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#### The Economy is recovering now

Sully 8/19 - Evan Sully, 8/19/21, Reuters, U.S. leading indicator points to further economic recovery in July, https://www.reuters.com/world/us/us-leading-indicator-points-further-economic-recovery-july-2021-08-19/ WJ

(Reuters) -A gauge of future U.S. economic activity increased in July, suggesting the economy continued to expand from the recession caused by the coronavirus pandemic even in the face of a resurgence in cases fueled by the Delta variant.

The Conference Board on Thursday said its index of leading economic indicators (LEI) rose 0.9% last month to 116.0. Economists polled by Reuters had expected an increase of 0.8%.

Even though the U.S. economy is forecast to grow this year at its fastest pace since the 1980s, there are signs the recovery could be cooling off. Supply-chain bottlenecks continue to slow manufacturing growth, and consumer sentiment plummeted in early August to a decade-low as Americans gave faltering outlooks on everything from personal finances to inflation and employment.

Meanwhile, consumer price increases slowed in July, the Labor Department said last week, but inflation overall remained at a historically high level amid supply-chain disruptions as well as stronger demand for travel-related services.

"The U.S. LEI registered another large gain in July, with all components contributing positively," said Ataman Ozyildirim, the Conference Board's senior director of economic research. "While the Delta variant and/or rising inflation fears could create headwinds for the U.S. economy in the near term, we expect real GDP (gross domestic product) growth for 2021 to reach 6.0% year-over-year, before easing to a still robust 4.0% growth rate for 2022."

The LEI's coincident index, a measure of current economic conditions, rose 0.6% in July after increasing 0.4% in June.

But the lagging index increased 0.6% last month after being unchanged in June and increasing 0.8% in May.

"Even with more moderate growth in the second half of the year, the economy’s momentum remains encouraging with constraints on labor supply easing, a trove of excess savings still waiting to be drawn down, and strong vaccine numbers that will insulate the economy from the worsening health situation more so than prior waves," said Mahir Rasheed, U.S. economist at Oxford Economics.

#### Biotech is resilient and fundamentals are strong – but this trend relies on innovation and investment

Cancherini et al 21 -- Laura Cancherini is a consultant in McKinsey’s Brussels office; Joseph Lydon is an associate partner in the Zurich office, where Jorge Santos da Silva is a senior partner and Alexandra Zemp is a partner, McKinsey, What’s ahead for biotech: Another wave or low tide?, April 30, 2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide WJ

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising

#### Reductions in IP protections kill medical innovation, economic growth, and knowledge building for the future510

McDole and Ezell 04/29 – Jaci McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at ITIF. She focuses on IP and its correlations to global innovation and trade. Her work includes ITIF’s Innovate4Health Initiatives (2017–2019) and A Covid-19 TRIPS Waiver Makes No More Sense for Copyrights Than It Does for Patents (2021). McDole comes to ITIF from the Institute for Intellectual Property Research, an organization she cofounded to study and further robust global IP policies. Stephen J. Ezell is ITIF vice president for Global Innovation Policy. He focuses on science, technology, and innovation policy as well as international competitiveness and trade policy issues. He is the coauthor of Innovating in a Service Driven Economy: Insights Application, and Practice (Palgrave McMillan, 2015) and Innovation Economics: The Race for Global Advantage (Yale 2012). The Information Technology and Innovation Foundation (ITIF) is an independent, nonprofit, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized by its peers in the think tank community as the global center of excellence for science and technology policy, ITIF’s mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress; April 29, 2021; “Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic”; <https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through> //advay

Innovation can—and does—happen anywhere and at any time. As society ground to a halt in 2020, innovators around the world worked tirelessly to develop treatments, vaccines, and solutions to COVID-19 pandemic-related challenges. From personal protective equipment (PPE) to treatments and vaccines to autonomous delivery robots to remote and social distancing solutions for the workplace, intellectual property (IP) played an indispensable role in enabling research, development, and commercialization of many of the innovations meeting the challenges of the pandemic. IP enables start-ups to gain access to much-needed capital. IP gives innovators the confidence to invest in research and development (R&D) and provides incentives for commercialization. Indeed, it is difficult to innovate without the protection of ideas.

Despite this, some—particularly anti-business IP opponents—have blamed IP rights for a host of problems, including limited access to therapeutics, vaccines, and biotechnology. They offer seemingly simple solutions—weaken or eliminate IP rights—and innovation will flow like manna from heaven. Eliminating IP rights might accelerate the diffusion of some pre-existing innovations, but it would absolutely limit future innovations. Innovators, a bit like Charlie Brown kicking the football held by Lucy, would be wary of trusting governments who might say, “Well, this time we won’t take away your IP rights, so go ahead and invest large amounts of time and money.” Given the nature of COVID-19, nations around the world cannot afford to take this risk. Future pandemics and other challenges for which we will need to rely on IP-protected innovations to overcome are near certain to arise.

Moreover, the blame game usually ignores the real, underlying problems. For access to innovations to fight COVID-19, especially biotechnology, vaccines, and therapeutics, the underlying problems are regulatory delays and a lack of adequate and appropriate manufacturing infrastructure.1 The lack of infrastructure has resulted in supply chain bottlenecks in places where few are currently equipped to handle the manufacturing requirements.2 Meanwhile, regulatory delays have prevented vaccines, therapeutics, and diagnostics from entering certain markets.3

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

#### Two Impacts430

#### 1] Pandemics - future pandemics are more likely and more deadly which makes innovation key to stop mass suffering

Ceballos 5/27 Gerardo Ceballos [PhD, Dr Gerardo Ceballos is an ecologist and conservationist at the Universidad Nacional Autonoma de Mexico. He is particularly recognized for his influential work on global patterns of distribution of diversity, endemism, and extinction risk in vertebrates. He is also well-known for his contribution to understanding the magnitude and impacts of the sixth mass extinction.], 5/27/21, “THE SIXTH MASS EXTINCTION AND THE FUTURE OF HUMANITY”, Population Matters, <https://populationmatters.org/news/2021/05/sixth-mass-extinction-and-future-humanity> DD AG

Somewhere, sometime in late 2019, a coronavirus from a wild species, perhaps a bat or a pangolin, infected a human in China. This could have been an obscure event, lost without trace in the annals of history, as it is very likely this has occurred many times in the last centuries. But this particular event was somehow different. The coronavirus became an epidemic first and a pandemic later. Covid-19 became the worst pandemic since the Spanish flu in 1918. The horrific human suffering it has caused, and its economic, social and political impacts, are still unraveling.

The reason Covid-19 and more than forty other very dangerous viruses, such as Lassa fever, HIV and Ebola, have jumped from wild animals to humans in the last four decades is the destruction of natural environments and the trafficking and consumption of wild animals.

The wildlife trade is to satisfy the insatiable and extravagant demand for these species in the Asian market, in countries such as China, Vietnam and Indonesia. The illegal wildlife trade is a gigantic business. It is as lucrative as the drug trade, but without the legal implications. The immense appetite of China and other Asian societies for exotic animals has promoted exponential growth in trade and profits. Wild and domestic animals sold in “wet markets” are kept in unsanitary and unethical conditions. There, feces, urine and food waste from cages at the top spill into cages at the bottom, creating the perfect conditions for viruses to leap from wild animals to domestic animals and humans. Thousands of wildlife species or their products are traded annually.

Wildlife trade is one of several human impacts, including habitat loss and fragmentation, pollution, toxification and invasive species, that have caused the extinction of thousands of species and threaten many more. Indeed, most people are unaware that the current extinction crisis is unprecedented in human history. Extinction occurs when the last individual of a species dies. The UN recently estimated that one million species, such as the panda, the orangutan and the Sumatran rhino, are at risk of extinction.

The second finding is that population extinctions, which are the prelude to species extinctions, are occurring at very fast rates (Ceballos et al., 2017). Around 32 percent of a sample of 27,000 species have declining populations and have experienced massive geographic range contractions. Population extinctions are a very severe and widespread environmental problem which we have called “Biological Annihilation”.

Finally, our third finding indicates that the magnitude of the extinction crisis is underestimated because there are thousands of species on the brink of extinction (Ceballos et al., 2020). Those species will likely become extinct in the near future unless a massive conservation effort is launched soon.

Many times, people have asked me why we should care about the loss of a species. There are ethical, moral, philosophical, religious and other reasons to be concerned. But perhaps the one that is most tangible for most people is the loss of ecosystem services, which are the benefits that humans derive from the proper function of nature. Ecosystem services include the proper mix of gases in the atmosphere that support life on Earth, the quantity and quality of water, pollination of wild crops and plants, fertilization of the soil, and protection against emerging pests and diseases, among many others. Every time a species is lost, ecosystem services are likely to erode and human well-being is reduced.

The loss of so many ecosystems and species is pushing us towards the point of collapse of civilization. The good news is that there is still time to reduce the current extinction crisis. The species and ecosystems that we manage to save in the next 10 – 15 years will define the future of biodiversity and civilization. What it is at stake is the future of mankind.

#### Secondary patents are key to pharmaceutical innovation

Holman 18 (Christopher M., Professor of Law @ University of Missouri-Kansas City School of Law) Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection, 9/21/18, <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> EE bracketed for ableism

Pharmaceutical development is prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself.

The Benefits of Follow-On Innovation

The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation.

Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive [patterns] ~~impairments~~. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day.

Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate).

“Evergreening” – an Incoherent Concept Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation. Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs. Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself. For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself. Compatibility with TRIPS The heightened requirements of patentability proposed in the Guidelines not only pose a threat to important follow-on pharmaceutical innovation, but if they were to be adopted could constitute noncompliance with certain international treaties, including in particular the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”), which the 164 Members of the World Trade Organization (WTO) have agreed to abide by. The TRIPS Agreement requires WTO Members to provide certain minimum levels of protection for patentable inventions, thus placing substantive limitations on the ability of WTO Members to raise the bar for patentability. The TRIPS Agreement in no way sanctions subject matter-specific heightened requirements of patentability; to the contrary, the antidiscrimination provision in the TRIPS Agreement affirmatively precludes such measures. Unfortunately, this point is all too often lost in discussions of international and domestic patent policy. Best Practices for Evaluating the Patentability of Follow-On Pharmaceutical Inventions Patentable Subject Matter In Patentability Standards my co-authors and I endorse what we believe to be the proper standards for assessing the patentability of follow-on pharmaceutical innovation, which are essentially the same standards currently being applied in the US, Europe and other nations in compliance with the TRIPS Agreement. As a general matter, inventions arising out of follow-on pharmaceutical innovation, and in particular the categories of “secondary” invention identified in the Guidelines, should be deemed patentable subject matter so long as the various substantive requirements of patentability, including novelty, non-obviousness, and practical utility are satisfied. Although the US Supreme Court’s 2012 Mayo decision appears to have rendered many diagnostic inventions patent ineligible in the United States, the Court explicitly noted that the decision was not intended to adversely affect the patent eligibility of new methods of using drugs, and the patent eligibility of drugs and drug improvements remains generally noncontroversial in the US. In particular, the Guidelines’ recommendations that new methods of using a drug should be presumptively treated as patent ineligible “discoveries,” and that drug metabolites are not patent eligible because they can be produced by physiological processes, should be rejected. An inventive method of using a drug to treat disease is a significant advance in medicine, not a mere “discovery,” and it is a mistake to conflate naturally-occurring metabolites with drug metabolites, which as a general matter are not naturally-occurring molecules and which can in many instances constitute important contributions to medicine in and of themselves. Utility / Industrial Application The requirement of utility/industrial application likewise should generally not be an issue for follow-on pharmaceutical innovation, since by their nature these inventions involve a new form or mode of use of a pharmaceutically active chemical entity of known therapeutic potential. It is important to emphasize that compliance with the utility requirement does not require a showing that the follow-on invention provide some beneficial utility not otherwise provided by the prior art. If a follow-on pharmaceutical invention does not provide any significant benefit over the prior state-of-the-art, regulatory authorities and a well-functioning market should ensure that the patent will not significantly impact access to medicine. Novelty Under the TRIPS Agreement, an invention can be denied patent protection if, as of the effective filing date, it is not novel (i.e., new) relative to the “prior art,” as defined by statute and case law in domestic systems. The prior art consists of publications and other public disclosure of the invention, and under some circumstances encompasses certain non-public uses and offers for sale. Significantly, in order to have effect the prior art generally must enable one skilled in that field of technology to make and use a claimed invention without engaging in undue experimentation. For example, the generic disclosure of a large group of molecules comprising some common structural core does not necessarily destroy the novelty of each and every molecule encompassed by that disclosure. The rationale behind this approach, which is well-established in jurisdictions such as the US and Europe, is that while a generic disclosure can easily be defined so as to encompass millions and even billions of individual molecules, it does not meaningfully enable the identification, synthesis, and clinical use of a specific molecule falling within the genus that is later found to provide some specific utilitarian benefit not shared by other members of the group. The Guidelines would upset the status quo by declaring patents directed to inventions of this type (referred to in the Guidelines to as “selection patents”) as generally invalid for lack of novelty. But if a paper disclosure encompassing a large group of molecules, the vast majority of which have never been made or tested, is deemed sufficient to render every molecule falling within the group unpatentable, the incentive for drug companies to invest in identifying and developing a potentially safe and effective pharmaceutical compound falling within the group will be severely dampened. Identifying a specific molecule with the safety and efficacy profile required of a successful human therapeutic is a veritable search for a needle in a haystack, and without the potential for patent protection in cases in which a valuable needle is recovered too many haystacks will remain inadequately searched. Nonobviousness This brings us to what most would consider to be the most fundamental and important requirement of patentability, the nonobviousness requirement (i.e., the requirement that an invention embody an inventive step). Not surprisingly, the Guidelines focus heavily on the nonobviousness requirement, recommending that patent offices interpret and apply the requirement in a manner that would effectively render most follow-on pharmaceutical innovation presumptively unpatentable; some categories of follow-on innovation, such as a new polymorph with improved properties, or an isolated enantiomer that does not cause the adverse effects associated with the racemate, would be treated as per se obvious and thus entirely excluded from patent protection. These recommendations are based on an oversimplified and highly abstract understanding of pharmaceutical research, and fail to take into account the unpredictability and technical challenges inherent to the research and development of follow-on pharmaceutical innovation. The criterion for compliance with the nonobviousness requirement is straightforward when stated in the abstract: a claimed invention satisfies the requirement if, and only if, as of the relevant date, i.e. the effective filing date, the invention would not have been obvious to a person of skill in that area of technology, given the state-of-the-art at that time. In practice, the nonobviousness/inventiveness inquiry is highly fact-specific, decided on a case-by-case basis in view of the state-of-the-art at the time of the invention, the knowledge and skill of those working in the field at that time, the extent to which those working in the field would have been motivated to try to make the invention, and the unpredictability associated with that area of technology during the relevant timeframe. The question of compliance with the nonobviousness requirement must focus on the specifics of the invention at hand, rather than relying on the broad categorization of entire categories of invention as either per se or presumptively obvious, the approach advocated by the Guidelines. In assessing whether an invention would have been obvious at the time it was made, it is important to avoid the well-established tendency towards hindsight bias. In retrospect, once an invention has been made and proven successful, there is an inherent tendency of humans to look back and think “I could have thought of that.” This is particularly problematic in the context of follow-on pharmaceutical innovation, where it is tempting to assume that a new formulation or new method of using a drug would have been “obvious to try,” once that formulation or method has been made, tested, and proven safe and effective. When viewed in the abstract, by a person not actually engaged in pharmaceutical research and development, follow-on pharmaceutical innovation can appear deceptively simple. However, the path to meaningful follow-on innovation is tremendously challenging, unpredictable, and more often than not results in failure. This explains why so many courts and patent offices around the world have explicitly found patents directed to follow on pharmaceutical innovations nonobvious and patentable. An invention should only be deemed obvious if the prior art would have motivated one of skill in the art to attempt that invention and would have created a reasonable expectation of success in the attempt. It is not enough to merely show that the skilled person could have attempted the invention; the question is whether that person would have been motivated to make the attempt. In some cases, invention can lie in the identification and solution of a previously unidentified problem. In other cases, the problem is well known, but the solution requires the inventor to overcome technical challenges that stymied contemporaries in their attempts to solve the problem. Sometimes an invention occurs when the inventor tries an approach that runs entirely counter to conventional wisdom, ultimately proving that conventional wisdom to have been wrong. Defense of Secondary Patents provides numerous examples of inventions of this type, explaining how courts have determined such inventions to be nonobvious based on the specific factors at play in each individual case. Concluding Thoughts Patent law is primarily concerned with rewarding and enhancing the creation of useful inventions. It is not an instrument that has been specifically designed to address crucial problems relating to ethics, access, health, competition and human rights policies. This is particularly true for the bio-pharmaceutical sector. It is therefore crucial that patent offices and courts continue to assess the inventiveness of all inventions, including inventions arising out of follow-on pharmaceutical innovation, based on the specific features of that invention when compared to the relevant prior art, rather than adopting the sort of technology-specific presumptions against patentability endorsed by the Guidelines. In cases where there are legitimate concerns that patents are being misused in a manner that restricts access to medicine, then that misuse should be addressed directly, rather than through a broadside attack on the patenting of follow-on pharmaceutical innovation in toto.

If the patent system is being misused in a manner that is anticompetitive, then antitrust and competition laws should be invoked to address the problem directly. If certain specific types of patent enforcement activities are deemed problematic, they too can be addressed directly. The US patent statute, for example, already provides an exemption from liability for doctors who use a patented method of medical treatment. This addresses concerns about doctors potentially being sued without depriving medical innovators of patents (which would still be enforceable against a competing medical device company, for example). It would be a mistake to upset the delicate balance of innovation policy embodied in the current consensus patent regime – to do so poses a grave risk of greatly diminishing the pipeline of future medicinal breakthroughs.

#### 2] Economic collapse

#### Biopharmaceutical research is the bedrock of our economy – even minor reductions in income result in mass unemployment and butterfly effects

Sullivan 11 – Thomas Sullivan (Thomas Sullivan is Editor of Policy and Medicine, President of Rockpointe Corporation, founded in 1995 to provide continuing medical education to healthcare professionals around the world. Prior to founding Rockpointe, Thomas worked as a political consultant), July 12, 2011, Study Shows Importance of Biopharmaceutical Jobs For US Economy,” Policy and Medicine, http://www.policymed.com/2011/07/study-shows-importance-of-biopharmaceutical-jobs-for-us-economy-for-every-20-billion-loss-in-revenue.html WJ

Biopharmaceutical research companies produce the highest-value jobs, the types of jobs Americans want in the 21st century economy, the kinds of jobs that can drive future economic growth. No other sector has the ability to drive innovation, create high-quality jobs and provide new life-saving medicines for patients.

According to a recent report from the Battelle Technology Partnership Practice (TPP), “nationwide, the biopharmaceutical sector supported a total of 4 million jobs in 2009, including nearly 675,000 direct jobs. Battelle is the world’s largest non-profit independent research and development organization, providing innovative solutions to the world’s most pressing needs through its four global businesses.

TPP has an established reputation in state-by-state assessment of the biopharmaceutical sector, and has recently undertaken major impact assessment projects for the Human Genome Project, the nation’s biotechnology sector, and major bioscience organizations such as Mayo Clinic. TPP has also been active in provision of analysis to industry organizations, including the Council for American Medical Innovation, PhRMA and BIO-the Biotechnology Industry Organization.

Each job in a biopharmaceutical research company supported almost 6 additional jobs in other sectors, ranging from manufacturing jobs to construction and other building service jobs to contract researchers and child care providers. Together, this biopharmaceutical sector-related workforce received $258 billion in wages and benefits in 2009.

“Battelle also found that across all occupations involved in the biopharmaceutical sector, the average wage is higher than across all other private sector industries, due to the sector’s role as a ‘high value-added sector.” Specifically, the annual average personal income of a biopharmaceutical worker was $118,690 in 2009 as compared to $64,278 in the overall economy.

Additionally, the biopharmaceutical sector’s total economic output (including direct, indirect and induced impacts) was $918 billion in 2009. The sector generated an estimated $85 billion tax revenues in 2009—$33 billion in state and local and more than $52 billion in federal. This impact comprises $382 billion in direct impact of biopharmaceutical businesses and $535 billion in indirect and induced impacts (an output multiplier of 2.4—meaning that every $1 dollar in output generated by the biopharmaceutical sector generates another $1.4 in output in other sectors of the economy).

To put this export volume into perspective, 2010’s total biopharmaceutical exports of $46.7 billion compares favorably to other major U.S. exports including: automobiles ($38.4 billion in 2010 exports); plastics and rubber products ($25.9 billion); communications equipment ($27 billion) and computers ($12.5 billion).

In addition, the U.S. Congressional Budget Office noted that, “the pharmaceutical industry is one of the most research-intensive industries in the United States and that pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm.”

At over $105,000 in biopharmaceutical R&D per employee, the sector is way ahead of the average across all U.S. manufacturing which stands at about $10,000 per employee—and is far ahead of the second and third ranked sectors of “communications equipment” and “semiconductors, which respectively spend $63,000 and $40,000 per employee in R&D annually.

PhRMA Statement on Battelle Report

Consequently, Pharmaceutical Research and Manufacturers of America (PhRMA) President and CEO John J. Castellani issued a statement discussing the results from this report and the biopharmaceutical research sector’s impact on jobs and the American economy.

Castellani asserted that, “at a time when the U.S. is facing a jobs crisis, evidenced by the terrible employment numbers from last Friday, it is critical that our policymakers embrace dynamic and innovative business sectors such as the biopharmaceutical research sector and refrain from stifling job growth through shortsighted proposals such as government-mandated price controls in Medicare Part D.”

Specifically, the PhRMA CEO pointed to a new paper from the Battelle Technology Partnership Practice, which underscored the pharmaceutical sector’s tremendous contribution to America’s economy. Castellani recognized that, “startling potential job losses would result from undermining the business foundations of biopharmaceutical companies.”

He noted that the Battelle report estimated “that a $20 billion per year reduction in biopharmaceutical sector revenue would result in 260,000 job losses across the U.S. economy” and a $59 billion reduction in U.S. economic activity. As a result, Castellani recognized that, “as the President and Congressional leaders negotiate an important agreement on the debt ceiling and the future of the nation’s economy, it is critical that the jobs crisis is not exacerbated.”

For example, Castellani noted how “the President and some in Congress have proposed including government-mandated rebates in Medicare Part D as part of a debt ceiling agreement.” However, he recognized that “such a provision would have a dramatic negative effect on the economy and patients, and could undermine the success of the Part D program, which has very high beneficiary satisfaction and has cost far less than original government projections.”

He pointed to the “Battelle numbers, which clearly demonstrated that reducing the biopharmaceutical sector’s annual revenue by $20 billion would be a serious blow to employment.” Castellani added that, “while the research is not specific to any one policy or event, proposals being considered, such as government-mandated Part D rebates, would be expected to have revenue impact of this magnitude.”

Moreover, he noted that, “Part D is an unparalleled success, providing unprecedented access to life-saving medicines for seniors.” Accordingly, Castellani asserted that PhRMA does not “believe policies that discourage R&D and cutting-edge science and that will inevitably slow the development of needed new medicines are fair for seniors waiting for new treatments against our most challenging and costly diseases.”

Battelle Report

The Battelle Report quantifies the economic impact of the biopharmaceutical sector on the U.S. economy and jobs using input/output analysis, measures the direct and indirect impacts of the biopharmaceutical sector, and quantifies the economic impacts that would occur if biopharmaceutical revenues increase or decrease from significant changes in the business operating environment.

The report also highlights some of the functional impacts of the sector—the wide-ranging benefits provided through the biopharmaceutical sector’s contributions to enhancing human health, improving life spans and sustaining the high quality-of-life that Americans enjoy—and assesses the contributions of the biopharmaceutical sector to key areas of importance to our economy— innovation, product exports and quality of jobs produced.

The Battelle Report starts by recognizing that the biopharmaceutical sector has all of the characteristics for an ideal industry for economic growth and sustainability in the U.S. Specifically, the biopharmaceutical sector:

Grows in output and employment even in tough economic times

Provides high wage, good quality jobs

Is innovative and deploys high-technology to generate comparative advantage for U.S. companies

Generates significant exports that boost the U.S. economy

Has a strong supply chain that drives further economic growth across the economy through “multiplier effects”

Builds on America’s long-standing strengths and investment in fundamental and applied research

Encourages capital flows to sustain growth, and is profitable to provide funds for reinvestment into the research and development (R&D) cycle;

Generates federal, state and local taxes and other economic contributions that support public services

Is sustainable and not a major drain on global resources

Is geographically dispersed, providing opportunities for job creation and economic growth across many areas of the nation, not just a few selected places

Produces a product of value to society, something that improves the quality of life for humankind, including

Improved life spans (personal longevity)

Improved productivity resulting from prevention and effective management of disease and chronic conditions; and

Reductions in unnecessary hospitalizations resulting in potential cost-offsets elsewhere in the health care system.

Fundamental to major progress in human longevity, reducing the marginalization of individuals from disease and disability, and generally improving our quality-of-life, biopharmaceuticals are a unique contributor to societal and individual well-being.

Moreover, the output of the biopharmaceutical sector is highly valued by society because the sector develops and manufactures a broad-range of unique products to treat disorders and diseases that, were they to go untreated, can ruin individual quality of life, personal abilities and productivity. In many instances, biopharmaceuticals are central to helping to prevent and treat a range of public health issues, address pandemic risk and thereby support national economic security.

For example, innovation in the biopharmaceutical sector, combined with the diagnostic and treatment skills of U.S. healthcare professionals, has contributed to a lengthening of the average life span of Americans. In 1900, the expected life span of an American at birth was just 47.3 years. With the advent of more modern medicines and advanced medical knowledge, life expectancy at birth has seen a steady increase rising to 69.7 years in 1960, and 77.9 years in 2007.

In fact, the National Bureau of Economic Research reports that “there is a highly statistically significant relationship between the number of new molecular entities [drugs] approved by the FDA and increased longevity.” Furthermore, Lichtenberg found in a study of FDA data that “approval of priority-review drugs—those considered by the FDA to offer significant improvements in the treatment, diagnosis, or prevention of a disease—has a significant positive impact on longevity.”

Additionally, the American Hospital Association (AHA) notes that “advances in medicine contribute to national economic growth by helping Americans recover more quickly from injury and illness, avoid lost or ineffective work time due to flare-ups of chronic conditions, and live longer with higher quality of life.” Without effective medicines and treatments for illnesses, injuries, pain and chronic conditions, the productivity of the U.S. economy would clearly be greatly impaired. Biopharmaceuticals are a key contributor to a more productive and healthy America and U.S. economy.

Beyond direct employment in biopharmaceutical companies, the biopharmaceutical sector is the foundation upon which one of the United States’ most dynamic innovation and business ecosystems is built. A large part of the modern biomedical economy is built upon a robust foundation of biopharmaceutical companies that perform and support advanced biomedical and technological R&D, and act as the funnel and distribution engine for getting life-saving and quality-of-life-sustaining therapeutics to the marketplace.

Providing R&D impetus and funding, capital resources, technology licensing opportunities, and a sophisticated market access and distribution system, the biopharmaceutical sector is of central importance to the much broader biomedical and life sciences economy.

Fueled by private investment capital, venture capital investments, and public/private collaborations, and enabled by the U.S. open market system, the nation has been able to advance biomedical innovation, which in turn has led to new start-up companies, business growth and exports across the world.

Conclusion

Despite the tremendous success in the biopharmaceutical industry, emerging infectious diseases continue to present new challenges and a substantial volume of long-standing diseases such as cancer, diabetes, neurodegenerative diseases, psychiatric diseases, immunological diseases, etc. continue to demand novel treatments and improved therapeutics. There are millions of people suffering from diseases and disorders for which a therapy has yet to be found. The need for ongoing biopharmaceutical research and development is simply enormous.

The only way the U.S. economy can stay ahead of international competition is by using advanced R&D and innovation to drive the growth of high value-added industries. By leveraging investment in federal lab, university and industry R&D, our nation is able to produce high-value, typically technologically advanced products that the rest of the world values highly. In recent decades, life sciences have come to the fore as a leading driver of U.S. technological innovation and competitive advantage, and the biopharmaceutical sector is a key foundation of the life sciences innovation ecosystem.

#### Bipoharma collapse causes economic meltdown – it’s far worse than previous recessions

Howrigon 17 -- Ron Howrigon “(President and Founder of Fulcrum Strategies. He earned a Bachelor's degree in Business Administration from Western Michigan University and a Master's in Economics from North Carolina State University, focusing in the area of Health Economics) http://www.kevinmd.com/blog/2017/01/health-care-crash-u-s-economy.html, January 19 2017, WJ

In recent history, the U.S. economy has experienced the near catastrophic failure of two major market segments. The first was the auto industry and the second was the housing industry. While each of these reached their breaking point for different reasons, they both required a significant government bailout to keep them from completely melting down. What is also true about both of those market failures is that, looking back, it’s easy to see the warning signs. What happens if health care is the next industry to suffer a major failure and collapse? It’s safe to say that a health care meltdown would make both the automotive and housing industries’ experiences seem minor in comparison. While that may be hard to believe, it becomes clear if you look at the numbers. The auto industry contributes around 3.5 percent of this country’s GDP and employs 1.7 million people. This industry was deemed “too big to fail” which is the rationale the U.S. government used to finance its bail out. From 2009 through 2014, the federal government invested around $80 billion in the U.S. auto industry to keep it from collapsing. Health care is five times larger than the auto industry in terms of its percentage of GDP, and is ten times larger than the auto industry in terms of the number of people it employs. The construction industry (which includes all construction, not just housing) contributes about 6 percent of our country’s GDP and employs 6.1 million people. Again, the health care market dwarfs this industry. It’s three times larger in terms of GDP production and, with 18 million people employed in the health care sector, it’s three times larger than construction in this area, too. These comparisons give you an idea of just how significant a portion health care comprises of the U.S. economy. It also begins to help us understand the impact it would have on the economy if health care melted down like the auto and housing industries did. So, let’s continue the comparison and use our experience with the auto and housing industries to suggest to what order of magnitude the impact a failure in the health care market would cause our economy. The bailout in the auto industry cost the federal government $80 billion over five years. Imagine a similar failure in health care that prompted the federal government to propose a similar bailout program. Let’s imagine the government felt the need to inject cash into hospital systems and doctors’ offices to keep them afloat like they did with General Motors. Since health care is five times the size of the auto industry, a similar bailout could easily cost in excess of $400 billion. That’s about the same amount of money the federal government spends on welfare programs. To pay for a bailout of the health care industry, we’d have to eliminate all welfare programs in this country. Can you imagine the impact it would have on the economy if there were suddenly none of the assistance programs so many have come to rely upon? When the housing market crashed, it caused the loss of about 3 million jobs from its peak employment level of 7.4 million in 1996. Again, if we transfer that experience to the health care market, we come up with a truly frightening scenario. If health care lost 40 percent of its jobs like housing did, it would mean 7.2 million jobs lost. That’s more than four times the number of people who are employed by the entire auto industry — an industry that was considered too big to be allowed to fail. The loss of 7.2 million jobs would increase the unemployment rate by 5 percent. That means we could easily top the all-time high unemployment rate for our country. OK, now it’s time to take a deep breath. I’m not convinced that health care is fated to unavoidable failure and economic catastrophe. That’s a worst-case scenario. The problem is that at even a fraction the severity of the auto or housing industry crises we’ve already faced, a health care collapse would still be devastating. Health care can’t be allowed to continue its current inflationary trending. I believe we are on the verge of some major changes in health care, and that how they’re implemented will determine their impact on the overall economic picture in this country and around the world. Continued failure to recognize the truth about health care will only cause the resulting market corrections to be worse than they need to be. I don’t want to diminish the pain and anguish that many people caught up in the housing crash experienced. I think an argument can be made, though, that if the health care market crashes and millions of people end up with no health care, the resulting fallout could be could be much worse than even the housing crisis.

#### Economic collapse increases the risk of conflict

Tønnesson 15 Stein Research Professor, Peace Research Institute Oslo; Leader of East Asia Peace program, Uppsala University, 2015, “Deterrence, interdependence and Sino–US peace,” International Area Studies Review, Vol. 18, No. 3, p. 297-311

Several recent works on China and Sino–US relations have made substantial contributions to the current understanding of how and under what circumstances a combination of nuclear deterrence and economic interdependence may reduce the risk of war between major powers. At least four conclusions can be drawn from the review above: first, those who say that interdependence may both inhibit and drive conflict are right. Interdependence raises the cost of conflict for all sides but asymmetrical or unbalanced dependencies and negative trade expectations may generate tensions leading to trade wars among inter-dependent states that in turn increase the risk of military conflict (Copeland, 2015: 1, 14, 437; Roach, 2014). The risk may increase if one of the interdependent countries is governed by an inward-looking socio-economic coalition (Solingen, 2015); second, the risk of war between China and the US should not just be analysed bilaterally but include their allies and partners. Third party countries could drag China or the US into confrontation; third, in this context it is of some comfort that the three main economic powers in Northeast Asia (China, Japan and South Korea) are all deeply integrated economically through production networks within a global system of trade and finance (Ravenhill, 2014; Yoshimatsu, 2014: 576); and fourth, decisions for war and peace are taken by very few people, who act on the basis of their future expectations. International relations theory must be supplemented by foreign policy analysis in order to assess the value attributed by national decision-makers to economic development and their assessments of risks and opportunities. If leaders on either side of the Atlantic begin to seriously fear or anticipate their own nation’s decline then they may blame this on external dependence, appeal to anti-foreign sentiments, contemplate the use of force to gain respect or credibility, adopt protectionist policies, and ultimately refuse to be deterred by either nuclear arms or prospects of socioeconomic calamities. Such a dangerous shift could happen abruptly, i.e. under the instigation of actions by a third party – or against a third party. Yet as long as there is both nuclear deterrence and interdependence, the tensions in East Asia are unlikely to escalate to war. As Chan (2013) says, all states in the region are aware that they cannot count on support from either China or the US if they make provocative moves. The greatest risk is not that a territorial dispute leads to war under present circumstances but that changes in the world economy alter those circumstances in ways that render inter-state peace more precarious. If China and the US fail to rebalance their financial and trading relations (Roach, 2014) then a trade war could result, interrupting transnational production networks, provoking social distress, and exacerbating nationalist emotions. This could have unforeseen consequences in the field of security, with nuclear deterrence remaining the only factor to protect the world from Armageddon, and unreliably so. Deterrence could lose its credibility: one of the two great powers might gamble that the other yield in a cyber-war or conventional limited war, or third party countries might engage in conflict with each other, with a view to obliging Washington or Beijing to intervene.

## Case

#### Evergreening doesn’t block generics

Holman 18 (Christopher M., Professor of Law @ University of Missouri-Kansas City School of Law) Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection, 9/21/18, <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> EE

“Evergreening” – an Incoherent Concept

Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation.

Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs.

#### Only patented drugs maintain a standard of quality. Generic drugs in developing countries increase microbial resistance, worsening pathogens.

Eban 19 Katherine Eban is an investigative journalist and the author of the New York Times bestseller [Bottle of Lies: The Inside Story of the Generic Drug Boom.](https://www.amazon.com/gp/product/0062338781/ref=as_li_qf_asin_il_tl?ie=UTF8&tag=time037-20&creative=9325&linkCode=as2&creativeASIN=0062338781&linkId=049085a04cf365d3012e00b134291a49)“How Some Generic Drugs Could Do More Harm Than Good”, 17 May 2019, https://time.com/5590602/generic-drugs-quality-risk/ | MU

But many of the generic drug companies that Americans and Africans alike depend on, which I spent a decade investigating, hold a dark secret: they routinely adjust their manufacturing standards depending on the country buying their drugs, a practice that could endanger not just those who take the lower-quality medicine but the population at large.

These companies send their highest-quality drugs to markets with the most vigilant regulators, such as the U.S. and the European Union. They send their worst drugs — made with lower-quality ingredients and less scrupulous testing — to countries with the weakest review.

The U.S. drug supply is not immune to quality crises — over the last ten months, dozens of versions of the generic blood pressure drugs valsartan, losartan and irbesartan have been subject to sweeping recalls. The active ingredients in some, manufactured in China, contained a probable carcinogen once used in the production of liquid rocket fuel. But the patients who suffer most are those in so-called “R.O.W. markets” — the generic-drug industry’s shorthand for “Rest of World.” In swaths of Africa, Southeast Asia and other areas with developing markets, some generic drug companies have made a cold calculation: they can sell their cheapest drugs where they will be least likely to get caught.

In Africa, for instance, pharmaceuticals used to come from more developed countries, through donations and small purchases. So when Indian drug reps offering cheap generics started arriving, the initial feeling was positive. But Africa soon became an avenue “to send anything at all,” said Kwabena Ofori-Kwakye, associate professor in the pharmaceutics department at the Kwame Nkrumah University of Science and Technology in Kumasi, Ghana. The poor quality has affected every type of medication, and the adverse impact on health has been “astronomical,” he told me.

Multiple doctors I spoke to throughout the continent said they have adjusted their medical treatment in response, sometimes tripling recommended doses to produce a therapeutic effect. Dr. Gordon Donnir, former head of the psychiatry department at the Komfo Anokye teaching hospital in Kumasi, treats middle-class Ghanaians in his private practice and says that almost all the drugs his patients take are substandard, leading him to increase his patients’ doses significantly. While his European colleagues typically prescribe 2.5 milligrams of haloperidol (a generic form of Haldol) several times a day to treat psychosis, he’ll prescribe 10 milligrams, also several times a day, because he knows the 2.5 milligrams “won’t do anything.” Donnir once gave ten times the typical dose of generic Diazepam, an anti-anxiety drug, to a 15-year-old boy, an amount that should have knocked him out. The patient was “still smiling,” Donnir said.

Many hospitals also keep a stash of what they call “fancy” drugs — either brand-name drugs or higher-quality generics — to treat patients who should have recovered after a round of treatment but didn’t. Confronted with the ailing boy at the Mulago hospital, Westerberg’s colleagues swapped in the more expensive version of ceftriaxone and added more drugs to the treatment plan. But it was too late. In the second week of his treatment, the boy was declared brain dead

Westerberg’s Ugandan colleagues were not surprised. Their patients frequently died when treated with drugs that should have saved them. And there were not enough “fancy” drugs to go around, making every day an exercise in pharmaceutical triage. It was also hard to keep track of which generics were safe and which were not to be trusted, said one doctor in Western Uganda: “It’s anesthesia today, ceftriaxone tomorrow, amoxicillin the next day.”

Westerberg, shaken by his newfound knowledge, flew back to Canada and teamed up with a Canadian respiratory therapist, Jason Nickerson, who’d had similar experiences with bad medicine in Ghana. They decided to test the chemical properties of the generic ceftriaxone that had been implicated in the Ugandan boy’s death. Another of Westerberg’s colleagues brought him a vial from the Mulago hospital pharmacy. The drug had been made by a manufacturer in northern China, which also exported to the U.S. and other developed markets. But when they tested the ceftriaxone at Nickerson’s lab, it contained less than half the active drug ingredient stated on the label. At such low concentration, the drug was basically useless, Nickerson said. He and Westerberg published a case report in the CDC’s Morbidity and Mortality Weekly Report. Although they couldn’t say with certainty that the boy had died due to substandard ceftriaxone, their report offered compelling evidence that he had.

Some companies claim that, while their drugs are all high-quality, there may be some variance in how they are produced because regulations differ from market to market. But Patrick H. Lukulay, former vice president of global health impact programs for USP (formerly U.S. Pharmacopeia), one of the world’s top pharmaceutical standard-setting organizations, calls that argument “totally garbage.” For any given drug, he says, “There’s only one standard, and that standard was set by the originator,” meaning the brand-name company that developed the product.

It’s not just those in developing markets who should be alarmed. Often, substandard drugs do not contain enough active ingredient to effectively cure sick patients. But they do contain enough to kill off the weakest microbes while leaving the strongest intact. These surviving microbes go on to reproduce, creating a new generation of pathogens capable of resisting even fully potent, properly made medicine. In 2011, during an outbreak of drug-resistant malaria on the Thailand-Cambodia border, USP’s chief of party in Indonesia Christopher Raymond strongly suspected substandard drugs as a culprit. Treating patients with drugs that contain a little bit of active ingredient, as he put it, is like “putting out fire with gasoline.”