $**3.2 billion**.45 IP rights—including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the **confidence** to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.46 Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.47 As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, **in the global public’s long-term interests.** Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”48 Put simply, the current market- and IP-based life-sciences innovation system is producing life-changing biomedical innovation. As Jack Scannell, a senior fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation has explained, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.” He continued, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”49 For example, on September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche’s Avastin, a breakthrough anticancer drug when it came out in the mid-1990s for lung, cervical, and colorectal cancer.50 In other words, a medicine to treat forms of cancer that barely existed 20 years ago is now available as a generic drug today. It’s this dynamic that enables us to imagine a situation wherein drugs to treat diseases that aren’t available anywhere at any price today (for instance, treatments for Alzheimer’s or Parkinson’s) might be available as generics in 20 years. But that will only be the case if we preserve (and improve where possible) a life-sciences innovation system that is generally working. The current system does not require wholesale replacement by a prize-based system that—notwithstanding a meaningful success here or there—has produced nowhere near a similar level of novel biomedical innovation.

#### Secondary and Follow-on patents are key to innovation.

IP Watch 18 9-21-2018 "Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection" <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> (a non-profit independent news service that provides professional coverage of global policymaking on intellectual property and innovation.)//Elmer

Why Protect Follow-On Innovation? The **attack on secondary** pharmaceutical **patents is based** in part **on** the **flawed premise** that **follow-on innovation is of marginal value** at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, **follow-on innovation** **can play** a **critical role in transforming** **an interesting drug candidate into a safe and effective treatment option** for patients. A good example can be seen in the case of **AZT** (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT **began** its life **as a** failed attempt at a **cancer drug**, and it was **only years later** that its potential **application in the fight against AIDS** was realized. Follow-on research resulted in a method-of-use patent directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate. Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include **Evista** (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), **Zyprexa** (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime. **Pharmaceutical development** **is prolonged and unpredictable**, and frequently **a safe and effective drug** **occurs only as a result of** **follow-on innovation** occurring **long** **after the initial synthesis** and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself. The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation. Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day. Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate).

### AMR

#### Low prices cause AMR.

Babu and Suma 6 Babu, Varsha, and C. Suma. "Antibiotic pricing: when cheaper may not be better." Clinical infectious diseases 43.8 (2006): 1085-1086. (Government Primary Health Center)//Elmer

To The Editor—Antibiotics in India have always been cheaper in absolute terms thanks to weak patent laws that have been in effect until recently. Because a direct translation of drug prices from US dollars to Indian rupees (INR) would have rendered most new antibiotics inaccessible to the vast majority of Indians, such patent violations were subtly encouraged. Even despite this, we were caught unaware when pharmaceutical representatives approached our primary care center in rural India, claiming that a 5-day course of levofloxacin would henceforth cost the patient ∼INR 20 (<$0.50). Reluctant to accept such a statement at face value, we consulted the CIMS Updated Prescriber's Handbook [1], a popular index of pharmaceutical drugs available in India. Here, we discovered that a 5-day course of oral levofloxacin (500 mg once daily) cost anywhere from INR 19.5 to INR 475 ($0.50–$10.50), with most companies pricing their brand at <$1 for a full course. The same course in the United States would cost >$100. Intrigued, we did some more research and came up with the following results. The cheapest 5-day courses of first-line antibiotics, such as oral amoxicillin (500 mg thrice daily) or oral erythromycin (500 mg 4 times daily), cost INR 45 ($1) and INR 90 ($2), respectively. On the other hand, the cost of a 3-day course of oral azithromycin (500 mg daily) was one-half that of a course of erythromycin. Despite the obvious price advantage to the patients, we find this trend troubling. **Lower prices** often **lead to wider prescription of a given drug**, especially in resource-limited settings. **If** second-line **antibiotics**—such as levofloxacin and azithromycin—**are made available at lower prices** than first-line antibiotics, **there is a high probability of their overuse and subsequent development of resistance**. In the face of **very low costs of medication**, patients are unlikely to complain of escalating medical expenses. The issue assumes more gravity when one considers the fact that levofloxacin is an important second-line drug for the treatment of tuberculosis [2]. Its widespread use in the community **is likely to lead to emergence of resistance** **among** **mycobacteria** **and** delayed diagnosis of **tuberculosis** [3]—an occurrence that India, with its large population of tuberculosis-affected patients, cannot afford. We believe we have encountered a situation where **low prices of antibiotics are likely to cause more harm than good**. In the post World Trade Organization treaty scenario, governments in resource-limited countries should use their privileges of essential drug control to ensure that the costs of first-line antibiotics remain lower than those of second-line drugs. Such a government-instituted ladder in antibiotic pricing is essential to prevent the misuse of antibiotics in the community and to ensure that antibiotic resistance is kept at low levels.

#### Secondary patents are key to innovation that solves AMR.

Salmieri 18 [Gregory; 2018; “*INTELLECTUAL PROPERTY AND THE FREEDOM NEEDED TO SOLVE THE CRISIS OF RESISTANT INFECTIONS*,” <http://georgemasonlawreview.org/wp-content/uploads/2019/04/26-1_7-Salmieri.pdf>] Justin

II. THE RIGHT TO THE VALUE CREATED BY RESPONSIBLE STEWARDSHIP Consider how the two-fold problem of growing resistance to our current antimicrobial drugs and the dearth of new antimicrobials under development looks once the specifics are omitted. Forget for a moment that the subject is drugs and microbes—or even inventions as opposed to other sorts of property—and just focus on the structure of the predicament.35 There is a resource of immense value that is being used myopically in a way that destroys existing stocks of the resource, and little is being done to find or develop new stocks of it. This is a pattern one expects to see with unowned resources, but not with owned ones. It is the classic “tragedy of the commons.” When a patch of grazing land is owned in common by everyone—which is just to say it is unowned—everyone has an incentive to make what use of it he can, leading to its overuse and destroying its value. By contrast, an owner can use land judiciously in ways that preserve its value or even to invest in improving the land. This is possible because the owner has exclusive control of the land in the present and therefore can control its uses, and because the owner expects to reap the benefit of the land’s future value. If deeds to land expired after twenty years, with the land reverting to the commons, land owners would have no financial incentives to preserve or enhance the land’s value past the twenty-year window. In this scenario, they could not afford to forgo shortterm gains that came at the expense of the land’s later value. Nor could they afford to invest in long-term improvement projects, such as clearing new land for grazing. This is the predicament with antimicrobial drugs. The profligate use of such drugs in the present destroys their value in a future in which they are unowned. This suggests the simple solution of extending the patent terms for antimicrobial drugs. So long as the drug remains under patent, the patent holder has both an interest in preserving its usefulness and the ability to control its use so as to preserve its value. How long should the patent term be extended? The five years of extra market exclusivity offered by the GAIN Act is calculated with a view to incentivizing companies to invest in developing new drugs. The aim of the present proposal is different. It is to enable the creators of drugs to profitably exercise their rights over the drugs in a manner that preserves the drugs’ effectiveness over time—ideally into the indefinite future. This requires extending the term of exclusivity not just a few years or decades, but as far into the future as there is reason to hope that the drugs’ effectiveness can be maintained. There are various ways in which this suggestion could be further developed; perhaps the most promising is simply to allow patents on antimicrobial drugs to be renewed indefinitely, so long as the drugs’ continued effectiveness can be demonstrated. (How exactly continued effectiveness should be demonstrated is a matter of detail, but likely by showing resistance to be below a certain threshold—perhaps 20 percent—in clinical isolates of interest.36) This would allow for a potentially infinite patent term. “Perpetual patents” have occasionally been proposed, 37 but the lack of a fixed term may do violence to the notion of a patent, so it may be better to conceive of this as a proposal for a new type of IP right that combines features of patents and trademarks. Conceptualizing the relevant right in this way highlights its basis. Like a patent, the right would pertain to an invention and would confer market exclusivity; like a trademark, however, it would be renewable in perpetuity on the grounds that the continued value of the property depends on the owner taking continuous action to maintain it. In the case of the right under consideration, the relevant actions would be those of stewarding the drug in such a manner as to prolong its continued effectiveness in the face of resistance. This new sort of property right could, in principle, be applied to drugs that are already off patent or otherwise ineligible for patent protection. The Chatham House Working Group proposes granting “delinkage rewards” to “firms registering a new antibiotic without patent protection (such as new uses for old drugs),”38 and it may be that the sort of IP protection proposed here would be applicable in such cases as well. If so, the right would be justified by the discovery of the new use for the drug and by the fact that intelligent management of this use is required for it to retain its value. A more difficult case is granting such rights to already known antibiotics that have gone off patent and are now available as generics. Removing these drugs from the commons would make it possible for an owner to profit by stewarding them responsibly. The difficulty here is determining who would own them. Professor Kades considers the possibility of granting a new patent to the original patent holder, but suggests “auctioning the patent rights [to such drugs] to the highest bidder.”39 Both are plausible solutions. Another option, in light of the issue of cross-resistance (which will be discussed in Part III) would be to apportion the IP rights to the relevant drugs among the owners of other drugs with similar mechanisms of action. Instituting the sort of property right described here (whether or not it is extended to drugs that are currently unpatentable and/or in the public domain) would create an environment in which pharmaceutical companies and other private entities can compete to develop new policies and business models that maximize the total value derived from antimicrobial drugs over time. An important advantage of this proposal is that it does not require policymakers (or authors of law review articles) to know in advance which specific practices would have this auspicious effect. However, some obvious possibilities suggest themselves. Pharmaceutical companies could sell new antimicrobials at a price high enough to make it prohibitive to use them as anything other than treatments of last resort. In addition to extending the drugs’ useful lives, the high prices would compensate for the lower initial volume of sales, and the drugs could eventually be repriced for wider use as second- and then first-line treatments. This repricing would have to be paced both to the growth of the resistant bacterial population and to the development of new antimicrobial drugs to take their predecessors’ place as treatments of last resort. One can imagine many variations of this strategy with different price points and development cycles. Pharmaceutical companies could also extend the effective lifespan of their antimicrobials through contractual arrangements with healthcare providers, which restrict the latter’s use of the drugs to certain protocols or best practices. Imagine the new business practices whereby pharmaceutical companies might profit from drugs that are never or hardly ever used. Licensing plans like the one proposed by Commissioner Gottlieb might be employed in innovative ways.40 For example, healthcare providers or insurance companies might pay a monthly fee for the right to use these drugs should it ever become necessary to do so. Or the various parties might negotiate a system whereby a pharmaceutical company (or an entity that has licensed drugs from multiple companies) charges a fixed price for treatment in accordance with a proprietary antimicrobial protocol that makes use of several of their drugs, specifying which drugs can used under which conditions. The suggestions in the last paragraph all amount to ways in which revenues from the creation of a new drug might be “delinked” from sales volume. In principle, this delinkage could occur simply through market forces, without any additional policy interventions, but since governments and multinational organizations account for most of the spending in the healthcare sector in much of the world, their adopting policies favoring delinkage would likely stimulate the development of these sorts of business models under an IP regime of the sort suggested. Indeed, such delinkage–promoting policies would likely fare better under the proposed IP regime than under the current IP system because, as The Chatham House Working Group observes, “patent expiry” creates some difficulties for such policies. Obligations for responsible use can be carefully crafted and functional when monopoly rights are in place, but are likely to fail once generic antibiotics are introduced upon the termination of the period of exclusivity. Generic manufacturers ordinarily rely on volume-based rewards, and low prices and large volume of sales without appropriate measures to conserve the antibiotics may be an important driver of indiscriminate use and resistance. A sustainable system will require controls on market entry after termination of the patent, and regulation of the way the generic products are marketed and prescribed.41 It bears emphasizing at this point that the best stewardship policies for antimicrobial drugs remain to be discovered. The Chatham House Working Group report (quoted several times above) represents the cutting edge of research on this issue, and it offers precious few details about the new “delinked” business model it says “needs to be developed.” Successful business models are rarely if ever specified from on high by public policy makers. Securing a long-range IP right to antimicrobial drugs would create the conditions in which the healthcare industry as a whole could invest the resources required to discover the practices, protocols, and business models that maximize the value of these substances. In addition, the ability to capture this value as profit would create an incentive to develop new drugs as needed. IP rights, and patents in particular, are sometimes understood as bargains between creators and society. The proposal under consideration grants a lot more to the developers of any new antimicrobial drugs than they are granted under current law, but it asks a lot of these developers in return—for it requires them to become good stewards of their drugs by discovering and implementing the means necessary to preserve the drugs’ value over time, so that the maximum potential benefit from them is realized.42 This is work that needs to be done by someone, and the sort of IP regime proposed here would enable those people and firms most qualified to do this work to profit by doing it. This leads to a deeper point. Although IP rights are often understood as special privileges granted by government and justified on utilitarian grounds, the dominant strand in early American jurisprudence, taking its inspiration from John Locke, regards all property rights as securing to a creator the fruits of his productive work.43 Among the reasons why patents and copyrights are finite in duration, whereas rights to chattels or land can be passed on from generation to generation indefinitely, is that chattels and land generally need to be maintained in order to retain their economic value over time, whereas this is not true of the economic value of an artwork or a method.44 But the case under consideration reveals that the continued economic value of certain methods does depend on an ongoing process of intelligent management by which one uses the method sparingly. It is this very fact that (according to the argument of this Part) justifies extending the IP right to the drug indefinitely. This raises the question of whether there are structurally similar cases in other fields, where the continued commercial value of a potential invention depends on its judicious use. If so, it may be that there are other values being destroyed (or never created) because of tragedies of the commons that could be rectified by policies analogous to the one suggested here.

### 1NC – Disease Turn

#### INNOVATION OCCURS BY BUILDING ON EXISTING MEDICAL ADVANCES, ALSO IMPROVES EFFICACY FOR TROPICAL DISEASES

**Eger 10** (Eger, T. (,Professor of Law and Economics at the University of Hamburg) P. Ebermann, and P. Ramanujam. "Incremental innovation and patent protection for pharmaceutical products in India." Economic Analysis of India (2010): 129.)

The pharmaceutical industry provides an excellent setting to test determinants of incremental and radical innovation. Radical innovation refers to the identification of new chemical entities and their development into potentially useful pharmaceutical drugs. Incremental innovation, on the other hand, works with already known chemical compounds that are merely altered or employed in a different use (Cool)20. Drug enhancements such as new dosage forms may appear at first sight to be unimportant or even trivial but they are important avenues of learning for firms. Incremental progress gives rise to families or classes of related drugs. Although several agents within a class may have the same general action, they often differ significantly in specific actions, side effects, and suitability for individual patients (Levy,21 Banbury and Mitchell22). Consequently, incremental innovation takes many forms, including improved safety and effectiveness, fewer side effects, new formulations allowing greater ease of use and improved compliance, new indications, and new versions of the medicine developed for specific groups of patients (such as children).23 It can also take the form of greater product stability during storage and transport which can be especially important in tropical climates like some regions of India.24 Thus in the pharmaceutical sector incremental innovation connotes the continuous improvement of medicines, which also requires large-scale research and development, including clinical trials, along with approval from regulators before the new product can be offered to patients. It therefore becomes important to afford protection to such innovations. 7.3.2 The Importance of Incremental Innovation For many years radical innovation had been the primary goal of research for firms in many areas of science and technology. However, breakthrough innovations are important but rare in medical research. Most medical advances—like in all other technological fields—happen by ‘incremental innovation’ that is, innovation that builds on previous inventions. In the last 20 years, a number of noticeable changes have taken place in the type of research undertaken in all industries, and pharmaceutical industries in particular. These changes were motivated by the realization that due to long-run time horizons, high failure rates, and a low probability of returns the possibility of discovering new drugs was decreasing (Min et al.;25 Bhaskaran26). As a result, the focus of research shifted and concentrated on the discovery of new uses of known substances (Cool;27 Levy;28 Banbury and Mitchell29). Th e problem that confronted researchers working in the area of incremental innovation was that traditional patent law refused to recognize the discovery of new advantages of an old product as being novel. Lionel Bently and Brad Sherman conceptualize this problem in the following example. Assume someone discovered and patented aspirin as a drug useful in curing headaches. Later someone else found out that the consumption of aspirin also thinned the blood and was thus useful in preventing blood clots. Th e second use would be not patentable due to the fact that aspirin is already patented as a drug for curing headaches (Bently and Sherman30). Th e reason for this is that traditional patent law in many countries treated a claim to a ‘product for a particular use’ as a claim to the product per se; consequently the product would lack novelty even if it had previously been employed in a different use.