Brook K. Baker response to questions from the UN Secretary-General's High-Level Panel Access to Medicines (London)

1. How does your proposal on creating a compulsory licensing facility compare with prior proposals to reestablish inventor's and creator's rights as liability rights instead of property rights?

Answer: Professor Jerome Reichman and others have argued that intellectual "property" rules should be modified into intellectual "liability" rules. These scholars believe that the costs of property-based exclusive rights are too high: they can interfere with the process of incremental innovation and scientific exploration, with transfer of technology to developing countries, and with affordable access to knowledge goods including global public goods like medicines. In a property-based regime, efforts to bargain for access rights remain in the near exclusive control of the rightholder and might be unavailing, whereas in a compensatory or liability regime the right to use will be routine and the liability-based right holder will either be compensated through enforcement of reimbursement rights or will be brought more reliably to the bargaining table to voluntarily license rights of use and sale.

To a significant extent, the proposed mandatory or presumptive CL proposal would result in a liability-based system. In fact, in some of the literature, compulsory licenses are described as prototypical liability-based mechanisms. Transforming the existing IPR regime into a total liability scheme might well require reform to TRIPS and to other regional and national IP regimes, because such regimes at present require exclusive rights, with some exceptions and limitations including CLs. More particularly, CLs under Article 31 of the TRIPS Agreement must ordinarily be granted on a case-by-case basis, rather than automatically, so approaching mandatory or automatic compulsory licensing might be considered by some to violate TRIPS and other IP systems. Nonetheless, we could get much closer to a liability scheme and perhaps not pass into TRIPS incompatibility with a presumptive CL regime on medical products.

2. How does your proposal on creating a compulsory licensing facility compare with the license of right regime used in Canada pre-NAFTA and pre-TRIPS?

Answer: As Dr. Hamied reported during the question and answer period, Canada issued hundreds of compulsory licenses on medicines in the pre-NAFTA and pre-TRIPS era. Canada had a system whereby licenses were automatically available on pharmaceutical products. Under this regime, Canada typically issued licenses to more than one licensee and allowed production for export as well as for domestic use to allow competitors to achieve efficient economies of scale and thus lower prices. *See*, J. H. Reichman with C. Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA*, UNCTAD/ICTSD Project on IPRs and Sustainable Development (2003). NAFTA and the TRIPS Agreement attempted to dismantle license of rights systems like Canada's both by requiring that compulsory licenses be

predominantly for domestic use and by requiring individualized assessments and other procedural safeguards.

In substance, my answer to this question is quite similar to the liability-rule answer above. In essence, my proposal recommends a return to the equivalent of a license-of-right system. Every patent regime can allow for voluntary licenses-of-rights (notation by the patentee that it will allow others to use the patent upon set conditions), but few appear to do so, despite the TRIPS-compliance of such a system. However, a voluntary license-of-right system would be inadequate for patentees who are unwilling to license use. Accordingly, I propose a return to a mandatory or license-of-right system while acknowledging that such a system might well face a TRIPS challenge. On the other hand, a presumptive license system for medical products could well be considered TRIPS compliant.

3. How would shareholders react to a compulsory licensing facility on medical products?

Answer: This question was asked by Andrew Witty, the CEO of GlaxoSmithKline. I think it is practically a rule of nature that shareholders would like their corporation to have monopoly rights if possible – in fact the more monopoly rights the better. After all, monopoly rights allow the rightholder to exclude competition and charge supra-competitive prices, especially for products with few equivalents and in high demand, like life-saving medicines. The implication of the question is that shareholders won't invest where monopolies are not available. However, individual and institutional investors invest in many businesses that are not monopoly based. Moreover, when one looks at the current economic dynamics in major transnational pharmaceutical companies, they rarely raise money from new investors – in fact, according to some, they now have an overabundance of retained earnings that are being used to buy back shares, not induce new investors. There is also growing evidence that shareholders are motivated by factors other than earnings alone, hence the social responsibility movement among shareholder groups.

That said, the question before the HLP is the proper remuneration of medical product inventors, not ensuring windfall profits to pharmaceutical companies and their shareholders. Inventors must be properly supported and rewarded, as must the organizations that help to facilitate their endeavors, but a properly structured reward system (economic and reputational) does not have to rely on intellectual property rights. Dozens of submissions before the HLP outline some of these alternative R&D systems.

This response may be posted on the HLP website.