International and Regional Economic Rule-making and the Enforcement of the Right to Health: the Case of Colombia

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Abstract
The regional policy level is often seen as a source of progressive policy-making, complementing or substituting national policy levels, which are perceived as underperforming. While it can certainly be argued that in the area of health policies, there are important opportunities to adopt regional approaches to tackle border-crossing health issues, this article draws the attention to the fact that the linkage between international/regional and national policy levels is not uni-directional. While in some instances the regional level may indeed take the lead in the promotion of (the right to) health, in other instances it may well be the other way round. This article focuses on the case of Colombia, where two types of international economic rules are analyzed with potentially effects on health. The first case refers to the reform of the health sector in the context of the IMF adjustment programs and the protection of the right to health by the Colombian Constitutional Court. The second case refers to recently signed FTAs, their potential effects on health policies, and how courts have been dealing with the tension between the promotion of free trade and the enforcement of the right to health. Implications are derived for regional social governance.

1. Introduction
The potential for the design and implementation of regional social policies in general (Deacon et al. 2010), and for new health policy initiatives in particular, is often argued. The regional level is thereby seen as a source of progressive policy-making, complementing or substituting national levels, which are perceived as underperforming. While we recognize that especially in cases of border-crossing health issues (communicable diseases, migration-related health issues, etc.) regional health policies are to be recommended, we argue that the linkage between international/regional and national policy levels is not uni-directional. While in some instances the regional level may indeed take the lead in the promotion of (the right to) health, in other instances it may well be the other way round. In this article the latter instance will be closer looked at in the case of Colombia. We show that while there is a potential for regions to promote health, in practice, regional and other international economic rules do not necessarily work in that direction (except courts), so that national institutions (mostly courts) have to step in and protect the right to health in the absence of regional balancing policies.

After a contextualizing section on the protection of the right to health (section 2), the influence of international and regional economic rules with different degrees of binding character will be analyzed, as well as how the Colombian Constitutional Court (CCC) has referred to the tension between the promotion of free trade and the enforcement of the right to health (section 3). We will first refer to the effects of IMF-supported structural adjustment on the health sector³, and then to the rules derived from the signature of free trade agreements with the US in 2006 (US-FTA) and the EU in 2012 (EU-FTA). In section 4, we analyze international property rights (IPR) issues and the role the Andean Community (CAN) has (or has not) played in this balancing exercise. Section 5 concludes.

2. Contextualizing the protection of the right to health

International level
The concept of the international human right to health is a framework for States seeking to promote health care, in accordance with their economic resources and cultural mores (Kinney 2001:1458). The most important international treaty recognizing the right to health is the Universal Declaration of Human Rights (UDHR) of 1948 (25) and the International Covenant on

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Economic Social and Cultural Rights (ICESCR) (12) developed the right to health further. The UN also created specialized institutions, such as the World Health Organization (WHO). At the level of the Organization of American States (OAS), the San Salvador Pact (10) recognized health as a public good (Kinney 2001:1460-2).

The ICESCR Committee adopted General Comment 14 which defined the international right to health. It required the national health systems to be institutionally capable to realize this right, which includes “the availability, accessibility, acceptability and quality of needed health care services and facilities”. It defined also the obligations of the states as the duties of respect, protection and fulfillment. In addition, the violation of the right to health was defined as the unwillingness “to use the maximum of its available resources for [its] realization”. Concerning the duties of fulfillment, the “failures of state parties to take necessary steps to ensure the realization of the right to health”, i.e. failures in recognizing the right to health mainly by legislative way, complemented with policies focused towards vulnerable groups, were seen as concrete violations (Kinney 2001:1467-71).

This General Comment specified also that concrete and immediate obligations are the exercise of the right without discrimination, the establishment of concrete steps in its full realization, and the rejection of regressive measures. It defined the minimum core obligations: (i) “the access to health facilities [...] on a non discriminatory basis”; (ii) “the access to the minimum essential food [...] to ensure the freedom from hunger to everyone”; (iii) “the access to basic shelter, housing and sanitation [...] and potable water”; (iv) the provision of “essential drugs” defined by the WHO; (v) the guarantee of an “equitable distribution of all health facilities”; (vi) the adoption and implementation of “a national public strategy [...] addressing the health concerns of the whole population”, particularly of the vulnerable population.

Although the aim is that the right to health be the same worldwide, the definition of the content, implementation and enforcement of the international right to health is not yet a concrete binding rule (Kinney 2001:1467-71). Therefore, the enforcement of the right depends on the concrete economic and cultural framework of each country but the promotion of “universal outcome measures” seeks to evaluate its implementation with the help of human development indicators to monitor the compliance of state duties. IMF programs have generally been signaled as an important obstacle in their implementation (Kinney 2001:1472-4).

The scarcity of resources imposes rationing and the need to make (equitable) choices about the type and amount of health services necessary to reach an adequate level of coverage (Gilain 1995:4; Kinney and Clarck 2004:289; Castaño 2006:3). The cost and management of health care depend therefore on the level of development and the budgetary restrictions, the latter also being the main obstacles to consider the right to health as an absolute fundamental right (Viseur 2001:S201).

A related issue is the competition between individual and collective rights because when the right to health is considered from an individual perspective, budget restrictions are ignored. The collective level instead involves the concept of distributive justice, because less favored social groups need more support from the State, although in many cases, the best organized groups are those who profit from the mechanisms to protect social rights and obtain a large share of the budget. When the individual right to health has an absolute character, a “de facto” rationing occurs at the cost of less favored people (Castaño 2006:17-8). Therefore, these choices should best be made via a democratic process, and the intervention of the judiciary is suitable only in case of possible violations of those general decisions (Cobbaut 1996).

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4The States should provide universal primary health care, universal immunization, prevention and treatment of endemic occupational and other diseases and special protection of most vulnerable groups.
At the national level, a general trend has been the progressive constitutionalization of the right to health. Kinney and Clark (2004:290) distinguish five types of provisions that address health care in national constitutions: a *statement of aspiration*, of *entitlement*, of *duty*, a *programmatic* statement, and a *referential* statement to international or regional human rights treaties that recognize the right to health. They found that, first, the main constitutional provisions worldwide, containing rights and obligations, aim at a healthy environment and workplace, the protection of the right to life and to promote general welfare. Second, 67.5% of the constitutions worldwide include provisions addressing health care. However, many countries that spend important resources on health do not have relevant constitutional rules regarding this right. In countries with the highest *per capita* government expenditures for health care only three out of 16 have constitutional health duties. Third, no correlation was found between the intensity of constitutional commitments and the government expenditures for health. The importance of legal remedies as access to courts and the opportunity to challenge policymakers who fail to enforce constitutional mandates also varies across countries. And fourth, legal actions do not necessarily provide enough protection of individual rights and they are not the best option to obtain health care because when judges adjudicate in this sense, they become policymakers in an environment of scarcity. The study concluded that policy duties created by the constitution and international human rights treaties are standards to evaluate the performance of governments in the realization of the ESC rights. Court intervention by providing *solutions* for governmental failures in the enforcement of rights is limited by budgetary restrictions which determine the realization of a satisfactory level of health care (Kinney and Clark 2004: 291,296,300-301).

**Andean Community (CAN)**

As early as 1971, the Andean Health Organism (ORAS-CONHU)\(^5\) was created as an intergovernmental institution, with the participation of the health ministries of Bolivia, Colombia, Chile, Ecuador, Peru and Venezuela, seeking to develop coordinated actions to grant the right to health.\(^6\) In 1999, the Andean Social Charter sought to find a compromise among member states on the universalization of all rights, including ESC rights (5). The social charter promoted the non-privatization of the basic health services (103), the use of traditional medicine (14), and the international cooperation in the prioritization of health programs (106). In 2012, the Andean Parliament sought to give it binding character, but until now it remains a declaration of intentions.

Although, for the time being, the most relevant regional rules on health remain the ones of CAN, we should not be blind for the fact that CAN has institutionally been affected by the signature of FTAs by Colombia and Peru because of a number of prior reforms required by these countries for this purpose (Helfer and Alter 2014). CAN member states have also been working with Mercosur and OTCA\(^7\) to develop a South-American agenda\(^8\) which is mainly being conducted by UNASUR. It remains to be seen, however, what will be the scope and impact of these forms of regional cooperation (Ortíz et al 2011). The weakening of Andean institutions can therefore be considered as a threat to the enforcement of the right to health.

Decision 598/2004 revoked Decision 322/93 in order to allow FTA negotiations by member-states with third countries. In principle, these FTAs had to preserve the Andean legal system and take into account the commercial sensitivities of the other member-states. Member-states

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\(^5\) *Organismo Andino de Salud Convenio Hipólito Unanue.*  
\(^6\) Argentina, Brazil, Cuba, Spain, Guyana, Panama, Paraguay, Uruguay and Dominican Republic participated as observers.  
\(^7\) Amazonian Cooperation Treaty Organization, whose member states are: Bolivia, Ecuador, Colombia, Peru, Brazil, Venezuela, Guyana and Surinam.  
\(^8\) The mains issues treated were the Andean epidemiological profile, universal access to medicines, the management of human resources in health, and the universalization of health systems.
should consult and inform the CAN Commission on the progress of such negotiations and respect the principle of the Most Favored Nation (MFN).

These reforms influenced health policies as follows: First, the Andean Tribunal of Justice (ATJ) has clearly ruled that CAN law is binding for the member states, including for international treaties signed by them. In particular, it held that the patent registration of proof data for medicines would threaten free competition but also the right to access to medicines because it may be a way to extending patents (Ruling 114-AI-2004 (08/12/2005), quoted by Uribe 2007: 115). However, this position was reversed through Decision 632/06 which interpreted Decision 486/00\(^9\) (266) and left each member state the choice whether to protect the proof data, including by preventing third party commercialization based on proof data information. This reform to the Andean IP system sought to validate the mentioned regulation of the Colombian government concerning the exclusive protection of test data rejected by the ATJ (Helfer and Alter 2014). The protection of proof data was also included in the FTA with the EU (231), which is seen as an obstacle for the production of generic medicines (Wolfran 2011 quoted by Saura 2013).

Second, Decision 689/08 modified Decision 486/00, a reform strongly opposed by Bolivia which challenged the new decision before the ATJ.\(^{10}\) This reform was proposed by Peru to ease negotiations of the FTA with the US and was justified by the fact that member-states may develop some IPRs through national legislation, seeking an equilibrium in a context of socio-economic asymmetries, and to complement the protection of IP according to multilateral standards. This Decision 689 gave a peremptory term (until 08/2008) to member-states to communicate to the CAN General Secretary the will to apply this decision which mainly allows the following: a) to extend the deadline to vindicate the right to priority\(^{11}\) up to two months; b) to request additional specifications in the description of the invention so that undue experimentation is not necessary for its realization (28); c) except in the case of the pharmaceutical patents, to create ways to compensate the owner of a patent for unreasonable delays\(^{12}\) of national authorities in the registration of the patent (Ch. V); d) the establishment of the *bolar clause*, i.e. member states may authorize the use of protected materials by a patent to generate the needed information to support the application to commercialize a product (53); e) the establishment of a multiclass register of trademarks (138) and a regime of border measures for trademarks of products in transit (Ch. III), while leaving it optional to register the licensing contract for the use of trademarks (162); f) to authorize the non-proceeding of the declaration of the protection of an appellation of origin when it may create a confusion with a trademark that has already been filed or registered with good faith or with a well-known trademark (202). However, this decision clarified that member states should promote and protect the certification of origin from other member states.

IP has been a highly relevant issue inside CAN. The binding character of the regulations is not in discussion, and all the national powers are due to apply it, including the judicial branch. The preliminary ruling is often used by national tribunals of member-states, and as a consequence, rulings of the ATJ are part of the legal system. Helfer and Alter (2014: 247-248) found that in 2007 IP preliminary rulings of the ATJ represented around 97% of their total preliminary rulings and Colombia is recognized as the most active member of the Andean Community in IPR

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\(^9\) It establishes the common regime on industrial property and its adaptation to the compromises adopted in the TRIPS agreement of the WTO.

\(^{10}\) However, in 2013 (ref 01-AN-2010) the ATJ ruled that Decision 689 does not contradict the common regime of the CAN (Decision 486) because it is a ‘Decision 486+’ scheme, this is, Decision 689 reflects the minimum criteria that may be complemented by national legislations of member-states.

\(^{11}\) The scope and effects of the right to priority are those provided in the Paris Convention for the Protection of Industrial Property (9).

\(^{12}\) These are: more than 5 years since the application filing date, or 3 years since the filing data for the patentability examination.
international expenditure has priority in the development plans and budget must be in line with the ESC right. Legal reforms aimed at putting in place a market-based scheme and at creating a competitive system that would supply efficient health services for the whole population. Before 1993, the Colombian health system was composed of three sectors: the public sector aimed at the population not included in the social security system and representing approximately 70% of the population; the social security system covered 15%; and the remaining 15% used private providers. The system was characterized by low coverage and access to services; 45% of urban population and 80% of rural population did not belong to any insurance system (Escobar and Panopoulou 2003:657).

In 1991, the new Constitution included a detailed regulation and protection of the right to health: First, weak population groups (children, elderly, disabled) receive special protection. Second, the legal nature of the social security is that of an obligatory “public service”: health services (promotion, protection and recovery) have to be supplied under the regulation of the State (i.e. by accomplishing the principles of efficiency, universality and solidarity; by regulating and monitoring the private health sector; by defining the competences of the levels of government and the private sector; and by setting the parameters for providing basic services to the whole population). Third, social expenditures (including health) have priority except in cases of war or for national security reasons. The corresponding investment budget cannot be lower than the budget of the previous year, as a percentage of the total budget.\(^{15}\)

Despite these parameters that place Colombia at the vanguard in Latin America, universal coverage is far from being achieved. The economic crisis at the end of the nineties contributed to the continuously rising deficit of the health sector. The decentralization model has presented some failures such as delays in the payment of intergovernmental transfers partly caused by the complexity of the system of resource allocation, together with the lack of clarity in the distribution of responsibilities among the levels of government (Lizarazo 2001; Gaviria et al. 2006; Acosta et al 2005). The social security reform of 1993 aimed at contributions that would be sufficient to maintain the whole system and protect the right to health for everybody. But in

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14 http://www.portafolio.co/economia/can-ordena-colombia-reverse-arregla-instructivo-patentes
15 The Constitution also establishes that the general welfare and the improvement of the quality-of-life of the population are social goals of the State and therefore, social expenditure has priority in the development plans and public budgets. This rule also applies to territorial entities when spending intergovernmental transfers.
practice, subsidies to the supply side continued, doubling the expenditures and affecting the coverage of the poorest population through the subsidized demand system and increasing the inefficiency of public hospitals (Acosta et al. 2005).

3.1 Judicial protection of the right to health

Provided that ESCR have the status of constitutional rights in Colombia, the CCC has been transforming their nature and scope by considering them as fundamental rights and, as a consequence, the State should guarantee them in an immediate way, in strong contrast with the traditional approach that considers them rather as goals of the State whose obligations are of progressive compliance. ESCR have been qualified as the cornerstone of the legal reasoning of the CCC and, among them, the right to health represents the paradigm of judicial protection of ESCR (Cepeda 2004:617).

Constitutional interpretation extended the use of the Action of Protection of Constitutional Rights (APFR) (or tutela action), foreseen only to protect civil rights and liberties (86), to constitutional ESCR when they "become fundamental by connection", when they are "fundamental in and of themselves" (e.g. the rights of children or to elementary education), and when it is necessary to preserve a "dignified subsistence or vital minimum" (Cepeda 2004:618). Following the general understandings at the international level, the CCC also admitted that those rights have an "essential, non-negotiable nucleus that may not be restricted" and another part of progressive fulfillment defined by law, i.e. ESCR become fundamental when their disregard may affect the dignity of a person and should be fulfilled immediately, including by judicial means (Cepeda 2004:617-42).

The enforcement of the right to health through the APFR is accepted by the CCC when the right to life and/or personal integrity is threatened. This sort of constitutional adjudication is accused of regulating this sector through the APFR, because the CCC applies directly the Constitution where the Congress has not yet regulated the scope of ESCR (Arango 2001, 2002; Cepeda 2004; Uprimny 2002, García and Uprimny 2002). The Court based its competence on the constitutional open model of fundamental rights and in the name of the effectiveness of rights, creating a large judicial liberty without the duty to respect precedents (García and Rodríguez 2001:453-4).

The justiciability of the right to health has led to discussions related to the distribution of competences to delineate the scope of those rights, and the difficulty, from the perspective of budgetary programming, to comply with judicial orders immediately, but also from the perspective of citizens, because they are forced to compete to obtain certain social services. The Court argues that if the State does not allocate fiscal resources to supply basic needs, the judicial power can intervene because the protection of ESCR is one of its main functions in view of reaching the objectives of the Legal Social State (Cepeda 2004).17

This approach has been strongly criticized arguing that the Court ignores the economic effects of their rulings. Economic authorities consider ESCR as a goal of the State so its duties can be limited, even if the judiciary orders its provision. The availability of public resources to provide health services is a necessary pre-condition, as well as the payment of taxes or fees, or the fulfillment of certain administrative procedures. They reject that the CCC has ordered to supply services to people who did not respect legal or contractual requirements by ruling without an explicit constitutional competence and creating new budget allocations (Palacios 2001:6). These cases have been impacting the growth of public expenditure, which may produce distorting

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16 The aim is to avoid human situations in extreme poverty. The "vital minimum" is defined as: "whenever the minimum subsistence conditions are not satisfied, and urgent or stringent circumstances exist, persons are entitled to demand positive actions by the State to fulfill their unresolved basic needs, even if that entails public expenditure" (Cepeda 2004:698. See also ICJ 2008).

17 A synthesis of the case law evolution on ESC rights is presented in López (2008:21-3).
effects for social policies oriented towards the poorest population (López O. 2001; López 2000: 119-24).

In the period 1992-2006, the APFR case law on ESCR was more important than the case law on civil and political rights (for which the action was conceived by the Constitution). ESCR implying a provision of a service ("welfare rights") represented 76% of the total APFR case law on ESCR, and most of them were conceded (García and Saffon 2007).

The periodical monitoring of the compliance of Colombia with the duties derived from the ICESCR in 2008\(^\text{18}\) showed the subjective appreciation of the government. It presented several legislative and administrative acts even if they were not directly related with concrete progress in the realization of ESCR. Constitutional case law was mentioned as a step forward in the compliance with the obligations of the ICESCR, notwithstanding the government criticizing strongly these rulings when it reported on compliance with IMF arrangements. But despite the economic constraints and criticisms, Colombian constitutional case law seems to follow the international guidelines of the ICESCR.\(^\text{19}\)

3.2 Structural adjustments and the right to health

Colombia followed a structural adjustment program under the parameters of precautionary arrangements with the IMF (1999-2006). The health sector was included in it mainly by freezing intergovernmental transfers earmarked for health and education in territorial entities, and by restructuring the public social security system in health (mostly staff reduction and privatization).

In general, the CCC has been enforcing the constitutional principles of the Legal Social State even when it revised the constitutionality of structural reforms enacted under IMF arrangements (cf. C931/04). Judicial review sentences mostly supported the structural reforms of the sector by defending policies of decentralization and the freedom of enterprise in the provision of health services. In turn, the IMF periodical Country Reports (CR) also referred to constitutional rulings mostly as distortions of adjustment policies.\(^\text{20}\) In only very few of these references the IMF considered that the revision of economic regulations, which are "sometimes overturned", by courts were positive for building institutional trust towards the state.\(^\text{21}\) The general position of the IMF, however, was that the CCC was a factor of risk for the structural reform agenda, given its capacity to revert some of the government’s economic policies (CR04/15:4 and 14-6).\(^\text{22}\) In the same line, the Colombian Executive Director at the IMF stated in the final C.R. of the precautionary program that “the results have been underpinned by a wide range of structural reforms. In some instances either Congress or the Courts failed to support or to uphold those efforts” (CR 06/408 1-4).

Meanwhile, APFR case law continued to stick with its precedent of giving superiority to the right to health over budgetary constraints. This recognition of rights by the judiciary against some general regulations is also seen as distorting because it creates privileges for some and disadvantages for those who are not in a position to use the same methods (Castaño 2006:30). In the adjustment period (2000-6), the APFR case law represented more than 70% of total case law of the CCC and APFR case law that orders the delivery of a health service represented 30% of the total number of APFR rulings of the CCC and 22% of the total number of Court case law (including judicial review\(^\text{23}\)). The percentage of conceded rulings, that order the protection of the right to health through the supply of a health service, is almost constant: 71% on average.


\(^{19}\) See, IG (2008) and Forman et al; (2013).

\(^{20}\) Cf. CR 01/68 12-3.

\(^{21}\) Cf. CR 99/149:24 and CR 01/68:64.

\(^{22}\) Cf. also CR 01/64:3, 7, 02/15:8, 03/18:19, 11 and 42, 04/15:10:41; 04/199:10, 05/1540: 7-8, (50 MEP).

\(^{23}\) Since 2005, it exceeded judicial review case law which is the main competence of the court.
Notwithstanding, neither the IMF nor the government analyzed those rulings. Only in one opportunity the IMF highlighted that the Court had been actively ruling with direct consequences for the budget (CR 99/149) and that some constitutional case law perturbed health service financing (CR 01/68). The IMF also considered that most of the social expenditure was earmarked to subsidies to the poorest in the case of health, in contrast with other sectors (higher education, mortgages) where the middle and upper classes were mostly benefited (CR 05/1540). In the last revision (CR 06/408), once the country met the goals of the adjustment, the IMF referred to the need to broaden the coverage of social services as health.

The legislator (Law 972/05) tried to correct the generalized use of the APFR and ordered the automatic delivery of health services for catastrophic illnesses and prohibited the entities of the social security system in health to deny them to those patients. However, catastrophic illnesses have not disappeared from these judicial controversies although they are not the most important cases anymore. The drop in the percentage of those cases has been compensated by other pathologies, not necessarily affecting in an immediate way the right to life or dignity, as the Court stated in its doctrine on justiciable rights.

Rather than linking it to the business cycle, a plausible explanation of these numbers is that it is easier to obtain subsidies this way than by following administrative procedures (Uprimny 2007). Some organized groups (e.g. pharmaceutical corporations) are accused of pushing the use of APFR to include new medicines in the Obligatory Health Package (Castaño 2006:28) as well as the Health Promoting Entities (Empresas Promotoras de Salud (EPS)) are accused of promoting the use of APFR to avoid the rationing and to report to the Public Health Fund (FOSYGA).

In fact, it is suggested that more than 95% of the APFR are presented by citizens affiliated to the social security system and therefore their rights would have a higher degree of justiciability than the rights of citizens outside the system (Castaño 2006:29). Another study found that 73% of the APFR was presented by the population covered by the contributive regime and 3% by the population benefiting from the subsidized regime (Procuraduría 2008:171; see also Clavijo and Torrente 2008:18).

The generalized use of APFR has been considered as being responsible for systematically increasing medical costs due to the “jurisprudential” enlargement of the Obligatory Health Package (Clavijo 2009:23; Carrasquilla 2008:20-4). The Council of State deciding Popular Actions, held that these delays in the reimbursement to EPS affected the provision of health services as a collective right and it held that the cumulated surplus of FOSYGA at the end of that year should be used to enlarge the coverage of the subsidized regime in the following year.

Despite the impact of constitutional case law on the enforcement of the right to health, universal coverage of good quality is not yet being granted through general regulation (Procuraduría 2008:171, 179; López 2008:45). Health care coverage increased from 28% at the beginning of the 1990s to 86% in 2006, of which the coverage of the subsidized regime increased from 12.4% to 46% and the one of the contributory regime grew from 13% to 40%, figures that have been interpreted as showing growing informality in the labor market (Carrasquilla 2008:3, Clavijo 2009:17).24

The legislator took again measures (Law1122/07) by increasing the employer’s contributions and created incentives to ESP to solve the complaints without the need for a judicial ruling (Clavijo 2009:23). However, ruling C463/08 decided that incentives established for cases of high

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24 In 2005, the drop in the number of affiliations to the contributive regime contrasted with the good economic performance. The evasion, supposed to be caused by the informality of the economy, pushes public expenditure in health (Lozano et al. 2007:17).
cost illnesses should be extended to all claims out of the Obligatory Health Package from both regimes (subsidized and contributive), which enlarged the subsidized Health Package (Procuraduría 2008:164).

But the most relevant constitutional adjudication has been ruling T860/07 considered as a real “judicial statute” on the provision of health services in which the CCC ordered the government to take measures to eliminate the “regulation failures” of health programs and, to assure its integral updating, the unification of both regimes and the appropriate and efficient provision of the service. More surprising was Annex II of the ruling where the Court, seeking “constitutional pedagogy”, quoted many international instruments to protect fundamental rights which “allow to state that the right to health is fundamental” and emphasized that the goal of universal coverage is to be reached. Ruling T760/08 apparently had an important effect because the number of APFR drastically reduced in 2009-10; however its use again increased by 12% in 2011 (Lamprea 2013:23).

A new legal reform (Law 1438/2011) sought to discourage the use of APFR for seeking health services and imposed more administrative mechanisms to follow claims together with a system of fines to entities that obstruct service provision. However, this law did not comply with the parameter of T860/07 and therefore, the government had to present a new bill, strongly opposed by interest groups (ESP, medical and pharmaceutical sectors and faculties of medicine). T860/07 served also as framework for the Statutory Law of the constitutional right to health enacted in 2013, which is being analyzed before the CCC.

Although the Colombian constitutional case law is not the only case of justiciability of ESC rights in the world (ICJ,2008:65-9), a recent study put in perspective the relevance of this case by showing that Colombia is the middle-income country “with the highest per capita rate of right to health litigation” with 3289 legal actions per million of persons, followed by Brazil (206), Costa Rica (109), Argentina (29), South Africa (0.3) and India (0.2) (Ottar et al 2011, quoted by Lamprea 2013:22).

3.3 New generation FTAs and the right to health

The Colombia-US FTA (2006) (Garay et al. 2011: 137-65) is the most relevant FTA from the perspective of constitutional case law, as it served as a precedent for subsequent constitutional assessments of FTAs, including the Colombia/Peru-EU FTA (2012). Concerning the right to health, the tensions between FTAs and human rights with both the US and EU have been related with IPR. These tensions have been denounced worldwide, pointing to possible negative effects of the implementation of the FTAs on the right to health.25

Although this should be a policy discussion, in Colombia the judiciary has again been highly active in the analysis of these issues, particularly in the case of the US FTA: during the negotiations through the popular actions and by means of the automatic preventive constitutional control of the statute approving the FTA by the Congress.26 Initially, the Administrative Tribunal of Cundinamarca (05/12/2005) did not allow the President to sign the FTA because it would violate collective rights; some IPR issues as the protection of test data, the extension of patents or patents for new uses of medicines that are already patented, would violate the right to health (i.e. the right to access to medicines) (Suarez and Rincón 2007: 149). This ruling was set aside by the Council of State which rejected the popular action27 based on the lack of competence of the administrative jurisdiction to control the negotiations of international

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25 E.g. Médecins sans frontières (2004); Zerda et al. (2005); Malpani and Bloemen (2009); Nasu (2010).
26 See Lizarazo et al. (2014).
treaties, which is an exclusive competence of the President. Another popular action against
the signing of the Colombia-US FTA\textsuperscript{28} was rejected with the same arguments.

The CCC has systematically upheld all recently signed FTAs. However, it ruled that the abstract
costitutional analysis of FTAs is not concrete judicial review because there are no factual
elements, which can only be determined when the FTA is enforced. Therefore, the authorities in
charge of the execution and enforcement of the FTA are constitutionally bound and their acts are
subject to administrative and/or judicial control. This means that the preventive constitutional
control is an \textit{a priori} ruling without a \textit{res judicata} effect because the effective constitutionality
control should be realized in the enforcement. Constitutional competences of national
authorities to control the execution of the FTA remain therefore unaltered as well as the use of
constitutional actions to protect fundamental rights, i.e. if the application of the FTA violates
fundamental rights, it can be challenged, which seems not totally compatible with the principle
of \textit{pacta sunt servanda} and with the intention of the Constitution whose preventive
constitutional revision sought to protect this international law principle.

Constitutional case law of FTAs had a strong focus on human rights (Lizarazo et al. 2014), with
particular reference to the right to life and the right to health. First, Sanitary and Phytosanitary
(SPS) measures were upheld because they sought the protection of health in accordance with
international treaties (e.g. WTO-SPS measures) and with constitutional regulations (consumer
protection, right to a healthy environment, duty of the State to provide public health services,
protection of the environment and food production). Second, IPR where linked to the binding
commitments concerning public health, biodiversity, traditional knowledge and the duty to
adhere to some pending international conventions besides the international framework whose
main parameters are the TRIPS of the WTO, the WIPO (World Intellectual Property
Organization) treaties\textsuperscript{29} and CAN regulations. As a result, patent registration should be subject to
these international commitments.

The CCC emphasized the potential and actual impact of IPR on fundamental rights and therefore
it held that FTAs should be enforced and interpreted according to the Constitutional Bloc\textsuperscript{30},
particularly regarding the right to health, the right to a healthy and diverse environment, and the
social goals of the State. Against the arguments in favor of setting aside the US FTA, the CCC
explained that FTAs are instruments for the enforcement of the cited rights: (i) the parties may
adopt measures to protect public health by promoting universal access to medicines, according
to the DOHA Declaration on TRIPS and public health (Cf. T1123/05 on generic medicines); (ii)
the mechanisms to avoid unjustified delays in the recognition of patents as compensatory
measures for non-pharmaceutical products, seek to comply with the constitutional principle of
administrative efficiency; (iii) the application of TRIPS mechanisms of flexibility in case of
national (health) emergency (by granting compulsory licenses and import medicines without
the authorization of the holder of the patent), is a way of balancing general interest with the social
obligations of IPR; and (iv) Colombia keeps the competence to decide how it will comply with
these duties, highlighting that in any case the right to health has a higher hierarchy than IPR.
These competences include the possibility of excluding the patentability of inventions to protect
higher constitutional or international interests as health, life of living organisms and the
environment.

Recent rulings of the Court have been putting these parameters in practice. First, ruling
C1051/12 struck down the highly controversial approval Law 1518/12 of the International
Union for the Protection of New Varieties of Plants (UPOV 1991) because it did not previously

\textsuperscript{28}Council of State: Ruling AP 25000-23-25-000-2003-00136-01 (AP) of 01.03.2007. The national pharmaceutical
industry asked the exclusion of multinational pharmaceutical companies from the negotiation of the FTA with the US.

\textsuperscript{29}http://www.wipo.int/treaties/en/

\textsuperscript{30}It is formed by the main international treaties protecting human rights and the International Humanitarian Law
together with the Colombian Constitution.
consult the ethnic minorities, and not because it violated the right to health. This convention was accused of contradicting CAN regulations (Decision 486/00 (15 (b), 20 (c)) and 345/93) 31, because -being one of the conditions of the US FTA-- it enlarges the possibilities of patent registration on living beings and allows the extension of a patent in case of administrative delays (Uribe 2007: 110-3). 32 Second, ruling C350/13 conditioned the application of approval Law 1515/12 of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure to the respect of some constitutional principles as the duty of the state and its citizens to protect the national natural and cultural resources, the ecological function of property, the competence of the State to regulate the import, export and use of genetic resources and the competence of indigenous councils to protect natural resources in their territories. This ruling analyzed the CAN regime (Decision 486/00(29)), which made reference to the Budapest Treaty of 1977 but not to the regulation of 2002.

4. Right to health versus IPR, and the role of regional integration

One of the most mentioned conflicts between human rights enforcement and international trade conventions, is the enforcement of the right to health in the presence of strict measures to protect IPR. It is thereby usually argued that human rights law is still soft law and that it lacks sanctioning measures in case of non-compliance (Crook: 2005:538; Van Hees 2004).

According to General Comment 14, the access to medicines is a component of the right to health, in turn linked to the right to life (Eli 2003). The Doha Declaration on TRIPS and Public Health of 2001 33 sought to flexibilize TRIPS enforcement in cases of public health crises (access to medicines) in developing countries. This declaration has been largely defended as a way to balance both rights from a legal and economic perspective and to make their enforcement possible. This is, balancing incentives for the production of IP (pharmaceutical subsidies or public funding to promote innovation) with the promotion of its widespread use (flexibilization of patent regulations in developing countries, e.g. by issuing compulsory licenses or by importing generic medicines) (Posner 2005, quoted by Crook 2005: 545, 550).

In the "Special 301" Report 34 the USTR refers to this conflictive relation between IPR and the right to health. It states that following the Doha Declaration, the US recognizes the right of trading partners to protect public health (especially the generalized access to medicines) but without forgetting that the patent system is crucial for the "creation of new and innovative lifesaving medicines" (USTR 2013:22). In addition, it also respects the right of trading partners to grant compulsory licenses but on the condition that IPR systems remain respected. Balancing is accepted when the US government recognizes “compulsory licenses to export pharmaceutical products to countries that cannot produce drugs for themselves” while at the same time the USTR should seek to “reduce market access barriers that US pharmaceutical and medical device companies face in many countries” (USTR 2013:23).

The FTA signed with the EU has even been more controversial. The initial text of this agreement was accused of strengthening IPR with negative consequences not only for the public health of the trade partner but also for free competition. Some initial assessments found it stricter than other FTAs, closer to EU legislation, and without the flexibility accorded in the TRIPS and the Doha Declaration (Ifarma and Fundación Misión Salud 2009; Seuba 2009: 65-8). The final

31 In another case, where CAN regulations were in conflict with approval Law 443/98 of the Patent Cooperation Treaty, ruling C246/99 was challenged because the CCC did not request a preliminary ruling from the ATJ on the application and scope of the communitarian regime in this respect. The CCC rejected the challenge because constitutional control does not refer to controversies concerning communitarian rules that do not belong to the Constitution or to the constitutional bloc (A036/99).
32 The FTA with the EU also refers to UPOV 1991 (Seuba and García 2010; Wolfran 2011, quoted by Saura 2013).
33 http://www.who.int/medicines/areas/policy/doha_declaration/en/
34 This refers to the annual global review of IPR protection and enforcement by the Office of the US Trade Representative (USTR).
The version of the EU FTA appears more adequate because its enforcement should respect the general interest, which may be related with the enforcement of the ICESCR. There is also a special reference to the Doha Declaration as an interpretative parameter for public health issues. In addition, it recognizes the relevance of the protection of traditional knowledge and a just distribution of resources generated by the use of genetic resources (Seuba and García 2010). These improvements in the final text were partly attributed to the lobbying by NGOs but also by national Ministries in Peru and Colombia, which supports our hypothesis that the national level is the one that is trying to enforce the right to health instead of the regional one.35 Despite these improvements, the EU FTA remains ‘TRIPS plus’, and the rules of observance seems to be stricter than the ones of the US FTA (Seuba and García 2010). One relevant negative issue for public health is that Colombia and Peru are supposed to find the way to compensate administrative delays to patent register (Seuba and García 2010), even if Decision 689/2008 of CAN excluded this possibility for pharmaceutical products.

A study of UNDP-UAIDS (2012) concluded that the advantages of TRIPS-plus protection in new generation FTAs as a way to increase foreign investment and/or innovation have not been fully demonstrated, and on the contrary, alerted about its possible detrimental effects worldwide. The main TRIPS-plus provisions that were identified as potentially threatening access to medicines were: 1. Broadening Patentability or the evergreening of pharmaceutical patents, i.e. the registration of new forms and new uses of known substances to extend the patent by modifying the molecules which “do not significantly improve the therapeutic effect of medicines”. 2. Restricting Patent Oppositions, seeking to avoid “patent applications that do not fulfil the requirements in national legislation for granting the patents”. 3. Extending Patent Duration beyond the 20 years at the cost of the use of generics. 4. Introducing Test Data Exclusivity and a Patent-Registration Linkage. 5. IP Enforcement Requirements, e.g. by seizing essential medicines in transit.

Returning to the Colombian case, between 1995 and 2010, patent applications increased by almost 52% with a notorious relevance of the pharmaceutical sector and other related sectors of medical devices. It is also the country that has the largest demand for trademarks in CAN, with pharmaceutical and other medical related marks prominently present (Ramírez 2012:31-3).

This evolution should be linked with the one of pharmaceutical expenditures in times of crisis in the health sector. In the period 2006-8, public expenditure on pharmaceuticals represented 1.3% of GDP, which drastically increased to 3.2% of GDP in 2009 (Andia 2011, quoted by Lamprea 2013:28). This situation was mainly explained by the deregulation of pharmaceutical prices by the government in 200636, which together with the high individual use of APFR has provoked a strong pressure on the financing of health services: “(...) the Constitutional Court’s precedent on the right to health is practically devoid of cases that address the constitutionality of the across-the-board deregulation of pharmaceutical prices that has caused a great fiscal havoc within the health sector” (Lamprea 2012:28-32).37

In 2012 the government overturned this regulation and regulated the price of 195 medicines, taking as a reference a basket of international prices.38 The government is now preparing a new list of 900 medicines whose prices would be controlled39, which –according to some observers--

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35 On the rights based approach to IPR and the relation with the right to health, see Narula (2011a,b).
37 In addition, it was estimated that TRIPS-plus provisions in the US-Colombia FTA would heavily increase expenditure on medicines by 2020, possibly provoking a drop in medicine consumption by 40% (Gamba 2006, quoted by UNDP-UAIDS 2012:4).
38 Circular 04/2012.
39 http://www.eltiempo.com/vida-de-hoy/salud/ARTICULO-WEB-NEW_NOTA_INTERIOR-13586156.html
could be considered as an additional argument to be kept in the Watch List\textsuperscript{40} of the Special 301 report of the US\textsuperscript{41} as occurred in 2013, despite the progress in implementing the FTA. The reason is that there are still some pending commitments, related mainly to trademarks, but it expresses also some concerns regarding "an overall lack of adequate resources and training for enforcement officials" (USTR 2013:46).

Related to the latter point, technical assistance and training of WIPO on IPR is also targeting the national judiciary. In Brazil, they are actually being trained with the support of the local industry, whereas the US Department of State is also promoting training of judges in Latin America (Abbott 2007:12). In Colombia, training has also been organized for Superintendency (SIC) officials (Ramirez 2012:31-3). Although this could be positive, it could also incline the balance in favor of IPR, at the cost of ESCR, which are currently highly protected by some Latin-American courts, including the Colombian.

4. Conclusions

Our hypothesis that the protection of ESCR, and more concretely the right to health, depends mainly on the will and capacity of national (judicial) actors to give binding character to international and constitutional rules and to address policy failures, has been supported by the empirical evidence from the Colombian case, where rights-based judicial adjudication has been crucial.\textsuperscript{42} Evidence also suggests that these national actors are only directly supported by the UN, which is highly committed to the universal enforcement of ICESCR.

From the case study on IMF-supported structural reforms, it appears that the government accepted adjustment policies even if they are not respecting the duties of the State concerning ESCR, whereas the CCC is systematically enforcing ESCR even in times of budgetary crises and going against governmental policies. From the case study on FTAs, it appears that the new generation FTAs are mainly seeking to strengthen the position of IPR holders mainly by an enlargement of the TRIPS and a progressive weakening of the Doha Declaration on Public Health (UNDP-UNAIDS 2012; Roffe and Spennemann 2006:85-6). Although the CCC has unanimously upheld all the FTAs, it also held that its automatic control of constitutionality is an \textit{a priori} revision without a \textit{res judicata} character, promoting this way the use of constitutional actions against rules that would enforce FTAs when they violate the Constitutional Bloc. But when potential retaliatory measures against Colombia for not complying with an FTA would be proposed, will human rights rules be considered as an acceptable argument to ignore the FTA commitments?

The CCC did not systematically analyze the potential conflict between FTAs and WTO or CAN rules on ESCR issues, in strong contrast with the academic literature and political discourses. Contradictorily, it found that FTAs are constitutional because they respect WTO and CAN regulations even if it argued that the constitutional analysis of FTAs does not refer to the compatibility among international rules.

Nevertheless, we should highlight the role of the judiciary (i.e. the CCC, and to a lesser extent the ATJ\textsuperscript{43}) in the enforcement of ESCR even going against trade liberalization and structural adjustments, without a consistent backing of the regional institutions. The role of CAN in

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\textsuperscript{40}The USTR defined “Priority Watch List” and “Watch List” as categories of trading partners with specific concerns regarding “IPR protection, enforcement, or market access for persons relying on IPR”. The Priority Watch List receives an "increased bilateral attention concerning the problem areas" (USTR 2013:58).


\textsuperscript{42}See also, Narula (2011a: 25, 2011b:2-4).

\textsuperscript{43}Whose case law was not taken into account by the CCC.
balancing free trade and health principles has been marginal, despite the case law of the ATJ. The proposed training of judges on IP issues might even be seen as an attempt to control judicial activism.

The IMF structural programs have often been considered as going against the enforcement of the ICESCR. What is—in a way—curious then is that European and US human rights conditionality in FTAs refers mostly to first generation rights, not to ESCR, ignoring the potential negative effects of certain IPR-related clauses (pushed in many cases by pharmaceutical multinationals with a stake in FTA negotiations) on the enjoyment of the ESCR of the trading partners’ populations. The new generation FTAs, mainly promoted by these economic blocks, tend to restrict the flexibility of the TRIPS and the related Doha Declaration, and they have apparently also been a factor of regional disintegration in CAN by eliminating regional rules that limited IPR at the benefit of social policies of the member states.

5. References


Saura Estapà J. (2013) “Implicaciones de derechos humanos en el tratado de libre comercio entre Colombia y Unión Europea”, INDRET Revista para el análisis del Derecho.

Seuba H.X (2009) La Protección de la Salud en el Nuevo Acuerdo de Asociación entre la Comunidad Andina (o Algunos de sus Miembros) y la Comunidad Europea a la Luz de sus Disposiciones en Materia de Propiedad Intelectual y Experiencias Recientes, Lima: HAI-AIS.


