

PHARMACEUTICAL INDUSTRY, PATENTING, HUMAN RIGHTS AND ACCESS TO TREATMENT IN DEVELOPING COUNTRIES: ANOTHER LOOK AT COMMERCIALIZATION OF BIO-MEDICAL RESEARCH

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[T]he commercial exploitation of knowledge must not be valued more than human life.
(*The Brazilian Delegation to the Doha Ministerial Conference*)¹

Introduction

Huge financial requirements for research necessitated the intervention and participation of corporate bodies, capable of shouldering the financial burdens, in the field of bio-medical research. However, unlike the charitable researchers of old, the new crop of researchers and their corporate financial backers want to profit from their efforts through the marketing of the products or processes derived from the research. One of the means of effectively achieving this is to obtain patents over such products or processes.

A patent vests in the patentee, in respect of products, the right to exclude any other person from making, importing or selling the products, or stocking the products for the purpose of sale or use. In the case of a process, a patent confers on the patentee the right to exclude all others from applying the process or doing, in respect of a product obtained directly from the process, any of the acts previously stated relating to products.² Generally, a patent subsists for a period of twenty years.³

Put simply, patent confers the patent holder with monopoly over marketing and other rights pertaining to the invention on which patent is granted.⁴ The goal of patenting is to encourage technological innovation.⁵ Essentially, the right is granted to the inventor in exchange for putting in his time, money and labour to invent the product, and then making it available to the public.

To safeguard the interest of patent holders across international frontiers, the World Trade Organisation (WTO) prepared the Agreement on Trade Aspects of Intellectual Property (hereafter TRIPS Agreement).⁶ This treaty, essentially, mandates state parties to protect and enforce patent granted in one country in other member countries.⁷

One consequence of the interaction of commerce and scientific research is the high cost of medical products. Another consequence has been the introduction of unwholesome practices, propelled by the drive for financial gains, into the realm of scientific research.

¹ C.M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (Geneva: World Health Organization, 2002), 11.

² See generally, s.6 Patents and Designs Act Cap. 344 Laws of the Federation of Nigeria 1990.

³ *Ibid*, s. 7.

⁴ B. William-Jones 'History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing' *Health Law Journal* vol. 10, 2002, 123

⁵ G. Radick, "Discovering and Patenting Human Genes" in A. Bainham, S. Dasclater & M. Ricahrds (eds), *Body Love and Laws*, Oxford: Hart Publishing, 2002, 64.

⁶ http://www.wto.org/english/tratop_e/trips_e/t_agmO_e.htm accessed on 25/04/2005.

⁷ *Ibid*. art. 1 together with arts. 27-34 generally

Through catalyzing prohibitive cost of some essential drugs, the commercialization of research affects access to health care, especially in the poor developing countries. Moreover, with access to health being a fundamental right under human rights law, commercialization has impact on human rights.

This paper discusses the commercialization of research from the human rights perspective. We start by discussing the entry of commerce into the field of scientific research. With reference to the development of gene therapy and anti-retroviral (ARV) drugs for human-immunodeficiency virus (HIV) treatment, we will analyze the human rights issues connected with commercialization of research. Related to this, I will examine the conflicting interests of investors on one hand and persons who need to have unhindered access to drugs to maintain their health.

Commercialization of Research

Originally, scientific research was regarded as a humanitarian or charitable calling. Researchers readily made their findings available to all. Money was not the primary drive for scientists and they were not interested in the privatization or commercialization of research findings. Prior to 1980, the scientific community “often frowned upon privatization of research findings as heresy.”⁸

Traditionally, governments and academic institutions have been funding scientific research. However, increasing cost of developing new drugs and the reduction of available funds for research necessitate the sourcing of funds from other avenues.⁹ This led to the intervention of corporate bodies in the funding of research.

Industry funding has been important for advances in medical research. It improves clinical practice and facilitates development in disease prevention and treatment.¹⁰ To stimulate and encourage further injection of industry funds into medical research and drug development, there must be means of ensuring that the pharmaceutical companies have profitable returns on their huge investments. The means designed to achieve this is the granting of patent.

The American Bayh-Dole Act¹¹ is regarded as the precursor of the wave of patenting or commercialization of the products of scientific research. The Act permitted and encouraged American institutions and individual researchers to obtain private privately owned patents over new products they developed, notwithstanding that the research leading to the product was undertaken with public funds.¹² The goal of the Act was to stimulate the development and commercialization of technology by providing researchers and institutions ‘with incentives to focus their research on marketable products.’¹³ Other countries have since followed the American example in commercializing research.¹⁴

To ensure that a patent granted in one country is protected and enforceable internationally, the TRIPS Agreement was entered into. TRIPS Agreement imposes mutual duty on World Trade Organization (WTO) member nations to protect patents.¹⁵ In that light, member nations shall not take measures that would infringe on the patent right

⁸ See T Lemmens, “Leopards in the Temple: Restoring Scientific Integrity to the Commercialized Research Scene,” (2004) *Journal of Law, Medicine and Ethics*, 644.

⁹ See T Bodenheimer, “Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry,” vol 342 (no 20) *Health Policy Report*, 1539.

¹⁰ *Ibid* at 1539 and 1543.

¹¹ Act of Dec. 12, 1980, Pub. L No. 96-517, section 6(a), Stat. 3015, 3019-28 (1980) (codified as amended at 35 U.S.C. Sections 200-212 (2993) (hereafter the Act).

¹² T Lemmens, *supra* note 8 at 643-644; M. Angell, “Is Academic Medicine for Sale?” *NEJM* vol. 342 no. 20 (May 18, 2000) obtained online <http://lawschool.westlaw.com/files> (accessed on 4/23/2005) p. 2 of 5.

¹³ T Lemmens *ibid.* at 644.

¹⁴ *Ibid.*

¹⁵ See notes 2 and 3 above

conferred on a person or institution in another country. Furthermore, a patent holder is entitled to institute legal action in any country where its right is threatened or infringed.

The formidable combination of monopoly power, financial muscle and the drive for profit introduces the strategies and intrigues of the business world into the domain of medical research. With eyes focused principally on profit, the companies use their financial and monopoly powers to protect their commercial interests.¹⁶

To ensure maximum profits, pharmaceutical companies adopt various means. These include selective publication of favourable studies, suppression of unfavorable evidence, facts and data, ghost writing and “fear-mongering” calculated to propel consumers to buy their products.¹⁷ Furthermore, with medical scientists joining or enticed into the “gold rush”, the interests of research subjects may become secondary, and “potential risks ... perceived more lightly.”¹⁸

Generally, the commercialization of medical research engenders myriad social and ethical consequences in the realm of science. Through commercialization, science seemingly caught a whiff of money and the dizzying effect is creating ripples in the household of scientific research.

Commercialization, given muscle by patent regime and TRIPS Agreement, has, seemingly, transformed research “into a highly lucrative, competitive market environment [which the] regulatory regimes aimed at protecting research subjects and the public have not been significantly adapted to.”¹⁹ As Trudo Lemmens notes,

[n]ot unlike the leopards in Kafka’s parable, the pharmaceutical industry has become a fundamental part of the ceremony of science. But while Kafka’s leopards are unaware of their role in the ceremony, industry has deliberately taken control...Industry can no longer be removed from the temple of which it has become a constitutive part. New rules will not evict them, but may still prevent them from interfering where it matters most...While the leopards will still roam around in some parts of the temple, they should no longer be allowed to dominate our most important rituals.²⁰

While, based on the above statement, the principal concern of Lemmens appears to be the desecration of the hallowed chambers of scientific research, the impact on human rights and public health is equally of great concern. Among others, due to high prices of drugs occasioned by commercialization and patenting,²¹ poor nations find it difficult to obtain drugs relevant for health care needs of their citizens.

Commercialization, Patenting and Access to Therapeutic Products

“The patent system is designed to enable patent holders to set prices higher than those that would be obtained in the competitive market.”²² The foregoing situation is the natural fallout of the monopoly enjoyed by a patent holder over a product. With respect to drugs for some particular diseases not having any alternative, the door is open for the patent holder to set its limit.

¹⁶ See generally B. Williams-Jones *supra* note 4, especially at 123-124.

¹⁷ See generally, Marcia Angell, “Is Academic Medicine for Sale?” *NEJM* vol. 342 no. 20 (May 18, 2000) as obtained from <http://lawschool.westlaw.com/files> (accessed on 4/23/2005) page 2 of 5; David Healy and Dinah Cattell, “Interface between Authorship, Industry and Science in the Domain of Therapeutics,” (2003) 183 *British Journal of Psychiatry*, 22-27.

¹⁸ T Lemmens *supra* note 8, 644 and 645

¹⁹ *Ibid* at 652

²⁰ *Ibid* at 654

²¹ See C.M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, Geneva: World Health Organization, 2002, 5

²² *Ibid*.

Apart from setting the prices at which he sells its products, the patent holder has the discretion on the quantity it releases into the market. To take advantage of principle of demand and supply, the patent holder may withhold supply from the market, thus creating artificial scarcity that further increase the price.²³ The effect of patenting on prices of products has attracted concern in different quarters. For example, members of the WTO have stated,

We recognize that intellectual property protection is important for the development of new medicines. *We also recognize the concerns about its effects on prices.*²⁴

To enhance its hold on the control of the price and supply of drugs, a patent holder can prevent other manufacturers from duplicating its products or interfering with his right in any other way. The Myriad Genetics case illustrates the extent of powers which patenting confers on the pharmaceutical industry.²⁵

In the United States, Myriad Genetics Inc., was granted a patent over “the first genes (BRCA 1 and BRCA 2) to be associated with susceptibility for hereditary breast and ovarian cancer.”²⁶ With the patent and by means of litigation or threat, notwithstanding the importance of cancer testing and research for women globally, the company barred competitors from making use of the products without its approval. The patent, backed by TRIPS, enabled Myriad Genetics to, literally, hold the whole world to ransom in respect of genetic testing for cancer and cancer research generally.²⁷

In view of the obstacle that it constituted to free flow of cancer genetic testing, the Myriad patents encountered resistance in some developed countries.²⁸ The underlying disaffection with the Myriad patents by the antagonists was that they escalated cost of the medical procedure, thus making it unaffordable to public health systems.²⁹ As a result the high cost, many women could not get access to the facility. If cancer genetic testing were unaffordable to the public health systems of developed nations, it would not be difficult to imagine the situation of poor third world nations.

Reflecting on the Myriad Genetics case, Williams-Jones states:

The Myriad patent is a forerunner or test case for a host of other gene and biological patents, and has implications for national and international patent law. If the BRCA patents stand, hundreds of other gene patents are likely to follow exacerbating the current rush to patent genes...Unrestrained DNA patenting could lead to a situation where all genes are patented and new research becomes prohibitively expensive...Unrestrained gene patenting would also have a significant impact on the provision of genetic services through the public health care system, *potentially making genetic tests and therapeutics unaffordable, and thereby raising serious issues of justice in access to medical services.*³⁰

As in Gene Therapy so also in HIV Treatment

True, genetic cancer testing may seem to be a luxury, alien to persons to in developing countries because of the level of development. That does not mean that such therapy is not important to them as health need, if available and affordable.

²³ See *Ibid* at p.3

²⁴ *Doha Declarations on TRIPS Agreement and Public Health*, paragraph 3 World Trade Organization Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, WT/MIN(01)/DEC/W/2 14 November 2001 (hereinafter the Doha Declaration) (emphasis added)

²⁵ My analysis of the matter is substantially based on the paper of B. Williams-Jones *supra* note 4

²⁶ *Ibid.* at 127

²⁷ *Ibid.* at 144

²⁸ *Ibid* at 138-144

²⁹ See *ibid.* at 139

³⁰ *Ibid* at 144 (emphasis added).

That being the case, the impact of commercialization of research equally manifests in the prohibitive cost of ARV drugs used in treatment of HIV. It is common knowledge that HIV/AIDS has reached pandemic level in developing countries, particularly sub-Saharan Africa.³¹

Due to the high cost of the treatment, many HIV sufferers in the poor countries lack access to ARV, because their countries' public health-care systems cannot afford the drugs, and the infected persons are equally too poor to afford them on their own.³² While appreciating that irresponsiveness and neglect by governments in some of these countries equally contribute to inaccessibility of essential drugs, it is important to note that the use of patent rights and the TRIPS Agreement to maximize profits also prominently feature.³³

Largely, the battle strategy of the corporate bodies in obstructing access to ARV is to invoke their patent rights, with backup from their governments invoking the TRIPS Agreement. The following two examples illustrate the scenario.

When Brazil wanted to procure ARV at prices lower than the prices charged by patent owners, in the course of its government-supported campaign against AIDS, United States of America filed a complaint of violating TRIPS Agreement against Brazil.³⁴

Similarly the United States confronted South Africa over its promulgation of the Medicines and Related Substances Control Amendment Act.³⁵ Reacting to the legislation, the United States promulgated a counter enactment³⁶ which provides, among others:

None of the funds appropriated under this heading may be available for assistance to the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997.

Furthermore, the Government of the United States in concert with several pharmaceutical companies challenged the South African legislation in court³⁷ on the ground that it was unlawful under both TRIPS and the South African Constitution's protection of property.³⁸

It is crucial to note that at the time the United States and the pharmaceutical companies were combating South Africa over its efforts to obtain ARV at reduced prices, the country had, and still has the largest number of people infected with HIV/AIDS in the world.³⁹

Manifestly, in view of the hardship confronting developing countries over access to essential drugs, particularly ARV to treat HIV, there have been "growing concerns

³¹ L Forman, "The Role of International Human Rights Law in Increasing Access to AIDS in Developing Countries," *Health Law and Policy Seminar Series*, Faculty of Law, University of Toronto, 2005,1-3.

³² *Ibid* at 3: "Drug access is in large part a question of poverty- of the individuals who lack the resources to purchase the drugs and the nations who lack the resources to fund them."

³³ *Ibid* at 3: "...as the events of the past five years reveal, this inaccessibility is as much due to the malignant neglect of African and wealthy governments and the active opposition of powerful vested corporate and national interests to price reductions. Where people's rights to access essential AIDS medicine have not been fulfilled, it is not simply due to inability but also active obstruction..." (emphasis added).

³⁴ C M Correa *supra* note 21 at 2 (note 6).

³⁵ No. 90 of 1997. *Inter alia*, section 15 (c) of that Act, was to facilitate procurement of ARV at reduced prices.

³⁶ US Public Law 105-277 (105th Congress, 1999)

³⁷ *The Pharmaceutical Manufacturers' Association and Others v The President of the Republic of South Africa* case no. 4183/98, Trans. Prov. Div.

³⁸ See L. Forman *supra* note 31, at 5; see also, C.M. Correa *supra* note 19, at 1

³⁹ L Forman *ibid*.

about the implications of the TRIPS Agreement (particularly the Agreement's provisions on patents) with regard to access to drugs."⁴⁰

Human Rights Perspective

Right to Health

The patenting of products of biomedical research, and by same token, the commercialization of research raises some human rights issues. Primarily, the issues of the Myriad cancer genetic testing and access to ARV drugs touch upon the right of citizens to health under international human rights law. Provisions guaranteeing right to health are contained in various international treaties.

Arguably, the epicenter of the right to health in international human rights law is article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).⁴¹ The article provides:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for...
 - (c) the prevention, treatment and control of epidemic, and endemic, occupational and other diseases;
 - (d) the creation of conditions which would assure to all medical service and medical attention in the event of sickness

In analyzing the right to health, the United Nations Commission on Human Rights had identified access to medication in the context of pandemics such as HIV/AIDS as a fundamental component in attaining "the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."⁴²

Similarly, the United Nations Committee on Economic, Social and Cultural Rights' General Comment 14 on the Right to Health analyzes right to health to include the treatment of prevalent diseases and the provision of essential drugs.⁴³ Furthermore, the Committee indicates that detrimental practices by pharmaceutical companies constitute an infringement on the right to health and that states have a duty to protect consumers from such practices. At the international level, the Committee maintains that states have obligations to ensure access to essential health facilities and that other international agreements do not adversely affect the right to health.⁴⁴

Health is the state of complete mental and physical well being and not merely the absence of disease or infirmity.⁴⁵ Medical test and assessment to know the health condition of a person, and to take appropriate action to correct any defect, logically constitutes part of the person's 'complete physical and mental well being'. In that light,

⁴⁰ C M Correa *supra* note , 21. "The HIV crisis in sub-Saharan African countries, the attempts by the pharmaceutical industry, backed by some governments, to block the implementation of TRIP-compatible measures by the South African Government, and the complaint brought by the USA against Brazil in relation to compulsory licences, were perceived as manifestations of conflict between intellectual property rights and essential public health objectives" at p. 3.

⁴¹ 26 December 1966, 993 UNTS 3, 6, ILM 360 (1967) (entered into force 3 January 1976) (hereinafter Economic Covenant).

⁴² Commission on Human Rights, "Access to Medication in the Context of Pandemics such as HIV/AIDS", U.N.Doc. E/CN.4/RES/2001/33, 20 April 2001, para. 1.

⁴³ United Nations Committee on Economic, Social and Cultural Rights (CESCR) General Comment 14, para. 6.

⁴⁴ See generally *ibid*, paras 6 and 39.

⁴⁵ See U.N., *Population and Development, Programme of Action at the International Conference on Population and Development, Cairo, 5-13 September 1994*, New York: United Nations, Department for Economic and Social Information and Policy Analysis, ST/ESA/SER.A/149.

genetic testing or other products of biomedical research constitute part of health care. Therefore, restricting access to such facility due to high cost occasioned by patenting, amount to violation of the right to health. The same argument applies to denial of access to ARV drugs for HIV treatment.

Inevitably, at certain points, states would experience conflict of interests as to which would prevail between their obligations under the TRIPS Agreement and obligations to ensure unhindered access to health under other relevant international treaties. The need to address this conflict motivated the Doha WTO Ministerial Conference in 2001, which gave birth to the Doha Declaration.⁴⁶ The restrictive impact of patents on access to medicine was a major item on the agenda at the conference.⁴⁷

Conflicting Rights of Patent Owners and Consumers

Apart from right to health discussed above, patenting also touches on some other rights. The invocation of the other rights at some points creates conflict between the interests of the pharmaceutical companies and persons who need to have access to pharmaceutical products. Article 15 of the Economic Covenant, among others, provides for the right of everyone “to enjoy the benefits of scientific progress and its applications”⁴⁸ and “the freedom indispensable for scientific research and creative activity.”⁴⁹

As illustrated by the Myriad case and accessibility to ARV drugs, patenting has the effect of restricting access of many persons to the pharmaceutical and diagnostic products as “benefits of scientific progress and its application”. On another note, the Myriad case illustrates a situation where patent has the effect of hindering the freedom of other scientists to undertake research in the area of cancer genetic testing.⁵⁰

Running parallel to the right to health is the economic right of entrepreneurs to hold and enjoy the proceeds of their intellectual properties, among others. Article 15 (1) (c) of the Economic Covenant recognizes the right of everyone “to benefit from the protection of the moral and material interests resulting from any scientific...production of which he is the author.”

In similar vein, Article 1 of the same covenant provides that “[a]ll peoples have the right of self-determination. By virtue of that right they freely determine their political status and *freely pursue their economic,*⁵¹ social and cultural development.” Article 3 also provides for “the equal right of men and women to the enjoyment of all *economic,* social and cultural rights set forth in the present Covenant.”⁵²

Looking at these provisions guaranteeing economic rights and intellectual property rights, one can safely argue that pharmaceutical companies or medical researchers using patent rights to pursue maximum economic advantage also have cover under international human rights law. Viewed from that perspective, commercialization of research, and the zeal of the pharmaceutical companies to enforce their patents, as in the *Myriad* and *Pharmaceutical Manufactures Association and Others v The President of the Republic of South Africa* cases, may not seem so obnoxious.

Moreover, safeguarding of rights should not be a one-way traffic affair where only the right of poor infected persons needing drugs would be acceptable. The universality of rights dictates that the rights of entrepreneurs should also be protected.

⁴⁶ Doha Ministerial Declaration on TRIPS and Public Health, WT/MIN(01)/DEC/W/2, 14 November 2001

⁴⁷ C.M. Correa *supra* note 21, 6.

⁴⁸ Article 15 1(a).

⁴⁹ Article 15 (3). See also Article 15 of Article 15 of the European Convention on Human Rights and Biomedicine (1997) which provides for scientific research in the field of biology and medicine to be carried out freely.

⁵⁰ See B. William-Jones *supra* note 4 at 139.

⁵¹ Emphasis added. I appreciate that the right in question applies to *peoples*, as perhaps, distinct from *individuals* or *persons*. Being as it may, the right still applies in the context in which it appears. For example, the cases earlier discussed, where the US challenged Brazil and South Africa over TRIPS can be understood as an exercise of the *American people* to freely pursue their economic development.

⁵² Emphasis added. See also Article 2(2) of the Economic Covenant.

The issue thus arising for determination is which should prevail between the conflicting economic rights of the pharmaceutical industry and the health rights of citizens who need to have access to drugs. We seek to address the issue of conflict in the next segment.

Vox Populi

In the light of the seeming conflict of economic and health interests, the largely accepted view is that health interest should prevail over economic interests of making money from patented health products.

At various points where the economic interests and health interests come in conflict across the globe, the voices in support of health have been tremendous. During the disagreements between the United States and South Africa, as earlier described, the US and the pharmaceutical companies experienced unflattering global media attention.⁵³

In the US AIDS activists provoked a dramatic shift in the US position when activist pressure against then Vice President and Presidential candidate Al Gore resulted in widespread negative media attention. The US government shortly thereafter withdrew its trade and political pressures against South Africa, and issued an executive order that the US would not seek the revocation or revision of intellectual property laws or policies of sub-Saharan African countries that sought to promote access to HIV pharmaceuticals or medical technologies in a manner consistent with TRIPS.⁵⁴

When the *Pharmaceutical Manufacturers Association and Others v The President of the Republic of South Africa* began, there were demonstrations in many cities round the world.⁵⁵ Ultimately, the unfriendly media attention attracted by the case compelled the pharmaceutical companies to withdraw their legal action against the South African government in April 2001.⁵⁶

From the above scenario, one can reasonably deduce that more people in the world favour the superiority of health interest over mere economic interest. In the spirit of holding health superior over corporate profits, different countries including the United States, on different occasions, have stood on the side of health when the invocation of patent rights appears to threaten public health.⁵⁷

In another vein, the various declarations and guidelines emanating from the WHO and other international bodies reflect the increasing international concern over the need for reasonable access to health care, especially HIV/AIDS treatment.⁵⁸

The Brazilian delegation to the Doha Ministerial Conference, quite agreeably, summed up the need for health interest to prevail over protection of economic interests:

[T]he commercial exploitation of knowledge must not be valued more than human life. There are circumstances in which the conflicts of interests will require that the State exercise its supreme political responsibility...Brazil promotes and upholds intellectual property rights...However, if circumstances so require it, Brazil, like many other countries, will not hesitate to make full use of the flexibility

⁵³ L. Forman *supra* note 31, 5.

⁵⁴ *Ibid.*

⁵⁵ *Ibid.*

⁵⁶ *Ibid.*

⁵⁷ See C. M. Correa *supra* note 21, 3: "The US was suddenly faced with a situation where there was a perceived need for immediate and widespread access to a product still on patent, where the exclusive owner of that patent, Bayer in this case, appeared unable or unwilling to offer enough supplies to meet immediate demand. The US Government's first instinct was to consider the compulsory licence option and seek out alternative manufacturers." Similarly, the Canadian government "took actions to ensure supply of the anti-anthrax drug despite the patent held by Bayer."

⁵⁸ See *e.g.*, WHO, "WHO Takes Major Steps to make HIV Treatment Accessible: Treatment Guidelines and AIDS Announced by WHO", Press Release WHO/28, 22 April 2002.

afforded by the TRIPS Agreement to legitimately safeguard the health of its citizens.⁵⁹

Going by the Doha Ministerial Conference, member nations of the World Trade Organization appear to have also recognized the need for ensuring unobstructed access to health care. It is particularly instructive to note that the Conference resolved that countries in appropriate circumstances can by-pass patent in the overall interests of public health. As set out in article 4 of the Doha Declaration,

[w]e agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.⁶⁰

Conclusion

The journey to Doha started with commercialization of medical research and patenting, catalyzed by the Bay-Dohle Act. These combined factors seemingly opened the gate for the leopards of commerce to stream into the hallowed chambers of science.⁶¹

In reality, it is trite that funds required to conduct research and manufacture drugs can be immense. Therefore, the pharmaceutical industry's financial inputs cannot be discountenanced if the vehicle of medical research has to remain in motion.

While it is important to safeguard the health of the people, the companies equally need assurance of reasonable returns on their investments. It is unrealistic to expect that they should be embarking on profitless ventures, more so when, in many cases they are answerable to their stockholders.

Building on the foregoing, the pharmaceutical companies have become, and would remain, an integral part of scientific research. Even, if it is possible to exclude them from the exercise, in view of the important financial implications, our view is that they ought not to be excluded, except there can be an alternative reliable sources of financing for research.

The important thing is to strike a balance between the interests of the pharmaceutical companies and the public health interests of various countries. I think that the above stated article 4 of the Doha Declaration, even if ambiguous in some respects,⁶² offers a means to achieve the required balance in the conflicting interests.

Apart from seeking to strike down patent rights as a means of having access to cheaper drugs, one way of reducing the high cost of pharmaceutical products is for the governments to alleviate the costs of the pharmaceutical industry in various ways like tax relieves and subsidies. In return, the countries can have the understanding of the pharmaceutical companies that patented essential medicines would be provided at reasonable costs when necessary. Alternatively, global funds like the one for HIV/AIDS

⁵⁹ C.M. Correa *ibid* at 11.

⁶⁰ See C.M. Correa *supra* note 21, 47: "The Declaration addresses most of the concerns of developing countries on the issue of public health. The ambiguous wording used in some paragraphs-particularly in paragraph 4- was the obvious price paid to build a consensus for the adoption of the Declaration. Despite such wording, the Declaration makes it clear that a conflict may exist between TRIPS standards and public health, and has reaffirmed the right of Members, particularly developing countries, to take measures necessary to protect public health. The Declaration has set the ground for a differentiation of intellectual property policies when necessary to protect health. Though an important political document, the Doha Declaration also has legal effects, equivalent to those of an authoritative interpretation under WTO rules."

⁶¹ See note 20 and the accompanying text.

⁶² See note 60.

can be created to make the essential patented drugs available for those needing them in the poor developing countries.

Furthermore, the pharmaceutical industry should also be willing to contribute to the society where appropriate; after all, every industry has some duty of social responsibility to its community. For the multinational corporations, whose products reach many parts of the world, I think the 'global village' should be regarded as their communities. Therefore, they should be willing to make drugs available at reasonable prices, especially for diseases like HIV/AIDS, which has reached the level of multiple holocausts in the poor countries of Africa.

In closing this paper, and in light of the above paragraphs, I deem it fit to reproduce the words of Justice John Harlan:⁶³

A fundamental principle of the social compact is that the whole people covenants with each citizen, and each citizen with the whole people, that all shall be governed by certain laws *for the common good, for the protection, safety, prosperity and happiness of the people, and not for the profit, honor or private interests of any one man, family or class of men.*⁶⁴

If the appropriate balance were struck between using patent strictly for profits and concern for humanity, then the hobnobbing of commerce and science would be a benefiting symbiosis for humanity. Consequently, commercialization of research and patenting would be among the tools for attaining that state of physical and mental well being, which health is.

⁶³ Adapted from L.O. Gostin, "Health of the People: The Highest Law?" (2004) Fall vol 32:3, *The Journal of Law, Medicine & Ethics*, 509-515, at 509.

⁶⁴ [Emphasis added]