THE ENDS OF INTELLECTUAL PROPERTY: HEALTH AS A CASE STUDY

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I
INTRODUCTION

On the tenth anniversary of James Boyle's pathbreaking examination of intellectual property, it is appropriate to reflect upon "big" questions in the field. Such reflection is particularly apposite in my case, as my decision to become an intellectual property scholar was greatly influenced by Boyle's book, *Shamans, Software, and Spleens*.[1] Madhavi Sunder's essay identifies one of these big questions when she suggests that the book may place undue emphasis on wealth maximization as a normative criterion.[2] Whether Sunder's critique is entirely fair is an open question. Indeed, in Boyle's carefully chosen examples of traditional knowledge, increasing overall wealth does not conflict with distributional considerations. If traditional resources held by poor people are taken from them without compensation, they will fail to invest in resource maintenance. In turn, the Western pharmaceutical firms that are dependent on these resources to secure large revenue streams will suffer. In Boyle's discussion of traditional knowledge, as in some real-life cases, equity and efficiency work in harmony.

Of course, equity can be in tension with efficiency. Some commentators have observed, for example, that national or tribal assertions of rights over genetic resources may create anti-commons effects for researchers who need access to materials that come from a variety of different geographical areas. In the domestic context, there is considerable concern that assertions of property rights by patients who are "sources" of genetic material may impede medical research. More generally, Sunder's critique raises an important problem for

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1. JAMES BOYLE, SHAMANS, SOFTWARE & SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY (1996).

2. Madhavi Sunder, *The Invention of Traditional Knowledge*, 70 LAW & CONTEMP. PROBS 95, 119 (Spring 2007).

intellectual property law and perhaps especially for patent law. In contrast with copyright scholarship, which is inflected with concerns about free speech and which therefore routinely takes account of issues other than wealth, patent law scholars have often accepted wealth maximization as the normative criterion by which they evaluate regulatory proposals in their field. Wealth maximization means Kaldor-Hicks efficiency: a proposal is superior to possible alternatives if the winners could in theory compensate the losers. As contrasted with Pareto-superiority, Kaldor-Hicks efficiency is not a normative criterion, at least if by normative one means moral. A regime that is Kaldor-Hicks efficient is merely potentially Pareto-superior. There is no need for the regime actually to be Pareto-superior.[3]

As contrasted with Kaldor-Hicks efficiency or wealth maximization, increasing welfare is a morally compelling criterion. Even if one does not accept welfare as the determinative criterion,[4] it is difficult to quarrel with the proposition that welfare matters. Moreover, a focus on welfare can incorporate the goal of giving greater weight to those with lower welfare levels.[5] Attempts to evaluate intellectual property policy through the lens of welfare are associated, however, with two familiar problems: first, there is the difficulty of identifying tractable metrics for welfare. Although wealth can be measured quite readily, measuring welfare is much more difficult.[6] The second difficulty is institutional: are welfare considerations that diverge from wealth maximization best addressed through regulatory regimes other than intellectual property? This brief commentary addresses these two questions.

II

MEASURING WELFARE

Many philosophers and economists have written eloquently on the subject of welfare. Recapitulating those discussions is unnecessary here. Rather, I will focus on systematic attempts to measure welfare. The World Health Organization "Quality of Life" (WHOQOL) index, which has been developed and tested over thousands of people in different countries and which aims to assess individuals' perception of their life circumstances in the context of their own culture and value systems represents one of the more comprehensive attempts to develop a metric of overall welfare. The WHOQOL index produces

3. Matt Adler and Eric Posner have made this argument, as have other scholars. *See, e.g.*, Matthew D. Adler & Eric A. Posner, *Rethinking Cost-Benefit Analysis*, 109 YALE L.J. 165, 187–94 (1999).

4. Some would have welfare be the sole criterion. *See generally* LOUIS KAPLOW & STEVEN SHAVELL, FAIRNESS VERSUS WELFARE (2002).

5. For example, in making distributional decisions, an analyst might give additional weight to the welfare of poor individuals on the theory that wealth has declining marginal utility. Of course, such weighting presupposes the possibility of interpersonal utility comparisons. But many economists and philosophers accept that possibility.

6. Measuring welfare is a problem even if one accepts the possibility of interpersonal welfare comparisons.

a multi-dimensional profile of scores across six domains (the physical domain, the psychological domain, levels of independence, social relationships, the environment, and the spiritual domain). Such a multi-dimensional profile has the virtue of breadth. Moreover, it does not attempt to make commensurate spheres of welfare that may be incommensurable. Whether it would represent a tractable mechanism for measuring the effect of a given policy intervention is less clear.[7]

As contrasted with the WHOQOL index, an index of welfare used by many public health and safety economists, the quality-adjusted life year (QALY), has been shown to be quite tractable. In the United States, presidential administrations dating back to Ronald Reagan have required cost-benefit analysis of major rulemaking.[8] In the context of public health and safety regulations, this has included the possibility of analysis based on QALYs.[9] Additionally, many countries, including Britain, Canada, and Australia, currently use QALY-based systems for determining which technologies should be covered under their national health-care systems.[10] Under a QALY-based approach (also known as cost-effectiveness analysis), an intervention is evaluated according to the additional life-years it yields, as adjusted by the quality of those life-years. Quality of life, in turn, is measured on a scale of zero to one (zero being death and one being perfect health) using survey instruments that focus on trade-offs between different health states. One standard instrument is the time trade-off: if the average person in perfect health reported that she would consider a lifespan that was twenty percent shorter than a full life span to be equivalent to a full life span in a given (suboptimal) health state X, then that state X would be rated at 0.8 on the zero to one scale. Moreover, a medical intervention that took a person with disease X and returned her to full health for the remaining twenty years of her life would confer a welfare benefit of four QALYs (0.2 times twenty).[11]

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7. *See* Matthew D. Adler, *QALYs and Policy Evaluation: A New Perspective*, 6 YALE J. HEALTH POL'Y L. & ETHICS 1, 50–52 (2006) (discussing difficulties with attempting to implement WHOQOL on a policy level).

8. *See, e.g.*, Robert W. Hahn & Cass R. Sunstein, *A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis*, 150 U. PA. L. REV. 1489, 1489 (2002) ("For over twenty years, the executive branch of the federal government has required regulatory agencies to assess the costs and benefits of regulation, and to attempt to ensure that the benefits outweigh, or justify, the costs.").

9. Indeed, the D.C. Circuit's opinion in *American Trucking Ass'ns, Inc. v. EPA*, 175 F.3d 1027, 1039–40 (D.C. 1999), *rev'd in part*, 531 U.S. 457 (2001), indicated that the EPA might be able to cure constitutional problems relating to non-delegation by using a QALY-based approach.

10. *See, e.g.*, Steven D. Pearson & Michael D. Rawlins, *Quality, Innovation, and Value for Money: NICE and the British National Health Service*, 294 JAMA 2618 (2005); David A. Henry, Suzanne R. Hill & Anthony Harris, *Drug Prices and Value for Money: The Australian Pharmaceutical Benefits Scheme*, 294 JAMA 2630 (2005).

11. Needless to say, this example is quite stylized. A valuable recent book on QALYs is PETER J. NEUMANN, USING COST-EFFECTIVENESS ANALYSIS TO IMPROVE HEALTH CARE: OPPORTUNITIES AND BARRIERS (2005). Other standard accounts of cost-effectiveness analysis include MICHAEL F. DRUMMOND ET AL., METHODS FOR THE ECONOMIC EVALUATIONS OF HEALTH CARE

The QALY-based approach has limitations. A voluminous literature documents controversies over implementation details—for example, it is not clear that respondents in perfect health are the appropriate population to survey in determining the quality-of-life figure that should be attached to a particular suboptimal health state.[12] Additionally, QALYs obviously focus only on physical and psychological health. They do not take into account various other conditions—social, environmental, spiritual—that may have an equal or greater impact on welfare. Nonetheless, in evaluating policy, including intellectual property policy, for those areas in which the primary impact is likely to be on health, they represent a reasonably tractable and transparent mechanism that can correct for various cognitive biases.[13] Thus, many Western countries use a QALY-based approach to coverage of medical interventions. For example, the British National Health Service does not generally cover interventions that cost more than $50,000 per QALY gained.[14]

Of course, the use of QALY-based analysis by payors is an indirect mechanism for channeling biomedical innovation in a direction that maximizes QALYs. Indeed, a payor-based approach does not involve intellectual property policy *per se* at all. Rather, it relies upon standards adopted by demand-side institutions. A more intellectual-property-based approach to maximizing QALYs might involve a patent prize system that calibrated rewards based on the number of QALYs produced by the technology.[15] After the prize had been given, the technology in question could be made available at marginal cost. This biomedical-innovation regulatory puzzle thus presents the question of whether insurance or intellectual property is the appropriate institution for promoting welfare and reducing deadweight loss. More generally, intellectual property policy analysts who aim to increase welfare must consider what institution is best suited for the task.

III

CHOOSING INSTITUTIONS

As a theoretical matter, the difference between a universal health-insurance scheme that relies on QALY-based purchasing and QALY-based prizes is not

PROGRAMMES (1987); M.R. Gold et al., *Cost-Effectiveness in Health and Medicine*, 276 JAMA 1253 (1996).

12. Some have argued that the relevant survey population should be those who are living in the particular suboptimal health state. These individuals often have higher valuations of their health state than those who have not experienced it. Other implementation questions include whether health benefits should be discounted and whether individual tradeoffs between quality and quantity of life are sufficiently diverse that it is inappropriate to average them.

13. *See* Arti K. Rai, *Pharmacogenetic Interventions, Orphan Groups, and Distributive Justice*, 19 SOC. PHIL. & POL'Y 246, 256–57 (making this point).

14. PEARSON & RAWLINS, *supra* note 10, at 2619.

15. Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation* (Jan. 17, 2005), *available at* http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf.

large.[16] Even the political economy of these proposals may not differ significantly, at least in industrialized countries where the primary purchaser of health-related technology is the government. In both cases, government officials will presumably be subject to significant lobbying by industry groups. Moreover, in both cases, government officials should bear primary responsibility for generating, or otherwise securing, the public good of unbiased cost-effectiveness data upon which to base their decisions.

In the United States, by contrast, the institutional calculus is somewhat different. Most obviously, unlike programs in other countries, U.S. health-insurance programs—whether private or public—have generally not used cost-per-QALY analysis.[17] Thus, at least until recently, insurance-induced moral hazard (the tendency of insured individuals to consume more health care than they would if they were paying full cost) has combined with the quasi-monopoly power allowed by patents to produce significant growth in biopharmaceutical expenditures and insurance premiums. This is true even in cases in which the biopharmaceutical technology in question has a small marginal health benefit relative to its marginal cost.[18] Meanwhile, the deadweight loss of monopoly persists for the significant percentage of Americans who are priced out of insurance.[19] Moreover, although there is some evidence that certain private-sector plans may be moving towards *sub rosa* reliance on cost-effectiveness criteria, such *sub rosa* adoption based on data of uncertain provenance is hardly equivalent to a rational system.

Many scholars, myself included, have proposed replacing the dysfunctional U.S. system with universal, voucher-based access to plans that compete based on cost-effectiveness criteria. This mixture of regulation and markets would avoid political economy-related concerns that might be raised by a more centralized system of health-care purchase while simultaneously promoting health-related welfare goals. But given the uncertain prospects for a rational system on the demand side—the struggle for universal coverage based on cost-effectiveness criteria has been waged and lost many times in U.S history—an institutional option worth considering may be experimentation on the intellectual property side. In other words, the possibility of experimentation

16. In both cases, decisionmakers have to evaluate, for example, whether the first drug in a class that achieves an appropriate QALY gain should be the one that is covered or rewarded, even in cases in which a later drug may be marginally better.

17. *See, e.g.*, Peter Neumann, *Why Don't Americans Use Cost-Effectiveness Analysis*?, 10 AM. J. MANAGED CARE 308 (2004).

18. By insulating consumers from cost at the point of purchase, insurance reduces the deadweight loss associated with monopoly pricing. *See* Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals*, 2001 U. ILL. L. REV. 173, 201 (2001). However, unless insurance companies rely on some mechanism of cost-effectiveness analysis in making coverage decisions, the advantage of deadweight-loss reduction is accompanied by the disadvantage that pharmaceutical firms can make large sums of money on interventions that produce relatively low marginal social-welfare benefit. *Id.* at 206 (discussing examples).

19. There is also considerable evidence that the prices paid by insurance plans are lower than prices paid by uninsured individuals.

with prizes calibrated according to number of QALYs achieved deserves serious attention.

A QALY-based prize proposal has considerable promise in the international arena as well. Many commentators have argued that there is a 10/90 gap in worldwide R&D expenditures—only ten percent of global R&D is addressed to ninety percent of the world's disease burden. Although this particular figure has been the subject of some controversy, there can be little doubt that a patent-based system can allocate significant resources only towards those diseases that have some market. By itself, a patent regime will not produce sufficient research on neglected diseases such as tuberculosis, let alone "very neglected diseases" such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis).[20] In addition to reward approaches based on QALY benefits, advanced purchase commitments for vaccines of specified efficacy[21] and "open source" approaches[22] may also have promise.

Finally, it bears emphasis that these health-related proposals do not need to engage the important debate over whether welfare concerns that diverge from efficiency goals are best addressed through broad-based tax and transfer systems or through more focused regulatory measures.[23] This is because a prize based on QALYs would presumably be paid out of general revenue, rather than through some narrowly focused levy. But intellectual property scholars confronting tensions between welfare and efficiency in other areas will surely have to engage this debate.[24]

IV

CONCLUSION

A welfare-based approach to intellectual property has promise, at least in areas in which analysts have devised tractable metrics for welfare. To be sure, such an approach will not cover all the goals that intellectual property scholars should address. But it does represent a concrete mechanism for incorporating within intellectual property analysis the broader social policy goals suggested by Boyle's book.

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20. The terms "neglected" and "very neglected" diseases are taken from the Report of the Commission on Macroeconomics and Health. *See* COMMISSION ON MACROECONOMICS AND HEALTH, MACROECONOMICS & HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT 78 (2001), *available at* http://www.cid.harvard.edu/cidcmh/CMHReport.pdf.

21. Ernst Berndt et al., *Advanced Purchase Commitments for a Malaria Vaccine: Estimating Costs and Effectiveness* (Working Paper, 2005), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=696741.

22. Stephen Maurer et al., *Finding Cures for Tropical Diseases: Is Open Source An Answer?*, 1 PLOS MEDICINE 180 (Dec. 2004).

23. *Compare* Louis Kaplow & Steven Shavell, *Why the Legal System is Less Efficient Than the Income Tax in Redistributing Income*, 23 J. LEGAL STUD. 677 (1994) *with* Chris Sanchirico, *Deconstructing the New Efficiency Rationale*, 86 CORNELL L. REV. 1003 (2001).

24. For some discussion of this question, see Arti K. Rai, Leveraging Innovation for Welfare: Do's and Don'ts (May 15, 2007) (unpublished manuscript, on file with author).