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INCORPORATING A RIGHT TO HEALTH PERSPECTIVE INTO THE RESOLUTION OF PATENT LAW DISPUTES

Emmanuel Kolawole Oke

ABSTRACT

This article adopts the view that the courts in developing countries can play an important role in improving access to medicines in their countries if they incorporate a right to health perspective when adjudicating patent cases involving pharmaceutical products. The article argues that, since patent rights are not human rights, they should not be allowed to trump the right to health. The paper examines two notable cases decided by the courts in Kenya that illustrate the crucial role that incorporating a right to health perspective can play in improving access to medicines. Finally, the paper provides five reasons why courts in developing countries cannot afford to ignore the right to health when adjudicating cases involving patent rights on pharmaceutical products.

INTRODUCTION

Prior to the current internationalization of patent rights via the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1994, countries were free to adapt their national patent systems to suit their economic and technological needs.[1] During this period, several countries (particularly European countries) excluded pharmaceutical products from patent protection in order to facilitate access to affordable medicines for their citizens and also to foster the growth of their domestic pharmaceutical industries by permitting them to ride on the coattails of pharmaceutical inventions made in other countries.[2] Today, several developing countries no longer have the freedom to adopt patent policies that are favorable to their domestic needs; they are instead confronted with demands for stronger patent protection that are not commensurate with their level of technological and economic development.[3]

The efforts made to amend the TRIPS Agreement with regards to the use of compulsory licenses to facilitate increased access to essential medicines in poor countries have yielded only marginal gains. In 2005, a protocol was adopted by the General Council of the World Trade Organization (WTO) to amend Article 31 of the TRIPS Agreement by introducing an Article 31*bis*.[4] Prior to this amendment, apart from some limited exceptions, members could only generally grant compulsory licenses for the supply of their own domestic market and they could not grant compulsory licenses to supply pharmaceutical products to foreign countries. In practice, however, this amendment has failed to achieve its aim as it has only been used once by Canada to supply antiretroviral drugs to Rwanda. This is largely blamed on the cumbersome procedure that countries are required to follow before they can utilize the amendment.[5] It is therefore imperative to examine the possibility of locating another forum where patients, public health activists, and governments of developing countries can curtail the current expansionist trends in international patent law and secure the protection of public health

interests in developing countries. This paper argues that domestic courts in developing countries can serve as effective forums for curtailing the negative impacts of patent rights on the public health systems in their countries. In other words, domestic courts in developing countries, by considering the right to health when adjudicating disputes involving patents on pharmaceutical products, can serve as forums for securing access to medicines.[6]

The right to health is recognized in several international legal instruments and in the constitutions of several countries across the world.[7] There is also judicial recognition of the right to health as an integral component of the constitutional right to life in India.[8] The recognition of this right in legal instruments, however, is not a guarantee that is being enjoyed on an equal basis all over the world. The enjoyment of this right is further being curtailed by the present global structure for the protection of intellectual property rights, especially patent rights. Patent rights have a direct impact on the right to health, especially in developing countries where pharmaceutical products are priced beyond the reach of poor patients. According to Sarah Joseph, "as intellectual property laws confer monopoly rights, they generally inflate prices. This circumstance is problematic as goods that are essential for the enjoyment of human rights, such as new medicines, can be priced out of the reach of poor people."[9]

In 2000, the UN Committee on Economic, Social and Cultural Rights (CESCR) adopted General Comment No. 14 in an attempt to provide further definition for Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).[10] Paragraph 12 of General Comment No. 14 is very relevant to the question of access to medicines. It enumerates four essential, interrelated components of the right to health: availability, accessibility, acceptability, and quality. In particular, it provides that essential drugs (as defined by the World Health Organization Action Programme on Essential Drugs) must be available in a country.[11] According to the World Health Organization (WHO), essential drugs are drugs that "satisfy the priority health care needs of the population" and "are intended to be available within the context of functioning health systems at all times in adequate amounts ... and at a price the individual and the community can afford."[12] In addition, General Comment No. 14 states that health care services must be economically accessible to everyone, suggesting that the prices of essential drugs should not be so expensive as to be unaffordable for poor patients.[13] This makes access to essential medicines an integral component of the right to health.[14] Furthermore, states are obliged to take steps "to control the marketing of medical equipment and medicines by third parties."[15] It has been suggested that this implies that "states should intervene where marketing of drugs by pharmaceutical companies is detrimental to the right to health."[16]

This paper will examine two notable cases from Kenya where the courts had to adjudicate on disputes involving the impact of patent rights on access to medicines. Kenya was selected because it is a typical example of a developing country with significant public health challenges that also has obligations to protect patent rights. It has been estimated that about 1.6 million Kenyans are living with HIV/AIDS.[17] There are also increasing concerns about non-communicable diseases such as cancer in the country. It has been estimated that cancer currently causes 7% of the total number of deaths in Kenya and cancer is ranked as the third highest cause of death in the country.[18] These trends suggest that more Kenyans will need antiretroviral and cancer drugs: in the absence of cheaper generic versions of these drugs, many Kenyans may not be able to afford these essential drugs. Though the focus will be on Kenya, in the course of the analysis, references will be made to relevant cases from other developing countries facing similar public health challenges as Kenya.

The paper is structured into three main parts. The first part will critically examine the relationship between patent rights and the right to health. Specifically, an attempt will be made to determine the extent to which the TRIPS Agreement allows states to frame their patent laws in a manner that accords with their obligation to protect the right to health of their citizens. In addition, the question of the status of patent rights within the framework of international human rights law will be considered, that is, whether patent rights have the same status as other types of human rights and how the relationship between patent rights and human rights should be conceptualized. The second part of the paper will be devoted to a discussion of the two notable cases from Kenya where the courts had to adjudicate on issues pertaining to the impact of patent rights on the right to health and access to medicines. The third part offers five reasons why courts in developing countries should not ignore

the right to health when deciding cases involving patents on pharmaceutical products.

THE RELATIONSHIP BETWEEN PATENT RIGHTS AND THE RIGHT TO HEALTH

The TRIPS agreement and the right to health

The TRIPS Agreement appears to give member states some leeway with regards to ensuring that the protection of intellectual property rights (IPRs) does not impede public health interests.[19] For instance, in setting out the objectives of the TRIPS Agreement, Article 7 provides that the protection and enforcement of IPRs should be done in a manner conducive to social and economic welfare. Article 8(1) of the TRIPS Agreement further permits states to adopt measures necessary to protect public health and nutrition as long as such measures are consistent with the provisions of the agreement. Thus, there seems to be an intrinsic recognition within the TRIPS Agreement that countries should protect IPRs in a manner that is calibrated to advance social and economic welfare.[20] However, the requirement that measures taken to protect public health interests must be consistent with the TRIPS Agreement constrains the freedom of countries to design their domestic patent systems in a manner that actually corresponds with their public health needs. For instance, a developing country cannot temporarily exclude pharmaceutical products from patent protection even if it becomes necessary to do so to facilitate the local production of essential medicines needed to save human lives.[21] Professor Carlos Correa, however, contends that in the light of Paragraph 4 of the Doha Declaration, Article 8(1) of the TRIPS Agreement would not prevent a derogation from certain obligations under the TRIPS Agreement if it is necessary to address public health needs. According to Professor Correa,

> the realization of public health has become, with the Doha Declaration, a clearly stated purpose of the [TRIPS] Agreement … Thus, if local situations posed such unusual problems as to merit a public interest exception, members may find it necessary to override or limit some provisions of the Agreement. For instance, members might determine patentability exclusions in cases of distinct public health emergencies as defined by the national government, and as distinct from ordinary everyday health and nutrition measures.[22]

It is, however, doubtful if a country can take the extreme measure of excluding pharmaceutical products from patent protection; this may be challenged by other countries as being contrary to the TRIPS Agreement and ultimately result in the imposition of trade sanctions on the country. At best, what can be done is to grant a compulsory license (i.e. a license issued by the government, or an administrative authority on behalf of the government, to a third party to exploit a patented invention without the consent of the patent owner) in accordance with the strict requirements of Article 31 of the TRIPS Agreement.

Apart from compulsory licenses, the TRIPS Agreement also offers certain flexibilities that countries can use to address public health challenges in their countries. Such flexibilities include the freedom to exclude new forms of known drugs from patent protection, freedom to adopt the principle of international exhaustion of patent rights to facilitate the parallel importation of drugs (Article 6), regulatory review exemption for producers of generic drugs, research exception, and delinking the grant of marketing approval for generic drugs from the patent status of branded drugs. The use of flexibilities was further reinforced and reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health of 2001.[23] According to the Doha Declaration, the TRIPS agreement "does not and should not prevent members from taking measures to protect public health ... in particular to promote access to medicines for all."[24] However, in practice, most developing countries are unable to make any beneficial use of these flexibilities (even when they are contained in their national patent laws) because of political pressure from industrialized countries.[25] Thus, the current global patent law regime does not greatly assist developing countries in securing the right to health of their citizens.

Are patent rights human rights?

Article 15(1)(c) of the ICESCR recognizes the right of everyone to "benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." A similar provision is also contained in Article 27(2) of the Universal Declaration of Human Rights. At first reading, these two provisions appear

to equate IPRs with other types of human rights; this has led some authors to conclude that they provide a human rights basis for patent rights and other forms of IPRs.[26]

However, the CESCR, in its General Comment No. 17 (adopted in 2006), has made it clear that human rights and IPRs are not on the same level, and it would be erroneous to rely on Article 15(1)(c) to equate IPRs with human rights.[27] The CESCR adopted the view that Article 15(1)(c) solely "safeguards the personal link between authors and their creations … as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living" while "intellectual property regimes primarily protect business and corporate interests and investments."[28] In essence, the human right contained in Article 15(1)(c) is not coterminous with intellectual property rights. The approach adopted by the CESCR is equally supported by the drafting history of both Article 27(2) of the UDHR and Article 15(1)(c) of the ICESCR. It has been noted that the provisions were included in both instruments after considerable debates and controversy.[29] According to Audrey Chapman, the drafting history supports "relatively weak claims of intellectual property as a human right."[30]

In an analysis of the relationship between human rights and IPRs, the CESCR noted:

> In contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person.[31]

There are divergent views on how the relationship between patent rights and human rights ought to be conceptualized. In his review of the literature, E. Gold identifies three broad approaches to the conceptualization of the relationship between patent rights and human rights:

- the "subjugation approach," which states that when patent rights and human rights conflict, human rights considerations should trump patent rights;
- the "integrated approach," which views patents as a human right; and
- the "coexistence approach," which asserts that patent law and human rights law are distinct but share a basic concern in defining the optimal amount of patent protection required to incentivize and practice socially useful innovation.[32]

This paper will not engage in an exhaustive analysis of all the three approaches here. However, the discussion above on General Comment No. 17 of the CESCR counters the assertion that patent rights are human rights (the integrated approach). In addition, it is important to note the decision of the Constitutional Court of South Africa in *Re Certification of the Constitution of the Republic of South Africa, 1996*, where with regards to the objection lodged against the failure of the new text of the South African Constitution to recognize a right to intellectual property based on the grounds that it was a "universally accepted fundamental right," the court held that the recognition of a right to intellectual property "cannot be characterised as a trend which is universally accepted."[33] Also, as Gold points out, one key problem with the coexistence approach is that, in practice, it is difficult to define "where to strike the balance between incentives for innovation on one hand and access on the other.[34]

The subjugation approach appears to be the preferable way to conceptualize the relationship between patent rights and human rights. Properly construed, the subjugation approach does not suggest that patent rights should be discarded or abolished; it rather recognizes the essential distinction between the fundamental nature of human rights and the instrumental nature of patent rights. As P. Drahos points out, "intellectual property rights [including patent rights] are instrumental rights that should serve those needs and interests which human rights discourse identifies as fundamental."[35] As the CESCR emphasized in General Comment No. 17, "intellectual property is a social product and has a social function" while "human rights are timeless expressions of fundamental entitlements of the human person."[36] P. Drahos and J. Braithwaite contend that in any principled

national legal system, a fundamental right such as the right to health should take precedence over utilitarian considerations.[37]

Thus, it is advisable for courts in developing countries—when adjudicating disputes involving patents on pharmaceutical products—to incorporate a right to health perspective that recognizes the essential distinction between the fundamental nature of human rights and the instrumental nature of patent rights. This does not necessarily mean that patent rights should no longer be protected, but it will ensure that patent rights are not exercised in ways that impede access to essential medicines.

INCORPORATING A RIGHT TO HEALTH PERSPECTIVE TO SECURE ACCESS TO MEDICINES

Before 1989, there was no local patent law in Kenya and the only route for registering patents locally was via the *Patents Registration Act* (enacted in 1962). Under this regime, only patents which had been granted in the United Kingdom could be registered in Kenya.[38] In a bid to establish an independent patent system, the *Industrial Property Act of 1989* was enacted to replace the *Patents Registration Act*.[39] Kenya was a founding member of the WTO in 1995 and a party to the TRIPS Agreement.[40] In compliance with the requirements of the TRIPS Agreement, the 1989 *Industrial Property Act* was reviewed to bring it in line with the TRIPS Agreement.[41] This process led to the enactment of the *Industrial Property Act of 2001*.[42]

In relation to the protection of patent rights, the 2001 Kenyan *Industrial Property Act* complies with the requirements of the TRIPS Agreement. It equally contains certain flexibilities such as provisions on compulsory licenses, research exception, and parallel importation.[43] These flexibilities were incorporated into the patent law in order to protect the public health system in Kenya. For instance, during the Parliamentary debates on the 2001 act, it was stated that the provision on parallel importation was specifically introduced to permit the importation into Kenya of "medicines which are required for human life, especially [for the treatment of] HIV/AIDS and [other] opportunistic diseases, as well as malaria."[44] It should also be noted that the right to health is a justiciable right in Kenya pursuant to Article 43(1)(a) of the Kenyan Constitution, which provides that everyone has the right to "the highest attainable standard of health, which includes the right to health care services, including reproductive health care." Thus, individuals can institute legal proceedings to challenge any governmental action (including legislative enactments on patent rights and other IPRs) that potentially or actually infringes on their right to health.

In 2012, a Kenyan High Court made landmark pronouncements on the relationship between the right to health and intellectual property rights.[45] Prior to this case, however, it appears that the courts in Kenya had never considered the potential impact that the enforcement of patent rights can have on the right to health. This is illustrated by the decision of the Kenyan Industrial Property Tribunal in an earlier dispute between a foreign multinational pharmaceutical company and a local pharmaceutical company in Kenya.[46]

In the 2008 case of *Pfizer Inc. v. Cosmos Limited*, Pfizer alleged that Cosmos had infringed its patent on a medicinal product known as "azithromycin dihydrate."[47] Cosmos, however, contended that the patent was not in force between 2003 and 2006 (when the alleged infringement occurred) due to the failure of Pfizer to pay the renewal fees on the patent. The tribunal, however, held that there was no evidence that the patent had lapsed or that it had been removed from the patent register at any time.[48] The patent in question was registered by the African Regional Intellectual Property Organization (ARIPO), of which Kenya is a member, and Kenya was among the designated states for the patent. Section 59 of the Kenyan *Industrial Property Act* provides that "a patent, in respect of which Kenya is a designated state, granted by ARIPO by virtue of the ARIPO Protocol shall have the same effect in Kenya as a patent granted under this Act."

Cosmos raised an alternative defense that it was entitled to import, manufacture, sell, and export the patented product without the authority of Pfizer by virtue of section 58(2) of the *Industrial Property Act*, which allows parallel importation. Section 58(2) provides that "the rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya." Cosmos presented evidence

to the tribunal establishing that the medicines containing the patented product were available in Kenya having been imported from India, Bangladesh, and China.[49] In other words, the patent rights of Pfizer, with respect to those products which were readily available in Kenya, had been exhausted. Cosmos was trying to rely on the principle of international exhaustion of patent rights as reflected in section 58(2), and though this principle might not give Cosmos the right to manufacture the patented product, it would entitle Cosmos to import those patented products from India, Bangladesh, and China and to resell them in Kenya.[50] However, in a rather curious and confusing manner, the tribunal conflated parallel importation with compulsory licenses and voluntary licenses. According to the tribunal, "... parallel importation ... is applicable for instance where the government has allowed a third party to exploit the patent, and that party imports the product from other countries where it is legitimately put on the market. ...This could also be with the authority of the patent holder by way of a contractual or voluntary license."[51] The tribunal could not comprehend a situation where a third party could engage in the parallel importation of a patented product without the authorization of the patentee or the government and its definition of parallel importation clearly contradicts what is contained in section 58(2). Section 58(2) does not require a person or a company to obtain government authorization or a compulsory/voluntary license before engaging in parallel importation.[52]

Cosmos equally argued that the patented product was used for the treatment of opportunistic infections in HIV/AIDS patients and that the WHO listed the product as an essential medicine for the treatment of genital chlamydia trachomatis and trachoma.[53] By raising this argument, Cosmos had highlighted a tension between the enforcement of Pfizer's patent rights on one hand and the need to facilitate access to this essential medicine for Kenyan patients on the other hand. The resolution of this tension therefore required a proper appreciation of the fact that patent rights are instrumental rights that should serve the needs and interests of fundamental rights such as access to affordable medicines. If the tension had been approached from this dimension, it would have enabled the tribunal to interpret the patent law with the objective of ensuring that it does not impede access to medicines. However, in this particular case, the Kenyan tribunal took the view that the product was not a first-line treatment for HIV/AIDS patients and that even if this were the case, it would not entitle the respondents to exploit the patent without authorization.[54]

The tribunal thus failed to appreciate the essential distinction between the instrumental nature of patent rights and the fundamental nature of access to essential medicines. It can be argued that the tribunal failed to appreciate this essential distinction because Article 43(1)(a), which made the right to health justiciable in Kenya, was introduced into the Kenyan Constitution in 2010—two years after the tribunal's judgment. However, even without invoking the constitutional right to health, a court that is mindful of the fundamental importance of securing access to medicines would have examined the rationale behind the inclusion of section 58(2) in the Kenyan patent law. As noted above, section 58(2) was introduced in order to facilitate the importation of medicines for the treatment of HIV/AIDS and opportunistic ailments. A court mindful of the fundamental importance of facilitating access to affordable medicines would have construed section 58(2) in accordance with the objective of ensuring that the enforcement of a patent right does not defeat the aims of the drafters of the patent law.

A classic example of a case where the court recognized this essential distinction, even in the absence of a constitutional right to health, is the English case of *Roussel-Uclaf v. G. D. Searle & Co.*[55] In that case, the plaintiffs (who held a license under a patent to exclusively sell certain drugs) sought to restrain the defendants from selling one of those drugs in the UK. However, the court refused to grant an injunction restraining the defendants from selling the drug because it was a unique, life-saving drug with no precise equivalent in the market as the plaintiffs were not yet selling the drug in the UK. Thus, the English court was clearly concerned about preserving access to this life-saving drug for patients in the UK.

A court that is mindful of the fundamental importance of securing access to medicines will never permit the enforcement of patent rights in a manner that impedes access to medicines. In the *Pfizer v. Cosmos* case, the approach adopted by the Kenyan tribunal essentially elevated the rights of patentees above

the right to health of patients in need of essential medicines. The tribunal lost sight of the fundamental importance of securing access to essential medicines while it was adjudicating the patent dispute between the parties.

In the more recent case of *Patricia Asero Ochieng et al. v. Attorney General*, the Kenyan High Court had an opportunity to consider the relationship between patent rights and the right to health.[56] In that case, the petitioners were HIV/AIDS patients, and they alleged that certain sections of the Kenyan *Anti-Counterfeit Act of 2008* threatened their access to essential drugs thereby infringing their right to life, dignity, and health.[57] The petitioners argued that the government failed to specifically exempt generic drugs from the definition of counterfeit goods in the Act.[58] Specifically, section 2 of the Act defined counterfeiting in relation to medicine to mean "the deliberate and fraudulent mislabelling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging." The respondents, however, argued that the *Anti-Counterfeit Act* was enacted to prohibit trade in counterfeit goods in Kenya and was not intended to prohibit generic drugs.[59] The respondents argued that the act was intended to "protect the public from the harm of using counterfeit goods and that extra care needs to be taken to ensure that the medicine in the market meets the required standard."[60]

The UN Special Rapporteur on the right to health, Anand Grover, filed an *amicus* brief in this case. According to the Special Rapporteur, "the definition of 'counterfeiting' within the Act effectively conflates generic medicines with medicines which are produced in violation of private intellectual property rights, and this conflation of legitimately produced generic medicines with those that possibly violate intellectual property rights is likely to have a serious adverse impact on the availability, affordability and accessibility of low-cost, high-quality medicines."[61] The Special Rapporteur agreed with the contention of the petitioners that the Act could endanger the right to health because it does not exclude generic drugs.[62] The Special Rapporteur also provided a definition of generic drugs (which was quoted in the court's judgment) as drugs that "have the same composition and contain the same substances as patented formulations of the same drugs, and are essentially identical copies [that] can be used for the same purposes as their non-generic counterparts."[63]

In its analysis of the meaning and implication of the right to health, the High Court referred to Article 43(1)(a) of the Kenyan Constitution which guarantees the right to health, Article 12 of the ICESCR, and General Comment No. 14 on the right to health. The High Court proceeded to delineate the nature of the state's obligation with regard to the right to health. The court held that the state's obligation entails both a positive and a negative duty. The state has a positive duty to ensure that its citizens have access to health care services and medicines; it equally has a negative duty to refrain from taking actions that would affect access to these health care services and medicines.[64] Thus, any legislative enactment that would make medicines too expensive for citizens would be in violation of the state's obligation.[65]

The court equally highlighted the danger inherent in conflating the definition of counterfeit drugs and generic drugs by referring to cases where generic drugs in transit were seized on the basis of being counterfeit.[66] Though the court did not mention any particular country, it is obvious that the court was referring to instances like the seizure by Dutch customs authorities in 2008 and 2009 of multiple shipments of drugs that were in-transit from India to developing countries in Africa and Latin America.[67] The court agreed with the petitioners and the Special Rapporteur that the "definition of 'counterfeit' in section 2 of the Act is likely to be read as including generic medication" and quoted from the Special Rapporteur's *amicus* brief, "this would affect the availability of generic drugs and pose a real threat to the petitioners' right to life, dignity and health."[68] The court disagreed with the respondent's argument that the Act was primarily intended to protect consumers from counterfeit medicines. According to the court "... the tenor and object of the Act is to protect the intellectual property rights of individuals."[69]

The court was of the view that the right to life, dignity, and health must take priority over intellectual property rights. The court noted that if the Act were implemented as originally written, "the danger that it poses to the right of the petitioners to access essential medicine ... is far greater and more critical than

the protection of the intellectual property rights that the Act seeks to protect. The right to life, dignity and health of the petitioners must take precedence over the intellectual property rights of patent holders."[70]

Thus, unlike the approach adopted by the tribunal in the *Pfizer v. Cosmos* case, the decision of the Kenyan High Court in this case demonstrates the court's recognition of the tension between the enforcement of intellectual property rights and the protection of the right to health. The court refused to be misguided into overlooking the fact that the *Anti-Counterfeit Act* was enacted to enhance the protection of intellectual property rights in Kenya. With the recognition that there was a tension to be resolved, the court equally demonstrated an implicit understanding of the essential distinction between the fundamental nature of the right to health and the instrumental nature of IPRs. This can be seen from the court's statement that the danger posed by the *Anti-Counterfeit Act* to the petitioner's right to access essential medicine was far greater and more critical than the protection of IPRs. It is therefore not surprising that the court, while not disparaging IPRs, held that the right to health must take priority over IPRs.

From the High Court's decision, a two-stage process is discernible in the incorporation of a right to health perspective into the adjudication of patent law disputes. The first stage involves the *recognition* of the tension between patent rights and the right to health. The second stage involves the *resolution* of this tension by distinguishing between the fundamental nature of the right to health and the instrumental nature of patent rights.

These two cases from Kenya illustrate the important role that courts can play in enhancing access to medicines in developing countries. In a situation where most courts adopt the approach of the tribunal in the *Pfizer* case, there is no doubt that patent rights will almost always trump the right to health. However, if courts adopt the more robust approach that was applied by the High Court in the *Ochieng* case, it will lead to two things: one, states will be careful in implementing legislation (especially patent laws) that can significantly impede access to medicines; and, two, pharmaceutical companies that own patents on pharmaceutical products will ensure that they do not exercise their patent rights in ways that negatively affect the enjoyment of the right to health.

However, it should be noted that the ultimate resolution of the tension between patent rights and the right to health in each case may not always be the same. In some cases the enforcement of patent rights may not necessarily impede access to medicines, and in such cases, the rights of patentees need not be disregarded. For instance, in the South African case of *Aventis v. Cipla*, the South African Supreme Court of Appeal granted an injunction to restrain the infringement of the patent on a drug (Docetaxel) after having satisfied itself that the injunction would not necessarily impede access to the drug in question as the patentee (Aventis) was already supplying the patented drug to the South African government at a price cheaper than that of the defendant's (Cipla) generic version.[71] It was established before the court that Aventis was already selling the patented drug to the South African government at the rate of R680 for 20 mg and R2327 for 80 mg while Cipla's generic version was being sold for R1000 and R3500 for 20 mg and 80 mg respectively.[72] Thus, Aventis' drug was more accessible to patients dependent on the public health care system.[73] Therefore, it is not in every case that the tension will be resolved against the patentee: it all depends on the facts of each case.

WHY COURTS SHOULD NOT IGNORE THE RIGHT TO HEALTH WHEN ADJUDICATING CASES INVOLVING PATENTS ON PHARMACEUTICAL PRODUCTS

There are five reasons why it is important for courts in developing countries not to ignore the right to health when adjudicating pharmaceutical patent cases.

One, the courts have to be more vigilant when scrutinizing legislation aimed at granting stronger protection to patents. Several bilateral and regional trade agreements currently pressure developing countries to adopt legislation providing stronger patent protection, but possibly significantly impeding access to medicines.[74] Courts should be vigilant and careful when interpreting such laws to ensure that the right to health of poor patients is not trampled upon. The Kenyan *Anti-Counterfeit Act* is just one example of the current expansionist trends in international patent law which, among other methods, seeks to use border and customs control measures to prevent the movement of counterfeit goods across international borders.[75] While such measures might actually be helpful in protecting people from harmful fake products,

such measures can equally restrict access to low-cost generic medicines. The failure of the Kenyan *Anti-Counterfeit Act* to clearly distinguish between counterfeit drugs and generic drugs demonstrates this danger. Thus, where a country has been compelled to include a similar provision in its patent law by means of a trade agreement, the provision can be held to be unconstitutional on the basis that it can potentially impede the enjoyment of the right to health. Similar arguments can also be made with respect to any other provision incorporated into the domestic patent law framework that might impede the enjoyment of the right to health. For instance, where a trade agreement requires a country to provide patent protection for new forms (or new uses) of known drugs, a court could rule that such a provision in the patent law would impede the enjoyment of the right to health by permitting pharmaceutical companies to extend the length of their monopoly rights on essential medicines. In other words, the fundamental and critical need of providing access to essential medicines would not be served by extending the lifespan of the instrumental (monopoly) rights of pharmaceutical companies on essential drugs.

Two, incorporating a right to health perspective into pharmaceutical patent cases enables a court to properly construe and apply the flexibilities already contained in the domestic patent law such as provisions on compulsory licenses and parallel importation. For instance, as seen from the analysis of the Kenyan cases, the tribunal in the *Pfizer* case failed to recognize the tension between patent rights and access to medicines; it is therefore not surprising that it also failed to properly construe and apply the provisions on parallel importation in the Kenyan patent law. However, in its decision in the *Ochieng* case, the Kenyan High Court incorporated a right to health perspective into its decision and properly construed the provision on parallel importation. The Kenyan High Court noted that:

> … [U]ntil the passage of the Industrial Property Act in 2001 … it was not possible for poor people infected with HIV/AIDS to access anti-retroviral medication as the only ones available were expensive branded medicines. Generic anti-retroviral drugs were not available in Kenya as the existing legislation did not allow parallel importation of generic drugs and medicines. Section 58(2) [of the 2001 Act] … allowed the parallel importation of generic drugs. It is on the basis of this legislation that availability and access to anti-retroviral drugs has increased and greatly enhanced the life and health of persons such as the petitioners who have been living with HIV/AIDS.[76]

The incorporation of a right to health perspective can therefore also assist a court in construing patent laws and flexibilities in a manner that serves the fundamental and critical need of securing access to medicines. In addition, a right to health perspective can be quite helpful when a court is considering the balance of convenience in a case where a pharmaceutical company is trying to obtain an injunction to prohibit or delay the production of cheaper generic drugs. For instance, in the Indian case of *Hoffmann-La Roche Ltd. v. Cipla Ltd.,* the Delhi High Court refused to grant an injunction sought by Roche against Cipla for the latter's production of the former's patented drug.[77] The Delhi High Court noted that:

> … [T]he Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted. … The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. … Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 [of the Indian Constitution, which provides for the right to life and which forms the bedrock of the right to health in India] so far as those [who] would have or could have access to Erloticip are concerned.[78]

Three, courts in developing countries should equally be aware that courtrooms are now forums for shaping and reshaping global health diplomacy. While multinational pharmaceutical companies can successfully lobby for stronger patent protection in

international trade forums, poor patients and civil society groups usually rely on domestic courts to ensure that their interests are protected at the local level. Consequently, in a situation where more courts in developing countries are adopting a right to health perspective in pharmaceutical patent cases, it will encourage litigants in other developing countries to seek the assistance of local courts to protect their right to health. These local courts may also decide to follow the example of other countries by incorporating a right to health perspective in pharmaceutical patent cases.

Four, as the impact of non-communicable diseases such as cancer continues to increase in developing countries, it is obvious that more patients will require access to expensive but essential drugs in order to sustain a healthy lifestyle. A right to health perspective will therefore ensure that courts are mindful of the importance of the availability of cheaper generic drugs in the market. The Kenyan High Court in the *Ochieng* case was mindful of the need to ensure that generic antiretroviral drugs remained affordable and accessible. The court noted that "[m]any of those who are infected with the virus are, like the petitioners, unemployed and therefore financially incapable of procuring for themselves the anti-retroviral branded medication that they need to remain healthy. They are therefore dependent on generic anti-retroviral medication which is much cheaper and therefore more accessible to them."[79] If the Kenyan *Anti-Counterfeit Act* had been implemented in the form in which it was enacted, it would have jeopardized the lives of the petitioners and other patients who rely on the availability of cheaper generic drugs.

Finally, it is important to note that, unlike the situation in industrialized countries where there are sophisticated mechanisms such as antitrust laws that can be used to curb the excesses of pharmaceutical companies, in several developing countries the legal framework to curb anti-competitive activities is either undeveloped, underutilized, or non-existent.[80] In several developing countries, the right to health is the only potent weapon that can be effectively used to ensure that pharmaceutical companies do not abuse their patent rights.

CONCLUSION

It is essential for developing countries to devise strategies to curtail the current expansionist trends in international patent law. In the midst of growing demands for stronger patent laws, the right to health can be utilized to reclaim some policy space for developing countries to design their national patent laws in a manner that facilitates access to medicines. Domestic courts have a major role to play in this regard: when they are adjudicating disputes involving patents on pharmaceutical products, they can recognize the tension between patent rights and the right to health and resolve this tension by distinguishing between the instrumental nature of patent rights and the fundamental nature of the right to health.

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