## 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.

## DA

#### The Debt Ceiling expansion gives Democrats two months to finalize and pass Biden’s spending package – every moment is necessary to resolve intraparty disputes

Cochrane 10/7 Cochrane, Emily. Emily Cochrane is a correspondent based in Washington. She has covered Congress since late 2018, focusing on the annual debate over government funding and economic legislation, ranging from emergency pandemic relief to infrastructure. "Senate Leaders Agree to Vote on Short-Term Debt Ceiling Increase." N.Y. Times, 7 Oct. 2021, www.nytimes.com/2021/10/07/us/politics/debt-ceiling-senate.html.

Senator Chuck Schumer of New York, the majority leader, announced that he reached an agreement with Senator Mitch McConnell of Kentucky, the minority leader, to raise the federal borrowing limit through early December. “We have reached agreement to extend the debt ceiling through early December, and it’s our hope that we can get this done as soon as today.” “Republican and Democratic members and staff negotiated through the night in good faith. The pathway our Democratic colleagues have accepted will spare the American people any near-term crisis.” Video player loading Senator Chuck Schumer of New York, the majority leader, announced that he reached an agreement with Senator Mitch McConnell of Kentucky, the minority leader, to raise the federal borrowing limit through early December.CreditCredit...T.J. Kirkpatrick for The New York Times Oct. 7, 2021Updated 3:17 p.m. ET WASHINGTON — Top Senate Democrats and Republicans said on Thursday that they had struck a deal to allow the debt ceiling to be raised through early December, temporarily staving off the threat of a first-ever default on the national debt after the G.O.P. agreed to temporarily drop its blockade of an increase. Senator Chuck Schumer, Democrat of New York and the majority leader, announced that he had reached an agreement with Senator Mitch McConnell of Kentucky, the minority leader, to clear the way for a vote as early as Thursday on a short-term extension, with potentially as few as 11 days left before a possible default. The movement came the day after Mr. McConnell partly backed down from his refusal to allow any such increase to move forward, offering a temporary reprieve as political pressure mounted to avoid being blamed for a fiscal calamity. “It’s our hope that we can get this done as soon as today,” Mr. Schumer said on Thursday morning on the Senate floor. But one day after Mr. McConnell indicated that Republicans would stand aside and allow the short-term increase to advance, he and his top deputies were laboring on Thursday to ensure his members will put aside their objections and clear the path for a vote. “We gotta see if the deal is done,” President Biden told reporters during a trip to Illinois. “I’m not sure of that yet.” The agreed-upon bill would boost the legal debt cap by $480 billion, which the Treasury Department estimates would be enough to allow the government to continue borrowing through at least Dec. 3. The current debt limit was reinstated at $28.4 trillion on Aug. 1, and the Treasury Department has been using so-called extraordinary measures to delay a breach of the borrowing cap since then. The agency estimated that the government would no longer be able to pay all of its bills by Oct. 18, once those fiscal accounting maneuvers were exhausted. Without congressional action before then, economists and lawmakers have warned of catastrophic economic consequences, including the U.S. government having to choose between making payments on the interest on its debt or sending out Social Security checks and other crucial assistance. The legislation under consideration on Thursday did not offer a hard deadline for when cash would run out, and it would not restart the Treasury Department’s ability to employ extraordinary measures, such as curbing certain government investments, a Treasury official said. Some Republicans said they thought the set dollar figure would ensure the limit would not be reached again until at least January. The actual “X-date” will be determined by tax revenues that the government receives and expenditures that it must make near the end of the year. Making such projections has been especially difficult this year because the pandemic relief programs that are in place have made it harder to predict when money is coming and going. “There is no way to predict with any precision exactly how much you would need to increase the debt limit by to get to a certain date,” said Shai Akabas, the director of economic policy at the Bipartisan Policy Center, an independent think tank. But in aiming for Dec. 3, the deal may position the next debt limit fight to overlap once again with negotiations over avoiding a government shutdown, as funding is set to lapse on that same day if Congress does not approve new spending legislation beforehand. Democrats hope nearly two additional months will give them space to focus on finalizing and enacting most of President Biden’s domestic agenda, including hammering out an array of intraparty disagreements over an expansive multi-trillion-dollar social safety net and climate change package. In raising the prospect of a stopgap extension on Wednesday, Mr. McConnell had said that Republicans would allow Democrats to use normal procedures to consider it. But that commitment appeared in doubt on Thursday afternoon, as Republicans privately objected and leaders toiled to line up the votes needed. Should even one senator demand a recorded vote, at least 10 Republicans would be needed to join every Democrat to muster the 60 votes needed to move the bill forward. Image The movement on debt ceiling negotiations came the day after Senator Mitch McConnell backed down partially from his refusal to allow any such increase to move forward. Credit...T.J. Kirkpatrick for The New York Times “We’re having conversations with our members and kind of figuring out where people are, but, as you might expect, this is not an easy one to whip,,” said Senator John Thune of South Dakota, the No. 2 Republican. He added that, “in the end we’ll be there, but it will be a painful birthing process.” Some Republicans were wary of angering their base by allowing the bill to move forward, especially after former President Donald J. Trump issued a statement on Wednesday that attacked Mr. McConnell for “folding to the Democrats.” Mr. Trump seemed to be pressuring Republicans to force a showdown in the face of a looming default, saying that Mr. McConnell had “all of the cards with the debt ceiling, it’s time to play the hand.” Even if Republicans clear the way to allow the measure to pass, it does nothing to address the crux of the partisan stalemate over the debt. Most notably, Republicans have not dropped their demand that Democrats ultimately use an arcane and time-consuming budget process known as reconciliation to lift the debt ceiling into next year. Democrats are currently using that process to steer around Republican opposition and push through a sprawling domestic package that would address climate change, expand the social safety net with more health care and education benefits, and increase taxes on the wealthy and corporations. “The pathway our Democratic colleagues have accepted will spare the American people any near-term crisis,” Mr. McConnell said on the Senate floor. The extension, he added, also means “there’ll be no question they’ll have plenty of time” to use the reconciliation process to approve a long-term increase.

#### Pushing a WTO 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.

#### Infrastructure package is sufficient, necessary, and the last opportunity to solve climate change – extinction

Leber 10/7 Leber, Rebecca. Rebecca Leber covers climate change for Vox. Before joining Vox, she was an environmental reporter at Mother Jones, where her investigations exposed government corruption and fossil fuel industry disinformation. She has worked as a staff writer at Grist, The New Republic, and ThinkProgress. A dozen more outlets have published her work over her decade as a climate journalist. "A last chance for US climate action: Democrats’ Build Back Better and infrastructure bills." Vox, 7 Oct. 2021, www.vox.com/22685920/democrats-infrastructure-build-back-better-climate-change.

The United States — the largest carbon polluter in history — is closer than it’s ever been to taking sweeping and lasting action on the climate crisis. The bad news is that if Democrats can’t pull it off, they may never get another opportunity like this — and the planet certainly won’t. Democratic leaders are trying to pass two major pieces of legislation — the $1 trillion bipartisan infrastructure bill and the up to $3.5 trillion Build Back Better Act — that they say can slash US pollution by up to 45 percent in the coming decade. In the outlined Build Back Better Act, Congress would flex its power to transform the electricity sector so that it runs on mostly clean energy, steer the transportation sector toward electric vehicles, and finally take action on methane pollution, one of the most harmful greenhouse gases. But there have been many recent moments when the precarious dealmaking in Congress seemed close to falling apart. One of the biggest sticking points has been with West Virginia Sen. Joe Manchin, who has questioned the party’s approach to passing both bills simultaneously. “What’s the urgency that we have?” Manchin asked on CNN’s State of the Union in late September. In part because of Manchin’s opposition, even progressive leaders have begun to manage expectations, signaling the ultimate bill will be less ambitious. Sen. Bernie Sanders of Vermont suggested that the $3.5 trillion figure would see some “give and take.” The package is likely to shrink to $2.3 trillion or less, the New York Times reported on Wednesday. So what is the urgency? Democrats only have one year before midterm elections could take away their narrow majorities in the House and Senate. That would leave them powerless to pass any legislation without help from Republicans. At the same time, the planet faces a rapidly closing window to avert the worst catastrophes of global warming. Every fraction of a degree will translate into lives and livelihoods lost. The world can’t afford another decade of American inaction, and what Congress does next will help determine the future of the climate. A last chance for Democrats Historically, the president’s party loses seats in Congress in midterm elections. Next November, Democrats could lose their narrow control of Congress if they lose even one Senate seat or more than a few House seats. “The middle of that Venn diagram — when we have leaders who care about science and we still have that window of opportunity — is now,” said Lena Moffitt, campaign director at the climate advocacy group Evergreen Action. Democrats in Congress are also relying on a roughly once-a-year process, known as budget reconciliation, to try and push the Build Back Better Act through the Senate. Reconciliation allows them to pass a budget with a simple majority, instead of the 60 votes that are usually required in the Senate. There might not be time or political will to make a similar move in 2022. And some Democrats remain unwilling to eliminate the Senate filibuster, which is the other way they could pass progressive policies. In short, if the historical pattern holds, Democrats may not get another chance under President Biden — or even this decade — to take serious action on climate. Some Republicans have been hinting at taking climate change more seriously, but much of the party’s leadership continues to downplay and deny climate science. The next time the US has an opening like this, climate change will likely be dramatically worse — and that much harder to stop. A flooded street of shops at night reflecting the lights in the water. Hurricane Ida caused record flooding in New Jersey in September. Climate change is already intensifying extreme weather such as tropical storms and heat waves. Anadolu Agency via Getty Images The best chance for the global climate Climate scientists have warned that once the atmosphere warms more than 1.5 degrees Celsius, we will live in a drastically changed world. If countries, corporations, and individuals don’t take immediate action to reduce pollution, the world may hit that grim milestone in just 10 years. Over the long term, if the world continues on its current polluting path, the world will warm more than double that amount, risking catastrophes humanity has never had to confront. The window to chart a new course is rapidly closing. And the world’s “last, best chance” to take decisive collective action is less than a month away, as John Kerry, who serves as President Biden’s climate envoy, has said. In early November, world governments will gather in Glasgow for the United Nations climate conference, COP26. Following up on the Paris climate accord, countries will pledge more ambitious pollution targets and tackle the challenge of financing a worldwide transition to clean energy. The US bears the most responsibility of any country for global warming, having released 20 percent of the world’s greenhouse pollution since 1850. Today, the country ranks second in emissions behind China. But the US also has the power to magnify its impact if it leads by example, or if it flexes its influence on the global economic system, for example by affecting global prices of fossil fuels by ending government subsidies. Climate experts say progress at the COP26 conference depends on the United States proving it can do its part, for symbolic as well as practical reasons. This is the first year the US officially returns to global negotiations after former President Donald Trump withdrew the country from the Paris climate accord. Now, Biden has to lead by example by showing that the country can swiftly change direction for good, demonstrating progress on its national pledge of cutting emissions 50 to 52 percent by 2030. “There is this sense of exhaustion about how long is it going to take for one of the biggest emitters in the world to do its fair share,” said Rachel Cleetus, the clean energy policy director at the Union of Concerned Scientists. It’s unclear whether Congress will deliver on climate-change legislation by the time the international community meets in Glasgow. But any steps forward would send “a very important signal that can really help catalyze more ambition from other countries,” Cleetus said.

## Case

#### 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

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/]

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.

Additionally, follow-on innovations are—and should remain—subject to the same patentability standards as any other technologies. Patents reward advancements that are novel, useful, and nonobvious, and our patent system has long recognized that patent claims are to be presumed patentable and nonobvious. The Graham amendment would have turned this established standard on its head, creating a separate and ill-defined hurdle for certain advancements in medicine.

The benefits of incremental innovation to public health and patients cannot be overstated. New formulations of malaria drugs, dosing regimens and delivery systems for AIDS patients, more efficient administrations of insulin for the treatment of diabetes, and developments in the treatment of cognitive heart disease have all been possible because of incremental innovation.

Imposing unjustified restrictions on the patentability of advancements like these would be disastrous for drug development, as the incentives that come with patent protection would be all but eliminated. Without the assurance that their innovative labor would be supported by intellectual property protection, pioneering drug developers would shift resources away from improving drug formulations and uses. The development of more effective treatments of some of the most devastating diseases would stall, as innovators would be unable to commercialize their products, recoup losses, or fund future research and development.

As critics continue to target myopically the patent system for a broader issue of drug prices in the American health care system, it’s likely not the last time that language like this will be proposed. In order to avoid the implementation of such ill-conceived standards into our patent laws, understanding what’s at stake is critical. The future of medical innovation depends on it.

#### It tips the entire industry into insolvency

Globerman & Lybecker 14 [Steven Globerman is Resident Scholar and Addington Chair in Measurement at the Fraser Institute as well as Professor Emeritus at Western Washington University. Kristina M.L. Acri, née Lybecker – Chair of the Department of Economics and Business, Colorado College. "The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY." https://www.fraserinstitute.org/sites/default/files/benefits-of-incremental-innovation.pdf]

Incremental innovation is a financial necessity for high-tech industries such as biotechnology and pharmaceuticals. Given the paucity and unpredictability of radical innovation, incremental advances sustain the industry financially, for no mature industry can do so from income derived from breakthrough innovation alone. As described by Wertheimer, Levy, and O’Connor, “[t]he pharmaceutical industry must generate revenue based predominantly on incremental innovations, which characterize the majority of products and contribute the majority of revenue” (Wertheimer, Levy, and O’Connor, 2001: 108–109). Evidence of the prevalence of breakthrough relative to incremental innovations is shown in figure 2.2 below. Over the entire period, products based on incremental innovations outnumber breakthrough products. In addition, it is essential to recognize the importance of risk management. Any technology portfolio will comprise projects of differing risk levels. In the case of the pharmaceutical industry, incremental innovation projects are an essential—and significant—component of this portfolio. The incremental innovation projects will be characterized by lower risk and a greater probability of reaching the market (Wertheimer, Levy, and O’Connor, 2001: 110).

#### Weakening IP encourages imitation, not innovation – it removes the financial incentive to invent

Globerman & Lybecker 14 [Steven Globerman is Resident Scholar and Addington Chair in Measurement at the Fraser Institute as well as Professor Emeritus at Western Washington University. Kristina M.L. Acri, née Lybecker – Chair of the Department of Economics and Business, Colorado College. "The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY." https://www.fraserinstitute.org/sites/default/files/benefits-of-incremental-innovation.pdf]

Finally, protecting innovation fosters economic growth and development, and that includes incremental innovation. A growing body of empirical evidence demonstrates that increasingly robust intellectual property protections, in combination with other policies, increase economic development, foreign direct investment (FDI), and innovation.5 A 2006 report from the United Nations Industrial Development Organization (UNIDO) studied the role of intellectual property rights in advanced nations in technology transfer and economic growth, concluding that protecting innovation creates benefits for countries at all levels of development. For developing countries, strengthening intellectual property rights encourages growth. For middle-income countries, evidence indicates that domestic innovation and diffusion of technology can lead to growth and that strengthening IPRs can encourage industries to shift from imitation to innovation. For advanced economies, stronger IPRs increase innovation and raise growth (Falvy, Foster, and Memedovic, 2006). Moreover, enforcing intellectual property rights and protecting innovation also drives research on cures. This is true of the diseases of both industrialized and developing nations. A recent study by Kyle and McGahan (2012) finds evidence of more research on diseases in nations with TRIPS-compliant IP provisions, as their patent provisions were put into place and implemented, than on diseases prevalent in non-TRIPS-compliant nations, controlling for the level of economic development and other factors.6

#### Cross-apply their disease impact ev.