### 1

#### Interpretation and violation – topical affs must defend two or more member nations.

#### Member nations means more than one member nation

#### Nations is plural. Requires multiple nations to enact the plan.

WordHippo, ND - ("What is the plural of nation?," ND, 10-5-2021https://www.wordhippo.com/what-is/the-plural-of/nation.html)//AW

**The plural form of nation is nations.**

#### Prefer our interpretation and vote neg

#### Neg Engagement – it’s the foundation of the activity and they destroy it

#### Ground – single countries have no lit base because few people write about them and the core of the topic centers on international policy

#### They allow hundreds of affs—one for every member nation—they could defend the US, China, Luxembourg, Israel, Iran, Canada, Iceland, Jordan, or anyone else reducing IPP—the aff will always be over-prepared against negs who have to prep against numerous tiny affs. Two impacts –

#### advocacy skills—they never have to defend their positions against well-researched objections since we can’t predict and prep for every specific aff ahead of time, which kills real world policymaking skills because we can’t debate what will be the best solution to the problem.

#### Loss of ground destroys fairness- generic disad don’t link – the neg loses an enormous part of the link to innovation, heg, and medical safety. Forcing bigger and more predictable affs solves. Means their topic prevents the neg from effectively preparing and kills clash.

#### Our interp allows multiple affs but avoids the limits disad – forcing them to defend multiple states limits the number of affs and forces affs to *read a single advantage to both* countries they defend so negs can’t just PIC out of one and read disads to the other—our interp substantially limits the topic but gives them affs like the EU member nations, China and Russia, India Pakistan.

#### Vote on competing interps - anything else is arbitrary and unfair.

### 2

#### The Aff’s portrayal of a world with reduced IP protections as an “information commons” where inequality is solved by deregulation perpetuates the neoliberal myth of increased competition ensuring a perfect market. This is exemplified by literally all of their tags claiming that improving the market will prevent war **Kapczynski 14** [(Amy, a Professor of Law at Yale Law School, Faculty Co-Director of the Global Health Justice Partnership, and Faculty Co-Director of the Collaboration for Research Integrity and Transparency. She is also Faculty Co-Director of the Law and Political Economy Project and cofounder of the Law and Political Economy blog. Her areas of research include information policy, intellectual property law, international law, and global health.) “INTELLECTUAL PROPERTY’S LEVIATHAN” Duke Law, Law & Contemporary problems, 2014. <https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=4710&context=lcp>] BC

Over the last decade or so, a powerful set of critiques has emerged to contest the dominant account just sketched out as well as the contemporary state of IP law.12 These arguments have come from many directions, some even arising from scholars who previously were champions of the dominant account.13 The most prominent and potent line of theoretical critique in the legal literature has come in the guise of arguments for free culture and the “information commons” and has been most influentially articulated by Lawrence Lessig and Yochai Benkler.14 Both have stressed the problems with expansive exclusive rights regimes in information and have also sketched a set of actually existing alternatives to market-based exclusionary forms of information and cultural production. Lessig has written a series of influential books that have made him a “rock star of the information age,”15 particularly for young Internet and free-culture activists. He has argued powerfully, for example, that existing copyright law is in deep conflict with the radical new possibilities for creativity in the digital age. As he points out, when a mother posting a video of her toddler dancing to a Prince song on YouTube is threatened with a $150,000 fine for copyright infringement, something has gone seriously awry.16 Lessig also contends that copyright law today is too long, too expansive, and instantiates a “permission culture” that is antithetical to free expression in the age of the remix.17 As he puts it, “the Internet has unleashed an extraordinary possibility for many to participate in the process of building and cultivating a culture that reaches far beyond local boundaries,” creating the possibility of markets that “include a much wider and more diverse range of creators,” if not stifled by incumbents who use IP law to “protect themselves against this competition.”18 Benkler’s work has also been extraordinarily formative in the field, particularly for his insights into the multiplicity of modes of information production. As he has stressed, the conventional justification for IP does not account for the many successful and longstanding modes of market nonexclusionary information production.19 For example, attorneys write articles to attract clients, software developers sell services customizing free and opensource software for individual clients, and bands give music away for free to increase revenues from touring or merchandise.20 More pathbreaking still is Benkler’s account of the importance of “commons-based peer production,” a form of socially motivated and cooperative production exemplified by the volunteer network that maintains Wikipedia or the groups of coders who create open-source software products such as the Linux operating system.21 In the digital networked age, as Benkler describes, the tools of information production are very broadly distributed, “creating new opportunities for how we make and exchange information, knowledge, and culture.”22 These changes have increased the relative role in our information economy of nonproprietary production and facilitate “new forms of production [that] are based neither in the state nor in the market.”23 Because commons-based peer production is not hierarchically organized and is motivated by social dynamics and concerns, it also offers new possibilities for human development, human freedom, a more critical approach to culture, and more democratic forms of political participation.24 This line of critique has been profoundly generative and has helped launch an important new conceptualization of the commons as a paradigm. That paradigm, as a recent book puts it, “helps us ‘get outside’ of the dominant discourse of the market economy and helps us represent different, more wholesome ways of being.”25 Proponents of the commons concept draw upon contemporary articulations of successful commons-based resource management by Elinor Ostrom and her followers.26 They do mobilize retellings of the political and economic history of the commons in land in Europe before enclosure,27 and recent evidence from psychology and behavioral economics that suggests that humans have deep tendencies toward cooperation and reciprocation.28 They argue that A key revelation of the commons way of thinking is that we humans are not in fact isolated, atomistic individuals. We are not amoebas with no human agency except hedonistic “utility preferences” expressed in the marketplace. No: We are commoners—creative, distinctive individuals inscribed within larger wholes. We may have unattractive human traits fueled by individual fears and ego, but we are also creatures entirely capable of self-organization and cooperation; with a concern for fairness and social justice; and willing to make sacrifices for the larger good and future generations.29 This stands, of course, as a powerful rebuke to the neoliberal imaginary, which “constructs and interpellates individuals as . . . rational, calculating creatures whose moral autonomy is measured by their capacity for ‘self-care’— the ability to provide for their own needs and service their own ambitions.”30 III Given this radical—and, in my view, critically important—attempt to rethink the subject at the core of neoliberal accounts, it is all the more striking that proponents of the commons often appear to adopt a neoliberal image of the state. For example, the introduction to a recently edited volume that gathers writings on the commons from seventy-three authors in thirty countries (entitled, tellingly, The Wealth of the Commons: A World Beyond Market and State) has this to say: The presumption that the state can and will intervene to represent the interests of citizens is no longer credible. Unable to govern for the long term, captured by commercial interests and hobbled by stodgy bureaucratic structures in an age of nimble electronic networks, the state is arguably incapable of meeting the needs of citizens as a whole.31 The commons, they suggest, is a concept that seeks not only to liberate us from predatory and dysfunctional markets, but also from predatory and dysfunctional states. Something immediately seems incongruous here. If people are inherently cooperative reciprocators, why are states irredeemably corrupt? After all, as Harold Demsetz famously wrote in his 1967 attack on Arrow’s optimism about state production of information, “[g]overnment is a group of people.”32 Lessig, one of the progenitors of the language of the commons in the informational domain, often leads with a similar view of the state: [I]f the twentieth century taught us one lesson, it is the dominance of private over state ordering. Markets work better than Tammany Hall in deciding who should get what, when. Or as Nobel Prize-winning economist Ronald Coase put it, whatever problems there are with the market, the problems with government are more profound.33 Lessig reveals his own sense of the power of this conception of the state when he seeks to tar IP law with the same brush; we should rebel against current IP law, he suggests, because we should “limit the government’s role in choosing the future of creativity.”34 Benkler is more measured but admits as well to viewing the state as “a relatively suspect actor.”35 We should worry, he suggests, that direct governmental intervention “leads to centralization in the hands of government agencies and powerful political lobbies,”36 a view that echoes the neoliberal account described above. It should perhaps not surprise us that leading critics of neoliberal information policy embrace a neoliberal conception of the state. After all, neoliberalism is not merely an ideology, but also a set of policy prescriptions that may have helped to call forth the state that it has described. As David Harvey puts it, “[t]he neoliberal fear that special-interest groups would pervert and subvert the state is nowhere better realized than in Washington, where armies of corporate lobbyists . . . effectively dictate legislation to match their special interests.”37 There are, it must be said, few areas of law that better exemplify this problem than IP law. For example, Jessica Litman has documented the astonishing process through which the 1976 Copyright Act was drafted, in which Congress delegated most of the drafting to interest groups that were forced to negotiate with one another.38 Other scholars have offered similarly startling accounts of the genesis of the most important IP treaty today, the TradeRelated Aspects of Intellectual Property Rights (TRIPS) Agreement. TRIPS came into force in 1996, revolutionizing international IP law by both imposing new standards and by rendering them enforceable through the WTO’s disputeresolution system, which authorizes trade retaliation to enforce its judgments. Most countries in the world are members of TRIPS, and the Agreement introduced, for developing countries in particular, substantial new obligations, such as the obligation to grant patents on medicines and food-related inventions. Several excellent histories of the treaty have been written, documenting its beginnings as a brash idea proposed by “twelve chief executive officers (representing pharmaceutical, entertainment, and software industries).”39 As Susan Sell has described, the TRIPS Agreement was a triumph of industry organizing. Through TRIPS, Industry revealed its power to identify and define a trade problem, devise a solution, and reduce it to a concrete proposal that could be sold to governments. These private sector actors succeeded in getting most of what they wanted from a global IP agreement, which now has the status of public international law.

#### Attempts to reform the WTO are neoliberal attempts to sustain the US regime of accumulation – the contradictions of neoliberalism are why credibility is low, not IP protection

Bachand 20 [(Remi, Professor of International Law, Département des sciences juridiques, member of the Centre d’études sur le droit international et la mondialisation (CÉDIM), Université du Québec à Montréal, Canada) “What’s Behind the WTO Crisis? A Marxist Analysis” The European Journal of International Law, 8/12/2020. https://academic.oup.com/ejil/article-abstract/31/3/857/5920920?redirectedFrom=fulltext] BC

To offer our own explanation, we must recall two aspects of our theoretical framework. The first is Robert Cox’s claim113 that the function of international organizations is to ensure the creation and reproduction of hegemony. To be more accurate, they serve, if we follow his argument, to defend and to expand the ‘mode of production’ (we elected to substitute this term for the concept of ‘regime of accumulation’ that appears to be more appropriate for our means) of the dominant social classes of the dominant state. Joining this idea with the école de la régulation and social structure of accumulation theory writing114 according to which a regime of accumulation needs some regulation institutions to help resolve its contradictions (and ensure profits and capital accumulation to dominant social classes), we can conclude that the Geneva organization’s function in the US hegemonic order is to make sure that neoliberalism works well enough to provide a satisfying rate of profit for US capitalists. Going in that direction, Kristen Hopewell shows that the WTO’s creation participated in a shift in global governance from ‘embedded liberalism’ to neoliberalism115 and was slated to be an important part of that governance. Using the conceptual framework developed earlier, we can infer that the WTO was thus given a regulation function that was to ensure the operationalization of counteracting factors to the fall of the rate of profit for US capitalists. Now, as we have seen, the US rate of profit has been extremely unstable in the last two decades and Chinese expansion (and that of other ‘emerging countries’) allows one to predict that the situation could easily worsen in the future. Consequently, it should come as no surprise that the crisis that has been striking neoliberalism for the last 20 years may also result in a crisis of the organizations that are supposed to manage its contradictions, especially the WTO. Concretely, this organization seems unable to fulfil its regulatory function anymore, which is to ensure US capitalists a good rate of profit and opportunities to operationalize enough counteracting factors to negate its fall. To go further, we now need to return to Stephen Gill’s claim that the function of an international organization is to limit political and economic possibilities. It is to exclude, in other words, options that are incompatible with the social order promoted by the hegemon from what is possible and achievable.116 Effectively, the WTO was created to play such a role. Indeed, promoting liberalization of goods and services, protecting (notably intellectual) property rights and attacking subsidies (in non-agriculture sectors), just to give a few examples, all serve to severely reduce state interventions into the economy and to circumscribe or at least to strongly impede the turn towards an alternative model to neoliberalism

#### Neoliberalism rips apart communal bonds to maintain the illusion that structural inequalities are individual problems – the impact is systemic victim-blaming, poverty, and violence.

Smith 12 [(Candace, author for Societpages, cites Bruno Amable, Associate Professor of Economics at Paris School of Economics) “Neoliberalism and Individualism: Ego Leads to Interpersonal Violence?” Sociology Lens is the associated site for Sociology Compass, Wiley-Blackwell’s review journal on all fields sociological] AT

There appears to be a link between neoliberalism, individualism, and violence. In reference to the association between neoliberalism and individualism, consider neoliberalism’s insistence that we do not need society since we are all solely responsible for our personal well-being (Peters 2001; Brown 2003). From a criminological standpoint, it is not hard to understand how this focus on the individual can lead to violence. According to Hirschi’s (1969) social control theory, for instance, broken or weak social bonds free a person to engage in deviancy. Since, according to this theory, individuals are naturally self-interested, they can use the opportunity of individualization to overcome the restraining powers of society. Bearing in mind neoliberalism’s tendency to value the individual over society, it could be argued that this ideology is hazardous as it acts to tear apart important social bonds and to thereby contribute to the occurrence of ego-driven crimes, including violent interpersonal crimes. Such a thought suggests that as neoliberalism becomes more prominent in a country, it can be expected that individualism and, as a result, interpersonal violence within that country will increase. When it comes to individualization, this idea is one of the fundamental aspects of neoliberalism. In fact, Bauman (2000:34) argues that in neoliberal states “individualization is a fate, not a choice.” As Amable (2011) explains, neoliberals have realized that in order for their ideology to be successful, a state’s populace must internalize the belief that individuals are only to be rewarded based on their personal effort. With such an ego-driven focus, Scharff (2011) explains that the process of individualization engenders a climate where structural inequalities are converted into individual problems.

#### The alt is to reject the aff in favor of a critique that cultivates educated hope - evaluate the aff and alt on the level of ideological commitments – these policies won’t happen which takes out consequentialism good offense – BUT until we unlearn the assumption that getting government out of the way will let markets flourish and solve all our problems, we'll never be able to engage in robust, communitarian policymaking that truly centers human need and our obligations to others. Wilson 17:

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New Stories for New Worlds As we will see in our mapping of the neoliberal conjuncture, competition's totalizing yet tenuous power over our everyday lives is rooted in what Keating calls “status quo stories”—those stories that get told in popular culture, and that we often tell ourselves, which cement our relationship to our present conjuncture and our investment in the world as we currently know it. She explains: Generally spoken with great certainty, these and similar comments (commands, really) reflect unthinking affirmation of the existing reality and a stubborn, equally unthinking resistance to change. Because we believe that our status-quo stories represent accurate factual statements about ourselves, other people, and the world, we view them as permanent, unchanging facts. This belief in the status-quo's permanence becomes self-fulfilling: We do not try to make change because change is impossible to make. “It's always been that way,” we tell ourselves, “so why waste our energy trying to change things?” “People are just like that-it's human nature, so plan accordingly and alter your expectations! There's no point in trying to change human nature!" Status-quo stories trap us in our current circumstances and conditions; they limit our imaginations because they prevent us from envisioning alternate possibilities.10 Status-quo stories double down on reality, making it seem like those socially constructed forces impinging on us are natural rather than historical, political, and subject to change. “Status-quo stories have a numbing effect,” Keating writes. “When we organize our lives around such stories or in other ways use them as ethical roadmaps or guides, they prevent us from extending our imaginations and exploring additional possibilities."11 One of my students aptly described neoliberal culture as a “status-quo storytelling machine.” To keep us living in competition, neoliberalism generates a host of status-quo stories about the naturalness and inevitability of self-enclosed individualism. Indeed, we might say that self-enclosed individualism operates as the foundational status quo story of neoliberal culture, where competition has become synonymous with all of life. Self-enclosed individualism keeps us not only divided from one another, but also actively pitted against each other. We are stuck in an oppositional consciousness that refuses to acknowledge our social interconnections, even though, as our shared anxieties suggest, we've never had more in common than right now! No matter where we are or what we're doing, neoliberal culture encourages us to see each other through a competitive lens that makes the transformation of our social world, and ourselves, impossible. We become incapable of acknowledging how our fortunes and fates are entwined with those of others who are living very different realities. We become callous and hardened to the suffering of others. We see suffering and death everywhere, and while this might register as bad or wrong or upsetting, we nonetheless stay stuck within the horizons of our own self-enclosed bubbles. The devastating powers of status-quo stories are clear in so many of the conversations we have on college campuses about power, privilege, and difference. In fact, I started teaching courses on neoliberal culture to help my students understand the broader histories and contexts that were impinging on these conversations and making them so fraught, and ultimately so unproductive. Time and time again, in open community forums and classroom discussions of systemic inequalities, I watched students voice painful personal experiences only to get nowhere. Indeed, when asked to consider various forms of privilege, many of my white, male students get defensive. The idea that they haven't earned their place through their own decisions and hard work, but rather benefited from inherited wealth and opportunity, means that they are not good people from the perspective of neoliberalism. Talking about issues of privilege threatens to diminish their sense of self and individual value, so they recoil from conversations that ask them to see their place within broader legacies of settler colonialism, patriarchy, and capitalism. Accordingly, they hold on tight to status-quo stories of self-enclosed individualism to protect themselves, doubling down on their privilege to secure their status in a competitive world. However, it is important to see that status-quo stories of self- enclosed individualism also inform my students from historically oppressed and marginalized groups. These students suffer daily: they live in an environment that professes to celebrate “diversity,” while, in the context of their own lives, they are reminded again and again just how much they don't belong or matter. Not surprisingly, they demand “safe spaces” and protection for themselves and their peers, and they often draw hard lines between allies and enemies. Here too though, we see neoliberal stories at work. What matters for my students, and rightly so, is the way that “microaggressions”—those daily, mundane experiences of discrimination that accumulate over time-diminish their own capacities for flourishing as self-enclosed individuals. My point here is not to suggest that privileged students and marginalized students are the same because they are both invested in a version of self-enclosed individualism. Rather, my point is they share a situation; despite their different and unequal social positions, they have similar feelings-of defensiveness and a fear of failure—and status-quo stories in common. These commonalities do not imply evenness or equality, but rather interconnection, that is, a shared conjuncture. It is the recognition of this conjunctural interconnection that can thread our lives together and open up possibilities for more egalitarian futures. However, living in competition and the oppositional consciousness it demands obscure these commonalities and the interconnections that could bring students into new relations with one another. As a result, we stay caught up in the world as we know it. We stay stuck in competition, even though we all are yearning for different worlds. We desperately need new stories, stories that offer us different pathways to each other. As Keating puts it, we need stories that help us move from “me” to “we” consciousness.12 However, this book is not going to write these new stories for you. Rather, the goal of this book is to provide you with the resources for writing these new stories in and through your own lives. The Work of Critique Ultimately, writing new stories will require a new sense of yourself and your world, as well as what is possible, and realizing this new sense will require, first and foremost, cultivating a deeply critical orientation toward the world as we currently know and experience it. This critical orientation dislodges the sense of inevitability of neoliberalism, self-enclosed individualism, and living in competition; it knows that things don't have to be this way and, thus, senses the possibilities for resistance and transformation that are everywhere. It is so crucial to understand that this critical orientation is not simply about saying that aspects of neoliberal culture are “bad” or "wrong.” Rather, the work of critique is about seeing the flows of power and ways of thinking that make the neoliberal conjuncture possible and hold it together. Critique is therefore a mode of knowing—a form of everyday intellectual work—that is aimed at exposing the myriad workings of power and its status-quo stories. As Michel Foucault explains, “A critique is not a matter of saying that things are not right as they are. It is a matter of pointing out on what kinds of assumptions, what kinds of familiar, unchallenged, unconsidered modes of thought the practices that we accept rest.”13 To clarify Foucault's idea, let's think back to the student discussions of power and privilege discussed above. The work of critique is not simply about pointing out privilege, although this is, of course, vital work. The work of critique goes beyond pointing out what's wrong and seeks to unravel the socially constructed conjuncture in which these problems emerge and get negotiated. For only then can we step outside of the competitive, oppositional consciousness of neoliberal culture and begin to imagine a radically different future built on equality and shared security. This work of dislodging the inevitability of our conjuncture and its status-quo stories is hard but vital intellectual work that requires not only critique of our social world, but also transformation of ourselves. Indeed, truly critical work is always profoundly disruptive of our own identities and knowledges. This work can be immensely painful, as it strips away the certainty and comfort provided by status-quo stories. This work can also be, and should be, immensely joyful and life-giving, as it enables us to free ourselves from the status-quo stories and devastating limitations they put on our lives, imaginations, and social relationships. This mix of pain and joy at the heart of critical work comes from the way that critique asks us to “lose confidence” in our world. As feminist theorist Sara Ahmed writes, Losing confidence: it can be a feeling of something gradually going away from you, being eroded. You sense the erosion. You might stumble, hesitate, falter; things might gradually unravel so you end up holding onto the barest of threads. It might be an experience in the present that throws things up, throws you off balance.... When you lose confidence it can feel like you are losing yourself: like you have gone into hiding from yourself.4 Losing confidence in your world is thus a form of existential crisis —you are disoriented; your world is shattered. At the same time, losing confidence in status-quo stories means gaining confidence for resistance and transformation. We become bolder, less anxious, more optimistic, capable of social interconnection, political intervention, and acting on and from a place of commonality. This is real freedom. Critique is ultimately about unlearning our world so that we might reconstruct it anew. Losing confidence in neoliberal culture means being able to say no to it in the conduct of our daily lives. In these capacities for resistance, we gain confidence that another world might actually be better, worth opening ourselves up to, worth fighting for. We begin to cultivate what Henry Giroux calls educated hope. Educated hope is not “a romanticized and empty” version of hope; rather, it is a form of hope enabled by critique that “taps into our deepest experiences and longing for a life of dignity with others, a life in which it becomes possible to imagine a future that does not mimic the present.” With educated hope, our sense of who we are and of what might be possible shifts in profound ways. This is when those new worlds we are longing for open up. What’s to Come Each of the chapters that follow offer a variety of intellectual tools for mapping the neoliberal conjuncture. Taken together, they are designed to produce a holistic and thick understanding of neoliberalism and its myriad powers to shape our identities, sensibilities, social worlds, and political horizons. Having a thick understanding of neoliberalism means that you feel in your bones that there is nothing natural or inevitable about neoliberalism and its status-quo stories. It means that you understand that neoliberalism is the outcome of a range of contingent historical processes that have consequences across social, political, economic, and cultural fields. In other words, by the end of our journey, you'll know how our neoliberal conjuncture has been, and continues to be, constructed. You'll also, therefore, be able to sense the other worlds on the horizon that are just waiting to be constructed, so long as, together, we can develop the resources, capacities, and stories of interconnection for bringing them into being. More specifically, the book is divided into two sections. The first section, titled “Critical Foundations,” focuses on cultivating a broad, critical orientation toward neoliberal culture. The first chapter charts the rise of neoliberal hegemony through four historical phases. The goal is to illustrate exactly how competition came to be the driving cultural force in our everyday lives. As we will see, there is nothing natural or inevitable about neoliberalism. It was a political and class-based project to remake capitalism and liberal democracy that was conceived, organized for, and eventually won. In the second chapter, we delve into the world of neoliberal theory and its critical consequences. Here we'll explore exactly what neoliberal thinkers believe about the state, markets, and human actors, and what distinguishes neoliberalism from earlier schools of liberal thought. We'll also interrogate what I call the four Ds—disposability, dispossession, disimagination, and de- democratization—which, taken together, enable us to clearly see and articulate what is so devastating about the rise of neoliberalism. The third chapter examines the cultural powers specific to neoliberalism. Neoliberalism advances through culture, specifically through the promotion of an enterprise culture that works to impose competition as a norm across all arenas of social life. In order to see and specify how neoliberalism works through culture, we take contemporary education as a case study and unpack the entangled cultural powers of neoliberal governmentality, affect, and ideology. The second section is titled “Neoliberal Culture.” In these chapters, we explore the worlds of neoliberal labor, affect, and politics respectively, tracing what happens when our everyday lives as workers, individuals, and citizens become organized around living in competition. The fourth chapter examines how neoliberalism turns everyday life into a “hustle,” where all the contexts of daily life become animated by the demands of neoliberal labor. At stake here are the ways in which we are all hustling to get by, yet we stay radically divided from one another along lines of gender, race, and class thanks to the norm of self- enterprise. The next chapter hones in on what it feels like to inhabit enterprise culture by exploring neoliberal affect and the care of the self. As we already know, living in competition breeds widespread anxiety, not to mention depression and illness, making self-care an ongoing, pressing problem of everyday life. While neoliberal culture offers us plenty of tools for self-care that ultimately keep us stuck in our self-enclosed individualism, this chapter also considers how self-care might be a site for resistance and political intervention. The final chapter focuses on neoliberal politics, tracing what happens to citizenship and social action in our contemporary conjuncture. As we'll see, neoliberalism privatizes our political horizons by remaking democracy into a market competition for visibility and equality. Throughout this mapping of the neoliberal conjuncture, we will engage in a mode of critical work that will, hopefully, enable you to unlearn neoliberalism and thus begin to write new stories about our conjuncture—including both our commonalities and differences—and the alternative worlds we are yearning for. Indeed, our critical work will only matter to the extent that it opens up our individual and collective horizons to a future beyond living in competition.

### 3

#### CP: The United States ought to provide development aid and technical assistance in the implementation of economic reforms to the Hashemite Kingdom of Jordan.

#### International support is needed to solve Jordan instability - Marlborough reads yellow

AC Al-Shami et al 4/13 “Jordan’s Thorny Spring Spells Trouble for the Middle East” Farah Al-Shami, Research Fellow, Arab Reform Initiative (ARI), Tuqa Nusairat, Deputy Director, Rafik Hariri Center for the Middle East - Atlantic Council, Paolo Maggiolini, Associate Researcher, Italian Institute for International Political Studies (ISPI) and Lecturer in History of Islamic Asia, Catholic University of Milan, Bruce Riedel, Senior Fellow, Foreign Policy, Center for Middle East Policy, Center for Security, Strategy, and Technology, Director - The Intelligence Project, Brookings, April 13, 2021 <https://www.ispionline.it/en/pubblicazione/jordans-thorny-spring-spells-trouble-middle-east-30024> SM

Jordan's image, painstakingly built by the country’s authorities as an oasis of relative stability within a turbulent Middle East, took a hit on April 3, when former Crown Prince Hamzah bin Hussein was accused of cooperating with “foreign entities” to destabilize the state. The incident, widely presented as a family disagreement, resulted in the arrest of eighteen people and Hamzah's oath of allegiance to the Crown and the Constitution two days later. While investigations are still ongoing, the recent controversy comes as an unexpected novelty for the country. Since the Hashemite kingdom's origins, Jordan has always been seen as an island of stability in an otherwise unstable neighbourhood. At the same time, King Abdullah II has long been held in high regard in the United States, as Washington has relied on his steadying influence and views him as a highly reliable partner. Today, Amman remains one of the United States’ closest allies in the region, especially in counterterrorism operations and intelligence-sharing in the fight against al-Qaeda and the Islamic State. Nevertheless, despite its apparent stability, the country faces substantial socio-economic challenges. Jordan has been hard hit by the coronavirus (it ranks among the highest COVID-19 infection and death rates per capita in the region), while its unemployment rate reached one-fourth of the population in 2020. Furthermore, the country is currently home to over 660,000 Syrian refugees while also hosting a large community of Palestinian refugees. Hence, coming at a particularly uncertain moment for the country and combined with pre-existing structural problems, the tensions within the ruling family risk detracting attention from long-needed socio-economic reforms.

Jordan’s uneasy geopolitical position

“The kingdom of Jordan has so far been spared a visit by the Arab Spring, apart from several random and discontinuous waves of protests. For years now, economic demands have been growing and calls for less corruption, and more transparency have been rising. Against this backdrop, the ruling family is not only facing challenges on the economic front but also subtle opposition from the Muslim Brotherhood, which has been very active in other countries visited by the Arab Spring as well. Moreover, Iran and its hegemony over Iraq, Syria, and Lebanon puts Jordan in a difficult geopolitical position that requires close collaboration with GCC countries to counterbalance, especially that these countries are also ruled by monarchies. Thus, at the moment, the ruling family is trying to avoid having these geopolitical challenges spill into the local political scene and cause a serious threat to its rule via a combination of chaos and uprisings.”

Farah Al-Shami, Research Fellow, Arab Reform Initiative (ARI)

Amman’s economy needs less foreign loans and more support for structural reforms

“One positive spill-over from the incident might be bringing Jordan back to the radar of its foreign allies, who tend to take the stability in the country for granted and have been ignoring quieting of Jordanians dissatisfied with dire economic situation in the country, further exacerbated by the Covid-19 pandemic. What Jordan needs, however, is not more loans – its foreign debt already amounts to over 90% of its GDP – but development aid and technical assistance in implementation of wise economic reforms that would not further harm the already impoverished population. Austerity is not an answer at a time when the cost of living is growing, remittances – falling, and officially one in four (and realistically more) Jordanians is out of work.”

Katarzyna Sidło, Director of the Middle East and North Africa Department, Center for Social and Economic Research (CASE)

Jordan’s social mobilization limbo and the risk of a security clampdown

“Jordan, a resource-poor country that was initially lauded for containing COVID-19, has struggled to manage the economic fallout. Remittances and tourism have declined as has assistance from neighboring Gulf countries. With many businesses in ruins due to COVID-19 lockdowns, the government has to do more to ensure social safety net programs help vulnerable populations climb out of economic despair. The government is also struggling to support the nearly one million refugees in the country. While Jordanians have been protesting for months, recent events involving Prince Hamzah are likely to make Jordanians think twice before going out into the streets. The government must act fast to address economic challenges while avoiding a security clampdown that could make matters worse.”

Tuqa Nusairat, Deputy Director, Rafik Hariri Center for the Middle East - Atlantic Council

Jordan-Israel relations must refocus on shared interests and avoid political calculus

“While it is still difficult to establish the extent of the alleged coup plot in Jordan, what seems particularly intriguing are the allegations of foreign meddling. Ten years ago, while protests and dissents were mushrooming, Amman was counting on Saudi aid and Israel’s implicit support. Today, while regional powers, including both countries, are voicing support for the king, Amman is becoming increasingly concerned that the rapprochement between Riyadh and Tel Aviv can be to the detriment of its legitimacy. The recent incident at the Israeli-Jordan border and the allegations pointing to Israel and Saudi Arabia are only the most recent episodes in a stream of tensions developing since 2017. These are like a wake-up call. Jordan-Israel relations have always been based on solid shared interests and not on political calculus. It is of utmost importance to recognize this for the future of the region and the security of both countries.”

Paolo Maggiolini, Associate Researcher, Italian Institute for International Political Studies (ISPI) and Lecturer in History of Islamic Asia, Catholic University of Milan

The US and international support for Amman is essential to preserve the region’s stability

“The Biden administration is facing an unexpected crisis in Jordan where King Abdallah faces unprecedented divisions within the ruling family exacerbated by foreign meddling, the pandemic and recession. At risk is the stability of the lynchpin of the region. Saudi support for Prince Hamzah’s challenge to the King raises serious questions about the reckless and dangerous behaviour of the Crown Prince Muhammad bin Salman. Biden has moved quickly to signal support for Abdallah. He needs to rally international help for Jordan’s weak economy and deep structural problems. Keeping Jordan stable is critical to survival of the Israel-Jordan peace treaty which is deeply unpopular.”

#### Their AC solvo defecit to US aid is only about aid not budgeted for economic development – Marlborough reads yellow.

Younes 18 “Jordan’s economic crisis threatens political stability” Ali Younes, 14 Feb 2018 <https://www.aljazeera.com/economy/2018/2/14/jordans-economic-crisis-threatens-political-stability> SM

Jordan’s economic crisis threatens political stability

Anger simmers after the government hiked taxes between 50-100 percent on key food staples such as bread.

Angry at the decision to increase food prices last month, restive Jordanians are demanding the government’s resignation and the dissolution of parliament.

Last month, the government implemented a tax rise of between 50-100 percent on key food staples such as bread, in order to decrease its $700m budget deficit.

Jordan’s debt has now reached $40bn and its debt-to-gross-domestic-product ratio has reached a record 95 percent, up from 71 percent in 2011.

The economic crunch that squeezes the country will be particularly acute this year, after Jordan’s Gulf Cooperation Council (GCC) allies – Saudi Arabia, UAE, and Kuwait – did not renew a five-year financial assistance programme with Amman worth $3.6bn that ended in 2017.

The United States is now the only donor that has committed itself to support Jordan. On Wednesday, US Secretary of State Rex Tillerson signed a five-year $6.375bn ($1.275bn a year) aid deal with Foreign Minister Ayman al-Safadi.

This surpassed the previous agreement of about $1bn a year, signed with the previous US administration, by about 27 percent, and increased in length from three years to five.

A US State Department statement said $750m was earmarked annually for economic support funds and $350m for the military. It was unclear what the remaining $175m would be used for.

“As part of this bilateral understanding, Jordan has committed to prioritise economic and security sector reforms that aim to support Jordanian self-reliance,” it said.

During a joint press conference in Amman, Tillerson said the increase would support Jordan’s security roles in fighting terrorism and the conflict in Syria.

However, even with the increased flow of US aid that has funded budgets and projects since the 1950s, it remains to be seen if Jordan’s economy will stabilise, according to analysts.

Hussam Abdallat, a political activist and former government official, told Al Jazeera the American assistance won’t benefit ordinary Jordanians.

“American aid to Jordan is useless to the average Jordanian; most of it goes to support the Jordanian military – which serves American interests, not Jordan’s – and the rest goes back to the US through US companies working in Jordan,” Abdallat said.

Any US aid that is not directly budgeted for economic development is “meaningless”, he added.

Regional stability

Journalist Salameh Aldarawi, editor of Maqar online newspaper, told Al Jazeera that Jordan’s economic problems are directly related to political stability in the region.

Aldarawi, who writes on the Jordanian economy, said devastating wars in neighbouring Syria and Iraq – the country’s biggest trading partners – have curtailed economic growth.

The harsh measures taken by the government will not improve economic stability and will only hurt the most vulnerable people in Jordanian society, he said.

“Prices and tax hikes are only hurting the poor and the middle class, especially in the absence of wage increases or social safety nets,” Aldarawi said. “These measures will only provide temporary quick fixes, not a long-term, strategic solution.”

He said tackling corruption was imperative, along with fixing the “collapsed education and healthcare systems.

“The government must start with fighting entrenched and endemic corruption within its ranks, recover billions of dollars of embezzled public funds, [and] create equality among the different segments of the population, especially towards those who pay more taxes but get fewer services and privileges,” said Aldarawi.

‘Economic disaster’

Abdallat, who leads several activist groups demanding political and economic reform, said Jordan’s political elite must be held accountable for their actions that have driven the country to the edge of financial ruin.

“People are protesting in several areas in the country and demanding the resignation of the government and the parliament, who are responsible for the economic disaster we are in now,” he said.

In Amman, where nearly half of Jordan’s 9.9 million population resides, criticism of government policies has spread over social media, but, so far, not significantly to the streets.

Analysts say that, unlike residents of the capital, people in the southern and northern provinces are more dependent on government largesse and employment and will suffer greater hardship when the government is no longer able to meet their needs.

“At this rate, I am afraid that we will end up with a revolt of the hungry,” said Abdallat.

Hussein Mahadeen, a professor of social development at Mutah University in Kerak, south of Amman, said Jordan has a foreign aid dependency problem because of its political and social structure.

Mahadeen said Jordan is still transitioning from its tribal society roots into a semi-modern state.

“Lacking solid legal and civic institutions, to safeguard the rights and liberties of citizens and their ability to contest government decisions, is a major impediment towards its political and economic development,” he told Al Jazeera.

“The Jordanian society, for several reasons, is not mature enough socially and politically to be able to mount a serious challenge to the state’s ability to impose strict economic measures.”

‘Violent revolt’?

For many decades, foreign aid and remittances from expatriate Jordanians in the Gulf region were the mainstays of the Jordanian economy that kept the country afloat.

This, however, created dependency, and a succession of Jordanian governments failed to take measures to wean the country off foreign assistance and become self-reliant, according to Mahadeen.

Jordan’s main problem is it hasn’t progressed and developed beyond its “functional state” roots,that is a state created to perform certain functions on behalf of others, after its creation by the British, after defeating the Ottoman Empire in World War I, he said

Abdallat – who has been imprisoned several times for his criticism of the government – said he was concerned the economic situation facing Jordan could result in an uprising.

“If the current economic crisis persists, it might lead to a revolt, and I am afraid it will be a violent one,” he said.

### 4

#### COVID has kept patents and innovation strong, but continued protection is key to innovation by incentivizing biomedical research – it’s also crucial to preventing counterfeit medicines, economic collapse, and fatal diseases, which independently turns case. Macdole and Ezell 4-29:

Jaci Mcdole and Stephen Ezell {Jaci McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at the Information Technology and Innovation Foundation (ITIF). She focuses on IP and its correlations to global innovation and trade. McDole holds a double BA in Music Business and Radio-Television with a minor in Marketing, an MS in Education, and a JD with a specialization in intellectual property (Southern Illinois University Carbondale). McDole comes to ITIF from the Institute for Intellectual Property Research, an organization she co-founded to study and further robust global IP policies. Stephen Ezell is vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He comes to ITIF from Peer Insight, an innovation research and consulting firm he cofounded in 2003 to study the practice of innovation in service industries. At Peer Insight, Ezell led the Global Service Innovation Consortium, published multiple research papers on service innovation, and researched national service innovation policies being implemented by governments worldwide. Prior to forming Peer Insight, Ezell worked in the New Service Development group at the NASDAQ Stock Market, where he spearheaded the creation of the NASDAQ Market Intelligence Desk and the NASDAQ Corporate Services Network, services for NASDAQ-listed corporations. Previously, Ezell cofounded two successful innovation ventures, the high-tech services firm Brivo Systems and Lynx Capital, a boutique investment bank. Ezell holds a B.S. from the School of Foreign Service at Georgetown University, with an honors certificate from Georgetown’s Landegger International Business Diplomacy program.}, 21 - ("Ten Ways Ip Has Enabled Innovations That Have Helped Sustain The World Through The Pandemic," Information Technology & Innovation Foundation, 4-29-2021, https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through)//marlborough-wr/

To better understand the role of IP in enabling solutions related to COVID-19 challenges, this report relies on 10 case studies drawn from a variety of nations, technical fields, and firm sizes. This is but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. From a paramedic in Mexico to a veteran vaccine manufacturing company in India and a tech start-up in Estonia to a U.S.-based company offering workplace Internet of Things (IoT) services, small and large organizations alike are working to combat the pandemic. Some have adapted existing innovations, while others have developed novel solutions. All are working to take the world out of the pandemic and into the future. The case studies are: Bharat Biotech: Covaxin Gilead: Remdesivir LumiraDX: SARS-COV-2 Antigen POC Test Teal Bio: Teal Bio Respirator XE Ingeniería Médica: CápsulaXE Surgical Theater: Precision VR Tombot: Jennie Starship Technologies: Autonomous Delivery Robots Triax Technologies: Proximity Trace Zoom: Video Conferencing As the case studies show, IP is critical to enabling innovation. Policymakers around the world need to ensure robust IP protections are—and remain—in place if they wish their citizens to have safe and innovative solutions to health care, workplace, and societal challenges in the future. THE ROLE OF INTELLECTUAL PROPERTY IN R&D-INTENSIVE INDUSTRIES Intangible assets, such as IP rights, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018.4 For start-ups, this means much of the capital needed to operate is directly related to IP (see Teal Bio case study for more on this). IP also plays an especially important role for R&D-intensive industries.5 To take the example of the biopharmaceutical industry, it is characterized by high-risk, time-consuming, and expensive processes including basic research, drug discovery, pre-clinical trials, three stages of human clinical trials, regulatory review, and post-approval research and safety monitoring. The drug development process spans an average of 11.5 to 15 years.6 For every 5,000 to 10,000 compounds screened on average during the basic research and drug discovery phases, approximately 250 molecular compounds, or 2.5 to 5 percent, make it to preclinical testing. Out of those 250 molecular compounds, approximately 5 make it to clinical testing. That is, 0.05 to 0.1 percent of drugs make it from basic research into clinical trials. Of those rare few which make it to clinical testing, less than 12 percent are ultimately approved for use by the U.S. Food and Drug Administration (FDA).7 In addition to high risks, drug development is costly, and the expenses associated with it are increasing. A 2019 report by the Deloitte Center for Health Solutions concluded that since 2010 the average cost of bringing a new drug to market increased by 67 percent.8 Numerous studies have examined the substantial cost of biopharmaceutical R&D, and most confirm investing in new drug development requires $1.7 billion to $3.2 billion up front on average.9 A 2018 study by the Coalition for Epidemic Preparedness found similar risks and figures for vaccines, stating, “In general, vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94 percent chance of failure.”10 Yet, a 2010 study found that 80 percent of new drugs—that is, the less than 12 percent ultimately approved by the FDA—made less than their capitalized R&D costs.11 Another study found that only 1 percent (maybe three new drugs each year) of the most successful 10 percent of FDA approved drugs generate half of the profits of the entire drug industry.12 To say the least, biopharmaceutical R&D represents a high-stakes, long-term endeavor with precarious returns. Without IP protection, biopharmaceutical manufacturers have little incentive to take the risks necessary to engage in the R&D process because they would be unable to recoup even a fraction of the costs incurred. Diminished revenues also result in reduced investments in R&D which means less research into cancer drugs, Alzheimer cures, vaccines, and more. IP rights give life-sciences enterprises the confidence needed to undertake the difficult, risky, and expensive process of life-sciences innovation secure in the knowledge they can capture a share of the gains from their innovations, which is indispensable not only to recouping the up-front R&D costs of a given drug, but which can generate sufficient profits to enable investment in future generations of biomedical innovation and thus perpetuate the enterprises into the future.13 THE IMPORTANCE OF INTELLECTUAL PROPERTY TO INNOVATION Although anti-IP proponents have attacked biopharmaceutical manufacturers particularly hard, the reality is all IP-protected innovations are at risk if these rights are ignored, or vitiated. Certain arguments have shown a desire for the term “COVID-19 innovations” to include everything from vaccines, therapeutics, diagnostics, and PPE to biotechnology, AI-related data, and educational materials.14 This could potentially open the floodgates to invalidate IP protection on many of the innovations highlighted in this report. However, much of the current discussion concerning IP focuses almost entirely on litigation fears or R&D incentives. Although R&D is an important aspect of IP, as previously mentioned, these discussions ignore the fact that IP protection can be—and often is—used for other purposes, including generating initial capital to create a company and begin manufacturing and, more importantly, using licensing agreements and IP to track the supply chain and ensure quality control of products. This report highlights but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. In 2018, Forbes identified counterfeiting as the largest criminal enterprise in the world.15 The global struggle against counterfeit and non-regulated products, which has hit Latin America particularly hard during the pandemic, proves the need for safety and quality assurance in supply chains.16 Some communities already ravaged by COVID-19 are seeing higher mortality rates related to counterfeit vaccines, therapeutics, PPE, and cleaning and sanitizing products.17 Polish authorities discovered vials of antiwrinkle treatment labeled as COVID-19 vaccines. 18 In Mexico, fake vaccines sold for approximately $1,000 per dose.19 Chinese and South African police seized thousands of counterfeit vaccine doses from warehouses and manufacturing plants.20 Meanwhile, dozens of websites worldwide claiming to sell vaccines or be affiliated with vaccine manufacturers have been taken down.21 But the problem is not limited to biopharmaceuticals. The National Intellectual Property Rights Coordination Center has recovered $48 million worth of counterfeit PPE and other products.22 Collaborative efforts between law enforcement and manufacturers have kept numerous counterfeits from reaching the population. In countries with strong IP protection, the chances of counterfeit products reaching the market are significantly lower. This is largely because counterfeiting tends to be an IP-related issue, and these countries generally provide superior means of tracking the supply chain through trademarks, trade secrets, and licensing agreements. This enables greater quality control and helps manufacturers maintain a level of public confidence in their products. By controlling the flow of knowledge associated with IP, voluntary licensing agreements provide innovators with opportunities to collaborate, while ensuring their partners are properly equipped and capable of producing quality products. Throughout this difficult time, the world has seen unexpected collaborations, especially between biopharmaceutical companies worldwide such as Gilead and Eva Pharma or Bharat Biotech and Ocugen, Inc. Throughout history, and most significantly in the nineteenth century through the widespread development of patent systems and the ensuing Industrial Revolution, IP has contributed toward greater economic growth.23 This is promising news as the world struggles for economic recovery. A 2021 joint study by the EU Intellectual Property Office (EUIPO) and European Patent Office (EPO) shows a strong, positive correlation between IP rights and economic performance.24 It states that “IP-owning firms represent a significantly larger proportion of economic activity and employment across Europe,” with IP-intensive industries contributing to 45 percent of gross domestic product (GDP) (€6.6 trillion; US$7.9 trillion).25 The study also shows 38.9 percent of employment is directly or indirectly attributed to IP-intensive industries, and IP generates higher wages and greater revenue per employee, especially for small-to-medium-sized enterprises.26 That concords with the United States, where the Department of Commerce estimated that IP-intensive industries support at least 45 million jobs and contribute more than $6 trillion dollars to, or 38.2 percent of, GDP.27 In 2020, global patent filings through the World Intellectual Property Organization’s (WIPO) Patent Cooperation Treaty (PCT) system reached a record 275,900 filings amidst the pandemic, growing 4 percent from 2019.28 The top-four nations, which accounted for 180,530 of the patent applications, were China, the United States, Japan, and Korea, respectively.29 While several countries saw an increase in patent filings, Saudi Arabia and Malaysia both saw significant increases in the number of annual applications, with the top two filing growths of 73 percent and 26 percent, respectively.30 The COVID-19 pandemic slowed a lot of things, but it certainly couldn’t stop innovation. There are at least five principal benefits strong IP rights can generate, for both developing and developed countries alike.31 First, stronger IP protection spurs the virtuous cycle of innovation by increasing the appropriability of returns, enabling economic gain and catalyzing economic growth. Second, through patents—which require innovators to disclose certain knowledge as a condition of protection—knowledge spillovers build a platform of knowledge that enables other innovators. For instance, studies have found that the rate of return to society from corporate R&D and innovation activities is at least twice the estimated returns that each company itself receives.32 Third, countries with robust IP can operate more efficiently and productively by using IP to determine product quality and reduce transaction costs. Fourth, trade and foreign direct investment enabled and encouraged by strong IP protection offered to enterprises from foreign countries facilitates an accumulation of knowledge capital within the destination economy. That matters when foreign sources of technology account for over 90 percent of productivity growth in most countries.33 There’s also evidence suggesting that developing nations with stronger IP protections enjoy the earlier introduction of innovative new medicines.34 And fifth, strong IP boosts exports, including in developing countries.35 Research shows a positive correlation between stronger IP protection and exports from developing countries as well as faster growth rates of certain industries.36 The following case studies illustrate these benefits of IP and how they’ve enabled innovative solutions to help global society navigate the COVID-19 pandemic.

#### Data exclusivity is uniquely key to innovation. Lybecker ‘14

Kristina Lybecker {Dr. Kristina M. Lybecker is an Associate Professor of Economics at Colorado College in Colorado Springs, where she is also the Associate Chair of the Department of Economics and Business and the Gerald L. Schlessman Professor of Economics. Dr. Lybecker earned a B.A. in Economics and Latin American Studies from Macalester College and received her Ph.D. in Economics in 2000 from the University of California, Berkeley. Her Dissertation was on “Counterfeit Pharmaceuticals: Product Piracy and the Transition to Stronger Intellectual Property Rights in Developing Countries.”}, 14 - ("When Patents Aren’t Enough: The Case for Data Exclusivity for Biologic Medicines," IPWatchdog, 7-9-2014, https://www.ipwatchdog.com/2014/07/09/patents-arent-enough-data-exclusivity-for-biologic-medicines/id=50318/)//marlborough-wr/

Biologic medicines are fundamentally different from traditional “small molecule” therapies, presenting a host of new challenges in the design and enforcement of the intellectual property (IP) architecture that will protect them.[2] Protecting the intellectual property of biologics is complicated, difficult, and essential to the future of medicine. This new frontier is also one of the remaining hurdles in the Trans-Pacific Partnership (TPP) Trade Agreement negotiations. The debate over protecting biologics focuses on a proposed twelve years of data exclusivity and the consequences this will have for international trade, global public health, and access to medicines. The nuances of producing biologics greatly complicate the logistics of protecting their intellectual property, making patents alone inadequate for safeguarding their IP. Data exclusivity protection allows for a period of time following marketing approval during which competing firms may not use the innovative firm’s safety and efficacy data, from proprietary preclinical and clinical trial results, to obtain marketing authorization for a generic version of the drug. From the moment when the compound first shows medicinal promise, data is generated and compiled, a process that is both expensive and time consuming. Data exclusivity provides the innovative firm with a period of protection for their investment in clinical trials and data collection, regardless of the length of time required to bring the drug to market. Although complementary, patents and data exclusivity protection incentivize innovation in different ways and serve distinct purposes. Patents provide protection for innovations that meet the standards of patentability and are novel, nonobvious, and useful. In the context of biopharmaceuticals, patents protect both breakthrough discoveries as well as incremental improvements. Due to the length of the drug-development and patent-approval processes, effective patent terms rarely correspond to FDA approval. Accordingly, in some cases innovative therapies may experience patent expiry shortly after making it to market. In contrast, data exclusivity protects the tremendous investments of time, talent, and financial resources required to establish a new therapy as safe and effective. This is accomplished by requiring competing firms seeking regulatory approval of the same or a similar product to independently generate the comprehensive preclinical and clinical trial data rather than rely on or use the innovator’s data to establish safety and efficacy of their competing product. Alternatively, the competing firm may wait a set period of time after which they are able to utilize the innovator’s prior approval in an abbreviated regulatory approval, eliminating the need for independently generated data. Data exclusivity is not an extension of patent rights, and it does not preclude a third party from introducing a generic version of the innovator’s therapy during the data exclusivity period, provided that the innovator’s data is not used to secure marketing approval. Fundamentally, data exclusivity protection incentivizes biopharmaceutical firms to invest the necessary time and financial resources in establishing the safety and efficacy of their product and prevents competitors from free riding on these efforts for a limited period of time. [Kristina] The Hatch-Waxman Act of 1984 provided innovative drug firms with a period of patent extension as well as a period of data exclusivity, in the hopes of providing a return on their investment and an incentive for future innovation.[3] These protections have been crucial to the development of the innovative drugs and therapies that currently enhance and extend life. They are even more critical to the future of the biopharmaceutical industry and the development of biologic medicines that are more targeted and more complex. In an analysis of the appropriate length of data exclusivity, a financial model was utilized to determine how long the exclusivity period must be to provide a typical pioneer biologic a positive return on investment. Drawing on a representative portfolio of pioneer biologics, the break-even period ranges from thirteen to sixteen years.[4] An appropriate period of protection is essential if the promise of biologics is to come to fruition. Beyond the importance of biologics to public health and longevity, innovation is crucial to trade and economic prosperity. As evidence of the importance of these sectors, in 2011 IP-intensive industries exported more than $1 trillion in goods and services, which accounts for approximately seventy-four percent of total 2011 U.S. exports.[5] Moreover, the biopharmaceutical industry is a significant contributor. The biopharmaceutical industry of the United States is the fourth-largest U.S. exporter among IP-intensive industries, with exports valued at $49.4 billion in 2010.[6] Accordingly, the TPP Trade Agreement should include the proposed twelve years of data exclusivity and provide innovative firms with the incentives needed to continue to invest in the breakthrough therapies that will extend and enhance life for years to come. Technology inevitably evolves faster than the legal architecture that surrounds it. The provision of data exclusivity protections is a straightforward legal step to catch up to the science that brings us biologic medicines. Biologic medicines are critical to the healthcare advances of the future, and data exclusivity is vital to innovative biologics. The period of data exclusivity provides innovators with an incentive to invest in the testing data necessary to prove a drug’s safety and efficacy by granting them a measure of certainty that they will enjoy a fixed amount of time during which they maintain proprietary control of the test data that resulted in the approval of its drug before requiring that data be made available to generic imitators. As technology changes to enable the development of new biologic vaccines and therapies, intellectual property protection must also evolve to ensure protection for these products. If we believe in the importance of biologic medicines for the future of healthcare, we must protect them.

#### Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.

Marjanovic and Fejiao ‘20 Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### Bioterror causes extinction---quick innovation key

Farmer 17 (“Bioterrorism could kill more people than nuclear war, Bill Gates to warn world leaders” http://www.telegraph.co.uk/news/2017/02/17/biological-terrorism-could-kill-people-nuclear-attacks-bill/)

Bioterrorists could one day kill hundreds of millions of people in an attack more deadly than nuclear war, Bill Gates will warn world leaders. Rapid advances in genetic engineering have opened the door for small terrorism groups to tailor and easily turn biological viruses into weapons. A resulting disease pandemic is currently one of the most deadly threats faced by the world, he believes, yet governments are complacent about the scale of the risk. Speaking ahead of an address to the Munich Security Conference, the richest man in the world said that while governments are concerned with the proliferation of nuclear and chemical weapons, they are overlooking the threat of biological warfare. Mr Gates, whose charitable foundationis funding research into quickly spotting outbreaks and speeding up vaccine production, said the defence and security establishment “have not been following biology and I’m here to bring them a little bit of bad news”. Mr Gates will today (Saturday) tell an audience of international leaders and senior officers that the world’s next deadly pandemic “could originate on the computer screen of a terrorist”. He told the Telegraph: “Natural epidemics can be extremely large. Intentionally caused epidemics, bioterrorism, would be the largest of all. “With nuclear weapons, you’d think you would probably stop after killing 100million. Smallpox won’t stop. Because the population is naïve, and there are no real preparations. That, if it got out and spread, would be a larger number.” He said developments in genetic engineering were proceeding at a “mind-blowing rate”. Biological warfare ambitions once limited to a handful of nation states are now open to small groups with limited resources and skills. He said: “They make it much easier for a non-state person. It doesn’t take much biology expertise nowadays to assemble a smallpox virus. Biology is making it way easier to create these things.” The increasingly common use of gene editing technology would make it difficult to spot any potential terrorist conspiracy. Technologies which have made it easy to read DNA sequences and tinker with them to rewrite or tweak genes have many legitimate uses. He said: “It’s not like when someone says, ‘Hey I’d like some Plutonium’ and you start saying ‘Hmmm.. I wonder why he wants Plutonium?’” Mr Gates said the potential death toll from a disease outbreak could be higher than other threats such as climate change or nuclear war. He said: “This is like earthquakes, you should think in order of magnitudes. If you can kill 10 people that’s a one, 100 people that’s a two... Bioterrorism is the thing that can give you not just sixes, but sevens, eights and nines. “With nuclear war, once you have got a six, or a seven, or eight, you’d think it would probably stop. [With bioterrorism] it’s just unbounded if you are not there to stop the spread of it.” By tailoring the genes of a virus, it would be possible to manipulate its ability to spread and its ability to harm people. Mr Gates said one of the most potentially deadly outbreaks could involve the humble flu virus. It would be relatively easy to engineer a new flu strain combining qualities from varieties that spread like wildfire with varieties that were deadly. The last time that happened naturally was the 1918 Spanish Influenza pandemic, which went on to kill more than 50 million people – or nearly three times the death toll from the First World War. By comparison, the recent Ebola outbreak in West Africa which killed just over 11,000 was “a Richter Scale three, it’s a nothing,” he said. But despite the potential, the founder of Microsoft said that world leaders and their militaries could not see beyond the more recognised risks. He said: “Should the world be serious about this? It is somewhat serious about normal classic warfare and nuclear warfare, but today it is not very serious about bio-defence or natural epidemics.” He went on: “They do tend to say ‘How easy is it to get fissile material and how accurate are the plans out on the internet for dirty bombs, plutonium bombs and hydrogen bombs?’ “They have some people that do that. What I am suggesting is that the number of people that look at bio-defence is worth increasing.” Whether naturally occurring, or deliberately started, it is almost certain that a highly lethal global pandemic will occur within our lifetimes, he believes. But the good news for those contemplating the potential damage is that the same biotechnology can prevent epidemics spreading out of control. Mr Gates will say in his speech that most of the things needed to protect against a naturally occurring pandemic are the same things needed to prepare for an intentional biological attack. Nations must amass an arsenal of new weapons to fight such a disease outbreak, including vaccines, drugs and diagnostic techniques. Being able to develop a vaccine as soon as possible against a new outbreak is particularly important and could save huge numbers of lives, scientists working at his foundation believe.

# CASE

#### Tons of alt causes –

#### Annexation - Their Lazaroff card is literally titled “Will annexation destroy Israeli-Jordanian peace, set kingdom aflame?”

#### water shortages, COVID, and refugee crisis. Marlborough reads yellow.

Wolf 4/14 “A Hashemite Family Reunion Can’t Hide Jordan’s Woes” Albert B. Wolf, an associate research fellow at Johns Hopkins SAIS and an assistant professor of political science at the American University of Central Asia. April 14, 2021 <https://foreignpolicy.com/2021/04/14/jordan-abdullah-hamzah-hashemite-family-reunion-cant-hide-economic-woes/> SM

­­A Hashemite Family Reunion Can’t Hide Jordan’s Woes

Making nice after an alleged coup attempt obscures serious challenges, including water scarcity, a refugee crisis, and unhelpful neighbors.

The Hashemite Kingdom of Jordan is no stranger to royal intrigues and attempted coups. The first 20 years of the late King Hussein’s rule was wracked with coup plots, assassination attempts, and a civil war with the country’s large Palestinian population. Most recently, the former crown prince and half-brother of King Abdullah II, Prince Hamzah, was accused of engaging in sedition and placed under the “protection of the king” (i.e., house arrest) until the two made a joint appearance on Sunday.

On Monday, the prince pledged his allegiance to the incumbent monarch and seemingly defused the latest royal tempest. But his display of deference doesn’t mean the end of instability in Jordan.

This episode is a symptom of the challenges Abdullah has faced since the outbreak of the Arab Spring, not the problem itself. It is unlikely to be the last challenge the king faces to his rule unless Jordan’s economy undergoes significant economic reforms—quickly.

Jordan has experienced multiple bouts of protests that were brought on by economic downturns (including during the Arab Spring and the COVID-19 pandemic) and were met with a combination of changes in economic tactics and giveaway programs, repression, and government reshuffles.

This plot supposedly came from within the royal court, giving a tabloid quality to a security threat, especially after the prince made his house arrest all the more unusual by issuing a personal statement online. However, Hamzah’s alleged plan to overthrow Abdullah is a distraction from Jordan’s ongoing strategic and economic problems that do not have readily apparent solutions.

Bruce Riedel, a senior fellow at the Brookings Institution, described the latest royal feud as the “most serious political crisis” Jordan has faced in 50 years. Regional experts have heard these warnings before. However, Abdullah’s combination of political savvy and luck in negotiating the challenges he has faced since the outbreak of the Arab Spring does not mean he will continue be lucky in the future.

Domestic stability cannot be taken for granted. Tourism, Jordan’s biggest industry, ground to a halt after the emergence of the COVID-19 pandemic. It had accounted for $5.8 billion in revenues in a $43 billion economy in 2019, but Jordan could not allow tourists back into the country as COVID-19 spread. Furthermore, remittances, which had accounted for $3.7 billion in 2018, were estimated to drop by nearly 20 percent for the entire region in 2020.

Two weeks ago, protests broke out in Amman along with other cities because of the deaths of six people from COVID-19 at government hospitals. The cause was low oxygen supplies. However, the literature on comparative authoritarianism shows that protests may provide elites with opportunities to reveal their preferences and split from the incumbent regime.

Should more protests occur due to the worsening economic situation, water shortages, the coronavirus crisis, or the strains of hosting a large refugee population, a window of opportunity may open for Prince Hamzah or another opportunistic contender for the throne. (According to Jordan’s Ministry of Planning and International Cooperation, 34 percent of the population are refugees, most of whom are Palestinian. The U.N. refugee agency counts 663,210 Syrians who have registered as refugees—while the Jordanian government counts more than 1.3 million.)

Many commentators and Jordan watchers have expressed shock and surprise at Hamzah’s open criticism of Abdullah. However, the more shocking display has been the public outpouring of criticism of the incumbent monarch. Popular radio programs have reported regular call-ins criticizing Abdullah, blaming him for the country’s poor economic performance and corruption.

Prior to the pandemic, the country had less than 2 percent annual growth, and nearly 1 in 4 adults were unemployed. Some Jordanians who have been left behind economically felt that Hamzah used the language of the Arab street to speak to people’s needs in order to advance his own interests. Even Jordanian Finance Minister Mohamad al-Ississ reportedly said, “Unemployment is this country’s greatest problem.” Official figures put unemployment at 24 percent currently.

Jordan’s supposed regional allies are not helping. The kingdom is surrounded by “frenemies” like Israel and Saudi Arabia, which, despite benefiting from the stability and cooperation of the Hashemite royal family, tend to engage in behaviors that undermine its steadiness. These frenemies’ behaviors exacerbate Jordan’s domestic political tensions.

One of the most significant issues is water. Access to water is a problem for many Jordanians—and water theft is a big business that the state has failed to address. While water consumption continues to rise, an agreement with Israel’s government over providing an additional 8 million cubic meters remains elusive. Because of these problems, ordinary Jordanians are at the mercy of water thieves who drill untapped reservoirs without the permission of the state and charge what they want to people currently unserved and underserved by the state. Jordan has made clear it hopes to build a canal to the Red Sea or Dead Sea to ameliorate these problems, but, so far, it has been unable to cut a deal with Israel.

There are rumors—and this time they are just that, rumors—that Saudi Arabia was involved in the alleged plot to overthrow Abdullah. It is important to note that once details of the arrests of Hamzah and others had leaked, most countries issued statements of support for Abdullah. However, some in Jordan fear that the Saudis are interested in a peace deal with Israel in order to displace the Hashemites as the guardians of Al-Aqsa Mosque and take over custodianship of Jerusalem’s holy places.

The royal family’s latest feud is an allegory for Jordan’s ongoing economic and strategic problems. Should they continue, it is highly likely that this moderate ally of the United States and the West will find itself convulsed by domestic challenges again in the future. This could come in at least two forms: The first is another civil conflict with Jordan’s large Palestinian population. The second could be another challenge for the throne, possibly from Hamzah or from another royal rival who has yet to reveal himself.

#### Comprehensive studies prove that data exclusivity is the best way to ensure innovative future medicines. This turns case. Goldman et al ‘13

Dana P Goldman (Dean of the USC Sol Price School of Public Policy, C. Erwin and Ione L. Piper Chair Leonard D. Schaeffer Director’s Chair, Schaeffer Center for Health Policy & Economics Distinguished Professor of Public Policy, Pharmacy, and Economics) et al., 10-21-2013, "The Benefits From Giving Makers Of Conventional `Small Molecule' Drugs Longer Exclusivity Over Clinical Trial Data," PubMed Central (PMC), [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334 //Accessed 10/6/2021](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334%20//Accessed%2010/6/2021) //JH

Data exclusivity refers to the period of time after approval of a new drug and before a generic manufacturer can access the clinical trial data that was submitted by the drug's originator during the approval process. Given the high cost of conducting clinical trials, data exclusivity provides strong intellectual property protection to pharmaceutical innovators. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, establishes the process by which generic drug manufacturers can seek approval from the Food and Drug Administration (FDA) to manufacture and market conventional drugs. Conventional drugs are created through chemistry, whereas the term biologics refers to drugs created from living organisms. ¶The Hatch-Waxman Act provides originators of new conventional drugs with five initial years of data exclusivity, and three extra years for supplemental applications, for uses other than the one[s] for which the drug was originally approved. In addition, the Food and Drug Administration Modernization Act of 1997 provides a six-month extension for previously approved drugs when such drugs are subsequently approved for use in pediatric populations. By comparison, the data exclusivity period in Europe is ten years for both conventional drugs and biologics, plus an additional year if a new indication is added for which the drug provides significant clinical benefits compared to existing therapies.[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R1) In the United States, biologic drugs were granted a 12-year exclusivity period under the Affordable Care Act. We are not aware of any pending legislation to lengthen data exclusivity for conventional drugs in the US. ¶In 2007, the National Academies of Science and Engineering called for the United States to “adopt the European [data exclusivity] period” of 10–11 years and recommended that research be conducted to determine whether even that period of time is adequate, “given the complexity and length of drug development today.”[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R2) The pharmaceutical company GlaxoSmithKline has proposed fourteen years of data exclusivity for conventional drugs.[3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R3) Unfortunately, the health policy literature contains no information about the effects such a policy would have on innovation, longevity, and social welfare. We believe our study is the first to address these issues. ¶Data exclusivity provides intellectual property protection that is distinct from patent protection. In the United States, a patent becomes effective at the date of filing—typically long before clinical trials start—whereas data exclusivity begins on the date a drug is approved for marketing by the FDA. ¶In addition, a patent is subject to challenge. The Hatch-Waxman Act allows a would-be generic competitor to contest the validity of a patent in court. Such litigation now occurs for the vast majority of new drugs, and typically commences shortly after FDA approval.[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R1) Data exclusivity, by contrast, cannot be legally challenged. ¶The duration of the data exclusivity period entails a trade-off between current and future generations. A longer period delays competition from generic drug companies, effectively extending the originator's exclusive position in the marketplace. The prospect of higher profits gives drug companies a stronger incentive to innovate—both to create new drugs and to find new indications for existing products. An increase in innovation, in turn, benefits future generations

of consumers. At the same time, however, a delay in generic competition imposes a greater spending burden on current consumers. So an increase in the length of data exclusivity benefits future generations, but at the expense of today's drug consumers. ¶Although some have questioned whether profits drive innovation, empirical evidence strongly supports this relationship. The Orphan Drug Act of 1983, which provides pharmaceutical companies with incentives to develop drugs for treating rare diseases or conditions for which there are small patient populations, was followed by a sharp increase in the number of drugs approved for this market.[4](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R4) Higher profits from vaccines have been associated with a significant increase in the number of clinical trials to develop new vaccines.[5](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R5) There is also evidence that manufacturers have delayed new drug launches rather than accept a lower anticipated price.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R6) ¶Daron Acemoglu and Joshua Linn[7](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R7) concluded that a 1 percent increase in the potential market size for a drug class leads to a 3–4 percent growth in the entry of new drugs.[7](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R7) To our knowledge, this is the only study that estimates this relationship for the entire drug market. As Darius Lakdawalla and colleagues observe,[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R8) the relationship identified by Acemoglu and Linn presumes that increases in the number or share of the aged population (60+ years old) driven by past baby booms or busts also increase innovation in drug classes targeted toward the aged. Moreover, it presumes that pharmaceutical innovation does not drive historical trends such as baby booms of busts; there is no evidence that contradicts this presumption. Applying this relationship between market size and innovation to average sales within a drug class, innovators produce one additional drug for every additional $97.5 million of annual potential revenue. Because the cost of a new conventional drug is estimated to be $800 million,[9](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R9) innovators require a 12 percent annual return on their investment—within accepted boundaries for the return on capital in the drug industry. ¶In this paper we analyze the effect of a longer period of data exclusivity for conventional drugs on both current and future generations. We do not consider the effects of a change in the data exclusivity period for biologics. We focus on a twelve-year duration because, as noted above, this is data exclusivity period recently approved by Congress for biologics. As such, it serves as a natural benchmark for extended data exclusivity for conventional drugs. ¶We address three specific policy questions: How would extending the initial five years of data exclusivity for new conventional drugs in the United States affect innovation? How would a longer period of data exclusivity affect the health of current and future generations? What is the dollar value of a longer period of data exclusivity to US society?¶ STUDY DATA AND METHODS ¶Our analysis has two main components. First, we estimated the effect of a longer period of data exclusivity on revenues to pharmaceutical companies. We used retrospective data from the drugs@FDA database[10](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R10) and the FDA Electronic Orange Book[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R11) of approved drug products to construct a representative profile of protection from generic competition during a drug's life cycle. ¶Second, we feed that result into our global pharmaceutical policy model[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R8) to determine the effect of increased pharmaceutical revenues on drug innovation and consumers' longevity. The model is a set of dynamic interactions that link present health and innovation to their future values. For example, next year's health status depends on today's health, on the drug treatments that are available, and on a set of random health “shocks” that vary with an individuals' own risk-factors such as age, health behaviors, and current disease conditions. An example of a shock would be exposure to an infection. ¶Following Joseph Lipscomb and colleagues,[12](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R12) we assume a real (inflation-adjusted) “social” discount rate of 3 percent in our baseline analysis. This discount rate captures the manner in which society discounts benefits in the future compared to benefits today. It is distinct from companies' cost of capital – the amount of interest they need to pay to borrow money – which is typically higher than 3 percent.[9](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R9) ¶For our baseline analysis, we assume an innovation elasticity of 3.0, meaning that a 1 percent increase in expected drug revenue leads to a 3 percent increase in the number of drugs approved within the class each year. This assumption is slightly conservative and understates changes in innovation, longevity, and welfare, relative to the findings of Acemoglu and Linn.[7](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R7) ¶Increased innovation in turn affects population health. The global pharmaceutical policy model uses the health benefits documented in the clinical literature as a result of recent drugs for seven major conditions (heart disease, hypertension, diabetes, cancer, lung disease, stroke and mental illness). The model also accounts for the increased likelihood of treatment associated with drug innovation. As innovation expands because of greater data exclusivity, the life expectancy of older Americans improves; this improvement results mainly from the increased likelihood of treatment, not the health benefits of new drugs. With longer life expectancy, the population of potential drug users grows, further increasing revenues and stimulating innovation over time. We model innovation and health through 2060. ¶The monetary value of increased longevity, that is, the amount consumers are willing to pay for longer life spans, has long been a subject of debate. An analysis by Richard Hirth and colleagues of attitudes and behavior related to mortality risk showed that the median value of a life-year ranges from $110,200 to $505,400 (in 2004 US dollars).[13](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R13) Research by Kip Viscusi and Joseph Aldy implies that the value of a life-year ranges from $150,000 to $360,000.[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R8),[14](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R14) ¶In our baseline analysis, we assign a monetary value for increased longevity of $200,000 per life-year, though in sensitivity analyses we consider a range of values for this and other parameters. Additional details about our methods, data, and assumptions are provided in a technical appendix.[15](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R15) ¶Limitations ¶Simulations of this sort have certain limitations. Because laws, regulations, science, and medicine are likely to change in unforeseen ways, the retrospective data we relied on may not characterize the future. Some plausible changes, for example, an increase in the number of successful challenges to patent validity,[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R1) may cause us to understate the effects of longer data exclusivity. Other changes such as government price controls, which would reduce potential profits available to drug companies, may cause us to overstate effects. Still other changes, such as advances or setbacks in science and medicine that are impossible to anticipate, could lead to either understated or overstated effects. ¶We do not model behavioral responses to a longer period of data exclusivity due to the technical complexity and lack of good evidence. For example, a generic drug company might attempt to bypass lengthier data exclusivity periods in the United States by conducting clinical trials of a generic version of an already-approved drug. If drug developers believe that generic manufacturers would behave in this way, our results overstate the long-term effects of longer data exclusivity. ¶We do not model non-mortality benefits, for example, treatments for mental health conditions, pain, and rheumatoid arthritis. Such benefits account for much of the value of many drugs, yet there was insufficient evidence on the non-mortality benefits of new drugs. If these benefits are important, our estimates of the benefits of longer data exclusivity are conservative. ¶Finally, we do not calculate the potential benefits of a data exclusivity period shorter than the current Hatch-Waxman provisions. ¶STUDY RESULTS ¶Applying our findings about increased revenues over a drug's life cycle, we found that extending data exclusivity to twelve years would increase lifetime drug revenues by 5.0 percent on average. ¶[Exhibit 1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/figure/F1/) explains how we reached this result. The exhibit shows the proportion of conventional drugs that had protection against generic competition under existing law—arising from either patents or data exclusivity—and the proportion of such drugs that would have had protection if data exclusivity had lasted twelve years. The drugs in our sample began facing generic competition eight years after launch. With a twelve-year period of data exclusivity, by contrast, all the drugs would have faced no generic competition for at least twelve years after launch. ¶We also determined that expanding data exclusivity to twelve years would result in 228 extra drug approvals between 2020 and 2060, relative to the number of approvals that we project under the current Hatch-Waxman data exclusivity provisions. We lay out these data in [Exhibit 2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/figure/F2/), which illustrates the impact of increasing the period of data exclusivity to twelve years on the number of conventional drug approvals in the United States. ¶We found that a twelve-year data exclusivity period has little beneficial effect on longevity at age fifty-five. Americans in the early 2020s will bear the cost of increased drug spending with relatively little increased innovation and therefore relatively little benefit in terms of longevity. However, people turning fifty-five in the year 2060 can expect increased life expectancy of 1.44 years as opposed to 1.30 years under the status quo ([Exhibit 3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/figure/F3/)). The difference—1.7 months—is a result of innovation in the interceding years—that is, the new drugs brought to market because of lengthier data exclusivity. As a point of comparison, the elimination of obesity in the United States could increase life expectancy at birth by 2.5 to 13.0 months. ¶By 2060, these Americans would spend $3,400 per capita (in 2009 US dollars) over their remaining lives on drugs developed as a result of longer data exclusivity ([Exhibit 4](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/figure/F4/)). Given the substantial value of a life-year, the benefit of increased longevity would be $13,800, or $10,400 when you calculate benefits minus costs. The increase in “welfare” or well-being is smaller, but still positive, between 2020 and 2060. ¶Sensitivity Analyses ¶The baseline model implies that a longer period of data exclusivity would be of value to future generations of Americans. How sensitive are these results to our assumptions? To answer this question, we varied the value of a life-year ($50,000 to $300,000), the innovation elasticity (0.5 to 4.0), the social discount rate (2 percent to 4 percent), and the revenue impact of a twelve-year period of data exclusivity (base case plus or minus 25 percent). ¶In most of these scenarios, the net benefit of a twelve-year period of data exclusivity to people age fifty-five was positive from 2020 through 2060. The costs exceeded the benefits—and so longer data exclusivity was harmful—only for the lowest levels of the innovation elasticity (0.5–1.0) and the value of a life-year ($50,000). These parameter levels are much smaller than the best available evidence (described earlier). Hence, even though there is uncertainty about model parameters, a lengthier data exclusivity period would likely be beneficial overall. ¶DISCUSSION AND POLICY IMPLICATIONS ¶Recent discussions about the appropriate length of data exclusivity for new drugs have focused on biologics,[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R1) but as noted above, the National Academies Committee on Science, Engineering, and Public Policy[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R2) and the pharmaceutical company GlaxoSmithKline[3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804334/#R3) have proposed increasing the data exclusivity period for conventional drugs, as several European countries have done. ¶Unfortunately, there has been no quantitative analysis of the effects of a longer data exclusivity period on innovation, longevity, and societal welfare. To our knowledge, this is the first study to provide such estimates. Our analysis suggests that Americans would benefit in the long term from a longer period of data exclusivity. ¶This finding is robust with respect to plausible assumptions about the effect of revenues on innovation and other factors. Nevertheless, there is uncertainty regarding potential changes in regulations, science, and medicine that were not incorporated into our model. ¶The idea of extending data exclusivity for conventional drugs has not garnered much political support. It appears that elected officials are unlikely to embrace legislation that would result in higher drug prices. Our research suggests such legislation would spur innovation that would benefit future generations.

#### Data exclusivity is necessary to ensure effective clinical research

Bing 21

Dr. Han Bing (senior research fellow at the Institute of World Economics and Politics of Chinese Academy of Social Sciences). “TRIPS-plus Rules in International Trade Agreements and Access to Medicines: Chinese Perspectives and Practices.” Global Development Policy Center, Global Economic Governance Iniative. GEGI Working Paper 049, April 2021. JDN. https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_\_Bing\_FIN.pdf

Undisclosed test or other data refer to the data obtained in the entire medicine development process to demonstrate the medicine’s safety, efficacy and quality. The medicines and healthcare products regulatory agencies in various countries analyze and evaluate whether to approve the marketing of a new medicine based on such data. Since it is obtained from scientific studies, undisclosed test or other data are unable to satisfy the requirements of patent grant and cannot be protected by patent rights. However, the cost of obtaining marketing approval is expensive and the first registrant needs to be significant to overcome the negative price effects of competition from pharmaceutical manufacturers that free ride on the initial registrant’s marketing approval. Therefore, it is argued that, without a period of monopoly, the new drug developers will have no incentive to “conduct the costly clinical research and trials necessary to obtain marketing approval” (Chow and Lee 2018). Given its importance to the pharmaceutical industry, the United States is a strong proponent of adding such a provision in the TRIPS Agreement (Chow and Lee 2018). However, since the TRIPS Agreement was formally implemented 25 years ago, WTO members had not yet unified their opinions on the application of this provision. The United States, the European Union, and some members argue that, taking into account the considerable amount of efforts and costs for generating the necessary data, unless permitted by the originator, undisclosed test or other data should be granted exclusive rights against disclosure for a specific period of time (UNCTAD & ICTSD 2013, 613-615). During the period, government agencies shall not only protect such data against disclosure, but also prevent generic drug manufacturers from relying upon the data to obtain marketing approval. Developing countries such as Argentina, Brazil, India, and Thailand provide a non-exclusive protection on undisclosed test or other data, that is, such data are protected against unfair commercial use, but not granted exclusive rights, which allows government agencies to rely on such data to approve the marketing of generic medicines (UNCTAD & ICTSD 2013, 615-616). Developing countries believe that if the US and European practices were adopted, the marketing of generic medicines would be delayed, thereby unreasonably restricting the public access to medicines (UNCTAD & ICTSD 2013, 621). Prior to accession to the WTO in 2001, there were no data exclusivity provisions in China. After joining the WTO, China has assumed the obligation to protect such data in compliance with the TRIPS Agreement. Unlike most WTO members, as a condition for accession to the WTO, China agreed to provide data exclusivity protection for a period of six years (Feng 2010). Included in the Part V “Trade-Related Intellectual Property System” of the Report of the Working Party on the Accession of China (World Trade Organization 2001), China reiterated the content of and added what is not stipulated in Article 39(3) of the TRIPS Agreement. That is, during the period of six years, China does not allow approval of marketing for generic medicines, in order to provide exclusive protection for undisclosed test or other data of new chemical entities (World Trade Organization 2001, 284). Moreover, such protection is independent of patent protection, which means such data are protected whether a medicine is granted patent or not. The period of six years exclusive protection for undisclosed test or other data is longer than the period of 5 years of protection in the US and a number of bilateral free trade agreements.

#### Oil prices are sliding – two days in a row, dollar strength, Ida, increased production, and tapering asset purchases

Paraskova 9/20/21 [Tsvetana is a writer for Oilprice.com with over a decade of experience writing for news outlets such as iNVEZZ and SeeNews. "Oil Prices Fall As Traders Anxiously Await Fed’s Decision." https://oilprice.com/Energy/Oil-Prices/Oil-Prices-Fall-As-Traders-Anxiously-Await-Feds-Decision.html]

Oil prices dropped early on Monday as the U.S. dollar continues to strengthen ahead of the Fed’s much-anticipated policy meeting this week, which could announce the beginning of stimulus easing.

As of 9:05 a.m. EDT, WTI Crude was losing 1.75% at $70.71 and Brent Crude prices were down 1.49% at $74.21.

The oil market is down for a second consecutive day after Friday’s session settled in the red, as broader markets are anxiously watching whether the Federal Reserve will announce the start of asset purchase tapering at its meetings on Tuesday and Wednesday. The U.S. dollar gains were depressing the oil market as a stronger greenback makes oil buying more expensive for holders of other currencies.

The risk to U.S. oil production in the Gulf of Mexico is now diminishing as more output is being restored in the wake of Hurricane Ida. The return of more production from the U.S. offshore also weighed on oil prices early on Monday.

“As this week starts, much of the US market tightening on account of Ida is already baked into prices, while outages in offshore oil production and Louisiana refining capacity are continuing to ease,” Vanda Insights said in a note early on Monday.

The U.S. dollar and the Fed meeting will be the key external factors that will determine oil’s direction this week, apart from the usual U.S. inventory reports by the API and EIA, ING strategists Warren Patterson and Wenyu Yao say.

“All eyes will be on the FOMC meeting on Wednesday, where some believe we could already see the Fed announce its intentions to start tapering asset purchases, though our US economist is of the view that an announcement is more likely in November. A tapering announcement this week would likely put some downward pressure on oil and the broader commodities complex,” they noted.

#### Middle East war won’t go nuclear – balanced alliances, Chinese non-intervention, and cooperation prevent great power draw-in

Mead 14 – Walter Russell Mead, James Clarke Chace Professor of Foreign Affairs and Humanities at Bard College and Professor of American foreign policy at Yale University, Editor-at-Large of The American Interest magazine and a non-resident Scholar at the Hudson Institute, 2014 (“Have We Gone From a Post-War to a Pre-War World?” *Huffington Post*, July 7th, <http://www.huffingtonpost.com/walter-russell-mead/new-global-war_b_5562664.html>)

The Middle East today bears an ominous resemblance to the Balkans of that period. The contemporary Middle East has an unstable blend of ethnicities and religions uneasily coexisting within boundaries arbitrarily marked off by external empires. Ninety-five years after the French and the British first parceled out the lands of the fallen Ottoman caliphate, that arrangement is now coming to an end. Events in Iraq and Syria suggest that the Middle East could be in for carnage and upheaval as great as anything the Balkans saw. The great powers are losing the ability to hold their clients in check; the Middle East today is at least as explosive as the Balkan region was a century ago.

GERMANS THEN, CHINESE NOW

What blew the Archduke's murder up into a catastrophic world war, though, was not the tribal struggle in southeastern Europe. It took the hegemonic ambitions of the German Empire to turn a local conflict into a universal conflagration. Having eclipsed France as the dominant military power in Europe, Germany aimed to surpass Britain on the seas and to recast the emerging world order along lines that better suited it. Yet the rising power was also insecure, fearing that worried neighbors would gang up against it. In the crisis in the Balkans, Germany both felt a need to back its weak ally Austria and saw a chance to deal with its opponents on favorable terms.

Could something like that happen again? China today is both rising and turning to the sea in ways that Kaiser Wilhelm would understand. Like Germany in 1914, China has emerged in the last 30 years as a major economic power, and it has chosen to invest a growing share of its growing wealth in military spending.

But here the analogy begins to get complicated and even breaks down a bit. Neither China nor any Chinese ally is competing directly with the United States and its allies in the Middle East. China isn't (yet) taking a side in the Sunni-Shia dispute, and all it really wants in the Middle East is quiet; China wants that oil to flow as peacefully and cheaply as possible.

AMERICA HAS ALL THE ALLIES

And there's another difference: alliance systems. The Great Powers of 1914 were divided into two roughly equal military blocs: Austria, Germany, Italy and potentially the Ottoman Empire confronted Russia, France and potentially Britain.

Today the global U.S. alliance system has no rival or peer; while China, Russia and a handful of lesser powers are disengaged from, and in some cases even hostile to, the U.S. system, the military balance isn't even close.

While crises between China and U.S. allies on its periphery like the Philippines could escalate into US-China crises, we don't have anything comparable to the complex and finely balanced international system at the time of World War I. Austria-Hungary attacked Serbia and as a direct result of that Germany attacked Belgium. It's hard to see how, for example, a Turkish attack on Syria could cause China to attack Vietnam. Today's crises are simpler, more direct and more easily controlled by the top powers.

#### No strikes – Israel would never

* They’d have done it by now – preemptively attacked Iraq and Syria within weeks of finding single reactors
* A strike would make the bomb more likely by emboldening Iran, they’d leave the NPT, kick out IAEA watchdogs, and sanctions support collapses – funds nuke mod in Iran
* It hurts Israel by eroding regional allies and Iran gets a face lift – independently messes up US-Israel ties and erodes assurances
* Veto players – Netanyahu needs approval from the IDF and security cabinet and they all hate him

Keck 15 [Zachary Keck is the Wohlstetter Public Affairs Fellow at the Nonproliferation Policy Education Center. Before that, he was a researcher at the Belfer Center for Science and International Affairs. "5 Reasons Israel Won't Attack Iran." https://nationalinterest.org/commentary/five-reasons-israel-wont-attack-iran-9469?page=0%2C1]

Although the interim deal does further reduce Israel’s propensity to attack, the truth is that the likelihood of an Israeli strike on Iran’s nuclear facilities has always been greatly exaggerated. There are at least five reasons why Israel isn’t likely to attack Iran.

1. You Snooze, You Lose

First, if Israel was going to strike Iran’s nuclear facilities, it would have done so a long time ago. Since getting caught off-guard at the beginning of the Yom Kippur War in 1973, Israel has generally acted proactively to thwart security threats. On no issue has this been truer than with nuclear-weapon programs. For example, Israel bombed Saddam Hussein’s program when it consisted of just a single nuclear reactor. According to ABC News, Israel struck Syria’s lone nuclear reactor just months after discovering it. The IAEA had been completely in the dark about the reactor, and took years to confirm the building was in fact housing one.

Contrast this with Israel’s policy toward Iran’s nuclear program. The uranium-enrichment facility in Natanz and the heavy-water reactor at Arak first became public knowledge in 2002. For more than a decade now, Tel Aviv has watched as the program has expanded into two fully operational nuclear facilities, a budding nuclear-research reactor, and countless other well-protected and -dispersed sites. Furthermore, America’s extreme reluctance to initiate strikes on Iran was made clear to Israel at least as far back as 2008. It would be completely at odds with how Israel operates for it to standby until the last minute when faced with what it views as an existential threat.

2. Bombing Iran Makes an Iranian Bomb More Likely

Much like a U.S. strike, only with much less tactical impact, an Israeli air strike against Iran’s nuclear facilities would only increase the likelihood that Iran would build the bomb. At home, Supreme Leader Ali Khamenei could use the attack to justify rescinding his fatwa against possessing a nuclear-weapons program, while using the greater domestic support for the regime and the nuclear program to mobilize greater resources for the country’s nuclear efforts.

Israel’s attack would also give the Iranian regime a legitimate (in much of the world’s eyes) reason to withdraw from the Nuclear Non-Proliferation Treaty (NPT) and kick out international inspectors. If Tehran’s membership didn’t even prevent it from being attacked, how could it justify staying in the regime? Finally, support for international sanctions will crumble in the aftermath of an Israeli attack, giving Iran more resources with which to rebuild its nuclear facilities.

3. Helps Iran, Hurts Israel

Relatedly, an Israeli strike on Iran’s nuclear program would be a net gain for Iran and a huge loss for Tel Aviv. Iran could use the strike to regain its popularity with the Arab street and increase the pressure against Arab rulers. As noted above, it would also lead to international sanctions collapsing, and an outpouring of sympathy for Iran in many countries around the world.

Meanwhile, a strike on Iran’s nuclear facilities would leave Israel in a far worse-off position. Were Iran to respond by attacking U.S. regional assets, this could greatly hurt Israel’s ties with the United States at both the elite and mass levels. Indeed, a war-weary American public is adamantly opposed to its own leaders dragging it into another conflict in the Middle East. Americans would be even more hostile to an ally taking actions that they fully understood would put the U.S. in danger.

Furthermore, the quiet but growing cooperation Israel is enjoying with Sunni Arab nations against Iran would evaporate overnight. Even though many of the political elites in these countries would secretly support Israel’s action, their explosive domestic situations would force them to distance themselves from Tel Aviv for an extended period of time. Israel’s reputation would also take a further blow in Europe and Asia, neither of which would soon forgive Tel Aviv.

4. Israel’s Veto Players

Although Netanyahu may be ready to attack Iran’s nuclear facilities, he operates within a democracy with a strong elite structure, particularly in the field of national security. It seems unlikely that he would have enough elite support for him to seriously consider such a daring and risky operation.

For one thing, Israel has strong institutional checks on using military force. As then vice prime minister and current defense minister Moshe Yaalon explained last year: “In the State of Israel, any process of a military operation, and any military move, undergoes the approval of the security cabinet and in certain cases, the full cabinet… the decision is not made by two people, nor three, nor eight.” It’s far from clear Netanyahu, a fairly divisive figure in Israeli politics, could gain this support. In fact, Menachem Begin struggled to gain sufficient support for the 1981 attack on Iraq even though Baghdad presented a more clear and present danger to Israel than Iran does today.

What is clearer is that Netanyahu lacks the support of much of Israel’s highly respected national security establishment. Many former top intelligence and military officials have spoken out publicly against Netanyahu’s hardline Iran policy, with at least one of them questioning whether Iran is actually seeking a nuclear weapon. Another former chief of staff of the Israeli Defense Forces told The Independent that, “It is quite clear that much if not all of the IDF [Israeli Defence Forces] leadership do not support military action at this point…. In the past the advice of the head of the IDF and the head of Mossad had led to military action being stopped.”