

UN HUMAN RIGHTS COUNCIL

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STATEMENT BY ANAND GROVER

**Special Rapporteur on the right of everyone to the enjoyment of the highest
attainable standard of physical and mental health
("Right to health" or "right to the highest attainable standard of health")**

President, distinguished delegates, ladies and gentlemen.

It is my pleasure to address you today in my capacity as the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

As you may recall, I was appointed in June and undertook my duties on 1st August 2008, succeeding Mr. Paul Hunt, whose six-year tenure expired on 31st July 2008. I am presenting today my first thematic report (A/HRC/11/12 of 31 March 2009), which analyses the effect of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Free Trade Agreements (FTA's) on the right to health, especially access to medicines and Paul Hunt's Report, (A/HRC/11/12/Add.2 of 18 May 2009), on his mission to GlaxoSmithKline (GSK).

But, before continuing with the presentation of the reports, I would like to briefly introduce my preliminary views on the mandate for the next three years.

Since undertaking my duties in August last year, I spent time to listen to you, to different stakeholders and duty-bearers, experts and the community - all those concerned by the right to health. I am also building upon the work of my predecessor who set basis for

further work in unpacking the right to health. I intend to ensure the continuity of the mandate and would focus on the importance of accountability, the need for monitoring the implementation of health related policies, the role of health indicators, and issues relating to maternal mortality. However, the right to health is vast, and there are number of other challenges and issues that I hope will be able to address.

I plan to apply lessons learned from HIV/AIDS field, where I've spent last 20 years, to the right to health more broadly. I believe experience has proven the particular importance of involving rights-holders themselves in decision-making and that means ensuring that I involve them in my own work as Special Rapporteur. Work on HIV has demonstrated the importance of supporting civil society organizations and mobilizing communities most vulnerable to HIV, including drug users, sex workers, and men having sex with men. In addition, my work in the HIV field has especially shown, that community input is extremely important as it offers a vast and diverse perspective to various issues central to the right to health. Human rights can help to identify effective, equitable and evidence-based policies to address complex issues and they have the potential to inform and empower disadvantaged communities I truly believe that widespread and lasting contributions to the progressive realization of the right to the highest attainable standard of health can be achieved if all concerned work increasingly together.

I would now like to present my report regarding access to medicines and intellectual property laws.

Nearly 2 billion people lack access to essential medicines, and massive inequalities still remain regarding access to health services and medicines around the world, which is partly due to high costs. Improving access to medicines could save 10 million lives a year, 4 million in Africa and South East Asia.

It is clear that intellectual property (IP) rights have an impact on the enjoyment of the right to health as it directly affects affordability of medicines. Patents confer on

inventors' legal rights, more importantly negative rights over process or product inventions. Patents rights holders can therefore, prevent persons not authorized by them from making, using, offering for sale, selling or importing the patented invention. Patents create monopolies, limit competition and allow patentees to establish high prices. While product patents confer absolute monopolies, process patents lead to relative monopolies. In this regard, when patents are used to limit competition, they can have a significant impact on access to medicines.

A product patent enables a patentee a complete monopoly and therefore to set monopoly or high prices. Higher standards of patent protection, by reducing the number of patents granted easily, can facilitate competition to lower prices of medicines, while lower standards of patent protection, by increasing the number of patents granted easily, can lead to higher prices. Generic competition in the field of pharmaceuticals has the potential of significantly lowering prices and increasing access. In this regard, I would like to highlight the example of HIV medicines and how generic competition helped reduce prices of first generation Anti-Retro Virals (ARVs) by more than 99 per cent. In fact, the availability of generic medicines from developing countries like Brazil, India, South Africa and Thailand has exerted a downward pressure on prices and increased the range of affordable options for national treatment programmes.

I am particularly concerned that the supply of generic medicines is now in doubt as countries that have been the generic producers have become TRIPS compliant and have had to introduce product patents. With the 2005 deadline for developing countries, the ability of companies to patent new pharmaceutical products on a near-global scale could inhibit further competition and prevent the price reductions needed to make ARV therapy more widely available.

The report further lays out the background and principles of TRIPS. It particularly highlights the flexibilities afforded by TRIPS and describes how countries have varied in the extent to which they have implemented TRIPS flexibilities. I noted that while some countries lack sufficient awareness about the full use of flexibilities and have limited

technical capacity to implement them, others have not sufficiently streamlined their patent laws to facilitate use. Furthermore, pressure from developed countries and multinational pharmaceutical corporations have played a prominent role in shaping the implementation of TRIPS flexibilities in developing countries and least developed countries (LDCs). For example, a number of developing countries, while attempting to implement TRIPS flexibilities in order to address public health concerns, have experienced pressures from developed countries and multinational pharmaceutical corporations.

Furthermore, while some countries took their time to become TRIPS compliant, several countries, particularly a number of LDCs complied with TRIPS well before their deadlines. Similarly, while many countries have adopted mechanisms to issue compulsory licenses, the grounds for use have varied and procedures in national laws are at times cumbersome and need to be streamlined and simplified to facilitate issuance of such licenses. Regarding to parallel importation, the choice of exhaustion regime to incorporate varies from country to country. While countries including South Africa, Kenya, Honduras and members of the Andean Community have adopted the international exhaustion regime to promote affordability and availability of essential medicines, a number of countries have adopted the national exhaustion regime. Others have applied the regional exhaustion principle. However, countries, which have incorporated an international exhaustion regime, have greater ability to facilitate access to medicines.

I therefore recommend that, within the context of the right to health, developing countries and LDCs should be enabled to use TRIPS flexibilities by introducing national laws that incorporate the flexibility to make full use of the transition periods; define the criteria of patentability; issue compulsory licenses and provide for government use; adopt the international exhaustion principle, to facilitate parallel importation; create limited exceptions to patent rights; allow for opposition and revocation procedures. In addition, countries need to have strong pro-competitive measures to limit abuse of the patent system.

Another issue that I addressed in my report is the impact of a number of FTAs, bilateral investment treaties (BITs), and other Trade agreements on access to medicines. These agreements are usually negotiated with little transparency or participation from the public and those who are likely to be affected, and often establish TRIPS-plus provisions, which, undermine the safeguards, and flexibilities that developing countries sought to preserve under TRIPS. Studies also indicate that TRIPS-plus standards increase medicine prices as they delay or restrict the introduction of generic competition.

FTAs and BITs can severely impede access to medicines as they aim to restrict countries from implementing TRIPS flexibilities. For example, a number of FTAs signed or currently being negotiated have restricted or even eliminated the flexibility to broaden the scope of patentability by requiring that parties provide patent protections for second uses, thereby allowing patentees to evergreen existing patents. Some FTAs also restrict procedural flexibilities, such as prohibiting pre-grant opposition procedures and others seek to limit the grounds on which compulsory licenses can be issued. Moreover, a number of FTAs have an impact on access to medicines as they seek to introduce TRIPS plus standards. Even though TRIPS-Plus provisions in FTAs differ from agreement to agreement, they primarily aim to extend the patent protection term, introduce data exclusivity, introduce patent linkage with drug registration and approval, and create new enforcement mechanisms for IPRs.

To conclude, I would like to reiterate that TRIPS and FTAs have had an adverse impact on prices and availability of medicines by creating obstacles for States to comply with their obligations to respect, protect, and fulfill the right to health. Similarly, the lack of capacity, together with external pressures from developed countries has created obstacles for developing countries and LDCs to use TRIPS flexibilities to promote access to medicines. I therefore recommend that developing countries and LDCs should review their laws and policies with a view to making full use of the TRIPS flexibilities.

Mr President,

I now turn to the report of my predecessor, Paul Hunt, on his mission to GlaxoSmithKline (GSK).

At the outset, on behalf of Paul Hunt, I would like to thank warmly GSK for the invitation and their cooperative approach throughout and after the mission. The Special Rapporteur notes that GSK is one of the world's leading research-based pharmaceutical companies and was ranked first in the Access to Medicine Foundation index listing 20 pharmaceutical companies on how they treat the poor and enhance access to medicines. The Special Rapporteur would like to mention that GSK has taken some positive steps that have to be mentioned— they have reduced some prices for ARVs, they are devoting more attention to neglected diseases and their recent initiatives with a view to improving their access to medicines strategies are commendable.

While states have an obligation to ensure the affordability of medicines and that implementing TRIPS flexibilities may serve as a basis to facilitate access to medicines, non-state actors, such as pharmaceutical companies, share a responsibility to help ensure the accessibility of affordable medicines. In this regard, the Special Rapporteur's report aims to emphasize the right to health responsibilities of pharmaceutical companies, particularly by drawing upon the analysis of policies ensured by GSK.

The Special Rapporteur visited the company's headquarters in London on 2nd and 3rd June 2008, with a view to identify the good practices and obstacles facing such a company. Based on the company's public, official policies and programmes provided by staff members based at GSK's headquarters, as well as independent commentaries from experts and civil society on those policies and programmes, the report looks closely at the scope and content of the right-to-health responsibilities of pharmaceutical companies. . Many of the right-to health-responsibilities apply to all pharmaceutical companies, including innovator, generic and biotechnology companies – all must respect medical ethics, provide medicines of good quality, safe, efficacious and affordable to as many people as possible. The Special Rapporteur notes however, that because access to medicines is a shared responsibility, whether or not a pharmaceutical company is able to

fully discharge all its right-to-health responsibilities will sometimes depend upon States, donors and others fulfilling their human rights responsibilities. There are other barriers hindering access to medicines in developing and developed countries which make it difficult to pharmaceutical companies to enhance access to medicines, and a few may be mentioned – weak health systems and regulatory environments, corruption and lack of distribution channels.

The Special Rapporteur's report emphasizes that pharmaceutical companies have a responsibility to integrate a human rights policy throughout the company, thereby ensuring that the right to health is integrated across all relevant policies and programmes. Pharmaceutical companies must also do all they reasonably can to ensure that medicines are available, accessible, including financially accessible, acceptable and of good quality to people within state jurisdictions and within a viable business model. They also should abide by the principle of transparency, by which health related information can become accessible. In addition, establishing appropriate monitoring and accountability mechanism to monitor whether or not a pharmaceutical company is doing what it is required to do in relation to the right to health and access to medicines, is of great importance.

GlaxoSmithKline

In analyzing the policies and practices of GSK, the Special Rapporteur's report highlights a number of improvements by GSK to its access to medicines strategy, including significant price reductions in least developed countries, a specific commitment to invest in the health systems of these countries, and patent pooling. Similarly, in April 2009, GSK and Pfizer announced their intention to create together a new company for the discovery and delivery of treatments for HIV.

The Special Rapporteur notes however, that GSK has also been heavily criticized. In 1998, for example, GSK's predecessors and over 30 other pharmaceutical companies filed a case against the South African government challenging the validity of South

Africa's Medicines and Related Substance Act. According to the pharmaceutical companies the Act, which provided for compulsory licensing, parallel importation and other TRIPS 'flexibilities', undermined intellectual property rights. The case generated fierce criticism of the pharmaceutical industry and was eventually the subject of an out-of-court settlement. This proved to be a turning point. Shortly afterwards, the prices of ARVs, including GSK's, fell from R1000 to under R100 in South Africa.

The Special Rapporteur notes and welcomes the action GSK in reducing prices of some of its drugs and further notes that such measures are reflective of the right-to-health responsibilities. However, Special Rapporteur notes that some prices remain beyond the reach of many and, even though GSK has tried to explore ways of enhancing access to medicines in general, the cervical cancer vaccine, the life-saving medicine, Cervarix, still remains very costly in developed and developing countries, thus unaffordable and inaccessible to a majority of women. Moreover, tariffs and markups imposed by governments significantly raise prices of such medicines, keeping them out of reach for millions of women. In this regard, greater transparency of pricing policies, and their rationale, will enhance monitoring and help ensure better access to medicines.

The Special Rapporteur also highlights that while commercial voluntary licenses have been used by GSK as a mechanism to help ensure access to necessary medicines in LDCs. He also notes that while GSK is not usually considered to be an industry hardliner on intellectual property issues, some of its positions, such as those in India, Thailand and Philippines, undermine its leadership position. In this regard, the Special Rapporteur urges GSK to respect the right of countries to use, to the full, TRIPS flexibilities and encourages GSK to make a public commitment not to lobby for TRIPS 'plus' standards.

Mr President,

Only two weeks ago, I came back from Poland where I undertook my first mission as a Special Rapporteur. I will prepare a mission report, which will be presented at the 14

session of the Human Rights Council in June next year. Without going into details of the mission, I would nevertheless like to make a few remarks.

First of all, I would like to thank the Government of Poland for inviting me and arranging a rich and interesting programme. Even though the focus of the mission was on very complex, sensitive and often controversial issues, such as sexual and reproductive health rights and harm reduction policies, I commend the Government for their openness and readiness to discuss and address them. It goes without saying that I am looking forward to receiving additional information I requested during the mission.

To conclude, these reports highlight that while it is primarily duty of the States to ensure the availability and affordability of medicines, non-state actors share that duty. Hence, the enjoyment of the right to health has to be implemented by States, by all intergovernmental organizations and by all non-state actors, including multinational corporations.

Thank you.