

# Are pharmaceutical patents protected by human rights?

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## ABSTRACT

The International Bill of Rights enshrines a right to health, which includes a right to access essential medicines. This right frequently appears to conflict with the intellectual property regime that governs pharmaceutical patents. However, there is also a human right that protects creative works, including scientific productions. Does this right support intellectual property protections, even when they may negatively affect health? This article examines the recent attempt by the Committee on Economic, Social and Cultural Rights to resolve this issue and argues that it fails. This is problematic because it means defenders of the present patent regime can continue using human rights documents to support their position. I offer a new framework for resolving the problem by examining the values that underlie human rights.

The relationship between intellectual property laws and the provision of new drugs to those who need them is contentious. Critics of the present patent system argue that the high prices supposed necessary to promote medical innovation prevent access to lifesaving drugs. Indeed, some maintain that this is a violation of the right to health recognised in international treaties. Others claim that intellectual property rights are similarly recognised by international treaties that protect the rights of authors.

In November 2005, the Committee on Economic, Social and Cultural Rights issued a general comment that attempted to clarify the relationship between the right to health and intellectual property (IP) rights. It strictly distinguishes human rights from IP rights, and thereby implies that the only human rights relevant to the access to medicines issue are those, like the right to health, which support universal access. This paper argues that the general comment fails to demonstrate that there is no conflict within the human rights framework between a right to health and IP rights, thus leaving open the danger that human rights documents will be used to defend pharmaceutical patents. It proposes an alternative strategy that has the potential to resolve this problem by analysing the justifications for protecting creative products.

A preliminary note on methodology is in order. This paper reaches its conclusions through ethical, not legal, analysis. Though it examines legal documents, the ultimate goal is not to draw conclusions about what the law is, but rather about what it ought (morally) to be. Consequently, I am concerned with the moral foundations of human rights claims, and my criticism of the general comment is that it fails to

give a compelling *moral* justification for its view of the relationship between the human rights of authors and intellectual property protections.

## HUMAN RIGHTS AND HEALTH

Human rights are claims against the state held by human beings in virtue of their humanity. Traditionally, they include so-called negative rights, such as the right not to be subject to arbitrary arrest, and so-called positive rights, such as the right to an adequate standard of living.<sup>1</sup> At root, human rights are moral claims: people deserve to have their rights realised independent of the legal regime under which they reside. However, many specific human rights are also enshrined in international agreements. These include the Universal Declaration of Human Rights (UDHR), the International Covenant on Economic, Social and Cultural Rights (ICESCR), and the International Covenant on Civil and Political Rights (ICCPR), which together constitute the International Bill of Rights. Political activists can make use of these treaty commitments to criticise and influence government policies. Historically, such criticisms have centred on violations of negative rights, epitomised by the work of non-governmental organisations like Amnesty International.<sup>2</sup> More recently, however, critics of state policies have begun to make extensive use of positive rights, including the right to health.<sup>3</sup>

The right to health is explicitly stated in the UDHR and the ICESCR (see UDHR article 25.1<sup>1</sup> and ICESCR article 12<sup>4</sup>). According to the ICESCR everyone has a right to “the enjoyment of the highest attainable standard of physical and mental health.” The content of the right is specified more exactly in the ICESCR and general comment no. 14, the interpretation of the right issued by the Committee on Economic, Social and Cultural Rights. The general comment asserts that states have a core obligation to “provide essential drugs, as from time to time defined under the World Health Organization’s Action Programme on Essential Drugs.”<sup>5</sup>

In 1994 the World Trade Organization (WTO) established the Agreement on Trade and Related Aspects of Intellectual Property Rights (TRIPS) to standardise worldwide intellectual property laws, including patent laws.<sup>6</sup> When TRIPS is fully implemented, in 2016, the international patent regime will require patents, including those on pharmaceutical products, to extend a minimum of 20 years from filing in all countries, including least developed countries (see TRIPS article 33<sup>6</sup>). This will constitute a substantial strengthening of international intellectual property protection. For

example, until its 2005 Indian Patents Act implementing TRIPS India recognised no pharmaceutical product patents at all, thereby facilitating a substantial generic drug industry.<sup>7</sup>

Patents give their holders a temporary monopoly on the manufacture, sale and use of the product or process patented. The holders of pharmaceutical patents, or their licensees, can therefore charge much more than the cost of production for drugs without being undercut by competition. This leads to drugs that are priced out of the reach of many people who need them. In the case of the HIV/AIDS epidemic, for example, though generic versions of first-line drugs are becoming increasingly accessible, the second-line anti-retrovirals needed by patients who have built up resistance to the original treatments are patented and consequently prohibitively expensive.<sup>8</sup> Though only a small proportion of the drugs on the World Health Organization's current list of essential medicines are under patent, this number is likely to grow as TRIPS is implemented and new drugs are developed. Access problems will be further exacerbated in cases of so-called TRIPS-plus agreements—principally bilateral agreements between the USA and individual developing countries that establish stronger IP protection and restrict the permitted exceptions to IP rights.

In short, the present IP regime leads to higher prices for essential medicines. Higher prices for essential medicines reduce the ability of people and governments to access them. Consequently, the international IP regime appears to be in direct conflict with state obligations under the right to health.<sup>9</sup>

### BALANCING HEALTH AND IP RIGHTS

Even though a state may not have incorporated into law its obligations under the human rights treaties to which it is a signatory, in the international arena it is normally assumed that these obligations should take precedence over other legal and treaty commitments. For instance, the WTO's "Doha Declaration" emphasised the legitimacy of public health exceptions to IP protection.<sup>10</sup> Many commentators are sceptical about how well this can work in practice: there are powerful trade interests involved and there is an effective enforcement apparatus for the WTO, but not for the ICESCR.<sup>11 12</sup> Nonetheless, in principle at least, a state cannot be required to violate its human rights commitments.

There are other tensions, however. The International Bill of Rights also sets out protections for people engaged in creative work. Article 15 (1) (c) of the ICESCR recognises the right of everyone, "[t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he [sic] is the author."<sup>11</sup> If we, plausibly, understand authors to include all those people who engage in creative work, this article will apply to a range of intellectual labourers, including writers, inventors and medical researchers. Consequently, article 15 (1) (c) appears to support intellectual property protection. It therefore looks like the clash between the medical patents regime and the right to health represents a conflict of two human rights claims.

Now, when the legal mechanisms put in place to protect one right appear to impact on the realisation of another, these mechanisms require special justification. It is generally considered that any policy that impacts on the realisation of a right,

<sup>1</sup> See ICESCR article 15 (c).<sup>4</sup> The moral interests of authors normally include the right to claim authorship, and the right to object to treatment of the work that negatively affects their reputation (see, eg,<sup>13</sup>) Material interests are the economic uses of a work. The control an author has over such uses, taking the meaning of author broadly, will vary depending on the intellectual object.

whether for reasons of social benefit or to protect other rights, must at a minimum meet two conditions: it must be necessary to achieve a particular goal, and the goal must be sufficiently important that its attainment justifies the restriction on the right.<sup>11</sup> The protection of other rights is *prima facie* a sufficiently important goal. Consequently, when faced with an apparent conflict between the means taken to realise two rights there are two possible solutions.<sup>11</sup> First, if the mechanisms needed to realise the rights genuinely conflict, we must attempt to balance the values that the two rights protect, and ensure that the mechanisms minimally restrict their realisation. Second, we can show that the legal mechanism is not necessary to protect the right, that the conflict is illusory, and therefore that the mechanism ought to be removed. I now turn to the Committee on Economic, Social and Cultural Rights' attempt at resolution.

### GENERAL COMMENT NO. 17

In November 2005, the Committee on Economic, Social and Cultural Rights published a general comment on article 15 (1) (c). The comment strictly distinguishes the human rights of authors from IP rights, stating that, "[i]t is ... important not to equate intellectual property rights with the human right recognised in article 15, paragraph 1 (c)",<sup>17</sup> and emphasises the interdependence of the various human rights. With regard to possible conflicts between human rights, it concludes:

States parties are therefore obliged to strike an adequate balance between their obligations under article 15, paragraph 1 (c), on the one hand, and under the other provisions of the Covenant, on the other hand, with a view to promoting and protecting the full range of rights guaranteed in the Covenant ... States parties should therefore ensure that their legal or other regimes for the protection of the moral and material interests resulting from one's scientific, literary or artistic productions constitute no impediment to their ability to comply with their core obligations in relation to the rights to food, health and education. (See general comment 17, paragraph 35.<sup>17</sup>)

Thus, according to the Committee, a balance needs to be struck between various human rights claims, including the

<sup>11</sup> For example, the "Oakes test" is now the accepted standard for determining whether laws that limit the rights given in the Canadian Charter of Rights and Freedoms are constitutional. It requires of any measures that impair Charter rights: "first, the measures adopted must be carefully designed to achieve the objective in question. They must not be arbitrary, unfair or based on irrational considerations. In short, they must be rationally connected to the objective. Second, the means, even if rationally connected to the objective in this first sense, should impair 'as little as possible' the right or freedom in question. Third, there must be a proportionality between the effects of the measures which are responsible for limiting the Charter right or freedom, and the objective which has been identified as of 'sufficient importance'. (R vs Oakes [1986] 1 S.C.R. 103)". Similar requirements, including a principle of proportionality are recognised by the European Court of Human Rights.

<sup>11</sup> It is a matter of dispute whether or not moral rights can be overridden for the sake of social goods that are not protected by rights. As Ronald Dworkin<sup>14</sup> explains: I shall say that an individual has a *right* to a particular political act, within a political theory, if the failure to provide that act, when he calls for it, would be unjustified within that theory even if the goals of the theory would, on the balance, be disserved by that act. The strength of a particular right, within a particular theory, is a function of the degree of disservice to the goals of the theory, beyond a mere disservice on the whole, that is necessary to justify refusing an act called for under the right.<sup>14</sup> Some philosophers believe that rights have unlimited strength (eg, Robert Nozick<sup>15</sup>), others think at least some rights can be overridden (eg, Judith Jarvis Thomson<sup>16</sup>). I do not need to take a position on this dispute here: as I argue below (see under the heading *The specification of human rights*), if the rights of the creators of pharmaceutical products are justified by their consequences, they should not conflict with the interests protected by the right to health.

rights of authors. However, IP rights, unlike authors' rights, are not human rights, and so are overridden by these human rights claims. Hence, the comment appears to rule in favour of the right to health.

### PROBLEMS WITH GENERAL COMMENT NO. 17

On the surface it seems that the comment unambiguously rules against intellectual property. However, it leaves a crucial question unanswered. Clearly, IP rights and the human rights of the author do not "necessarily coincide," but is the present IP regime (or one very like it) needed for states to fulfil article 15 (1) (c)? If it is, then a balance must be struck between IP rights and other human rights. Only if an IP regime similar to the current one is not needed in order to realise the human rights of authors will conflicts between intellectual property and human rights claims be straightforwardly resolved in favour of the latter.

There are two arguments in general comment no. 17 that seem to suggest that IP rights are not guaranteed by the article, and therefore that IP rights should always be subordinate to other human rights. Neither argument is compelling. This leaves the correct relationship between authors' rights and intellectual property unclear, and therefore the extent to which access to medicines is protected by human rights uncertain.

First, the general comment distinguishes the source of human rights from the source of intellectual property rights: the former derive from the "dignity and worth" of human beings and the latter from legal regimes (see general comment 17 paragraph 1<sup>7</sup>). This allows the nature of the two sorts of rights to be contrasted. Human rights are "timeless expressions of fundamental entitlements of the human person," whereas intellectual property rights "may be allocated, limited in time and scope, traded, amended and even forfeited." (see general comment 17 paragraph 2<sup>17</sup>). On this view, IP rights are not human rights. Since human rights take precedence over other rights, this would imply that IP rights should be subordinated to human rights, like the right to health.

This argument is predicated on a confusion, however. While it is true that particular IP rights have properties not possessed by human rights—like alienability through trade—it does not follow that the right to acquire or hold intellectual property is likewise different. The right to acquire or hold intellectual property would be a right to have certain alienable, forfeitable, etc, rights over creative works. It need not itself, however, be alienable, forfeitable, etc, and so could be a human right. If this is true, then something like the present legal IP regime might be needed to protect the right. This point may be clarified by an analogy with property rights. Particular property rights are the product of legal regimes, can be alienated or forfeited, and so on. Thus they are not human rights. Nevertheless, the International Bill of Rights includes a human right to own property (see UDHR article 17(1)<sup>1</sup>). Legal regimes that establish property rights may then be assessed, in part, by how well they protect that human right. Similarly, with regard to intellectual property, the crucial question is what sort of legal regime is needed to safeguard the human rights of authors, whatever they turn out to be, not whether the legal rights created by that regime are themselves human rights.

The general comment also distinguishes human rights from IP rights on the grounds that only humans can be the bearers of human rights, but other legal entities—such as corporations—can possess IP rights. This is correct, but it will not help to resolve cases in which people claim rights in intellectual works that are needed for the health of others. Moreover, it would

seem to be a tenuous way to defend people's rights to patented medicines: it would surely just lead corporations to revise their patenting strategies so that their employees would patent medicines on their behalves. The possibility of such a manoeuvre suggests that this cannot explain why IP rights are not protected by human rights: if it is wrong to let IP rights take precedence over people's health it is not because of who possesses the IP rights, but because of the nature of the rights themselves.

The second argument that can be found in general comment no. 17 tries to limit the extent of the material interests of authors by reference to the function of authors' rights. In a number of places the Committee suggests that the material interests are justified because they "are necessary to enable those authors to enjoy an adequate standard of living" (see general comment 17 paragraph 30<sup>17</sup>). It is not immediately clear how to interpret this claim, but one possibility is that the Committee believes that authors' material interests would be satisfied if they were given the means to an adequate standard of living. Thus, for example, 15 (1) (c) could be substantially realised by the implementation of a minimum wage for creative workers. This would then show that authors' rights need not conflict with the right to health.

Again, however, this cannot be the correct understanding of the right. It is obscure how a claim to an adequate standard of living could be justified by a person being an author. There is, in fact, a human right to an adequate standard of living, but that right is not conditional on the profession of the right-holder; rather, it is conditional on the right-holder being a human person (see UDHR article 25.1<sup>1</sup>). A closer inspection of article 15 (1) (c) indicates how it should be interpreted. The article guarantees to everyone protection of the material interests "resulting from any scientific, literary or artistic production of which he or she is the author" (see ICESCR article 15 (1) (c)<sup>4</sup>) (*italics added*). Thus the content of the relevant material interests result not from characteristics of the author, but from characteristics of his or her scientific, literary or artistic productions. This implies that what is protected is some opportunity of the author to material gains from the productions; for example, through control over how they are used. Nor is it the case that the author is guaranteed such gains: it seems reasonable that if the production is not of value, then it will not generate significant material interests. Again, the analogy to property rights may help. The value of property is not given by characteristics of the property owner, it is given by characteristics of the property; for example, land may be valuable because it is fertile. This is the case independently of what justifies having the legal regime of property rights.

The arguments we might read into general comment no. 17, which would entail that IP rights were always subordinate to other human rights, have been shown to be unconvincing. Thus the comment fails to show that the present IP regime, or one similar to it, is not justified by the moral rights underlying article 15 (1) (c). Without a method for specifying the content of human rights, this leaves it open for supporters of the present IP regime to continue to defend it using human rights documents, even if the regime is not morally justified.<sup>18 19</sup> Consequently, this paper now turns to the development of such a method.

### THE SPECIFICATION OF HUMAN RIGHTS

Though the Committee may be recognised as an authority, its word does not decide the content of human rights. As their preambles make clear, human rights documents are supposed to

reflect underlying moral rights—they are not the product of positive law. At best, the Committee is reporting its considered view of what those moral rights are. It can therefore be mistaken and is open to criticism. This means that the Committee's conclusions should be compelling only if it provides a compelling justification of its interpretation of the content of the right. However, outside of the arguments outlined above, general comment no. 17 does not explain the reasoning process of the Committee in a way that allows the reader to determine how it reached its conclusions about authors' rights.

One way to determine the content of a moral right is to look at the moral considerations that underlie it. This tells us what values the right protects; the right's content will be whatever is needed to protect them. For example, suppose we want to make a claim about the content of the human right to water.<sup>20</sup> A possible ground for human rights like this is that they protect the conditions necessary for basic human functioning. Such functioning is needed for all sorts of valuable human characteristics, including, for instance, the capacity for autonomous action. To remain healthy, humans need 2–4.5 litres of drinking water each day, and another 2 litres for food preparation.<sup>21</sup> This implies that people have a right to at least this quantity of potable water.

What values underlie authors' rights? The comment does mention one ground for them: the "inherent dignity and worth of all persons," which is supposed to be a fundamental ground for all human rights. But the nature of dignity is unclear. No one has specified it in a way that shows its relationship to authorship. Consequently, it is not obvious what manner of protection of human creations is most conducive to human dignity.

If, instead of starting with a vague notion of human dignity, we look to more specific arguments that have been given to justify intellectual property rights, it becomes clear that the content of the human rights of authors is highly dependent on which justification is correct.

For example, suppose we consider an instrumentalist defence,<sup>22</sup> like that implied by the US Constitution.<sup>23</sup> Justified by its effects, the IP regime seeks to balance the efficiency gains of pricing competition with the innovation gains of allowing temporary monopolies to inventors. In the context of healthcare, the relevant gains are increases in the supply of useful medicines. This means that IP laws are there to balance maximising the supply of present medicines with maximising the supply of future medicines. Presumably, the optimal balance is that which maximises the beneficial impact of those medicines on health. It is hard to see how this would conflict with the fulfilment of those aspects of the right to health concerned with access to medicines. Consequently, on this justification there is no balancing of human rights needed. Instead, careful empirical work is needed to determine exactly what legal regime would optimise access to present and future medicines. A great deal of the debate over access to medicines and patent laws concerns the answer to this question.

Similarly, if what is important is to protect creative works as expressions of the personality of individuals, an alternative way in which intellectual property has been defended, then it will be most important to protect the moral interests of authors—their material interests may not require special weight.<sup>24</sup> In this case, it is again unlikely that the human rights of authors and the right to health would be in genuine conflict.

We may contrast these two defences with Lockean justifications of intellectual property, according to which labour

provides a ground for ownership of its product.<sup>15</sup> If such a justification were correct, then inventors would deserve some control of the use of their creations over and above the expected effects of this control on people's wellbeing. Such control would be similar to property rights. Here, the values underlying authors' rights and those underlying the right to access medicines would be distinct and liable to conflict, since the creators of medicines might want to do something with them other than maximise their impact on health. Hence, a Lockean view would require some balancing of rights. This brief analysis shows that it matters *why* authors have rights, since that determines what the content of those rights are, and how they should be weighed against other moral considerations with which they might conflict. Moreover, it suggests that only if Lockean accounts of IP are correct will the conflict between authors' rights and the right to health be genuine.<sup>1v</sup>

The general comment tried to solve the potential conflict between the right to health and IP rights by arguing that IP rights are not human rights and therefore the right to health should trump IP rights. I have argued that this strategy failed. However, this does not imply that the current IP regime is in fact justified. Rather it indicates that talk of human rights will not substitute for detailed analysis of the underlying ethical and empirical issues, including (insofar as IP is instrumentally justified) working out which legal system will maximise access to present and future essential medicines.

The particular lesson we should draw is that it is not possible to resolve the apparent conflict between article 15 (1) (c) and other human rights, like the right to health, without considering what justifies these rights. But this lesson can be generalised. Much of the time, if we are to get detailed policy recommendations using human rights, and if we are to be able to resolve apparent clashes between rights, we need to understand what underlies them.

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<sup>iv</sup> Proper analysis of which justification should be preferred is outside the bounds of this paper. However, telling arguments against a Lockean grounding for strong intellectual property rights may be found in.<sup>25</sup>

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