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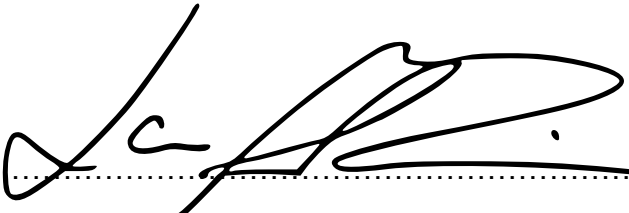
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# **A Hermeneutic of Intellectual Property Rights: Theory, Law, and Economy.**

## **Defending the Essence and Dignity of Human Rights**

**Luca Bonadiman**

### **Abstract**

*There are two opposed directions, namely the nature of the object and the ontology of law, that meet in the moment of reality of law. Intellectual Property is a particular type of object, the nature of which is difficult to adequately inquire; the inquiry is crucial for the adherence of law to the reality given as such, as well as for the socio-historical context that defines the political understanding of the object given in the form of law. Law has become incapable of thinking itself exhaustively; there are no efforts in measuring the degree of legitimacy of its assumptions. Therefore, law is the equivalent of an order issued through formally correct procedures and having the force of obliging people to its respect. Yet, the legislator shall not impose impossible commands that follow an ideal order detached from the given one. Intellectual Property does not genuinely constitute an element that its same genetic naturalness would permit to translate into juridical categories. Law is incapable to absorb Intellectual Property and the same credibility of law is at risk: it is all about force/violence of the system to impose effectiveness. The reading of the complex phenomenology of Intellectual Property Rights permits their own hermeneutic.*

# **A Hermeneutic of Intellectual Property Rights: Theory, Law, and Economy.**

**Defending the Essence and Dignity of Human Rights**

**Luca Bonadiman**

Supervisor: Prof. J. Klabbers

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## ABBREVIATIONS

ACTA	Anti-Counterfeit Trade Agreement
CAMR	Canada's Access to Medicine Regime
DCs	Developing Countries
DD	Doha Declaration
DVCs	Development Countries
EC	European Community
ECHR	European Convention for the protection of Human Rights
ECtHR	European Court of Human Rights
ECJ	European Court of Justice of the European Union
EPC	European Patent Convention
EU	European Union
FDIs	Foreign Direct Investments
FTAs	Free Trade Agreements
GATT	General Agreement on Trade and Tariffs
GDP	Gross Domestic Product
GPCs	Generic Pharmaceutical Companies
HRs	Human Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IMF	International Monetary Fund
IP	Intellectual Property
IRPs	Intellectual Property Rights
LDCs	Least Developed Countries
MSF	<i>Medicine Sans Frontieres</i>
NAFTA	North America Free Trade Agreement
NGOs	Non-Governmental Organizations
PHCs	Pharmaceutical Companies/Corporations
R2P	Responsibility to Protect
R&D	Research & Development
TNCs	Transnational Corporations

TRIPS	Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Program
US	United States
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

## PREFACE

**a** § Words make violence to ideas. Words reduce and often even betray ideas. The verbalization of ideas constitutes the main difficulty that the writer has to face. Academic Researchers have been increasingly engaged in data-production and data-organization. Almost anything can be eligible for falling into the subject matter of “data”. However, the Academia should be equally concerned in studying such data; the purpose cannot be the one of providing some sort of interpretations since interpretations are equal to opinions: everyone can advance an opinion. Indeed, this is an immediate and superficial re-action of the rationality. Furthermore, it is often deviating the attention from the very important point under discussion. As it is evident, most of the discussions, not only academic but also political, are focused almost exclusively on the *content* instead of the *dynamic* of a certain issue. Not surprisingly, the same is true for Intellectual Property Rights: they have been accepted and recognized but never seriously inquired. The efforts reveal the tendency to emphasize the content of certain norms and their justifications in the context of the present socio-economic system: no one has dealt so far with the entire and complete dynamic that has led to Intellectual Property Rights and, obviously, no effective insight is possible regarding the next future. The present work aims at delivering a comprehensive inquire of the topic of Intellectual Property: a hermeneutics of intellectual property rights that are eviscerated through the *vulnus* of the access to medicines, which is a particularly sensitive point where justifications tend to screech.

The entire structure reflects a sort of circular movement, continuously around the given subject; therefore, different study areas, usually kept carefully separated from each others, appear in this analysis very much interconnected, hiding each other to the point that the reader may be confused. Moreover, the role of the Academia should not be the one of delivering “truths” (we leave such difficult mansion to politicians and their promises) but rather the one opening non-obvious questions on that particular something appearing in the common reality. The reading of the phenomenon has to consider several different perspectives in order to maintain a high degree of coherence to the reality as such. Especially, Humanities have to pay particular attention in order to

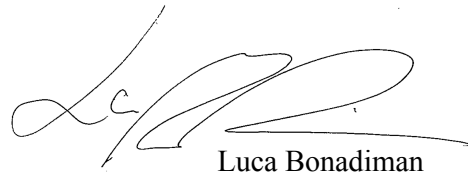


avoid falling into the trick of pretending to be Sciences just because of the followed method of analysis. The Academia should serve “the thinking”. The idea is here intended as self-revealing, accordingly to Heidegger’s theory on “a-letheia” (α-ληθεια, truth); subsequently, it is not the writer *employing* words to express his/her own ideas, but rather ideas self-revealing themselves through words. The author merely serves them. The approach of the present text is of a particular kind: the reader is continuously required to maintain a very high degree of attention linking different elements. It is a non-linear proceeding, moving all around the subject in order to get involved and absorbed in the self-revealing dynamic of the discourse in order to measure its eventual content of truth, if any. Indeed, the division of the sections is ordered using Greek letters (α-ω) precisely to give the idea of non-linearity but rather circularity, *exitus-reditus*.

It is not that relevant to develop a scientific research but more to challenge sciences themselves thinking whether they are capable of effectively individuating the problem. Actual sciences are far from reflecting the original meaning of “knowledge”; sciences are artificially produced matching two core features: (i) the pretended scientific method of structural development of a certain discourse around (ii) the given topic (*positum*) [Heidegger]. Sciences proclaim themselves scientific. The scientific character of works does not really depend by the degree of intellectuality and comprehension of reality but rather on the criteria artificially imposed by the so-called Academic Community, which is itself institutionalized within the University and therefore more focused on protecting acquired power rather than carry out the genuine work it would be supposed to do. Indeed, institutionalization implies structural and organized power: “scientific” criteria are political since they reflect power in the precise decision of admitting or excluding people and their works from the community, which is not anymore so – precisely due to such bureaucratic obstacles. In the artificiality of requirements for researching methods and drafting of conclusions, thinking is already gone, suffocated in the overwhelming structure perpetuating the intrinsic power through subliminal means. It is then evident that the crystallization of power in the restrict élite of Professors facilitates the intrusion of other power-related elements deriving from other areas: the Academia is unable of protecting itself since it is corrupted to the very depth of its own essence, the thinking is

living a crisis started a long ago and still left unanswered. There is a sort of political scheme that aims at preventing ideas to effectively challenge the *status quo*. Intellectuals are not anymore a very democratic counter power but rather a silent and efficient mean of power. This is why I selected the present topic: it better permits the understanding of the actual reality, which cannot be shown through the traditional Academic writing. The same is more and more a collage of others' analysis with marginal clarification of data.

Helsinki, 16 June 2012



Luca Bonadiman

## INTRODUCTION

“The basic conclusion (...) is that intellectual property monopoly are unnecessary”  
[Boldrin & Levine]

§ Intellectual Property (IP) and the connected regime of rights (IPRs) have become one of the major global issues along the last twenty years or so. The two categories are interrelated but not coincident. IP represent a theoretical concept, thus it is a political assertion reflecting cultural contents. Differently, IPRs have legal nature, they embody the further step in the social debate, which means that certain political ends are vehicle throughout the law; IPRs define a regime of *status*, entitling defined subjects to the enjoyment of certain rights<sup>1</sup> and binding others to prescribed duties, i.e. positive correlated obligations usually put upon states. Since the establishment of the new Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), back in 1994, IP has developed into one of the most controversial and debated topics both within Academia and in the main political *fora*. Vast literature already exists in almost every field of the sciences on the topic. It is possible to approach IP from several different points of view, which is itself clear evidence of the complexity of the subject matter. If many have spent time and effort to analyse and describe the various sides of IPRs, very few have been able to effectively define the problem as such, due to the fact that the preponderant majority of the works inquire the content<sup>2</sup> of IPRs rather than their intrinsic logic and nature. As it is common nowadays, the attention is more likely to be given to the effects<sup>3</sup> (and how to mitigate them)<sup>4</sup> instead of the causes. The type of analysis varies according to the object of it: IP

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<sup>1</sup> “(...) intellectual property rights are rights of exploitation in information (...)”. Drahos (1999), p. 14.

<sup>2</sup> “(...) disputes have raged over which works to protect, for how long, and to what extent”. Besen and Raskind (1991), p. 3.

<sup>3</sup> Even if: “The links between the incentives granted through the patent system and its broader impacts on society were only superficially addressed”. Cullet (2007), p. 412.

<sup>4</sup> “The World Health Organization (WHO) was largely absent from the TRIPS negotiations (...). A small technical group within the WHO began to prepare and distribute concrete recommendations for coping with TRIPS by using the built-in flexibility (...). Abbott (2002), p. 474. This proves the run to find remedies without even wondering whether TRIPS as a whole is acceptable.

falls mostly in the interest of philosophy or, more generally, social matters including the pre-juridical arguments in support of its legalization; IPRs, due to their juridical nature, touch upon all of the other disciplines. An enormous quantity of publications has dealt with the effects of such norms within certain fields. Whatever juridical or *para*-juridical analysis is too narrow, the legal nature of the insight smothers the potential range of such inquiry.

Undertaking the study of IP means dealing with hundreds different, and often self-contradictory, *justifications* of the present regime;<sup>5</sup> of course, justifications are necessary if the *factum* is not immediately and evidently *iustus* in itself.<sup>6</sup> As the same verb reveals, there is no need to *just-ify* something that is already *just*.<sup>7</sup> It is noteworthy to reach a better comprehension of the term *iustitia*: it is at the same time a social value and a personal virtue;<sup>8</sup> while the latter encompasses the acceptance of ethics, the former mostly relates to the political organization of a certain society and its decision upon the distribution of wellbeing and power among the members of the same. According to this mentioned logic, IP is not truly an important argument taken as such but it is crucial for what it is capable of revealing, especially when dealing with HRs. What is fundamental is thus defeating all the possible ideologies hiding political intents and unfair distributions of power.<sup>9</sup> What do IPRs protect really? The present research aims at addressing some major questions that have been unfortunately left aside in the available literature. In order to undertake such enquiry, the analysis has to be framed into epistemological and *meta-topical* perspectives based on certain assumptions:

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<sup>5</sup> “The principal justifications for references to rights in intellectual property agreements (...) arise from efforts to realize the economic and instrumental benefits (...)”. Helfer (2007), p. 980. “It seems possible to adopt a position only by a political choice: a choice which must ultimately defend itself in terms of a conception on justice”. Koskeniemi (1990), p. 9.

<sup>6</sup> See for instance the vane effort of Hettinger: “Justifying Intellectual Property” (1989). “These legal relationships between individuals, different sorts of objects, and the state are not easy to justify. This is especially true of intellectual property” at p. 31. See also Himma (2006).

<sup>7</sup> An interesting analysis is developed in “Ex Ante Versus Ex Post Justification for Intellectual Property”. Lemley (2004).

<sup>8</sup> During the Middle Age, there were four core cardinal virtues, namely: (i) *prudentia*; (ii) *iustitia*; (iii) *fortitudo*; (iv) *temperantia*. The order is not casual but rather hierarchical. The prevalence of *prudentia* is evident: it means “acting coherently to the reality after having appropriately inquired it”. It would be impossible to ensure justice without the effective comprehension of reality as such. Later on, especially during the XIX and XX Centuries, justice has become the main value, an utopia to realize politically (see Nazism and Communism), regardless the effective state of the things into reality.

<sup>9</sup> Because: “Property institutions fundamentally shape a society.” Hettinger (1989), p. 31.

( $\beta_I$ ) The world lives different and *dis-chronic* temporalities; different people and states have reached different *chronological* stages of their existence. This observation does not imply any sort of *value-judgment*, on the contrary, it simply states an objective difference not yet appropriately recognized, especially by the law. Western countries are driven by the so-called “ideology of progress”<sup>10</sup>, which is all about technological advancement. Other cultures may be more interested in what has been defined as “human development” that just marginally encompasses the modern obsession about productivity. It is interesting to wonder what faster cars and slimmer Ipads are providing to the wellbeing and the cultural progress of the human kind (that other things would not be able of delivering).

( $\beta_{II}$ ) Law has always cultural contents, which turn every juridical matters into political debates. Since most of the actual states are based on the principle of the “democratic representation”,<sup>11</sup> culture plays an incredibly important role, often underestimated due to the preference for a *functional* approach. Yet, is it functional to what? Objectives are political in nature.

( $\beta_{III}$ ) International law is one of the Foucault’s forms of *subliminal power*, it is the phenomenological evidence of a tacit struggle among different civilities. As it may be clear studying law and its nature, law has the tendency to become the *concubine* of the strongest. IPRs make no exception, the political powerlessness of states (facing a certain *input*<sup>12</sup> from the generality of the people) has – as usual in these cases – led to the “*juridi-fication*” (“*ius-facere*”, legalization) of IP. Having undefined borders IP differs essentially from tangible property and it is thus free in nature. Yet, the Hobbesian structure of states<sup>13</sup> pursues control and power, forcing what “is in nature” into rigid, politically organized, frames. Most of the elements concerning the law are simply shifted from the national to the international level, which makes them completely inadequate and unable to satisfy even the “political” intent of such norms.

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<sup>10</sup> Benjamin (1995).

<sup>11</sup> It is legitimate to ask who and what do such representatives represent. See Section C.

<sup>12</sup> Easton (1984).

<sup>13</sup> “Private [intellectual] property can be justified as a means to sovereignty”. Hettinger (1989), p. 45.

IPRs and HRs have one main feature in common: they are both self-contradictory in terms. *Intellectual-Property*, as well as *Human-Rights*, sound senseless.

(Sub  $\beta, \beta_I$ ) “*Intellectus*” means “capacity of comprehending” and it implies, as evident, such capacity; thus, one main concern is about the social justice of a system that does not consider the fact that human beings have different degrees of capacity by born.<sup>14</sup> “*Intelligere*” is the act of communicating sensible elements in the common process understanding of facts, things, and events.<sup>15</sup> This opens to a complicated philosophical inquiry, which goes back to Anaxagoras and Plato, but it fundamentally underlines the fact that the intellect is merely a faculty of the mind of comprehending/intuiting things that may be both belonging to the “world of the ideas” or to the material and concrete reality. The possession of such faculty is given by nature, the “privatization” of the systematized capacity of “*intelligere*” seems senseless because it is impossible. (Sub  $\beta, \beta_{II}$ ) Defining a certain catalogue of rights as *human*, pose the question regarding all the others: is the law as such inhuman? The answer seems positive, especially if it is recognized that the structure and the conceptual categories have an intrinsic divine derivation, at least in the Western systems.<sup>16</sup> Law is given in the power, thus it is everything but not *human*. It is built upon the assumption that human beings have to be deprived of every possible connatural power. Modern law, especially, individualizes.<sup>17</sup> One of the many paradoxes of HRs arises from this last consideration: while they would be supposed to establish the framework for a new ethic-based global community, they still operate through law, which atomizes human beings into powerless individuals.

Two highly aporetic topics clashed apparently without possible compromises. Creating such binomials is contradictory and dangerous: instead of re-thinking the regulative system of human societies, it has been preferred to establish new branches of the law,

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<sup>14</sup> In this regards, it is valuable the debate around social justice developed between Rawls (2008) and Sen (2002; 2010).

<sup>15</sup> Heidegger (1987; 2009; 2011).

<sup>16</sup> Schmitt (1998; 2003).

<sup>17</sup> See generally Agamben (2009; 2010).

which make them relative defusing the potential for real changes. Relativism is thinking's most terrible disease: if nothing is (totally) true, it automatically implies that nothing can be seen as completely false; therefore, every single fact or assertion can legitimately claim to be as closed to truth as everything else. If truth may be continuously challenged<sup>18</sup>, the same should not apply in regard of what is concretely wrong. Relativism serves the power: since nothing is true and nothing is false, the decision is finally totally arbitrary – pure exercise of force.

**Y § The History** – This second section aims at providing a historical overview regarding origins and evolutions of both IP and IPRs.

( $\gamma_I$ ) *IP history* – It would be interesting to inquire IP history but unfortunately there are no documents at all providing any form of background for such conceptual category.<sup>19</sup> While the *intellectus* has fascinated thinkers and philosophers for thousand years, the binomial IP seems to appear at the exact same time of the claims for certain rights.<sup>20</sup> The new legal category was in need of a definition, which was thus provided: traditions are simply invented<sup>21</sup> *ex post facto* in order to strengthen or provide legitimacy for the new legal regime. Paradoxically, it is first necessary to get an overview on the history of IPRs in order to better understand IP as such. The political end is canalized through law framing the content of IP as conceptual category. Lacking an independent history, IP reveals the inconsistency of IPRs and their ideological nature.

( $\gamma_{II}$ ) *History of IPRs* – The evolution of the legal category and the range of rights that it protects appears linear.<sup>22</sup> There have been controversies regarding the kinds of subject matters that IPRs should cover, the subject eventually entitled to such rights, and the organization of the power allocating rights over certain categories of people. Events, facts, and the description of the main phases of the evolution of IPRs have

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<sup>18</sup> Popper (1972; 2003).

<sup>19</sup> The term appeared along the XIX Century already within the juridical codification. See North German Confederation Constitution of 1867.

<sup>20</sup> “Intellectual Property is a generic term that probably came into regular use during the twentieth century. (...) Most definitions simply list examples of intellectual property rights (...) rather than attempting to identify the essential attributes of intellectual property”. Drahos (1999a), p. 349.

<sup>21</sup> Hobsbawm (2002).

<sup>22</sup> For an extended explanation of IPRs history see Merges and Duffy (2002), pp. 54 and following.

already been exposed in several works thus it is pointless to reproduce in details the entire spectrum of notions.<sup>23</sup> It is however appropriate to describe some turning points that have built what IPRs are today. Some authors fed the monotonous practice of dividing the history into particular ages or phases according to the angle of reading adopted. The latter effort<sup>24</sup> may impress the reader, who risks falling in the temptations of attributing prestige to a subject that does not deserve it. Surprisingly, while most pages of actual history books contain narrations of the struggle for reaching a fairer distribution of power (i.e., democracy), IPRs move in counter-tendency since they constitute the main expression of the original sovereign power, which cedes or sells monopolies in those fields not of interests of the state – or that the state would eventually have higher profits from the concession rather than administering affairs directly.<sup>25</sup> What many people understand as erosion of the economic power of states, through the handing over of increasingly larger number of monopolies, remains in substance nothing but an indirect acknowledgment and legitimatization of the constituted power. The nature of states rests the monopoly of power, thus whatever field of economic relevance that may occasionally represent an interest of the same, does not affect in any way its essence: the exercise of the force may suddenly revert the benefit recognized to a certain person or enterprise. IPRs history makes it perfectly evident: law can change from a day to another, just revoking privileges or expanding them to other subject matters.<sup>26</sup> This crucial evidence shows the effective *status* of IPRs: they are concessions, rights derived from the self-limitation of the State's power and thus mere reflected rights.<sup>27</sup> IPRs do not genuinely arise from any social debate or conflict, they are granted on the sole base of concrete and material interests of states. It is almost unanimously agreed that the IPRs first appeared into a systematized legal framework in

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<sup>23</sup> See Prager (1944); Drahos (1999b).

<sup>24</sup> Among others, Joseph (2003), p. 23; and Drahos (1999a).

<sup>25</sup> “The fight for *propriété littéraire* was not a fight for monopoly but, instead, a request to abolish a particular hideous royal monopoly: that over ideas an expression”. Boldrin and Levine (2008), p. 31.

<sup>26</sup> “In modern societies property rights are in a constant state of adjustment. They are means by which governments solve externalities problems”. Drahos (1999a), p. 355.

<sup>27</sup> Jellinek (2002). Law is administration; it is the mean through which states are administered. Rights are intended as self-limitation of the absolute power of states, recognizing limited spaces of freedom to individuals. Still today, most of the administrative laws move from the assumption of “self-limitation”.



Venice,<sup>28</sup> when in 1474 the Venetian Republic issued a Statute granting a ten-year protection time to all the inventors patenting their works. The mercantilist constitution of the town made of strategic interest to attract people capable of innovating and providing technology. Since the very first advent of one form of IPRs, these were not minimally conceived to empower and recognize the work and personality of the inventor as such but rather to attract skilled people and gains in terms of technology, which constitutes an important strategic advantage.

The second page of IPRs' history has been written by England and it is connected to copyright. Guttenberg's invention caused the explosion of publications, and – as Kant pointed out – the “freedom of pen” should be the only right effectively granted by the Sovereign.<sup>29</sup> Criticisms were eventually possible privately not publicly. The state (the Crown)<sup>30</sup> was very much interested in controlling publications preventing publicity of critics. Printing machines could have seriously made the challenge between the political and the intellectual powers<sup>31</sup> fair (on equal foot); this is why such possibility has been immediately prevented. The “Statute of Anne” (1709) marks the beginning of the copyright saga. Along with patents and trademarks, copyright constitutes one of the three pillars of IP. In the present analysis the focus falls on patents.<sup>32</sup>

States enforce IPRs that are of national range in genesis. Humans' history is a long narration of inventions and copies of such inventions, of creative processes between people in the attempt of improving the level of wellbeing of their communities. More recently, due to the political organization of the European continent, fragmented into

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<sup>28</sup> “It was Venice that first marshalled its customs into statutory form when, in 1474, it enacted what has come to be known as the Statute of Venice (...) The Venetian Statute contained all of the essential features of a modern patent law”. Fisher (2007), p. 26. There are evidences of certain privileges granted to inventors that may be considered patents even before such date.

<sup>29</sup> Kant (2009) was trying to solve the Hobbesian labyrinth regarding the representative principle and the law-making process in order to draw the way out of it. Unfortunately, Hobbes' machine is almost perfect thus Kant reached the conclusion that the only possibility left is to allow citizens to criticize the activity of the Sovereign so He can correct its eventual mistakes.

<sup>30</sup> Drahos (1999a), at pp. 350-351, reports that there was “(...) an unprecedented democratization of the printed world” in a context where “(...) royal privilege-giving seems to have operated in most of medieval Europe” that later brought to “(...) protectionist impulse”.

<sup>31</sup> Political Sciences recognize three different forms of power: politic, economic and intellectual. See Sartori (1995).

<sup>32</sup> The reasons why of this choice: “Infectious diseases kill over 10 million people each year (...). Prohibitive drug prices are often the result of strong intellectual property protection”. t’Hoen (2003), pp. 40-41. “The major pharmaceutical corporations are able to charge high prices for (...) drugs because they hold the patents (...)”. Joseph (2003), p. 428.

different nations competing against each other, technological progress became the key for the supremacy within the international order. IPRs are of political nature. Consequently, there was increasing interest in the protection of industrial secrets and innovative inventions: not for the interest of the poor inventor but for the greatness of the state.<sup>33</sup> This led to the promotion of multilateral conventions and agreements, the first of which was the Paris Convention for the Protection of Industrial Property (1883), immediately followed by the Berne Convention for the Protection of Artistic and Literary Works (1886),<sup>34</sup> and the Madrid Agreement on Trade Marks (1891). With the creation of the United International Bureaux for the protection of IP, these three separate issues have been brought within the same basket. Since then, the regime of protection remained almost unchanged until the signature of the Convention establishing the World Intellectual Property Organization (WIPO, 1967),<sup>35</sup> which became active three years later in 1970. WIPO has been the main *forum* for the discussions, drafting and approval of IP conventions and treaties<sup>36</sup> becoming then one of the United Nations (UN) Specialized Agencies.<sup>37</sup> Most of the evolution has occurred within national laws and institution; the regimes were deeply different moving across the European borders (colonies applied the same rules of the dominant).<sup>38</sup> The three mentioned components of modern IP have grown separately and deal with different social issues. This seems to be reflected at least until the second half of the XX Century. Indeed, the first international agreements are focused on separate topics. Briefly, at the regional level: in 1973 the European Patent Convention (EPC) entered into force (later reviewed in 2000); the European Union Commission has recently submitted the text of the Anti-Counterfeiting Trade Agreement (ACTA, 2011) to the Court of Justice of the

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<sup>33</sup> “[P]atent systems are not created in the interest of the inventor but in the interest of national economy”. Michel (1974) quoted in Gana (1996), p. 328.

<sup>34</sup> “The Paris and Berne Conventions ushered in the multilateral era of international cooperation in intellectual property”. Drahos (1999b), p. 19.

<sup>35</sup> Drahos (1999a), p. 352.

<sup>36</sup> Before the strategic switch to the trade context.

<sup>37</sup> “WIPO became a specialized agency of the United Nations in 1974”. Drahos (1999b), p. 20.

<sup>38</sup> “Outside of Europe, intellectual property grew along colonial pathways”. Drahos (1999b), p. 17. “As colonies, developing countries were not signatories to the early international intellectual property treaties although the treaty provisions often extended to them through the colonial administration”. Gana (1996), p. 329.

European Union in order to see whether it is compatible with the fundamental rights granted by the EU.<sup>39</sup>

( $\gamma \cdot \gamma_I$ ) The mentioned legal instruments and sources became soon insufficient<sup>40</sup> in the view of developed nations due to the lack of effective remedies<sup>41</sup> available to oblige parties to respect and enforce IPRs. These facts point out that the main reason of concern and commitment for such states are not the rights of poor and powerless inventors but rather the pressure from main lobbies and corporations.<sup>42</sup> This has led to the adoption of a new strategy: linking IPRs to the main structural advantages of Developed Countries (DCs), trade.<sup>43</sup> The main juridical instrument in the field of IPRs is the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, concluded in 1994 in Marrakesh after a long negotiation process that began in 1986 with the first round of diplomatic discussions at Punta del Este and lasted over eight years. Such very long bargaining has passed to history with the well-known definition of *Uruguay Round* and has brought to the establishment of the World Trade Organization (WTO) beside the GATT regime (established during the Geneva Round already in 1947).<sup>44</sup> The United States (US), the European Community (EC), Switzerland and Japan (the so-called “Quad” during the consultations) introduced the issue of IPRs in the agenda, while most of the Developing Countries (DVCs) and the Least Developed Countries (LDCs) were mainly focused on the effective creation of the free market in economic areas such as agriculture (highly protected and funded by both US and the EC). The outcome has been, not surprisingly, in favour of the DCs since they could obtain the full adoption of almost all their main interests set in the agenda. DVCs and LDCs gained mere promises never maintained. The entire negotiations reveal the strategic interests of DCs that only incidentally finds its means into IPRs. The

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<sup>39</sup> Charter of Nice (2000).

<sup>40</sup> “The international period was a world in which lot of free-riding was tolerated. (...) Not everybody in the U.S.A. was happy with this *laissez faire* attitude towards the enforcement of intellectual property rights”. Drahos (1999b), p. 21.

<sup>41</sup> “The WTO Agreement establishes a Council for TRIPS, which is required to monitor members’ compliance with their obligations under the agreement”. Drahos (1999b), p. 23.

<sup>42</sup> “IPRs have always been used by states to secure market place objectives (...)”. Drahos (1999a), p. 350.

<sup>43</sup> “If a set of intellectual property standards could be made part of a multilateral trade agreement it would give those standards (...) global coverage [and] enforcement mechanisms (...)” Drahos (1999a), p. 353.

<sup>44</sup> WTO also expanded the subject matters from sole tradable goods to services and intellectual property.

ideological rhetoric about development and long-term gains has taken little time to be proved false by reality itself. Despite the failures of most of the analyses elaborated within the Academia, the World Bank and the International Monetary Fund (IMF),<sup>45</sup> world leaders have been tricked once again at the expenses of hundreds million people all over the globe.<sup>46</sup> In a culture avoiding the idea of responsibility, no one is effectively responding for the extermination of unknown people that exist only in the form of numbers within statistics.<sup>47</sup> If the theory is wrong, who is paying the “human” bill?<sup>48</sup> History provided the answer.<sup>49</sup> Since symptoms of the grave illness affecting global policies started to become evident, increasingly LDCs and DVCs<sup>50</sup> started to campaign to review the framework permitting a broader interpretation of the flexibility apparently (but not *de facto*) allowed by TRIPS. Most of the DCs have been promoting the so-called “TRIPS-plus” throughout bilateral negotiations and agreements,<sup>51</sup> linking the respect of higher standards to vital interests of the bargaining states. These facts are eloquent regarding the inadequacy of the legal regime in which negotiations are held: the *fiction iuris* of equality (*entem superiorem non recognoscentes*) causes dramatic outcomes in the final agreements, definitely in favour of the stronger but apparently fair due to the diplomatic discussion. Arriving at the table compact and determinate,<sup>52</sup> DVCs and LDCs could obtain the famous Doha Declaration on the TRIPS Agreement

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<sup>45</sup> One leading case: the World Bank Adjustment Programs.

<sup>46</sup> “In the six years since the enactment of the North America Free Trade Agreement (NAFTA), poverty in Mexico has increased and wages have dropped”. Anderson & Cavanagh (1999).

<sup>47</sup> Joseph (2003) at p. 436 demands: “What are the human rights responsibilities of Big Pharma in regards to health crises (...) in the developing world?” pointing out that this issue should rather be discussed in terms of legality and not of morality. The author forgets that “responsibility” is a forbidden word in modernity and she is finally obliged to state: “In the absence of direct human rights duties on Big Pharma, one must turn to examine the salient human rights duties to governments (...); p. 438.

<sup>48</sup> “IPRs are well protected by the WTO – at the expenses of human beings”. Cohn (2001), p. 437.

<sup>49</sup> “Globalization has been a boon to multinational corporations – at the expense of all of us”. Cohn (2001), p. 428.

<sup>50</sup> These countries were supported by NGOs offering expertise. “NGOs have played a key role in drawing attention to provisions of TRIPS (...)”. t’Hoen (2003), p. 46. Read also at p. 55: “A growing and active international NGOs movement ensured the issue would be high profile, and that NGOs would monitor different countries’ positions”.

<sup>51</sup> “Developing countries are under pressure from industrialized countries and the pharmaceutical industry to implement patent legislation that goes beyond the obligations of TRIPS. This is often referred to as ‘TRIPS-plus’”. t’Hoen (2003), pp. 42-43.

<sup>52</sup> “The developing country members were extremely well prepared and operated as one bloc”. t’Hoen (2003), p. 55.

and Public Health (DD)<sup>53</sup> and later also the adoption of a Protocol Amending TRIPS (Decision of the Council of 6 December 2005).<sup>54</sup> Such achievements have been celebrated as victories, proving the capacity of weaker countries to win negotiations. Yet, this is not a victory but rather the most dangerous downfall. Even if DD is aiming at mitigating the most disruptive effects of such system (especially due to the clamorous HIV/AIDS case), they do not minimally change the regulative framework as such; on the very contrary, the Document strengthens the validity and legitimacy of TRIPS, both directly – openly proclaiming it – and indirectly – due to the fact that states are obliged to comply with their obligations not minimally arguing that the entire regime should be put down. Doha, far from opening better perspectives, stabilize the regime permitting DCs to argue that eventual problems can find their solution within the legal framework without evoking the “state of necessity” nor changing the Agreement substantially.

§ **The philosophy** – IP lacks substantial and credible theoretical background substituted by different justifications, arising from separate disciplines.

( $\delta_I$ ) A decent understanding of the possible philosophy granting IPRs the minimum degree of legitimacy required in order to be effectively law is still lacking.<sup>55</sup> Otherwise, IPRs would be arbitrary impositions of a structure of power: *Gewalt* (violence).<sup>56</sup> The attempt of the present section is providing an initial investigation of the different theories superficially brought in the political and Academic discussions in the vane effort of turning IPRs in something historically and morally acceptable.<sup>57</sup> Philosophy has been increasingly re-evaluated due to its potential of providing moral arguments in favour of certain positions; this technical use of rhetoric capacity has been labelled as “*sophistic*”. Philosophy is useless but not pointless: on the contrary, it aims

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<sup>53</sup> WT/MIN(01)/DEC/2 of 20 November 2001.

<sup>54</sup> WT/L/641. Not yet in force due to the lack of the minimum number of ratifications required, see WT/L/785 of 21 December 2009.

<sup>55</sup> “The concept of a right to property, from a constitutional and even a customary international law perspective, often avoids defining the nature of property”. Nagan (2002), pp. 185-186. Such miss becomes even more problematic when dealing with intellectual forms of property claimed as rights.

<sup>56</sup> Benjamin (1995).

<sup>57</sup> The natural right thesis is a moral justification based upon the assertion that the individual has a natural property right in their ideas. Fisher (2007), p.66.

at generating wisdom.<sup>58</sup> The topic may seem misleading but the full understanding of philosophy and its importance in theoretically grounding legal categories is crucial. Indeed, law appears as a *continuum* moving from ethics and ending up in the absolute and pure violence exercised by the monopoly of the force (the state).<sup>59</sup> Democratic societies lie in the middle of such spectrum since part of law is built upon values morally<sup>60</sup> embodied and the other part reflects the performative power of states.<sup>61</sup> The intrinsic role of law is drawing destinies into a given system.<sup>62</sup> If law could purely reflect ethics<sup>63</sup> humans would realize their ontological destinies; differently, when law is imposed from the top, destiny is given by external entities.<sup>64</sup> Ethics is not possible in modernity<sup>65</sup> thus the aim shall be to formulate laws as closer as possible to an ethical horizon. Law is the surrogate of ethics and it is worth stressing that the greater is the need for codified rules, the lower is the degree of culture and human development concretely reached; in other words: culture and law are inversely proportional. Law is not the benchmark of higher degrees of civilization but rather the exact opposite, it symbolizes the downfall of the human kind into a spiral of ontological collapse.<sup>66</sup> Saint Thomas elaborated a model recomposing the fracture is his Christian theory of law: *Lex Aeterna* dominates the entire Universe, thus both *Lex Naturae* and *Lex Divina* have to be coherent to their source.<sup>67</sup> Below *Lex Naturae* and *Lex Divina* it is possible to codify *Lex Humana* but accordingly to all the superior norms and especially coherently to the *Lex Naturae* that has to be interpreted throughout the reason, that God has given precisely for the purpose of understanding the Divine order. With the progressive

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<sup>58</sup> Plato, *Phaedo*.

<sup>59</sup> The classical definition has been finalized by Max Weber, see Bobbio (1999).

<sup>60</sup> Not ethically perhaps.

<sup>61</sup> States are today seen as policy-makers. Since law constitutes the way states talk, finally laws and policies end up being coincident. It is necessary to re-politicize politics de-legalizing different areas of social life and activity. See, in general, Tomba (2007).

<sup>62</sup> Benjamin (1995).

<sup>63</sup> Making itself unnecessary, ethics does not need law.

<sup>64</sup> The performative external entity for Centuries has been seen to be God but nowadays it may be the state or the “market”, revealing the strongly theological foundation of both these organizational forms. See Schmitt C.

<sup>65</sup> Ethics is even less credible in post-modernity, said that post-modernity does not effectively exist in the opinion of the writer.

<sup>66</sup> Heidegger (2007).

<sup>67</sup> Authors such as Kelsen, Hart, Jellinek have merely translated this system shaping a constitutional model of law.

emancipation (secularization) of the human kind from nature and God,<sup>68</sup> the normative theory translated the humans' aspiration to empower themselves against their destiny of misery. The positivist approach gained importance substituting to the previous hierarchy (having God at the top) a new one delivering supreme power to men. Men were finally entitled to shape their own kingdom of equality, freedom, and justice.<sup>69</sup> If *prudentia* was the leading virtue during Middle Age, modernity has progressed under the principle of *justitia*. The latter, is not intended as a virtue or a principle but rather a utopia: history has shown the results.<sup>70</sup> Morally speaking, World War II marked a turning point; yet, it has not seriously discussed the legal and political conceptual categories that caused such terrible disasters preferring the unusual route of dismantling culture,<sup>71</sup> basing the anthropological foundation on utilitarian-functionalist models downgrading the human essence to (ideally) ensure peace and order. Law today is almost entirely drawn upon utilitarian and economic/functionalist arguments, morally justified *ex post*, but always intrinsically aimed at perpetuating given political models.<sup>72</sup> What worked nationally should have functioned internationally. Unfortunately, the predominant end of utilitarian-functionalist approaches is to ensure the efficiency of the order-making machine forgetting about human beings and their culture.

( $\delta_{II}$ ) The utilitarian-functionalist regime cannot work in absence of a *rationale* feeding it.<sup>73</sup> Modern *rationale* is perfectly matching Descartes's assumption: *cogito ergo sum*,<sup>74</sup> constituting the actual anthropological foundation. This idea generates two core side-effects:

( $\delta_{II}, \delta_I$ ) *Individualization*. Reasoning is the proof of my existence, thus it is the principle of reality, the origin of it: reality begins from the individual's reasoning. The mind has intrinsic skeptical attitude since the only certainty it can have is only its own presence (*Da-sein*). Scepticism reveals automatically a

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<sup>68</sup> Formally and historically the process started with the French Revolution attacking the *ancien Regime*.

<sup>69</sup> It is worth recalling the motto of the French Revolution: "*Liberté, égalité, fraternité*".

<sup>70</sup> The Communist, the Fascist and the Nazism totalitarian regimes.

<sup>71</sup> Badiou (1995; 2006; 2009)

<sup>72</sup> Political models mainly based on institutions providing the perception of justice, and therefore relative order and peace. See Rawls (2008).

<sup>73</sup> "The strongest and most widely appealed to justification for intellectual property is a utilitarian argument based on providing incentives". Hettinger (1989), p. 47.

<sup>74</sup> Descartes (2011).

narcissist self-referential behaviour that is selfish in essence.<sup>75</sup> This modern anthropological foundation individualizes people turning them in powerless, scared, and atomic entities. It represents the total overthrow of Aristotle's idea of "anthropon zoon politikon" (ανθρωπον ζων πολιτικόν): human beings are so exclusively within the community. Parallel, "anthropon zoon logos ekon" (ανθρωπον ζων λόγος έχον): humans become so dialoguing, turning the reasoning into substantial thinking (together). Human beings turned themselves into individuals deprived of any natural power; individuals are powerless neutral entities. As for the mythological figure of the "Hydra" (Υδρα),<sup>76</sup> the apparent solution of one problem provokes two others.

( $\delta_{II}$ .  $\delta_I$ . Sub I) Since all human beings' connatural powers disappeared in the neutralized form of the individual, such entity is dominated by the desire of power.<sup>77</sup> Being made at image of God means that individuals aspire to be equally absolute and omnipotent. Ethic is unthinkable and life is based only on incidental, subjective, and relative moral values.<sup>78</sup> Individuals are necessarily inscribed in the Hobbesian scenario: *homo homini lupus*.

( $\delta_{II}$ .  $\delta_I$ . Sub II) The main gain of the individual form is the absolute equality derived from the complete emancipation from nature. Abandoning given roles and connaturate responsibilities means leaving room to free will. Total free will is impossible as individuals; effective freedom *become real* only in the ethical form of the state and therefore within the state.<sup>79</sup> The Leviathan is free and individuals can be so as undistinguished part of it.<sup>80</sup> There cannot be any *ego* outside the *nos*, and

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<sup>75</sup> Hegel (1999; 2000).

<sup>76</sup> The Hydra is an apparently (Hercules proved to be capable of the contrary indeed) immortal and invincible multiple heads monster with the peculiarity of having two heads growing when one was decapitated.

<sup>77</sup> Nietzsche is the one theorizing the will of power, on which Adler based his entire psychological theory opposed to the Freudian mainstream regarding the libido. Finally, it is worth mentioning that Heidegger reveals a further level: the desire of the desire of power, the fact that the desire of power is one of the many desires but also the prevalent one.

<sup>78</sup> Arendt (2012).

<sup>79</sup> Hegel (1999; 2000).

<sup>80</sup> *Ibidem*



the *nos* is the people.<sup>81</sup> The “people” are the “friends”, those sharing the same blood<sup>82</sup> and having representatives.<sup>83</sup> This scheme reveals the introversion of Aristotle’s idea as correction for the disappearance of ethics. Yet, it is a mere surrogate inversely working thus causing massive damages.

( $\delta_{II}$ ,  $\delta_{II}$ ) *Relativization*. Scepticism is destructive and leads to the conclusion that the only existing thing, the only important thing is precisely itself: the mind, which is therefore narcissist. If the mind, and consequently the person (mask) as first and concrete possession of the mind, is the only element of importance, what counts are her utility and desires that become constitutive of her identity. Having a multitude of entities advancing conflictual claims and pretending to be equal, the balance between individuals’ rights and collective interests is impossible.<sup>84</sup> The entire organizational system is based upon contracts of utility between individuals. The state administers institutions functional to such mechanism occasionally exercising its monopoly of the force, which is its utility and desire, for the respect of given rules. Law as such is completely emptied, it is a tool arbitrarily used and filled of whatever content. The same society gets its born into a so-called “social contract”:<sup>85</sup> the only thinkable system of justice must embrace the rules behind rules, those permitting contracts to work, the *rule of law*. Formal/procedural justice instead of substantial justice. Social justice immediately falls out of the interests of the law. Contracts as base of/for societies cause distorting effects on the perceived reality (of law): contracts require formal equality between contracting parties that is possible exclusively throughout a *fictio iuris*. Human beings are made equal before the law because of their legal personality. Intuitively, law does not protect the natural person but rather its opposed representation,<sup>86</sup> the juridical one, betraying the real subject.<sup>87</sup>

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<sup>81</sup> Heidegger (1987; 2011).

<sup>82</sup> Schmitt (1998; 2003).

<sup>83</sup> Hobbes (2010).

<sup>84</sup> “[I]t is difficult to imagine any society that is not both individualistic and communitarian”. Nagan (2002), p. 183.

<sup>85</sup> It has never really existed historically. See Locke (2000), Hobbes (2010), Rousseau (2009).

<sup>86</sup> Schopenhauer (2010).

Whatever juridical attempt of harmonizing HRs and IPRs is senseless. The state in its schizophrenic functioning is overcome by multiple contradictory inputs that it is unable of processing. Eventual contrasts among branches of law seems impossible to fully comprehend: analytical tools are insufficient. A deeper investigation is necessary to re-order conceptual and legal categories.

( $\delta_{III}$ ) Philosophy is not a self-service restaurant: concepts and theories cannot be taken just partially or in that precise segment supporting the argumentation. Whether it is worth further investigating IP arguments is understandable examining the philosophical content and meaning of the concept of property, one of the most controversial issues ever arisen. Not just property as such but also the increasingly important qualification of *private* property, since the latter term is very generic. Private means that someone else is deprived of it and the action of one individual is deducting a defined thing from other possible users or beneficiaries. In modern terms the discussion becomes critical when related to *efficiency*, even if the same is not successfully explained remaining a vague and metaphysical principle.<sup>88</sup> Property is intrinsically political:<sup>89</sup> if its legalization may be acceptable, the type of legalization is not equally of immediate digestibility. Property should be seen as a *relational right* instead of an individual one.<sup>90</sup> Such scheme permits to balance individuals' claims and public interests. Using property as *medium* leaves ideas free, otherwise it would be self-contradictory. The modern political form is drawn upon Hobbes' theory, elaborated starting from an imaginary initial natural regime where individuals become so due to their desires projected on the outside. Conflictual desires over scarce resources imposes the truth of *homo homini lupus*. In the state of nature craftiness and force constitute the main characteristics to win threats and survive. Hobbes' (and Locke) conclusion is that an agreement is needed to put everyone under the sword of the Leviathan who is

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<sup>87</sup> The main assumption of modern law is to be just. See generally Hegel (1999; 2000)

<sup>88</sup> "Efficiency" in respect of what purpose? Humans' wellbeing? Beside, regarding the metaphysical moment of law, see Kelsen (2006; 2010).

<sup>89</sup> Politics/political: everything connected to the definition of relationships among members of a certain society. Politics is relational and therefore may become a power (and not *vice versa* as in Foucault, 2005 and 2009).

<sup>90</sup> Hegel and Marx understood labour and property as *medium* between modern individuals. In that, they systematized ius-naturalist theories. This view opens to the historical materialism and to the idea that "(...) the relationship[s] of human beings with each other [pass] through things". Nagan (2002), p. 182.

overseeing the respect of contracts (and the proportionality of punishments) among its members. This is the only possible guarantee beside the right to life, the one substantially endangered by the state of nature and thus the only effectively recognized right by the sovereign.<sup>91</sup> In modern states, property is of the Leviathan who can arbitrarily decide about. Intelligence and force are connatural qualities of human beings that are unequally distributed by<sup>92</sup> but are neutralized in the framework of the state turning them into equal citizens. IP is impossible in the Hobbesian state. Differently, Locke is more concerned about the eventual fairness of punishments: states are needed because Courts and trials avoid brutal and excessive forms of self-made justice (revenge). Locke extensively describes what property is:<sup>93</sup> in his view, the labour of a man on natural materials – to which he confers shape – permits the onset of a right to property, which has still to be socially recognized.<sup>94</sup> The right to property *might* arise and its recognition does not amount to an obligation;<sup>95</sup> the natural right is effectively so as long as the individual drags out the amount of natural-common-resources needed for gaining dignified life. Presumably, abuses would be punished revoking the property right. Labour generates possession (not property), which is only incidentally tangible since the only effective gain that the individual has in terms of natural right to property is precisely the possession of the experience gained through the labour, and not the material result of it. The subsequent moment of the formal property on objects derives from the social and political recognition that is everything but not natural nor inherent. Practically: (i) the object represents a symbol of my labour, not the labour as such; (ii)

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<sup>91</sup> “Generally, the concept of property has been viewed as a construct, or creature of the sovereign”. Nagan (2002), p. 182. See also Nozick, *Anarchy*, pp. 175-182.

<sup>92</sup> Rawls (2008) theorizes the need of the “veil of ignorance” in these regards.

<sup>93</sup> For the original text see Locke (2000), *Second Treaty*, Chapter Five. For an interesting explanation of Locke’s theory in the field of IP see Fisher (2007), p. 67.

<sup>94</sup> “The notion that a labourer is naturally entitled as a matter of right to receive market value of her product is a myth. (...) [It is] a question of social policy (...). [A] right to profit by selling a product in the market is something quite different. This liberty is largely a socially created phenomenon”. Hettinger (1989), pp. 39-40.

<sup>95</sup> Rousseau sees the origin of the human collapse in the social acceptance of private property. “Private property enhances one person’s freedom at the expenses of everyone else’s. Private intellectual property restricts methods of acquiring ideas, it restricts the use of ideas, and it restricts the expression of ideas (...)”. Hettinger (1989), p. 35. Hugo Grotius, the father of the International Law (considered an atypical *ius-naturalist*), understood property as consequence of the disruption of the human kind, as the proof of the collapse from the original state of pureness: the *Communio primaeva bonorum*. Maintaining this sort of theological angle, labour could be viewed as the punishment to the original sin. For the general philosophy see Todescan (2006).

the labour is only projected on the object and it is not effectively intrinsic to it; (iii) the symbol is perceived as necessary when a certain something is not felt in essence and thus it had to be made manifest in the outside requiring political recognition. Today machines produce, not humans: modern individuals are unable of experience at all; are machines gaining property rights? Do human beings possess anything really? Labour has social value remunerated in the society: the entitlement to the right to property is one of the possible forms of reward.<sup>96</sup> Locke does not mentioned IP;<sup>97</sup> whatever intellectual element developed in the work is inherent to the individual and such fact is not modifiable by any law. Labour is relevant in the understanding of the right to property: what intellectual works should deserve such high degree of recognition and protection in the form of a right?<sup>98</sup> It is necessary to measure the effect of the labour on the detection of a right: “*intelligere*” means “interacting”, interacting with elements of the reality: how can such operation be rewarded with the insurgence of a right? Otherwise, the interaction with another human being may lead to property rights arising on the auditor at the benefit of the speaker: teachers would materially own children in their classes.<sup>99</sup> The simple labour is insufficient: tangible and measurable results are crucial. So property rights regard things, not processes on them.<sup>100</sup> In *Critique of the pure reason*, Kant pursues the edification of a new *a priori* synthetic system. There are two stages in the process, the intuition and the elaboration of it, namely the thinking; the moment of the physical perception comes only later thus it is possible to clearly

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<sup>96</sup> “[L]aw wishes to conserve entitlements in the form of rights, and in doing so it runs into the paradox of intellectual property”. Nagan (2002), p. 184. The Italian author Bobbio (1996) underlines how, within a positivist paradigm of law, the rights of slaves compete with those of slavers because law is incapable of finding an intrinsic balance. Equally, it depends very much by the socio-economical context and the existing structures of power where the line between these interests can be drawn.

<sup>97</sup> Notably, Locke – as well as Kant and any other author of those times – still conceived the reasons to be universal. Locke (2000) and Kant (2009).

<sup>98</sup> It is important to notice how: “(...) assuming that labour’s fruits are valuable, and that labouring gives the labourer a property right in this value, this would entitle the labourer only on the value she added, and not to the total value of the resulting product”. Hettinger (1989), p. 37. The problem, in the case of ideas, is to measure such added value. How to remunerate Plato or Aristotle for their contributions when we ideally think through mind structures they invented? Indeed, “(...) intellectual activity is not creation *ex nihilo*”. *Ibidem* p. 38.

<sup>99</sup> Criticism is needed precisely to operate distinctions: “Intellectual capital is an economic and cultural resource. Property is an evolving, mutating institution”. Nagan (2002), p. 185.

<sup>100</sup> “(...) how something is said is very much part of *what* is said (and vice versa)”. Hettinger (1989), p. 32. Nonetheless, the “how” represents the phenomenological expression of the “what” and only the former is protectable.

distinguish between tangible and intangible. What the individual does with the intuition is undoubtedly intellectual labour. Is it protectable by law? No, it is not. The process cannot be effectively protected while the result of it, the elaborated idea, is more substantial and it may be secured through individual rights. However, the idea as such is impossible to effectively lock up: preventing people's freethinking is absurd. Fixation makes protection feasible but on that thing, not on the idea behind. Law can act merely preventing others from economically exploiting *an* idea (not *the* idea), therefore it would not be genuinely IP but rather commercial or trade law.<sup>101</sup> Hegel is often mentioned as main supporter of IPRs because of the link between artistic/intellectual works and the personality. Hegel refers to (the exercise of) possession. The first and concrete moment of existence of human beings "is" their bodies as means of experience (*Erfahrung*). The *Erfahrung* is the most essential concept within Hegel's theoretical framework: representing the first superficial moment of it, property is merely incidental. The real product of intellectual efforts is the person as such, thus it is self-contradictory to fashion the person with weak rights such as the one to property.<sup>102</sup> If the physical body is an object and not the subject, the former can be deprived of its freedom without effectively operating violence on the real subject: "education" is the real violence since it aims at changing what a person is in essence. If tangible property is somehow left to the ethical organization of the rational state, IP remains unthinkable in the Hegelian regime. The *intelligentia* is aiming at a Universal end driven by the *Geist* thus it is simply against the intrinsic logic of reality to privatize the possession of certain intellectual processes: they are stolen from the community depriving it of accomplishing history.

ε     § **Organization and structure of the work** – The philosophical tradition has shown that theorizing the category of IP is impossible. It would be necessary to deconstruct the legal and political systems in order to re-think them coherently to an institution such as the IP. If IP simply results unthinkable, it is difficult to state that

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<sup>101</sup> The jurisprudence reveals the immense problems regarding "private use" of goods obtained in violation of IPRs. Liberals are also lost in this unsolvable contradiction.

<sup>102</sup> Hegel (1999; 2000) wants to reach the ethical moment of the state empowering the human beings to the point that rights (individual rights) would be unnecessary.

IPRs have a reason to exist. Tangible properties fall into the concept of *res factum* while IP seems to be a claim if not a mere want. Consequently, laws enforcing IPRs promote the interests of a certain group of people.

( $\epsilon_I$ ) The present analysis aims at understanding IP and IPRs as a whole; since IPRs are conflicting<sup>103</sup> with HRs<sup>104</sup> it is important to inquire if the former have any meaningful reason to affect the enjoyment of inherent rights.<sup>105</sup> If IP has been derived as one possible form of property,<sup>106</sup> is it eligible for legal protection and in what form?<sup>107</sup> May dreams or remembrances become intellectual goods to secure into IPRs?<sup>108</sup> Is the law enforcing such protection coherently to its own nature and to reality? Is the law as such the correct means to defend IP? These are the basic demands at the base of section A, facing the juridical analysis of the legal sources and the norms regulating IPRs. If IPRs are not genuinely of juridical nature but rather the expression of legitimate interests, what sort of interests is the law protecting and promoting?<sup>109</sup> Is it effectively reaching the proclaimed ends?<sup>110</sup> Is the method proportioned to the aim?<sup>111</sup> The mentioned interrogatives are the nucleus of section B, overlooking the economic essence of IPRs and their legitimacy and utility. Finally, the results of the previous

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<sup>103</sup> "(...) the WTO 1994 Agreement on Government Procurement, which prohibits consideration of non-commercial factors, such as human rights (...). Cohn (2001), p. 433. Human rights are seen as obstacles to trade.

<sup>104</sup> "The exercise of patent rights has implications for the right to health". Drahos (1999a), p. 349.

<sup>105</sup> Considering that "The WTO has consistently chosen the protection of property over the sanctity of human rights". Cohn (2001), p. 434.

<sup>106</sup> "(...) property can, using a variety of taxonomies, be disaggregated into a number of different types (...)". Drahos (1999a), p. 355.

<sup>107</sup> "Patents enable companies to stake out and defend a proprietary market advantage". Rivette and Kline (2000), p. 56. The question is then why companies need the law to be capable of remaining competitive on the market. In general, four main theories have been advanced on the function of patents: (i) incentive function; (ii) transactional function; (iii) disclosure function; (iv) signalling function. Some theories stress one core advantage, but it is arguable that patents satisfy all of the listed functions at the same time. See WHO (2006), pp. 32-33.

<sup>108</sup> See, for example, the "experience machine" in R. Nozick or imagine whether scenarios similar to the one presented in the movie "Blade Runner" may become real: clones would be suddenly in need of proper memories, eventually bought as normal commodities on the market.

<sup>109</sup> "The objective of intellectual property protection is to create incentives that maximize the difference between the value of the intellectual property that is created and used and the social cost of its creation, including the cost of administering the system". Besen and Rasking (1991), p. 5.

<sup>110</sup> "The failure of intellectual property rights to meet their economic goals in fully capitalist, industrial societies invites scepticism about the ability of these rights to achieve either conservation or equity goals in less developed countries". Brush (1993), p. 667.

<sup>111</sup> Helfer believes that there are "(...) serious normative deficiencies of intellectual property law from a human rights perspective". Helfer (2003), p. 52.

sections furnish elements to analyse the actual international regime and the mechanism of Global Governance – if existing. The suspect is that once again law, in this case *International-ized* IPRs may serve as instrument of power within the global context.<sup>112</sup> If so, IPRs would reveal their ideological nature leaving untouched the right to health. This is the theme addressed in the conclusions where some suggestions are provided in order to get out from the *impasse*.

( $\varepsilon_{II}$ ) Even if the formal topic of the present work is the existing contrast between HRs<sup>113</sup> and IPRs, the analysis is not focused on a comparative method aimed at finding a compromise.<sup>114</sup> It is far from it since the direct “clash” would implicitly recognize equal dignity to the two branches of the actual law, while here it is discussed the legitimacy of IPRs to exist. Before juxtaposing HRs to patent rights it is crucial to see whether the latter has any effective reason for challenging the former. Most of the Academic works are more or less moving from the assumption that IPRs exist and the only possible way is to find a compromise but such position does not seem acceptable. It leaves the decisional power to those promoting economic interests against everything else.<sup>115</sup> It is indeed crucial to defend the intrinsic dignity of the law as apparatus for the protection and promotion of the human dignity.

( $\varepsilon_{III}$ ) The methodology used in the present work is essentially philosophical. The aim is to investigate a certain phenomenon, in the sense expressed in the verb “istoreo” (ιστόρειω), meaning “inquiring, exploring”. Such inquiry should not be external to the object of the research, as it is becoming increasingly habit, but rather internal to it. Providing only external justifications leave problems unsolved eventually addressing only marginal effects.<sup>116</sup> Thus, willing to avoid the risk of further complications generated by ineffective measures, it is essential to individuate the cause of the hitch.

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<sup>112</sup> “The global transfer of economic and political power (...) to multinational corporations is a disaster for human rights (...) and democracy”. Cohn (2001), p. 427.

<sup>113</sup> In particular the access to medicines within the right to health and thus patents on drugs. Indeed, “The patent right is the most powerful in the intellectual property system (...)”. Besen and Raskind (1991), p. 6.

<sup>114</sup> A valuable contribution on the topic has been provided in Dutfield and Suthersanen (2005).

<sup>115</sup> “(...) WTO’s *raison d’être* is the elevation of property above the protection of human rights. (...) In each and every environmental case that has come before the WTO, it has ruled against protecting the environment and in favor of protecting the interests of big business”. Cohn (2001), pp. 427 and 431.

<sup>116</sup> As it is the case for many mathematical and geometrical problems: see Hegel, *Phenomenology of the Spirit* in the Preface.

## SECTION A

“Current Patent Laws cannot claim  
the backing of Human Rights”  
[Gordon W.J.]

§ **IPRs and HRs** – IP has not existed as conceptual category before the introduction of IPRs<sup>117</sup> and it is also evident that philosophy has been used mostly as *ex post* justification of the applied legal regime instead of constituting the genuine base for the arising of certain social claims subsequently recognized as rights. For such reasons, the first step to move is precisely the acknowledgment of the concrete object of the analysis. Norms and sources represent the first moment of the reality of IPRs thus, in order to have a greater coherence to their essence, it is necessary to list them and inquire, more generally, the existent legal framework. The present work aims at delivering a full comprehension of the phenomenon of IPRs, looking whether it can challenge HRs.<sup>118</sup> The end is not to draw a harmonized game of balance but rather to investigate the legitimacy of IPRs in defeating fundamental rights. It is here provided an *intra-juridical* insight of the main legal sources and norms regarding IPRs. The discussion about whether IP has any link or even the recognition within the HRs framework is highly controversial.<sup>119</sup> It is necessary to pass through two levels of scrutiny: the first regards property as such, the second the intellectual form of the same.

(ζ<sub>I</sub>) *The right to property* – The UDHR deals with property in art. 17 but it does not encompass in any way the idea of *private* property,<sup>120</sup> even if it is possible to

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<sup>117</sup> “‘Intellectual Property’ is a generic term that probably came into regular use during the twentieth century”. Drahos (1999), p. 13.

<sup>118</sup> Since “[c]ontemporary models of intellectual property protection cannot be fully reconciled with the human rights regime”. Gana (1996), p. 339. “The paradox is said to arise when (...) intellectual property rights are used to restrict access to information that could be deployed in ways that satisfy [human rights]”. Dreyfuss in Grosheide (2010), p. 72.

<sup>119</sup> “(...) it is important to identify the human rights attributes of intellectual property rights and distinguish them from the non-human rights aspects of intellectual property protection”. Yu (2007a), p. 711.

<sup>120</sup> Scott (2001) quoted in Yu (2007a), p. 733.



assume that it should be implied or at least the today context would oblige to interpret it as so.<sup>121</sup>

At the regional level, there can be found two main provisions, respectively art. 1 of Protocol I to the European Convention for the protection of Human Rights (ECHR, 1950) and art. 17 of the Charter of Fundamental Rights of the European Union<sup>122</sup> (Charter of Nice, 2000). In ECHR, Protocol I Art. 1<sup>123</sup> contains, at least, five core elements to point out: (i) the word used is *possession*; (ii) the enjoyment of such possession has to be *peaceful* (no-harm principle); (iii) the *public interest* may provide the legitimacy for depriving an individual of the conferred right; (iv) the conditions for the exercise and enjoyment of the right are dictated by the law; (v) both the *natural* and the *legal* persons are entitled to such right.<sup>124</sup> One of the ECtHR mistakes is to devote attention to companies and corporations<sup>125</sup> and their rights.<sup>126</sup> First of all, it is to wonder how is it possible to attribute HRs to something that is not human at all and that has gained juridical personality only thanks to a *fictio iuris*. Even if companies and corporations are indirectly owned by individuals, the Court shall not defend any sort of interest advanced by entities different than genuine human beings. In other words, the Court should consider exclusively those rights belonging to the natural person otherwise there is a great risk to affect the dignity of the HRs as such. There is the risk of downgrading for HRs while their dignity has to be carefully protected, especially in the practice. It has to be taken into account the fact that the liberal inspiration of certain phrasing of the ECHR has been caused by the historical contraposition between the two

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<sup>121</sup> Nevertheless, “(...) there is no human right to property under the Covenant (...)” on Economic, Social and Cultural Rights. Cullet (2007), p. 421.

<sup>122</sup> It has become legally binding with the entrance into force of the Treaty of Lisbon (December 1st, 2009).

<sup>123</sup> For an interesting analysis, see Yu (2007a), p. 729. Art. 1 Protocol I states:

1 § Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.

2 § The preceding provisions shall not, however, in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties.

<sup>124</sup> For an interesting insight of the recent jurisprudence of the ECtHR, see Helfer (2008).

<sup>125</sup> Helfer (2008), pp. 3-4. In particular, “(...) the decision protects the fundamental rights of multinational corporations rather than those of natural persons”.

<sup>126</sup> “Although there has been a growing expansion of corporate intellectual property rights, none of these rights would qualify as a human right”. Yu (2007a), p. 728.

blocks, thus ideological free-market oriented positions should now be dismissed and simply delivered to other competent *fora*, such as the European Court of Justice of the European Union (ECJ), which is more likely to deal with problems connected to functional rights.<sup>127</sup> In facts, the phrasing of the first paragraph of art. 17 of the Charter of Nice<sup>128</sup> is very interesting since it makes a distinction between the act of acquiring *possession* on something and the further moment of exercising *property* rights on such possession, proving the more functional view undertaken within the EU. However, also in this case states can regulate the use of property in order to protect the general interest.

(ζ<sub>II</sub>) *The Intellectual Form of Property* – Starting again from the UDHR it is now possible to move to IP: art. 27.2 recognizes the right of the author to protect moral and material *interests*;<sup>129</sup> the last term does not immediately reach the dignity of “right”.<sup>130</sup> The provision seems to be aimed at ensuring democratic and accessible mechanism to protect certain legitimate interests. Interestingly, the norm is in favour of authors but not of inventors and it is not even possible to deduce by dynamic interpretation that corporations or businesses of any kind should claim such right. More importantly, art. 27 is composed of two paragraphs where the first one is strongly in favour of the diffusion of the knowledge and the possibility for all the members of the society (to be intended as global) to enjoy the benefits of the scientific progresses. Further limiting the range of action of art. 27.2 there is art. 1 recognizing the essential value of the human dignity as absolute imperative on the light of whose the whole text of the Declaration has to be interpreted. More or less the same phrasing has been used in

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<sup>127</sup> The two Courts have been challenging each others regarding the competences and hopefully the contrast will be re-composed soon since the EU as such should become part of the ECHR.

<sup>128</sup> 1 § Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest.

2 § Intellectual property shall be protected.

<sup>129</sup> 1 § Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

2 § Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

<sup>130</sup> It is not to forget that: “During the drafting of the UDHR, the delegates were widely concerned about the abuse of science and technology during the Second World War and the wide use of conscripted scientists and engineers in Nazi Germany and Stalinist Russia”. Chapman (1998) quoted in Yu (2007a), p. 723.

art. 15 of the ICESCR;<sup>131</sup> many consider art. 15.1(c)<sup>132</sup> the main evidence of the HRs background for IPRs.<sup>133</sup> The same considerations operated in the regards of the UDHR shall be done in this other case, even strengthening the responsibilities put upon the State for the safeguard of the general well-being and of the fundamental rights (art. 2.1).<sup>134</sup> It is in the nature of the HRs to balance the interests of the different members of the society giving prevalence to the community rather than to individualistic wants or interests. Individuals are intended to receive protection when the community and its systems of power are abusing their roles. Thus, even accepting that authors have the right to protect their moral and material interests, it is eventually true that the same must be mitigated by the broader interests of the whole society.

Descending to the regional level, the ECHR does not contain any norm regarding explicitly IP. Despite this evident absence of a clear recognition of IP as form of property, the practice of the Court (ECtHR) has virtually recognized IPRs as part of the broader right to property.<sup>135</sup> However, it is worth recalling the fact that the Court analyses the practice occurring in the different member states, thus the already overwhelming recognition of the IPRs as part of the broader regime of property rights has consequently led the Court to assess the existence of such rights. Yet, they do not find any real ground in the Convention or in any of the Protocols, the basis has been elaborated throughout dynamic interpretation of art. I Protocol I that now includes IPRs. The Court is still not an indisputable source of truth, and it is not infallible. On the very

<sup>131</sup> The CESCR dedicated a specific General Comment on the point (No. 17)

<sup>132</sup> For a better analysis, refer to Helfer (2007), in particular starting from p. 989.

<sup>133</sup> 1 § The States Parties to the present Covenant recognize the right of everyone:

- (a) To take part in cultural life;
- (b) To enjoy the benefits of scientific progress and its applications;
- (c) 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.

2 § The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.

3 § The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

4 § The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.

<sup>134</sup> The CESCR dedicated a General Comment (No. 3) on the duties arising for the State in regards of programmatic rights already in the 1990. See UN, Office of the High Commissioner for Human Rights, The Nature of States parties obligations (Art. 2, par. 1): CESCR General Comment No. 3. UN, 1990.

<sup>135</sup> See *Anheusers-Busch Inc. v. Portugal*, App. No. 73049/01.

contrary, in both a positive direction and a negative one, the ECtHR has exercised a certain activism that has turned into a very political action, which is by nature object of polemical discussions. The Court has to decide if it is supposed to protect inherent rights or if every sort of legitimate interest and expectation directly or indirectly connected to any of the recognized rights risks to turn into a subject matter on which the Court would rule, producing arbitrariness and uncertainty instead of preventing them. The other main legal instrument, the Charter of Nice, again at art. 17.2 states the importance of protecting IP, but it does not immediately recognize it as a right and the type of protection may vary. Indeed, it is not specified what IP is intended to be or what form of IP deserves what form of legal or economic safeguard. While the first paragraph of the same article extensively explains the regime of tangible property, nothing is said regarding its intellectual side. By intuition, it is possible to advance the hypothesis that the Convention applies the same provisions both for material and intellectual forms of property, which is not likely to result effective. More importantly, it is necessary to bear in mind that the EU has mainly economic purposes, thus its fundamental rights are not immediately equivalent to HRs. The same definition of fundamental implies the idea that it is so due to the connection to a certain system, while HRs are – as already said – inherent to the human being as such.

(ζ, ζ<sub>I</sub>) In conclusion, it is possible to assert that IP finds little or no ground at all in the HRs sphere.<sup>136</sup> HRs do understand property as an interactional *medium* eligible for a certain degree of protection in order to allow a discretionary exercise of some connected freedoms. In other words, there is no *freedom of property*<sup>137</sup> but the same may be needed in order to fully accomplish the realization of other HRs and thus it acquires the required degree of importance to be included in the HRs catalogue. On the other side, what emerges quite clearly is the necessary balance to be drawn between the community and individual's rights. Unfortunately, the wording of almost all the documents regarding what should be considered “public interest”, “general interest”, etc. is vague and left to the arbitrariness of politics, while TRIPS Agreement is specific in shaping

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<sup>136</sup> “[M]ost property rights cannot be included in the category of fundamental rights”. Drahos (1999a), p. 355.

<sup>137</sup> It would be likely to reflect a sort of Hobbesian state of nature.

the regime and its possible exceptions. IP does not genuinely arise from the conceptual and legal category of property – on the contrary, IPRs are politically generated – and does not constitute a linear extension of already existing HRs. It is thus indispensable to move to the analysis of the peculiar norms of IPRs at the international level.

**η § IPRs, Patents and TRIPS** – IPRs cannot rely on an authentic genesis and they do not have any sort of consistent connection to HRs – if not indirect and merely functional to a certain social and economic system. Therefore, it is relevant to read the main norms taken as such since they are the only effective sources for the understanding of the real nature of IPRs. First, it is interesting to discover where global policies and connected norms have been elaborated, and secondly it is appropriate to undertake the single provisions of concern for the present work. The present analysis focuses on patents; they influence, *inter alia*, the access to technology and information, (high) education, and especially the pharmaceutical production, which is the *vulnus* of the present analysis.

( $\eta_1$ ) WIPO would genuinely be the *forum* for the drafting of the most important legal instruments in the field of IPRs. For long time, it has been so. However, WIPO has nowadays lost such prominent role since it is lacking enforcement mechanisms that are conversely offered within the WTO system. With the successful inclusion of IPRs within the Uruguay Round of negotiations (1986-1994), WTO has become the most effective route for the enforcement of the mentioned rights. TRIPS Agreement<sup>138</sup> is the most important document regarding IPRs.<sup>139</sup> It imposes a “universal minimum standard” of protection,<sup>140</sup> assessed that “minimum” is defined as such by the drafters (and the supporters of the document), while it is not objectively so. Similarly, “universal” is not related to the intrinsic essence of the protected rights but to the range

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<sup>138</sup> TRIPS Agreement is considered to be “(...) a compilation of previous multilateral conventions on the matter (...)”. Botoy (2003), p. 122.

<sup>139</sup> “The TRIPS agreement is, without doubt, the most important development in the governance of IPRs in the last 100 years or so, having set in motion a legally-binding ‘one-size-fits-all’ global IPRs regime which has visibly expanded and strengthen IP protection and enforcement across most of the world”. Muzaka (2011), p. 38.

<sup>140</sup> “TRIPS Agreement adopted a relatively high minimum standards of protection for all the WTO members”. Helfer (2003), p. 54. However, “TRIPS agreement sets minimum, uniformly applicable IP standards regardless of their levels of development, and socio-economic circumstances”. Gibson (2008), p. 56.

of action of such Agreement<sup>141</sup> that, being a pre-condition to join the WTO,<sup>142</sup> is obviously accepted by almost all the countries in the world. Notably, the universal *acceptance* is not equivalent to the universal *recognition*,<sup>143</sup> the former is more likely to reveal the existence of an imperialistic form of economic and legal power while the latter relates to the natural conception of law. It is not so difficult to apprehend the reason why of this *forum* switch:<sup>144</sup> it is not simply the presence of enforcement mechanisms but rather the fact that within such framework those countries with major economic development and trade capacities implicitly bear the control of the discussions, into and outside the WTO – as in the case of Free-Trade Agreements (FTAs)<sup>145</sup> bilaterally concluded and improving the regime of protection bringing to the so-called “TRIPS-plus”.<sup>146</sup> Nevertheless, WIPO has won back some of its importance as “right-arm” of WTO; since the conclusion of TRIPS Agreement it has been supporting member states, especially DVCs and LDCs, to fulfil their obligations<sup>147</sup> and draft adequate norms within their legal system.<sup>148</sup> Notably, these countries often have technical lacks, paradoxically caused by the brain draining implemented by the technological and economic gap that TRIPS is enlarging rather than decreasing or solving.

( $\eta_{II}$ ) TRIPS Agreement establishes the patents’ regime in Part II, Section Five (artt. 27-34) to be interpreted, as expressed in the Vienna Convention on the Law of the Treaties, “...in the light of its object and purpose” and in good faith (art. 31.1), thus the

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<sup>141</sup> “The minimum ‘universal’ standards of TRIPS Agreement are not the product of any real consensus. The modern intellectual property system treats developing country ideas about both what constitutes “property” and what may be monopolized by a single individual against the larger community as irrelevant”. Gana (1996), p. 340. TRIPS is thus far from codifying genuinely universal norms.

<sup>142</sup> “The TRIPS Agreement was made binding on all members of the WTO. There was no way for a state that wished to become or remain a member (...) to side step the TRIPS Agreement”. Drahos (1999), p. 22.

<sup>143</sup> “Does it follow from their universal recognition that they are universal norms?”. Drahos (1999), p. 32.

<sup>144</sup> Helfer (2007), p. 981.

<sup>145</sup> “FTAs are arrangements between two or more countries whereby tariffs are eliminated between participants and other trade concessions are extended according to the principle of reciprocity”. Switzer (2007), p. 125.

<sup>146</sup> “Developed countries and intellectual property owners, too, are leaving the field, not for other multilateral organization but for bilateral and regional trade and investment treaties”. Helfer (2007), p. 975. See also Switzer (2007), p. 124: “The United States’ efforts to unilaterally impose TRIPS-plus standards (...)”.

<sup>147</sup> “Industrialized countries and WIPO offer expert assistance to help countries become TRIPS-compliant. This technical assistance, however, does not take into account the health needs of the populations (...)”. t’Hoen (2003), p. 43.

<sup>148</sup> Abbott (2002), p. 476.

Preamble and Part I (artt. 1-8) – on “General Provisions and Basic Principles” – have to be considered as well.<sup>149</sup>

The Preamble furnishes the general scope of the document, namely “...to reduce distortions and impediments to international trade...”, acknowledging “...public policy objectives (...) including developmental and technological objectives”, but recognizing “...the special needs of the LDCs...”;<sup>150</sup> consequently, the document as such is functional in nature and does not minimally aim at guaranteeing any sort of protection to the “inventor”. The only specification made regards the fact that there is the general recognition of IPRs as *private rights*. If they are so, it means – as usual – that they are conferred by a certain structure of power, which has a peculiar culture and systemic understanding of reality. Traditional knowledge and connected people’s rights are left aside and not even mentioned, demonstrating the lack of interest for the topic of IP as such. The same is merely a mean for further ends not openly expressed.

Part I contains at least one crucial provision, which is not immediately problematic taken as such but has become so after the entering into force of the Agreement due to some practices that have taken place in order to higher the level of protection of IPRs. The norm under discussion is art. 4 titled “*Most-Favoured-Nation Treatment*”, measure already codified within the GATT regime but surely of major importance with the increasing pressure put upon DVCs and LDCs by the US and the EU throughout bilateral negotiations or FTAs. As soon as the same are concluded with one of the WTO Members, all the others shall have equal access to such conditions due to the validity of art. 4. Since EU and US’ markets are of vital importance for most of the DVCs and LDCs, the formers manage compelling bargaining power. The recurrent practice of

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<sup>149</sup> The main IPRs regimes, respectively of the US and the EU, have some peculiarities that TRIPS does not completely harmonize. In the US, an invention has to be new, mono-obvious and useful. The European patent law, governed by Article 52 of the EPC, stipulates that the basic requirements for a patentable invention are novelty, inventive step and industrial application (i.e. inutility test). See Lidgard (2004), pp. 20-21.

<sup>150</sup> “(...) in conjunction with both the Preamble to the TRIPS Agreement itself and article 8.1, it must be generally understood that the implementation of internationally IP standards is necessarily limited by criteria of reasonableness”. Maskus and Reichman (2004), p. 308.

raising IPRs normative protection has finally led to a *de facto* regime of “TRIP-plus” standards.<sup>151</sup>

Measures related to patents as such are just few since the juridical instrument of the patent is left to members states to be defined only procedural concerns are addressed in the document. Art. 27 states that “...patents shall be available for any invention (...) provided that they are new, involve an inventive step and are capable of industrial application. (...) Patents shall be available and patent rights enjoyable without discrimination as to (...) the field of technology”; however, paragraph two limits the range of action of patents assessing that exclusion from patentability is possible in order to safeguard “...public order or morality”.<sup>152</sup> The same are vague and so senseless if opposed to the specific provisions listed in artt. 30 and 31 obliging states to respect a long list of criteria at the advantage of the rights-holders in case of exploitation of the inventions. It is worth stressing that art. 31 is probably the longest of the entire Agreement. The rights conferred to the owner, at the senses of art. 28, are substantially delineating what is normally intended as a monopoly. The only relevant condition imposed to the applicant is set by art. 29, requiring to “...disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art...”; such person must be highly educated/skilled in the subject matter, thus the provision cannot be equally applied to all the Member States: most of them lack the effective capacities to run out the mentioned test relying on examination made in other more developed countries, which gain an additional structural advantage. Finally, art. 32 asserts that patents can be revoked but there is no explanation on how it would ever be possible – on which factual and legal bases –, thus DCs will be always powerful enough to impose their conditions while DVCs and LDCs tend to avoid

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<sup>151</sup> “[I]t is possible to identify five main ‘TRIPS plus’ provisions (...): data exclusivity, parallel importing, compulsory licensing, patent term extension and patentability criteria”. Muzaka (2011), p. 114. See also Helfer (2003), p. 59; Hestermeyer (2007), pp. 289-291.

<sup>152</sup> The article continues with a further comma:

3 § Members may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.



“dangerous” decisions because of the risk of costly juridical disputes. Indeed, most of them do not even have the expertise and the needed professionals to challenge main companies often supported by their hosting states.<sup>153</sup>

**9 § The Pharmaceutical Production** – The obstacles posed in the availability of drugs<sup>154</sup> is exterminating right now millions people around the globe.<sup>155</sup> Subsequently, it has the dignity to be treated as a priority and it represents the *vulnus* from which the entire analysis has been inspired.<sup>156</sup>

(9<sub>1</sub>) *TRIPS flexibility* – Despite the so-called “flexibility” attributed to the TRIPS Agreement, the same has brought a considerable number of serious concerns at the attention of many DVCs, LDCs and NGOs.<sup>157</sup> Such quality does not belong exclusively to TRIPS but is generally recognized in law and, especially, in international law. In the present case, the attribute is more nominal than substantial.<sup>158</sup> The specific provisions contained are binding member states to enforce not just a certain system of legal protection but a precise idea of IP and IPRs, which is not universal yet *universalized*. The flexibility is inferable from the combined reading of artt. 1.1, 6, 8, 27.2 and 27.3, 30, 31, 66. States “...shall give effect to the provisions of this Agreement...” (art. 1.1) but they “...may (...) adopt measures necessary to protect public health...” (art. 8.1). Art. 27.2<sup>159</sup> is non-sense: allowing states to exclude certain inventions from

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<sup>153</sup> Like in the case of the WTO dispute settlement.

<sup>154</sup> “(...) accessibility of medicines and their affordability are two central components of the right to health”. Cullet (2007), p. 416. On the other side, there has been an attempt to prove the usefulness of patents: “Anxiety about adulterated or forged medicines was endemic and well founded. (...) It was from this conjunction that pharmaceutical patenting emerged. It did so partly as a mechanism to secure not property but authenticity”. Adrian (2009), pp. 83-85.

<sup>155</sup> “While the lack of access to medicines will lead to deaths in the immediate future, the lack of access to educational and cultural materials may result in slow death in the distant future”. Yu (2007a), 719.

<sup>156</sup> “(...) the only industry in which patents are thought to play an important role in bringing new products to market is the pharmaceutical industry”. Boldrine and Levine (2008), p. 212.

<sup>157</sup> Among others: “The US government had persistently threatened to impose trade sanctions and withdraw economic benefits from countries that granted compulsory licences”. Abbott (2002), p. 487. Furthermore, flexibility may be useful in the legal context while it does not itself “solve socio-economic problems”. Yamane (2011), p. 518.

<sup>158</sup> “The existence of these built-in flexibilities by no means guarantees the adequate protection of human rights”. Yu (2007a), p. 737.

<sup>159</sup> (2) § Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

patentability, such limitation would work merely within national borders while the global competition is so intense that most countries would rather compete to accept what for others is morally inadmissible. It is business: a race to the bottom that makes economically disadvantageous to refute certain patents. The main evidence is nowadays given by the increasing enlargement of the fields of patentability:<sup>160</sup> segments and DNA codes are eligible for patent protection. It is a linear consequence: the first to come is the one taking all. As soon as one country admits the practice, all the others do have to follow in order to not lose the competitiveness. The US led the way and now the competition is open in the name of progress. Art. 27.2 works in the opposite direction than it would suppose to. The same is true for artt. 30 and 31 (a)-(l): what is passed-off as flexibility is the exact contrary due to the immense amount of bureaucracy required, definitely disproportional to the end and to the degree of importance to attribute to the rights connected to patents. Paradoxically, precisely those measures addressing cases of emergency or necessity are also the ones prescribing major burdens to the member states: these burdens are not protecting people (those in need of medicines) but money. The “queen” norm in terms of flexibility is art. 66.1 recognizing the different *status* of certain DVCs and LDCs and allowing a three to ten years derogation before the enforcement of the contained provisions. Art. 66 underlines the invalidity of the Agreement: treaties require contracting Parts to be equal while the same Document is stating that they are not effectively so. The coherence of law is absent thus the same turns into a mere tool of power. And it has been perceived as such: due to the increasingly widespread HIV/AIDS crisis, a global movement pushed for a different IPRs system in the field of public health and drugs production. The scandals caused by the case submitted by 39 Pharmaceutical Companies (PHCs) against South Africa,<sup>161</sup> along with the pressure exercised by the US on Brazil, brought to a strong stress arising from the public opinion all over the world. In both cases, TRIPS flexibility was used to issue “compulsory licencing” for HIV/AIDS related drugs. Main PHCs feared it could become a common practice as soon as one case would have been successful. Ironically,

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<sup>160</sup> “The continuous expansion of intellectual property rights is alarming (...)”. Yu (2007a), p. 712. See also Lidgard (2004).

<sup>161</sup> *Phar. Mfrs. Ass’n v. President of the Republic of South Africa*, No. 4183/98 (Transvaal Provincial Div., filed February 18, 1998). See Nagan (2002), p. 164. Consider reading also t’Hoen (2003), p. 43-44.

in the attempt of preventing such scenario to turn real, they caused the exact opposite effect.<sup>162</sup> The practice demonstrated the totally ideological presumption regarding the flexibility of the Agreement.<sup>163</sup> The point was of crucial importance thus DVCs and LDCs successfully networked and, with the precious support of NGOs,<sup>164</sup> could impose in block their request that was finally welcomed during the Doha Round of negotiations, culminated in the “Declaration on the TRIPS Agreement and Public Health” (DD).<sup>165</sup>

(*ϑ<sub>II</sub>*) *The Doha Declaration* – It should be evident how TRIPS flexibility is finally so only at the advantage of the strongest,<sup>166</sup> as in the case of the US<sup>167</sup> threatening Bayer<sup>168</sup>. The presumed flexibility may work as bargaining argument but only when states are strong enough to challenge PHCs with the subsequent risk of losing foreign investments. Evidently, this is not the case for either DVCs either LDCs. The same sometimes base their entire economy on Foreign Direct Investments (FDIs). DCs have stressed the importance of IPRs in order to attract FDIs since the very beginning of the Uruguay Round.<sup>169</sup> As previously mentioned, in November 2001 the Ministerial Conference adopted the DD composed of seven paragraphs of which no. 5 is the one of greatest importance. Par. 5 (b) and (c) underlines what should be intrinsic both in the Agreement and in the idea of sovereignty<sup>170</sup>: each member state has the right to grant compulsory licences and to decide what are the circumstances constituting national emergency. It is somehow paradoxical that states have to draft a ministerial

<sup>162</sup> In the ancient Greek tragedies, arrogant people were conceived as committing an act of “ubris” (ὕβρις), exceeding their connatural form and power and thus immediately punished by nature and gods.

<sup>163</sup> In principle, “WTO rules permit the sovereign a very broad measure of discretion in issuing compulsory licences”. Nagan (2002), p. 167.

<sup>164</sup> “(...) activists went head to head with lobbyists and experts from some of the most prosperous and politically connected pharmaceutical companies in the world. They did so by becoming as technically expert as their adversaries on every aspect of international trade in medicines”. Beyrer and Pizer (2007), p. 422.

<sup>165</sup> WT/MIN(01)/DEC/2.

<sup>166</sup> Assessing that “TRIPS does not limit the right of countries to establish compulsory licences on grounds other than those explicitly mentioned in the Agreement”. Kuanpoth (2010), p. 33.

<sup>167</sup> “Several trade diplomats cite the terrorist attacks (...) on 11 September as a special alternative explanation for the Doha Agreement”. Odell (2009), p. 28.

<sup>168</sup> In order to have Cipro (ciprofloxacin) anti-anthrax drugs available. See Mercurio (2004), p. 223. “It is interesting to note how quickly the United States and Canada were to threaten the Bayer patent, and how quick were media commentators to question Bayer’s profit margin on Cipro, at a time when the United States had thirteen anthrax cases with three deaths”. Joseph (2003), p. 446. A clear example of double standards.

<sup>169</sup> See Muzaka (2011), pp. 61 and 63.

<sup>170</sup> That is implied in the conclusion of every international Treaty.

declaration recognizing not a right but a power, which is already given within sovereignty.<sup>171</sup> This further element contributes to show the ideological character of TRIPS Agreement behind the initial confusion. Yet, not only the DD perpetuates the uncertainty of the regime, since par. 3 and 4 reinforce IPRs protection and the commitment to the TRIPS Agreement, but the same Document is controversial. The effective legal status is unclear: while the labelling as of “Declaration” would turn it into a mere statement of common political commitments legally meaningless, the whole process that has led to its adoption and the same fact that it is a ministerial document would lead to the opposite conclusion.<sup>172</sup> The DD leaves open one further issue, related to art. 31 (f) of TRIPS,<sup>173</sup> addressed but not solved in par. 6, which simply drops the question to the TRIPS Council. The solution was expected by the end of 2002; in August 2003, a new decision moved a step back. The matter regards those countries with no technical means and manufacturing capacities in the pharmaceutical sectors capable of providing certain essential drugs, even under compulsory licence.<sup>174</sup> With the Ministerial Decision of December 6<sup>th</sup>, 2005<sup>175</sup> a Protocol amending the TRIPS Agreement<sup>176</sup> was adopted inserting art. 31bis after art. 31; the former, composed of five paragraphs, permits the production and import of a certain drug under compulsory licence on behalf of another state unable of producing such medicine. In the Appendix of the Protocol is explained that all the LDCs are deemed to have insufficient capacities while the same provision can be applied to other members established that such productive capability is effectively lacking. The document has to be ratified by two-thirds of the members before entering into force; the goal has not been reached as yet. For this reason, the deadline for its ratification has been pushed repeatedly ahead over time.

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<sup>171</sup> France v. Turkey (S.S. Lotus), P.C.I.J., No. 10 (1927).

<sup>172</sup> “The legal status of the Doha Declaration and Paragraph 6 decision after 2007 remains uncertain (...)”. Kerry and Lee (2007), p. 7.

<sup>173</sup> Mercurio (2004), p. 212, 221-222. See also Abbott (2002), pp. 490-504.

<sup>174</sup> “[N]early 60 developing countries have no manufacturing capacities at all (...). Only a few developing countries (...) are capable of manufacturing a patented pharmaceutical through reverse engineering”. Kaplan and Laing (2005) quoted in Muzaka (2011), p. 88.

<sup>175</sup> See in general Muzaka (2011), pp. 103-108. Original document: WT/L/641.

<sup>176</sup> Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

( $\vartheta$ . $\vartheta_I$ ) Approaching the issue from a broader perspective, TRIPS Agreement is not the only obstacle to the global access to medicines. However, it is ideally the main symbol of unequal distribution of wellbeing and sources among the world population.<sup>177</sup> DD and the Protocol do not constitute a victory but rather the main failure in the global match: both these Documents accept and even improve the TRIPS regime while the real challenge was to dismiss such framework and re-think completely IP and IPRs – especially when connected to trade. Some PHCs have also changed their policies in order to respond to the increasingly higher concerns of the public opinion (i.e. “costumers”). They are lowering prices and even delivering free drugs to people in disadvantaged economic conditions. Such outcome is ideological for a long list of reasons: (i) people economically in need are present all over the world, including in nations as the US where the 20% of the population lives on or under the poverty line; (ii) such actions are not inspired by concrete ethical concerns but merely by marketing reasons turning human rights and humanitarian needs into tools for marketing;<sup>178</sup> (iii) the ethic of business and the social corporate responsibility are both intrinsically impossible.<sup>179</sup> Companies and corporations are not moral entities. The tradition of the law attributes legal capacity to those morally capable,<sup>180</sup> in the sense that they are conscious and aware of their actions and able of distinguishing between the good and the evil.<sup>181</sup> The main purpose of such entities is the profit, which by nature lies at the exact opposite extreme of morality. Recently there have been attempts to *moral-ize*

<sup>177</sup> And “where incomes are low – below a dollar a day – even the cheapest medicines are out of reach. A third of the world’s population has no access to essential drugs”. The Panos Institute (2002), p. 4.

<sup>178</sup> Importantly, the relative material gain achievable through these means is counter productive since it is seriously affecting the dignity of human being and human rights. The source of problems is addressing measures not to defeat the radical cause but to mitigate consequences depending by its same existence. Humanitarian and human rights issues are here mere means in the marketing strategy of Companies: not pure ends but only means.

<sup>179</sup> On ethics in business see Chyssides and Kaler (1993); Nelson (2005); Parboteeah and Cullen (2012). See also Report of the Special Representative of the Secretary-General (SRSG) on the issue of human rights and transnational corporations and other business enterprises (A/HRC/4/035/2007), available at the link: <http://www.business-humanrights.org/Documents/RuggieHRC2007> (last visit: 3 June 2012).

<sup>180</sup> Morality derives from the two Latin terms: *mores* and *alia* (*mor-alia*), respectively meaning “costumes” and “alter/different”. H. Arendt interprets morality as mere social labels, costumes in the superficial sense, but she is forgetting that, also for Romans (due to the influx of Greeks), costumes reflected attitudes, the nature of a person intended as self-revealing and in the nature was given a certain destiny. Thus, morality has to be intended as: “alternative/different destiny”, implying the capacity (the force and freedom) to choose. Later, this capacity has been interpreted in the Christian sense: acting morally refuting the evil and loving God. See St. Augustine.

<sup>181</sup> See Pufendorf in Todescan (2006).

companies turning them into *moral-istic* entities. The only possible way to moralize business groups is to impose certain laws but this would turn into struggle always won by the strongest that is not necessarily the state, especially when Transnational Corporations (TNCs) deal with LDCs.

¶ § **Juridical Analysis** – Most of the international agencies, NGOs, including academics, have immediately surrendered facing IPRs formalized within TRIPS Agreement. IPRs have always been a matter of internal law, something given to the authority of the state to decide thus somehow under democratic rules. The global *harmon-ization* constituted a great success for those supporting the general idea of IP and the need for strong legal protection of it. The entire discussion has focused on the economic interests connected to IPRs; the debate has been ideological on both sides turning the issue into a mere political match with *pro-et-contra* groups. Most of the relevant elements regarding IPRs codified into TRIPS have been left aside with no meaningful analysis.

(*u*<sub>1</sub>) The first issue regards whether IP as such has any legitimacy to exist as conceptual category and therefore whether the law would ever constitute the only or the more appropriate way to defend it. While the former question has mostly philosophical relevance, the second one is strictly juridical thus it is worth to inquire the functioning of post-modern law in order to see if such tool can fit within IP, safeguarding the connected rights. Law has *pervasive* tendency since it aims at covering all the possible subject matters. It is in the intrinsic logical of any legal system. The consequence is the inflation of the law and of individual's rights that are then arbitrarily assessed within Courts by Judges acting more and more politically, deciding what norms to apply, more than how to fit them into the specific case (interpretation). Modern law is built upon modern rationality that has rationalizing character and continuously subsumes everything in itself: nothing outside rationality can exist in an intelligible way. The pervasive aspiration of the law is genetically connected to the desire of total control and absolute power: the law serves as mean of imposition of a certain order following a top-down movement – even if some logical traps give the perception that such system

would work the other way around.<sup>182</sup> Once the law is approved, there are virtually no limits to it: no borders protecting morality or public interest since the law as such is already expression of them; no means for securing the content of the law; no protection for individuals' rights. Law is abstract and universal thus it betrays: (i) the concrete subject (or natural person) it is supposed to empower; (ii) the connected rights since there is no effective distinction regarding the content; (iii) the society as a whole because no norm balances interests improving general wellbeing. Law is imposing destinies on people: the content of law is incidental and often temporary, what counts is the enforcement, the exercise of power.<sup>183</sup> Allowing law to “protect” IP would open the doors to the possibility of the state to enforce an even higher degree of control and pervasive power. Most of the measures already enacted have conducted us in what is intended as *biopolitics*.<sup>184</sup> In the present case, law secures all those forms of IP having economic relevance (art. 27.1 TRIPS). Value is not intrinsic to the object – it cannot consequently be protected *per se* – but it is produced throughout the market dynamic.

(*l<sub>II</sub>*) This last point opens one crucial demand: who is the subject of the law within IPRs and – more importantly – TRIPS? As already stated, it is not the object *per se*, but it is not even the real “producer” since the wording of TRIPS relates to the “applicant” and subsequently to the “right holder”; the poor inventor deprived of his legitimate economic reward by cruel criminals and pirates never appears in the text of TRIPS.<sup>185</sup> Therefore, what receives protection, as openly stated, is the economic relevance of the IP, thus the economic capitals invested in it.<sup>186</sup> The real subject of the

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<sup>182</sup> It is possible to provide at least two core examples: the first one lies in political theory and is based on the principle of people sovereignty (the laws are made by representatives elected by people); the second one is connected to political sciences and it supports the idea of the political process and a productive system: input-output-feedback. See Easton (1984).

<sup>183</sup> Benjamin (1995).

<sup>184</sup> Foucault (2005; 2009).

<sup>185</sup> “In the real world, it is only large companies holding intellectual property rights, such as patents (...)”, consequently it has to be stressed how: “(...) it has become difficult to distinguish the right of the individual author and the rights that may accrue to businesses under intellectual property rights frameworks”. Cullet (2007), p. 421-422.

<sup>186</sup> “Economists refer to the net benefit to society from an exchange of social surplus. With intellectual property, the innovator collects a share of the social surplus she generates (...)”. Boldrin and Levine (2008), p. 127.

law is *the capital* that is primarily financial but also – eventually – human too.<sup>187</sup> If the law as such has no intrinsic limits (they are provided throughout a legal hierarchy) and the concrete protected subject is the possibility for the capital to gain profit, which has not essential limits as well, IPRs are arbitrarily driven by contextual interests. It is difficult to draw the line of where IPRs have to stop: are DNA sequences patentable? Is the cloning process eligible for patents? More easily, what is genuinely not patentable? The answer is nothing precise because the law is abstract and universal and the capital undefined with tendency to infinite. It is now taking place the race to the bottom, where countries are challenging each others to enlarge the actual limits to patentable subject matters and – at the same time – strengthening control and protection on those already existing. This is possible, of course, because IPRs are not protecting individuals and not even their eventual IP but merely the capitals invested in the production and commercialization of certain intangible goods.<sup>188</sup>

(*l<sub>III</sub>*) Acknowledging the actual global system that is driven by economic-financial interests, IPRs constitute a political use of law. Politics is intended as the process through which relationships among members of a society get shaped; law provides those values relationships are based upon. Today, politics is power and frames relationships as destinies at the national and at the international levels, generating the opposite of democracy. The actual distribution of wellbeing and possibilities (as expression of freedom and power) is unfair. IPRs perpetuate and worsen the already high degree of social injustice. The protection of the invested capitals in intellectual goods secure and reinforce those who own and manage such financial capitals.<sup>189</sup> It is important to measure inequality of IPRs from the two possible directions:

(*l<sub>III</sub>.l<sub>I</sub>*) *Bottom-up (people)* – IPRs do not effectively empower people and do not grant any benefit to the inventor or to the intellectual good *per se*. The registration process is long and costly: an inventor may need to refer to expert

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<sup>187</sup> How then can IPRs comply with human rights since “(...) human rights are not only universal entitlements, but also empowerment rights (...)”. Yu (2007a), p. 713. The case proves that human beings are objectivized becoming means finalized to increase capitals.

<sup>188</sup> This point is crucial because: “There is no equality of rights between the different actors in presence”. Cullet (2007), p. 413. Therefore, IPRs worsen asymmetries at the advantage of those already managing the greatest power.

<sup>189</sup> “For pharmaceutical companies like Pfizer, intellectual property was an investment issue”. Drahos (1999a), p. 352.



lawyers to appropriately draft the claims; the present system does not protect the inventor since expensive legal battles often take place to defeat the insurgence of a patent on a certain process or product. Such trials last for a quite long time and are used strategically to prevent single inventors to work independently or to temporarily block the entrance into the market of products. Furthermore, the financial resources required are almost always dragged away from the research, turning the weaker part into a much less competitive actor on the market. IPRs – including those codified in TRIPS Agreement – go in favour of the strongest, coherently to the mainstreaming capitalistic system.

( $t_{III}$ ,  $t_{II}$ ) *Top-down (States)* – One of the core assumptions of the present work is that world lives different temporalities. The law has to be coherent to reality in order to avoid unbearable degrees of cultural violence. Such is the case dealing with TRIPS that are not merely ignoring the strong inequalities existing between countries, but are mostly willing to perpetuate them.<sup>190</sup>

( $t$ ,  $t_I$ ) In order to defuse the risky consequences of the political arbitrary and ideological use of it, law has to accomplish an introspection regarding its own forms and expressions. The law as such still *appears as* law, causing serious consequences, including inflation. An *ontology of the law*,<sup>191</sup> assessing one main difference between (i) *iuris dicere* and (ii) *iuris prudentia*, is necessary. The former reflects the modern positivist approach to the law (the law is intrinsically just and it is so when appropriately promulgated), while the latter perceives the law as a tool that has to be used coherently to itself (tradition) and reality. The second way is preferable and permits to inquire the essence of law and understand whether differences within the same are intrinsically present. Moving from the top of such hierarchy it is possible to list:

- a. Inherent rights: those arising from the common dignity of human beings (that being having, revealing and exercising human essence).

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<sup>190</sup> The argument is better developed in Section C (see *infra*).

<sup>191</sup> Mazzei and Opocher (editey by, 2010).

- b. Fundamental rights: those historically achieved and on which the entire political organization of a certain society is based upon.
- c. Recognized, accepted, and codified rights: those rights drawing a balance between opposed interests in order to organize the society and its functioning accordingly to historically prevalent values.
- d. Legitimate expectations: those claims deriving from an existing obligation put upon an individual, group of people or organization, and/or the State.
- e. Legitimate interests: those claims that are promoted by individuals or group of people in order to upgrade their social status within their political organization of the society in a particular historical time. Such legitimate interests can turn into the rights *ex post* (c). Usually, legitimate interests are connected to the exercise of fundamental rights into the given system, thus they often permit the recognition of further functional rights.
- f. Pretensions/wants: these are political in nature and constitute an arbitrary revendication of privileges or interests that are not legitimate or not immediately so.

HRs can be distributed between points (a) and (b)<sup>192</sup> while IPRs fall into the groups described by points (c), (e) and (f)<sup>193</sup> since they arise from the actual/contextual historical organization of economy as base of social and political life.<sup>194</sup>

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<sup>192</sup> “(...) human rights are (...) recognized by the state but are inherent rights linked to the human dignity”. Cullet (2007), p. 404. Conversely, “IPRs are rights granted by the state as mean of meeting certain policy objective – these rights are in no way inherent”. Hanses (2002), p. 80-1.

<sup>193</sup> “It is impossible to monopolize knowledge, except by keeping it strictly private and secret or by the help of a sovereign power. (...) monopoly rights exist for a limited time, and these rights are transferable” thus they cannot be inherent nor fundamental. Brush (1993), p. 654. “Human rights are inalienable. While corporations may have obtained rights from individual authors and inventors through assignment or under a work-made-for-hire arrangement, the human-rights-based interests of these individuals are not transferable”. Yu (2007a), p. 728.

<sup>194</sup> “(...) the existence and exercise of some rights presupposes the existence of other rights. (...) The central claim is that the rights created through the enactment of intellectual property laws are instrumental rights (...) [that] would be pressed into service on behalf of human rights. (...) Property and contract law have indeed been foundational in enabling capitalism to take off”. Drahos (1999a), pp. 358-359. “Human Rights regime continues to expand (...) [generating the need for] quality control (...) [since] many more interests become the subject of rights claims (...)”. Drahos (1999b), p. 28. Importantly, the same codification of these rights prove they are not inherent nor natural: “If property in ideas is a natural right, there is little logical basis for that right to be limited to a term of years, rather it should be perpetual”. Fisher (2007), p. 68.

κ § **Function of the Law** – It is expectable that law would end up being a political act aiming at balancing relevant contrasting interests within societies, promoting common values and guaranteeing peaceful coexistence and general order. Interests have to be not just relevant but also legitimate and such quality arises when it is proven that the recognition of a right would increase the general wellbeing (social justice). The same cannot be understood merely under the economic perspective but in a holistic sense. The way wellbeing is measured is crucial: the overwhelming utilitarian view supports the idea that the individuals' utility feeds the general one.<sup>195</sup> Yet, this can be seen either as an organic (ordo-liberalism) natural system or as a mere quantitative way of looking to wellbeing. Indexes, such as the national GDP and the GDP *per capita*, are unable of truly revealing anything about social justice and the distribution of the available wealth within a state. Thus, it is fundamental to bear in mind one further question: who is gaining the major benefit from the introduction of a new normative framework? The improvement, indeed, has to be promoted for the society as a whole and for the society taken as such: higher levels of culture, better services, fairer distribution of wealth and goods, more transparent and equitable access to public and private positions, etc. The point now is to measure whether IPRs are coherent to these arguments and therefore eligible for being recognized as, first, legitimate interests and, secondly, as rights. Some economic-related issues can be seen as relevant within the present system and for the complete enjoyment of fundamental and inherent rights to the point that they would turn into legitimate interests for both the supporters and the society as a whole. IPRs protect invested capitals and they do so in order to promote innovation. Such arguments are clearly *extra-juridical* and therefore cannot be discussed within a legal context.<sup>196</sup> The protection of capitals is not a genuinely legal issue; it is an economic-related argument that capitalist economy finds cheaper to solve outside itself.

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<sup>195</sup> The strong stress on individualism leaves no room to protect common rights, thus “(...) one starting point for protection should be the protection of traditional knowledge holders who are largely excluded from the protection provided by intellectual property rights regime while often being subjected to biopiracy”. Cullet (2007), p. 426. Brush (1993), p. 643: “Another ethical issue concerns the use of knowledge that is freely given in one culture but then commoditized for private profit in another” since “the legal status of indigenous groups and their control over culturally specific but widely useful information” are neglected within IPRs regime. See also Helfer (2003), p. 52-54. “Pharmaceutical and biotechnological companies are looking at ways to exploit indigenous medicinal knowledge, plants and other resources that are often found in developing countries”. Hanses (2002), p. 76-2.

<sup>196</sup> Nagan (2002), at p. 159, talks about “(...) the economic foundations of intellectual property law (...)”.

An economic inquiry of IPRs and the context in which IPRs play is consequently necessary to prove or disprove their legitimacy.

## SECTION B

“Domestic stability has been purchased in developing countries by externalizing cost of adjustments to developing countries”.

[Lang T.]

λ § **The economic nature of IPRs** – The juridical analysis individuated the real subject of the law within the legal category of IP. What is still missing is the study of the insurgence of IPRs. It is important to list the constitutive elements of the right to IP. According to the philosophical and juridical arguments, they shall be: (i) the labour; (ii) the conscious and free will in order to pursue (iii) an objective end (*factum*) – in the present case, a product. The first point is controversial since it is not clear whether the quantity or the quality of the work should have any importance in the definition of the right; such qualities descend from the connatural capacities of the person thus there are concerns regarding social justice. There is no actual system awarding inventors in such a way; patents are given through the precise opposite route.<sup>197</sup> The economic relevance of a certain application of an idea leads to the possibility of winning patent protection. This brief reasoning proves how far IPRs can be from any classical legal argument since they aim at securing invested capitals. A balance with HRs is unthinkable: the two kinds of rights belong to opposite systems established upon reciprocally conflicting paradigms.<sup>198</sup> IPRs’ supporters never argued within the legal framework but rather referring to economic data emphasizing a strictly financial rationale. States have echoed the points made by PHCs; these have stressed the strong existing link between IPRs and development, reaching the funny conclusion that in the “long term” they would have

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<sup>197</sup> A better understanding of the economic interests behind is offered in Scotchmer (2002), read in particular: “There is no economic rational for protecting the inventors *per se*” at p. 1. Of course, this sounds paradoxical since “the patent system is based on the idea that the grant of a monopoly will automatically secure to an inventor a reward which is commensurate with the value of his invention. [Even tough], in many cases the greater portion of the profit may go (...) to a firm”. Meinhardt (1946), pp. 24-25.

<sup>198</sup> Human rights merely “serve as counter balance [/limitation] of patent law”. Van Overwalle in Grosheide (2010), p. 237.

been beneficial to all the LDCs and DVCs.<sup>199</sup> Since the entire discussion around IPRs has been economical in nature – and only *ex post* legal and theoretical<sup>200</sup> – it is crucial to investigate whether economic reasons for supporting IPRs may effectively exist and be sufficiently credible to legitimize the TRIPS Agreement regime. It is true that IPRs play a consistent role in the economic development yet it is not that clear what this role precisely is. Is it positive or negative?<sup>201</sup> Data are showing that the gap between most of the LDCs and DCs is broadening instead of decreasing. The so-called “economic science” has the defect of applying one unique model to a universe of cases, often obliging the same to fit within the given model just labelling destructive consequences as “externalities”. IPRs make no exception: “one size fits all”, both *ratione personae* (states) and *ratione materiae* (products).<sup>202</sup> States are only virtually equal and therefore it is worth questioning whether harmonizing legal doctrines at the global level may work since the globe itself is everything but not harmonized. It would turn out into a terrible cultural violence eventually causing deep economic crises in many countries. Products can be all subsumed in the abstract universal<sup>203</sup> but they are not always comparable.<sup>204</sup> The commodification tendency is producing incredible confusion especially within the law, where categories have to be accurately differentiated in order to guarantee the efficiency of the legal procedure. Can medicines be considered as every other type of tradable goods?<sup>205</sup> This is where HRs and IPRs clash. The latter support the utilitarian model of economic progress leading – in the long term – to widespread general wellbeing,<sup>206</sup> the former are, paradoxically, slightly more realist promoting the

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<sup>199</sup> “Innovative and dynamic industries emerge either because intellectual monopoly is not present or because it can easily be bypassed”. Boldrin and Levine (2008), p. 53. “We define monopoly as ‘the power, gained by the elimination of the competition, to control the conditions and the price at which the public can obtain particular goods or services’ (...). Meinhardt (1946), p. 36.

<sup>200</sup> See Lemley, in note n.

<sup>201</sup> “As creativity slowed down, consolidation took place, and a few large monopolies emerged, the demand for (...) patents later grew”. Boldrin and Levine (2008), p. 42.

<sup>202</sup> Wisely, “patentable subject matter need not to be defined with a single transcendent doctrine; it may also be decided on an industry-by-industry or field-by-field basis”. Merges and Duffy (2002), p. 165.

<sup>203</sup> Hegel (1999; 2000).

<sup>204</sup> Especially, “(...) patients are not like customers in other markets”. Muzaka (2011), p. 31.

<sup>205</sup> “(...) drugs are inherently different to most other commodities”. Joseph (2003), p. 436.

<sup>206</sup> This ideology permits authors to come out with incredible statements: “IP serves both the economic and social development of the whole society. All depends on the moment when the conflict between the two interests appears (...). A country which does not take steps to achieve the full realization of the right of the inventor to benefit from a full and robust protection of the moral and material interests (...) will not

idea(l) of human security and development, right here, right now – because “...in the long term we are all dead”. The way economic progress is measured turns human beings into factors, often labelled in weird ways, like “human capital”. The main benchmark remains the capital as such.<sup>207</sup> It may be argued that since the capital is still a form private property belonging to some individuals and IPRs protect such capital when invested in innovation, IPRs are HRs; it is of vital importance to defeat the present rhetoric: moving on such way property rights would become constitutive of the (legal) nature of a human being, which is clearly inadmissible.<sup>208</sup> The main question to address in the present section is whether it is reasonable to measure progress throughout the number of patents recorded every year.<sup>209</sup> Are these patents effectively useful? If so, useful to what? There is a race, taking place worldwide, in patenting everything and not those innovations possibly falling into one of the protected subject matter but even outside such categories since the risk is always to lose the chance to exploit a certain idea before others. This is particularly true regarding health, the human genomes, and infinite biological substances.<sup>210</sup> Since the *rationale* of IPRs is not legal but rather economical, whatever seems valuable becomes immediately eligible for patent protection. It is absolutely impossible to put a limit: it mostly depends by morality; unfortunately, culture and morality change quite often<sup>211</sup> (but they rarely improve) and fewer and fewer people have moral refrains before economic arguments. The global competition drives states to grant patents on every possible field in order to boost financial gains (plus-valence). The pattern is clear but the debate is constantly distracted or made impossible: IPRs problem is not complex *per se* but rather *complex-ified* (made complex), especially due to the often inaccessible language used by economists. Yet,

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experience the diffusion and the transfer of technology in its territory”. It seems like a threat! Botoy (2003), p. 125. Botoy is probably lacking some historical data.

<sup>207</sup> “The US Court of Appeals (...) has deliberately remoulded that system to protect investments as such, rather than discontinuous technical achievements that elevate the level of competition”. Maskus and Reichman (2004), p. 297.

<sup>208</sup> Property, as the capital is, represents an additional non-determinative attribute of the person. It is an further specification regarding relevant interactional qualities of the subject not changing the basic juridical qualification that has to be equal and equivalent for everyone regardless of their economic status: people are not defined accordingly to their properties.

<sup>209</sup> “The period of the Industrial Revolution is (...) greater economic progresses achieved without patents and thanks to open competition”. Boldrin and Levine (2008), p. 51.

<sup>210</sup> See in particular Lidgard (2004).

<sup>211</sup> Arendt (2012).

where these are leaving room for a decent understanding, lawyers and bureaucrats step in. Also experts seem confused since they regularly miss the point. Main IPRs' opponents, including NGOs, tend to focus on the element of the *price*, qualifying themselves immediately as *consumers* (like in the case of HIV/AIDS drugs). Such approach is reductive; a more systematic inquiry of the economic aspect of IPRs is necessary

μ § **Understanding economy** – The word “economy” derives from “oikonomia” (οἰκονομία: οἶκος-νόμος), which literally means “the rules governing the house”. Extensively, “oikos” (οἶκος) symbolizes “the goods of the Master, of the family” while the understanding of the normative theory in the ancient time would lead to the conclusion that “nomos” (νόμος) can equally refer to the necessary virtues to run the activity of the house. The house as such cannot be understood in modern terms, it is not the small flat hosting a limited number of people: the house was the living place of a broad community, as the presence of the “oi” clearly reveals. The “oi” reflects the implied idea of plurality: of goods, people and activities. The actual understanding of the law is far from the Greek interpretation, thus the best translation of the concept of “oikonomia” (οἰκονομία) would be: “the necessary virtues and norms to run the activities of the house and provide the needed goods to the family/community”. If this is the nature of the economy, it is evident that different models can be applied while it is not so clear what economic sciences are supposed to do. Modern economists, on average, like certain terms more than others and this helps in understanding how economy actually thinks itself: “long-term”, “efficiency”, “innovation”, “externalities”, etc. All of these words are similar to the political terminology of “public order” and “morality”: they are empty concepts serving political purposes and therefore highly ideological. For instance, “long-term” does not express precisely when; “efficiency” does not indicate in respect of what (aiming at what end);<sup>212</sup> “innovation” does not explain what to innovate and especially what “innovation” as such would be. Innovation is linked to development: is it merely financial (numbers) or human? Is “innovation”

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<sup>212</sup> “[This is] (...) an age of increasing faith in ‘the efficiency’ of the market solutions and the private sector (...)”. Cohn (2001), p. 441.



immediately progress and, if so, progress of what in which direction? “Externalities” are all those elements that challenge the veracity of the model or theory. They can also refer to those damages eventually provoked by that model or theory with the scope of neutralizing them in the speech. Modern economy uses its own language and its *medium* (the currency) for all the interactions taking place within its system. Since modern economy frames relationships and organize them,<sup>213</sup> it is immediately acting politically. It represents one possible form of politics itself. This is particularly true looking to the deep crisis affecting politics today.

( $\mu_I$ ) There are some economic elements that are relevant for the understanding of IPRs. First of all, there is a substantial difference between tangible and intangible goods: the formers are subjected to rival use among people while the latters are not.<sup>214</sup> Even in the cases of IP applied to certain objects or devices, the fact that someone takes advantage of that particular invention does not prevent others from doing so; of course, the use of the one device in possess of that individual turns it into a rival good. The tangible good is rival, not its IP added value. The crucial element to underline is precisely that IP originally constitutes an *added value* to the object as such. This is clear because of the improved “value in use” for that precise object. Therefore, it is possible to claim that patents shall eventually secure only the defined product while they shall not protect the implied idea in it nor the process followed to complete the product itself.<sup>215</sup> Such principle would perfectly fit within the pharmaceutical production permitting continuous research and innovation stimulating competition while still permitting PHCs to win a valuable degree of protection for their products in order to cover the expenditure for Research and Development (R&D).<sup>216</sup> Theoretically speaking, if the alienation of the whole work of a person would lead to the selling of the person

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<sup>213</sup> While the “oikonomia” (οικονομία) was the organization of existing relationships.

<sup>214</sup> See Muzaka (2011), p. 2. “There is a general tendency to that intellectual property is just like any other form of property”. Mylly (2009), p. 236.

<sup>215</sup> “Before TRIPS, patent duration was significantly shorter in many counties. (...) Importantly, before TRIPS agreement came into force, many countries provided only process, not product, patents”. Muzaka (2011), p. 35. See also Gana (1996), p. 324; Cullet (2003), p. 154. See India previous Patent system especially concerning drugs, *inter alia*, in Kuanpoth (2010), pp. 46 and following. Remind that: “[t]he same chemical product can be obtained by different processes and methods, and even by starting from initially different materials and components”. Boldrin and Levine (2008), p. 216.

<sup>216</sup> Since this constitutes the main complaint moved by PHCs.

herself<sup>217</sup> (turning her into a slave), the alienation of an idea – conceived as IPRs supporters argue, intended as direct expression and representation of the person, shall not be accepted.<sup>218</sup> The interesting qualitative distinction is that there is no need to alienate all of the ideas but only one as immediate synthesis of the whole person and her capacities. Again, the product as such may be eligible for protection within a certain economic system, if legitimate reasons are provided, but the idea and the process to fashion it in one particular way cannot. It is anti-economic to disqualify any other way to fashion the same idea or even similar ideas fashioned in the same or in different modes. A further step aims at defeating the self-conviction that monopolies are the only or just the most adequate forms of IPRs. Monopolies are just one of the many possible forms of protection and rewarding and surely not the best<sup>219</sup> – at least according to the economic theory itself that has been fighting against the *ancien regime* and all of its monopolies. IPRs are logically contradictory in the economic theory and they undermine the democratization of economic forces. During Middle Age and until very recently (1950-60's) education was a privilege for few. Not only it was so, knowledge constituted the main tool of power: the clericals and the nobles were the only able of reading and writing while the rest of the population was left in ignorance to permit easier control over the same. Similarly, IPRs are promoting a new “*restauration*” in counter tendency to democratic principles embraced by modern economy and – at least ideologically – by capitalism.<sup>220</sup> The IPRs regime is clashing against the original meaning of economy since it is not aiming at promoting the general level of wellbeing of people but merely the economic advantage of some. Economy wants the good of the community that is to be intended, nowadays, as global. Modern economy pursues the furniture of products and services at cheaper prices optimizing resources: IPRs are not

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<sup>217</sup> Marx (2010).

<sup>218</sup> “(...) when an inventor sells the exclusive rights to an idea, what is being traded is a copy of the idea plus the right to now prevent the original inventor from using her idea”. Boldrin and Levine (2008), p. 125.

<sup>219</sup> “For those who require compensation, patent rights are only one alternative”. Grosheide (2010), p. 81.

<sup>220</sup> It is necessary to consider that “(...) some advanced industrialised countries had set in motion a clear shift of their economic make-up from industry-based to knowledge-based economies”. Muzaka (2011), p. 45. This, in the moment when an increasing number of DVCs are reaching high productive capacity in the industrial sector. “The TRIPS Agreement is but one part of a much deeper phenomenon in which IP is playing a crucial role (...). Property law constitutes the objects of property; contracts enables the exchange of those objects. Through contract the object of property become tradable capital”. Drahos (1999b), p. 24.

coherent to such principles. However, these are just marginal symptoms of an overwhelming trend that may be seen as the disease of economy or distortion of it. Everything is systematically commodified in order to maximize the financial gain. Services are intended as particular types of products, thus health and all the other rights are consequently turned into commodities, tradable goods.<sup>221</sup> People can enjoy them if they can afford the costs. IPRs are definitely coherent to this last deformation of economy that.

( $\mu_{II}$ ) *Economy and capitalism* – *Capital-ism* means maximization of the capital. The present model has intrinsic contradictions and infinite problems that economy itself is unable of solving dismissing them at the expenses of politics and individuals. If the capital may be useful as economic tool, its absolutization produces deformations in every connected procedure and activity. The capital becomes the start and end of the economic cycle in which human beings are mere factors: they count in the production and consume of goods. When falling out one of the few given categories, they are labelled as groups affected by “externalities”. Capitalism is the disease of economy.<sup>222</sup> The market is perfect but the actors within are not: it would be funny to ask capitalist what is then the difference with their eternal enemy, namely communism, which has had the same problem. Again, the market is perfect but not always: it cannot be so because people are not machines – even if the present tendency is to compete with them in order to turn individuals in super efficient workers. All the economic terms mentioned above have now a sense: “efficiency” measures the coherence of a system in reaching the maximization of the capital and the minimization of expenditure (including use of human resources). Not surprisingly, this economic model finds impossible to solve the conflict regarding medicines: these are conceived to help human beings in addressing basic needs regarding health while the capitalist-based model aims at maximizing the capital.<sup>223</sup> All the rest is marginal or incidental. Delivering goods and services is functional. The promotion of the *medicalized* society generates people asking

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<sup>221</sup> “Intellectual property transforms cultural and innovative objects into intellectual capital, enabling its accumulation, like money”. Mylly (2009), p. 60.

<sup>222</sup> It is thus senseless to “(...) address problems [related to IPRs] caused (...) by the expansion of capitalism by employing tools of capitalism”. Brush (1993), p. 666.

<sup>223</sup> “[T]he ability of IPRs to provide the necessary incentives for biomedical R&D in diseases affecting people with no or little purchasing power [is] non-existent (...)”. Clift (2006).

drugs for solving every thinkable disturb, even those completely invented.<sup>224</sup> Every mean is justifiable to reach the final goal, including norms within the legal system. The capitalist system does not immediately challenge state sovereignty: it happens when there are conflicting interests but these are rare. Indeed, the State is finally finding back its original form: administration of people and territory, dismissing the entire welfare structure now abandoned to market “forces”. Why economic actors have to instrumentalize norms if they believe in the market for rewarding merit, efforts and quality? The argument sounds opportunistic since it is used when needed and discarded when contradicted by facts against the interests of the strongest actors, such as Trans-National Corporations. Capitalism has two core dynamics: (i) commodification (it subsumes everything in its dynamic) and (ii) expansion of its cycle. The second point deserves attention: in the initial phase this economic model seeks for spatial expansion intended in the geographical sense. As soon as it has covered the entire globe, the economic cycle – in order to avoid overwhelming debts and inflation – has to keep expanding and it thus starts invading every further conceptual dimension. The commodification is not just a pre-requisite of capitalism but also its main consequence: everything becomes tradable. Before such step, what has to be traded must be obviously *de-fined* as products and this is where IP steps in. IPRs are necessary in order to define a certain product with the purpose of make it tradable. This is not the only advantage of IPRs: patents have one core feature, they can arbitrarily modify the *exchange value* of products (while the “value of use” remains unchanged) boosting financial gains in trading. A further systemic surplus derives from the possibility of delocalizing production of goods in LDCs or DVCs without the risk of IPRs infringement or unfair business practices.<sup>225</sup> TRIPS secured this productive gain due to the global harmonization of IPRs and the effective *quasi-juridical* remedy offered. If normal non-essential products are heavily affected by such practice, medicines are even more due to

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<sup>224</sup> Notably, PHCs have recently started to prefer the production of drugs regarding chronicle problems that cannot be qualified as diseases, such as cholesterol. Propaganda regarding risks is widespread throughout medias raising serious concerns regarding bioethics and deontology.

<sup>225</sup> Despite the lower production costs, the value of goods remains arbitrarily decided because of the existing patents or TradeMarks. PHCs have started trademarking names of drugs in order to defeat Generic Companies’ competition. Interestingly: “...the impression one gets from a cross-country comparison is that the less competitive and more inefficient the news industry of a country is, the stronger is the demand for monopolistic protection from new entrants”. Boldrin and Levine (2008), p. 27.

their particular nature: people need drugs. In the capitalist model, people are not the end; people are not perceived as people! The continuous expansion of the economic cycle creates progressive increasing of prices of every kind of product but – proportionally – a higher rise will occur where monopolies exist or in cases of very essential goods.<sup>226</sup> Higher prices for people do not always provoke immediate loss of wellbeing as long as the wages and the general wealth raise proportionally.<sup>227</sup> Yet, the Arab Spring exploded because of the massive cost of essential goods, is clearly revealing the risks connected to the present economic model: the disease of a certain system may cause two outcomes, namely the succumbing of it or its healing. *Tertium non datur*.

**v § Medicines' costs and the problem of patents** – Accordingly to art. 66 of TRIPS, DVCs and LDCs can use a three to ten years *interim* period in order to develop the needed pharmaceutical expertise and set up home production. Beside, normative adjustments could have been gradually introduced within the legal system. The definitive deadline was due to 2008 but the same has been further prorogued. Several LDCs, especially in Sub-Saharan Africa, remained stuck into the following vicious circle: technology has unaffordable costs,<sup>228</sup> human capacities are lacking due to the absence economically accessibly drugs, such as ARVs. A large proportion of the population is affected and progressively exterminated.<sup>229</sup> The healthy most skilled people just emigrate (brain-draining) serving in DCs. Overcoming the deadlock seems impossible in the present regime. It is relevant then to get a better insight to the

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<sup>226</sup> Indeed, the curve of the demand of these tends to be quite inelastic.

<sup>227</sup> Nonetheless, "Intellectual property rights raise prices and thus can reduce the global movement of intellectual goods". Grosheide (2010), p. 87.

<sup>228</sup> "While developing countries with little technological and innovative capacity are bearing the cost of implementing the TRIPS agreement, there are no documented cases of positive impact on innovation in the medical field as yet. If there is to be an impact it will be in those developing countries that already have a promising science and technology base". WHO (2006), p. 100. Consider also that: "Worldwide, so-called diseases of poverty (i.e. communicable, maternal, perinatal and nutrition-related diseases) contribute to over 50% of the burden of diseases in low income developing countries - nearly ten times higher than their burden in developed countries". *Ibidem* at p. 15.

<sup>229</sup> "There is a considerable tension between intellectual property rights and the right to development. Patent systems restrict access to life-saving drugs, by raising the price of those drugs (...) [lowering] its stock of human capital (...)". Drahos (1999a), p. 356. Notably, this is still an economic argument, the human being as such is not considered.

economic process rising medicines' costs.<sup>230</sup> There are three core steps contributing to the delivery of drugs to people: (i) R&D; (ii) production; (iii) distribution.<sup>231</sup> Beside, other contextual elements have relevance: the entity of the market and the presence of effective institutions providing, *inter alia*, security controls and education (both basic/primary and professional).<sup>232</sup> All of the three levels listed above are affected by the existence of IPRs: R&D has to deal with both patents and copyright, the productive processes are often patented separately; distributed products are subjected to trademarks.<sup>233</sup> Falling into the subject matter of business methods, some distribution processes may be now eligible for patents. IPRs obviously increase costs more than proportionally at every subsequent stage. Most of the (pseudo) analysis developed within the Academia has stressed the only problem of the price.<sup>234</sup> Economists, excited by the sole term "price", stated that PHCs should find new price strategies. Price discriminations according to the market of destinations are possible<sup>235</sup> – even if they do not constitute the real solution but rather a compromise<sup>236</sup> – yet PHCs fear the possible

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<sup>230</sup> Along with other therapeutic technology.

<sup>231</sup> For a broader analysis, see Abbott (2005a), p. 91-92.

<sup>232</sup> "Issues of access to existing patented medicines are linked to a number of factors, such as price, insurance schemes, availability of medical staff and the state of public health infrastructures and spending, to mention a few". Muzaka (2011), p. 31. See also Yamane (2011), p. 336: "One of the most difficult obstacles to the access to medicines would be the lack of adequately trained medical personnel to prescribe and administer appropriate medicines".

<sup>233</sup> "Companies also use trademarks law to extend their market power beyond the patented drug's expiry date. Patented drugs are usually marketed under their brand name rather than the generic name". UNCTAD-ICTSD Project on IPRs and Sustainable Development (2004), p. 99.

<sup>234</sup> Moon & Al. (2011), p. 2-3. The article offers an overview of different price strategies concerning drugs and possible drawbacks. Some suggested that: "Higher inventive step in DVCs should allow less patents and lower prices of products". Yamane (2011), p. 420. This does not mean that the argument of pricing is not relevant and complicated, consider for example: "A new TB antibiotic may cost significantly more than its predecessors but the overall cost of the treatment may be much lower because the treatment time is shorter. (...) The relevant concept in this case is 'opportunity cost'. (...) Nevertheless, the pricing of the product itself is extremely important in developing countries because most medicines are purchased directly by patients". WHO (2006), p. 127.

<sup>235</sup> Besen and Raskind (1991) advanced the idea of distinguishing between "discrimination" and "legitimate differentiation". The latter term approach the question from the other side, it is not the producer to discriminate the price but the market of destination to possess those critical elements such to deemed the same as eligible for legitimate price differentiation.

<sup>236</sup> Differential pricing (...) has been presented (...) as an alternative use of flexibilities (...). Some companies have offered voluntarily to sell their drugs at heavily reduced prices in some markets (...). UNCTAD-ICTSD Project on IPRs and Sustainable Development (2004), p. 98. For pricing policies see WHO (2006), p. 129: "Because incomes are very unequally distributed in most developing countries, companies may find it best for their profitability to concentrate only on high income segments in developing countries, in particular because it is more difficult to apply a differential pricing policy within

parallel trade to other countries having higher costs for the same product. Such reasoning reveals two main facts: patients and ill-people are far from being the first and main concern of PHCs, profit is; the eventual price discrimination, which has been passed off as “humanitarian choice”, reveals the existence of an absolute and odious monopoly that leaves the right holder the possibility to arbitrarily decide prices, independently from production costs only aiming at maximizing incomes. Downing prices in LDCs is a perfect marketing option (largely advertised all over the world) to win the public opinion and private investors’ sensitivity on certain issues.<sup>237</sup> Price strategies work on the effects and not on the real causes of high prices. The battle of many generic producers had the important role of revealing the incredible gain surplus<sup>238</sup> permitted by monopolistic regimes,<sup>239</sup> nonetheless, Generic Pharmaceutical Companies (GPCs) are business as well and their match against PHCs is entirely about innovation and competition within the market system. Even if some GPCs aims at delivering drugs at fair prices,<sup>240</sup> still the first target is not people but profit.<sup>241</sup> Some

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developing countries than it is between them”. More generally, Joseph (2003), pp. 448-450; Yamane (2011), p. 274.

<sup>237</sup> “(...) corporations have gone further by donating drugs. (...) [but] they do not provide a long-term solution to the problem of lack of access”. UNCTAD-ICTSD Project on IPRs and Sustainable Development (2004), p. 98. Notably, “It would be much simpler and less expensive if more companies were to make a commitment not to take out patents in low-income developing countries or not to enforce existing patents”. WHO (2006), p. 141.

<sup>238</sup> Made possible due to the fact that “(...) the pharmaceutical industry is largely cartelized (...)”. Joseph (2003), p. 428.

<sup>239</sup> “(...) huge profits of Big Pharma (...) are abnormally large and persistently so. A signal, we agree, of a highly monopolistic industry”. Boldrin and Levine (2008), p. 232. “The pharmaceutical industry has consistently, for many decades, been an extraordinarily profitable sector”. Angell (2000) quoted in Joseph (2003), p. 432.

<sup>240</sup> However, “(...) competition from generics does not always bring prices down (...)”. The Panos Institute (2002), p. 12. Furthermore, “Whether a medicine is generic or not depends on both IPR protection and national regulatory rules for marketing approval. (...) Generics for one country may not be generics for another country”. Yamane (2011), pp. 297-298.

<sup>241</sup> Nevertheless, it is important to stress that “(...) me-too drugs (...) are very expensive because of patent protection” that has to be extended also on data protection preventing the use of results of previous trials for the approval of the same compound. Boldrin and Levine (2008), p. 231-232 and 237. “[T]he US and the EU have adopted an ‘exclusive rights model’, which protects data against use for five years and 8+2 years respectively. (...) data protection (...) poses a huge obstacle to generic competition and, probably, to access data for compulsory licensing purposes”. Muzaka (2011), p. 114. “Data exclusivity refers to the keeping confidential by drug regulatory authorities of data on the safety and efficacy of a new medicine for a set period. This data would be especially useful to generic producers which need only demonstrate through such data that their product is therapeutically equivalent to the original. (...) access to such data substantially reduces time, expense and effort needed for registering new drugs”. Kerry and Lee (2007), p. 4. There has been an attempt to limit the data protection, which is *de facto*, contradicting the usefulness of patents in the part they disclose information; see Bolar Amendment in Milenkovich (1999); Pugatch

NGOs do act differently<sup>242</sup> but they constitute the exception rather than the normality. It is now worth better explaining direct and indirect causes of price rise.

(v<sub>1</sub>) *Direct effects* – As noted above, there are three stages in the delivery of medicines to people in need. IPRs affect every single step. PHCs-provided data assess that the first two levels have a cost, on average, of \$800 million.<sup>243</sup> This incredible amount has to be adequately verified. In the R&D the technology in use is almost always of the very last generation, which implies high costs boosted by the presence of patents; the research encompasses data covered by copyright (and not available under fair use) and many patented molecules and substances on which royalties have to be paid.<sup>244</sup> It has been found that a broad part of the research has been publicly financed and carried out by Universities.<sup>245</sup> The further step consists in the production that has normal functioning if there are no patents covering the productive methods. Yet, this is increasingly the practice. In the distribution phase PHCs have adopted the practice of trademarking names of drugs in order to defend products from competition of generic ones; possible patented business practices also rise final prices. Finally, drafting successful claims to win patents and the necessary research to investigate whether previous patents have been granted on products add the costly bills of lawyers.<sup>246</sup>

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(2005); Himma (2006); King and Kanavos (2002). For more detailed information on Europe see CMS (2007).

<sup>242</sup> “(...) it is worth noting the launch in 2002 of the Drugs for Neglected Diseases Initiative, a non-profit, needs-driven research entity designed to develop drugs for the diseases neglected by market-driven R&D”. Joseph (2003), p. 435.

<sup>243</sup> See WHO (2006), p. 31. “[D]espite the continuous technological advances and the existence of pharmaceutical IPRs, the pharmaceutical R&D process has lost its innovative edge. (...) the pharmaceutical R&D process has become not only less innovative, but also more lengthy and expensive”. Muzaka (2011), p. 26. See also Boldrin and Levine (2008), p. 215 and 232.

<sup>244</sup> “Monopoly (...) raises the cost of producing the idea. The innovator must pay all the other monopolists more to use their ideas to create his own”. Boldrin and Levine (2008), p. 150.

<sup>245</sup> “Public institutions also play a major role in research”. The Panos Institute (2002), p. 9. “(...) most of those university laboratories are actually financed by public money (...) private industry pays for only about one-third of biomedical R&D (...) and two-third outside biomedical area”. Boldrin and Levine (2008), p. 227. “[T]he riskiest and most expensive basic research (early R&D) has traditionally been funded largely by public money, with the industry only becoming involved when such research indicates promising results”. Muzaka (2011), p. 27. “(...) 73% of private patents were based on knowledge generated by public sources such as universities and nonprofit or government laboratories”. Thurow (1997), p. 98.

<sup>246</sup> Claims are particularly relevant since: “The scope of protection offered by a patent is determined by its claims, which are technical descriptions of the process, machine, method, or matter contained in the original patent application”. Besen and Raskind (1991), p. 7.



( $v_{II}$ ) *Indirect effects* – These are mainly caused by the dimension of the internal market – if existing – the adequacy of the institutions in allocating resources (including public spending) and in addressing policies on different aspects, including, *inter alia*, quality controls.<sup>247</sup> It has been discovered that almost one fourth of the total expenditure for medicines in LDCs<sup>248</sup> is completely wasted because of substandard quality of products.<sup>249</sup> Beside, counterfeit medicines are equally threatening patients' health but the personnel are not always adequately formed to recognize improper products.<sup>250</sup> States shall prevent distributors from creating cartels or from establishing unfair monopolies. Basically, better infrastructures and sanitations along with appropriate education would eradicate several diseases or, at least, decrease the amount of medicines needed.

( $v, v_I$ ) *Hidden costs* – What is not adequately shown in any calculation is the cost of the capitals that becomes increasingly higher due to the required amount and connected interests to be paid. Higher R&D costs means bigger capitals to be invested with higher interests rates and heavier opportunity costs to be compensated in the price. If every stage encompasses increased expenditures (also) because of the existence of IPRs, the total costs increase more than proportionally.<sup>251</sup> In the access to medicines for DVCs and LDCs further monetary issues have to be undertaken: the exchange rate on

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<sup>247</sup> “The fundamental problem is the lack of effective demand in the market for products that are required to prevent, treat or cure illnesses that affect poorer people in developing countries. (...) Where there is no purchasing power - either on the part of the government or the patient - the market is not an adequate determinant of the value”. WHO (2006), pp. 28-29. See also Yamane (2011), p. 336.

<sup>248</sup> The problem exists also for developing countries that “(...) often purchase drugs without adequate reference to quality standards”. Caudron & al. (2008), p. 1063.

<sup>249</sup> “Substandard medicines can have serious clinical and public health consequences (...). In the industrialized world drug regulatory authorities have developed strict standards and controls to ensure drugs are effective and safe. However, in the less-developed world, lack of human and financial resources within the health sector as a whole limits the capacity of drug regulatory agencies, resulting in a suboptimally regulated environment in which substandard drug production can persist (...)”. Caudron & al. (2008), p. 1062.

<sup>250</sup> “Where pharmacovigilance systems are weak or not existent, a higher degree of responsibility is placed on medical staff (...) [but there is an] acute lack of health staff in most developing countries (...)”. Caudron & al. (2008), p. 1064.

<sup>251</sup> Indeed, note: “total R&D expenditure showed an increasing upward trend in DVC during 2000-02 [since the entrance into force of IPRs]”. Yamane (2011), p.401.

currencies destroys the purchase power on the international market.<sup>252</sup> If products are directly purchased in foreign currency the same has high costs and very high interests rates if loaned. Beside this purely financial arguments, other hidden costs have to be shown: the bureaucracy (registering patents is costly), including legal litigations – often started for mere strategic purposes<sup>253</sup> –, the advertising, and the marketing budgets.<sup>254</sup> It has been proved that the latter attract up to the 35% of the total budget of PHCs.<sup>255</sup> What is missing is the incidence of taxes for every passage: if some can be deduced,<sup>256</sup> others cannot and are only reflected on the final price.<sup>257</sup> Inadequate norms and inefficient bureaucratic structures may also lead to further avoidable spending, i.e.: (i) the requirement of conducting tests on equivalent drugs as they were totally new products; (ii) the researching duplicate costs since many PHCs may conduct the same study but just the first is awarded with the patent while the others are prevented from marketing their substances.<sup>258</sup> Finally, most of these arguments are referred to innovative drugs while nothing has been said regarding well-known diseases and related remedies, such as the case of diarrhoea, costing life to hundreds thousand children in

<sup>252</sup> “(...) particularly in Africa, with their typically low reserves of foreign currency (...)”. Gana (1996), p. 333. These countries cannot even afford royalties for basic uses of products and inventions.

<sup>253</sup> There are also the so-called “submarine patents”, which are purchased by companies waiting to exploit their property merely on the base of legal litigations. See Boldrin and Levine (2008), p. 84.

<sup>254</sup> “Pharma companies spend about 15 percent of their revenues on research and development, but a much larger portion of expenditures goes to administration, advertising, and promotion, which are also covered by patent rents. (...) patent protection almost certainly results in higher prices for new medicines”. Abbott (2005b), p. 325.

<sup>255</sup> “(...) the top thirty representative firm spends about twice as much on promotion and advertising as it does on R&D”. Boldrin and Levine (2008), p. 226. See also, The Panos Institute (2002), p. 9; and Muzaka (2011), p. 30 that includes a table with useful data.

<sup>256</sup> Indeed, “R&D costs do not necessarily take into account the generous tax deductions available in many countries to the pharmaceutical industry”. Joseph (2003), p. 433.

<sup>257</sup> “If there were weaker patent rights, (...) taxpayer costs would be considerably smaller”. Joseph (2003), p. 440. Furthermore, taxes are calculated in percentage on the price thus higher prices bring to proportionally higher taxes on the same products.

<sup>258</sup> The case of simultaneous discoveries undermines the idea that innovative products deserve protection because they deliver creative solutions to existing problems. “(...) if others were going to discover it in a few years anyway, the nit scarcely made sense to give a long-term monopoly. (...) simultaneous discoveries tend to be the rule rather than the exception (...) Academics, playing all kinds of tricks to plant their flag first (...)”. Boldrin and Levine (2008), pp. 202-203. If the innovation is effectively so, the company will have enough time to sell its product covering the investments before competitors may be capable of marketing similar products (it takes time). The patent system causes large waste of resources and incentive immoral ways of competition since the first wins all. “The combined expenditures of two firms seeking the same patentable invention in a patent race (...) may be greater than is socially optimal”. Loury (1979), Dasgupta and Stiglitz (1980) quoted in Besen and Raskind (1991), p. 6. Notably, higher costs are not a problem for corporations but for consumers since they are then paying the socially non-optimal allocation of resources.

LDCs.<sup>259</sup> Many LDCs and DVCs need very basic and possibly cheap diagnostic technology that is not made available since it would be economically counter-productive for any business. It is equally unexplainable, on the base of production costs argument, the reason why almost all the PHCs regularly practice the so-called “ever-greening”<sup>260</sup> patenting of second and further uses of the same drug or substance.<sup>261</sup> It is not even credible that maximizing the profit would bring more and better R&D since data clearly states that PHCs devote 5-10% of the total budget to such activity.<sup>262</sup> What this section may have proved is the non-economic causes of high costs. Financial and institutional elements<sup>263</sup> concur to boost final prices and IPRs play a major role triggering a vicious circle leading to increase costs, *coeteris paribus*, more than proportionally.

§ § **Economic analysis** – Talking about IPRs as necessary tool for innovation sounds strange.<sup>264</sup> They are more likely to be the main evidence that most PHCs are

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<sup>259</sup> “It is a violation of the dignity of persons to starve while food is plentiful, or for the children of the poor to die of preventable disease for which affordable vaccines exist. (...) The limited use of rights-based approaches and analyses (...) failed responses to population-level health threats are all too common as well, as the many millions of deaths each year from preventable causes such as diarrheal diseases and childhood illnesses attests”. Beyrer and Pizer (2007), p. 5.

<sup>260</sup> “(...) pharmaceutical companies often use patents to unduly delay or restrict generic competition, in some cases for several years beyond the 20-year patent duration. ‘Ever-greening’ or ‘line extensions’ are terms used to refer to the use of IPRs for extending the monopoly, or at least the market dominance, of a drug beyond the life of the original patent protecting it”. UNCTAD-ICTSD Project on IPRs and Sustainable Development (2004), p. 99. See also von Braun and Pugatch (2005) and Muzaka (2011), pp. 28-29.

<sup>261</sup> According to TRIPS art. 27.3(a), new uses of the same compound can be patented. The US allow the practice while the EU approach is stricter due to the application of art. 42(4) of EPC. Incredible political pressure has been exercised on India when, in 2005, approved the Amendment on its Patent Law admitting recognition of Patents on the same substance, drug or product only for the first second-use discovered. Notably, the fact that such use would have been discovered and not invented would lead to the conclusion that it should not be patentable at all since Patents secure inventions and not mere discoveries.

<sup>262</sup> “There is evidence that the amount reinvested into R&D (...) is disproportionately small (...). [P]harmaceutical corporations routinely overestimates their R&D costs (...). [Furthermore] much of the R&D (...) is actually done at public expenses”. Joseph (2003), pp. 432-433.

<sup>263</sup> Both the World Bank and the IMF are indeed playing an increasingly important role. See Abbott (2002), p. 477; Yamane (2011), p. 261 note in particular that “ [i]n underdeveloped state (...) for most patients [remains problematic] to get access even to old, unpatented drugs”.

<sup>264</sup> There are least two core assumptions: “(...) that strong IPRs are good and necessary for innovation and technological advancement. [And] (...) that the lack of strong IP protection is a barrier to free trade which needs to be eliminated”. Muzaka (2011), pp. 38-39.

unable or unwilling to innovate<sup>265</sup> and pretend to defend their market position through the law.<sup>266</sup> Not only they slow down improvements<sup>267</sup> but they also neglect several not-so-innovative but equally crucial researches, such as those on tropical diseases or other illnesses affecting people with poor or no purchasing power at all.<sup>268</sup> It sounds even more incredible since most of the infections and maladies responsible of the highest number of victims are well known since long time,<sup>269</sup> like in the case of malaria.<sup>270</sup> GPCs are prevented from developing experimentations<sup>271</sup> before the expiration of patents, causing delays in the improvement of the same products – thus it is not only a matter of price.<sup>272</sup> WTO's mission is to improve trade<sup>273</sup> and such end is important because trade is supposed to increase the general wellbeing of people in different sides of the world. It is unclear how TRIPS complies with this general purpose: the Agreement causes concrete disadvantages to people, even when conceived as

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<sup>265</sup> “Big Pharma spends much of its R&D money on drugs, known as ‘me-too’ or ‘copycat’ drugs, which are innovative enough to attract patent protection, but in fact add little therapeutic value to existing medical treatments”. Joseph (2003), p. 434.

<sup>266</sup> “Drugs companies will often try to stretch out their exclusive rights over successful drugs for as long as possible, especially when they are heavily dependent on a small number of highly profitable products”. UNCTAD-ICTSD Project on IPRs and Sustainable Development (2004), p. 99.

<sup>267</sup> Instead, “[d]isproportionate research is put into drugs to combat lucrative problems (...). Comparatively little research is conducted into third world killers like malaria or tuberculosis”. Joseph (2003), p. 435.

<sup>268</sup> “Developing countries (...) account for less than 10% of the global pharmaceutical market”. t’Hoen (2003), p. 39. “Evidence that correlates poverty with high disease burden is compelling. (...)Poverty affects purchasing power, and the inability of the poor people to pay reduces effective demand, which in turn affects the degree of interest of for-profit companies”. WHO (2006), p. 13; while on orphan diseases read pp. 102 and following.

<sup>269</sup> For instance, “penicillin production has been progressively abandoned (...)”. Caudron & al. (2008), p. 1064.

<sup>270</sup> “Patent protection does not ensure that the most common diseases will attract the greatest amount of research”. Lanjouw & MacLeod (2005), quoted in Cullet (2007), p. 416.

<sup>271</sup> The disclosure of the information would permit other Companies, generic and non-generic, to conduct experiments in order to improve the quality and the effects of such drug or even find different applications. Unfortunately, the question has been considered merely under the business perspective leading to the conclusion that some experiments are possible (this is why many PHCs now want data protection) the most meaningful and important are prohibited as well as the practice of stockpiling: producing a certain drug and store it in order to put it into the market immediately as soon as the Patent expires. See Dutfield and Suthersanen (2005), p. 136. See also Muzaka (2011), pp. 115-116.

<sup>272</sup> Nevertheless, GPCs are equally economic actors just pursuing a different strategy. Their main goal remains profit and they are probably exploiting the general battle against main PHCs to gain a better position on the market and also ideologically appear as “the good ones”.

<sup>273</sup> “The WTO provides a forum for negotiating agreements aimed at reducing obstacles to international trade and ensuring a level playing field for all, thus contributing to economic growth and development.” Further information are provided at the following link: [http://www.wto.org/english/thewto\\_e/whatis\\_e/wto\\_dg\\_stat\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/wto_dg_stat_e.htm) (visited March 18, 2012).

consumers. The “long-term” argument may work for different questions but in the case of health, problems are very evidently right here and right now, requiring immediate solutions. WTO itself embodies a living paradox:<sup>274</sup> liberal capitalism seeks deregulation while the same companies are now promoting rules – at their own advantage.<sup>275</sup> If the market has anomalies or failures, it is unacceptable to address adequate attention and deliver solutions only to some of such gaps; if IPRs are necessary to overcome the failure of the market regarding innovation,<sup>276</sup> it is equally valid to pretend other legal tools to solve the failure in delivering medicines to people in need. The change of route recently decided by several PHCs, far from being proof of their morality, it is mere marketing. Proving their self-sufficiency<sup>277</sup> in solving the main critical issues arising in the field of the pharmaceutical production, they aim at avoiding external regulations. States appear slightly dumb at the eyes of an impartial observer: they feed research through public funding and they provide the national health care system often paying (at least in welfare models) part of even the entire cost of medicines for citizens. Yet, not satisfied, now states pay the bill of IPRs protection, which is immensely costly. As much it gives, as little it gets.<sup>278</sup> It is to stress how IPRs requires an increasingly higher degree of pervasive control over larger portion of people’s life<sup>279</sup> that is not just a concern for freedom but it also implies new costs, i.e. more taxes. Such absolute control is against the same liberal idea inspiring modern

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<sup>274</sup> Especially when referring to TRIPS Agreement.

<sup>275</sup> “We find it ironic that, as tariffs, quota, and other formal barriers to trade are dismantled, there has been a strong push to re-regulate world technology markets”. Maskus and Reichman (2004), p. 282.

<sup>276</sup> For example, “The reward by monopoly theory calls for protection in the name of fairness; to secure the inventors their just reward, proportional to the usefulness of the invention to the society. As this reward cannot be guaranteed by reliance upon the ordinary market forces, State intervention is justified in the provision of temporary monopoly. (...) The incentive theory posits that in order for inventive activity to be maximized it is necessary to offer specific enticement. It is based on a series of assumptions about the basis economics of the inventive process”. Fisher (2007), pp. 68-69 and 73. Yet, “(...) complex R&D projects at every level will become increasingly impracticable if too many owners of too many rights have to be tithed along the way”. Maskus and Reichman (2004), p. 298. On innovation see also WHO (2006), p. 148.

<sup>277</sup> PHCs are not self-sufficient since they constantly rely on different institutions of the state.

<sup>278</sup> People often pay drugs twice: they purchase the product at constantly higher prices and they are required to contribute to the State expenditure with taxes; the latter go, in part, to financing public research than exploited by private PHCs, to the justice system enforcing IPRs and to compensate the part of cost covered by the State.

<sup>279</sup> “The legal system may be able to stop factories from copying and selling CDs or books in volume, but it cannot stop individuals from replicating the materials for themselves or selling small numbers to their friends”. Thurow (1997), p. 99.

economy and the market system proving that main financial and business groups are trying to impose a new form of “*restauration*” crystalizing their position of power.<sup>280</sup> The proportional increase of costs, described in the previous section, goes in favour of the biggest groups and of the financial institutions: those economic actors (PHCs) managing greater financial resources can push out of the competition all the smaller ones just suing them for IPRs infringement absorbing all their financial capacities in the legal litigations,<sup>281</sup> distracting them from R&D thus slowing down their pattern of innovation and relative best capacity on certain products.<sup>282</sup> Paradoxically, these smaller businesses are more likely to pursue research on rare or neglected diseases in order to attract public financing and win a market niche, but they get often neutralized.<sup>283</sup> When R&D costs are too high, again main PHCs enjoy structural advantage.<sup>284</sup> One more evidence regarding the claim that IPRs secure invested capitals:<sup>285</sup> financial companies providing capitals and credit are those gaining the most from the continuous rise of costs. Huger capitals means higher interest rates due to the connected risk. Furthermore, there is a substantial gain in terms of subliminal power: the constant growing of costs means greater exchange value of products in the international markets preserving the

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<sup>280</sup> Since capitalist economy, and Modern economy in general, aspire to frame relationships among member of societies and provide an order to the same, they have political relevance and thus are subjected to the same diseases, such as Michel’s “Iron rule of oligarchy”. See also Boldrin and Levine (2008), p. 17: “Intellectual monopoly is not a cause of innovation, but rather an unwelcomed consequence of it”.

<sup>281</sup> “Increasingly, intellectual property is becoming central to strategic battle plans. Companies such as Intel have big legal budgets to defend what they think is their property, but they are also accused of aggressively attacking what others think is theirs in order to create uncertainties, time delays, and higher start-up costs for their competitors”. Thurow (1997), p. 97.

<sup>282</sup> IPRs far from be genuinely rights, they are mere claims thus the justice system falls in the trick of constantly recognizing structural advantage to the strongest, contradicting the nature of the legal system as such, which is neutralizing meaningful inequalities. Biggest firms destine a consistent percentage of the annual budget to legal litigations intended as business strategy!

<sup>283</sup> “People who argue that patents are good for small firms do not realize that, because of the patent system, most small firms (...) are forced to set themselves up as one-idea companies, aiming only at being purchased by the big incumbent”. Boldrin and Levine (2008), p. 75.

<sup>284</sup> Consider also that: “(...) higher protection of IPRs in the South stimulates R&D investments in the North”. Fink and Primo Braga (1998), p. 174. Not surprisingly, “The major patent-holding pharmaceutical companies are concentrated in few countries, including the US, Great Britain, Germany, Japan and Switzerland. These countries earn substantial rents from the exploitation of pharmaceutical patents”. Abbott (2005b), p. 324. Importantly, “France, Germany, Italy, Japan, Sweden and Switzerland, home of some of the most innovative pharmaceutical companies, persistently resisted providing pharmaceutical product patents until their industries had reached a certain degree of development”. Hanses (2002), p. 80-2.

<sup>285</sup> In general, commodification (of ideas) means “*monetarization*”, giving immediate structural advantage to those issuing credit.

primacy of the currency.<sup>286</sup> Having preserved an asymmetric position within the global economic system, it is then possible to buy or blackmail weaker actors throughout the so-called Foreign Direct Investments (FDIs).<sup>287</sup> FDIs have constituted one main argument during the Uruguay Round of negotiations: in order to attract them states must enforce IPRs.<sup>288</sup> As recent history reveals, foreign capitals and FDIs are volatile thus they may disappear from a day to another for mere short-term profit interests.<sup>289</sup> Very often, FDIs feed another negative phenomenon, namely the brain draining: where TNCs step in they immediately attract the most skilled workers (internal brain-draining)<sup>290</sup> or eventually become sponsor of young students to travel abroad in order to study. What is passed as worthy charitable action *de facto* deprives these countries of smart minds. In general, DCs attract the few very skilled people from many DVCs and most of the LDCs. After the brain draining, of whatever type, IPRs are an insult added to the damage! Such argumentation also defeats the traditional rhetoric assessing that the wealthier are so because smarter and of good will, deserving thus to be favoured, otherwise innovation risks to slow down or even die.<sup>291</sup> There are deep structural deficiencies causing terrible inequalities.<sup>292</sup> The counter-prove is immediately provided: those countries that have challenged or not applied IPRs at all,<sup>293</sup> are now those more

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<sup>286</sup> Phenomenon of the “seigniorage”.

<sup>287</sup> Smith (2004), p. 2318. For a satisfactory understanding of the FDIs-IPRs relation, from a purely economic perspective, see: Mansfield (1994); Fink and Primo Braga (1998).

<sup>288</sup> Notably, one possible form of FDIs is the establishment of productive activities that has become possible precisely because of the protection of both goods and production methods. “(...) firms are more likely to invest in countries with strong protection, since the smaller risk of imitation leads to a relatively larger net demand for protected products [but] higher levels of protection may cause TNCs to switch their preferred mode of delivery foreign production to licensing. (...) The importance of IPRs regarding the composition of FDIs depends to a large extent on whether firms are able to maintain control over their proprietary assets in the absence of legal protection”. Fink and Primo Braga (1998), pp. 172-173. Note how the entire discussion is centred on corporations and firms, nothing regarding IPRs is really about people.

<sup>289</sup> Nonetheless, FDIs remain mostly a political “weapon”.

<sup>290</sup> Smith (2004), p. 2315.

<sup>291</sup> This constitutes a reflection of the utilitarian (pseudo) thinking: the maximization of the capital, in general, is intended as maximization of the utility of the individual, which is immediately the utility of the group since it improves the general wellbeing. There is very little room for social justice concerns and no mention at all is done to capacities and merits.

<sup>292</sup> Indeed, “Raising drug prices globally [because of patents] will, all else being equal, generally adversely affect the health of the populations of poorer states”. Drahos (1999), p. 30.

<sup>293</sup> At least for a certain period of time. See *infra* at 94.

likely to compete on the international market: China, Brazil and India.<sup>294</sup> It is therefore evident how senseless would be to establish an unfair and unbalanced system since there is the risk of backfiring against those who have promoted it as soon as the international equilibriums change.

o § **Political Economy** – Two core types of concerns arise: the first is of theoretical nature while the second is of major importance since it regards social justice at the global level.

(o<sub>1</sub>) The IPRs regime has an incredible merit: thinking and innovation now pretends economic incentives.<sup>295</sup> In absence of them probably people do not think at all. Purchasing a copy of a certain idea does not immediately transfer the effective possess of it: the practical application of the same idea may paradoxically represent an impediment to the real comprehension of it. The concept, as one possible definition of the idea, is fixed or fashioned in an object in possession of a person but what the customer paid is the added valued given by IP thus whether the idea is not intellectually appreciated there is sufficient ground to claim that there has been a fraud.<sup>296</sup> This is the point of clash between economy and law: if someone acquires the IP such client shall get immediately in possess of the idea otherwise the increased costs are unjustified within the economy theory and therefore punishable by the law as a deceit. If I buy the idea I want that idea for which I spent the money for.<sup>297</sup> Such reasoning reveals the counter-sense of allowing monopolies in the filed of IP.<sup>298</sup> Unfortunately, there are no effective remedies available to defeat fraudulent monopolies: the abuse of dominant

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<sup>294</sup> For an interesting analysis regarding China, see The Panos Institute (2002), pp. 22-24. In general, on India, China and Brazil, see Yamane (2011), pp. 396-415.

<sup>295</sup> “In a world where ideas are money there is no sense of sharing. Instead of fostering the creation of new thoughts, by making ideas property, we become more secretive and less likely to share our ideas”. Halbert (1999), p. 158.

<sup>296</sup> “A critical confusion in the case of ideas is the difference between an abstract idea and a concrete copy of it. Owning an abstract idea means that you have the right to control all copies of that idea; owning a copy of an idea means that you have the right to control only the copy of that idea. We favour the latter (...)”. Boldrin and Levine (2008), p. 153.

<sup>297</sup> “Intellectual property is the “right” to monopolize an idea by telling other people how they may, or more often may not, use the copies they own”. Boldrin and Levine (2008), p. 123.

<sup>298</sup> “It is fairly difficult for me to learn your idea without your active assistance”. Boldrin and Levine (2008), p. 157. The effort and work here proved are constitutive of the right on that idea, thus it produces a vicious logic circle backfiring IPRs.



position is usually punished with a fine. TRIPS Agreement does not provide any relevant information regarding how to revoke patents, revealing a dramatic injustice in social terms.

(*o<sub>II</sub>*) There is a massive race to patenting everything possible. Weaker Countries follow DCs in order to attract FDIs often broadening the tolerance on moral issues. Two scenarios arise: LDCs hosting private structures offering health care practices not permitted in DCs; DCs dispose of the best technology to cure even the most recent diseases attracting the economic elites from all the DVCs and the LDCs, that are subsequently not very interested in supporting the creation of national health care structures. Both phenomena can be equally labelled as “sanitary/health tourism” and clearly point out the serious social injustice produced by IPRs.<sup>299</sup> Wars and social rebellions all over history have exploded because of the unfair distribution of rights, freedoms, wellbeing, and power. The question thus is how to avoid and prevent such tragedy to happen once again and, this time, on global scale. A first step to undertake is to question the fairness of the actual regime. Since no one would ever asked a medical consultation to any bank employee it is not very clear why banks and financial institutions should ever have a voice in deciding or even remotely influence the pharmaceutical production. Medicines are not goods to get produced and traded as any other.

(*o. o<sub>I</sub>*) The importance of health simply does not fall into any economic model or consideration. Such are cultural problems that become immediately of political relevance. Law merely reflects values: claims and HRs are too often flattered on the juridical argument, when not neutralized by the capitalist rhetoric, defusing the social demand for a more just system. Therefore, the issue of IPRs and of the TRIPS Agreement does not regard genuinely law nor economy but politics at the very global level.<sup>300</sup>

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<sup>299</sup> Moreover, “(...) health tourism can exacerbate the shortage of doctors in rural [remote] areas because of internal brain drain”. Blouin (2007), p. 169.

<sup>300</sup> “More careful scrutiny (...) would reveal that the situation was less juridical than it was political”. Nagan (2002), p. 176. “IPRs tell us who can own, control and make use of what type of knowledge and who cannot; for this reason, they are political (...)”. Muzaka (2011), p. 2. “[T]he institution of property is

## SECTION C

“TRIPS (...) represents the beginning  
of property globalization”  
[Drahos P.]

**π § The political side of IPRs** – The present work is not economic in nature: the previous analysis is functional to the concrete understanding of IPRs as a whole. IPRs constitute a mean of political economy. Indeed, a further step regards IPRs from the political point of view. Politics is management of existing relationships among members of a same community or society. Over time it has turn into an exercise of power: politics frames relationships through law.<sup>301</sup> Law is not anymore reflecting those values implied by existing relationships but rather imposing such relationships because of the predominance of certain values, often merely ideological. The action of the law is violent, it obliges to a given order. The law acts as surrogate of ethics and thus it is functional; in order to discover what aim the law serves it is necessary to inquire the “telos” (τέλος) of the norms. IPRs protect the invested capitals, thus the implied purpose of IPRs is to feed and maintain a precise social order. Legal systems pursue the creation and perpetration of social peace/order. Their success descends by the degree of legitimacy enjoyed by institutions and norms. This is where ideologies step in. Modern

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complex, contested and highly political, and that of intellectual property is perhaps even more. Property is (...) an entitlement (...). Drahos (1996).

<sup>301</sup> Law materially draws the shape of given relationships: rapports between people take effective form only within the legal context decided by the state. See Koskeniemi (1990), pp. 6-8, note in particular: “The modern view is a social conception of law. For it, law is not a natural but an artificial creation, a reflexion of social circumstances”.

economy is one possible form of politics: “political-economy” means increasing economization of politics.<sup>302</sup> It is not the broad economy to devour politics yet one particular model. As for any political system of government, different groups organize themselves to gain – more or less democratically – power. The same is valid within economy: different models compete to win the degree of absoluteness. Supporters of one or another of these models have obvious interests often hidden behind ideological rhetoric. The question then is not if politics serves economy or *vice versa* yet who is gaining the most from their interdependence. Indeed, structures and *medium* of both fields are given. Therefore, there is a further level of power behind, interested in “politicizing” every argument defusing claims into binomial decisional system: yes or no. The argument is entirely deprived of its intrinsic value and ideologically instrumentalized. It reflects the possession of non-political terms for polemical purposes.<sup>303</sup> Dealing with IPRs, words such as “development”, “innovation”, “progress”, human rights”,<sup>304</sup> “democracy”, “piracy” have been widely (ab)used just by the one side already advantaged in the negotiations, preventing the opposed faction from effectively discussing these issues in an appropriate way. Supporters of different IP policies stand on equally ideological positions, demonstrating their inadequacy: providing essential drugs and medicines in the LDCs is surely crucial but still very much connected to the ill ideal of progress, which is totally Western. Infinite technologies and well-known remedies to different diseases should be available at incredibly cheap prices but they are not anymore produced. Instead of caring about the very last piece of art produced in the field of technology or medicine, it is surely more important to provide several people (not countries) basic technology also for diagnosis.<sup>305</sup> Saving *biological* lives<sup>306</sup> is not enough; without changing the actual

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<sup>302</sup> Indeed, “there is a need for counter-weights and limitations on the totalising tendencies of the economy”. Mylly (2009), p. 48.

<sup>303</sup> Schmitt C.

<sup>304</sup> It is crucial to avoid the very serious risk of instrumentalizing HRs submitting them to political purposes: the dignity of HRs has to be safeguarded.

<sup>305</sup> “(...) for poor countries to take advantage of globalization opportunities, they need to absorb, implement, and even develop new technologies”. Maskus and Reichman (2004), p. 281. “There is too little innovation that relates to improving access to diagnosis and treatments in developing countries in ways consistent with their needs and resources”. WHO (2006), p. 118. More generally, on the importance of technology transfers, see pp. 287-291.

<sup>306</sup> I am adopting the differentiation formulated by Agamben (2009).

global social order it is non-sense: the right to life turns into a condemnation to a miserable existence. Many IPRs supporters probably believe that avoiding delivering medicines simply facilitates the maintenance of a certain (global) order preventing people from emigrating or organizing local or global “terrorism”.<sup>307</sup> Modernity is still struggling for accomplishing what the French Revolution has started: freedom and equality are nowadays – at least – formally given but brotherhood/sisterhood, on global scale, are still missing. Greater is the need for norms and rules, lower is the degree of culture and ethics within a certain human group or society; subsequently, IPRs are far from being a benchmark of (legal) civilization since they reveal the historical trend on the precise opposite route, hidden by external indicators – such as technology. The existence of TRIPS raises the interrogative on whether the present global political system is or is not an imperialistic regime. Property (regardless of the form) is political in nature: it mediates between individuals.<sup>308</sup>

**p § Legality** – The establishment of law represents the second moment within the creation of states: the first step, since the Roman Empire, is gaining monopoly of the force. Most of the actual modern law heavily relies on Roman models and canons; it is therefore implicitly accepted that the *imperium (cum) animo domini* is essentially (*West*) the precondition and meta-juridical foundation of the law as such. Therefore, law has to be constantly criticized.<sup>309</sup> Such criticism has to target the genesis, the negotiations of IPRs. In the WTO, NGOs have no consultative status; inversely, the UN would have offered different *fora* that could have been more appropriated and relatively accessible from a democratic perspective.<sup>310</sup> The implicit demand aims at inquiring whether the

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<sup>307</sup> Terrorism is labelled as such due to the nature of the attack against the constituted power but it is a concrete act of democracy asking to give back attention and power to people, all of the people.

<sup>308</sup> It is the *medium* assessing legal capacity of persons to establish juridical relationships among them. “Law transfers communication from the public and private spheres of the lifeworld into a form understandable for the economy and the administration”. Habermas (1984), p. 354.

<sup>309</sup> On the topic, see Kant (2009) and the freedom of pen.

<sup>310</sup> Like in the case of the United Nations Conference on Trade and Development or the WIPO. Yet, “(...) contests over WIPO IP conventions convinced IP-reliant industries that WIPO was not the forum to be trusted with IP protection worldwide (...)”. Nonetheless, *fora-swift* has been used also positively: “(...) with issues related to traditional knowledge and ‘life-patenting’ which, from the perspective of developing countries, remain intrinsically linked to food security, agricultural sustainability, the rights of indigenous peoples and protection of traditional knowledge (...) many of these IP-related issues had

whole negotiations may have been conducted in *mala fide*. Guaranteeing flexible bargaining procedures, less influence from civil society organizations and NGOs (but not from economic lobbies<sup>311</sup>), and structural advantage to those countries having privileged positions in trading (also in terms of expertise), WTO was the natural *forum* to bring the discussion from the DCs' perspective.<sup>312</sup> Power equilibriums were not respected: it is hard to accept the theory of equality since the game, starting from the very initial decision regarding the "game-field", has been directed by a *élite*.<sup>313</sup> The same *élite* was in turn lobbied by an even smaller *élite*: there is nothing less democratic. So far, there are (some) DCs with high trade capacity interested in obliging other states to open and liberalize their internal markets but securing IPRs within. DCs attracted DVCs and LDCs into an institution they have established and therefore offering them structural advantages.<sup>314</sup> Negotiations have been conducted in a discussable way (see *infra*) imposing norms then made compulsory also at the moral level appealing to the theory of legality. Is the TRIPS Agreement valid? Artt. 49 and 52 of the Vienna Convention on the Law of the Treaties help in measuring the degree of legality of such

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already spread and 'shifted' to other regimes". Muzaka (2011), pp. 44 and 75. See also Maskus and Reichman (2004), p. 304.

<sup>311</sup> "[S]tates are economically beholden to multinational corporations". Cohn (2001), p. 429 but see also p. 437. "Commercial enterprises in the industrialized Northern Tier of countries sought to increase their information and technology rents from the Southern Tier of developing countries by demanding an enforceable set of intellectual property rules". Abbott (2005a), p. 80; and Abbott (2002), p. 485. "The WTO (...) is corporate-managed trade, and we want people-managed trade". Wallach in "Whose Trade", *The Nation*, December 6, 1999.

<sup>312</sup> "(...) DVCs were drawn into doing so both through coercion and strategic use of the institutional mechanisms of the GATT". Muzaka (2011), p. 55. It is necessary to consider also other routes still unexplored by the literature: in the same time the World Bank and the IMF were continuously bargaining with LDCs and DVCs and every project in both the *fora* was subjected to the so-called "Washington Consensus". In other words, political pressure through economic means was hitting LDCs and DVCs position. "[T]he developing country group had little option but to accept the TRIPS Agreement". Switzer (2007), p. 123. Nevertheless, this new position was defensive since it was lost the initial hope to declare "(...) science and technology the common heritage of the mankind". Gana (1996), p. 337.

<sup>313</sup> "TRIPS, it might be argued, was an agreement that was produced as a result of bargaining amongst sovereign and equal states (...)". Drahos (2002), p. 769. "GATT/WTO decision-making rules based on the sovereign equality of states are organized hypocrisy (...). [W]eaker states may be coerced by powerful states into consensus support of measures skewed in their favour. By threatening to make weaker state worse off (...)". Steinberg (2002), pp. 365 and 349. See also pp. 347-48. "[D]eveloping countries simply did not have the political or economic where-withal to negotiate better terms [for the Agreement]". Gana (1996), p. 333.

<sup>314</sup> *Inter alia*, they already developed expertise training appropriate professional to work within.

treaty.<sup>315</sup> Analysing the main rhetoric regarding IPRs and their essential roles in boosting innovation and guaranteeing fair and sustainable development, it is fairly arguable that DCs organized a fraud at the expenses of the other countries. Promises, as the opening of the EU agricultural market or the reduction of subsidies,<sup>316</sup> have never been maintained but played a major role in convincing DVCs and LDCs to accept IPRs. The recording of a DVC or LDC within the US Section 301 list may be interpreted as violence.<sup>317</sup> it is an expression of a certain form of force, which has not to be necessarily military. The US tend to approach international law as a self-service stressing its importance when it comes to IPRs but neglecting it in several occasion, as for Iraq in 2003. The consciousness of the social, economic and political results, also in the field of human rights, would have raised the question on the *bona fide* as pre-requisite of the

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<sup>315</sup> Article 49 – Fraud: If a State has been induced to conclude a treaty by the fraudulent conduct of another negotiating State, the State may invoke the fraud as invalidating its consent to be bound by the treaty.

Art. 52 – Coercion of a State by the threat or use of force: A treaty is void if its conclusion has been procured by the threat or use of force in violation of the principles of international law embodied in the Charter of the United Nations.

<sup>316</sup> Like in the case of US cotton producers. See Abbott (2005a), p. 78. “The poor had opened their markets in the expectation of gaining increased market access, especially in agriculture, textile and clothing, but the rich had failed to deliver valuable opening in these areas”. Odell (2009), p. 15.

<sup>317</sup> “The Omnibus Trade and Competition Act of 1988 (Pub. L. No. 100-418, 102 Stat. 1107, 1988) come into force on 23 August 1988 to modify the Trade Act of 1974 to strengthen US retaliatory power. (...) The US Trade Representative was regarded as a more appropriate entity to implement US trade policy than the President because it is not involved in diplomatic and political concerns at home and abroad. (...) The key mechanism to combat the violation of US intellectual property rights is established under a special provision (...) called ‘Special 301’ (102 Stat. 1164-76, 1179-81, 1988). The ‘Special 301’ is a specific provision connecting intellectual property protection with trade issues. (...) ‘Priority foreign countries’ refers to countries whose acts, practices, or policies are the most onerous or egregious, and have the greatest adverse economic impact on US commerce; and those countries not entering into good-faith negotiations (...). Since 1988 (...) the US Trade Representative created three lists (...): (1) ‘priority foreign countries’, (2) ‘a priority watch list’, and (3) ‘a watch list’. (...) Naming countries on the ‘priority foreign countries’ list would clearly e an attempt to put the pressure on other countries to yield to the US demands on multilateral intellectual property negotiations which was at the same time taking place in the Uruguay Round”. Kuanpoth (2010), pp. 40-43. “Imposing a sanction for not having adequate intellectual property law is not a justification, it is a violation of the GATT”. Hudec (1989), p. 322. “The US Special 301 procedure continued to pressure other countries to ‘improve’ their pharmaceutical IPRs. (...) In addition to this relentless pressure to ‘improve’ IP protection standards, an effective way to drive IP protection standards upwards and ensure the developing countries’ swift integration into the global IP regime has been through bilateral and regional free trade agreements (FTAs) involving either the EC or the US (which has used this route most aggressively) and a weaker state or group of states”. Muzaka (2011), pp. 117 and 72. See also Drahos (1999b), p. 22; Abbott (2002), pp. 772-774, note in particular that: “The European Community also enacted something similar to Section 301 in 1984 (Council Regulation 164/84), but the European Commission found it difficult to obtain consensus on its use”. See also Switzer (2007) at pp. 133-134; Dutfield and Suthersanen (2005), p. 133; Maskus and Reichman (2004), p. 295.

agreement.<sup>318</sup> Reading TRIPS carefully, it is evident how it will enlarge the existing gap between DCs and LDCs, contradicting the arguments brought during the negotiation and the axiological principle of the law always aiming at equality.<sup>319</sup> The self-contradictory character of these arguments makes them legally void and outlines the equivalent of *mens rea* of those supporting IPRs. Law, as such, can legitimately discriminate but it shall not produce discriminant effects in its enforcement since the end of the legal system is formal and substantial equality. IPRs are increasingly appearing as an abuse of law through the law. Law must be coherent to reality, respecting the different temporalities in which social, economic and legal systems are operating, otherwise the outcome is (cultural) violence. Such violence becomes unacceptable if hidden behind the theory of progress, the rhetoric of human rights and civilization, requiring the respect of the principle of legality that has been firstly violated by those now supporting it. It is not merely about the double standard but broadly about modern legal thinking. WHO definition of health and public health are wide and open, while TRIPS shapes precise norms: the latter wins on the juridical level because of the legal principles.<sup>320</sup> International Treaties are, at the same time, confirming and eroding states' sovereignty.<sup>321</sup> These phenomena have inhomogeneous characters: why limitations of sovereignty are accepted and immediately enforced in the case of IPRs and not for HRs? If people are sovereign – at least within democratic

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<sup>318</sup> “(...) the tendency of rich countries, that traditionally urged free competition on the rest of the world, to demand strong legal monopolies to protect private knowledge goods in international trade (...)”. Maskus and Reichman (2004), p. 293. “The US-EC-Japan-Swiss alliance that drove the Uruguay Round negotiations presented a case that their intention also was to serve the interests of the Southern Tier because strong IP regimes would generate benefits for developing countries. These were not empirically-supported arguments, and they were understood to be the basis for negotiations. If developing countries concluded that stronger IP protection was in their own interests, they did not need the Northern Tier to force them to adopt it”. Abbott (2005a), p. 81. Evidently, “there was an overall assumption that these countries would “develop” in the same way that Western countries did (...)”. Gana (1996), p. 332. Precisely for this reason, IP has been set to prevent DVCs to develop threatening the wealth of DCs. See also Primo Braga (1989) for a better understanding of eventual benefits for Southern countries.

<sup>319</sup> See Abbott (2003) and Maskus and Reichman (2004), p. 294-295, note in particular: “Those few developing countries that have built some capacity to participate in standard-setting exercises may run into coercive pressures from governments and corporations whose interests they challenge”.

<sup>320</sup> *Inter alia, lex specialis derogat lex generali*: the degree of specificity leads a certain norm to prevail. It symbolizes the progressive legalization of illegal practices. Yet, justice has to go beyond its formal expression, considering that: “Making the rules identical and legally binding whether you are a very rich country (...) or a poor country (...) seems to be tremendously expensive and risky for the latter type of country”. Dutfield and Suthersanen (2005), p. 134.

<sup>321</sup> Yet, “for many developing countries TRIPS does not represent a loss of sovereignty because these countries for most of their history have never exercised meaningful sovereignty”. Hansen (2002), p. 82-3.

countries, as DCs pretend to be – where are the sovereign people in the WTO? Would people really prefer IPRs to HRs? The TRIPS Agreement and the Doha Declaration recognize the sovereign exercise of defining the content of the “public interest” and the circumstances for declaring the “state of necessity”. Assessing the latter reveals who is effectively sovereign, internally and externally.<sup>322</sup> Since most of the LDCs and DVCs have been pressured and prevented from using such sovereign power, and internally main concerns have been addressed to the issue of FDIs, it is proved that most of the LDCs are only formally sovereign. The compulsory licencing constitutes a sovereign exercise that only those not in need can effectively employ while those other actors more in need of it are refrained from doing so.<sup>323</sup> Sovereignty and the theory of representation undermine seriously the validity of TRIPS in terms of legitimacy, which is a further level over legality.

σ § **Legitimacy** – TRIPS precludes the possibility of legal norms being contested and developed domestically.<sup>324</sup> The question is therefore whom the National representatives at the WTO were effectively representing during the negotiations. It is a *vulnus* into the model of representative democracy.<sup>325</sup> The violence occurred during the Seattle round of negotiations was legitimate since the pacificator system of fiduciary representation has been broken.<sup>326</sup> WTO is one of the less democratic institutions and even states’ practices within appear as non-democratic.<sup>327</sup> There are no effective channels to discuss rights that people formally enjoy and that are menaced by new legal

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<sup>322</sup> Schmitt C., Agamben G.

<sup>323</sup> “One aspect of sovereignty is the liberty to ‘legislate’ international norms which bind oneself. Wherever particular norms have not been thus established, the metaprinciple of sovereign liberty – the ‘Lotus principle’ – remains valid”. Koskeniemi (1990), p. 13.

<sup>324</sup> Muzaka (2011), p. 60. “Without a legitimizing governance process that adequately represent all stakeholders (...)”. Maskus and Reichman (2004), p. 295.

<sup>325</sup> “Where civil society is abrogated and democracy denied, human rights violation (...) are more likely to occur”. Beyrer and Pizer (2007), p. 6.

<sup>326</sup> “[P]articipating in regime processes does not occur along pluralistic or democratic lines. (...) global governance itself emerge as a dynamic, conflictual and contested process”. Muzaka (2011), pp. 10-11. “There is no transparency in the proceeding and African countries are being marginalized and generally excluded on issues of vital importance for our people and their future”. Odell (2009), p. 19.

<sup>327</sup> “[I]f the TRIPS negotiations do not meet the minimal conditions of democratic bargaining, this raises questions about the Agreement’s efficiency, as well as its legitimacy. (...) three conditions [must be] met: [representation, full information, and non-domination]”. Drahos (2002), p. 770. See also Steinberg (2002), generally.



frameworks or policies. Those condemning violence are ignoble;<sup>328</sup> they forget the genesis of democracy: wars and conflicts that have been solved thanks to the representative mandate in order to better organize the distribution of power and wealth within a certain society constituted as a State. Indeed, TRIPS was not driven by a common concern and consensus about creating a balanced IP(Rs) regime that reconciles the interests of the different actors both at the domestic and global level.<sup>329</sup> This has been possible because of a double degree of secrecy (and secrecy is enemy of democracy):<sup>330</sup> the first is individuated in the lack of an effective democratic mandate between people and their representatives, revealing how weak the democratic structures within DCs are; the second level is seen among the representatives due to the insane practice of inviting small groups of countries in the Green Room in the attempt of dividing, weakening and finally defeating the opposed coalitions against IPRs.<sup>331</sup> Beyond the ideological rhetoric on better trade, FDIs, and development – appearing as the main points on the surface – the US and their allied, the EU, Switzerland and Japan, played “dirty”. Especially, the US started to fill non-complying countries in the inglorious Section 301 list, later enriched of a further special procedure, loading such states of an enormous pressure. One cannot realistically expect the technological gap between DCs and DVCs or LDCs to be reduced by TRIPS. The latter were negotiated precisely with the aim of establishing and protecting the competitive advantage of certain actors.<sup>332</sup> Thus, IPRs are violence and Seattle has been an act of self-defence. *Private* monopolies are protected and supported at the expenses of the state that is a public force intended to act in favour of the whole population. The state is taking its part of the cake when charging fees and taxes and through the imposition of bureaucratic procedures feeding its own desire of control.<sup>333</sup> Unfortunately, IPRs supporters claim

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<sup>328</sup> Benjamin (1995).

<sup>329</sup> See Muzaka (2011), p. 61; Maskus and Reichman (2004), pp. 283-284.

<sup>330</sup> “Representatives of the 135 WTO member countries meet in secret, excluding non-governmental organizations (...)”. Cohn (2001), p. 429.

<sup>331</sup> “Major industrialised countries, seeking to protect the interest of transnational pharmaceutical companies, have pursued a “divide and conquer” strategy”. Kerry and Lee (2007), p. 6. “(...) *Divide et impera* tactics in multilateral negotiations (...)”. Dutfield and Suthersanen (2005), p. 133.

<sup>332</sup> May (2000), quoted in Muzaka (2011), p. 62.

<sup>333</sup> “I think we often exaggerate the degree to which national governments are constrained by global forces. Often governments find it too easy to say, ‘We can’t do this or that because corporations will flee or we’ll lose exports’”. Rodrick “Whose Trade”, *The Nation*, December 6, 1999. Furthermore, there are

that this would be a battle of civility and democracy, while it is precisely its exact opposite. It is a case of *im-possess-ment* of non-political terms for polemical ends.<sup>334</sup> Downgrading normal citizens protesting for the terrible effects of IPRs on their fundamental and human rights to mere criminals or even terrorists, states are acting with a double degree of violence proving their intrinsic fascist and despotic tendency. Violence is likely to feed future stronger struggles, not taking place now due to the lack of immediate interests and awareness of most of the people in those countries that “count”. States oppose the argument of people’s future economic wellbeing as core national interest: in reality, IPRs *cum*-participate the progressive imposition of an order neutralizing sources of arbitrariness. This end fits the economic ideal of rationally foreseeable, intelligible and manageable information. The capital is protected from arbitrary nationalizations, taxations or other measures that whatever sovereign state shall undertake when its people are in need – it should be intended as integrating the discipline of the Responsibility to Protect (R2P).

( $\sigma$ ,  $\sigma_I$ ) TRIPS have been signed in 1994 when most, if not all, the main international legal HRs instruments were already ratified and into force. The obligations descending from such Conventions were supposed to bind States, governments, and their representatives to the pre-existing acceptance of validity of such rights. Two hypotheses can follow: (i) governments ignored the other already subsistent obligations or they were not aware of the consequences (so, they should not govern because incapable); (ii) they consciously accepted the new regime and its devastating effects on HRs, realizing a wilful misconduct (they should respond at least politically of their actions).<sup>335</sup> Representatives “produce” people (and the nation) or use them as surplus of legitimization, people are never sovereign outside revolutions. This section aims at raising

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interests due to taxation: “(...) the provision of royalties to an inventor effectively resulted in taxation of the public due to the associated increase in prices”. Fisher (2007), p.78. In other words: higher is the price, higher is the percentage of taxes risen by the state.

<sup>334</sup> The general theory is taken from Schmitt. It is interesting to note some of the arguments brought to support IP: “(...) IP piracy is inimical to development, it deters investments, it is immoral or unfair, it supports terrorist activities (...)”. Dutfield and Suthersanen (2005), p. 133.

<sup>335</sup> “(...) states cannot be presumed to have surrendered sovereign police and welfare power in the course of intellectual property standards-setting exercises at which their ministries of health, education, agriculture, and public welfare played little or no roles”. Maskus and Reichman (2004), p. 307.

serious on the legitimacy of the Agreement that is a pre-condition for its validity and legality: not every command is equivalent to law. Supporters pointed the relative flexibility of TRIPS, intended as dictating sole minimum standard to harmonize the global system, and the compulsory licencing system given within. Furthermore, it has been sustained that the existence of a dispute settlement mechanism is the guarantee for an equitable and effectively democratic regime. Consequently, it is worth having a better insight into the present arguments.

**τ § Policies on the Pharmaceutical Production and Essential Drugs** – Despite the efforts of different Agencies, *in primis* the WHO,<sup>336</sup> there are no coherent and systematic policies addressing the problems of drugs production and of the deliver of the same to the people in need at the international level. Apparently, the only available tool is the compulsory licencing, which appears as residual and partial remedy.<sup>337</sup> It somehow how TRIPS has very little concerns for the whole picture of states' capacity to elaborate efficient policies in order to guarantee fundamental rights of people and, at the same time, to establish an efficient market; the main purpose is rather to defend privileges at the advantage of some.<sup>338</sup> he attribution of monopolies does not erode the

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<sup>336</sup> The WHO has prepared a list of around 300 essential medicines of which about the 74% are not subjected to the Patent regime. “[T]he World Health Assembly unanimously passed a resolution [already] in May 1999 which encouraged member states to ensure equitable access to essential drugs and review options under international agreements (...). [T]he UNDP, UNCTAD and World Bank had also become involved with analysing the potentially negative impacts of TRIPS upon developing countries”. Muzaka (2011), p. 78. See also the Amsterdam Statement at the WHO website: <http://apps.who.int/medicinedocs/en/d/Jh1461e/1.4.html> (last visit Wednesday, 30 May 2012). Equally relevant, “In February 2004, the WHO Director-General established the Commission on Intellectual Property Rights, Innovation and Public Health to review the available evidence and recommend ways forward to improve systems for developing and accessing drugs in low and middle-income countries”. Kerry and Lee (2007), p.6.

<sup>337</sup> “After the Doha Declaration of 2001, IP-access to medicines issues were largely reduced to the issue of compulsory licensing (...)”. Muzaka (2011), p. 13. “Compulsory licensing may have primarily been a negotiating instrument for reducing the price. (...) [Yet], Compulsory licensing could be an effective solution in certain situations, but, in the complex reality, could be a tool of political, or an inefficient industrial policy”. Yamane (2011), pp. 319 and 337.

<sup>338</sup> “Given such disparity in bargaining power, it is not surprising that the negotiations at the TRIPS group proceeded largely in ways conducive to the interests of key developed countries and their IP-reliant industries”. Muzaka (2011), p. 56. Only with Doha a counter-tendency emerged: “[T]he most notable development in the Doha process was the emergence of a cohesive group of developing countries articulating and advocating an essentially common position. The explanation (...): (1) The issue of access to medicines involves highly shared common interests among developing countries. (...) (2) The comparative lack of resources among developing country delegations in Geneva is a systematic and persistent problem”. Abbott (2002).

sovereignty as such, but the formal sovereignty of certain countries. While DCs confer monopolies-related rights proving their sovereign capacity of doing so, since such action remains an exercise of Sovereign power, DVCs and LDCs end up facing the opposite result: their sovereignty is heavily affected due to the lack of effective control and power over a certain area of policy. In DVCs and LDCs, most patents are filled by foreigner TNCs, officially established in DCs. Therefore, as soon as whatever DVC or LDC may even express the willingness of issuing a compulsory licence, the representatives of such DCs (where main TNCs have their headquarters) will immediately stand up defending the interests of their companies, both throughout diplomatic measures and before the TRIPS disputes settlement panel at the WTO.<sup>339</sup> Human rights, public health and compulsory licencing have been sources of major attention bringing to the adoption of the Doha Declaration and of a Protocol emending the TRIPS Agreement (not in force as yet).<sup>340</sup> DVCs<sup>341</sup> have always been in favour of the compulsory licencing system while the so-called QUAD group tried to oppose a very narrow interpretation of TRIPS. Whatever juridical agreement may be suspended or even denounced in the state of necessity declared by a state. Such case would be very much unlikely to happen in DVCs or LDCs where political instability scares FDIs that remain the first and major end to pursue. After the terroristic attack of September 11 (2001), the US arrived very close to issue compulsory licence to produce drugs in fear of large-scale attacks with *antrax*.<sup>342</sup> Such decision obliged the US to slightly change their position allowing a broader interpretation of art. 31 of TRIPS Agreement.<sup>343</sup> Nevertheless, it has been assessed that the actual procedure to issue compulsory licences

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<sup>339</sup> It has been suggested to promote networking and alliances in order to issue compulsory licences opposing a greater defence against DCs.

<sup>340</sup> See Kerry and Lee (2007), p. 2.

<sup>341</sup> LDCs could take advantage of a longer period of exemption. Note that: “Until January 1, 2005 (...) if a developing country in Africa, for example, wanted to grant a compulsory licence to import a low-priced generic version of an ARV to treat HIV/AIDS, I could import the medicine from an Indian producer”. Abbott (2005b), p. 320. Indian generic producers have played a major role in general, see Yamane (2011), pp. 278 and 397, read in particular that: “Indian drugs cost about one-tenth of the international price, their production costs are one-fifth, and the R&D costs are one-eighth of those in developed countries”.

<sup>342</sup> Bayer was the right-holder and at the end reached an agreement for a shameful low price with the US Government. See Muzaka (2011), p. 82; Muse (2002), p. 449; Correa (2002); Sell (2005).

<sup>343</sup> The discontinuity in the conduct of the state is equal to lack of coherence and substantiality in its juridical expressions, which are finally void. See Jellinek.

is a sort of bureaucratic hell that contradicts the character of emergency under which a licence is supposed to be issued. Even worse is the case of states lacking productive capacity and thus issuing licences seeking for a third state to produce the needed drugs. Canada has been the sole country seriously committed to deliver medicines to those states unable to produce.<sup>344</sup> In 2005 the Canada Access to Medicine Regime (CAMR)<sup>345</sup> was approved, permitting the first and still only case of foreign support: Rwanda used the CAMR in 2007 to obtain antiretroviral drugs from a Canadian manufacturer.<sup>346</sup> Apotex, the GPC that accepted to produce such medicines, declared that it would have been the first and also last case if the legal framework remained the same.<sup>347</sup> And it did, nothing has changed so far. The historical case proved that the compulsory licence is just rhetoric to make TRIPS somehow acceptable.<sup>348</sup> It does not work for at least two reasons: (i) the criteria set by art. 31 are almost impossible to satisfy, especially for those countries lacking adequate experts and diplomatic capacities facing situations of extreme necessity;<sup>349</sup> (ii) whenever states may be willing to use the compulsory licencing system, it is certain that the home state of the interested firm will drag them to the dispute settlement procedure of the WTO, which is neither accessible nor transparent.<sup>350</sup> Eventual contrasts between TRIPS and HRs are solved removing, by

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<sup>344</sup> “[T]he first countries to implement the Decision were developed countries – Canada and Norway”. Abbott (2005b), p. 322.

<sup>345</sup> “CAMR was among the first domestic statutes implementing WTO 30 August Decision regarding paragraph 6 of the Doha Declaration. CAMR provides a system for pharmaceutical manufacturers to export generic drugs to least developed countries and developing nations through compulsory licensing. (...) CAMR aims to balance the commercial interests of current pharmaceutical patent holders with broader humanitarian objectives (...)”. Tsai (2009), p. 1064.

<sup>346</sup> On July 17, 2007, Rwanda became the first country to notify the WTO that it intended to take advantage of the compulsory licensing provisions of the (...) by importing the generic HIV/AIDS cocktail drug Apo TriAvir from Canada”. Hestermeyer (2007) quoted in Tsai (2009), p. 1076.

<sup>347</sup> See Muzaka (2011), pp. 102-103. “As of the March 2009, only one shipment of Apo TriAvir tablets has reached Rwanda. (...) it took more than a year for a shipment to be delivered (...). There are no time limits prescribed for how long a generic manufacturer must negotiate (...) the voluntary license negotiation requirement [by CAMR] may entail quite a bit of time and expenses”. Tsai (2009), pp. 1077, 1079, and 1082. Visit also: <http://www.msfaccess.org/our-work/overcoming-barriers-access/article/1358> (last visit, Wednesday, 30 May 2012).

<sup>348</sup> The length of the entire bureaucratic process and the burden put on both states and generic producers contradict the same character of emergency that is required to call upon the flexibility in order to issue a compulsory licence.

<sup>349</sup> Finally, it sounds very similar to the case of comma 22.

<sup>350</sup> Furthermore, “A generic manufacturer who elects to manufacture a pharmaceutical for export under the CAMR legislation exposes itself to considerable commercial liability for little economic benefit”. Tsai (2009), p. 1080. About WTO procedures: “The WTO has vast powers to adjudicate trade disputes and invalidate regulations it deems impediments to trade through “expert” tribunals meeting secretly in

interpretation, whatever HRs concern rather than seriously consider the disastrous consequences of some measures.<sup>351</sup> The home state of the company, often flanked by other stakeholders, tends to apply domestic retaliation measures affecting trade. Despite the productive cooperation with NGOs started after the 1994 Marrakesh Conference, LDCs and DVCs access the dispute settlement panel in an inferior position; they lack experts such as highly specialized lawyers. Paradoxically, the very few human resources are often dragged away due to the internal and external brain-draining.<sup>352</sup>

( $\tau, \tau_I$ ) The whole picture drawn so far has proved not just the inefficiency of compulsory licencing but also its intrinsic contradictions in terms of political ends. It is insufficient since it addresses merely extreme cases of clear emergency and it does not even satisfy such need because of the complex criteria set and the strong opposition of DCs and TNCs<sup>353</sup> slowing down the process and thus compromising the capacity of addressing serious cases immediately. TRIPS and compulsory licencing are structurally thought to favour main TNCs while smaller enterprises enjoy much less attention. Therefore, inequalities do not arise at the sole international level but they are replicated at every grade. TRIPS shapes what should be defined as an empire of global dimensions.<sup>354</sup>

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Geneva. In effect, it's a form of world government with almost no popular accountability". Henwood in "Whose Trade", *The Nation*, December 6, 1999, p. 15.

<sup>351</sup> "Trade rules need to be pruned back. They've invaded a variety of areas where it's inappropriate to have a uniform, externally imposed global norm. (...) Human beings are either labour or consumers (...). Diversity = democracy and cultural differences = inefficiency". See generally Wallach in "Whose Trade", *The Nation*, December 6, 1999. "(...) only a few, mainly the large and well-resourced [could take advantage of] TRIPS flexibilities designing more balanced IPRs laws. It turned out that even some developing countries (...) found themselves either facing a WTO dispute panel or subject to bilateral pressure, or both. (...) WTO litigations was used strategically by bringing cases which had good chances of success (...). At the same time, the Panel paid little attention to third parties' interests, including those explicitly recognized by TRIPS itself, such as health and social and economic welfare (...)". Muzaka (2011), pp. 67 and 70. See also Hestermeyer (2007), pp. 209-210; Kuanpoth (2010), pp. 44 and 47; Shadlen et al. (2011), pp. 162-168 (specifically on Brazil-US dispute).

<sup>352</sup> Human Capital theorists pretend that brain-drain is not anymore a real issue since technology permits to share discoveries and distribute the connected advantages to the global population. Of course, it is false but the Academia is spending consistent energies in elaborating theories to shield political decisions.

<sup>353</sup> 39 Pharmaceutical Companies v. The President of South Africa. See Muzaka (2011), p. 77; Shandlen et al. (2011), pp. 29-32; Hestermeyer (2007), pp. 7-9.

<sup>354</sup> "[T]he majority of countries in the world now grant and protect similar types of IPRs regardless of their specific politico-socio-economic context, and are legally bound to do so, thanks to the WTO's ultra-binding dispute mechanism". Muzaka (2011), p. 3.

v § **Political analysis** – The investigation on the pharmaceutical production permits to conclude that IPRs perpetrate a certain regime of power in the fluid context of globalization through international law. Global governance is likely to shift influence/power over different areas and geographical regions; IPRs arise as device defusing any possible change at the social, economic and political level.<sup>355</sup> Some final observations regarding the political understanding of IPRs are now listed.

(v<sub>I</sub>) Human rights and their definitions, especially when it comes the health, cannot be narrow: it would be intrinsically contradictory.<sup>356</sup> They encompass a complete universe of elements centred on the human being as such. Medicines are the very last point when talking about health: they constitute the short-term remedy while greater attention shall be addressed on systemic causes and thus prevention.<sup>357</sup> Coherently to the actual perpetual state of emergency, drugs monopolize the entire idea of “health”. Aiming at visible goals in the short term, politics becomes schizophrenic.<sup>358</sup> Policies on medicines reveal the sickness of politics as such.

(v<sub>II</sub>) Compulsory licencing wins the real interest of the international community when the national security of DCs is at risk.<sup>359</sup> Health attracts politics under paradoxical conditions: medicines for those in needs are not about HRs but a national security issue. Immigration and globalization spread diseases regardless of any sovereign border. Possible terroristic uses of chemical substances put pharmaceutical productions under strict protection/control to guarantee full availability of antidotes. The human being appears just at the very end: after the state, the economic interests and several

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<sup>355</sup> “The current arrangement that governs intellectual property, or what is referred to here as the IPRs regime, is one particular manifestation of this historical struggle, and one which is bound to change. The current IPRs regime, that is, its principles, norms and rules, delineates the way in which knowledge is created, owned, controlled and diffused, domestically and globally”. Muzaka (2011), p. 2. See also Gana (1996), pp. 316-317, note in particular: “[T]he TRIPS Agreement limits the scope within which developing countries may pursue national policies to stimulate indigenous innovation in the pursuit of development”. See also Bello in “Whose Trade”, *The Nation*, December 6, 1999.

<sup>356</sup> See Cullet (2003), pp. 139-140 and 142.

<sup>357</sup> “Achieving sustainable results in the managements and control of most diseases requires a strategy that incorporates prevention, diagnosis and treatment, as well as overall health promotion and education”. WHO (2006), p. 18.

<sup>358</sup> There are interests in winning the incoming round of elections: drugs permit quick results in relatively little time.

<sup>359</sup> “(...) the emergence of infectious diseases as an item on national security agendas. The securitization of infectious diseases led western states to increase their support for surveillance and response measures [in the] fear that bioterrorists might use deadly pathogens as a weapon of war”. Davies (2008), pp. 296-298.

considerations evidently more evaluated than the human being himself. If politics does not care about human beings, it is not anymore politics.

(*v<sub>III</sub>*) Almost no attention is given to the obligations arising from the ICESCR, especially those set in art. 2. The so-called “4As”<sup>360</sup> scheme does not appear anywhere in the debate of IPRs and access to medicines. All the actors involved are conducting ideological battles: winning is the real end while people have been objectivized in rhetorical argumentations of different kinds, if ever considered. Few have addressed concerns on the acceptability of IPRs’ *raison d’être* and their justifications. The most unbelievable and unacceptable excuses have been taken seriously: they have been discussed attributing them legitimacy. A genuine and straight politics should have systematically refused and dismissed all of them.

(*v.v<sub>I</sub>*) The TRIPS Agreement creates an unfair regime.<sup>361</sup> Unfair distribution of freedoms, rights, wealth, and (social) justice caused conflicts all over history. The danger as yet appears of global proportions: what has been done to avoid injustice? What to prevent present and future violence? Nothing. Yet, these are the two core intrinsic objectives of politics.<sup>362</sup> Effectively, the only lesson history can offer is that history leaves no lessons at all.<sup>363</sup> Politics is progressively disappearing leaving room to

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<sup>360</sup> Availability, Accessibility, Acceptability and Adaptability. See E/C.12/1999/10 regarding the Right to Education, but the criteria set should be considered valid for every programmatic right, including the Right to Health. See also Cullet (2003), p. 149. For broader framework analysis on “4As” and medical/pharmaceutical production see WHO (2006), p. 24. Note in particular that: “Technologies that may have been developed elsewhere may need to be adapted to make them acceptable locally”. *Ibidem* p. 123.

<sup>361</sup> “(...) the ratcheting up of intellectual property standards will boomerang against the capacity to innovate in developed countries”. Maskus and Reichman (2004), p. 299. Economically speaking, “overly strong intellectual property protection leads to the problem of excessive monopoly costs (...) and therefore under-investments in innovation [and all what follows]”. Hansen (2002), p. 82-1. While, from an ethical perspective: “While we have the technical capacity to provide access to lifesaving medicines, vaccines or other interventions, which are indeed widely available in the developed world, millions of people, including children, suffer and die in developing countries because such means are not available and accessible there”. WHO (2006), p. 21. Also in presence of compulsory licence, note that: “[c]ompulsory licensing presupposes that the local manufacturing or import sources of products are quality-assured and that the cooperation of the patent-holder is not needed to provide the necessary know-how for designing, manufacturing and administering the product”. Yamane (2011), p. 335.

<sup>362</sup> Pursuing justice avoiding violence is the essence not just of political systems in general but of democratic political systems.

<sup>363</sup> Hegel (2010).



mere economic speculation and brutal exercise of different forms of power.<sup>364</sup> IPRs are the flag of the “*restauration*” revealing the imperialistic trend, taking place globally.<sup>365</sup>

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<sup>364</sup> “The success of international law depends on this formality; this refusal to set down determining rules or ready-made resolutions to future conflict. (...) I shall attempt to show that our inherited ideal of a World Order based on the rule of law thinly hides from sight the fact that social conflict must still be solved by political means (...)”. Koskeniemi (1990), pp. 28 and 7.

<sup>365</sup> “(...) intellectual property accumulates and enables concentration of power (...)”. Mylly (2009), p. 228. Notably, the concentration and centralization of wealth and power are typical of empires.

## CONCLUSIONS

“Intellectual Property Protection is  
essentially about wealth”

“IPRs were earlier on seen as *privileges*,  
today we refer to IPRs as *rights*”

[Muzaka V.]

¶ § **In theory** – The work offered different perspectives on the same object of observation: different lens stressed peculiarities otherwise difficult to note from other angles of scrutiny. IPRs are now better focus. IPRs are intrinsically incapable of thinking integrally the human being in his multidimensional reality and essentiality.<sup>366</sup> Knowledge has always been the common heritage of the human kind as well as his capacity to continuously and creatively re-elaborate it.<sup>367</sup> IPRs signal the radical crisis affecting the thinking: not only the tendency is to marginally deal with effects leaving causes untouched but more and more often politico-economical decisions are generating new sources of problematic. Indeed, economy and law both work based on assumptions, often of ideological derivation: without true, radical and critical democracy these assumptions are destructive.<sup>368</sup> In particular, economy and law are of political genesis,

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<sup>366</sup> “TRIPS Agreement treats IP protection as a trade matter, marginalizing the many other issue-areas (...) such as health”. Muzaka (2011), p. 3. More superficially, the entire rhetoric on the inventor has been proved false: “[i]n our society, most patents and copyrights are owned by institutions”. Hettinger (1989), p. 46. See also, more recently, Grosheide (2010), p. 167: “It is likely that most patent rights are held by corporations”.

<sup>367</sup> Thurow (1997), p. 97.

<sup>368</sup> “All of these outcomes would accelerate the economic development of poor countries, which should result in the alleviation of poverty in such countries”. Joseph (2003), p. 432. “Property rights are now recognized as essential for economic progress. In a property-rights regime, the public *does* benefit from privately owned goods”. Giovanetti and Matthews (2005). Yet, if everything has been privatized, including knowledge, what is the exact meaning of “public”? Where is the public? “[P]rivate control over knowledge and innovation versus public access to it. More specifically, the conflict is between business actors (...) and, ultimately, patients”. Muzaka (2011), p. 4. “It is undeniable that new pharmaceuticals improve health care (...). And it is precisely the implementation of intellectual property protection that has resulted in widespread creation and distribution of new pharmaceuticals (...)”. Giovanetti and Matthews (2005). In absolute terms, this assertion may seem right, but then the problem is about distribution of the scientific achievement in the perspective of global social justice. Furthermore, the authors seem to approach the topic unaware of the methodology of measurement of progress: quantity is not equal to quality, indeed most of the so-called innovation subsequent to the enforcement of patent protection has resulted obsolete when compared to previous inventions and discoveries, especially in the health sector.

they have to be constantly kept under careful observation; economic sciences often appear as the triumph of non-sense: formulating theories observing socio-political trends building then models of pretended universal application (one-size-fits-all) proving the veracity of the same is not just mindless but often criminal. Theories have supported, *inter alia*, the progressive privatization of every activity: privatization means fragmentation and individualization, pauperization of the cultural richness of communities and their culture; privation, far from constituting an empowerment, it leads to the exact opposite end, the deprivation of every sort of effectively democratic power before reality. Reality today dominated by apparently uncontrollable emergencies that are nonetheless strengthening the position of power of some. The process, formally started with the French Revolution, aiming at democratizing (in relative terms) the power held by few (“*L’état c’est moi!*”), has now taken a paradoxical route: deducting power from states it is giving it back to a strict global oligarchy. The democratization of states has been defused through new political means. IPRs figure among these latter. In particular, the *juridification* (*iuris-facere*, legalization) constitutes, at the same time, an *iper-politicization* of concepts for polemical purposes and the *de-politicization* of events. Concepts are generated in the political sphere, systematized and formalized into the Academia, and finally legitimized by law while law should be legitimized by concepts. The *iper-politicization* leads the concept to be intrinsically just and thus naturalized within the socio-political law-fare. It produces a *surplus* of legitimization for the group in power for its policies. The *de-politicization* disqualifies events marginalizing them from the genuine political discussion that is normally supposed to take place among people and within institutions: the works at the WTO as well as every IPRs-related issue have been kept carefully secret and aside from the necessary public debate. Secrecy is the disease of power; it is anti-democratic in essence. Some clarity, especially from the intellectual/theoretical side, is imperative. Indeed, IPRs are much stronger than traditional property rights: they give birth to incontestable monopolies of global range legitimized, protected and enforced by increasingly pervasive power.

( $\varphi_I$ ) Hegel has theorized a shift of the dialogical interaction from the “logos”/talk to the possession ( $\neq$  property). The body and the person (in the sense of “mask”) constitute the *medium* between the real and myself: the exercise of the will on

these two elements generates possession (still not property). In Hegel, the will is central: projection of the will, proving its existence, is the desire; the will re-integrates itself taking possession of the something exterior object of its original desire. The *im-possessionment* (taking possess of, defined as “negative dialectic” by Adorno) serves the narcissistic aim of the mind (will): proving its own existence and absoluteness. Possession does not truly pursue property as such; it is a mean of development of self-consciousness. Nevertheless, the base should be: the exercise generates possession; the latter may be socially recognized and protected in the form of right. The exercise proves the existence of the subject that has the means to get self-consciousness of his presence in reality: life is finally thinking. Thinking is a practice as well, but the exercise of it does not lead to any possession: the possession refers to the experience as such, intended as constitutive essence of the human being. The same is not transferrable, it is inherent to the subject: it is possible to share it, communicate it, but surely not transfer it that is the basic pre-requisite to establish a right. In this sense, on the base of modern philosophy, there can be nothing like IPRs since they prevent the genuine development of the human being himself.

( $\varphi_{II}$ ) More technically, where the idea is applied to an tangible property, it would be necessary to distinguish the productive process of the idea from the one of the mere object in order to maintain two different categories of law: property rights, on the object that is materially purchased; and intellectual property rights, on the added value imprinted by the idea. Yet, if the idea is proved to be intrinsic to the object, the market has to reward it, not law. The only element of coherence with economy is paradoxical: the capital represents the new level of immanence that has now turned against itself since it has become its own limit. IPRs temporarily fix some of the intrinsic limits of capitalism, from the theoretic-economical point of view; they equally permit the generation of a sort of time-bubble in order to gain advantage in the thinking of new political strategies and means before the immanent collapse of the present ones.

( $\varphi, \varphi_I$ ) IPRs are non-legitimate and non-legal. Not every command (of the power) is equal to law, even if it has the same degree of coercion due to the enforcement system. The methodologically correct process does not minimally change the intrinsic

unacceptability of IPRs: legally, economically, and theoretically it has been proved they are self-contradictory, inconsistent and incoherent.<sup>369</sup> Therefore, they lack the genetic code to win the frieze of law.<sup>370</sup> Finally, they are unfair and inhuman,<sup>371</sup> which is a meta-logical argument since it is stronger of whatever element of usefulness around IPRs.

χ § **In practice** – There is increasing need for a complete new system, not genuinely for intellectual property, but for innovating and doing economy.<sup>372</sup> In particular, protection is not necessarily equal to “rights”, there are different economic and political forms of protection excluding the use of law, which implies the previously observed complications. As long as rights are maintained, the respect of them, on a global level, should be suspended precisely on the base of international law.<sup>373</sup> *inadimplenti non est adimplendum*. The axiological element of law, that is parity, has not been respected both in the drafting and in the application of IPRs. More in general, international law reveals strong asymmetries stressing the room for more sympathetic interpretations of law itself: *inter alia*, the US are particularly inglorious for the low respect for international law, the respect of which is conditioned by national

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<sup>369</sup> “Patents reward people for their inventions, thus encouraging creativity and innovation. (...) the money raised from patent protection is said to be necessary to fund the considerable costs of R&D. (...) the content of a product patent (...) are disclosed (...) otherwise [they] would have been kept secret (...)”. Joseph (2003), p. 431. Yet, data protection now *de facto* nullifies the benefit of the disclosure (see *infra*). “The multinational pharmaceutical industry argued from the beginning that a declaration [on public health] was not necessary because: (a) patents are not a problem; (b) weakening patent protection would have devastating effects on the R&D (...)”. t’Hoen (2003), p. 55. If patent are not a problem, why to seek them? In countries where there are absolutely no benefits from the actual R&D what is then the sense of enforcing patents? In general, it has been proved, over this entire work, the ideological nature of most of these arguments.

<sup>370</sup> The law should juridically reflect the sense of a real-life rapport progressively obtaining first a juridical rapport and then a juridical institute. The idea (implied in the law) is the transcendental value of law: materialism and historicism have abolished this element empowering the idea of law as the way through which the juridical matter takes form. Reversely, law must adhere to socio-historical conditions of real-life, the legislator cannot ask the impossible: the idea of law as core essence of law itself shall have its strength in the force of facts intended as certainty and security of law. IPRs do not match any of the present elements. For a further investigation see Radbruch (1948), p. 157 and following.

<sup>371</sup> *Inter alia*, “(...) children are still being neglected despite the fact they represent approximately the 15-20% of the global burden (...)”. Du Cros et al. (2011), p. 855.

<sup>372</sup> “A realistic view of IP is that it is the disease rather than a cure”. Boldrin and Levine (2008), p. 244. See also Thurow (1997), p. 95.

<sup>373</sup> Still, within international law, it has to be considered that “[m]any countries base their health and food safety regulations on the ‘precautionary principle’”. Cohen (2001), p. 431.

(idiosyncratic) interests; surprisingly, strong emphasis on international law, rule of law, and legality are put when it comes to IPRs. The latter must be de-legalized and re-politicized at the international level. The actual trade-link risks to possibly fire-back due to the increasing need for import/export from/to countries where IPRs play a crucial role for the life of people. It is absurd to have patents opposed to people: if patents have to be intended in the form of rights, they hold an intrinsic limit before the life of people (in the specific case the patient) because the insurgence of the same concept of right is connatural to the human life and his dignity. Moving from this perspective, the work of the Academia shall focus on the distinction, within law, between what is just and what is useful. Despite the existence of some correlation between the two, occasional and contextual elements of utility have to be kept clearly aside from the common ideal of justice around which the community lives. As argued, IPRs protect invested capitals: the protection of capitals is not a legal but an economic-related argument that capitalist economy finds easier to solve through law. It is clear that dominant élites are making abuse of their position:<sup>374</sup> again, not every command is equal to law. In this case, the absolute lack of legitimacy, regardless of the several *ex-post* attempts of justification, makes IPRs entirely void, at least in the international sphere.

¶ § **Final remarks** – This last section offers few operative points aiming at mitigating the negative and more dangerous effects of IPRs.<sup>375</sup>

- Imposing balance: higher degrees of protection for latest products imply proportionally higher degrees of responsibility for: (i) devoting a given percentage, prescribed by law, of incomes to the research on rare diseases; (ii) providing older drugs at accessible prices (on the base of the local market). The non-respect of such clauses or the fraud should be punished with the revocation of existing patents on the products marketed by the same firm.

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<sup>374</sup> Indeed, “[m]onopolies innovate as little as possible and only when forced to; in general, they would rather spend time seeking rents via political protection while trying to sell at a high price their old refurbished products to the powerless consumers (...). Economists call this socially inefficient rent seeking. It is ugly, but the polite academic jargon *rent seeking* means ‘corruption’ (...)”. Boldrin and Levine (2008), p. 233.

<sup>375</sup> To gain a better understanding of the on-going processes see Deere (2009). For more considerations and suggestions see: Boldrin and Levine (2008), pp. 257-259; WHO (2006), pp. 174-184.

- Introducing clear clauses for the abuse of right: the TRIPS Agreement says nothing on the revocation of patents and equally no mentions are addressed for the cases of abuse of law and abuse of rights. Supposedly, these measures are left to the national legislator to assess. DVCs and LDCs should introduce stricter rules on the abuse of rights and law related to patents using the given flexibility of TRIPS. In particular, the exhaustion of the right, left to the national level to frame, has to be connected with the possibility to revoke the patent for abuse of law and rights. When patent rights are abused, the patent is revoked. This mechanism may prevent states from issuing compulsory licencing solving the problem of access within the national legal framework.
- Introducing human rights clauses in IPRs:<sup>376</sup> the EU has been very much committed to the promotion of human rights to the point it decided to link trade to the respect of human rights with third parties. The same should be done for IPRs, introducing an internal clause to the right itself, which binds to the respect of human rights. It would work as “self-destruction-mechanism” preventing the recurrent abuse of power and dominant position in the procedures before the Courts. The Courts just have to access the correct enforcement of the human-rights-clause as constitutive part of the patent rights themselves. Notably, the human-rights-clause is related to every single human being and not to the patent-rights-holder. In other words, the respect of others’ human rights is pre-requisite for the exercise and enforcement of patent rights.
- Different products want different patents: the old and narrow-minded approach “one-size-fits-all” should be dismissed elaborating one particular form of patent exclusively for medicines and therapeutic technologies. In particular, the patent should be linked to the amount of incomes generated in order to decrease the degree of protection proportionally to the level of profits already gained. In particular, separating the cost of experimentation from the research costs,<sup>377</sup> individuating the

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<sup>376</sup> See Cullet (2003), pp. 155-156. Consider also that: “[i]f compliance with TRIPS leads to reduced access to drugs, this might imply a substantive violation of the ESCR Covenant”. Indeed, it may also constitute a regressive measure in DCs.

<sup>377</sup> Abbott (2005a), pp. 92 at point (4) and 95. In particular, it is possible to disaggregate clinical trials from basic research. Boldrin and Levine (2008), at p. 257, suggest further: “Free pharmaceutical industry

contribution of public actors, such as Universities, it would be possible to maximize the profitability of taxpayers' money and balance the level of patent protection with the progressive gains of the firm, guaranteeing redistributive justice.<sup>378</sup>

- [Linked to the previous point] Re-think the policy on stockpiling, leaving free access to data also on trials, that is the base of scientific studies, as the Bolar Provision already states.<sup>379</sup>
- Establishing a flexible regime in the global context: globalization seeks flexibility, it is paradoxical to ask such flexibility to workers and people in general while keeping normative schemes rigid and indisputable. The principle of *geometrie variable* should be considered in the context of IPRs opening to multilevel and adequately differentiate regimes of enforcement of IPRs, balancing global justice and humans' needs.
- DVCs and LDCs should establish regional agreements (preventing the most-favoured-nation clause to work) in order to network the research, experimentation, and production of medicines, promoting internal development of IPRs limiting the imposition force of external actors.<sup>380</sup> Pooling<sup>381</sup> and networking should be used to buy larger stocks of commonly needed medicines downing prices thanks to the increased bargaining strength.<sup>382</sup> Regional agreements and regional organizations are more likely to opposed resistance to unfair regulations imperialistically imposed

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of the stage two and three clinical trial costs, which are the really heave ones. Have them financed by the National Institutes of Health on a competitive base”.

<sup>378</sup> “According to classical intellectual property theory, knowledge begins life as a public good available to all and as an input into the generation of additional knowledge. It subsequently becomes artificially scarce as states grant IPRs to stimulate investments in the production of private knowledge goods”. Maksus and Reichman (2004), p. 291 and read further at p. 293.

<sup>379</sup> In the Canada's Access to Medicine regime there was a “(...) stockpiling provision (...) allowing generic manufacturers pre-emptively to violate a patent in order to have on hand an inventory of drugs upon expiration of the patent”. Tsai (2009), p. 1089. In the US it has been initially proposed under the name of Bolar Amendment, immediately removed from legislation, see Milenkovich (1999), pp. 763-765 and not also the difference approach between the US and the EU on the case.

<sup>380</sup> Consider that: “(...) copying to catch up is the only way to catch up. (...) Third World countries (...) have to copy”. Thurow (1997), p. 100.

<sup>381</sup> “A pool is an agreement (...) to share patents [R&D costs, and information]”. Boldrin and Levine (2008), p. 63.

<sup>382</sup> “International arrangements for pooled purchasing can generate additional price reductions through enhanced negotiations capacities and economies of scale in production and distribution”. WHO (2006), p. 145.



and/or introducing specific regional clauses to the codification and enforcement of IPRs.

Democracy and a genuinely pure politics can intervene immediately to adjust IPRs giving again a human face to law.<sup>383</sup> “The development of innovative capacity requires an array of interlocking policies, including in the spheres of education, intellectual property and technological transfer”.<sup>384</sup> “Patent rights do not justify denial of access (...) and pharmaceutical companies should not consider developing countries merely from a marketing point of view”.<sup>385</sup>

“At the end, we are all just footnotes to Plato”

[Heidegger M.]

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<sup>383</sup> Considering both single human being and the various collective actors, such as: the biotechnology sector, the generic drug industry, the civil society groups, groups of DVCs, Universities, non-profit organizations, and so forth. Clearly, the number of contrasting interests is destined to grow and accommodating all of them is concretely impossible. The credible solution is not the fake democracy based on the power to influence, directly or indirectly, political decisions (lobbying). Law has to be just and it has to aim at the effective good of the (now global) community as a whole.

<sup>384</sup> WHO (2006), p. 163.

<sup>385</sup> Yamane (2011), p. 513.

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“We all own royalties to God for the use of reality”

[Unknown]

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