Flexible Drug Patent Terms: A Proposed Mechanism to Stimulate Global Innovation and Health

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A major problem for humankind rests in the seemingly unresolvable competing vested interests found within the global patent system. Adequate access to medicines, particularly in developing countries, is necessary to promote health and ultimately, economic development, but the prolonged time period required for the successful R&D of novel products to make medicines available (one component of accessibility) means that private sector actors must be incentivized by being awarded exclusivity rights. This comes at the expense of affordability (the other component of accessibility). Clearly, reform proposals need to facilitate the finding of the balance that needs to be struck between incentives for drug development and access to medicines. This paper presents a theoretical proposal for global drug patent system reform that attempts to find the balance between these interests in the form of flexible patent terms.

Keywords: Patent system, Intellectual property, Innovation, Access to medicines

JEL Classification: O31, O34, O38

I. Introduction – The Debate

A major problem for humankind rests in the seemingly unresolvable competing vested interests found within the global patent system. Incentivizing drug development and equitable access to medicines are most often considered mutually exclusive goals. Adequate access to medicines, particularly in developing countries, is necessary to promote health and

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ultimately, economic development, but the prolonged time period required for the successful R&D of novel products to make medicines available (one component of accessibility) means that private sector actors must be incentivized by the awarding of exclusivity rights and this comes at the expense of affordability (the other component of accessibility). The current system places a premium on drug patent protection. This creates barriers to access for those parties who cannot afford the price of medicines on patent. Clearly, any reform proposals need to facilitate the finding of the balance that needs to be struck between incentives for drug development and access to medicines.

The patent is a construct of intellectual property law that influences drug research and development (R&D) and access to medicines. The traditional economic rationale for patents is that they encourage innovation and hasten technological development by providing financial incentive through property protection to patent holders (Sherwood *et al.* 1999). A central idea to all patent systems is that rewarding the inventor for an invention provides the incentive for more inventions, which in turn, benefits society. A second idea is that patents not only provide financial incentives for the invention of novel technologies, but also encourage the dissemination of knowledge through disclosure requirements. The inventor agrees to publicize the invention in exchange for a period during which the invention is under the inventor's exclusive economic control. These two functions of patents; (1) to promote innovation through financial rewards stemming from exclusive property rights, and (2) to disseminate scientific information, ideally serve to advance the development and distribution of technology (Merges and Duffy 2002). In considering the appropriate level of patent protection for innovative drug products, this paper takes a trans-disciplinary approach drawing on concepts from economics, law, and public health.

Economic theory views patent protection as the second best way to pay for drug development (Stiglitz 1991). When all consumers whose marginal benefit exceeds marginal cost use the product we have a fully efficient outcome. Patents, however, permit pricing above marginal cost. Some consumers may forego using the product even though their marginal benefit exceeds marginal cost. A patent system which enables innovator firms to charge prices above marginal cost for a given period of time post-market approval is generally viewed as the most pragmatic approach to funding private sector drug R&D (Danzon and Towse 2003). This means that no first best solution is possible at present given the upfront costs of drug development. Government R&D subsidy models have been con-

sidered as an alternative approach. The allocation of public funds to clinical drug development with uncertain outcomes, however, undermines equity to other important sectors of the economy. The question however, of "what is the appropriate time period for drug patent protection?" remains.

The pharmaceutical industry, it must be noted, is characterized by an intense ongoing conflict between "research-based" and "generic-based" competitors. There are significant differences in their business models and the challenges each faces when bringing a product to market. Research-based companies must raise sufficient capital to face at least two key challenges. First, capital must be devoted to funding basic research for innovative drug products. Secondly, provided research leads to a product, they must engage in development activities that involve clinical trials to demonstrate safety and efficacy. These two challenges lead to research-based pharmaceutical companies placing the utmost importance on ensuring an "adequate and effective" global patent system (Roffe *et al.* 2006). Revenue generated by on-patent pharmaceuticals ultimately provides much of the capital to bringing future pharmaceutical products to market. Generic-based companies, on the other hand, are focused on the production of substitute copies of formerly on-patent pharmaceuticals and therefore do not have the large, fixed, upfront costs for conducting R&D. Generic companies must instead establish the bioequivalency of their products; proof of which is essentially achieved by laboratory testing (Birkett 2003). Generic companies focus on drug products at the end of their patent term and any flexibility that enable them to establish bioequivalence of generic versions prior to that end date. The differing priorities of these two business models are reflected in social concerns regarding the need to balance necessary incentives for private actors to conduct drug R&D to make medicine available and the affordability of patented, market-approved medicines. This means that achieving the two components of access; availability and affordability, are often viewed as contradictory goals both with societal importance (Hertz 1997).

This paper presents a theoretical proposal for global drug patent system reform that attempts to find the balance between these interests. The sole acceptable exception to the general economics rule that monopolies are undesirable for economic efficiency in functioning competitive markets as they lead to price fixing is the area of patents. Drug patents are a *sui generis* group to this discussion because of their relationship to human health. As such, drug patents should be analyzed outside the realm of other economic literature on patents and technology. I do not

advocate for the abolishment of drug patents. However, substantive reforms to the drug patent system are needed. Upstream reform at the patent application and approval stage is advocated for in order to provide solutions. Effective use of global trade safeguard mechanisms, such as compulsory licensing by governments, may facilitate access to medicines but are inadequate (Cohen-Kohler 2007). The appropriate patent term to achieve a reasonable return on investment for research-based pharmaceutical firms remains an open question (Hore 2000; Cohen 2003). It is difficult to determine with precision the length of a drug patent term that appropriately balances the rights of private sector patent holders with the ability of public health care providers to procure affordable medicines for its population. In Section 2, my theoretical approach to drug patent system reform is presented as a solution to this problem in the form of flexible patent terms. Section 3 briefly addresses how the theoretical patent reform should be adopted into the existing international legal framework. Section 4 concludes.

II. Flexible Patent Term – The Proposed Solution

There is a competitive market distortion problem in the pharmaceutical industry created by the current twenty-year monopoly patent term. This distortion will only increase if patent terms become longer under international trade agreements that set out minimum levels of IP protection. It is difficult, however, to estimate the effects of this distortion, and thus solutions to minimize it are less than forthcoming. In order to resolve this problem, the question how do we provide an adequate term of proprietary protection to private actors involved in drug development needs to be answered. The current static approach to patent terms does not strike an appropriate balance. A flexible patent term, however, would add some much needed dynamism in this area.

In this approach, government patent offices would decide the current patent term to be awarded to all patent applicants during any given time period. This patent term would be based on an assessment of relevant global innovation and access conditions. The concept is similar to the idea of flexible interest rates that are adjusted by a country's central bank in monetary policy decision-making to grow or stabilize the economy as according to the Keynesian feedback rule. As a flexible patent term, the length of time patents grant exclusivity rights to an applicant, at time of application, is dependent upon relevant conditions at the time and is

set by the patent office. Upon approval of a patent to its applicant, the patent term is set at this currently offered time period. If at a societal level, it is decided that more affordable medicines were needed then offered patent term would be shortened. If innovation of new drug products were assessed as faltering due to perversely short patent terms, then they would be lengthened. Reassessments would be conducted periodically. This reform if properly implemented would address the market distortion created by fixed twenty-year monopoly patent terms that often extend well beyond the successful market approval date of drugs.

I will now discuss in detail the theory behind why the flexible patent term approach improves upon the current drug patent system. Implementation of this avenue for patent system reform has three concomitant steps:

1. Understanding the Advancement of the Scientific Frontier;
2. Determination of Average Drug Development Time; and,
3. Determination of the Flexible Patent Term.

Step 1: Understanding the Advancement of the Scientific Frontier

In the early years of medical science discovery and invention, humankind knew little and the knowledge applied to invention required only short development times. Exclusivity periods needed to develop innovative products were minimal. The first patents date back to 500 BC. In Sybaris, a Greek city located in what is now southern Italy, citizens were encouraged to discover new refinements in luxury by promising them that they would receive profits arising from their discoveries for a period of one year secured to the inventor by patent (Anthon 1881). Over the years, our scientific knowledge frontier has advanced and innovations became increasingly complex and useful to humankind (Mokyr 1993).

Figure 1 above represents how initially total knowledge was low and as a result, we did not need long patent terms. As history progressed, our total knowledge is increasing (K), and the rate of new knowledge is increasing. As such, we needed longer patent terms to develop the increasing number of increasingly complex medical innovations being patented. Eventually, however, there is an inflection point as the rate of new knowledge (K/t) meets a maximum even though total knowledge is still increasing. This is shown as the inflection point in Figure 1 and also the maximum point in Figure 2. An assumption is made here that

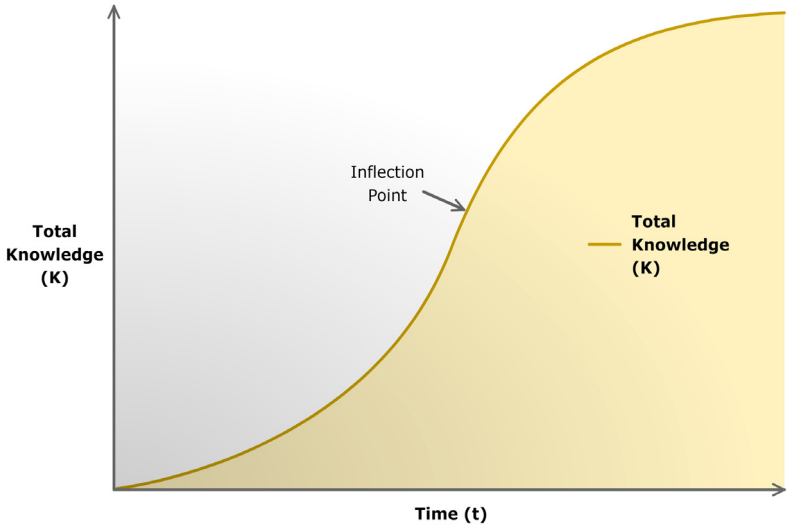

FIGURE 1
ADVANCEMENT OF SCIENTIFIC FRONTIER KNOWLEDGE CURVE

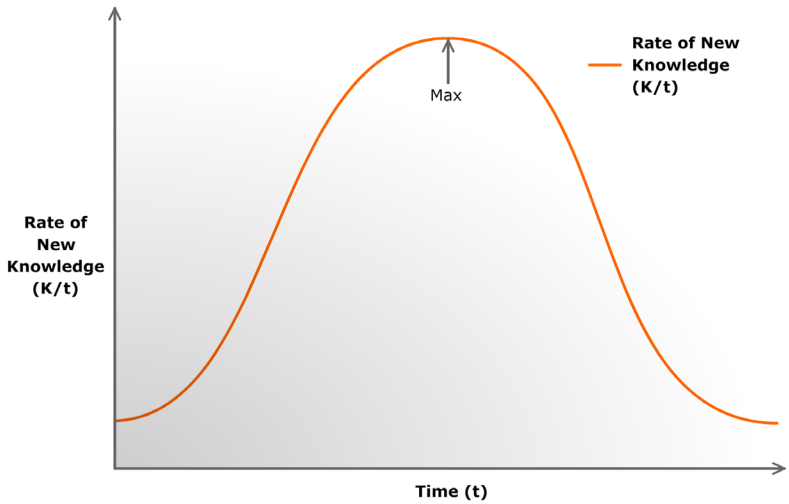

FIGURE 2
RATE OF NEW KNOWLEDGE CURVE

the rate of scientific advancement is independent of demand and appropriability conditions and is something that is inherent in the human condition in the form of curiosity and the struggle for human survival (Rosenberg 1982).

The global patent system is a response to the world's advancing scientific frontier that allows for identification, organization, and management. As science advances it introduces new issues to society, and the law must respond accordingly to the benefit of the public. Patents play an important role in humankind's developmental process. Frontier scientific knowledge is drafted in patent claims and through the patent approval process that requires novelty, non-obviousness, and utility, that frontier is verified and documented. Past the inflection maximum point, however the rate of new knowledge is decreasing and patent term can also begin to decrease as the rate of increasingly complex innovations being patented beyond this point decreases and we focus our average energy on developing those technologies already patented. *I.e.,* the point where the maximum rate of new knowledge curve is reached is the point in time where patent term also meets its maximum. As we move further along in time and our total knowledge frontier moves towards infinity and the rate of new knowledge curve's horizontal limit approaches zero, patents (*i.e.*, exclusivity) can be shortened as less capital, both in terms of time and money, needs to be allocated for drug development because safety and efficacy can be proven with shorter more intelligently designed R&D models.

Support for the position that we may have already reached a maximum rate and that the rate of new knowledge is now decreasing can be assessed, albeit indirectly, by examining the rate at which new patents are issued coupled with the content of those patents. Patents represent new knowledge by their granting requirements of novelty, non-obviousness, and utility. It is, however, important to note that the actual number of drug patents per annum obtained for distinctly new products is declining. Thousands of patents are granted for drugs, but the majority of these cover minor modifications of older existing pharmaceuticals. The National Institute for Health Care Management in the U.S. reported that from 1989-2000 only 153 or 15% of all new drug approvals were medicines providing a significant clinical improvement (Correa 2007). The number of new molecular entities (NMEs) approved by the U.S. Food and Drug Administration has drastically declined since the mid-1990s (from 53 in 1996 to 17 in 2002) (Lexchin 2006; Roffe *et al.* 2006). A decline in innovative productivity has been apparent since the mid-1990s (OECD

Health Policy Studies 2008). This data analysis supports the view that while total knowledge increases, the rate of new knowledge is decreasing and drug patent term could begin to be shortened. Recognition of this trend suggests that longer drug patent terms are not necessarily leading to increased innovation of new drug candidates. The decrease in issuance of patents for novel drug products combined with increased efficiency in clinical trial execution assessing efficacy and safety are two strong factors that advocate for shorter drug patent terms, or at least a flexible term — to be discussed further below. In summary, in spite of an increasing patent term the output of new drugs has declined, and most drug innovation of late has proven to be incremental rather than radical (Rasiah and Govindaraju 2009). Factors that support shorter drug patent protection, not longer.

Step 2: Determination of Average Drug Development Time

Ever increasing new knowledge is created as the scientific frontier expands, however as science improves with that so does the scientific process. We reach a level where clinical development execution becomes shorter as safety and efficacy, if present, can be demonstrated faster. This is linked to Part 1 that the rate of new knowledge being created decreases as our knowledge base expands. Clinical development becomes shorter because as the rate of new knowledge decreases so too does the time required to prove already established medical knowledge.

Figure 3 above illustrates the second step in the flexible patent term approach, which is to determine average drug development time for market approval of new candidates at any given time (y-axis) and over time (x-axis). Figure 3 is analogous in shape to the rate of new knowledge curve shown in Figure 2. As time advances the curve's horizontal limit re-approaches zero as it was in early years of drug development (Scannell *et al.* 2012). As the average drug development time curve's horizontal limit re-approaches zero patent term can be shortened due to earlier market launch and achieved return on investment.

Figure 3 is also supported by undeveloped literature on the subject. Companies under pressure to reduce drug development costs are intensively searching for efficiencies in their product development process (Vogelson 2001). A number of reasons for this phenomenon have been identified. For example, pharmaceutical companies are outsourcing their clinical research to contract research organizations (CROs) due to knowledge specialization capacities. Studies have shown that CROs are able

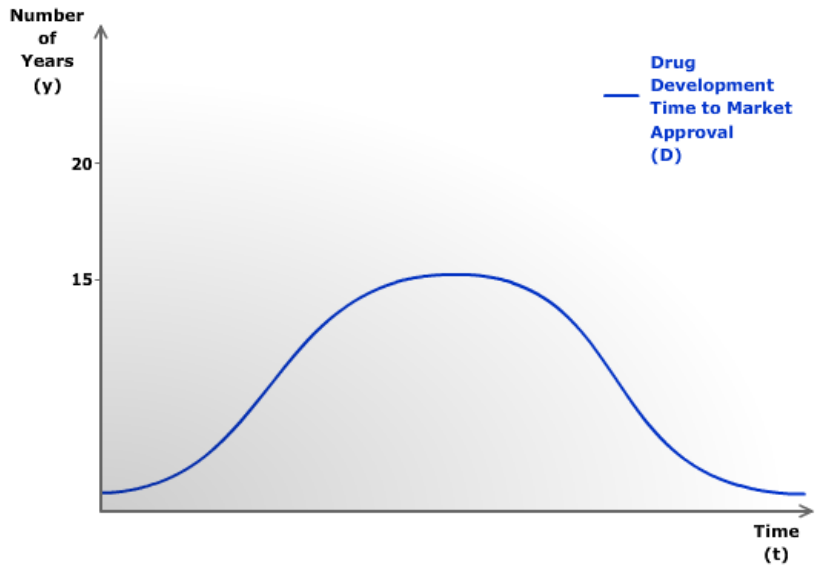

FIGURE 3
AVERAGE DRUG DEVELOPMENT TIME TO MARKET APPROVAL

to complete drug development faster than the pharmaceutical companies (Getz 2006). Other ways to increase the speed of new drug development is to adopt information technology to streamline patient recruitment and selection, and manage the enormous amount of clinical trial participant data collected for statistical analysis (Brooks 2006; Etheredge 2007). These trends all suggest the average duration needed for market approval of a new drug candidate should be decreasing. This would be a benefit for access to medicines.

Step 3: Determination of the Flexible Patent Term

The third step in the approach is the determination of the patent term. As discussed in Part 2, patent terms have increased globally to the current fixed standard of twenty years, aided in part by the proliferation of trade agreements (Danzon and Furukawa 2011). It seems likely that this trend will continue unless academic analysis presents sufficiently attractive alternatives. Average patent terms should be able to slowly decrease with a decreasing rate of new knowledge and improvements to clinical trial execution that reduce inefficiencies and the time required for development of novel drug products. This enforced by the fact that

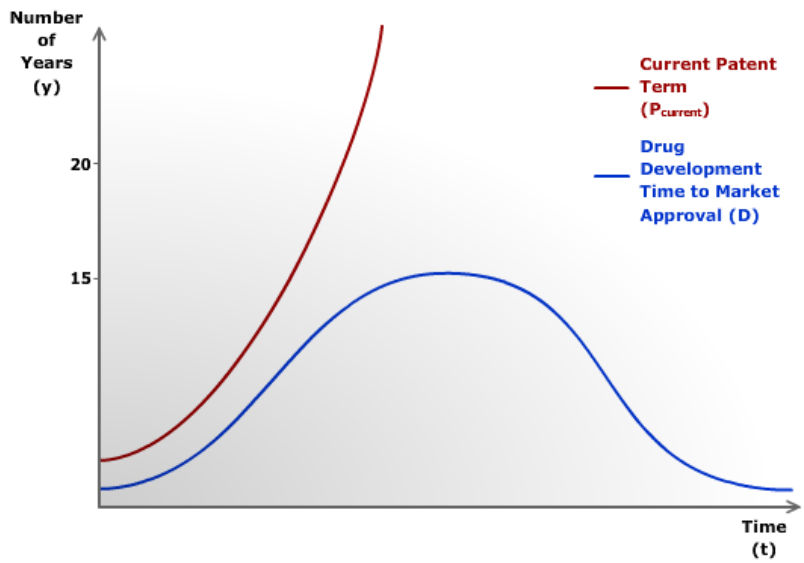

FIGURE 4
CURRENT PATENT TERM TRAJECTORY

an increasing body of evidence is pointing to the fact that longer drug patent terms are not incentivizing any further recognizable innovation. This move towards shortening, however, must coincide with the option to adjust a flexible patent term longer again if we notice our innovation processes faltering, making it a – Flexible Patent Term.

The red curve in Figure 4 is a rudimentary smoothed curve exaggeration of the trajectory we are following for patent term over time. As time has progressed, we are almost exponentially increasing our patent term, based on a justification that this lengthening is necessary to recoup the heavy upfront R&D costs of high risk and increasingly complex large scale clinical drug development (Hemphill and Sampat 2012).

As shown in Figure 5, above, average drug development time at some point begins to decrease and patent terms should run concomitant and only slightly higher than the blue curve that represents average drug development time for a candidate to achieve market approval by a government health authority in order to sufficiently satisfy the economic rationale behind their existence. Figure 6 below, illustrates the economic inefficiency in the system created or pronounced market distortion (beyond what is necessary to incentivize innovation) to access incurred if

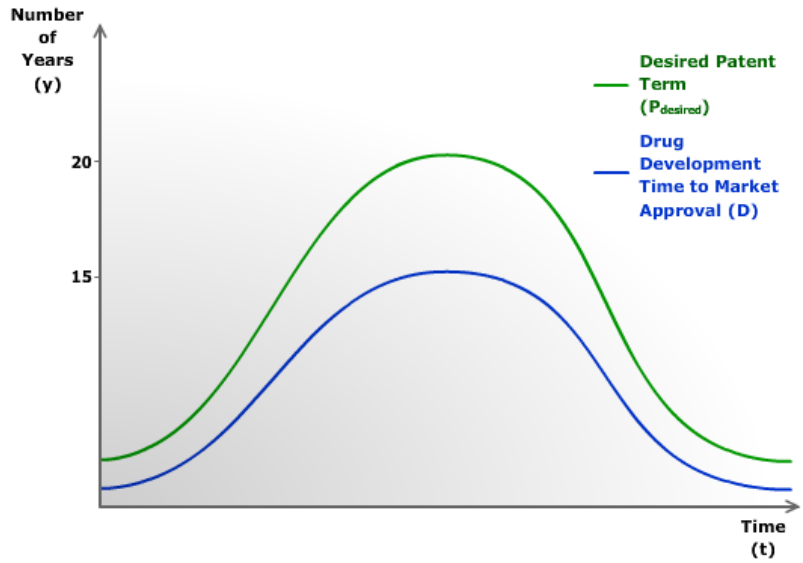

FIGURE 5
DESIRED PATENT TERM TRAJECTORY

our choice is to continue expanding patent term based on the argument that we are being faced with having to run larger and longer trials on increasingly complex drug interventions for chronic disease. The argument that drug patent term must be longer as clinical development becomes longer and more expensive with the recruitment of growing numbers of patients to increase statistical power is a misguided approach and is resulting in a misallocation of valuable resources. This is because the rate of new knowledge being achieved is decreasing and our ability to develop drugs on incrementally inventive candidates that we already have some degree of understanding about the science behind is improving (*i.e.*, shorter and less resource intensive).

It is difficult to determine, however, exactly where we are on this time line and thus what is the ideal patent term at any given time period. I have put forward an argument that we have already passed the maximum point in the curve and that patent term should be trending downwards, others would disagree. Some authors do claim that shortening of patent terms is responsible for the decline in R&D productivity (Higgins and Graham 2009). This, however, in large part is exactly why the patent term must be flexible as opposed to fixed as represented below in Figure

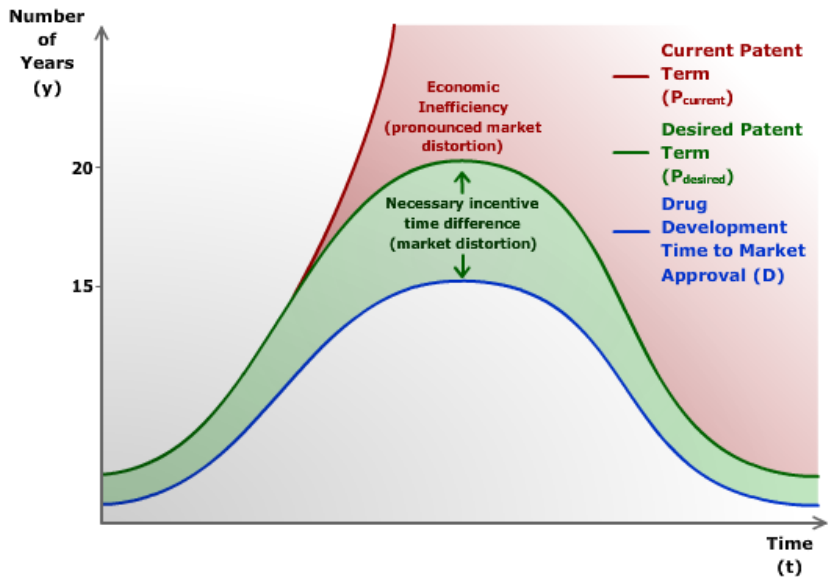

FIGURE 6
COMPARISON OF PATENT TERM TRAJECTORIES

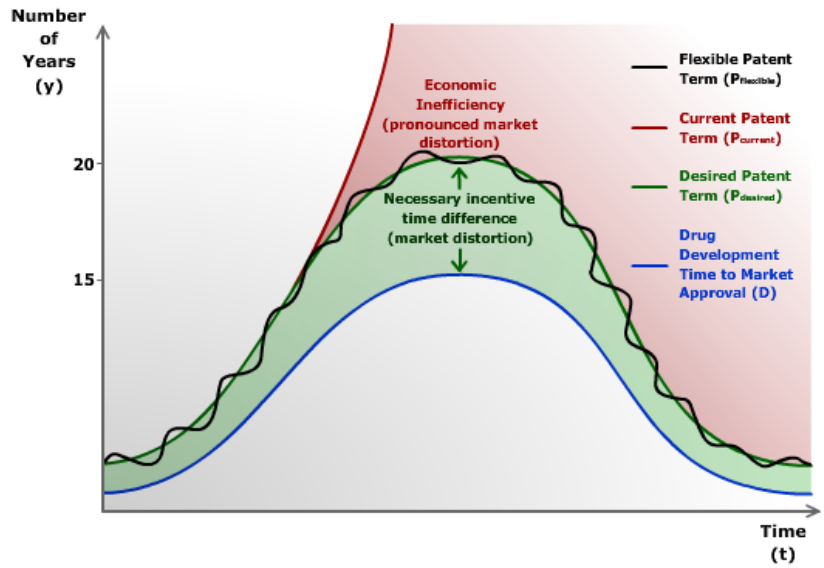

FIGURE 7
FLEXIBLE PATENT TERM

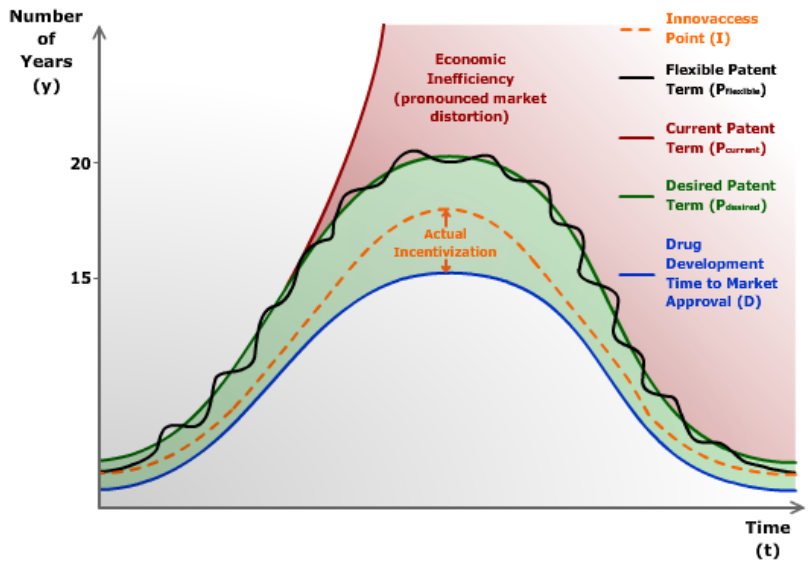

FIGURE 8
THE INNOVACCESS POINT

7. Our goal is to work towards keeping the average drug development time and the desired patent term as tightly coupled as possible. The patent system needs the flexibility of adjustable patent terms to attempt to minimize the time period where drugs are on market, yet on patent. The aim being to keep this time period as short as possible to promote access, while still incentivizing private sector drug development.

A close coupling is accomplished by identifying average drug development time and then through ongoing assessments of global conditions that focus on finding the opaque trade-off point between innovation and access created by patent exclusivity. I have termed this trade-off point the Innovaccess point, representing the point along the time continuum in drug development where the patent loses its function as a tool for incentivizing innovation and simply reduces access due to monopoly pricing. This is shown below in Figure 8.

Patent offices will have a statutory mandate and ability to adjust a flexible term in attempting to achieve this aim. This discussion only applies to drug patents that have human medical applications that require safety and efficacy to be demonstrated though clinical development. An economic argument for patents that need twenty-year exclusivity periods

as having any value for incentivizing innovation not directly related to the conduction of large-scale clinical trials for human health benefit is highly debatable.

The closer the desired patent term curve and the average drug development time curve are together, the closer marginal cost is to marginal benefit at any given point in time and the outcome is more efficient. However, the outcome is never fully efficient due to a necessary period of exclusivity to incentivize further development. Patent terms will only ever reach zero, and a fully efficient outcome achieved, if science advances to a level of understanding where clinical development is no longer needed — drug development time approaches zero. Until then, some patent term is necessary under our current business model for drug development.

The government should begin to allow for a flexible drug patent term that could be adjusted upon yearly review or as deemed necessary. At initiation of reform, I would suggest starting with the current twenty-year patent term award as a baseline term for incoming patent applications, but with the understanding that this is now a flexible term and then begin to ever so slightly reduce the term awarded to incoming patent applicants. We are looking for away to balance, and in fact improve upon, the current trade-off between goals of promoting access to affordable medicines within a patent system that incentivizes development for novel drugs by determining more clearly the Innovaccess point. The best way to achieve gains in satisfying both goals is to adjust a flexible patent term based on surrounding conditions. A limitation of my theoretical proposal at present is whether there is sharp enough feedback in the system at any given time to determine whether patent terms on average are too long or short. Clarity on this question will be achieved through further ongoing empirical evaluation of relevant metrics. This will also provide evidence in support of the theory presented in this paper. Ideally, we see a trend towards the shortening of number of patent exclusivity years awarded that ends at zero, but this cannot be achieved overnight given the present stage of our necessary evidentiary-based model of drug development. We must be sensitive to the economic rationale behind drug patent exclusivity.

III. Adoption of Reform

The suggested patent reforms should be incorporated into a new multi-

lateral treaty amalgamating procedural and substantive issues into one treaty advanced by joint efforts of the WTO, WIPO, and the WHO. The Patent Cooperation Treaty (PCT) harmonizes formal procedures, while TRIPS covers substantive issues. The patent system harmonization principles of these treaties should be amalgamated. The treaty should be specific to the drug industry and supersede existing treaties as opposed to the current complex web of legal instruments covering IP over a range of technological products. This treaty would include provisions on current drug patent law for the protection of novel inventions and the theoretical drug patent system reform recommended in Section 2. This would add clarity to the current landscape that exists for participant stakeholders.

Extracting the drug patent system issues into a separate trade agreement approach would also benefit negotiations for expanding positive guided free trade. The efforts by anti-globalization movements to stall or permanently dismantle the proliferation of other liberalizing free trade agreements, such as the Free Trade Area of the Americas (FTAA), were largely due to the controversial nature of the IP chapters, drug patents, and their implications for public health (Imam 2003). This is a negative outcome since trade integration that might otherwise have had many other positive economic benefits for developing countries wishing to experience advanced epidemiologic transition to developed world health burdens so that problems can be more holistically addressed as a global community: fails to occur (Lippert 1998). The inclusion of drug patent system harmonization obligations under larger trade agreements that encompass all sectors of economic activity results in a confusing and conflict-enhancing landscape where resources that could be spent on drug discovery, development, and delivery are lost due to time spent in contractual negotiations or even litigation.

IV. Conclusion

Ongoing empirical evaluation of the implications of the theoretical patent system reform presented here is an exercise beyond the scope of this paper. Future research in the area that identifies appropriate global innovation and access metrics to be analyzed and modeled longitudinally will provide more evidence and enable decision-makers to be more enlightened when contemplating appropriate patent term at any given time period.

The need for twenty-year patent terms is predicated on attracting the enormous financing necessary for conducting long-term clinical drug development, yet it is clear that reform to our existing patent system is needed. It is philosophically foreseeable that scientific knowledge will approach a time where long-term clinical development is no longer needed to prove safety and efficacy of new drug candidates. As this level of scientific knowledge approaches, there will no longer be a need to allocate large amounts of capital resources, as up-front fixed costs diminish, and patent term can be shortened.

The granting of patent terms from a fixed twenty-year life period to a flexible term that would change over time would improve both global equity in access to medicines and reduce economic inefficiencies in our current model for drug development, while maintaining adequate incentives for innovation. The global drug patent system must be developed with law-making in mind that is responsive to innovation and access conditions at any given time period. Consequently, the patent system reform recommended herein addresses a complex equation that requires ongoing evaluation for global patent system improvements. A flexible patent term would lead to improved innovation as individual inventors and firms become faced with a greater impetus to compete. Access is improved, as the time from market approval to patent expiry date is more sensitive to current global health conditions. At the end of the day, the global patent system is still evolving to a normative standard. It must be routinely assessed in order to find the best course of action to maximize human benefit.

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