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## Market Competition in Aid of Humanitarian Concern: Reconsidering Pharmaceutical Drug Patents

Michael Ilg

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# MARKET COMPETITION IN AID OF HUMANITARIAN CONCERN: RECONSIDERING PHARMACEUTICAL DRUG PATENTS

Michael Ilg\*

## Abstract:

*The grant of monopoly patent protection is justified normally as a means for giving incentive for innovation. Market-driven innovation is not necessarily equitable, however, and the development concerns over the international intellectual property regime governing the products of medical research are particularly pressing given the basic necessities involved. The market patent system may be said to fail individuals in developing countries in regards to both focus and access, as no incentive is given for research into maladies not present in wealthy marketplaces; or even if a medicine is universally required, then access is precluded economically from the poor.*

*The following paper considers recently popular prize fund alternatives to the patent system, and arrives at a new alternative that is based upon market reward and the retention of patentability. The proposal offered attempts to incorporate global health measures into a competitive system of tradable patent terms. Under this proposal pharmaceutical advances which serve a humanitarian purpose would receive a patent term that is severable from the originating idea or formula, so as to become a free-floating and tradable patent term. Discoveries of humanitarian medicines, or their donation, may in this manner achieve market value through the trade and application of the floating protection term to another, more commercially viable pharmaceutical product. Ideally, this proposal would serve to equate advances of a humanitarian and non-market nature with the most lucrative market drugs, and to further have blockbuster drug sales indirectly finance humanitarian advances.*

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## Introduction

In an ideal world, advances in the health sciences would reward each according to their contribution from each according to their need. Yet, in a world of limited resources and easily shared knowledge there is little incentive for anyone to undertake the substantial costs and risks of research when the reward is shared by any who wish to mimic the advance. The traditional regulatory solution of granting patents has alleviated in part the incentive problem of research, but it has been an imperfect solution that has given rise to its own set of attendant problems. There is first an economic inefficiency associated with all instances of monopoly pricing, which sees many willing consumers excluded on the basis of an inability to pay the monopoly premium.<sup>1</sup> Second, when research returns are to flow from monopoly pricing, the incentive for research investment will be directed by marketability potential amongst relatively well-off consumers rather than by the usefulness of the insight on health improvement terms alone.<sup>2</sup>

These twin patent failings on the health issues of access and research focus are only exacerbated when considering an international humanitarian context. When a large proportion of the worlds' population is precluded from access to needed medicines,<sup>3</sup> and when research activity largely ignores conditions prevalent only within poor populations,<sup>4</sup> it may be said that the economic difficulties associated with the patent solution for pharmaceutical

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<sup>1</sup> The social welfare loss due to monopoly pricing is defined by the economic term of deadweight loss. Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525, 529-30 (2001). For discussions on deadweight loss and the pharmaceutical industry, see generally R Guell and M. Fischbaum, *Estimating Allocative Inefficiency in the Prescription Drug Industry*, 4 APPLIED ECON. LETTERS 419, (1997); K. Douglas & R. Guell, *The Structural Dynamics of the Pharmaceutical Industry*, 1 (2) THE INDUSTRIAL GEOGRAPHER 74 (2004); Jerry Avorn, *Powerful Medicines* 261 (Alfred A Knopf, a division of Random House 2004). (arguing that deadweight loss may arise even in circumstances of full insurance, since insurers may opt to not cover certain conditions); Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation*, 7-8 (Jan. 17, 2005) (unpublished manuscript, available at <http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf>).

<sup>2</sup> On the general difficulties of patent research incentive, see e.g., James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHI.-KENT L. REV. 1519, 1520 (2007) (listing current systems failings as including "impact of high prices on access to medicine, the wasteful spending on marketing and R&D for medically unimportant products, and the lack of investment in areas of greatest public interest and need."); Mark D. Shtilerman, *Pharmaceutical Inventions: A Proposal for Risk-Sensitive Rewards*, 46 IDEA 337 (2006); Hollis, *supra* note 1, at 1.

<sup>3</sup> Love and Hubbard, *supra* note 2, at 1522; Shtilerman, *supra* note 2, at 1.

<sup>4</sup> Kevin Outterson, *Patent Buy-Outs for Global Disease Innovations for Low – and Middle – Income Countries*, 32 AM. J.L. & MED. 159, 160 (2006) (comparing the data on global sales proportions occurring in the developed world, from 80 to 90 percent, with the incidence of need in developing societies, and then concluding that the "global burden of disease falls most heavily where the market is least attractive.").

drugs attain an added measure of moral illegitimacy. Given the increasingly pressing international humanitarian challenges surrounding medicine distributions<sup>5</sup>, it is unsurprising and welcome that momentum has developed for finding alternative reward systems for pharmaceutical research. The purpose of the following paper is to contribute to this theoretical development by offering a proposal of research reward that is appealing economically and ethically, on both issue levels of access and research direction.

The most popular theoretical alternative to the patent system is that of the prize fund.<sup>6</sup> The prize concept serves to separate economic reward from the marketing of research advances, by, in effect, providing a one-time reward payment for the donation of research knowledge to the public realm. Under a prize approach, economic reward is concentrated upon the satisfaction of a public goal, rather than on a continuing marketing requirement to sell the advance at the highest price during the monopoly patent protection period. What is essential, then, is for reward systems to define an alternative measure of value from that of market reward which is to quantify the attainment of the public goal. Unlike general exceptions and alternatives to market pricing, which may rely upon vague notions of other social value, in this context of health science the potential exists for observable assessment. A prize approach, therefore, often proceeds upon a universal concept of health impact, generally multiplying the number of those afflicted by the amount of health improvement provided.<sup>7</sup>

Although a universal sense of health impact may identify a promising potential of a relatively objective and observable measure<sup>8</sup> to stand in place of market ability to pay, there remains a challenge of translating this concept into a viable system of compensation – the economic reward to follow upon the alternative reward basis of actual

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<sup>5</sup> While eighty to ninety percent of pharmaceutical sales occurs in the thirty wealthy Organization for Economic Cooperation and Development (OECD) countries, the vast majority of patient need occurs outside this group, it as contains eighty-four percent of the world's population.

<sup>6</sup> Love and Hubbard, *supra* note 2. For a general overview of prize approaches, see Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 114 (2003). Recent papers by Joseph Stiglitz on prizes have attracted considerable attention. See, e.g., Joseph Stiglitz, Give Prizes Not Patents, NEW SCIENTIST, Sept. 16, 2006, at p.21 ; Joseph Stiglitz, Scrooge and Intellectual Property Rights, 333 BRIT. MED. J. 1279 (2006). See also Burton Weisbrod, Solving The Drug Dilemma, WASH. POST, Aug. 22, 2003; Joseph A. DiMasi & Henry G. Grabowski, Commission on Intellectual Property Rights, Innovations and Public Health, Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D (June 25, 2004), <http://www.who.int/intellectualproperty/news/en/Submission3.pdf>; Dean Baker, Ctr. Econ. & Policy Research Issue Paper, Financing Drug Research: What are the Issues? (2004), <http://www.who.int/intellectualproperty/news/en/Submission-Baker.pdf>; Hollis, *supra* note 1; Thomas W. Pogge, Human Rights and Global Health: A Research Program, 36 METAPHILOSOPHY 182 (2005).

<sup>7</sup> A common standard type for the evaluation of individual health improvement is that of Quality Adjusted Life Years, or QALYs. See, e.g., Hollis, *supra* note 1, at 19-20.

<sup>8</sup> Interpersonal comparisons of pain, or any sensation, are of course problematic. For a discussion of the pros and cons of QALY implementation, see Alan Krupnick, Resources for the Future, *Valuing Health Outcomes: Policy Choices and Technical Issues* (2004), <http://www.rff.org/rff/Documents/RFF-RPT-ValuingHealthOutcomes.pdf>.

impact. Indeed, multiple challenges face the prize approach: of how the prize reward is to be funded, and in what relation to health impact gains; and of what relation the prize approach is to have to the patent system. For reasons that combine both economic and political justifications, a parallel and optional prize-reward system has gained the most attention. Pharmaceutical companies, under such a system, could opt for either patent protection or a prize reward based upon their assessment of optimal return. This optional system, though admirable in its intent, unfortunately does not address the business decision-making concerns of pharmaceutical company officials who ultimately decide upon research investment.

When considering the options available to research investment planning under a parallel prize-reward system, it appears that prize availability would be preferable only for unforeseen research gains into non-market drugs that would receive a new incentive for product completion and distribution. The main failing of such a prize approach is that it does not sufficiently alter research planning, which must operate within the dictates of market gains recouping for the majority of research and development risk that goes unrewarded. To truly alter access and research decisions on the part of pharmaceutical company actors there must be a greater economic incentive toward the universal health impact measure—a potential windfall in researching toward this alternate valuation.

While this paper offers a critique of prominent prize fund approaches, and the optional type of prize in particular, it also aims at a theoretical proposal that offers an improvement upon other alternative systems. Accordingly, this paper proposes a system that grants transferrable patent terms for significant humanitarian drug developments and their donation. This proposal would remain consistent with the separation of humanitarian and marketable drug developments and the utilization of a universal health impact measure. The proposal would differ, however, in rewarding an increase to public health knowledge not in the form of a monetary payment (which suffers from fund distributional problems and of substantial company reward uncertainty), but rather on the basis of patent protection. Therefore, a pharmaceutical company whose drug has achieved a certain standard upon a universal health impact measure may then surrender its patent rights into the public knowledge domain in exchange for a free-floating patent term. Significantly, this patent term may in turn be sold to other pharmaceutical companies for the highest price. Those buying the rewarded patent term may then apply it to extend the monopoly term of a patent which they currently hold.

The benefit of a transferable patent reward system is that economic value becomes more certain for research and business decision-makers; rather than an unknown share of a public fund for donated drugs, the gains

are individually achieved, and arguably more enticing as a lucrative option. The value of the donated research is set by what another pharmaceutical company is willing to pay to extend an *existing* patent within the separate and more marketable realm. The price of the humanitarian drug advance is thus tied to market competition amongst pharmaceutical companies based upon what they are willing to pay, and equates the humanitarian advance at an economic reward level very near to that of the current and most lucrative blockbuster drug in the marketable segment of patent reward.

The economic windfall potential of humanitarian drug donation under patent transferability is argued to be an improvement upon other prize systems, as it combines health impact concerns with the viability of separate research treatments, and does so in a way that furthers both access and research within the scope of the most pressing humanitarian health concerns. Admittedly, a transferable patent system shifts the unavoidable costs of humanitarian drug distributions and research unto current users of patented and expensive medicines by prolonging their monopoly price period. This would then be the opportunity for the introduction of government fund relief, compensating monopoly users for their additional payments under a monopoly extension. This post-transfer approach would offer the advantage of greater payment flexibility, as governments could pursue different compensation means and amounts rather than agreeing to a prior outcome rule. Additionally, the health impact target could be set higher to reward only truly universal insights; or, the amount of patent transfers may be limited to specific term grants to each purchaser so that the awarded patent cannot be sold to any one company in total.

Despite pragmatic calculations that would render the transferable proposal more palatable politically, it remains that it offers the potential of valuing a humanitarian research gain upon the same basis as blockbuster drugs are currently. The hoped-for prospect is that individuals in developed countries may express a commitment to reward insights into the most pressing global health issues upon the same economic-reward basis that currently holds in their own countries. At some significant point of health impact, it may be just and realistic to treat the blockbuster drug in the developed market as not only equivalent to the humanitarian drug advance, but also as driving the reward amount for that advance.

## **I. Context of the Problem**

Research into health-drug advances corresponds with the economic problem of public goods: there is no incentive for any one private individual to undertake the responsibility of providing a service that is of undeniable

social benefit because the costs are borne by one, but the benefits may be shared by all.<sup>9</sup> Therefore, public goods generally suffer from the difficulty of non-exclusivity and the inability to render the provided benefit a compensated-for return. The lighthouse is a textbook example.<sup>10</sup> Society gains from the safety improvements for sea transit, but since any ship may benefit from the illuminated conditions without charge, there is little incentive for any private actor to attempt to provide this light service. Explanation of point introduced in previous cite The case of health research is analogous to the lighthouse in that the social benefits are generated through expense that will not be recouped in a private market, as it is too easy for others to free-ride and enjoy the benefits without cost. While health research is a substantial cost for the initial researcher, which may or may not increase social welfare, a competitor may simply adopt the content or formula of the advance without cost once it is shown to be of value. This latter adoption of the successful advance, after all of the cost and risk, serves to render the research a pure economic loss or charitable service, from the researcher to the community without reward

While the lighthouse example lends itself to government provision as a potential solution, the health research case does not. Within a capitalist system, and with the failure of the Soviet style of public control of research and production, it is difficult to conceive of a viable political option for a *wholly* government-controlled and-directed research programme for society.<sup>11</sup> Obviously, government-funded research may be a substantial factor in many forms of research, but this project limits itself to consideration of how non-governmental, private actors respond to research incentives. And in view of these private actors, the traditional solution has been to use the legal mechanism of patent protection (of term-limited monopoly protection for the advance) to ensure that there is economic incentive and reward for research. No less than a thinker than J.S. Mill advocated that a patent solution was preferable, as it “leaves nothing to anyone’s discretion; because the reward conferred by it depends upon the invention’s being found useful, and the greater the usefulness, the greater the reward.”<sup>12</sup>

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<sup>9</sup> See, e.g., Shtilerman, *supra* note 2, at 1 (citing *Mazer v. Stein*, 347 U.S. 201, 219 (1954) (“[T]he economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in ‘Science and useful Arts.’”)); See also, Shavell & Van Ypersele, *supra* note 1, at 529-530.

<sup>10</sup> For a modern treatment of public good problems, see e.g., GLOBAL PUBLIC GOODS (Inge Kaul, et al. eds., Oxford University Press) (1999); for an interesting and famous contrarian position, see, Ronald H. Coase, *The Lighthouse in Economics*, 17 (2) J.L. & ECON. 357, (1974).

<sup>11</sup> Interestingly, the Soviet Union was a noteworthy example of using prizes to encourage research production. See, J.W. BAXTER ET AL., WORLD PATENT LAW AND PRACTICE 44-51 (Matthew Bender & Co. Inc. 1998) (1968); See also, Shavell and Van Ypersele, *supra* note 1, at 527.

<sup>12</sup> JOHN STUART MILL, PRINCIPLES OF POLITICAL ECONOMY WITH SOME OF THEIR APPLICATIONS TO SOCIAL PHILOSOPHY 563 (William J. Ashley ed., Longman, Green, & Co. 1909) (1848).

The patent solution has arguably alleviated the main incentive and public good problem of health research, for it has provided a very lucrative goal to be achieved as the outcome of costly research. Indeed, the profitable nature of the monopoly protection solution has produced a healthy and very profitable subset of economic actors. But it should be noted, of course, that there are attendant difficulties with the ideal of patent reward due to usefulness, or more accurately, and in reality, of market monopoly protection reward.

Before providing a summary of the difficulties that arise with the patent solution, it may be appropriate to comment upon a feature of modern regulatory reality that may be identified with vesting interests and the problem of political path-dependence. While Mill presented an argument in favour of patent protection on the basis of social welfare, or perceived justice for individual usefulness, it should be observed that this view was far from uniform at a historical point of patent adoption and origins. In an influential paper on the subject, Shavell and Van Ypersele drew upon historical sources to note that the patent solution was far from universally accepted amongst economists, with the German academy in particular aligned against such a solution.<sup>13</sup> Why does this matter? Because it indicates that there is an economic weight to legal regulatory design, which in turn may move into the political realm based upon the economic gains under said regulatory design.

Path-dependence theory indicates that built-up infrastructure around a once optimal solution may become so substantial that, even when it is no longer optimal after changed circumstances, that adaption may be inconceivable.<sup>14</sup> To render the analogy, a legal policy choice that was once a matter of significant debate may become an entrenched and difficult-to-topple base of the political and economic status quo. A past regulatory decision that provides significant economic and sectorial gains may thus result in vesting political interests, whose economic power is derived from the past regulation and whose political power, in expending some of the economic gains, is turned to ensuring this dependent regulatory relationship. This momentum of vesting interests may explain, at least somewhat, why patent alternatives have been a dormant topic of discussion and serious debate until only

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<sup>13</sup> Shavell and Van Ypersele, *supra* note 1, at 526-27.

<sup>14</sup> “If society cannot think effectively about the alternative path because it lacks the vocabulary, concepts, or even belief that the other path could exist, then that society cannot consciously choose either to return to the branch point of the two paths (and then go down the other path) or jump to the other path.” Mark Roe, *Chaos and Evolution in Law and Economics*, 109 HARV. L. REV. 641, 651 (1996); A common example of path dependence is that of the QWERTY keyboard – named after the uppermost left row of letters, illogically placed to slow early typists who were too fast for the early, crude mechanisms that would jam repeatedly when pressed. Word processing having obviously surpassed this mechanical impediment, the debilitating delay designed into the keyboard is no longer necessary or efficient. Yet the old form remains, a sign of an initial economic advantage long since having worn out its rationale. Paul A. David, *Clio and the Economics of QWERTY*, 75 AM. ECON. REV. 332, 335 (1985).



relatively recently.<sup>15</sup> In moving forward, an appreciation of the imbedded interests within the patent may be useful in recognizing the scale of the status quo to be altered and the potential need for staged reform.

### *A. Context and Calls for Reform*

After years of critical inattention, challenges to the health patent system have grown in frequency, and have offered alternative visions of research reward.<sup>16</sup> A core difficulty of the patent approach, inherent since its inception, has been the loss of willing consumers due to monopoly pricing, identified as deadweight loss in economic terms.<sup>17</sup> So as monopoly pricing extracts a lucrative price premium, it is inefficient, in that many willing consumers who would be able to purchase at a price lower than the monopoly price are excluded, and there is a block of lost purchasers due to the artificially-high price floor of the monopoly patent protection. While the loss of efficient pricing because of monopoly protection is an abstract issue of access which concentrates upon lost potential consumers, the question of access has gone far beyond deadweight loss and optimal purchase price.

The issue of access has shifted perceptibly from abstract shades of grey into stark relief; from concerns over lost consumer purchasers at a monopoly price point to pointed humanitarian concerns over receipt of needed relief. In the wake of globalization, with increased market movements met by increased interconnections of information, and indeed the awareness of circumstances in the poorest regions of the world, the disparity of health access has become glaring. The extent of seeming injustice is straightforward enough, and may be demonstrated in the hugely-disparate number of those afflicted and left without attention in the developing world in comparison with those of the developed.<sup>18</sup>

As with issues of access that move from general to humanitarian and development concern, the issue of research focus may be seen to move in a similar fashion. By rendering research returns as premised upon monopoly protection, the patent system approach clearly depends upon market viability to give economic effect to the monopoly protection. As a marketable drug is required to give economic effect to monopoly protection, research is to be directed to marketable segments of society. What this incentive scheme leads to is research based upon ability

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<sup>15</sup> CHRISTINE MACLEOD, *INVENTING THE INDUSTRIAL REVOLUTION 191-96* (Cambridge University Press 1989) (noting multiple instances of specific reward Parliament legislation between 1750 and 1825); *see also* Shavell and Van Ypersele, *supra* note 1, at 526-28 (observing a long period of dormant reward interest or academic activity, with few exceptions).

<sup>16</sup> *See supra* note 5.

<sup>17</sup> *See supra* note 1.

<sup>18</sup> Outtersen, *supra* note 4, at 160.

to pay rather than ultimate social use. This market research focus presents the danger of marketability overtaking the private research agenda, so that it overwhelms the patent justification altogether.

On the one hand, pharmaceutical drug research may be diverted into the purely superficial or cosmetic ailments of insecurity that may be fuelled by advertising.<sup>19</sup> Or, more troubling, are the instances of the so-called ‘me too’ drugs.<sup>20</sup> Even assuming a genuine health advance is offered by a patented drug, there is the tendency to alter slightly the patented formula so as to achieve a new protection period for a drug new in nearly name alone. The lucrative protection period of patents works under such schemes not as means of recouping expense and rewarding research risk, but of providing an undue profit return to a drug that is marketed heavily enough to replace a previous drug despite little or no health improvement, or worse, a minor chemical alteration that is later found to have negative health consequences.

Beyond the marketing competition engendered by patent protection remains a more fundamental problem of research focus. The above marketability issues speak to a distortion within the existing realm of research, but it does not speak to the greater problem of the research left undone: the research not attempted for lack of an available market. When medical conditions do not conform to a waiting and viable market, there remains no incentive for research into these maladies under the marketability patent system. The result is that conditions that afflict mainly the poor south, with malaria as the most prominent example, do not receive the research attention that the number of afflicted would indicate that they deserve.<sup>21</sup> It may be said, certainly, that the most pressing global medical conditions, such as cancer or AIDS, are of a global nature not confined geographically between rich and poor.<sup>22</sup> Yet, it should be acknowledged that conditions which afflict mainly the poor are still deserving of attention, and that research into global conditions of affliction may be lessened by a pharmaceutical company concentration upon superficial drugs and their marketing and re-marketing.

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<sup>19</sup> See, Love & Hubbard, *supra* note 2, at 1519-1520.

<sup>20</sup> Shtilerman, *supra* note 2, at 1 (quoting Philip Ma & Rodney Zemmell, *Value of Novelty?* 1(8) NAT. REV. DRUG DISCOVERY 571 (2002) (indicating that of thirty-three blockbuster drugs, which had 1 billion plus of annual sales, launched between 1992 and 2001, and of those twenty-three were “me too” drugs.); *See also*, Hollis, *supra* note 1, at 6.; Sjoerd van Bekkum, et al., *A Real Options Perspective on R&D Portfolio Diversification*, 38(7) RESEARCH POL’Y 1150, 1154 (2009) (“low risk projects in R&D are most often of an incremental nature; examples are ‘me-too’ inventions that imitate a successful competitor’s invention”).

<sup>21</sup> *See supra* note 2.

<sup>22</sup> Outtersen, *supra* note 4, at 163.

## II. The Separation of Research From Market Value

When considering drugs of equal global effect, which may have equal health impact despite marketability or ability to pay of those afflicted, the unequal distribution of the drug should be taken as an economic effect and not primarily a moral one. It may be assumed, or rather hoped, that pharmaceutical companies only dispute free access of their patented drugs in the poorest regions of the world for reasons of maintaining their monopoly rights in developed markets. The prospect of price discrimination may be held to be a prime justification for why companies will not donate drugs into regions which will not be a conceivable market for the foreseeable future. Africa, as a prominent example, may not for some time have the economic capacity to serve as a viable pharmaceutical marketplace, but if patented drugs were simply to be donated into such poor regions, they might easily find their way back into developed countries via the black market. In this regard, this ability of black market drug-price arbitrage serves to delimit the potential for true pharmaceutical donation and the designated, permissible free-riding of the poor.<sup>23</sup>

The potential for price discrimination, or of drug leakage between markets, also serves to limit reasonable alternatives to the dominant patent system. For instance, it might seem reasonable to construct an international fund to compensate pharmaceutical companies for their forgone revenues in developing countries for unenforced patent rights.<sup>24</sup> Such a system would maintain the all-important developed-country markets for drug makers, with the relatively minor loss of developing-market sales treated as a charitable loss.<sup>25</sup> Such a system is reasonable, again, because it captures the unequal distribution of market importance, but it may fail for reasons of the pharmaceutical company's fear of drug arbitrage of (where drugs bought in the developing world being sold in the developed world for far less).<sup>26</sup>

It is perhaps for this reason of price discrimination, of separate worlds of sales, that many alternative visions of health research reward have taken a more universal approach. Rather than conceiving of the world as a collection of markets, the trend of alternative approaches has been to conceive of research as a global knowledge

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<sup>23</sup> On the basic challenges of price discrimination to the international patent system, and potential qualifications, see e.g., Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Drug Prescription Markets*, 5(3) YALE J. HEALTH POL'Y L. & ETHICS 193, 203 (2004).

<sup>24</sup> In an interesting proposal Kevin Outterson argues that the forgone profits from potential sales of needed medicines in developing countries be 'bought out.' Outterson, *supra* note 4, at 160, 171.

<sup>25</sup> *Id.*

<sup>26</sup> The potential incentives for drug arbitrage, of importing drugs between different pricing zones, or of selling pirated copies of patented drugs, are perhaps best indicated in the simple fact of price discrepancies that can range from \$10,000 per year of individual drug use in the US versus less than \$200 for generic substitutes. Outterson, *supra* note 4, at 160.

good. Instead of a patent that protects an insight post-development, then, the ideal is to offer a prize that would reward research based upon its satisfaction of prior conditions. To make the prize notion flexible enough that research could be directed toward a general outcome of health improvement, so as to avoid waste without exact success, would require that the prize be of an undefined content. A single monetary prize for a single medical advance would be unrealistic and overly inflexible, ignorant of the sporadic, unforeseen nature of scientific advance. Any viable and systematic research reward program should hold out a general target of health impact as opposed to a specific treatment or condition target: to give value to the unpredictable nature of research; to mitigate against wasted research that misses the target but might otherwise be of social value; and to promote different and simultaneous attempts at humanitarian purpose.

#### *A. Valuation*

For reward to replace market, there must exist a different quantum of assessment. As the market reward for monopoly patent protection has been based upon ability to pay, a prize definition would need to proceed upon an alternative basis, and most likely that of alleviated need. To depart in this fashion from a market valuation would require some independent valuation based a universal health value. A fair sense of alternative need could be identified, in the most general sense, as that of individual degree multiplied by the number afflicted. For ease of articulation, such impact measures have already been identified, with the concept of QALYs – quality-adjusted life years – foremost amongst such measures.<sup>27</sup>

While a measure that includes individual impact multiplied by the number of individuals afflicted is perhaps universal and indeed utilitarian in its measurement of greatest benefit across the greatest number, it is not necessarily a complete picture of fair reward. Individuals may suffer from debilitating and intense conditions that are rare and shared little amongst others, rendering these individuals and their conditions closed to QALY-type system relief. Yet these individuals' suffering should not necessarily be diminished in relation to conditions more widely shared. A truly universal and abstract view of suffering would count the rare disease equally on a universal moral basis of individual suffering.

Though a regulatory system may need to avoid discrete metaphysics of individual suffering comparison, it remains that a systemic approach should not altogether do away with more unique instances of medical malady. The

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<sup>27</sup> See Hollis, *supra* note 1, at 2, 18-20 (other health indicators include Disability Adjusted Life Years (DALYs) and the Health Utility Index (HUI)).

notion of an orphan drug, for diseases whose small number of patients renders research and development unreasonable economically, illustrates the need for flexibility within universal health impact assessment.<sup>28</sup> What the example of orphan drugs points to is the pressing need to also recall and consider health suffering upon individual terms apart from global utility.<sup>29</sup> The very seriousness of conditions of the few should not be discounted on moral or distributional grounds simply because they do not share an affliction with a wider group. And as a practical note within this regard, the tax benefit approach in the United States did yield important gains in this otherwise unmarketable area of research.<sup>30</sup> For these above reasons, or the example of orphan drugs and the failings of a purely universal measure, a more discretionary approach is a compelling feature for any alternative reward system.<sup>31</sup> A vision of QALY-plus could proceed with an administrative body that is provided with a mandate to retain a discretionary distribution that may be targeted toward orphan-type drugs or conditions.<sup>32</sup>

### *B. Prize Scope and Definition*

If an alternative valuation method through QALYs is available and established as viable, it remains to address the relationship of this new alternative means to the status quo patent system. The question becomes whether the health impact alternative is to replace the patent system for health drug research in its entirety, or whether it may operate as a parallel or complimentary system to the patent model. It may appear ideal in the first instance to initiate an exclusive reward system, replacing the patent model for pharmaceuticals completely. Such a wholesale replacement would offer the potential of substituting the flaws of the pharmaceutical patent approach, including research misdirection and inaccessibility, with a truly global means test of reward.<sup>33</sup>

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<sup>28</sup> For a description of orphan drugs, as wells as their regulatory improvement to research through US tax policy, see, e.g., Shtilerman, *supra* note 2, at 339.

<sup>29</sup> This may be characterized as a Kantian equality of individual suffering, in which each has universal merit, to be juxtaposed with a more utilitarian aggregation of global need.

<sup>30</sup> Shtilerman, *supra* note 2, at 339.

<sup>31</sup> For example, Love and Hubbard use the orphan drug class as one of the justifications for a more discretionary approach to fund distribution under their proposed model. Love & Hubbard, *supra* note 2, at 1531.

<sup>32</sup> *Id.*

<sup>33</sup> The pure prize approach may be represented in the *Sanders Bill*, introduced by then Representative Bernard Sanders as H.R. 417 in the 109<sup>th</sup> Congress; and the work of Love and Hubbard, which claims to be the Bill's inspiration. See Love & Hubbard, *supra* note 2, at 9. ("Sanders based his bill on the proposals championed by Hubbard and Love . . . ." The proposal set the fund at 0.05% of US GDP and would be administered by a management structure. "H.R. 417 does not do away with the patent system. Innovators can still get patents, and use patents to protect inventions, up until the point when a product is registered for sale. At that point, however, rewards for the invention from the prize fund replace the exclusive rights of patent as the incentive mechanism. In effect, it changes the way the patent system works and provides a new system of intellectual property incentives.").

The pure reward replacement, however, suffers from difficulties of both practical and political implication. As a practical and entry-level concern, the substantial administrative challenges of reward funding, including amount, contributions, and distribution, are the most extreme when considering a wholesale system replacement. In terms of economic efficiency between systemic options, it should be noted that in a leading article within the field, Shavell and Van Ypersele found an optional reward system to be optimal.<sup>34</sup> In a political sense, however, the most obvious obstacles to a pure reward system adoption may well be the vested interests in the present patent system. However, and as a further political or justificatory matter, it may be unreasonable to disincentivize the market-based advances generated by patents and consumer demand in developed markets, either as a point of health impact or resource distribution. As to distribution, it may be unpalatable politically to have the funding of global reward emanate almost exclusively from individuals within the rich, developed markets and to not maintain at least some specific research reward possible for these developed-country consumers. This specific research reward possibility may encompass medical conditions of higher proportion in developed nations, including slight discomfort alleviations or even the purely superficial, such as hair loss treatments.

While a global means standard of health impact is undeniably more equitable than a pure market valuation, it may be that initial reform may need to alleviate ability to pay with a measured space remaining open for willingness to pay, rather than treating developed consumers and citizens as primarily as the location for funding. For if the benefits of a reward system are to be spread globally but the payment is not, self-interest among developed country citizens may undermine support for what is in effect a redistributive program in its entirety. A blended system, at least as a way station on the way to a future and ideal reconfiguration, may offer a more appealing and pragmatic, if not purely redistributive, blend that would be a needed political sales qualification amongst the funding demographics

As to the practical realities of a global and uniform treatment of research outcomes, it may be that a total prize reward system may unduly demarcate between humanitarian and global maladies and market-driven concerns, even when of a superficial basis. This demarcation may be counterproductive on social utility measures as potentially contrary to scientific outcomes. Just as the present patent approach unduly demarcates between market return based upon ability to pay, a pure reward system based upon global health impact may unnecessarily constrict types of research and development. A primary benefit promised by the reward concept is the business consideration

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<sup>34</sup> Shavell and Van Ypersele, *supra* note 1, at 525-45.

for research into new directions previously without market incentive. Although the humanitarian and egalitarian appeal of global health impact may be undeniable, to replace one uniform valuation means with another, however idealistic, is perhaps unnecessarily restrictive and unappreciative of unpredictable science research outcomes. Many health research initiatives may come to nothing, while others may lead to unforeseen drug developments. To promote a holistic reward approach for research reward, whether market or humanitarian, is to ignore the extent that heterogeneous research may produce gains across a category. Therefore, to preclude humanitarian concern from market research direction is not only morally flawed; it limits the potential and unforeseen variations of research that may ultimately be of use within the very same market system and upon market terms. Logically, a more idealized humanitarian system may suffer from the same instance of system self-interest isolation; of excluding potential variations that would be of value when turned back into the system.

A pure health impact reward system would certainly alter research direction, conceivably into wholly humanitarian conditions and away from any market reward for the more minor or superficial conditions of the developed world. However, such a radical redesign would face the political challenges mentioned above, as well as excluding the entirety of market benefit, both in regards to the distribution of funds versus demographic concern and, most importantly, as to the content of research that may be of unpredictable and ultimate social use.

### **III. Research Incentives**

#### *A. Research Unpredictability*

A uniform reward type, of either market or global prize, affects first stage business decision-making into the nature of condition researched toward, but it does not address the later research stages in which a project may be transformed by results into yielding a potential advance into the 'other' type of reward. Under the market system, research that is inadvertently tending toward a humanitarian advance may not be pursued fully, or at all, as there is no market reward for continuing on the risk of this research project. Conversely, the inadvertent market potential may be discarded when a global impact measure is the only basis of reward and research recoup. The question then is why there should not be compensation for unintended research advances, even if it does not correspond with a uniform system of valuation? A blended approach, or parallel systems of patent and prize, therefore, offers an

equitable treatment of research efforts that may transform into unintended outcomes that are of some value to others, even if not a systemic priority of either market or global health impact.

Of even more research import may be the tendency of a uniform system to discount the early-stage development for research that does not point to enumerated or contemplated reward, even as later-stage developments may inadvertently transform to become an advance across demarcated lines of market or global health impact. The question under this heading of research unpredictability becomes why should a system limit the possible number of research attempts and programs when the ultimate form or outcome of non-system research may come to serve the interests of that reward system and its promoted values? The premise of this brief critique of systemic uniformity is that a diversity of research attempts may, through their unpredictable paths forward, serve both society and stated system priorities. It would appear counterproductive to reward drug research projects upon a solitary calculus alone. In thumbnail view, the possibility of alternative valuations may produce unforeseen developments that may advance the stated ends of one normative system in a way that would not have been possible but for the incentive to start on a research path with the ends of another system in mind.

The possibility of reward across valuation systems thus seems a stronger incentive to diversity in research attempts, which, when combined with the unpredictable outcomes of research, may yield unintended benefits to the interests or individuals that are addressed by another system. The humanitarian aims of global health impact may be aided by research initiated by the potential of market reward, but which was fostered later on by the recognition of reward for humanitarian outcomes. A safety valve of reward between two systems may be the optimal way to assure the most varied attempts are made, given the unique incentive momentum of increased avenues of reward.

### *B. Parallel Systems of Reward*

For many of the above reasons that indicate against an exclusive prize system, an optional and parallel system of prize fund reward is a leading proposal. A leading example may be found in the work of Thomas Pogge and Aidan Hollis, two prominent prize fund advocates joined together in both a global research project and a resulting book.<sup>35</sup> Although there are remaining and significant difficulties with the optional prize approach, the comprehensiveness of Pogge and Hollis's reasoned argument and admirable intentions are, at the very least, a testament to building a moral and intellectual call to change

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<sup>35</sup> AIDAN HOLLIS & THOMAS POGGE, *THE HEALTH IMPACT FUND, (Incentives for Global Health 2008)*, available at <http://www.yale.edu/macmillan/igh/#>.



The optional approach, of pharmaceutical research producers being able to opt into either a market or health impact system of reward, results in three broad categories of drug advances: 1) drugs likely to favour market valuation, 2) those likely to favour health impact reward solely, and 3) drugs that may find reward under either a market or prize valuation.<sup>36</sup> A means to evaluate the potential theoretical advantages of such an optional approach may be found in examining research incentives at two significant time frame points: at the initial funding decision-making stage and at the mid-research stream when marketability decisions may be altered. The standard evaluative measure, then, would naturally be the ability of a proposed system to change business decision-making and incentives that direct research funding. An important contextual feature imposed upon this evaluative measure may be one of pragmatism, recalling both a need to consider political reality and the desirability of some market role in research reward and valuation.

### *C. Mid-Stream Research Direction*

In regards to midterm research considerations, an optional approach solves conceivably the problem of research transience, of unforeseen connections and overlap between research outcomes. Let us first consider the hypothetical of a drug research program initially targeted at market reward, but which has come to indicate that the target will not be achieved. From the vantage of pharmaceutical company management decision-making, which is a significant factor in considering alternative risk and reward schemes for research direction, one may now imagine that the optional approach gives a potential research lifeline to projects whose findings no longer point toward the intended market outcome which supported the project initially. Yet, it must be said that such a likelihood is slight, of a market-driven research project devolving/evolving into a productive humanitarian one. This might assume that there is a positive correlation between the proposed market and humanitarian advances, whereupon a miss upon the former stage could redound to a conceivable advance upon the latter.<sup>37</sup> Or apart from the slight chance of secondary application, might lie the even slighter chance that a market-targeted drug begins to point to purely humanitarian outcomes. In this case, and however slight the chance, the additional and new incentive to follow the research process through to development, because of the additional and new economic reward of the prize, would be of remarkable social value.

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<sup>36</sup> See, e.g., Hollis & Pogge, *supra* note 35, at 17-18 (indicating the general drug type of most appeal for registration within their optional system).

<sup>37</sup> Van Bekkum et al., *supra* note 20, at 2, 6, 14.

Assuming the slight circumstances of this secondary humanitarian drug capture, then such an optional system would provide an undeniable benefit in that mid-stream research that no longer points to an intended insight or development of market reward may nevertheless find a reward in humanitarian donation, at least at the level of recouping costs. The three categories of the optional approach mentioned above effectively extend the scope of unpredictable research to include humanitarian and non-market considerations in a manner that mirrors research transience between intended and realized market drug products. The benefit of this optional approach may be summarized, therefore, as providing the potential that humanitarian drugs are produced and delivered that would not have been otherwise when market focus was the both the instigation and result alone.

#### *D. Basic Research Direction*

Unfortunately, the advantage of the optional approach appears limited to the purely humanitarian category of drug development – or, the third category listed above, which applies to those developments which are exclusively of non-market appeal. The ability to donate the rights of an advance into the public domain, so as to effectively opt-in to a humanitarian category of regulation, may not be a viable economic alternative for those all-important second category goods, which may have distributional appeal upon either a humanitarian or market basis, with AIDS medicines a prominent example.<sup>38</sup> There is a serious uncertainty over whether humanitarian donation would provide an economic gain or preference over market exclusivity. This uncertainty is emblematic of larger difficulties with prize fund distribution, which act within a wider investment uncertainty that would indicate against the reformist potential of such optional approaches. These investment uncertainties serve to undermine the humanitarian direction of research, with the basic question of why pharmaceutical companies and their executives would commit resources to a humanitarian focus or category over that of the market.? The above section indicated that in rare circumstances the humanitarian category and optional prize could see different drugs developed out from market initiatives, but the more fundamental question of research direction remains: why begin on the humanitarian path of research?

Prominent amongst the general difficulties with prize funds are questions of funding and its subsequent distribution.<sup>39</sup> Were prize distribution to be tied securely to a direct correspondence to QALY improvement, this would similarly secure the potential of a drug advance to a predictable reward outcome. On the other hand, this

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<sup>38</sup> See, e.g., Outterson, *supra* note 4, at 163-167.

<sup>39</sup> See, e.g., Hollis & Pogge *supra* note 35, at 18-19; Love & Hubbard, *supra* note 2, at 7.

secure commitment would require a substantial, variable, and unpredictable international state commitment for funding that may make for unpalatable arrangement. Systemic uncertainty would thus fall upon its funders, international governments, who would have to commit to a fluctuating amount of contribution from year-to-year based upon yearly medical advances. This may be supportable morally, but again touches upon difficulties of international political realism and attendant obstacles to change. This pragmatic or political problem may account for why a once-leading advocate for strict one-to-one QALY correspondence, Thomas Pogge, has joined Aidan Hollis in advocating for a fixed fund distribution.<sup>40</sup> This alternative may be both pragmatic and realistic politically, but it does pay the cost of rendering the prize fund rewards as necessarily uncertain.

The potentially fatal uncertainty of the fixed prize fund, by way of research incentive alteration, exists in the lack of foreseeability of how much prize will be available in a given year for a given advance or research donation. Suppose, for instance, that a pharmaceutical company donates an advance in the same year that another company donates a monumental advance, perhaps a large-scale QALY provision by way of a malaria advance, or some other affliction that is widespread but not common amongst individuals in wealthy markets. The company donating the more minor advance faces the prospect that their reward will be given a smaller slice of the reward pie, or none at all, based upon factors that are neither predictable nor within its control.<sup>41</sup> Now it could be argued that annual prize distributions may be limited to a percentage ceiling, whereby no firm may claim above a certain fund percentage,<sup>42</sup> but this only shifts the risks of under reward from the small producer to the large.

The fixed QALY system then provides for a fluctuating means of recovery, dependent upon other unknown contributions during a given year from other competitors, which further exacerbates the uncertainty problems of reward under prize systems. Therefore, added to the risk of unsuccessful research is the further challenge of anticipating how much prize fund will be available and how it will be distributed in a given year. Indeed, some economists have argued that when faced with investment in the face of potential government regulation, that the willingness of firms to invest will be lowest when both the outcome amount of regulation and the trigger amount for

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<sup>40</sup> Pogge had proposed originally a system that would reward QALYs at a fixed rate or dollar per QALY basis, Love & Hubbard *supra* note 2, at 9, but has since joined Aidan Hollis in a project advocating for an optional system that is based upon a fixed fund limit instead. See Hollis & Pogge, *supra* note 35, at 13.

<sup>41</sup> See Hollis & Pogge, *supra* note 35, at 18-20 (observing that a fixed fund amount shifts costs onto the registrants that their advance may be under rewarded.)

<sup>42</sup> *Id.*

application are both uncertain.<sup>43</sup> Here, by analogy, the outcome amount may be defined as the year-to-year fund available, and the trigger amount may be defined as the needed amount of QALYs to be awarded a percentage of the fund in a given year. And these significant uncertainties do not even address the question of how donated advances are to be treated when they are built upon or varied by other producers.<sup>44</sup> Nevertheless, the central problem with this potential optional system is of speculative and fluctuating incentives or the lack thereof; why would a company opt into the more speculative system of divided humanitarian reward when the more established market reward system exists as an alternative?

When confronted with an uncertain slice of prize fund reward, it is difficult to conceive of why, in the case of borderline blended drugs of the second category above, pharmaceutical company management would opt for humanitarian donation classification, for it adds an additional level of uncertainty unto an already uncertain risk and reward project. This should be considered in light of the longstanding and fundamental assumption in the literature of finance and economic theory that firms invest less in conditions of greater than usual uncertainty.<sup>45</sup> If such challenges of risk assessment are persuasive, the danger is that the donation opt in will not occur for either-or drugs at the point of research direction or near full-term development decision-making

### *E. A Third Approach?*

Given the uncertainty of humanitarian reward classification in comparison with marketability on the level of dual application, it remains that the most fundamental question of research direction may be relatively untouched by the optional prize approach. Turning to the initial evaluative stage of research funding, arguably the more significant inquiry into systemic priority shift, it appears, unfortunately, that the optional approach suffers from a lack of radical incentive alteration. The optional approach may be said to fail in providing too little of what the exclusive prize approach provides too much of: namely, altered incentive to consider research and distribution in fundamentally different ways at the intersection of the field's most troubling areas of access and research content.

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<sup>43</sup> Grzegorz Pawlina & Peter M. Kort, *Investment under Uncertainty and Policy Change*, 29 J. ECON. DYNAMICS & CONTROL 1195 (2005).

<sup>44</sup> See, e.g., Hollis & Pogge, *supra* note 35, at 15 (authors claim, that additional drug variations should be rewarded on their incremental health impact improvement).

<sup>45</sup> See, e.g., Michael J. Brennan & Eduardo S. Schwartz, *Evaluating Natural Resource Investments*, 58 J. BUS. 133 (1985); Robert McDonald & Daniel Siegel, *The Value of Waiting to Invest*, 101 Q. J. ECON. 707 (1986); James L. Paddock et al., *Option Valuation of Claims On Real Assets: The Case of Offshore Petroleum Leases*, 103 Q. J. ECON. 479 (1988); Sergei Antoshin, *Investment Under Uncertainty* (Nov. 2006) (unpublished manuscript, available at <http://savickas.net/GWfinance/36/0.0409960570550574.pdf>).

Whereas the exclusive prize approach contemplates a wholesale replacement of market rewards and thereby is susceptible to both political and economic challenges, the optional approach may not do enough to alter pharmaceutical management decision-making as to what types of drugs are attempted. The unfortunate consequence of the optional, opt-in approach, is that the third category of market will remain the most secure.

If at the hypothetical margin of decision-making as to classification—and if the market is the more secure and likely profitable selection—this further compounds the difficulty of humanitarian research funding at the outset, that is, before transience of research may or may not occur. At the initial funding and planning stage, the essential question is of why the humanitarian classification is to be either planned for or opted into if there is a market alternative? The fundamental difficulty with the optional approach is that for the either-or-drug types, there will be a strong tendency for market classification. Potentially, the only drug developments that would be aided by such an optional approach would be those that were initiated with a market target but later failed to continue along the research path as planned. The humanitarian classification could then serve to promote a continuance of research in an otherwise abandoned project, for the humanitarian prize would be a means to recoup the costs of the diverted project. This new incentive for research continuation may provide important drug contributions, but it can hardly be described as a radical system revision. Humanitarian opt in classification would exist primarily as a potential means of otherwise sunk cost salvage, not as significant alteration of research focus or direction.

#### **IV. A Humanitarian & Market Proposal**

If the most radical and ambitious systemic revision would entail the complete replacement of market determinations, and more pragmatic solutions envision a middle position required before radical alteration becomes feasible, then the proposal of this paper is presented as a preferable middle step. The proposal proffered is intended to be relatively modest in scope and is intended to combine valuations based on universal health impact alongside that of market competition. Rather than the opt in approach above, in which alternative systems exist in parallel, the health impact criterion is to serve as an initially limited alternative but attached valuation system, as if a satellite to the market system, which provides rewards that allow for reincorporation of advances. This proposal would thereby have market forces give effect to incorporated standards of humanitarian value and donation.

The benefits of this middle-way proposal are argued to be those of market competition in general, in that competitors in pursuit of their own self-interest will set the value of the incorporated humanitarian drug advance. To combat the tendency of market factors affecting research funding decision-making, the present proposal seeks to define humanitarian aims, at a first stage, upon the recognition of universal impact of a donated advance, and its reward on a windfall-type basis. Rather than the muddled calculations of alternative or parallel system classifications that will likely favour the market classification within systemic options, the idea is to hold out the prospect of undeniable and more certain gains for significant humanitarian advances. By allowing for market competition to define the sought-after incorporation values of humanitarian drug advances, it may be possible that the system serves to both introduce humanitarian valuations into public and policy conceptions and to give a preliminary and working estimate of how humanitarian advances may be given economic value. But before future consequences and beneficial variations are pointed toward, first the proposal should be sketched out.

#### *A. A Tradable Pharmaceutical Patent Proposal*

The initial and primary difference in this proposal lies in the connection between the measure of global health impact, as on a QALY basis for instance, and the reward given for humanitarian advances and significant improvements within such a measure. Unlike the traditional prize fund model which rewards a monetary amount for health impact gains—such as a percentage payment out of a given fund amount for a given year or, in a more straightforward fashion, on a dollar per QALY basis<sup>46</sup>—the present proposal would advocate that a monopoly patent term be awarded on a proportional basis for the level of health impact gain. Where a general prize fund conception would roughly equate a proportional distribution of monetary payment per health impact gain, this proposal would instead reward a patent term of monopoly protection. If, upon a simple hypothetical basis, the health advance donated were to result in one monetary increment of fund reward (which would then be likely a division between allotted monetary increments annually), the present proposal would result in one patent increment. Further, assuming an international standard of twenty year patent monopoly protection, then the awarded increment could be identified with two years of protection, for example.

Apart from a general sense of similar proportional distribution, it remains to operationalize the market utilization of this basic increment identification. Initially, it may appear odd to join the language of patent monopoly

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<sup>46</sup> See *supra* note 40.

protection with that of humanitarian drug donation, but the position is reconciled by the notion of a severable and free-floating patent term. Humanitarian drug donation thus results in a neutral patent term, determined distributively according to health impact, which is not tied to the idea, formula, or compound upon which the donation is made. An advance donated to the public sphere is rewarded with an increment that stands alone as a monopoly protection period that is unconnected to any specific product or advance and is simply a patent protection period free of content.

The market competition component of this proposal emerges in the conception of tradable patent terms. The content-neutral and free-floating patent term would, therefore, become a saleable asset, differentiated from other patents in its tradable nature. Pharmaceutical companies that hold a lucrative patent for an existing marketable drug would no doubt wish to prolong the term of its exclusivity. These companies would be able to do so should they purchase a free-floating humanitarian patent term from another company, or if they themselves had donated a humanitarian advance and acquired a free-floating right which they could transfer in-house between drug designations. The economic efficiency potential of such a proposal would exist in the market competition amongst producers that sets the price for the transferable humanitarian patent term. Unlike traditional prize fund conceptions, this proposal would permit a form of market competition within the parallel quantification of humanitarian advance.

So while humanitarian advances are accorded value initially in a non-market fashion, according to some measure of universal impact such as QALY, instead of having a government supply price determination by way of a political fund, the present proposal involves market competition to arrive at the price of the universal health advance. In place of a government or system administrator pre-outcome assignment of reward, this proposal places the reward in the hands of market competitors. The advantage of this market approach lies not only in the competitive pricing and arguable efficiency gains over a price setting administration, but also in the responsiveness of the system as it may fluctuate over years. Instead of a given prize fund total per year, which is in turn divisible and dependent upon donations within that year, this tradable and transferable approach would both reflect the market and further allow donating firms to sell their patent term as they see fit. This discretionary sale may then be held over from one year to the next, or until a satisfactory price is offered. The humanitarian advance in this regard truly becomes an asset possessed by the donating firm, with all the attendant financial advantages that may hold over a one-time reward entitlement.

*B. Basic Outlines of a Tradable Patent*

The basic premise of the tradable and transferable proposal is that the humanitarian drug donation will result in a patent term that may be utilized in application to a lucrative market drug product. In a simple thumbnail example, this would entail that the developer of a significant humanitarian drug advance, which we will call ABC drug, which alleviates or even eradicates malaria hypothetically, would be able to sell the resulting patent term to the highest bidder. We can further assume that the producer with the most incentive to purchase the prize term would be that which has the most lucrative product period of exclusivity, say for a lifestyle improvement drug XYZ that decreases some real or imagined discomfort. We can take this as the initial and optimal exchange partnership. This would assume that the producer of XYZ had valued the ABC transfer at some amount above what other competitors were willing to pay, but below that of what XYZ is expected to profit annually. The continuing inference would be that the producer of XYZ has bid the highest for the patent transfer due to ABC, meaning that the producer could now extend the patent of XYZ beyond a standard monopoly period of twenty years.

While the payment due to the producer of drug ABC for the continuation of XYZ for a double term of monopoly protection might certainly qualify as a windfall for the humanitarian donation, there are further considerations that militate against a strict one-to-one correspondence between donated drug and extension. That a drug already on the market, and providing substantial returns, should suddenly be doubled in monopoly protection is an imperfect reading of needed, necessary change. Apart from the serious distributional issues facing the users of the market drug, which will be addressed below, there is the disconnection between potential and actual return. For each drug research project there are two fundamental uncertainty issues: of research success in culmination of a marketable product, and of the economic reward available for a product brought to market. The object of this proposal is to allow for humanitarian drug donation recovery at market rates for a pharmaceutical advance only at the peak time of pharmaceutical return.

What this distinction entails is that as the standard monopoly term is not a pure profit recovery period, in that it includes costly and time-consuming certification processes for instance, it would be overly compensatory to grant transferable patent terms as if this significant period of unprofitability did not exist within a monopoly term. As the donating producer will have had to undergo similar certification processes before donation, to grant a twenty year patent period in addition to this process would be inconsistent with general market conditions and research expectations. The most realistic view of tradable patents would then extend upon a notion of profitability *within* a



patent term. A pre-determined maximum of tradable patent term may then identify a realistic approximation of the profitability period that is available for transfer and sale.

This systemic constriction may not only serve the interests of consistency in regard to traded assets, of profitable periods within monopoly terms; it may also relate to the realistic future prospects of purchasing firms. A standard twenty year patent term purchase may be an unrealistic attempt at profit continuance for a monopoly protected cash cow, for that time frame leaves open too much of a possibility that the drug will be surpassed by numerous other health developments. A more measured time extension of five or ten years may then be preferable in regards to both appropriate recovery for the donating firm and the future risk assessment of the patent purchasing firm.

### *C. Terms of Tradability*

Having discussed the need for a post-donation discount of the standard patent term to account for the realities of the profit periods within drug development, it may be useful to account for other factors pointing toward different valuations of donation. For one, it may be a prudent option to establish a baseline of humanitarian qualification, of a minimum entrance of health impact before a producer may gain a transferable and tradable patent term. The above discussion indicates a case for a donation discount, or maximum donation term to be tradable at the profitable apex of market competition, of perhaps .5 or 1 out of a standard term of 2, or of one quarter to one half of the present twenty year term for instance.

More problematic is the issue of a minimum amount of universal health impact satisfaction. It should be noted that having no minimal requirement would make the system more egalitarian at the risk of overwhelming the private market system that is to fund the satellite humanitarian one. On the other hand, while the establishment of a minimal standard of universal health impact may be conducive to the notion of some windfall return to successful producers, it does introduce a further level of uncertainty: Pharmaceutical companies, when confronting the decision of whether to invest or continue to invest in a given humanitarian research project may have to question whether an achieved advance would qualify for reward at all. As a guiding rationale of this project is the alleviation of uncertainty in the pursuit of humanitarian ends, the former option of no minimum requirement for health impact is advocated for here. What may make the entry of all humanitarian donations into a market reward system plausible and workable is a concept of incrementalism. An incremental approach to transferable patent reward not only serves

to account for the lesser end of health impact contributions, it also renders it more flexible in its economic scope of distribution. At the lower end of donation and application, an incremental system may serve to give a 0.05 tradable patent term for a relatively minor global advance. This term would be tradable and available for sale all the same. At the high end of donation and application, in which we may return to the example of the ABC donation, we may assume a 1.0 tradable patent term. Perhaps the minor advance would result in six months of extended patent protection, while that of ABC would be worth the full ten year term possible (or whatever the maximum patent profitability period is identified as).

Yet, an incremental approach not only serves to indicate low end inclusiveness for lesser humanitarian advances, it also indicates an added potential for the sale of transferable rights. The initial and thumbnail introduction of this transferable method dealt with an unrealistic one-to-one sale of total patent term protection. But if the above arguments indicated against a standard patent term reward, an incremental view would look beyond the one-time transaction to recognize the ability of further severability. Just as the transferable patent is severable from its originating humanitarian drug donation, so too should the transferable patent be a divisible product. The ABC example would then result in a ten year protection period, divisible and marketable upon a number of smaller increments. Returning to the perceived uncertainty of an annual prize fund award, the incremental approach would allow humanitarian drug donation producers to sell their transferable term in portions and over time. A potential range of six months to ten years could be distributed and sold amongst pharmaceutical buyers. The advantage of this incremental possibility is that the system is more flexible and open to policy caps upon transfer to anyone one drug, and efficient on a system wide basis should there be small distributions to each of a wide number of companies' best performing drug.

## **V. Systemic Restraints and Limits**

### *A. Patentability and Marketing*

For the above proposal to work most effectively the alternatives of market producers should be as limited as possible in regards to the sustainability of their lucrative patents. This entails that patentability be sufficiently narrow and difficult to achieve. Without a narrow interpretation of patentability there exists the possibility that

pharmaceutical companies may be able to patent a minor variation to their existing drug, a “me too drug,”<sup>47</sup> and begin a marketing campaign to replace the old with the new regardless of health merit. With easy patentability for little real or beneficial chemical variation, the calculations of pharmaceutical companies may simply result in a view of patent extension as a means of marketing sustainability. Considering the increasingly vast sums that may be contributed to a pharmaceutical product campaign, the potential that patent expiration will render this investment a sunk and unrecoverable cost is not insignificant.<sup>48</sup> Yet, an appropriately narrow standard of patentability would mean that pharmaceutical companies must consider sunk marketing costs alongside that of lost monopoly pricing. With appropriate patentability standards, the full costs of past marketing and of lost monopoly pricing would influence a company’s incentive to bid for a humanitarian patent transfer.

### *B. Distributional Policy Considerations*

Traded extensions to monopoly protection terms result undeniably in increased costs for purchasers and users of the marketable drug. Indeed, the very reason that the humanitarian drug transfer is purchased at all, and at the highest rate, is because there is a group of consumers willing, or compelled by health concerns, to pay the high prices of the marketable drug under monopoly patent protection. When the purchased humanitarian patent transfer is applied to the marketable drug, it is these consumers who will ultimately pay the price of the humanitarian advance. Simply, what enables the lucrative purchase price for the humanitarian advance and its tradable patent term increment is that there is a pre-existing set of consumers who render the market drug especially profitable. If the assigned market drug is not purely cosmetic, or if one amongst a number of market drug increment assignments is life-preserving and an essential medicine, then the consumers of this needed market drug are to bear the cost of the systemic drive to humanitarian relief in a manner that is suspect morally.

Arguably with any global redistributive system, which provides a benefit that otherwise would not have been delivered, it remains that someone must bear the cost. While the present proposal points initially to cost-bearing by certain and unfortunate drug users in developed countries, this is taken to be the time of global fund introduction and monetary distribution. Rather than pre-commitments to a set amount of system funds to be

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<sup>47</sup> On ‘me too’ or copycat drugs, *see* references under *supra* note 20.

<sup>48</sup> For instance, some health researchers have estimated that pharmaceutical companies spend as much as twice on marketing as that for research and development. *See*, Gagnon M-A, Lexchin J (2008) The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States, *available at* <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050001>.

distributed, this proposal would allow governments, or an international administration, to buy out the additional personal payments that result from humanitarian patent transfer. Most significantly, the global pre-commitment necessary to initiate a prize can surely be marshaled equally to deliver post-competition relief upon the same grounds. This post-compensation approach also offers the pragmatic benefit of government payments being more flexible, dependent upon economic circumstances and qualified upon the condition payment alleviated.<sup>49</sup>

### *C. Proposal Advantages from a Firm Vantage*

Established within economic literature is the notion that firms invest less in conditions of greater uncertainty.<sup>50</sup> Therefore, systems which limit the conditions of uncertainty may be deemed as more conducive to firm investment. As indicated above, a clear advantage of the tradable market proposal is that it does not introduce a further level of investment uncertainty. The primary investment uncertainty within any system exists in the general requirement of success for the entire drug project, of translating research through certification into a rewarded product. The project uncertainty under the patent market status quo thus ranges from research, through certification, to market reward. Similarly, the uncertainty of the optional parallel approach must proceed through research and certification to health impact reward. A serious and potentially costly risk of failure exists within each of these stages, including: the multi-stages of research conditionality, which for the pharmaceutical industry is held to contain six stages, each of which must be satisfied before the next is undertaken;<sup>51</sup> the multi-stages of health regulation certification; and then the ultimate question of reward receptiveness, of how consumers/patients will respond to the new drug, or how much of a health impact number will be assessed.

If these above and substantial uncertainties may be classified as the general conditions of drug research, the optional approach may be seen to another further level of uncertainty, namely that of prize distribution. For even assuming that a company has been able to move a product through the difficult stages of general project unpredictability, there remains a further uncertainty for distributional questions that is unique to the prize approach. Again, these further uncertainties may be defined in terms of three broad questions that diminish the business appeal

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<sup>49</sup> A further policy clarification on domestic policy within developed countries may be needed. While a pressing modern challenge of developed societies is how to reconcile growing pharmaceutical drug costs, the present proposal will remain relevant so long as patent monopoly terms continue within a system. Therefore, if price caps for particular drugs becomes a more utilized policy tool, this simply alters the world within humanitarian drug donation may operate within.

<sup>50</sup> See sources in *supra* note 45.

<sup>51</sup> Van Bekkum et al., *supra* note 20, at 16.

of the optional approach: first, what is the future amount of government, or supranational, funding available for a given year and how secure is this admittedly political arrangement; second, how the funds, if secure, are to be distributed in a given year—will a company advance be limited by a pre-set ratio of reward; and third, what relationship of reward will be established to differentiate foundational advances from later variations built upon them, and how could this possibly be a predictable amount of return?

While the above three factors of uncertainty point to additional difficulties in general and thereby detract from the appeal of the optional approach, further advantages of risk assessment may be found within a market approach as qualified by the tradable patent proposal. Essentially, the optional approach may add another layer of uncertainty and risk into business calculations which renders additional obstacles and costs for less than radical reform and potential outcomes. The tradable patent proposal, on the other hand, does not introduce a further level of certainty beyond that of research, as the outcomes of humanitarian research are necessarily transferable into the prevailing market valuation system. Moreover, the tradable proposal offers a significant additional advantage in the general firm treatment of business risk, as it opens up a further avenue of risk spreading than would be otherwise available under either an exclusively market or humanitarian system. If the added uncertainty of prize fund distribution may result in an added business detriment of risk, the tradable patent proposal first eliminates this risk and then adds a further business strategy advantage in regards to risk aversion.

Although economic literature indicates that firms invest less during times of uncertainty, moving on from this common sense proposition presents the arguably more important matter of how firms confront the challenge of investment risk. A basic and pervasive notion is that firms, and economic actors in general, will seek to lessen their risk exposure by spreading their investments across a spectrum of uncertainty. Should one investment or project prove to be unsuccessful, the overall consequences to the investor may be mitigated by a wider field of investments, which will stabilize the consequence and ideally compensate to a positive amount. An influential extension of the basic idea of hedging one's bets is found in portfolio theory, which is underlied by a premise of diversification and speaks to spreading risk across a number of options, with the hope of efficiently discounting risk through a basket of investments.<sup>52</sup>

In terms of research and development, the notion of risk avoidance has been articulated as a patent portfolio, whereby pharmaceutical firms try to mitigate the risk of research failure through the multiplication and

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<sup>52</sup> Seminal and originating work in the field of portfolio theory was conducted by the renowned economist Harry Markovitz. See, e.g., H. Markowitz, *Portfolio Selection*, 7 J. FIN. 77 (1952).

diversification of their attempts.<sup>53</sup> Interesting arguments have been made which indicate the riskiness of a research project is not even throughout the stages of approval unique to pharmaceutical drugs, nor to the nature of research in relation to other projects.<sup>54</sup> Simply, it has been argued that higher risk attaches to early stage and fundamentally new research, obviously, and also to research projects which are not aimed at a potential cluster of ailments.<sup>55</sup> When research seeks for a completely new advance, rather than a variation upon existing medicines, the risk is greatest, only to be lessened with each successful stage toward approval and marketability. As to the cluster of aims, it may be that a firm may devise a research project in such a way so that a failure within a specific target goal may nonetheless hit a related and indirect target. One project working toward a heart disease drug of a certain scope may fail and yet yield insight into a lesser, though related, heart drug advance.<sup>56</sup>

Despite the variance of risk within pharmaceutical firm approaches to risk assessment, of varying risk between stages and related projects, it remains that an additional block of research market concern would provide a further means of risk diversification. As humanitarian advances may be transferable directly into market reward, upon an equal or above basis, this entails that the scope of marketable drug advances should also be extended for pharmaceutical firms and their decision-makers. In effect, the market range would be extended as if another new population of wealthy sick had been introduced into the consideration of pharmaceutical executives. The thought may appear crass, of course, but again a fundamental failing of the present system is the lack of recognition of maladies that are life-threatening but not lucrative in potential return. By rendering the previously excluded health conditions with potential economic value, the tradable proposal not only serves to give market weight to humanitarian concern, it also renders this concern a means of research investment diversification. The drug company seeking to diversify its research portfolio may now consider a whole new range of efforts and attempts, all of which may count equally in the end point of marketability and economic return. In effect, the tradable proposal serves to widen the market of contemplated research reward, so as to allow humanitarian gain to act as an important means of risk spreading for rational pharmaceutical company actors.

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<sup>53</sup> See, generally, Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 PENN. ST. L. REV. 1 (2005).

<sup>54</sup> Van Bakkum et al., *supra* note 20, at 16-18.

<sup>55</sup> *Id.* at 18 (noting that the economies of scale, as with marketing, are not present yet in the early stages of development); and 2, 6, 14, (as to the nature of research correlation); and *supra* note 48.

<sup>56</sup> *Id.* at 19 (identifying examples of positive correlated research targeting, as with HIV medicines or between the relation between cardiovascular diseases and lung cancer).

## Conclusion

Under the proposed tradable patent system, investment in humanitarian research may act as further extension of market attempts at reward. New economic value may be given to humanitarian concern, as the humanitarian concern may provide for a new means of risk portfolio diversification. This modest stage of incorporation, of humanitarian concern into market competition, may serve as an intermediary stage of system change, indicating both the potential of health competition and perhaps setting a measure of value for future reform which may be more exclusive and ambitious in nature.

Supposing that a completely alternative system in the future is to be desired, in which health need rather than market value determines research reward, then no doubt some reasonable means of transition may be worthwhile. A transition period is reasonable not merely for the practical considerations of the political and economic embeddedness that will be an obstacle to change, but also for questions of how to operationalize any new system. How exactly will humanitarian advances compare with our past notions of research and how will they fit conceivably in a total system of reward? Such difficult questions may be addressed and anticipated at least in part under a transition system of tradable patent terms. In this manner, the tradable proposal offered above may serve as a pragmatic and humanitarian first step, and also the prefiguration of how to predict and treat differing levels of humanitarian impact.

Now, and finally, this middle point usage of the tradable system is contingent upon the ideal and fair-sounding exclusive approach as actually desirable. But again, it may be morally and economically worthwhile to retain the ability for individuals to pay and reward their desired drug or supplement, even if it be of a purely lifestyle nature. And of greater importance from a social utility standpoint is the possibility that the research funded and directed toward a purely lifestyle outcome may, through the unpredictable intricacies of scientific research, result in a humanitarian advance that would not otherwise have been attempted nor achieved. And so if the ideal of a unitary system is less than ideal, from both a vantage of personal and universal objectives, then the intermediate step of a tradable market proposal becomes something more: a promising solution of improvement for the present alone. This present solution may then be held up as an instance of working toward an incremental ideal of having humanitarian advances carry similar weight as that of the highest marketable drug, and what is more, having those marketable drugs fuel the reward of the humanitarian gain.