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1 February, 2023

Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (USPTO Docket No. PTO-P-2022-0025)

The Initiative for Medicines, Access, and Knowledge (I-MAK) appreciates the opportunity to provide comments concerning USPTO initiatives to ensure the robustness and reliability of patent rights.

The patent system is not working as intended, and the public is paying the price. Astronomical prescription drug costs are straining the healthcare system and the budgets of American families and employers. Prescription drug spending on retail and non-retail drugs is poised to grow 63% from 2020 to 2030, reaching \$917 billion dollars.¹ This increase is fueled by spending on patent-protected and branded drugs. Branded drugs make up just 8% of prescriptions (versus 92% generics), but account for 84% of all drug spending in the U.S.² The status quo is unsustainable.

Primary patents on 7 out of 10 of America's top selling drugs are set to expire this decade. In theory, when these patents expire, generic or biosimilar competition should enter the market, and drug prices should come down. However, major pharmaceutical companies have significant financial incentive to delay the inevitable competition in the market once the primary patents expire. As addressed herein, I-MAK believes that changes to the patent system in the following areas may

¹ Charles Roehrig and Ani Turner, [Projections of the Non-Retail Prescription Drug Share of National Health Expenditures Report](#), Altarum, July 2022.

² [The Use of Medicines in the U.S 2022](#), The IQVIA Insitute, April 21,2022.

start to address these problems: (a) continuation applications; (b) terminal disclaimers; and (c) double patenting practice.

The Patent Thicket Problem is Real

Pharmaceutical companies prepare for looming patent expirations by filing or amassing dozens or hundreds of patents related to the drug (i.e. creating a “patent thicket”) in order to expand and protect their monopoly power. Many of the patents forming the patent thicket are acquired through the continuation practice. A patent thicket can include both granted patents as well as patent applications. Granted patents allow pharmaceutical companies to block competition. The 741 granted patents on America’s ten top selling drugs in 2021 give pharmaceutical companies substantial power in litigation and negotiations to keep lower cost generic and biosimilar alternatives off the market for longer, and out of the hands of the American public.³ Contrary to what some defenders of current patent system argue, patent applications also deter competitors. Generic or biosimilar companies do not only evaluate granted patents when assessing freedom to operate and whether to enter the market, they must also track and review patent applications, including abandoned ones that may resurface as continuation applications, to make their decision. Currently there are over 140 patent applications filed on average for each of the 10 top selling drugs in America. Notably, over 66% of patent applications were filed after the FDA approved the drug to be on the market, indicating that drugmakers are attempting to prolong the existing exclusivity for as long as possible.⁴

The high volume of both filed patent applications and granted patents creates a complex web of both actual barriers and potential or likely barriers that generic and biosimilar competitors must avoid, while still complying with the law. This creates a great deal of uncertainty that deters generic and biosimilar competitors from entering the market, as well as uncertainty for Americans as to when they will have lower-cost medications. Patent thickets have significant negative consequences for the country, including:

- Harming public health
- Straining household budgets
- Overstressing the USPTO
- Creating uncertainty in the market
- Blocking research and competition

³ The Drug Patent Book, <https://drugpatentbook.i-mak.org>

⁴ *Ibid*

Also, as described further herein, the pharmaceutical companies rely on terminal disclaimers often to overcome double patenting rejections to amass more patents in the patent thicket. The strategy of securing additional patents extends their monopoly power far beyond the 20 years of patent protection intended under the law for an invention. When a top selling drug generates a high percentage of a company's revenue, the pharmaceutical company will often build a patent thicket to block or delay the inevitable competition that will enter the market once primary patents expire. The company has a strong incentive to protect the revenue stream by any means permitted under current law, and the drug's outsized importance to the company's bottom line leads to aggressive patenting activity. Pharmaceutical companies use this extended monopoly power in different ways, including extracting settlements in litigation from generic or biosimilar companies. These anti-competitive practices will in turn delay or block lower-cost drugs from entering the market, at substantial cost to the public. The drug pricing problem cannot be solved until the drug patent problem is solved.

Primary patents – or the patents that cover the main active ingredient or molecule – are set to expire this decade on 7 out of 10 of America's best-selling drugs. When a product is a key source of earnings and growth for a pharmaceutical company, there is significant financial incentive to mitigate the negative impact on the bottom line – or at least to delay the inevitable. Excessive patenting on existing products is one key strategy drugmakers use to extend their monopolies and their revenue streams. Generics and biosimilar companies in turn may want to enter the market for the top selling drugs, but this entails significant risk and resources because of the dense patent thickets protecting the monopolies on these products. As a result, while they are litigating the patents, generic and biosimilar companies are more likely to settle with the branded company rather than wait for a final ruling, regardless of the strength of their case. In many cases, the certainty of the settlement and earlier revenues outweigh the risks of prolonged litigation.

An example of how a patent thicket may be constructed is the cancer drug Imbruvica (AbbVie). As of June 2022 there are approximately 195 patent applications associated with Imbruvica; to date, 96 patents have been granted. Since the first patent filing on Imbruvica in 2006, approximately more than one patent has been filed every month for the last 15 years until the last application filed in 2021. 62% of the patent applications on Imbruvica were filed after its first FDA approval in 2013. 68% of patent applications cover the different indications and formulations of the drug, not

the active substance itself.⁵ Imbruvica has 29 years of patent protection from December 2006 to March 2036. Despite litigating AbbVie's patent on Imbruvica, six generic companies have entered into settlement agreements. As a result of these agreements, competitors will delay introduction of generic versions until 2032 and 2033. This is five to six years after AbbVie's main patents expire on Imbruvica in 2026. These additional years will cost Americans billions more dollars on branded Imbruvica. Even if AbbVie was not able to realise the full 29 years of patent protection it has accumulated on Imbruvica, the thicket of patents have delayed generic entry and will have provided it with a total market exclusivity of at least 18-19 years since the drug was approved in November 2013.

'Drip-feed patenting strategy'

Analyzing the Imbruvica patents reveals a “drip feed” patenting strategy. The initial patent applications on Imbruvica cast a wide net of scientific knowledge and protection, including potential indications and formulations. This knowledge is then disaggregated and patented in phases with more specificity. Because the current patent system is one-size-fits-all—all patents are rewarded with the same 20-year period of exclusivity—the additional granted patents on Imbruvica to date have lengthened its patent protection by nine years. This raises important questions about patent standards, rewards, and incentives.

It is commonly accepted that patents are needed to incentivize the investment required to bring a new drug to market. However, patenting activity did not stop once Imbruvica was launched. In fact, 62 % of patent applications for Imbruvica were filed after the drug was approved by the FDA in November 2013 and brought to market.

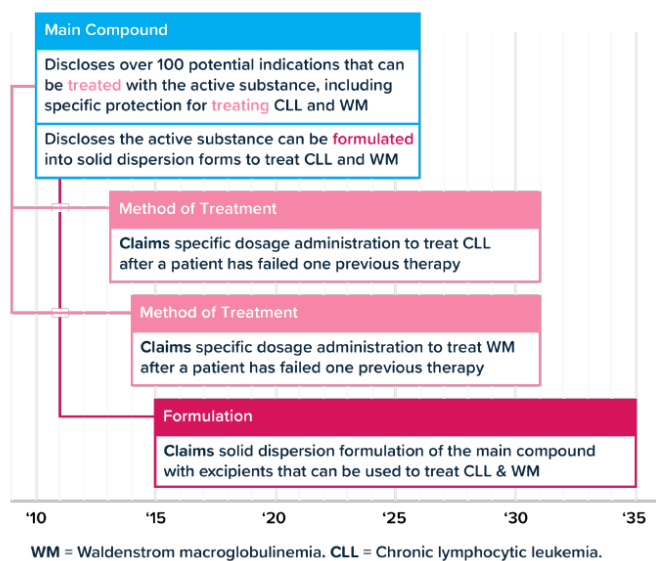
As described above, the majority of the patents in Imbruvica's patent wall cover indications (methods of use) and formulations—not the active substance. The active substance is what provides the therapeutic or medicinal benefit of a drug. Indications and formulations refer to the conditions a medicine can be used for and how it is taken (a tablet or a capsule, for example). Patents covering the active substance are often referred to as “primary patents” and typically reflect the main medical and scientific advancement on a drug. Patents on indications and formulations, called “secondary”

⁵ *Ibid*

patents, usually cover sub-components of the main invention described in the primary patent. Secondary patents constitute the majority of Imbruvica's patent wall.

There is a pattern of patenting in which knowledge related to an invention is “drip fed” out over time. That is, knowledge broadly disclosed in early patent applications is defined ever more narrowly and specifically in subsequent patent applications. For example, as shown in figure below, one main compound patent broadly describes more than one hundred possible indications for Imbruvica, as well as potential formulation routes. It also seeks protection for several defined indications. Three additional patents were subsequently filed that further specified aspects of the main patent. Two of these patents protect the active substance for indications that were disclosed and protected by the main compound patent, but with the addition of a specific oral dose for a subpopulation who have failed at least one therapy. The third patent specifically protects how to formulate the active substance for treating chronic lymphocytic cancer (CLL) and Waldenstrom macroglobulinemia (WM) using common techniques already described in the main compound patent. These three additional patents extend five to nine years beyond the main compound patent, expiring in 2031–2035.⁶ This kind of “drip feed” strategy, in which knowledge was disaggregated and then distributed over time with more specificity, was employed across Imbruvica's patent portfolio. Early patents on the main compound served as a roadmap for future patenting activity, signaling the potential for multiple different indications, formulation types, crystalline forms, combinations with other active substances, prodrugs, and more, while leaving enough room for subsequent patents to define these details more precisely. This raises important questions about what was known at the time of filing on the main compound and whether certain scientific findings were staged to lengthen the monopoly term given current patent law allows for such practices.

⁶ I-MAK, [Overpatented, Overpriced, Imbruvica's Patent Wall](#), Revised July 2020.



This analysis raises important questions for policymakers who are searching for impactful solutions to the drug pricing crisis. The current one-size-fits-all patent system enables the “drip feed” patenting strategy seen in Imbruvica. The first patent on the main compound and subsequent patents all receive the same 20 years of exclusivity, regardless of what was already known at the time the first patent was filed. As a result, pharmaceutical companies can file initial patents quite broadly and then file separate, subsequent patents on aspects of the original invention. In many cases, these later patents reveal marginally more information or specificity than earlier patents. Nevertheless, companies can substantially extend monopoly terms using this strategy. If subsequent patents are written specifically enough to be considered outside the scope of disclosure of the first patent(s), the potential to keep stacking additional patents on a single, already patented active substance is limitless.

Recommendations

To address these problems, the USPTO (perhaps in conjunction with Congress) need to evaluate and redefine what is novel and non-obvious. There is a question as to whether subsequent patents should be considered inventive if they cover subject matter already disclosed in the first patents. Addressing this question may close a loophole in the patent system that the current “drip feed” patent strategy exposes that allows pharmaceutical companies to amass dozens or hundreds of patents, as well as extending their monopoly protection on a single active substance.

With respect to continuation applications that are used to build up patent thickets, although the term of a continuation patent typically expires at the same time as the original patent expires, the existence of multiple patents can increase litigation burdens and potentially delay the launch of generics and biosimilar products. In the case of the drug Humira, over half of the patents identified in the Purple Book are continuation applications that generic and biosimilar entrants must consider in addition to the primary patents and other secondary patents associated with Humira. Accordingly, it would be advisable to consider limiting the number of continuation applications that may be filed related to a product to no more than two and which must be filed within a window of 12 months of the parent application. Additionally, or alternatively, heightened examination of continuation applications and/or increasing filing/search/examination fees for continuation applications may cause pharmaceutical companies to give more consideration as to whether continuation practice should be used. Also, only claims not previously included in the parent application should be allowed and applicants must provide justification as to why it was not possible to include the continuation claims in the first application. It is important to recognise that continuation applications essentially serve as a roadmap for applicants to overcome any prior art objections raised in the first or other related applications.⁷ The system of continuations enables companies to game the examination system and the patent system itself and which ultimately inflicts harm on the public.

As for terminal disclaimers, a terminal disclaimer is a statement in which a patent applicant disclaims or dedicates to the public the entire term or any terminal part of the term of a patent or patent to be granted. As noted above, over half of the patents in the Purple Book associated with Humira are subject to a terminal disclaimer. However, currently, each patent stands on its own for the purpose of invalidation or other challenge by generic/biosimilar entrants. To reduce the amount of litigation related to these patents, it is advisable to amend the practice so that if the primary patent (or a member of the patent family) is invalidated, the patents that are subject to a terminal disclaimer with respect to that invalidated patent also should be invalidated so that they do not need to be separately litigated.

Patent abuse is not limited to a few bad actors. The current patent system is the problem. It has become a system that is incentivising and creating bad actors. A growing body of evidence demonstrates that an essential part of the pharmaceutical industry's business model for top selling

⁷ C.Chen, [Using Continuation Applications Strategically](#), Cooley LLP

drugs is now built on maintaining market control by exploiting an outdated patent system. Pharmaceutical companies secure hundreds of patents to block competition because they can: as long as abusive patent practices are permitted by law, the drug pricing crisis will persist. In addition to making corrections to the continuation and/or terminal disclaimer practice, the USPTO should hold hearings and invite public comments on pharmaceutical patenting practices and their impact on drug prices for public and private payers, and households across America. The USPTO should also invite non-profit organisations and other experts that represent the public interest voice on the patent system to have permanent seats on the Public Patent Advisory Committee. Congress should also hold hearings to assess how pharmaceutical patenting practices affect federal health care programs and households, while taking effective oversight of the USPTO and other federal agencies that have the authority to address the overpatenting problem.

Congress, federal agencies, and the White House need to use their power to rein in these exploitative practices that harm public health, strain household budgets, and negatively impact research, competition and ultimately the American economy. There is growing bipartisan consensus that when the patent system is abused, Americans suffer. The time has come to tackle the root of the drug pricing crisis by modernising and fortifying the patent system to truly serve the public. Promoting competition and rewarding ingenuity are both core American values.

The US Constitution grants Congress the power to “promote the progress of science and useful arts by securing for *limited* times to authors and inventors the exclusive right to their respective writings and discoveries.” But patenting activity today goes well beyond the time limited monopoly intended by the Constitution, and these longer monopolies too often come at an incalculable cost. It is time to return the patent system to what it was always intended to be: not a vehicle for unprecedented profits, but an engine for discoveries that are truly unprecedented

Sincerely,

A handwritten signature in black ink, appearing to read 'Tahir Amin', with a stylized flourish at the end.

Tahir Amin

Co-Executive Director