## 1

#### Counterplan Text: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by implementing a one-and-done approach for patent and exclusivity protection except for Markush claims.

#### Eliminating Markush claims shreds innovation

Holman JD and PhD 18 (Christopher M. Holman, Professor of Law @ University of Missouri-Kansas City School of Law, PhD in biochemistry from UC Davis; Timo Minssen, Professor of Law at the University of Copenhagen; and Eric M. Solovy, partner at Sidney Austin LLP, JD Harvard Law School, DC Circuit Bar member)

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There is one category of secondary patent discussed in the Guidelines, so-called “selection patents,” which deserves mention in this regard, since the Guidelines improperly suggest an interpretation of the novelty requirement that is entirely inconsistent with established practice and good policy. The Guidelines define a “selection patent” as a patent claiming:

a subgroup of elements … selected from a larger group and claimed on the grounds that a new, unexpected property has been found. For instance, if a Markush claim was admitted in relation to a set of pharmaceutical compounds, the patent owner might later file a new patent application covering one or more of such compounds.80

The Guidelines recommend that selection patents should not be granted, asserting that the “selection of elements included in the disclosed group lacks novelty, such as in the case of compounds disclosed in a prior generic chemical structure or included within a numerical range.”81 To the contrary, it is well-established in multiple jurisdictions that disclosure of a genus of structurally related molecules, either in the context of a Markush claim or otherwise, is not necessarily sufficient to render a subsequent claim directed to one or more species of the genus on the basis of lack of novelty or obviousness.82 The rationale behind this principle of patent law is that, as a practical matter, a paper disclosure of many structurally related molecules does not necessarily provide sufficient direction for one of skill in the art to identify a specific member of the genus possessing a desirable pharmaceutical property, especially a property not shared by most other members of the genus. At the same time, the selection of a specific member or members of a genus that possess a property to a greater degree than most members of the genus can constitute a patentable invention of great benefit to patients.

Identifying this potentially groundbreaking pharmaceutical agent from an astronomical pool of candidates can be like finding a needle in a haystack. Although a disclosure of thousands or millions of chemical compounds might in some hyper-literal sense disclose each compound, practically speaking it does not in any way put society in possession of those rare needles that might provide very real health benefits. It is very easy to disclose on paper that an astronomically large genus is of structurally related molecules, but such a disclosure does not put the public in possession of particular members that have exceptional pharmaceutical properties, which are in many cases only identified through painstaking research.

#### Markush claims are also key to avoiding copycats which kill innovation

Holman 17 (Christopher M., Professor of Law @ University of Missouri-Kansas City School of Law) In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination Professor of Law @ University of Missouri-Kansas City School of Law 5/12/17 <http://journals.iupui.edu/index.php/inlawrev/article/view/21522> EE

The rationale behind this longstanding practice is that there is a certain degree of predictability in chemistry, and certain substitutions at various sites of a relatively complex core molecular structure can be predicted to result in a molecule that retains the utility of other molecules in the genus that have been synthesized and tested. Given this predictability, there can be a relatively high 40 likelihood that many of the molecules in a claimed genus will share this activity. If an inventor was only permitted to patent molecules that had actually been synthesized and tested, the patent claims would be quite narrow and in many cases quite easy to circumvent. Someone could simply use the disclosure of the patent as a template for designing and synthesizing unpatented analogs sharing the pharmaceutical utility of the claimed molecules. A genus claim 41 encompassing these variations prevents this sort of easy circumvention by a copyist.

Although a million compounds sounds like a lot, it must be recognized that when there are multiple sites for substitution on a complex molecule, and multiple possible substitutions at each of the sites, the number of possibilities grows exponentially. For example, if there are ten sites of substitution, and ten possible substituents at each of the sites, then there are ten to the 10th power, or 10 billion possible drugs that share the same core as the molecules that have been tested and found to be pharmaceutically active. Of course, it is impossible for an inventor to actually synthesize and test anything approaching this number of compounds, but if she is not allowed to obtain a claim encompassing them, a copyist can easily circumvent a narrow patent and develop an analogous molecule to compete with the original inventor. The Guidelines seem to totally disregard the valid policy basis behind the allowance of Markush claims. 42

#### The counterplan competes – it’s a secondary patent

Holman 17 (Christopher M., Professor of Law @ University of Missouri-Kansas City School of Law) In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination Professor of Law @ University of Missouri-Kansas City School of Law 5/12/17 <http://journals.iupui.edu/index.php/inlawrev/article/view/21522> EE

The heart of the Guidelines is a category-by-category examination of twelve types of pharmaceutical patent claims: Markush claims; selection patents; 4 5 polymorphs; enantiomers; salts; ethers and esters; compositions; doses; 6 7 8 9 10 11 combinations; prodrugs; metabolites; and new medical uses. Patents with 12 13 14 15 claims of this type are sometimes referred to as “secondary” pharmaceutical patents, distinguished from “primary” patents directed toward a novel active ingredient. There are those who consider secondary pharmaceutical patent 16 claims somehow less legitimate and worthy of protection than primary claims, and less necessary for incentivizing pharmaceutical innovation. Some 17 developing countries have sought to curtail their patentability. For example, 18 India excludes from patentability the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. 19 Brazil and South Africa are reportedly considering legislation along similar lines. 20

## 2

#### Innovation high now

Dunleavy et al 21 Kevin Dunleavy [staff writer for Fierce Pharma. He joined the Fierce team after working 26 years as a newspaper sportswriter], Eric Sagonowsky, Noah Higgins-Dunn, Fraiser Kansteiner, Angus Liu, 7-6-2021, "Innovation on hold during the pandemic? FDA says no with 29 approvals in first half of 2021," FiercePharma, https://www.fiercepharma.com/special-reports/innovation-hold-during-pandemic-fda-says-no-27-approvals-first-half-2021, accessed 7/23/2021 EH

Many pursuits have been put on hold during the coronavirus pandemic. But biopharmaceutical innovation isn’t one of them. In 2020, the FDA approved 53 new drugs, the second-most in a single year, after 2018’s bounty of 59. And the momentum has continued through the first half of 2021. With the FDA endorsing its 29th novel drug on June 30, the industry was slightly ahead of last year’s pace. No. 29 came last week with a green light to Jazz Pharmaceuticals for its blood cancer therapy Rylaze. It was the first FDA approval in 23 days. Perhaps the U.S. regulator needed a break after the uproar that ensued after its June 7 nod for Biogen’s Alzheimer’s disease treatment Aduhelm. It was an approval so divisive that three members of the FDA’s advisory committee that reviewed the drug quit in protest. In his resignation letter to acting FDA commissioner Janet Woodcock, Harvard Medical School professor Aaron Kesselheim called the move a “debacle” and “probably the worst drug approval decision in recent U.S. history.” Within hours of its green light, Biogen ignited another firestorm when it revealed the treatment’s annual price tag of $56,000 and provided a new flashpoint for the decades-old drug-pricing debate. Before the Aduhelm controversy eclipsed everything else, the year had featured a lot of other high-profile approvals. GlaxoSmithKline and ViiV Healthcare earned a nod for Cabenuva, a long-awaited monthly injectable for those with HIV. ADC Therapeutics won a green light for Zynlonta, the first single-agent CD19-targeted antibody-drug conjugate for diffuse large B-cell lymphoma. And Apellis scored with Empaveli for the rare, chronic blood disorder paroxysmal nocturnal hemoglobinuria (PNH). Another high-profile approval came in late May for Amgen's new cancer drug Lumakras. The non-small cell lung cancer treatment has been highly anticipated, as it targets KRAS mutations which were previously believed to be “undruggable.” The green light for Lumakras triggered a Memorial Day weekend splurge for the FDA. On the same Friday afternoon, Alkermes’ schizophrenia drug Lybalvi and BridgeBio’s bile duct cancer therapy Truseltiq also won approvals. Then the Tuesday after the holiday, Scynexis gained an FDA nod for its potential blockbuster Brexafemme, the first new treatment for vaginal yeast infection in more than two decades. The approval for Truseltiq was particularly noteworthy because it was the second this year for tiny BridgeBio, which reported $8.2 million in revenue last year. The only other firms with two approvals in the first half are companies on the other end of the industry spectrum. Pharma giant Johnson & Johnson earned nods for NSCLC antibody Rybrevant and multiple sclerosis therapy Ponvory. Bristol Myers Squibb scored two CAR-T approvals, as well. In terms of treatment areas, it is of little surprise that oncology accounts for 12 of this year’s approvals. That figure represents 44% of all new drug approvals this year, an even higher rate than in 2020 when 20 of 53 new drugs were in the oncology class. Even during a pandemic, don’t expect the pace of innovation to subside. It’s a sign of the times, and successes will only fuel further innovation, according to Ernst & Young industry analyst, Arda Ural. “The acceleration in the successful development of truly novel platform technologies and therapeutics offers the opportunity for higher returns on investment and are driving pipeline priorities,” Ural wrote in his analysis of first-quarter trends this year. “Gene therapy, mRNA vaccines and therapeutics, cell therapy and gene editing once seemed like science fiction but now are a reality.”

#### 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.

#### Critiques of evergreening are wrong – crucial medicines come out incrementally and it’s essential to encourage competition in the market.

Thomas 09 summarizes [John R. Thomas, “Patent “Evergreening”: Issues in Innovation and Competition”, Georgetown Law Center faculty, Visiting Scholar at the Congressional Research Service, inaugural Thomas Alva Edison Visiting Scholar at the U.S. Patent and Trademark Office] //DD PT

Although the practice of evergreening has attracted considerable criticism, many observers believe these critiques are misplaced. Indeed, some consider the term “evergreening” to be inappropriate, and even derogatory in nature.62 They explain that the patent laws promote both original and improvement inventions, that most technological advance occurs incrementally, that improvements may be developed by competitors of the original innovator, that many improvement patents cover advances that are of considerable medical significance, and that patents on improvements may not impede the ability of competitors to market products that were covered by expired patents on original technologies. This report reviews these assertions in turn. First, these observers note that the patent system allows patents to be obtained on both original and improvement technologies. As a result, the patent law encourages the development of both kinds of inventions. They also explain that under the Patent Act, each invention must fulfill a number of requirements in order to be subject to patent protection. Among these criteria are that the invention must be novel,63 nonobvious,64 and fully disclosed in an application submitted to the USPTO.65 These statutory standards are applied neutrally to each kind of invention, whether it may be characterized as an “original” (such as a medication that has never been previously approved by the FDA) or an “improvement” (such as a new formulation of a known medication). Patent law experts believe that these legal standards appropriately recognize that most technological progress occurs on an incremental basis. Attorney Ivar Kaardal explains that “most patents ... are granted for incremental, or even insignificant, technological advances.”66 Some observers believe that, on an individual or collective basis, patents on more marginal improvements may provide the public with valuable sources of technological information. As Jeanne C. Fromer, a member of the Fordham Law School faculty, states: while there are a rising number of patents for incremental technical advances, which individually might not be commercially or informationally valuable, the collectivity of incremental advances provides essential information for further innovation in many areas… Some commentators also believe the critique that many “evergreen” patents represent trivial variations of earlier technologies is misplaced. They assert that many patented improvements provide significant practical benefits. For example, a new formulation may make a known medication easier to use, leading to greater patient compliance, or cause fewer side effects.68 Observers also note that the developer of the “original” product is not always the same entity as the developer of “improvement” technologies. Sometimes competitors of the “original” patent proprietor, including generic drug companies, develop and patent the improvements.69 The ability of any innovator to obtain a patent is said to encourage competition among different firms, both in innovation and in the marketplace.70

#### 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.

#### Extinction

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 w

## Case

#### Evergreening reflects an incomplete understanding of the patent system; inventiveness is a pre-req to a second patent and 95% of generics are available

Rory Moore, 7-6-2016, "Opinion: Patent Evergreening," Moore Intellectual Property, <http://www.moorepatent.co.za/opinion-patent-evergreening-a-valid-concern-in-south-africa/#easy-footnote-bottom-5>

The term “evergreening” is used pejoratively to refer to perceived attempts to extend the duration of patent protection by various means. Attempts by patent holders to obtain multiple patents covering different aspects of the same product are characterised by some observers as evergreening. Disapprobation is expressed regarding patents for improved versions of existing products, especially in the pharmaceutical sector. In our view the concept of evergreening is specious, especially in the South African context. It is based on an incomplete understanding of the patent system. South Africa is currently contemplating changes to its patent system. The Department of Trade and Industry published an Intellectual Property Consultative Framework (IPCF) on 6 July 2016.1 The IPCF seeks to promote public health and to balance the interests of the public and industry development by stimulating innovation. One of the proposed changes relates to South Africa’s simple “depositary” patent system whereby patent applications are subjected only to a rudimentary check of the documentary requirements. The IPCF proposes that South Africa do away with its depository system and replace it with infrastructure for the substantive search and examination (SSE) of patent applications. There has been a groundswell of opinion since 2011 advocating for substantive patent examination. The Fix the Patent Laws Coalition was launched in 2011, comprising 15 health institutions in South Africa such as Treatment Action Campaign, Doctors Without Borders and Section 27. The coalition advocates for reform of the South African laws to address issues that block access to affordable medicines in the country. The argument is that a substantive examination will ensure that patents are only granted on real innovations, thus limiting the grant of weak patents. In 2008, a survey was conducted between South Africa and Brazil (which examines patent applications). The statistics showed that South Africa granted 2 442 pharmaceutical patents in 2008 alone while Brazil only granted 278 patents from 2003 to 2008. The argument is that these disparities show that the bulk of South Africa’s patents relate to inventions not worthy of patent protection. It is also argued that the United States and Patent Office and the European Patent Office both rejected approximately 40% of the applications granted by South Africa.2 The calls for substantive examination, and some of the other proposed changes, appear to stem from a perception that pharmaceutical patents have an obstructive impact on the roll-out of health services in South Africa. Philip Stevens of the Geneva Network, a research organisation focusing on health, intellectual property and trade, provides the following insight into concerns relating to pharmaceutical patents:3 “Debates on how to improve healthcare in developing countries often start from the same premise: patents can potentially raise drug prices, so they should be abolished for better public health. “In the early 2000s, this argument drove the campaign against patents on HIV drugs in SA. This month, it anchors new nongovernmental organisation (NGO) campaigns against a proposed European Union (EU)-India Free Trade Agreement and the Regional Comprehensive Economic Partnership in Asia — both of which may include heightened intellectual property provisions. “NGO disquiet about drug patents has even led to the creation of a UN high-level panel on access to medicines…” South Africa’s achievements in the field of healthcare, especially in relation to HIV treatment, are laudable. It is not our intention to oppose the country’s ongoing work to make generic medicines widely and inexpensively available to those in need. However, it is our contention that the government’s proposed “fixes” to the South African patent system will not advance this cause and may in fact hinder it [availability]. The existing South African patent system promotes and encourages the development of both original and improved technologies. As long as an improvement upon a technology includes a new technical step, is non-obvious and is capable of being used in trade, industry or agriculture, such an improvement is eligible for patent protection. Any attempt to “evergreen” an invention by means of obvious and trivial improvements cannot pass muster under the scrutiny of South African patent law, and any such patents, even if granted under South Africa’s depositary system, are susceptible of revocation by the Court of the Commissioner of Patents. Opponents of evergreening sometimes argue along the following lines4: If an originator pharmaceutical firm files a patent application in 2020 claiming an active ingredient, the resulting patent will expire in 2040. If in 2025 that same company files a second, original patent application claiming an extended release formulation of that active ingredient and the application is granted, that second patent will not expire until 2045. However, inventiveness (non-obviousness) will always be a prerequisite for the grant of the second patent (the patent to the extended release formulation). This requirement means that trivial improvements with no value are already excluded by the patent system. If there is nothing inventive about the extended release formulation then a valid patent will not be available. If, on the other hand, there is an inventive step involved then it is appropriate for that new development to be protectable. Why should third party competitors (e.g. generic manufacturers) be empowered to exploit a newly developed, inventive formulation without having made any investment towards its development? In what way does a new and inventive formulation become somehow less so by virtue of the fact that its active ingredient is already known? At such time as the first patent expires, generic drug companies will be able to sell the original release formulation of the pharmaceutical. The marketplace will ultimately decide whether the higher costs associated with the extended release formulation are worthwhile expenditures. Opponents may try to rely on Section 39 of the South African Patents Act, in terms of which a patent for an improvement can be obtained even if the improvement is obvious having regard to the main invention. This argument is unfounded because Section 39 provides that the term of an improvement patent of this type (called a “patent of addition”) cannot extend beyond the date of expiry of the patent for the main invention. John R. Thomas5 has highlighted certain fallacies surrounding the concept of evergreening: “Some commentators … believe the critique that many “evergreen” patents represent trivial variations of earlier technologies is misplaced. They assert that many patented improvements provide significant practical benefits. For example, a new formulation may make a known medication easier to use, leading to greater patient compliance, or cause fewer side effects. “Observers also note that the developer of the “original” product is not always the same entity as the developer of “improvement” technologies. Sometimes competitors of the “original” patent proprietor, including generic drug companies, develop and patent the improvements. The ability of any innovator to obtain a patent is said to encourage competition among different firms, both in innovation and in the marketplace. “Industry experts further observe that patents on improvement inventions may not block competitors from marketing competing products that were covered by patents that have expired. In this respect, it should be appreciated that the scope of protection provided by a particular patent varies in accordance with the degree of technological advance provided by the patented invention. In particular, a patent that claims a new active ingredient for use in a pharmaceutical typically provides more robust proprietary rights than improvement patents.” There is also a fallacy in the basic underpinning of the argument that patents somehow block healthcare improvements in developing countries. In a 2016 study6, researchers investigated patents and how they affect access to medicines, by counting how many of the World Health Organisation’s (WHO’s) list of essential medicines were subject to patent protection in developing countries. The objective of the report was to identify which of the 375 items on the 2013 Model List of Essential Medicines (MLEM) of the World Health Organization (WHO) (18th edition) were patented and where. The MLEM is a list of medicines considered by WHO experts to be the most important. It was found that where patents were filed, this appeared to be more common in countries where there was market and manufacturing opportunity, namely, middle-income nations with larger populations, higher health spending per capita and pharmaceutical manufacturing capacity. The researchers found the following: (1) Patents for 95% medicines on the MLEM list had expired. The implication is that patents are not relevant to the vast majority of drugs typically used by physicians in developing countries. (2) Owners of patents for medicines either don’t register or do not enforce their patents in the poorest countries. According to report there was “a relative scarcity of patented medicines appearing on the 2013 MLEM and of those patents typically being filed in developing countries.” In summary, if the patent system were to be abolished it would make little difference to the cost or availability of most medicines used in developing countries. Even so, these medicines are frequently unavailable in public health systems. A study by the University of Utrecht in the Netherlands found that, on average, essential medicines were available in public sector facilities in developing countries only 40% of the time.7 According to Philip Stevens:8 “While generic medicines are cheap to make, with no royalties to pay, they are still too costly for most people in developing countries. … The reasons behind the expense and scarcity of essential medicines in developing countries are complex, but failures of governance loom large. Mark-ups along the distribution chain inflate the final price of medicines and include import tariffs, sales taxes, value-added taxes and retailers’ and wholesalers’ margins.” … Dysfunctional medicine supply chain management is another culprit. A 2015 survey by Medecins Sans Frontières (MSF) reported one in three health facilities in South Africa have shortages of crucial HIV and tuberculosis drugs. The drugs are imported in sufficient quantities, but fail to reach patients due to “local logistical and management problems, ranging from inaccurate forecasting to storage or transport issues”, said MSF.” “These are the major influences on access to medicines. Public health would be best served if the political focus were on these issues, rather than patents.” Evergreening cannot hold up to scrutiny as a justification for revisions of the South African patent system. The IPCF’s ambition to provide a substantive patent examination in South Africa is admirable but it will be difficult to implement, both logistically and financially. Patent examiners operate at the cutting edge of technology, meaning that post-graduate qualifications are required. This makes competent examiners expensive to hire even if they can be found in sufficient numbers. The process of examining even one patent application is a long and involved one, and often involves a protracted process of amendment, review, objection, argument, and further amendment. The South African Patent Office is currently only barely able to meet its commitments to the basic depositary system. It has had a long-standing service delivery shortfall relating to its filing service provider, with the result that patents open to public inspection cannot be accessed. Recordals of transactions in patents are behind and, as of the date of writing, some patents filed in 2014 have not yet been accepted despite acceptance being dependent only upon the need to satisfy formal requirements such as the submission of a Power of Attorney. The attempt to introduce a substantive examination is likely to exacerbate the current situation, and indeed may backfire by causing even longer delays in the grant of patents. This is not in the interests of South Africa’s competitiveness and attractiveness to investment. Para. 4.1.2.iv of the IPCF concedes that: “We are conscious that the implementation of [substantive search and examination] SSE like any new administrative procedure may have teething problems. For this reason, CIPC is considering entering into outsourcing arrangements with certain patent offices that are known to be highly efficient. This would be a contingency against the accumulation of inordinate backlogs.” That the European Patent Office rejects 40% of patent applications corresponding to those granted in South Africa is also not a cogent argument. The grant of a patent in South Africa does not preclude an interested party from applying for its revocation. In other words, a person who believes that he or she is entitled to exploit the subject matter of a patent, because he or she believes that the patent is invalid, may apply to the court for revocation of the patent. It is a relatively simple matter to check whether an equivalent European or U.S. patent was refused, or whether the scope of the claims had to be narrowed by comparison with the corresponding South African patent. Parties interested in the subject matter of such a patent may then either apply to court for revocation of the patent, or, since South African patent law adheres closely to global patent law principles, proceed on the understanding that the patent is invalid and that an infringement action on the basis of the patent would either not be in the interest of the patent holder to initiate or, if undertaken, would be likely to fail. An invalid patent cannot be infringed. Conversely, the introduction of a substantive examination cannot and will not stop the grant of valid patents, even for subject matter such as new formulations. Patents which claim new and inventive technical developments will still be valid even if they undergo examination. Thus, there are still going to be patents for secondary or improvement inventions. A patent for a new and inventive method of manufacture of a known drug, or a revised formulation, will still have to be granted. On the other side of the coin, even under South Africa’s existing, non-examining system a patent that fails to claim a new and inventive improvement is invalid even if it is accepted onto the Register. A patent of this type is invalid with or without an examination system in place. Put simply, the introduction of an examination system in South Africa will have no effect on the number of valid patents in South Africa, except in so far as the number of applications filed may decrease because of the increased burden of costs, administrative burden and length of time taken to obtain patents. Far from being an unfavourable feature of the South African patent system, the country’s depositary character is arguably favourable in the context of a developing country. The fact that examination is not substantive means that patents can be granted more quickly and less expensively than in most other countries. Yet quality is retained because the protection conferred by a patent remains constrained to the legal requirements. Indeed, an advantage of the existing South African patent system is that, since substantive decisions on novelty, obviousness, etc. are left to a specialist patent court rather than an examining division at a Patent Office, a more detailed and rigorous consideration of these matters can be undertaken in respect of those patents which are particularly important. The introduction of substantive examination will inevitably increase costs significantly since higher official fees will be payable to finance the examiners’ salary bills, and significant professional fees will become payable to patent attorneys for prosecution through examination (preparing responses to official actions, amending, etc.) Substantive examination will also inevitably expand the timeline from filing to grant significantly. One egregious consequence of this is that many potential patentees will be excluded from the system because of financial limitations. Already, the grant of patents to individual local inventors and SMME’s is a significant financial burden. An examination system will drive the protection of patents even further away from the general population and further into the arms of the large corporations, which become the only entities able to justify the costs of the system and the substantial financial risks that inevitably accompany embarking upon a patent programme. It is not sufficient to argue that financial backing can be sought by inventors. The procedural hurdles to be overcome to secure such funding are not insignificant and the award of the funds is uncertain. Futhermore, even where funding can be secured, it is often set up as part-funding with the inventor still being held responsible for a proportion of the costs. The end result is that, for the citizen of lower or even average income in South Africa a patent is out of reach or not worth the risk. This “innovation chasm” is likely to become deeper and wider with the introduction of an examining division at the Patent Office.

#### The purpose of evergreening is to make money—medical advances are direct effects of the money big pharma makes.

**Collier 13** [Collier, Roger. “Drug patents: the evergreening problem.” CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne vol. 185,9 (2013): E385-6. doi:10.1503/cmaj.109-4466] //DD PT

“Typically, when you evergreen something, you are not looking at any significant therapeutic advantage. You are looking at a company’s economic advantage,” says Dr. Joel Lexchin, a professor in the School of Health Policy and Management at York University in Toronto, Ontario. “The response from the brand side is that they are trying to protect their markets so they can further invest in R&D [research and development]. And even if they make a modification to a drug, doctors are still quite able to prescribe the generic version of the older product. Having said that, the brand-name companies put an awful lot of money into marketing the newer version, and that marketing is designed to affect what doctors do.” Evergreening has been a hot topic of late because of the recent ruling by India’s Supreme Court to refuse to grant Swiss pharmaceutical company Novartis a patent for a new version of its cancer drug Gleevec (imatinib mesylate), or Glivec, as it’s known in some countries. Novartis claims the drug is more easily absorbed into the blood and, considering it is used to fight leukemia, that is enough of an improvement to warrant patent protection. But India’s trade and industry minister, Anand Sharma, has defended the decision, and was quoted by Agence France-Presse as saying it was “absolutely justified under the law” and that India’s patent law “does not accept evergreening.”

ON LBL:

On Feldman:

#### Feldman’s study sucks is and patent extensions are necessary for innovation.

**Risch 17** [Michael Risch, 11-21-2017, "Data for the Evergreening Debate," No Publication, <https://writtendescription.blogspot.com/2017/11/data-for-evergreening-debate.html>] //DD PT

I think the data the authors have gathered is extremely important, and I think that their study sheds important light on what happens in the pharmaceutical industry. That said, as I explain below, my takeaways from this paper are much different from theirs. My concerns are fourfold. First, even assuming that every one of the efforts listed by the the study were an attempt to evergreen, I have no sense for whether evergreening actually happened. This study doesn't provide any data about generic entry or pricing. For example, the study describes 13 listings for OxyContin, but I'd bet dollars to donuts that there was plenty of generic oxycodone available. Similarly, many of the new listings are changes from Drug 1.0 to "new and improved!" Drug 2.0. This, of course, has been criticized as anti-competitive (since generics rely on auto-substitution laws), but the study presents no data about whether insurers refuse to pay for Drug 2.0 and instead require the generic, nor does it explain why generics can't do their own advertisements to get doctors to prescribe Drug 1.0. Second, many of these listings and the new patents that go with them are for advances, like extended release and dissolvables. These can be critically important advances, and they are preferred by consumers. Thus, one person's "evergreening" is another person's innovation. I take extended release drugs (and expensive generic) to avoid side effects and I gave my son dissolvable Prevacid when he wouldn't stop crying with GERD (and was glad for it). Without consumer data or patent data, it is impossible to tell just how much evergreening is going on (or how harmful it is). Now, if these patents are obvious because making them dissolvable or extended is easy, I'm all for stripping protection - but that's a different issue. Third, the article speaks of orphan drug approvals as if they are a bad thing. This made me bristle, quite frankly. My mother has an extremely rare autoimmune disease that is very painful. I often wondered, isn't there some incentive to develop drugs to treat it? Turns out there is, and though she got no relief, apparently a bunch of other rare diseases did, and that's the whole point behind orphan drug exclusivity. Concern about this exclusivity seems misguided anyway. If it turns out that drug companies are gaming it and nobody actually needs the drug, then the the loss is not too large, because it's a small population and nobody needs the generic anyway. And if it turns out that they do need it, the Orange Book only limits labeling, and doctors are free to prescribe a generic for off-label use. Without evidence that doctors refuse to do so, there's no real evidence that Orphan exclusivity does much harm. In another personal story, my wife was prescribed a generic drug in a different formulation than the patented tablet for off-label use. Fourth, and most generally, the article speaks of new patents as if there is no innovation. New use discoveries are important. Many of our most important drugs are not for their original uses. As far as I know, generics are not barred from finding new uses and patenting them, either, though admittedly their hands are tied for patient use. So, where the authors see evergreening, I see innovation. Maybe. Maybe it's obvious. But we can't tell that from this high level, and I'm not ready to write it all off as evergreening. It is telling that I was able to provide four personal stories about how supposed evergreening efforts benefited, would have benefited, or did not increase costs for my family or me (and thankfully none of them involved oxycodone).

#### One-and-done doesn’t solve international evergreening – alt causes aren’t included in patents, an orphan drug designation, a period of data exclusivity named by Feldman.

**Hennebry PhD 18** [Sarah Hennebry, 01-31-2018, "When a 20 year patent term just isn't enough: Market and data exclusivity," FPA Patents, <https://www.fpapatents.com/resource?id=483>] //DD PT

2. Europe In addition to periods of data exclusivity, the European Medicines Agency (EMA) also provides for periods of market exclusivity. Market exclusivity refers to a period where a party wishing to sell a follow-on product is prohibited from doing so, even if regulatory approval has been obtained. a) Data exclusivity Current European regulations provide 8 years of data exclusivity for pharmaceutical products. The period of exclusivity commences from the first marketing authorisation date and relates to the preclinical tests and clinical trials on a medicine that are provided to the EMA to obtain first regulatory approval of a product. During the period of data exclusivity, a third party wishing to obtain regulatory approval of a biosimilar or generic product, may not rely on the data submitted to the EMA in respect of the regulatory approval of an originator product. b) Marketing exclusivity The 8 year data exclusivity period referred to at a) above, is followed by a 2 year market exclusivity period. Ostensibly, this provides the innovator company with a 10 year period from the time of obtaining regulatory approval wherein market entry of a competitor is prohibited. There are no difference between the data and marketing exclusivity periods provided to small molecule pharmaceuticals or biologic pharmaceuticals under the provisions of the EMA. c) Extra market protection The cumulative 10 year period (8 years' data exclusivity plus 2 year marketing exclusivity) may further be extended by 1 year for certain new indications that are demonstrated to provide additional clinical benefit over previous indications. This is often referred to as “extra market protection”. The 1 year extra market protection can be obtained if approval for a new indication is obtained during the initial 8 year period and: there are no existing therapies for that indication; or there are existing therapies for that indication, but there is a significant clinical benefit to using the drug for which the extra market protection is sought. d) Orphan designation The EMA assigns orphan designation to a pharmaceutical product that is approved for the treatment of: a rare condition, where < 5 individual in 10,000 are at risk of the condition; and the condition is serious (ie life threatening or chronically debilitating). The period of market exclusivity for an orphan designated pharmaceutical product is 10 years (rather than 8 years of data exclusivity plus 2 years marketing exclusivity if no orphan designation). This means that a competitor cannot rely on any information submitted to the EMA in respect of the regulatory approval of a follow-on product, until 10 years after the initial marketing approval of the originator product. Market exclusivity is extended by a period of 2 years if the orphan designation also relates to a Paediatric indication. The market exclusivity provisions in respect of pharmaceuticals with orphan designation run in parallel with the data and marketing exclusivity provisions for other pharmaceuticals. For more information on market and data exclusivity in Europe, please see: European Medicines Agency Data Exclusivity 3. Japan There are no data or marketing exclusivity provisions for pharmaceutical products in Japan. However, the effect of post market pharmacovigilance provisions is to ostensibly act as a data exclusivity provision and prevent any generic from coming onto the market during the Post Marketing Surveillance period. Post Market Surveillance is a process whereby the Japanese regulatory authority (Pharmaceuticals and Medical Devices Agency) re-examines the safety and efficacy of new chemical entities and previously approved pharmaceuticals later approved for new indications. The re-examination period lasts for between 4 to 10 years, during which time any data submitted to the regulatory authority by the drug sponsor which relates to the safety of the drug cannot be obtained by generic companies. It is not until after the conclusion of this period that a generic company is able to commence marketing of their product. The re-examination period is 8 years for new chemical entities, and 4 years for new indications. The re-examination period for orphan drugs is 10 years. For more information on post-marketing surveillance in Japan, please see: Post-marketing Safety Measures in Japan 4. Australia The period of data exclusivity is with respect to confidential information submitted to the Therapeutic Goods Administration (TGA) or the Australian Pesticides and Veterinary Medicines Authority (APVMA) by a first sponsor, for the purposes of obtaining regulatory approval of a new product containing a pharmaceutically active ingredient for human use, or products containing active ingredients for veterinary or agricultural use. During the data exclusivity period, the confidential information provided to the TGA or AVPMA cannot be used by a third party, without the consent of the first sponsor. The Therapeutics Goods Act (1989) provides that certain information is ‘protected’ if it meets the following criteria: the information concerns an active component (but not a device) which is contained in an application to register a therapeutic good; the information is not in the public domain and the sponsor has not given written permission for the Secretary to use the information; at the time the application for regulatory approval was lodged, no goods containing the active ingredient were (or had ever been) included in the ARTG; and the therapeutic good has been included in the Register for less than 5 years. Under the Therapeutic Goods Act (“the Act”), the Secretary (of the ARTG) is prohibited from using information that is deemed protected under the Act, when evaluating therapeutic goods (ie other therapeutic goods) for registration in the ARTG. This is slightly different to the situation in other jurisdictions, such as Europe, where the data exclusivity provisions prevent the review or submission of any generic or biosimilar product during the relevant period. Under the Australian provisions, such regulatory approval may still be sought by a competitor during the data exclusivity period, however, the applicant may not rely on any confidential information provided to the TGA in support of the subsequent approval. (In other words, if a third party wishes to obtain approval of a generic or biosimilar product during the data exclusivity period, a full data package must be submitted to the TGA). The period of data exclusivity is 5 years from the date a new product is registered under the Act. Unlike the US and Europe, the Australian data exclusivity regime is restricted to confidential information associated with the registration of new chemical entities. Confidential information associated with the registration of new dosage forms, new routes of administration, new indications or combination products is not eligible for protection by data exclusivity provisions. The result of this is that the first applicant to register, for example, a new indication of a known drug, must rely solely on patent protection to block a competitor from entering the market.

On your AMR impact:

#### Secondary patents are necessary for innovation to prevent AMR.

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

II. THE RIGHT TO THE VALUE CREATED BY RESPONSIBLE STEWARDSHIP Consider how the two-fold problem of growing resistance to our current antimicrobial drugs and the dearth of new antimicrobials under development looks once the specifics are omitted. Forget for a moment that the subject is drugs and microbes—or even inventions as opposed to other sorts of property—and just focus on the structure of the predicament.35 There is a resource of immense value that is being used myopically in a way that destroys existing stocks of the resource, and little is being done to find or develop new stocks of it. This is a pattern one expects to see with unowned resources, but not with owned ones. It is the classic “tragedy of the commons.” When a patch of grazing land is owned in common by everyone—which is just to say it is unowned—everyone has an incentive to make what use of it he can, leading to its overuse and destroying its value. By contrast, an owner can use land judiciously in ways that preserve its value or even to invest in improving the land. This is possible because the owner has exclusive control of the land in the present and therefore can control its uses, and because the owner expects to reap the benefit of the land’s future value. If deeds to land expired after twenty years, with the land reverting to the commons, land owners would have no financial incentives to preserve or enhance the land’s value past the twenty-year window. In this scenario, they could not afford to forgo shortterm gains that came at the expense of the land’s later value. Nor could they afford to invest in long-term improvement projects, such as clearing new land for grazing. This is the predicament with antimicrobial drugs. The profligate use of such drugs in the present destroys their value in a future in which they are unowned. This suggests the simple solution of extending the patent terms for antimicrobial drugs. So long as the drug remains under patent, the patent holder has both an interest in preserving its usefulness and the ability to control its use so as to preserve its value. How long should the patent term be extended? The five years of extra market exclusivity offered by the GAIN Act is calculated with a view to incentivizing companies to invest in developing new drugs. The aim of the present proposal is different. It is to enable the creators of drugs to profitably exercise their rights over the drugs in a manner that preserves the drugs’ effectiveness over time—ideally into the indefinite future. This requires extending the term of exclusivity not just a few years or decades, but as far into the future as there is reason to hope that the drugs’ effectiveness can be maintained. There are various ways in which this suggestion could be further developed; perhaps the most promising is simply to allow patents on antimicrobial drugs to be renewed indefinitely, so long as the drugs’ continued effectiveness can be demonstrated. (How exactly continued effectiveness should be demonstrated is a matter of detail, but likely by showing resistance to be below a certain threshold—perhaps 20 percent—in clinical isolates of interest.36) This would allow for a potentially infinite patent term. “Perpetual patents” have occasionally been proposed, 37 but the lack of a fixed term may do violence to the notion of a patent, so it may be better to conceive of this as a proposal for a new type of IP right that combines features of patents and trademarks. Conceptualizing the relevant right in this way highlights its basis. Like a patent, the right would pertain to an invention and would confer market exclusivity; like a trademark, however, it would be renewable in perpetuity on the grounds that the continued value of the property depends on the owner taking continuous action to maintain it. In the case of the right under consideration, the relevant actions would be those of stewarding the drug in such a manner as to prolong its continued effectiveness in the face of resistance. This new sort of property right could, in principle, be applied to drugs that are already off patent or otherwise ineligible for patent protection. The Chatham House Working Group proposes granting “delinkage rewards” to “firms registering a new antibiotic without patent protection (such as new uses for old drugs),”38 and it may be that the sort of IP protection proposed here would be applicable in such cases as well. If so, the right would be justified by the discovery of the new use for the drug and by the fact that intelligent management of this use is required for it to retain its value. A more difficult case is granting such rights to already known antibiotics that have gone off patent and are now available as generics. Removing these drugs from the commons would make it possible for an owner to profit by stewarding them responsibly. The difficulty here is determining who would own them. Professor Kades considers the possibility of granting a new patent to the original patent holder, but suggests “auctioning the patent rights [to such drugs] to the highest bidder.”39 Both are plausible solutions. Another option, in light of the issue of cross-resistance (which will be discussed in Part III) would be to apportion the IP rights to the relevant drugs among the owners of other drugs with similar mechanisms of action.