## AI CP

### NC – Innovation CP

#### The member nations of the World Trade Organization should integrate centralized medical records and genetic information with machine learning technology and make data commercially available for biotechnology and pharmaceutical companies.

#### Combining centralized records with genetic info shifts research to a genotype first approach---both are key for synching gene variants with their medical effects. Excluding people from coverage ensures bottlenecks that undermine research.

Broad 14. (The Eli and Edythe L. Broad Institute of MIT and Harvard, often referred to as the Broad Institute, is a biomedical and genomic research center located in Cambridge, Massachusetts. Innovative “genotype first” approach uncovers protective factor for heart disease. June 31, 2014.https://www.broadinstitute.org/news/innovative-“genotype-first”-approach-uncovers-protective-factor-heart-disease)

**Extensive sequencing of DNA from thousands of individuals** in Finland has **unearthed scores of mutations that** destroy gene function **and are found at unusually high frequencies**. Among these are two mutations in a gene called LPA that may reduce a person’s risk of heart disease. **These findings are an exciting** proof-of-concept **for a new “**genotype first**” approach to identifying** rare genetic variants **associated with, or protecting from, disease followed by** extensive medical review **of carriers**. The new study by researchers from the Broad Institute, Massachusetts General Hospital (MGH), the University of Helsinki, and an international team of collaborators appears in a paper published online July 31 in PLOS Genetics. The **researchers** studied exomes — the portions of the genome that correspond to protein-coding genes — from 3,000 Finns and compared them to those of 3,000 non-Finnish Europeans. They identified 83 gene-deactivating variants that were at least twice as prevalent in Finns and went on to study these variants in over 35,000 Finns. Recent examples in heart disease, HIV, type 2 diabetes and Crohn’s disease have demonstrated that such mutations – known as “loss-of-function” mutations – in some cases protect from, rather than cause, disease and thereby **suggest** new paths **toward** therapeutics. **Geneticists have known that** Mendelian, **recessive genetic diseases** – such as Tay-Sachs or cystic fibrosis that **are caused by a single, mutated gene** – are **more common in** isolated populations **because of a phenomenon known as “**bottlenecking**.”** When a small population is isolated for tens to hundreds of generations, the population’s genetic diversity becomes restricted, and occasional rare genetic variations can by chance become much more common. While this has long been recognized as the source of the unique rare disease patterns seen in isolated populations, this paper demonstrates that the same principles can help researchers identify rare, loss-of-function variants in genome-wide association studies on these isolated populations. In the current study, researchers chose to study modern Finns – a population that descended from a well-documented bottleneck that occurred around 4,000 years ago. Comparing Finns with their non-Finnish European counterparts gave the researchers strong, empirical data. The LPA gene encodes Lipoprotein(a), a type of lipoprotein, first identified in 1963 and a known risk factor for heart disease. The variants described in this paper reduced levels of LPA gene expression causing lower levels of Lipoprotein(a) in the blood. The research team examined Finnish medical records and found that the loss-of-function variants were not associated with other health problems, making blocking LPA expression a potentially exciting therapeutic approach. **The availability of** centralized medical records **available in Finland enabled the researchers to** shift the paradigm **of** medical genetics **to a “genotype first” approach**. “**This new approach could significantly change how researchers analyze rare variants for complex diseases**. **It gives us a** window **into the** genetics of complex diseases **that we haven’t had before**,” said co-senior author Mark Daly, co-director of the Program in Medical and Population Genetics at the Broad Institute and chief of the Analytic and Translational Genetics Unit for the Center for Human Genetic Research at MGH. “By combining the information from detailed medical records with the information contained in the genomes of a bottlenecked population, we’re uncovering rare variants that contribute to complex diseases.” Heart disease is a leading killer globally. The World Health Organization reports that cardiovascular disease was responsible for 30 percent of all global deaths, or 17.3 million people in 2008. Therapeutics able to specifically address this risk by targeting LPA could have a global impact on medical outcomes. This work highlights the potential for using rare variant analysis in isolated populations to study complex diseases, an approach that had previously been largely limited to Mendelian traits. **The approach can now be applied to other complex diseases that have many contributing genetic factors.** “We’ve illustrated the validity of this approach by identifying rare, loss-of-function variants with promising therapeutic potential for the treatment of heart disease, but **this work also represents a** reproducible approachthat can be used to increase our understanding of other complex diseases as well,” said co-senior author Aarno Palotie (Broad Institute, Massachusetts General Hospital, Harvard Medical School, Institute for Molecular Medicine Finland FIMM, University of Helsinki).

#### Only data integration solves pharma collapse---the plan saves the industry

**Shaywit**[**z**](https://www.forbes.com/sites/davidshaywitz/)**13** (David, Medicine reporter for Forbes, “What's Holding Back Cures? Our Collective Ignorance (And No, Not A Pharma Conspiracy)” <https://www.forbes.com/sites/davidshaywitz/2013/05/10/whats-holding-back-cures-our-collective-ignorance-and-no-not-a-pharma-conspiracy/#eda1100236fd>)

The unfortunate truth is that drug companies really want to cure disease, but rarely know how. [Medical science simply isn’t up to the challenge](http://www.forbes.com/sites/davidshaywitz/2011/12/02/biopharmas-dirty-secret-revealed-science-is-fragile-forecasting-is-unreliable-now-deal-with-it-2/). Most diseases aren’t well enough understood to enable the rational development of truly transformative treatments. When high-profile pharma studies fail – such as the slew of recent Phase 3 Alzheimer’s Disease trials – it’s fashionable to characterize them as yet another industry failure. There’s some truth to this: the proximal cause may well be a poor decision to continue the development of a questionable drug. But the root cause is likely insufficient understanding of disease pathophysiology. We should also be careful about dismissing the value of incremental advances– a reflex I know I still have, although I’ve [recognized](http://www.nytimes.com/2002/07/16/health/improved-drug-regimens-help-patients-take-their-medicine.html) the value of seemingly small tweaks from the time I was a resident. Even today, when I critique (as derivative) formulation plays like liquid Ritalin, I’m glad to be [reminded](https://twitter.com/kevintoshio/status/312306291261448192) of the kids who stand to benefit from just such a medication. What’s Next? As the healthcare system looks more critically at value – demanding more evidence of effectiveness from providers and products alike – drug companies will be faced with two options. The best choice, of course, would be to figure out how to come up with truly revolutionary treatments. Perhaps unexpected insights will emerge from big data and the [integration](http://www.forbes.com/sites/davidshaywitz/2012/12/30/turning-information-into-impact-digital-healths-long-road-ahead/) of phenotypic and genotypic information, in the [framework of system biology](http://www.nature.com/nrd/journal/v8/n4/abs/nrd2826.html); maybe a new therapeutic modality will arrive on the scene. It’s possible intensified [collaboration](http://www.forbes.com/sites/davidshaywitz/2012/03/29/youre-welcome-the-vital-role-companies-play-in-pressure-testing-academic-medical-research/) between academic and industry researchers will eventually yield something useful, or that [open-data approaches](http://www.sagebase.org/philosophy/) (as championed by organizations like [Sage Bionetworks](http://www.sagebase.org/)[disclosure: I served as a founding advisor]) will achieve critical mass, and deliver impactful insights. But unless something substantial changes, progress is likely to remain slow and stochastic, and truly game-changing novel therapeutics will continue to be the exceptions rather than the rule. Given the ongoing challenges of creating transformative medications, there’s likely to be intensified focus on capturing, in a more granular fashion, the benefits of incrementally improved drugs; such assessments will not be a “nice to have” but a “must have,” table stakes for consideration by payors, and (to the extent these measures are used to demonstrate efficacy) regulators as well. I also suspect pharmas will increasingly look to offer “solutions” (e.g. associated app or access to an online community) not just pills, to deliver value, though it’s unclear whether such approaches will either prove effective or represent an attractive value proportion for the relevant stakeholders.

### NC – DA

#### Debt limit and government funding will pass now—everything else is delayed

BRESNAHAN 9/15 [JOHN BRESNAHAN, ANNA PALMER AND JAKE SHERMAN, Punchbowl News Legislataive Outlook 9/15, https://email.punchbowl.news/t/ViewEmailArchive/t/E48C6AF0C3714E452540EF23F30FEDED/C67FD2F38AC4859C/]

As we’ve been writing for you in Punchbowl News AM, we’re in the middle of the busiest legislative period in years. September has a stunning number of fiscal and legislative deadlines. The biggest of these, of course, is the end of the fiscal year on Sept. 30. This issue has become caught up in the debt-limit debate as Democrats plan to attach a debt-limit increase to a short-term funding bill. Republicans have vowed to oppose this move, raising the risk for the two sides to blunder into a government shutdown or debt crisis.

Suddenly, the Democrats’ $3.5 trillion reconciliation package and the $1 trillion bipartisan Senate infrastructure bill -- long the top priority in D.C. -- are taking a back seat to the meat and potatoes of governing. It now seems at least somewhat likely that the “Build Back Better” agenda -- made up of infrastructure and social safety net measures proposed by President Joe Biden -- could be delayed until later this fall.

One theory among Democrats is that Republicans will cave -- if not initially, then after a brief government shutdown or debt default scare during which the Democrats win the political argument that the GOP is an irresponsible partner in governing. Good luck getting someone to say that on the record, but it’s the reality we hear privately in the Capitol.

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#### Medical IP takes time, energy, and political capital away from domestic legislation – big pharma and EU allies

Bhadrakumar 5/9 M K Bhadrakumar is a former Indian diplomat. "Biden’s talk of vaccine IP waiver is political theater." Asia Times, May 9, 2021, asiatimes.com/2021/05/bidens-talk-of-vaccine-ip-waiver-is-political-theater.

On the other hand, Biden, whose political life of half a century was largely spent in the US Congress, is well aware of the awesome clout of the pharmaceutical companies in American politics. From that lobby’s perspective, the patent waiver “amounts to the expropriation of the property of the pharmaceutical companies whose innovation and financial investments made the development of Covid-19 vaccines possible in the first place,” as a senior scholar at the Johns Hopkins Center for Health Security puts it. The US pharmaceutical industry and congressional Republicans have already gone on the offensive blasting Biden’s announcement, saying it undermines incentives for American innovation. Besides, the argument goes, even with the patent waiver, vaccine manufacturing is a complex process and is not like simply flipping a switch. Senator Richard Burr, the top Republican on the US Senate Health Committee, denounced Biden’s decision. “Intellectual property protections are part of the reason we have these life-saving products,” he said. “Stripping these protections only ensures we won’t have the vaccines or treatments we need when the next pandemic occurs.” The Republican senators backed by Republican Study Committee chairman Jim Banks propose to introduce legislation to block the move. Clearly, Biden would rather spend his political capital on getting the necessary legislation through Congress to advance his domestic reform agenda rather than spend time and energy to take on the pharmaceutical industry to burnish his image as a good Samaritan on the world stage. Conceivably, Biden could be counting on the “text-based negotiations” at the WTO dragging on for months, if not years, without reaching anywhere. The US support for the waiver could even be a tactic to persuade pharmaceutical firms to back less drastic steps like sharing technology and expanding joint ventures to boost global production quickly. So far Covid-19 vaccines have been distributed primarily to the wealthy countries that developed them, while the pandemic sweeps through poorer ones such as India, and the real goal is, after all, expanded vaccine distribution. Biden is well aware that there will be huge opposition to the TRIPS waiver from the United States’ European allies as well. The British press has reported that the UK has been in closed-door talks at the World Trade Organization in recent months along with the likes of Australia, Canada, Japan, Norway, Singapore, the European Union and the US, who all opposed the idea.

#### Agenda change has a cascading effect

Joly 19, [Jeroen Joly is a Doctor Assistant at Universiteit Gent, Punctuated equilibrium theory and foreign policy, The research for this chapter was financially supported by the French Ministry of the Armed Forces, Directorate General for International Relations and Strategy (DGRIS), https://www.researchgate.net/profile/Jeroen\_Joly/publication/331073786\_Punctuated\_equilibrium\_theory\_and\_foreign\_policy/links/5c66ec3092851c1c9de446f2/Punctuated-equilibrium-theory-and-foreign-policy.pdf]

Further Theorization of Existing Concepts

Finally, agenda-setting scholars have continued to improve our understanding of some mechanisms and key concepts of PET. Several agenda-setting studies, for example, examined how friction and cascading contribute to the typical pattern of policy punctuations. Cascading is best understood as a self-reinforcing process of positive feedback whereby attention from one actor generates attention from another actor, which, again, draws even more attention from the initial actor, overthrowing the existing friction mechanisms (Jones and Baumgartner 2005; Walgrave and Vliegenthart 2010). Looking at mass media and parliament, Walgrave and Vliegenthart (2010) found friction and cascading to operate independently from each other to create punctuations, and showed under which conditions these mechanisms are more likely to occur.

The notion of cascading closely relates to the wider agenda-setting literature examining how attention from one actor influences that of another. We know, for example, that political parties heavily influence each other regarding the issues they focus on in parliament (Vliegenthart et al. 2011). Several studies have also confirmed the mutual influence between news media, parliament and government influence in the issues they focus on (for a comprehensive review of the literature on the media’s influence on parliament and government, see Van Aelst and Walgrave (2016) and Walgrave et al. (2006)), also for foreign policy issues (Edwards and Wood 1999; Wood and Peake 1998).

#### Debt default is the easiest way to wreck the US economy—ruins the US dollar and financial reputation

Egan 9/8 [Matt Egan is an award-winning reporter at CNN, covering business, the economy and financial markets across CNN's television and digital platforms, "'Financial Armageddon.' What's at stake if the debt limit isn't raised", 9/8/21, <https://www.cnn.com/2021/09/08/business/debt-ceiling-default-explained/index.html>]

The easiest way to spark a financial crisis and wreck the US economy would be to allow the federal government to default on its debt. It would be an epic, unforced error — and millions of Americans would pay the price.

And yet that unlikely situation is once again being contemplated. If Congress doesn't raise the limit on federal borrowing the federal government will most likely run out of cash and extraordinary measures next month, Treasury Secretary Janet Yellen warned lawmakers on Wednesday.

In short, a default would be an economic cataclysm. Interest rates would spike, the stock market would crater, retirement accounts would take a beating, the value of the US dollar would erode and the financial reputation of the world's only superpower would be tarnished.

"It would be financial Armageddon," Mark Zandi, chief economist at Moody's Analytics, told CNN. "It's complete craziness to even contemplate the idea of not paying our debt on time."

But it's a crazy world.

Lawmakers in Washington are again playing chicken with America's creditworthiness. And the path to raising the debt ceiling is not clear.

Even though Congress has in the past raised the debt ceiling with a bipartisan vote, Senate Minority Leader Mitch McConnell vowed in July that Republicans will not vote to raise the debt ceiling.

JPMorgan Chase (JPM) CEO Jamie Dimon urged lawmakers not to even think about going down this path again. During a hearing in May, Dimon said an actual default "could cause an immediate, literally cascading catastrophe of unbelievable proportions and damage America for 100 years."

'Irreparable damage'

In her letter to Congress, Yellen said history shows that waiting "until the last minute" to suspend or increase the debt limit "can cause serious harm" to business and consumer confidence, raise borrowing costs for taxpayers and hurt America's credit rating.

"A delay that calls into question the federal government's ability to meet all its obligations would likely cause irreparable damage to the U.S. economy and global financial markets," Yellen wrote.

A US default would undermine the bedrock of the modern global financial system.

"We pay our debt. That's what distinguishes the United States from almost every other country on the planet," Zandi of Moody's said.

Because of America's long track record of paying its debt, it's very cheap for Washington to borrow. But a default would force ratings companies to downgrade US debt and shatter that borrowing advantage. Markets plunged in 2011 when that debt ceiling standoff caused Standard & Poor's to downgrade America's credit rating.

Higher borrowing costs would make it much harder for Washington to borrow to pay for infrastructure, the climate crisis or to fight future recessions. And refinancing America's nearly $29 trillion mountain of existing debt would become that much more expensive. Interest expenses, which totaled $345 billion in fiscal 2020, would quickly rival what Washington spends on defense.

#### Extinction

Joshua Zoffer 20, Investor at Cove Hill Partners, Fellow at New America, JD Candidate at Yale University Law School, AB from Harvard University, “To End Forever War, Keep the Dollar Globally Dominant”, The New Republic, 2/3/2020, https://newrepublic.com/article/156417/end-forever-war-keep-dollar-globally-dominant

In early 2016, Obama Treasury Secretary Jack Lew cautioned that the dollar’s dominance as a global currency rested, in part, on the U.S. government’s reluctance to fully weaponize it. If foreign markets and governments “feel that we will deploy sanctions without sufficient justification or for inappropriate reasons,” he warned, “we should not be surprised if they look for ways to avoid doing business in the United States or in U.S. dollars.” Lew’s case stemmed from the more fundamental view that the dollar’s international role is “a source of tremendous strength for our economy, a benefit for U.S. companies and a driver of U.S. global leadership”—in other words, a role worth keeping. This view is emblematic of American financial governance since the Second World War. U.S. economic analysts, especially at the Treasury, have jealously guarded the dollar’s role and the many benefits it offers: the ability to run large deficits at low cost and disproportionate influence over the structure of the global economy, among others. Yet in their recent article in The New Republic, David Adler and Daniel Bessner argue the U.S. should abandon these advantages. In their view, the dollar’s role has encouraged American militarism and should be relinquished to curb such behavior. Dollar hegemony is not without cost, but to renounce it would be a profound mistake. Adler and Bessner’s view neglects the sizable economic benefits the dollar’s role confers on the U.S., as well as its possible use as an antidote to military adventurism. It ignores the enormous good that can be done with deficit spending, much of which has gone to the American military but could instead fund progressive programs. And it elides the inability of the U.S. and its global trading partners to shift away from dollar dominance without creating worldwide financial distress. Adler and Bessner are right that the U.S. has misused its privilege, but Washington should not abandon it; rather, American leaders should seek to transform it. Generations of American policymakers have been right to protect the dollar’s key currency role for economic reasons. Most notably, dollar hegemony affords the U.S. the ability to run large and prolonged budget and balance-of-payments deficits. The dollar represents 62 percent of allocated foreign exchange reserves, is used to invoice and settle roughly half of world trade, and accounts for 42 percent of global payments. Because governments, banks, and businesses worldwide need lots of dollars, the world market always stands ready to absorb new U.S.-dollar-denominated debt without charging higher interest rates. Adler and Bessner correctly point out that the rest of the world considers the dollar’s role as the world’s reserve currency to be an “exorbitant privilege,” a term coined in the 1960s by then French Finance Minister Valéry Giscard D’Estaing. The ability to spend beyond its means has enabled the U.S. to fund its impressive military might, whether one views that power as the fountainhead of Pax Americana or the source of illegitimate military adventurism. But these economic benefits go beyond just deficits. The demand for dollars also pushes up the dollar’s value against other currencies, enhancing American purchasing power and offering consumers access to imports on the cheap. The dollar’s role also means American firms rarely need to do business in foreign currencies, reducing transaction costs and exchange-rate risks. More broadly, America’s central economic role gives it outsize influence at crucial moments. At the height of the financial crisis that began in 2008, the Federal Reserve was able to inject vital liquidity into the global financial system by selectively offering dollar swap lines to trusted foreign central banks. Dollar hegemony enabled the U.S. to act swiftly, effectively, and on its own terms. In addition, the dollar’s role offers a potent alternative to kinetic military action as a means of pursuing foreign policy objectives. The dollar’s broad use means access to dollar liquidity—which in turn requires access to the U.S. financial system—is essential for foreign governments and businesses. For foreign banks, especially, being cut off from dollar access is essentially a death sentence. That makes sanctions that do so a powerful tool in the international arena. In 2005, for example, the U.S. used the dollar to strike a devastating blow against North Korea without firing a single shot or even formally enacting sanctions. Using authority provided by Section 311 of the Patriot Act, the Department of the Treasury crippled Banco Delta Asia, a bank accused of facilitating illegal activity by the North Korean government, by merely threatening to cut off its access to the American financial system. Deposit outflows began within days; within weeks the bank was placed under government administration to avoid a full collapse. Pyongyang was hit hard, as other banks ceased their business with it to avoid meeting the same fate. Similarly, though the Trump administration has worked hard to undo it, the Joint Comprehensive Plan of Action with Iran to limit the development of nuclear weapons was made possible, in part, by painful dollar sanctions that brought Iran to the table. Far from being a proximate cause of military conflict, the dollar’s central global role has often been used to contain adversaries without military intervention. Still, skeptics are right to point out that the dollar’s role has indirectly funded American interventionism and that dollar sanctions have been overused, provoking the ire of American allies. But these facts suggest we should use our dollar power to forge a more progressive U.S. order, not abandon the advantage altogether. America’s exorbitant privilege need not fund warships and missiles: The same low-interest borrowing could be used to fund a new universal health care system, expand access to higher education, or pursue any number of large-scale social policy objectives, including financing global public goods that no other country or consortium of countries is prepared to fund, such as climate change mitigation.

## OFF

### NC – Evergreening CP

#### CP TEXT: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by increasing penalties for patent abuse and evergreening fraud in the pharmaceutical industry.

#### Evergreening links to politics and collapses innovation, BUT the downsides are empirically debunked media hype – shifting enforcement for existing patent law solves abuse without harming pharma

Madigan & O'Connor 19 [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

This week, the Senate Judiciary Committee was to mark up a bill limiting patent eligibility for combination drug patents—new forms, uses, and administrations of FDA approved medicines. While the impetus was to curb so-called “evergreening” of drug patents, the effect would have been to stifle life-saving therapeutic innovations. Though the “No Combination Drug Patents Act”—reportedly to be introduced by Senator Lindsey Graham (R-SC)—was wisely withdrawn at the last minute, it’s likely not the last time that such a misconceived legislative effort will be introduced.

An Exaggerated Response to a Disputed Theory

The bill would have established a presumption of obviousness for drug or biologic patent applications whose invention was a new: dosing regimen, method of delivery, method of treatment, or formulation. While there was a rebuttal provision where the claim covered a new treatment for a new indication or “increase[d] . . . efficacy,” the latter was almost certain to introduce years of uncertainty and litigation. Further, the bill would have covered a broader class than true combination drug patents, in which one active ingredient is combined with another or with a non-drug.

Like many recent legislative efforts, the amendment sought to address a perceived lack of affordability of prescription drugs. After praising the America Invents Act of 2011 and subsequent Supreme Court rulings for strengthening the US patent system, the bill claimed that rising drug prices have outpaced “spending on research and development with respect to those drugs.” In addition to applauding Supreme Court decisions that have injected unquestionable uncertainty into patentable subject matter standards, the amendment went on to blame high drug prices on continually overstated issues related to advanced drug patents.

According to critics, combination drug patents have granted drug makers unearned and extended protection over existing drugs or biological products. But, quite simply, when properly issued by the USPTO under existing patentability standards, these are new patents for new products or processes.

Combination patents have been maligned as anticompetitive, resulting in a “thicket” of patents that impedes innovation through transaction costs and other inefficiencies. Unfortunately, notwithstanding a lack of empirical evidence validating the harm of follow-on innovation patents, patent thicket rhetoric is now being echoed by the media, the academy, courts, and policy makers in a fraught attempt to fix drug pricing.

Reports (see here, here, here, and here) from leading antitrust experts and intellectual property scholars have detailed the value of incremental innovation and challenged the notion that patent thickets are a true threat to competition and innovation. These studies have exposed patent thicket claims—much like the “troll” narrative that for years infected patent law debates—as an empty strawman theory, the repetition of which has led to undue confidence in its accuracy. The reality is that what critics point to as problematic cases of combination patents are in fact infrequent outliers, strategically highlighted to discount evidence of the value of new and innovative drug uses and administrations.

#### CP solves the aff while fostering innovation – directly comparative to the aff

Holman 20 [Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Congress Should Decline Ill-Advised Legislative Proposals Aimed at Evergreening of Pharmaceutical Patent Protection” p. 29-30 https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3593954]

Senator Thom Tillis, in his opening remarks prepared for one of the Senate’s hearings on drug pricing and intellectual property, expressed his concern that “[some members of Congress are] trying to take a sledgehammer to a problem that needs a fine tuned and highly efficient scalpel[, and that] by just focusing on patent protections, and the number of patent protections available to a single product, [Congress] may be doing more harm than good to our nation’s innovation economy.”112 Instead, he would support legislation that will “promote innovation and competition, allow the United States to continue to be the leader in medical and pharmaceutical research, and will ultimately lower drug prices for consumers.”113 It is important to bear in mind that the reason there has been such an uproar over the price of drugs is that these drugs provide huge benefits for society, far exceeding most other patentable innovation, and were it not for the patent incentive, it is very unlikely these products would have been made available to patients in the first place. In his testimony prepared for the same Senate hearing, Professor Olson reminded the Judiciary Committee that “even studies casting doubt on patent law’s efficacy generally tend to find that in the area of pharmaceuticals, patent law has a large, positive effect on social welfare by providing incentive for significant levels of drug development that otherwise simply would not occur.”114 By ~~impairing~~ impeding the ability of pharmaceutical companies to obtain patents on their inventions, the legislation discussed in this Article could discourage the investment necessary to bring the next generation of pharmaceutical innovation to patients. If pharmaceutical companies are deemed to be misusing patents to the detriment of patients and third-party payers, then it is that misuse of patents that should be targeted by legislation, not the patents themselves. For example, if the allegations regarding product hopping are true, and doctors are prescribing and patients using far more expensive follow-on products that provide little if any benefit to the patient, then that is a problem with the market that should be addressed, rather than denying patent protection for truly worthwhile product improvements. If pharmaceutical companies are using anticompetitive means to coerce patients and doctors into switching drugs, then antitrust laws can provide the remedy, as discussed above.115 Likewise, if the sheer number of patents that could be infringed by a single generic or biosimilar product exceeds the litigation capacity of any company attempting to bring such a product to market, then courts have it within their means to require the patent owner to limit infringement litigation to some reasonable number of patents and patent claims, and Congress could pass legislation that would encourage courts to do so, if such a reform is deemed necessary. By targeting misuse of patents by pharmaceutical companies, rather than pharmaceutical patents per se, it should be possible to address any valid concerns with the way pharmaceutical companies are using the patent system, while maintaining adequate incentives for the next generation of innovation.

## Case

#### Pharmaceutical innovation is accelerating now – new medicines are substantially better than existing treatments.

Wills, MBA, and Lipkus, PhD, 20 – Todd J. Wills [Managing Director @ Chemical Abstracts Service, MBA from THE Ohio State University] and Alan H. Lipkus [Senior Data Analyst @ Chemical Abstracts Service, PhD Physical Chemistry from the University of Rochester], “Structural Approach to Assessing the Innovativeness of New Drugs Finds Accelerating Rate of Innovation,” ACS Medicinal Chemistry Letters, Vol. 11, 2020, <https://pubs.acs.org/doi/pdf/10.1021/acsmedchemlett.0c00319> C.VC

Despite recent concerns over an innovation crisis, this analysis shows pharmaceutical innovation has actually increased over the last several decades based on the structural novelty of approved NMEs. The higher proportion of Pioneers over the most recent decade is a sign that innovation within the industry is accelerating rather than slowing. It is also an encouraging sign for the state of innovation in drug discovery that these Pioneers are significantly more likely to be the source of promising new therapies that are expected to provide substantial clinical advantages over existing treatments. Drug hunters are discovering Pioneers in newer and less explored regions of chemical space as they are increasingly found on scaffolds first reported in the CAS REGISTRY five or less years prior to their IND year or on scaffolds populated with 50 or less other compounds at the time of IND.

As scale becomes less of a strategic advantage, Big Pharma’s share of Pioneers has decreased even though the number of Big Pharma originated Pioneers has increased. This has created a structural innovation gap between Big Pharma and the Rest of Ecosystem which has widened over the last two decades as the Rest of Ecosystem is now responsible for originating almost 3 out of every 4 Pioneers. Pioneers originated by the Rest of Ecosystem are increasingly on new scaffolds, while a majority of Big Pharma originated Pioneers have historically been on new scaffolds.

The work presented here was intended as a study of drug innovation at a macro level. As a result, it included substances of various sizes with different degrees of complexity belonging to a range of functional and drug classes. Even though it was outside the scope of the present work to study specific subsets, such focused studies could yield additional insights into how innovation at a more micro level has changed over time. Other interesting subsets of our data set are the shapes and scaffolds of the Settlers and Colonists. Many of these shapes and scaffolds are privileged in the sense that they are seemingly capable of serving as ligands for a diverse array of target proteins. A separate study of the Settlers and Colonists as well as their side chains could provide insights into possible target-specific innovation trends.

As it often takes more than 10 years after initial discovery for an experimental drug to gain FDA approval, any measure of drug innovation that relies on the time of approval incorporates a significant time lag between initial discovery and ultimate approval. However, characterizing drug innovation based on structural novelty provides a means to assess the forward-looking innovation potential of an experimental drug at the time of initial discovery by comparing its framework information (at the scaffold and shape level) with prior FDA-approved drugs. Therefore, a separate study of drug candidates with publically disclosed structures currently in clinical development could provide additional insights into innovation trends at an FDA regulatory review level and serve as a leading indicator of innovation trends at an FDA approval level.

Given the tremendous opportunity represented by the vast amount of chemical space yet to be explored, drug-hunters of all types will continue pushing the boundaries to find promising new therapies in previously unexplored areas of chemical space. The race to discover these new drugs will be fueled by further advancements in screening approaches and in-silico methods (including innovations related to machine learning algorithms and molecular representations). However, comprehensive data on known shapes and scaffolds can fast track the identification of meaningful open areas of chemical space (shapes or scaffolds that are potentially important but have never been used as the basis for a molecule) to further explore.

#### The biopharmaceutical industry is uniquely reliant on IP protections – undermining them would kill innovation by making an already expensive process completely unfeasible.

Kristina M. Lybecker, PhD, 17 [PhD Economics, Associate Professor of Economics @ Colorado College], “Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up,” Fraser Institute, January 2017, <https://www.fraserinstitute.org/sites/default/files/intellectual-property-rights-protection-and-the%20biopharmaceutical-industry.pdf> C.VC

The unique structure of the innovative biopharmaceutical industry necessitates a variety of intellectual property protection mechanisms. In particular, the industry is characterized by a research and development (R&D) process that is lengthy, expensive, uncertain, and risky. According to DiMasi and colleagues, the estimated cost of developing a new medicine is US$2.6 billion (DiMasi, Grabowski, and Hansen, 2016).2 In addition, the time required to develop a new drug is also significant, averaging 10 to 15 years without any guarantee of success (PhRMA, n.d.). While these figures are highly controversial, biopharmaceutical innovation is unquestionably an expensive and lengthy undertaking.3 For the biopharmaceutical industry, innovation and its protection are essential and the source of both profits and growth. As such, patent protection is disproportionally more important for ensuring that the innovator appropriates the returns to R&D for the biopharmaceutical industry than virtually any other. Extending the findings of the 1987 “Yale Survey” (Levin, Klevorick, Nelson, and Winter, 1987), the “Carnegie Mellon Survey” established that while patents are again considered “unambiguously the least effective appropriability mechanisms,” the drug industry and other scholars regard them as strictly more effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996). The industry’s disproportionate reliance on patents and other forms of intellectual property protection is confirmed in numerous other studies.4

In essence, IPR protections provide innovative biopharmaceutical firms with an assurance of some return on their investment, thus creating incentives for the development of new technologies that could otherwise be easily replicated and sold by competitors. Due to the tremendous fixed costs required to develop new treatments and cures, a significant potential exists for free riding by follower firms, a market failure that would prevent investment in innovation were it not for the patents and other forms of intellectual property protections that provide a limited period of market exclusivity or other such incentives. Fundamentally, patents amount to an efficiency tradeoff. Society provides innovators with a limited period of market exclusivity to encourage innovation in exchange for public access to this knowledge. In exchange for the temporary static loss from market exclusivity, society gains complete knowledge of the innovation through disclosure, a permanent dynamic gain. Through this tradeoff, the existing patent system corrects the market failure that would stymie innovation. In its Apotex Inc. v. Wellcome Foundation Ltd. finding, Justice Binnie wrote for the Supreme Court of Canada, “A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act” (para. 37).

The biopharmaceutical industry is characterized by a number of legal and economic issues that distinguish it from other research-intensive industries. Danzon (1999) describes three features that are particularly noteworthy. First, given that the biopharmaceutical industry is characterized by an unusually high rate of R&D, intellectual property protection provides for the potential for significant market power and monopoly pricing that raises numerous public health policy questions surrounding prices and profits. Second, virtually every aspect of the industry is heavily regulated, from safety and efficacy to promotion and advertising, to pricing and reimbursement. Danzon describes the impact of these regulations as “profound and multidimensional even within a single country, affecting consumption patterns, productivity, R&D and hence the supply of future technologies” (Danzon, 1999: 1056). Lastly, while research and development costs are borne solely by the innovator, the resulting product is a global public good. “Each country faces an incentive to adopt the regulatory policies that best control its pharmaceutical budget in the short run, free-riding on others to pay for the joint costs of R&D and ignoring cross-national spillovers of national regulatory policies through parallel trade and international price comparisons” (Danzon, 1999: 1056). The combination of these characteristics defines a set of unique economic and legal challenges for the innovation of new drugs and the public health policies that surround their production, marketing, and distribution.

Innovative companies make far greater investments in time, resources, and financial support than do generic firms. Notably, innovation-based companies spend more than 200 times that which generic companies spend on the development of a particular drug (CIPC, 2011: 10). In addition, the investment of time, from laboratory to market, is also close to double for innovative companies relative to generic producers. Table 1 highlights the differences in the drug development processes of innovative and generic companies. For innovative biopharmaceutical companies, the development process is expensive, risky, and time consuming, all of which points to the need for strong IP protection to encourage investment and ensure companies are able to recover their investments.

The risk involved in biopharmaceutical development is starkly illustrated in a recent report by Biotechnology Innovation Organization (BIO), which reports that less than one of every 10 drugs that enter clinical trials is ultimately approved by the Food and Drug Administration in the United States. The report finds a success rate of merely 9.6%, a calculation that is significantly smaller than the widely-cited 11.8% figure from a 2014 study by the Tufts University’s Center for the Study of Drug Development.5 The International Federation of Pharmaceutical Manufacturers and Associations (2012) estimates that more than 3,200 compounds were at different stages of development globally in 2011, but only 35 new medicines were launched (Dawson, 2015).

Fundamentally, research-based biopharmaceutical companies incur greater expenses and risk in the development of their products than do generic manufactures. These investments of time and financial resources should be recognized and the effective patent life should be sufficient to recoup these investments. Continued investment and innovation are contingent upon strong, effective intellectual property protection and the ability of innovative firms to recoup their investments. Patents and other forms of intellectual property protection are disproportionally important to the research-based biopharmaceutical industry. Consequently, the legal architecture necessary to foster a robust innovation-based industry is multifaceted and is a powerful force shaping the biopharmaceutical industry, its profitability, productivity, and innovative future.

#### Vague standards for new patents are unenforceable and explode costs – the link alone turns case because the plan is unenforceable

Madigan & O'Connor 19 [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

While the amendment provided for a rebuttal to the presumption of obviousness, the language was ambiguous and likely to render the patent system even more unreliable than it already is. The proposed statute said that an applicant may rebut the presumption of obviousness if the covered claimed invention “results in a statistically significant increase in the efficacy of the drug or biological product that the covered claimed invention contains or uses.” It is unclear what would qualify as “statistically significant,” and proving this vague standard would be nearly impossible.

In order to show a “statistically significant increase in efficacy,” long and costly head-to-head clinical trials would be necessary. To be clear, this is not a standard required by the FDA for new drug approval, let alone patentability.

#### Eliminating evergreening ends the pharmaceutical industry – incremental developments are key to global breakthroughs on emerging pathogens

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Like most forms of innovation, the development of medicines and therapeutics is a process by which one builds and improves upon previous discoveries and breakthroughs. Sometimes those improvements are major advancements, but often they are incremental steps forward. In the pharmaceutical field, incremental or follow-on innovation frequently results in new therapeutic uses for existing drugs, which address serious challenges related to adverse effects, delivery systems, and dosing schedules. While they might not sound like medical breakthroughs on par with the discovery of penicillin, these advancements in the administration and use of pharmaceuticals improve public health and save lives.