WHO GUARDS THE GUARDIAN'S GUARDIAN?

Case Study:

"LIFE SCIENCES, GENOMICS AND BIOTECHNOLOGY FOR HEALTHCARE COMMITTEE"

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ABSTRACT

Throughout this paper I tested the relationship between comitology and the democratic deficit in the European Union. My work consisted in checking to what extent the revealed preferences of member states towards the highly contested "Patents on Life" as framed within the Biotech Directive 98/44/EC are articulated inside the comitology "Committee on Life Sciences, Genomics and Biotechnology for Health". I engaged in Qualitative analysis, namely Process Tracing conducted through Within Case and Document Analysis, since it allowed for the evaluation of both rival hypotheses crystallized in the literature: intergovernmental bargaining or supranational deliberation. I measured comitology as the locus of intergovernmentalism or supranationalism by using as proxies the revealed attitudes towards EU legislative outcomes. When checked both against the theoretical expectations and the official attitudes of the Member States as proxies for measuring their interest, the Summary Records of the analyzed comitology Committee portrays its working input as a representative of the supranational interest. The data analyzed – showed little congruence between Member States' expressed preferences and the Biotech Committee's working output. In conclusion, comitology committees represent a locus for supranational interest representation as opposed to intergovernmental interest representation (the initial purpose of their creation). Whether it is at this particular level that further action should be taken in order to check and consequently address potential breaches in the democratic decisionmaking process will make the testing object for further research. My current findings cluster observations around two composed concepts: "multilevel governance" and "guardianship" – which I have called "the interaction effect" and can be generalized inside the framework of First Pillar Legislation, concerned with deepening the Single Market.

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1 INTRODUCTION

Throughout this paper I will test the relationship between comitology and the democratic deficit in the European Union. My research curiosity makes sense in a context where comitology has been pointed at as a potential locus for democratization of decision-making inside the EU. Explicitly, governance in the European Union is often referred to in the literature as "governance by committees." Comitology committees have attracted extensive attention from the part of enthusiastic young scholars and prestigious names alike who questioned the lack of procedural transparency as a sore link in the decision-making chain. Whether comitology committees constitute "a forum in which national and supranational experts meet and deliberate in search of the most efficient solutions to common policy problems" or, on the contrary, "a control mechanism designed by EU governments to supervise the Commission in its implementing duties" has emerged as an ardent issue of scholarly debate in the last years. (Pollack, 2003) The competitive testing of this hypotheses is relevant through the attributed implications, namely, the potential that comitology displays in democratizing the EU decision-making structure through the alleged positive impact it is due to trigger upon input legitimacy.

Building on this research direction, I will however limit the scope of my paper to inferring upon the intergovernmental versus supranational nature of the working outputs in the "Life sciences, genomics and biotechnology for health" comitology Committee monitoring the implementation of the Biotech Directive in the Research Area. I will employ Qualitative, namely Within Case Study Analysis through Theoretically Guided Process Tracing. "Biotechnology is an area in which many morally questionable inventions are generated. Controversial patented biotech inventions include: isolated genes, sequenced DNA, medical procedures, embryonic stem cells,

genetically modified transgenic animals, and methods of cloning mammals. The moral controversy concerning these and other Biotech inventions stems from several concerns, including those surrounding the mixing of human and animal species, denigration of human dignity, destruction of potential human life, and ownership of humans." (Bagley 2003) Traditionally, biotechnology related inventions have been tackled at the national level, through patent law. Namely, patent law being territorially tied, with states granting patents on the basis of their sovereignty and providing the possibility of right enforcement for patentees only within national borders, the whole process was fairly manageable in that controversies were solved by taking into consideration and eventually balancing internal society interests. That underlying logic obliges a person who wants to legally protect any sort of invention in different countries to apply for a patent in each country of interest, since no exclusionary right provided extends beyond national borders.

The "commodification of human life" (Fukuyama 2000, Habermas 2001, Harris 1993) has been conceptualized from a multidisciplinary perspective overlapping philosophy, law as much as political science related measurable implications, in the quest of balance between efficiency and morality. In a nutshell, despite the challenging intellectual exercises that such speculations may prove to be, biotechnology has moved from the futurologist agenda straight to the policy making agenda worldwide. It is in the daily context of different national/regional answers to similar global questions that I position my theoretical endeavor, specifically on property rights over living material as defined by WTO throughout the TRIPS Agreement and implemented within EU and US through "Life Patents". I will zoom over the healthcare biotechnology area and place special emphasis on the conflict between the ethic and economic

argument in the use of human cells. “The moral claim” in its subsequent avatars enjoys legal recognition under the principle of “human dignity” and has special relevance in the political debate over the maintenance of “public order” as reflected in the different evolution/internalization of Biotechnology “Patent Law” in US and EU respectively.

2 CHAPTER I: METHODOLOGY

2.1. Intergovernmentalism or supranationalism?

Two strategic research directions for the empirical study of comitology have been articulated in the literature, accompanied by adherent methodological tools: the rational choice approach making use of case study and process tracing as methods for emphasizing the presence of bargaining between Member States and the Commission, versus the sociological institutionalist approach making use of interview data to identify the presence of deliberative supranationalism among the negotiators. The rational choice approach to comitology extracts its theoretical assumptions from the study of American politics. Specifically, it builds on principal – agent models of delegation by legislative principals (here EU Member States as the equivalent of US Congressional representatives) to executive or judicial agents (here an exclusive focus will be given to the EU Commission as a supranational organization equivalent to the US regulatory agencies). Arguably, comitology is the tool through which Member States exert control over potential delegation losses by limiting supranational discretion. (Pollack 2003). For testing hypotheses about institutional preferences researchers can employ either quantitative data, to measure revealed preferences, or qualitative data consisting in case studies of interinstitutional/ intergovernmental negotiations and primary sources alike. I will employ Qualitative Methodology, specifically Process Tracing (Alexander George and Andrew Bennett 2005) through document analysis on the specific case of the moral argument as formalized by the Directive 98/44/EC of the European Parliament and of the Council, of July 6 1998, on the legal protection of biotechnological inventions.

2.2. Theoretically Guided Process Tracing conducted Within Case Study

"Qualitative analysis, with its close-up look, can identify mechanisms, going beyond sheer association. It is unrelentingly local, and deals well with the complex network of events and processes in a situation. It can sort out the temporal dimension, showing clearly what preceeded what, either through direct observation or retrospection. It is well equipped to cycle back and forth between variables and processes, showing that <stories> are not capricious, but include underlying variables, and that variables are not disembodied, but have connections over time." (Miles and Huberman, 1994 in Falleti 2007) Consequently, I chose using small N over large N cases mainly due to the latter's focus on causal mechanisms, whereas statistical methods account for explaining causal effects as the expected variation in outcome when presumaby only one independent suffers modifications. Such scenarios assume environments which can be controlled through designed experiments but less through observational studies. Therefore, I will operationalize on the Theory Guided Process Tracing (Robert Bates et al. 1998, Tim Büthe 2002, and Peter Hall 2003 in Falleti 2007) as an attempt "to account for outcomes by identifying and exploring the mechanisms that generate them". Epistemologically, process tracing is compatible with a positivist or, to be more precise, scientific realist understanding of causation in linear terms. (Checkel 2005)

Mechanisms operate at an analytical level below that of a more encompassing theory; they increase the theory's credibility by rendering more fine-grained explanations (Johnson 2002 in Checkel 2005). According to one widely cited definition, a mechanism is "a set of hypotheses that could be the explanation for some social phenomenon, the explanation being in terms of interactions between individuals and other individuals, or between individuals and some social

aggregate" (Hedstroem and Swedberg 1998 in Checkel 2005). As "recurrent processes linking specified initial conditions and a specific outcome" (Mayntz 2003 in Bennett and George 2005), mechanisms connect things. "How does one then study these causal mechanisms in action? Process tracing would seem to be the answer as it identifies a causal chain that links independent and dependent variables. Methodologically, process-tracing provides the how-we-come-to-know nuts and bolts for mechanism-based accounts of social change. But it also directs one to trace the process in a very specific, theoretically informed way. The researcher looks for a series of theoretically predicted intermediate steps." (Checkel 2005) Conceptually, when talking of mechanisms and process tracing in this chapter, I have adopted a micro-perspective. Theoretically, this means I examine what are sometimes called 'agent-to-agent' mechanisms (Bennett and George 2005, 145).

Acknowledging that "the process of doing a case study is not easily articulated because a case study is not really a <methodology>, but rather it is an approach to research that is predicated on in-depth case analysis" (O'Leary, 2004, pp. 117), I will rely on process tracing through document analysis on the specific case of the moral argument as formalized by the Directive 98/44/EC of the European Parliament and of the Council", of 6 July 1998, on the legal protection of biotechnological inventions. My case selection owes to the intrinsic value of this case, which intuitively displayed further on confirmed potential to debunk an existing theory as much as to bring new variables and consequently enrich the explanatory equation. The underlying contradiction at the basis of my selection resides in the discrepancy between Member States refusing to implement a piece of legislation which was otherwise being evaluated as unproblematic by unanimous accept in the comitology committees. "Case studies are generally

multi-method and often rely on interviews, observation and document analysis in a bid to obtain rich qualitative data." (O'Leary, 2004, pp. 118) Process Tracing (Bennett and George 2005).

"Fieldwork" and "Archive Research", with "Elite Interviewing" and "Document Analysis" as contextual representatives in Political Science, constitute equally legitimate components of Theory Guided Process Tracing. Nevertheless, whereas Elite Interviewing is suitable for measuring the quality of the decision-making input, I will strictly rely on "Document Analysis" as I am concerned with drawing inferences about the implications of decision-making output. Even so, the diverse nature of instruments I had at my disposal as proxies to measure intergovernmentalism and supranatationalism respectively, ranges over summary records of formal meetings, official declarations, reports, manifestos and strategies as much as over media excerpts of newspapers which have shown a involvement in covering the issues at stake. Thus, I need to measure the revealed preferences of the Commission and Member States alike, and check them against the results of the Committee's working output, in order to test the intergovernmental versus supranatational hypotheses. Finally, I will relate the data to the theoretical expectations, and, depending on the obtained result, engage in drawing inferences about the implications that comitology working outputs trigger for the democratic nature of the decision-making process. The ultimate purpose of my research would be contributing to the diagnosis of the breaking links in the democratic nature of the decision-making chain, and eventually inspire subsequent practical insights.

Specifically, to measure the Commission revealed preferences for the desirable development of the Biotech Industry Sector, as proxy of the economic argument, I use the

following documents: indirectly, I will take the Commission communications “Life sciences and biotechnology – A Strategy for Europe” (January 2002) as a point of reference. Directly, I will rely on the Commission communications “Life sciences and biotechnology – A Strategy for Europe – second progress report and future orientations” (April 2004) and “Life sciences and biotechnology – A Strategy for Europe – third progress report and future orientations” (October 2005). Additionally, I will use the EuropaBio “Healthcare Manifesto” (22 September 2005), to check its congruence with the Commission's official expressed position from the perspective of the consistency and chronology synchron alike. To measure the revealed preferences of the Member States, as a proxy for the ethic argument where officially expressed opposition occured, I will employ the “State of Play of the Implementation Directive EC/44/98”, but moreover, I will rely on media excerpts from sources which have manifested a constant preoccupation for the issue, with preeminence given to the policy files published regularly on the WebSite www.Euractiv.com. Occasionally, articles from newspapers with proved credibility like “The Economist” or “The Spiegel” are quoted. As a last step, I corroborate all these observations and check them against the results provided by the official Summary Records in the “Life sciences, genomics and biotechnology for health” from 28 October 2004, 12 April 2005 and 5 April 2006.

”Case studies are useful, as Harry Eckstein and Arend Lijphart noted at all stages of the formation, development and testing of the theories.” “The process tracing method attempts to identify the intervening causal process – the causal chain and causal mechanism – between an independent variable (or variables) and the outcome of the dependent variable.” (George and Bennett 2005, pp.207) “The challenge in using process tracing is to choose a variant of it that fits the nature of the causal process embedded in the phenomenon being investigated.” (George and

Bennett 2005, pp 212) Following Lijphart's typology of case study, I would qualify the current endeavour as theory infirming, resulting in hypothesis – generating. (Lijphart, in George and Bennett 2005) “Most case studies are outcome oriented, they focus on explaining variance in the dependent variable. But when researchers or policymakers wish to assess the causal power of a particular factor – such as an independent variable that policymakers can manipulate – they have an interest in explaining the contingent conditions under which similarity or variance in the independent variable can lead to different outcomes.” (Bennett and George 2005, pp 219) “Assess it by means of plausibility involving other cases” (Bennett and George 2005, pp. 222): software patents directive rejected according to the same path, biotech, without ever entering the comitology stage. Consequently, my guess is that Member States exert voice options before WTO negotiations, thus if a locus for democratization needs to be found, the focus should shift on analyzing expert groups & consultative committees.

2.3. ***Conceptualization, Systematization, Operationalization; Measurement***

2.3.1. Dependent Variable: The Democratic Deficit

I start from the main assumption that democracy as a system of governance has displayed transformative potential translated into the practical capacity to perpetually redesign itself (Dahl 1989), the three “democratic revolutions” of contemporaneity, labelled as such despite the changes having occurred without widespread violence or institutional discontinuity, center around size, scale and scope of democratic governance. First, the US system replaced the belief that democracy is suitable only for small scale constitutencies such as the Greek polis or Swiss cantons. Second, universal standards replaced the belief that citizenship is restricted to

privilleged social categories. Third, democratic regimes became responsible of governing an ever increasing range of distributive and re-distributive issues, engendering progressive delegation to regulatory agencies under the function of guardianship. The scope of this paper resides in applying the conceptual framework to the European Union, with the purpose of analysing the effectiveness of intergovernmental supervision of the guardian, namely the Commission, through comitology committees in a highly contested policy.

Throughout this paper, I will systematize the concept along the dimensions provided by the literature relying on the second understanding, namely "technocratic decision-making, lack of transparency, excessive use of administrative discretion, inadequate mechanisms of control and legitimacy". (Majone, 1999, pp. 15) Thus, by "democratic deficit" I understand the breaking of the democratic decision-making chain in specific links "that arises whenever important policymaking powers are delegated to bodies operating at arm's length from government, such as regulatory authorities". (Majone, 1999, pp. 15) The "democratic deficit" of the European Union entered public attention throughout five synthetic points clustering around the European Integration having equalled a decrease in the power of legislatives accompanied by a proportional increase in the power of executives. (Anderson and Burns, 1996, in Follesdal and Hix 2005) Currently, the European Integration literature provides two different arguments favoring concurrential understandings of the term. (Majone, 1999) The two arguments build on standard infringements derived from checking legitimacy standards against the theory and practice of parliamentary democracies, and against the practice of non-majoritarian institutions respectively. Zooming on the two competing claims, one could argue the second understanding of the democratic deficit constitutes an actual subcategory of the first category, by basically

developing on the argument of majoritarian standards as opposed to non-majoritarian practices:

The first classification is structured around four traditional criteria: 1). standards based on the analogy with national institutions, 2). majoritarian standards as opposed to non-majoritarian practices, 3). derived standards (from the legitimacy of Member States) and 4). social standards. "If the expression is taken literally – an absence or incomplete development of institutions which we take for granted in a parliamentary democracy – then a deficit of democracy is indeed a distinctive feature of a process within which economic and political integration not only move at different speeds but also follow different principles – supranatationalism in one case and intergovernmentalism in the other." (Majone, 1999, pp. 14) As for the second classification, it addresses new modes of governance through delegation, be it to improve 1). cognition, 2). efficiency, 3). responsibility or 4) "credible commitment" of the regulating bodies. Thus, "democratic deficit, in this second sense, refers to the legitimacy problems of non-majoritarian institutions, i.e. institutions which by design are not directly accountable to the voters or to their elected representatives." (Majone, 1999, pp. 14) I am concerned with testing the whether comitology committees, initially created to protect the intergovernmental interest in the relationship between the agent, European Commission, and its principals, the Member States, is currently contributing to the democratic deficit by moving away from the Member States' official preferences or, on he contrary, it represents an arena for the potential democratization of decision-making. If comitology Committees are still committed to the initial aim of their creation, we could infer the democratic decision-making chain breaks at the national level, basically before entering the comitology arena. It is outside the scope of this paper to measure the nature of the decision-making process inside the committees, therefore I will focus

exclusively on the working output of the "Life sciences, genomics and biotechnology for health" upon which I will further construct my argument.

2.3.2. Independent Variable: comitology committees

Complementary to the existing literature on the democratic deficit caused by the main protagonist throughout the delegation phase, namely the European Commission, this paper will focus on testing the democratic deficit hypothesis caused by the main protagonist throughout the post-delegation phase, namely comitology committees. Conceived in the 1960's on the purpose of controlling the Commission, the institution is now suffering serious critique in terms of mal-functionality and incapacity of fulfilling its goal. Subsequent scholar debate splits between supranatationalists and intergovernmentalists who dispute the positive versus negative impact on comitology over the democratic deficit it should have solved. A key distinction between the committees participating in the European governance divides them into those which operate in the preparation of legislation (expert groups and consultative committees) and those which operate in the implementation of legislation (comitology committees).[1] Although the former were created by an official decision and thus officially involved in the drafting phase, their varying influence has been outruled in attention by "the less formalized structures which have attracted more controversy, particularly aimed at the forums comprised of large firms which were used by the enterprise and technology related services of the Commission from the mid 1990's onwards."

I claim that since the scope of comitology committees resides in supervising policy implementation, checking its empirical performance against normative claims that belong to the

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realm of policy legislation results in fallacy through conceptual stretching. Therefore, I set the ground for further debate by delimitating between policy legislation and policy implementation as chronologically distinctive and successive phases inside the policymaking cycle. This distinction acquires particular importance in the EU due to the peculiar division between the executive and legislative. Contrary to the nationally postulated separation of powers, the legislative function is performed by the European Parliament together with the European Council, whereas the executive function is performed by the European Commission alone. Correspondingly, policymaking should have follow the same pattern had the overwhelming process of implementation not been delegated to the European Commission since 1967 - CAP.

"Comitology committees include a variety of types of committees which differ in their regulatory powers and which involve an estimated 50.000 representatives from national administrations and experts from civil society." (van Schendelen, 1998 in Greenwood 2007) The literature surrounding the history of comitology, besides abundent and dry, it is outside the scope of this paper. The main argument revolves around its initial "raison d'etre", namely a supervisor of the Member States interest throughout the implementation of the CAP Reform by the European Commission. The question that arises repetitively is to what extent comitology committees, which should be the correspondents of "the guardian's guardian", in an equation where the European Commission is the guardian, continue to safeguard Member States' interests. According to the logic of interest delegation, principals choose the option of delegating responsibility to a commonly designated authority which they acknowledge as agent on the grounds of enhancing the legitimacy of their interest representation in the decision-making process.

Four main key functions[2] are usually being delegated from principals to agents as postulated in the literature: “monitoring compliance with agreements among principals”, “solving problems of <incomplete contracting>”, “adopting credible, expert regulation of economic activities in areas where the principals would be either ill-informed or biased” and “setting the parliamentary agenda so as to avoid the endless <cycling> of policy alternatives that might otherwise result from the possession of agenda setting powers by the principals themselves” (Pollack 2003, p 21). As for the representative shortcomings characterzing the post-delegation phase, they seem to revolved around monitoring agency behavior with the purpose of correcting the ineludable asymmetry infomation and influencing policy results through the application of positive and negative sanctions respectively (Pollack 2003). Under these particular theoretical considerations, consensus seems to have emerged around signalling comitology as an ingenious mechanism designed by the member states on the purpose of controlling the powers delegated through agency.

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3 CHAPTER II: CASE STUDY PRESENTATION AND MISSING PIECE IN THE PUZZLE

3.1. Policy Overview:

In January 2002, the European Commission launched ‘’Life Sciences and Biotechnology: A Strategy for Europe” (EuropaBio Official Website), with the specific purpose of fostering transition towards bio-economy as stipulated in the Lisbon Agenda. Implementation of the strategy has been subjected to yearly reviews invariably concluding its validity and utility despite repeated signals of staggering implementation from the part of the member states. Specifically, in April 2007, the Joint Research Commission Center launched a mid-term review entitled symbolically „Bio4EU”, which qualifies the strategy as successful, relevant and awaiting further implementation, as "an important step towards a competitive and sustainable Knowledge Based Bio-Economy (KBBE)” (www.Euractiv.com). The study replaced the initial 30 points target with five interdependent priority actions: enhance research and market development directed towards life sciences and biotech applications, foster knowledge transfer and innovation from laboratory to industry, encourage informed societal debates on the benefits and risks inherent to life sciences and biotechnology, ensure a sustainable contribution of modern biotechnology to agriculture and last but not least improve the implementation of the legislation with specific care for impact on competitiveness.

“Biotechnology is an area in which many morally questionable inventions are generated. Controversial patented biotech inventions include: isolated genes, sequenced DNA, medical procedures, embryonic stem cells, genetically modified transgenic animals, and methods of

cloning mammals. The moral controversy surrounding these and other biotech inventions stems from several concerns, including those surrounding the mixing of human and animal species, denigration of human dignity, destruction of potential human life, and ownership of humans." (EuropaBio Official WebSite) Traditionally, biotechnology related inventions have been tackled at the national level, through patent law. Namely, patent law being territorially tied, with states granting patents on the basis of their sovereigity and providing the possibility of right enforcement for patentees only within national borders, the whole process was fairly managaeable in that controversies were solved by taking into consideration and eventually balancing internal society interests. That underlying logic obliges a person who wants to legally protect any sort of invention in different countries to apply for a patent in each country of interest, since no exclusionary right provided extends beyond national borders.

Presently, OECD distinguishes between modern and traditional biotech, in as follows: „The application of Science and Technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services" (OECD Official Wbesite) is acknowledged as overlapping traditional biotechnology related activities. According to the same source, modern biotechnology is defined as „the application of scientific and engineering principles to the processing of material by biological agents and the processing of biological materials to improve the quality of life by isolating, modifying and synthesising the genetic instructions responsible for actual biological processes." As for the classification employed, the following table shall provide a comprehensive overview of the current areas refered to as biotech applications. Nevertheless, one shall keep in mind that present reasearch is directed mainly towards what we acknowledge as green, red and

white biotechnology.

Colour Type	Area of Biotech Activities
Red	Health, Medical Diagnostics
Yellow	Food Biotechnology, Nutrition Science
Blue	Aquaculture, Coastal and Marine Biotech
Green	Agricultural, Environmental Biotech, Biofuels, Biofertilisers, Bioremediation, Geomicrobiology
Brown	Arid Zone, Desert Biotechnology
Dark	Bioterrorism, Biowarfare, Biocrimes, Anticrop Warfare
Purple	Patents, Publications, Inventions, IPRs
White	Gene-based Bioindustries
Gold	Bioinformatics, Nanobiotechnology
Grey	Classical Fermentation, Bioprocess Technology

Insofar, noteworthy debate has been revolving around green biotechnology. Thus, genetically modified organisms (GMOs) are an over-represented sample enjoying special media coverage due to its excessive politicization. In addition, white biotechnology started to receive special attention caused by the urgency of regulating bio-fuels. However, the current paper builds on the equally fascinating example of „life patents". Until around 1980 it was commonsense to assume living organisms, be they plants, animals or microorganisms cannot be patented, as they were not invented by humans, but already given by nature. Basically, until the US Supreme

Court introduced the „patent race" (Emmott 2002) by patenting the first famous genetically engineered oil-eating bacterium, institutionalizing the "patenting of life" belonged at best to the Sci-Fi realm. Nevertheless, following this event, biotechnology industry in Europe built an entire case around losing ground in economic competitiveness towards the US unless the Commission adopted the above mentioned Directive.

3.2. Ethics versus Economics Debate – What is there to Protect versus What is there to Promote?

The "morality" criterion in patent law is put forward especially by NGOs as well as by any other non governmental actor determined exercise the ex ante legitimacy claim in the policymaking process. As a Human Rights related claim accusing infringements over the right to dignity as a human person, it secures direct access to the regulatory framework ("Patents on Life" Consumer Lobby Campaign, 1995). Since the working tool in biotechnology is living matter, more or less realistic nevertheless still plausible anxieties develop in accordance with each particular subcategory. Surprisingly, in Europe surveys (Euro-barometer: Europeans and Biotechnology: Patterns and Trends, 1991 - 1996) show a correspondence between a perceived need from the public that policy makers should regulate moral protection and the increased strictness of standards as applied to humans, animals then plants and not the other way round. Six such studies gradually building up to the point where more than 50% Europeans draw a direct correlation between adopting biotechnology and increasing the standards of life have been conducted between 1991 and 2006, whereas the remaining half still displays "moral" objections. The "moral" objection is present in the US also, however the field of concern is restricted to human biotechnology, America having already liberalized its markets to Genetically Modified

Food, for instance. The debate is structured around the ethic argument of "human dignity". Legally, this argument is valid and applicable through its contextual translation concerning the nature and subsequent use of human cells as tools for pushing economic efficiency in the race towards competitive knowledge based economies as providers of improved life standards for modern consumers.

Specifically, biotech for healthcare involves the use of human embryonic and somatic stem cells (the latter isolated from foetal or adult tissue). In Europe, the question of whether the Directive specifically addressed the patentability of stem cells persists. It was first raised officially in the "1st 16c Report" of the European Commission and referred to the "European Group of Ethics" in 2002 (COM 2002 – 545 final). They assessed (Opinion No 16, 1st Report 16c) that no substantial ethical reason should justify a complete banning on patenting those inventions which relate to somatic stem cells or stem cell lines provided that the normal requirements for patentability are met. For pluri-potent embryonic stem cells whatsoever, the Group of Experts classified the question of patents as closely linked to the definition of what constitutes an embryo and the adherent scope of research allowed, whose determination is let at the latitude of national legislations. However, "in the light of the clear divergences which currently exist between Member States as regards the acceptability of research relating to embryonic stem cells, the continuing and rapid developments in this field, and the fact that the Directive itself provides for Member States to refuse patents on grounds of <ordre public> or <morality> under Article 6(1), the Commission considers it is premature to give further definition or provide for further harmonization in this area" (Opinion No 16, 2nd Report 16c)

3.3. The US approach: 'Moral Utility' → 'Utility': "Patent first, ask questions later" (Bagley 2003)

In order to have a better background understanding of the debate and pressure emergence towards competitiveness in the European Patents Market, it is imperious to turn to the US experience. The legal body performing technical regulation of patents in the US is USPTO (United States Patents and Trademark Office Official Website). Established by the US "Patent Act" "as an agency of the United States, within the Department of Commerce", Title 35 (Bitlaw Website) of the US Code, the USPTO is supposed to grant patent authorization to inventions which fulfill the "usefulness" criterion. Unlike the EU situation which I will develop upon further on**,** the 1952 Patent Act contains no provisions which should eventually defend denying patent protection to morally controversial inventions on a statutory basis, neither by the USPTO nor by Courts. "The Patent Act of 1952 provides that a person is entitled to a patent if her invention meets the statutory patentability requirements specified in the Act. The burden is thus on the USPTO to show that a person does not meet the statutory requirements, and, since there is no statutory morality inquiry, the U.S. has a de facto system of patenting first, and asking questions later." (Bagley 2003, pp. 19) Although no concrete operationalization of public order through standards or standard infringement, as we will further observe in the European case, is specified throughout the act, "usefulness" as an underlying condition for receiving patent protection is presently delimitated along three criteria out of which at least one must be fulfilled, therefore I will list them the context of my present inquiry: "specificity, credibility, and substantiality" (US Examination Guidelines).

Nevertheless, it is the case that in the first phases of development that patent law

underwent, the moral criterion had to be fulfilled by an invention as part of utility expectations. The emblematic decision taken by Justice Story is supposed to have provided the first articulation of this doctrine throughout the 1817 Lowell v. Lewis decision. Specifically, "[a]ll that the law requires is that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word 'useful' therefore, is incorporated into the act in contradistinction to mischievous or immoral." (Bagley, 2003, pp. 15) Justice Story sedimente therefore the legal foundation of what will have been internalized as the "moral utility" requirement throughout the judicial review process, namely the idea that "utility" of a patent inherently encompasses judicially identified and consaequently rooted morality standards. For the following 150 years, US courts cited this the "moral utililty" requirement as the underlying reason for accepting or rejecting every morally controversial application. The situation did however change dramatically in the 60's, with the acceptance to grant patent fr the oil bacteria engineered by in the *Chakrabarty* case. The Court extracted this phrase from 1952 Patent Act legislative history, with the purpose of backing the broad scope originally designed by the Congress. The phrase stood as underlying argument for the Court's unusually concluding in 1980 Diamond v. Chakrabarty, that any living organism, starting from the case of man-made bacteria displaying different properties from any known naturally existing organism, represented an application eligible for patentability. The same phrase was further on repeated by the Supreme Court in Diamond v. Diehr, a case which claimed having used a natural law within a computerized manufacturing process, thus set the ground for utility patents concerning computer software.

The above mentioned principle still applies to most recent cases such as J.E.M. Ag

Supply v. Pioneer Hi-Bred and State Street Bank v. Signature Financial, both relying heavily on the Chakrabarty decision and impacting mainly on expanding patent eligible applications on business methods and other traditional nontechnical subjects, for instance accounting or the industry of financial services. Thus, from the perspective of an empirical comparison, the US Patent Law, with a specific focus on Human Biotechnology, represents a very interesting case of cohabitation between very strict rules prohibiting federal funding, debate sessions being re-opened periodically and the patent system which basically provides incentives for private funding aimed at developing otherwise morally unsanctioned patent applications. Basically, prohibiting federal funding cancels out with allowing patentability of Biotech inventions on a statutory basis since it does not encompass moral criteria. USPTO, on behalf of the agency received from its principals, the Congress and the Courts, in the patent protection granting process, administers the scope of eligible matter, the actual requirements, and the adherent legal rights conveyed by any issued patent. However, it is the Congress designs the law, afterwards it is Federal judiciary's turn to interpret it. The USPTO manages the laws that the Congress has enacted and that the Federal courts interpreted. According to current law, once requirements settled through statutory patentability are met, no further basis for denying patent applications can be invoked. Having agreed that the judicially created and perpetrated moral utility claim on patent protection suffered judicial demise, a moral void remained synthesized by the U.S. Supreme Court synthesized as “anything under the sun made by man” (Bagley 2003).

Recently it is argued that based on its statement (even if labelled as unnecessary in terms of consequences or precisely because of it) regarding the chimera application (Coughlin 2006), USPTO will revive the claim to moral utility for tackling morally controversial patent

applications. Counterarguments focus on the extreme difficulty to resurrect a rule shaped throughout judicial interpretations but without a real statutory basis whatsoever, since it is not included under the 1952 Patent Statute. Last but not least, there is an ultimate argument centering around the fact that morally controversial patent applications resulting into eventual biotech inventions carry the potential to help cure disease. (Bagley 2007) The Supreme Court's Final Declaration in this respect states: “Congress never intended that the patent laws should displace the police powers of the States, . . . [t]hose powers by which the health, good order, peace and general welfare of the community are promoted. . . . Of course Congress is free to declare particular types of inventions unpatentable for a variety of reasons, including deceptiveness. . . Until such time as Congress does so, however, we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public” (Bagley 2003, pp. 18)

3.4. The EU approach: Moral Exclusions on patenting life in the EU - “Abhorrence” and “Unacceptability”: (Plomer 2007)

In the EU, the „TRIPS Agreement” under WTO authority „requires Member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced” (Article 27.1 (WTO Official Website). In the EU understanding, “public order” as a predictor of morality concerns corresponds in particular to ethical or moral principles recognized in each Member State. As a common denominator whatsoever, “public order” is used

interchangeably with “morality” and relies on four main conditions (Warren Jones 2003, p. 10) to be fulfilled by patent applications before being granted protection, namely: (1). rule of law & critical morality, (2) critical & positive morality, (3) legislation & regulation and (4) legislation & social moral norms. From different interpretations out of which a series has been previously acknowledged, two separate standards have emerged, namely abhorrence and unacceptability, the main criterium for differentiating being the authority of issuance itself. Thus, in the first case the standard of abhorrence is set by EPO and builds on the action of refusing market authorization. Conversely, where the patent morality standard is set at the level of unacceptability, granting protection may accord with the assessment taken later by the applicable marketing authority, but it represents a doubling up of consideration and leaves scope for disparities which cannot be easily accounted for. Similarly, patent protection being refused on the basis of unacceptability doesn't cancel any decision of the regulatory body setting it is an acceptable social development in the future.

Social morality in the context of biotechnology is highly reliant on the level of information, therefore even where a standard of morality can be agreed, it is in principle volatile and questionable in terms of morality standards perpetrator. (Warren Jones 2003) Interpretations concerning which standard should prevail differ are illustrated throughout Warren Jones' research endeavour entitled “Beauty and the Beast: a Moral Tale of Human Biotech”. Conceived as an analysis of the common basis which constructs “public order” starting from the above enumerated four points, the paper reunites concurring points of view sketched within legal theory, in as follows: Professors Beyleveld and Brownsword (“Mice, Morality and Patents” in Warren Jones 2003) agree upon morality as having to encapsulate both rule of law and critical

morality. Professor Straus ("Patenting Human Genes in Europe - Past Developments and Prospect for the Future", in Warren Jones 2003) on the other hand, subsumed the “moral assessment” to broader law principles “inherently contained within subject-specific legislation” (such as "the inviolability of human dignity and the right to life, physical integrity and personal freedom") or “overtly apparent in subject-specific legislation” (such as: germ-line gene therapy; human cloning; commercialisation of human embryos). Prof Schatz (Patents and Morality" in "Biotechnology, Patents and Morality”, in Warren Jones 2003) considered the assessment should fix upon primary societal values embeddied in customary rather than primary law. Professor Moufang (Warren Jones 2003) considere the assessment should require inventions to comply with moral principles translated in legislation and resting on a majoritarian socially accepted basis.

4 CHAPTER III: HYPOTHESES TESTING = SUPRANATIONALISM OR INTERGOVERNMENTALISM?

4.1. Interest to be safeguarded: the Member States'

Directive 98/44/EC on „the legal protection of biotechnological inventions" innovation aimed to stimulate the industrial development and investments within the EU (Burhoi, Ledendal, 2006). The European Commission's White Paper from 1985 stated that differences in intellectual property laws among Member States had a direct and negative impact on the intra-Community trade. Thus, the original purpose of the 1998 EU Biotechnology Directive was to establish legal certainty in the biotechnology inventions area within the European Community and to help European biotechnology companies to become more efficient in promoting innovation and attracting investment. It is also refered to as a pioneer in the history of patent law, in that it establishes a set of rules allowing for „broad biotechnology patents" on „biological material", „biotechnological processes" and „products containing or consisting of genetic information". (Leskien 1998) Basically, the directive provided the legal framework for research covering most sensitive issues to be performed. The implications may not be obvious since the effects it is supposed to trigger are not visible in the present. As show in the previous chapter, patents have been granted for almost a century, however the standards inventions should have fulfilled differed amonf individual Member States. Such a situation is clearly detrimental to the ideal of economic efficiency, since it entails a perpetual process of adaptation and coordination from the part of the economic actors. Thus, the primary purpose of achieving harmonization at the European level was to secure favorable market access to pharmaceutical companies.

Following the negotiation of the Directive, a final implementation compromise between the bio-industry lobby and the consumer lobby has been reached in the form “moral exclusions” to be introduced in the final form submitted to approval which was subsequently voted by the European Parliament accordingly. The Biotech Directive 98/44/EC explicitly forbids “processes for cloning human beings”, “processes for modifying the germ line genetic identity of human beings”, and “uses of human embryos for industrial or commercial purposes”. Nevertheless, while human reproductive cloning is clearly forbidden in terms of attracting patent protection, therapeutic cloning and embryonic stem cell therapy are still ambiguously dealt with. The ambiguity is grounded in lack of consensus regarding the granting of legal human status to embryos. Under these circumstances, embryonic stem cell therapy analogically falls within similar uncertainty. The question which raises is once the stem cells have underwent the differentiation process is what happens to the particular cells derived from the artificial production of embryonic stem cells in terms of patentability. As for modifying the germ-line of humans is prohibited, but this permits processes involving somatic cell gene therapy to be patented, as well as the genetic/cellular products associated with either somatic or germ-line gene therapy.

As shown above, two main arguments are raised against “life patents”. Firstly, the moral claim which qualifies the implications of granting patents over „specific characteristics shall extend to any biological material derived from the patented material, provided the patented material still possesses those same characteristics” as problematic. Second, the utilitarian claim, questioning the tradeoff between granting knowledge monopoly to companies and the distributive social justice the will fail to return unless specifically hold accountable. Basically,

inside EU law, directives[3] are acknowledged as „secondary legislation", „binding as to the results which must be achieved", the choice for implementation being left at the latitude of the Member States. By all means, before 30 July 2000, the implementation deadline, 9 Member States failed to implement the directive, which signals discontent towards the result to be achieved, irregardless of the means. I advance the discontent towards results claim as opposed to the technical failure to implement alternative on behalf of expressed discontent coming from a third of the Member States, namely Germany, Austria, Belgium, France, Italy, Luxembourg, the Netherlands, Portugal and Sweden. Netherlands detaches itself as the most extreme example, having brought Case C-377/98 before the European Court of Justice against the adoption of the directive with six different pleas out of which the Court didn't grant any. In reaction, the European Commission has officially requested these countries to uphold their commitment to implement the Directive, in order to avoid damaging the European biotechnology sector and implicitly affect standards of competitiveness on the Lisbon Agenda. The requests took the form of „reasoned opinions", which represent the second stage of formal infringement proceedings under Article 226 of the EC Treaty, the next step being legal settling of issues mediated by the European Court of Justice. (Press Release)

Complementarily, only 6 out of 15 states had implemented the Directive in due time, with France and Louxemburg directly speaking against patenting of genes, seconded by Germany and several medical, environmental, development and farmers organizations respectively. (Greenpeace Documentation 2005) Eventually, while part of the member states complied with requirements in due time, the deadline for effective entry into force was prolonged until 2006 in

[3] Luther, Kurt Richard and Muller-Rommel, Ferdinand, Political Parties in the New Europe; Political and Analytical Changes, Chapter 3, Oxford University Press;

some cases (European Commission WebSite), securing bargaining over concessions from the approved version. Explicitly, „the controversial plan to allow patenting for products derived from living things was endorsed only after it had been altered to exclude all cloning and the patenting of human embryos. The revisions demanded by MEPs, to guard against abuses rule out the patenting of any human body parts or any new experimentation involving the use of human embryos for industrial or commercial purposes." (GreenPeace Documentation 2005) Nevertheless, against contentious ethic debate, „like the US Patent Office, the European Patent Office has been granting patents on human genes since 1990. By now the EPO has received more than 6000 applications and has already granted between 400 and more than 1000 patents on genes according to estimations of experts. Since 1999 the Office refers to the EU Directive (see above, section 4), even though the Directive is neither valid for all members of the EPC nor has been transposed into national law by all EU members"

Consequently, on 22 September 2005 representatives of the biotech industry launched a common complaint in the form of a "Healthcare Manifesto", articulating its concerns about the problematic implementation of the "Life and Sciences" Strategy inside the Member States: "Europe is the only region in the world to have a real strategy on biotechnology and that strategy is worth its weight in gold if, and when, implemented". The Manifesto represented the official call for EU policy support to ensure "innovative healthcare" (from the categories of innovative medicines, drugs to treat rare diseases and advanced therapies), as much as "engagement with society" and "creation of wealth" through securing a favourable environment for the development of Small and Medium Enterprises in the sector. The dialogue between the Commission and the industry continued in the form of a "Progress Report" through which the

latter identified the main shortcomings as well as corresponding solutions. Specifically, the lack of national implementation of internal market legislation in the form of the Directive is said to be hampering the biotech industry development as much as the slow progress of the Community Patent, having as a direct consequence diversion towards the US patent granting system.

4.2. What sort of result does the voting/ working output reflect: supranational or intergovernmental?

Biotechnology for heath displays an ever more accentuated future oriented nature in comparison with the already mentioned biotech branches. Therefore, special emphasis is placed on how ethic and economic concerns are being accommodated so that they produce not only economically but also socially sustainable consequences. Consequently, at the implementation stage, supervision was taken over by the "Life sciences, genomics and biotechnology for health" comitology Committee, functioning under "Sixth Framework Programme 2002 – 2006". The Framework reunites seven priority fields which constitute the engine of an ideally first class performance towards a European knowledge based society: "Life sciences, genomics and biotechnology for health", "Information Society Technologies", "Nanotechnologies and nano-sciences, knowledge-based multifunctional materials and new production processes and devices", "Aeronautics and Space", "Food Quality and Safety", "Sustainable Development, Global Change and Ecosystems", and last but not least, "Citizens and Governance in a Knowledge Based Society". Illustratively, "Life sciences, genomics and biotechnology for health" has been granted the leading role not only in "meeting the expectations of European society but also the hopes of developing countries where health conditions must not deteriorate any further". (The priorities of the Sixth Framework Programme 2002-2006)

The "Life sciences, genomics and biotechnology for health" comitology Committee met regularly once a year, to evaluate and consequently vote on batches of proposals organized in calls private Biotech created projects. I chose to analyze the output of these meetings for the years 2004, 2005 and 2006. First, they constitute the core of the Sixth Framework Programme 2002-2006, and second, they display symmetry potential around the year 2005, when the Biotech Industry Manifesto complaining about the poor implementation of the Directive was launched. The event was cornered by the "Life Sciences and Biotechnology – A Strategy for Europe" Second Progress Report and future orientations in April 2004 as well as by the "Life Sciences and Biotechnology – A Strategy for Europe" Third Progress Report to the Competitiveness Council on 11 October 2005. Given the proactive attitude of the Commission reflecting a lobbying activity which disapproves with the officially expressed attitude of a Member State majority (9/15), I would expect the following: The requests evaluated positively by the committees should grow slightly from 2004 to 2005 and heavily from 2005 to 2006 if the comitology committees represented the supranationalist interest. On the contrary, a heavy decrease or at least stalemate in the number of requests evaluated positively should occur if comitology committees followed the pattern of the officially expressed scepticism by the Member State qualified majority.

4.3. Data Analysis:

According to the Summary Record from 28 October 2004[4], since a formal written opinion had been requested by letter on 25 October concerning the 10th batch of two proposals

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from the 1st call, and the 1st batch of 29 proposals from the 2nd call, a vote during the Committee meeting was not necessary. Though it did not vote on them during the meeting, the Committee had basically examined and given a positive opinion to 31 proposals. According to the Summary Record of 12 April 2005[5], a positive opinion was given by the Committee on the 6th batch of 15 proposals (9 requiring a formal opinion) for the 2nd call (314 votes in favour, plus 7 not presented). Strikingly, according to the Summary Record of 5 April 2006[6], a total of 808 proposals were evaluated. Additionally to the previous reports, the Chair provided a detailed account of the situation concerning the Committee opinions delivered by written procedure on batches of proposals from third call. Information was also given on the auxiliary call open until 16 May on the issue of ongoing contracts with third country participants. Furthermore, the Chair summarized the results corresponding to the two calls for proposals FP6-2005-LIFESCIHEALTH-6 (standard call) and FP6-2005-LIFESCIHEALTH-7 (Small and Medium Enterprises call).

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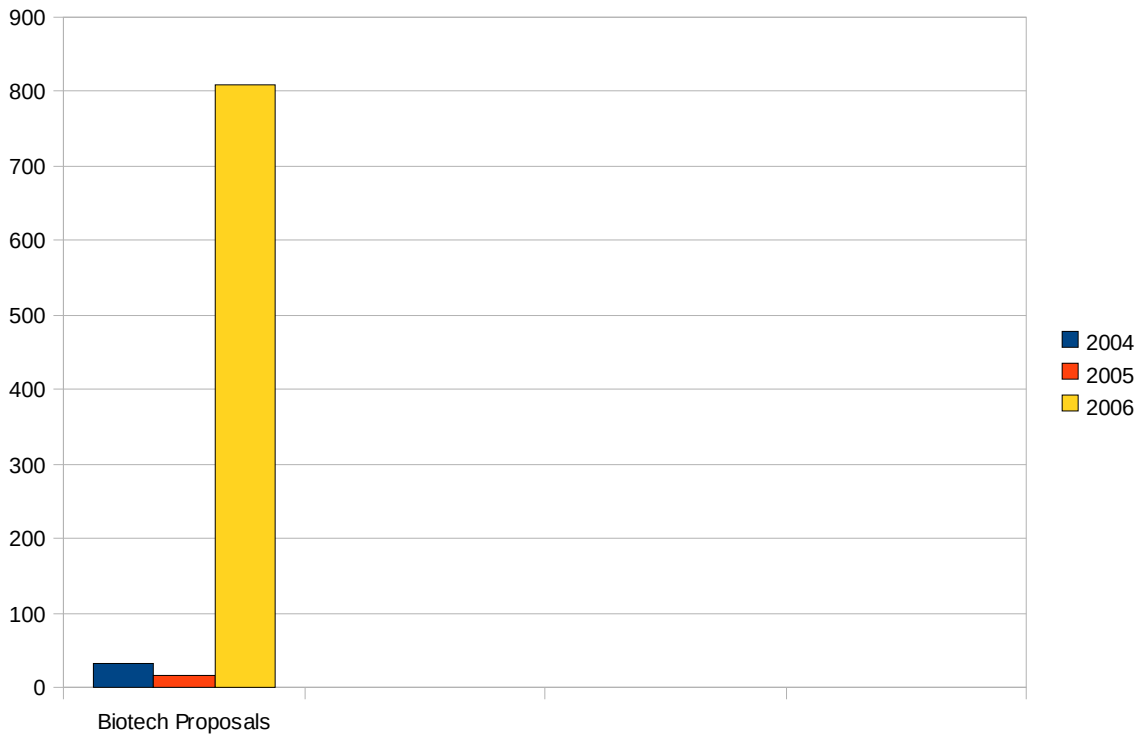


- Data Interpretation:

Interestingly, the data shows neither an ascending, nor a descending trend. Nevertheless, the results appear to be more relevant than expected for the second hypothesis tested in the actual research context. Explicitly, in 2004 a number of 31 proposals coming from private companies in the Biotech Sector received a positive approval from the Commission, whereas in 2005 the number dropped by approximately 50%. We don't know what the cause is (whether it is a proof supporting the intergovernmentalist or supranationalist hypothesis), nevertheless, through its functionality we are allowed to interpret it as an impulse for the Industry Manifesto's occurrence. Furthermore, this strain of argument is supported first by corroboration with already analysed Process Tracing complementary observations and second with the future predictions for the year 2006. First, the meeting of the Committee took place in April 2005, therefore chronologically it

preceded the September 2005 Industry Manifesto, which in its turn preceded the October 2005 Commission Reaction in the form of a Second Report of Progress. The Report displayed general negative assessments in tune with the Manifesto, to which it added the identification of particular obstacles and their adherent corresponding solutions. Which links my findings to the initial argument: as a supranational body whose main role was creating the Single Market, the Commission is acknowledged as the engine of the European Integration. Its reaction in this context, further promotion of the economic interest, was thus coherent, plausible and expectable.

Nevertheless, the function of the comitology committees, "Life sciences, genomics and biotechnology for health" in our case, was to represent, reflect and protect the officially expressed interests of the Member States. Out of which only 6 implemented the Directive in due time, 9 of them displaying constant public disagreement, and two of them entering the 1st sanction phase for refusing to comply with the provisions. Whether the dramatic fall from 2004 to 2005 in terms of positive evaluations granted (15 as compared to 31) is a result of intergovernmntalist behaviour becomes irrelevant in front of the 26 times overwhelming growth when compared to 2004 and the 53 times explosive growth when compared to 2006. Furthermore, the transcript includes a specific reference to the Small and Medium Enterprises calls, which was one of the key problems hampering the development of the Biotech Sector that the industry put forward in the "Manifesto" and the Commission subsequently addressed in the "Second Report for Progress". Last but not least, Commission's updates on the Directive's State of Play[7] show that by 2006 all Member States implemented the Directive. In conclusion, when checked both against the theoretical expectations and the official attitudes of the Member States as proxies for measuring their interest, the Summary Records of the analyzed comitology

[7]

Committee portrays its working input as a representative of the supranational interest.

5 CHAPTER IV: FINDINGS "THE INTERACTION EFFECT" BETWEEN "GUARDIANSHIP" AND "MULTILEVEL GOVERNANCE"

(as an Intervening Variable)

Throughout this chapter I will provide a description of the mechanism that I identified as being responsible for the main findings of my research, namely the supranational nature of the interest represented through the working output of the "Life sciences, genomics and biotechnology for Health" comitology committee. I emphasize that it was outside the scope of this paper to qualify the decision-making process of the committee as either intergovernmentalist or supranational, rather, I was concerned strictly with qualifying the working output in view of its further utility as a missing link in the explanatory chain perpetuating an alleged correlation between comitology and democratic deficit, which, if addressed, will potentially contribute to the democratization of the decision-making process through soft governance inside the European Union. Consequently, I endorse comitology as a locus of supranational interest representation, however not as a locus for supranational interest formation. I support my claim with invoking the existence of an interaction effect between the phenomena of "guardianship" and the international level of "multilevel governance", which I identify as the locus for supranational interest formation which is taken for granted as decided, therefore only defended and rarely attacked within comitology procedure. The current analysis responds to the "why" question incorporated by the Within Case Study Analysis Process Tracing Method, whose main asset is its procedural nature, manifested through the insight into causal mechanisms that it aims to provide as opposed to the typical quantitative outcome oriented methods.

5.1. MULTILEVEL REGULATION: Identification of Levels and adherent Nodal

Points:

"Multilevel" as a background concept refers to "a variety of forms of decision making […] characterized by a complex interweaving of actors operating at different levels of formal jurisdictional or administrative authority, ranging from the local level, via the national level, to the macro – regional and global level." (Follesdal, Wessel and Wouters, 2007, pp 11). "Regulation" as a background concept refers to "the setting of rules, standards and principles that govern conduct by public or/and private actors" (Follesdal, Wessel and Wouters, 2007, pp 12) "accompanied by some mechanism for promoting and monitoring compliance with these rules and standards" (pp. 22), where "princinples" are are understood as the most flexible instruments, allowing for space "to balance a number of (policy) considerations". At the opposite end on a hierarchical scale of coercion reside "rules", which are "the most constraining and rigid". In between one can find "standards", defined as instruments which "leave a greater range of choice and discretion". My systematized concept will strictly cover only those "standards" that undergo at least one stage in the metamorphosis procedure towards becoming "legislation" in the form of a lowest common denomiator negotiated, signed, implemented and consequently monitorized through comitology at the European Union level.

Multi-level governance is referred to as "the second contemporary revolution within Real Existing Democracies – or, better, with particular intensity within European REDs." (Schmitter 2005) Political scientists insofar have devoted increased attention to analyzing the micro-level of the phenomenon, namely the devolution of political responsibilities to sub-national units, on the specific purpose of avoiding alienation between the rulers and the ruled. But paralleling this micro-level universe, increasingly or as important through the implications it endangers seems to

be the macro-level, which has whatsoever particularly made the object of study for law scholars. Thus, the novelty and value-added of this paper consists in the attempt of providing an interdisciplinary overview connecting the perspectives of political science, law and public policy on the same issue. “The often repeated assurance that only national states can be democratic is no longer true in Europe, even though in practice it is often difficult to separate the various levels and determine which rulers should be held accountable for making specific policies.” (Schmitter 2005) Such is the case with European Directives, which are perceived and directly internalized in national law systems as “European legislation”. Depending on the pillars discussed, Directives constitute the result of negotiations performed by the Commission with a number of different International Regulatory Agencies (IRAs) in the name of the Member States.

I will further rely on a threedimensional operationalization of the concept, as follows: “(1) a written articulation of rules that (2) have legally binding effects as such and (3) have been promulgated by a process to which express authority has been delegated *a priori* to make binding rules without affirmative a posteriori assesnt to those rules by those bound.” (B. Oxman, The International Commons, the International Public Interest and New Modes of International Lawmaking, in Follesdal, Wessel and Wouters, 2007, pp 13). Specifically, I will try to identify how a certain piece of lgislation enters the domestic legal orders on behalf on the competencies that the institutions hold in representing the Member States, however, it originates in another international body. In order to measure “standard legislation” by checking the incorporation of “standards” into the “legislative framework” along the international, regional and national dimension, I will quantify and qualify two main binding papers released by the international regulatory agencies (IRA's) which function as nodal points in the legislative delegation chain,

namely the "Agreement on Trade-Related Aspects of Intellectual Property Rights" (TRIPS), issued by the World Trade Organization (WTO) and the "Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions" issued by the European Commission following the harmonization measures internalized through the European Patent Office (EPO).

5.2. The International Level: The World Trade Organization

Decisions passed by the World Trade Organization enjoy legislative standard setting status, without being subjected to any democratic procedure that would account for legitimacy. In the current paper, I will strictly exemplify through TRIPS, namely "Part II: Standards concerning the Availability, Scope and Use of Intellectual Property Rights", "Section V" on "Patents". It is not only through DSB (Dispute Settlement Body) of the WTO that enforcement is secured inside the EU, but most strikingly, through the ECJ itself, which indicated the necessity that Community Law be interpreted in accordance with the WTO Law. Despite the "direct effect" of the WTO Law not having been accepted by the ECJ, there is widespread debate in the literature concerning the legitimacy of the WTO Law. Following the line of argument developed insofar, I will systematize legitimacy along its "input" or "procedural" dimension. "In most modern constitutional systems, a norm is legitimate if it was set up in a democratic process and if it meets the fundamental societal values such as individual rights or collective goods." (Krajevski, 2001) Given that "societal values" covers a rather lax and volatile reality, through its permanent potential for change, I will measure the extent to which decision making is democratic inside the WTO through analyzing its main components, namely the conditions of "territorial congruence" and "supranational deliberation". I will further on detail upon these two components chosen for the current operationalization.

First, a decision can be considered legitimate if those affected by the decision making were the participants of the decision making process, therefore if, through any channel of representation, they overlapped the power ceded to the decision-makers. This principle has been refered in the international

law literature as “affectedness”, namely a legitimate system of decision-making requires that the governed are represented if not on a unanimous basis (e.g. ideally, the EU claims in maintaining consensus voting for second pillar policies), at least on pluralistic basis, in the name of nationality, citizenship, or, in the current case, “territorial congruence”, comprising all objects and subjects of governance alike, irrespective of their nationalities. (Zurn, in Krajevski 2001) Second, building on the underlying assumption that majority representation does not equal minority subordination, thus minorities will not acknoowledge the rule of the majority as a form of self governance unless the perception of legitimacy is maintained, international law scholars have borrowed from the political science literature “deliberation and rational discourse” as an identity building tool. Democratic deliberation, commonly defined as “the exchange of information and arguments by advancing, supporting and criticizing different proposals and offering reasons for the positions taken”, is irrelevant for the scope of this paper as long as the morality exceptions were open to neotiations. (Cohen, “Deliberation and Democratic Legitimacy”, in Krajevski 2001)

Furthermore, I second the claim that a model of democratic decision-making operationalized as “territotial congruence” and “supranational deliberation” is a minimalist one, and despite the simplification that such a trade-off over models derived from national constitutions would

introduce, the “moral claims” cannot be ecluded and are officially recognized under TRIPS Article 30? stipulating exceptions. Testing for democratic legitimacy without incorporating fundamental rights and individual values would have resulted in methodological fallacy given that, on the one hand, that participants in the WTO negotiate on different democratically scaled traditions, and on the other hand consensus upon what constitutes a morally acceptable claim is divided not only inside the Western democracies and their counterparts upon the Atlantic, but even or moreover inside the EU. The debate over the degree of morality ranking WTO set standards through TRIPS becomes utterly relevant at the comparative empirical level, anaysing how the American and European society have differently negotiated and incorporated the morality standards and its subsequent implications. The role of comitology committees resides in supervising the agent over the proper implementation of a piece of legislation that has been previously agreed upon in a number of stages. Nevertheless, comitology has been advanced as an undemocratic mechanism of interest formation and followed by subsequent measures of democratization (“parliamentary scrutinity”) with the expectation of a corresponding increase in legitimacy, which might not be fulfilled after all.

Biotechnology as an officially reckoned driver of EU conversion into the most competitive knowledge based economy according to the Lisbon criteria has made the object of excessive politicization and thus contestation during the past decades. Thus, my unit of analysis will consist of EU Secondary Legislation, with a specific focus on EU Directive 98/44/EC on „the legal protection of biotechnological inventions” as my unit of observation. The current case selection emerged from the peculiarity of „Patents on Life” Directive, as it later became known to the public through extensive media coverage, the first piece of legislation vetoed by the

European Parliament in May 1995 on enhanced post Maastricht co-decision prerogatives and approved in May 1998. Public opinion and institutional setting as independent variables being constant, explanations are commonly linked with the ability to influence collective outcomes through mobilization among transnational Environmentalists and Industrialists respectively. This paper will zoom on one specific segment of input, namely deliberation inside comitology Committees. The lobby campaigns per se will not constitute the focus of the current endeavor due to time and resources restrictions in terms of testing the hypotheses endorsed in connection with them. Nevertheless, they prove extremely useful in monitoring the actors involved and their public statements.

5.3. The Supranational Level: The European Commission

In the context of multilevel governance, "guardianship" represents a tangential contemporary revolution impacting upon the functionality of REDs. (Schmitter 2005) Essentially, legislative authority is being transferred to "regulatory institutions" with the purpose of increasing the efficiency of technical expertise based policy production under the assumption that experts acting on behalf of scientific knowledge are automatically conferred neutrality thus display no bias in representing interests other than the public good. Thus, real existing democracies have progressively been deprived of having a say in issues iterfering with the regular citizen in major visible ways. "Democracies without choice is the expression that has emerged, especially in neo-democracies, to describe and decry the situation. Even more potentially alienating is the fact that some of these guardians are not even national, but operate at the regional and global level." A peculiarity of the European Commission acting in the posture of a guardian maintaining checks and balances is its strategic attempt to institutionalize interest representation on a twofold

purpose, namely consolidating the internal market and the democratic participation. The formative years of the European Union were dominated by Neo Keynesianism, namely indirect mediation between industries and European Welfare States through National Industry Assosciations. It was the 60's-70's massive deregulation that brrought about an OECD „Code of Conduct for Multinationals", eventually providing incentives for big business to organize at the European level. It is argued that „these large companies went global first and European second". (Maria Green Cowles 1995) Increased support from business representatives for the liberalization caused by „Single Maket" Project as a positive response to the incentives put forward by the Commission in its political entrepreneur hiposthasis followed. Last but not least, the competitive nature of companies themselves facilitated or obstructed organization at the EU level (Wallace and Young, Ch 7) in that „while private interest representation has snowballed through the 1990s, public interests have responded in the early years of the 21st century to these new opportunities and learned to create complex advocacy alliances and political presence via 'gate keeping' and identity-creating functions".

Classical theory derived from empirical observation of US lobbying provides a functional justification of pressure groups as vital drivers towards a value pluralist society (Olson 1965). Building upon a cautious attempt to find an equilibrium position between Hegelian idealism and anarchism, Bentley and Truman argue in favor of increased constitutional share for private organizations, be they trade unions, churches or cooperatives. Arthur Fisher Bentley in "The Process of Government" (1908) claims the direction taken by government politics represents the resultant of clashing interests defining societal climate at a certain moment in time. Furthermore, he qualifies it as 'a reasonably just determinant' achieved by pressures equal in number with

existing groups and directly proportional in intensity with adherent sizes. Following this logic, the expected outcome should be that the more general public interests will inherently defeat the narrow special interest. Bentley argues in favor of the adjusting power that special interest representation holds over distorted effects triggered by imperfect legislatures on the public interest. In "The Governmental Process: Political Interests and Public Opinion" (1951) David Truman qualifies the rate of formation as a good indicator for the stability inside a given society, whereas the number reliably measures its degree of complexity. Recent literature on US interest groups advanced a series of explanations against the classical narrative portraying an ideal relationship between interest group representation and functional democracy. E.E. Schattschneider (Keller and Packell 2007) draws attention upon the 1960's being dominated by private business groups. Opposition from public pressure groups was merely formal in that these were in fact dominated by high class citizens also. Subsequent rise of middle class consumer groups created substantial opposition, however low class is still under-represented, especially in the health care system.

"The flaw in the pluralist heaven is that the heavenly chorus singes with a strong upper-class accent" [Schattschneider, 1960: 35] could summarize the slightly different evolution of European interest groups which eventually became known in the literature as „elite pluralist" (Cohen 2007) in the sense that „the characterization of the EU as a regulatory state legitimizes this exclusive focus on legislative lobbying" (Majone 1994). The Commission (Lobbying in the EU Working Paper) distinguishes between two categories: non-profit and profit-making. Meanwhile, scholars have differentiated among four different stages in the relatively short history of European pressure groups (Cohen 2007, Green Cowles 1995). Following the theoretical framework

developed by Aspinall and Greenwood (Chapter 1), each of these subsequent avatars can be considered the dependent product of four corresponding independent variables: the state context, the regional environment namely the EU context, the international environment consisting in standardization of lobby activities, as well as the changing nature of firms themselves. First, the formative years of the European Union were dominated by Neo Keynesianism in the form of indirect mediation between industries and European Welfare States through National Industry Associations. It was the 60's-70's massive deregulation that brought about an OECD „Code of Conduct for Multinationals", eventually providing incentives for big business to organize at the European level. It is argued that „these large companies went global first and European second". (Green Cowles 1995) Increased support from business representatives for the liberalization caused by „Single Market" Project as a positive response to the incentives put forward by the Commission in its political entrepreneur hypostasis followed.

6 CHAPTER V: IMPLICATIONS OF "THE INTERACTION EFFECT"

6.1. Who did what to protect versus to promote which interest?

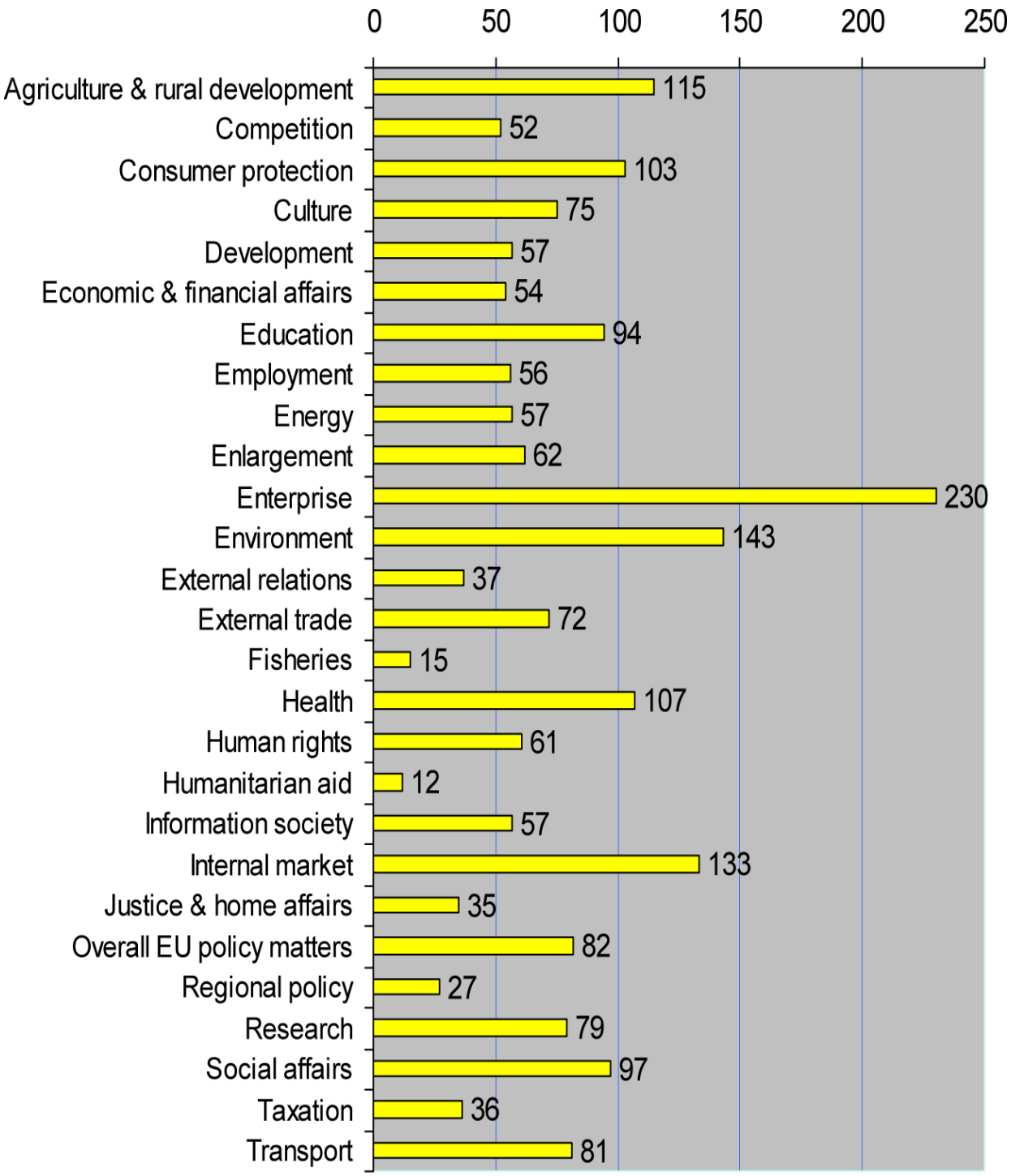
The "interaction effect" as a responsible intervening variable for causing the democratic deficit identified in and automatically attributed to comitology, takes place when the "guardianship" and "multilevel governance" intertwine. Here I advance it as a causal mechanism explaining why comitology committees evolved to be a locus of supranational interest representation as opposed to intergovernmental interest representation, which constituted the initial purpose of their creation. Due to the "unitary character of EU trade relations" (Leal - Arcas2001), through Article 133 of the EC Treaty, the EC has been granted exclusive competence to create common commercial policy in the field of external trade relations. This is the general rule which secures the functionality and further expansion of the second pillar in the EU, namely the Internal Market. However, the exclusiveness of this competence suffered a number of limitations in a number of area like services, investment and intellectual property rights, where Member States share competence with the EC, thus entering the area of "mixed competence". Nevertheless, it is argued that "in practice, Member States cede their negotiating role to the EC negotiator, and the European Commission negotiates. The Commission therefore attends negotiations on behalf of the EC and Member States via a third party (the third party has to be a non-member state to the EU) without prejudice to legal competence." I identify this specific link as crucial for the breaking or strengthening of the democratic decision-making chain, depending upon how Member States understand, articulate and manage to reflect their positions in the final output presented by the Commission at the negotiations with the WTO. Whether the pre-negotiations between Member States and the Commission takes place within consultative or expert

committees is irrelevant for the purpose of this paper, whose main claim is that comitology committees reflect a previous set interest, be it supranational or intergovernmental, depending on how it is previously negotiated.

The competitive nature of private companies facilitated or obstructed organization at the EU level (Wallace and Young, Chapter 7) in that „while private interest representation has snowballed through the 1990s, public interests have responded in the early years of the 21st century to these new opportunities and learned to create complex advocacy alliances and political presence via 'gate keeping' and identity-creating functions". Cram (Cram 2001) draws extensive attention to the Commission constituting a main target for lobbying activities, due to its primary role as agenda setter. Coen (Coen 2007) insists that hard statistics revealing business and professional organizations represented approximately 76% of EU interest groups compared to 20% of public interest groups represent an unoffficial view of an otherwise selective elitist European lobbying style. Mazey characterization of the EU as a regulatory state legitimizes this exclusive focus on legislative lobbying" (Majone 1994). Within this specific institutional context, the „theory of resource dependency's", as Cohen claims, displays high explanatory potential. Exchange theory and resource dependence identifies „the key to understanding the lobbying activities of business interests in the European institutions" as conceiving the relation between private and public actors in the form of „an exchange relation between two groups of interdependent organizations" (Bowen 2002).

Illustratively, in Bowen's acception, regarding business lobbying as a unidirectional activity of private actors *vis-`a-vis* the EU institutions is not justified by the latter's availability for interaction within a target private sector, needed to fulfill their institutional role. As further

conceptualized by the author, insights from administrative science, organization theory and organization sociology constitute the foundations of a new theory of access relying on three variables acknowledged as „access goods": „Expert Knowledge" (EK), „Information about the European Encompassing Interest" (IEEI) and „Information about the Domestic Encompassing Interest" (IDEI). Overall these are expected to provide the Commission and Parliament respectively with necessary expertise and technical know-how from the private sector to understand the market. Insider information is indispensable in developing effective EU legislation, much more in such sensitive domain as biotech, accounting for considerable expected share in knowledge based growth production (The Lisbon Strategy). As supported by the following graph, „EU interest groups have recognized that the locus of activity is primarily a function of the policy cycle: with interests focusing on agenda-setting and formulation of EU directives at the European institutions, and the implementation of directives and 'day-to-day' regulatory monitoring in the member states." (Coen 2007)



6.1.1. Key Events in EU regulatory framework for life patents (constructed along the lines of the classification provided by „The European Corporate Observer"):

1988 - The European Commission introduces the „European Union Directive for the Legal Protection of Biotechnological Inventions" to the European Parliament.

1995 - March 1st, the European Parliament rejects the draft Directive against the will of the European Commission and the Council of Ministers the first time the Parliament used its post Maastricht veto powers to reject a draft EU legislation.

1996 - The European Commission reintroduces the proposed Directive, almost identical to the previous one, to the European Parliament, allegedly with the Parliament's concerns having been taken into account.

1997 - July 16th, the European Parliament adopts the draft Directive with 66 amendments.

1997 – August, the European Commission submits a new draft of the Directive, allegedly minor changes encompassing claims articulated by the Parliament included. In November the European Council concludes its negotiations with a majority vote for an amended text which promotes patents on life.

1998 – May, the European Parliament votes in favor of the Commission/Council proposal, with 432 votes to 78.

6.2. National and Supranational Representatives:

In the case of „No Patents on Life" (Emmott 2001) the coalition was formed by animal-rights advocates, religious authorities irrespective of positioning on the religious spectrum (among which Britain's chief rabbi and Bishop of Oxford) and environmental groups. In June 1988, 50 NGOs and development agencies from twelve European countries met in Denmark, setting the

basis for the „Seeds Action Network in Europe". In October 1988 GRAIN (Genetic Resources Action International) also known as the ICDA SEEDS Campaign together with representatives of the elected Green Parties in the European Parliament reacted to the official publication of the Directive by organizing a public hearing on the purpose of debating the highly controversial draft. They coalesced around opposing the directive and for the next seven years focused on organizing educational seminars in view of broadening public contestation. The campaign clustered around developing extreme scenarios around the pharmaceutical industry eventually engineering super-babies. (The International Herald Tribune) In the 90's the environmental NGOs Greenpeace and Friends of the Earth got involved, paralleling the efforts of the Greens in the Parliament to convert the issue into a hot debate. Their efforts accounted for three readings in the plenary and over forty amendments. (Emmott 2002) In a nutshell, environmental pressure groups have been fighting a fierce campaign against biotechnology and especially its uses in agriculture and food. Moreover, they opposed patents on all genes. "Life is not an industrial commodity. When we force life forms and our world's food supply to conform to human economic models rather than their natural ones, we do so at our own peril" (Greenpeace Documentation) Comparatively in the case of „No Patents, No Cure" (Industry and Patents 1998) the coalition was formed by the most powerful representatives of relevant industries.

Namely, EuropaBio itself has joined a new lobby group set up specifically to push for the life patent directive, called the Forum for European Bio-industry Coordination (FEBC). The FEBC enjoyed the membership of sector-specific industry groups such as AMEEP (food and feed enzymes), CEFIC (chemicals), CIAA (food), COMASSO (plant breeders), EDMA (diagnostic products), ECPA (plant protection products), EFPIA (pharmaceuticals), FAIP (farm animals),

FEDESA (animal health products), FEFAC (compound feed), FEFANA (feedstuffs additives) and GIBIP (plants and seeds). The Forum has issued a flood of lobby papers, including briefing papers on specific scientific and legal principles raised in the Directive. Considering the complexity of the issues, and the limited information that MEPs have, such briefings could have played a significant role in influencing decisions. They provided interpretations of the text of the Directive, suggesting that all of the MEPs concerns were addressed properly in the Commission draft. EuropaBio distinguished itself inside the coalition as „the political voice of the biotechnology industry in Europe." (EuropaBio Official WebSite) It emerged in 1996 as „an association of bio-industries representing the voice of 81 corporate and 5 associate members operating worldwide, 6 Bioregions and 25 national biotechnology associations, representing 1800 small and medium sized biotech companies in Europe." Its primary focus was the European Union but however due to the global character of the business they also represented transatlantic and worldwide for a. (EuropaBio Official WebSite) By actively engaging in dialogue with the European institutions, EuropaBio succeeded in bringing its contribution to the legislative framework, analogously ensuring a steady flow of information about biotechnology to the European Parliament, the European Commission and the Council of Ministers.

As for The European Federation of Pharmaceutical Industries and Associations (EFPIA), through its direct membership of 32 national pharmaceutical industry associations and 43 leading pharmaceutical companies, it constitutes the voice on the European scene of about 2,200 companies committed to researching, developing and bringing to patents new medicines that improve health and quality of life around the world. In particular, EFPIA called for progress on the Community Patent and on national implementation of the Biotechnology Patent Directive in

the context of declining competitiveness of the European pharmaceutical sector and persistent threats to intellectual property rights. „For that, we call upon all stakeholders to work together with a renewed sense of urgency to reorganize healthcare systems and make them fit for the 21st century. We are determined to bring Europe back as a centre of pharmaceutical excellence." (Euractiv Policy File on Biotechnology) *T*he employers' federation UNICE discourse on the other hand focused on emphasizing the classical „attractive climate needed for investors, entrepreneurs and researchers", in the context of the current „brain drain" preventing Europe from „reaping the fruits of biotechnology" At that particular moment „65% of all biotech patents are of American origin, while European companies account for only 15%" (BBC News). UNICE (Euractiv Policy File on Biotechnology) considered that clear decisions on the issue of legislation are of the utmost importance to restore confidence in EU biotechnology. The organization has therefore called for governments to improve authorization procedures for new biotech products and to fully transpose the Biotechnology Patents Directive.

6.2.1. Drawing correspondences between strategies and outcomes

Whether as a function of citizens beliefs about collective benefits, the ability to influence collective outcomes, or the selective costs/benefits of participation, mobilization among transnational Environmentalists triggered, at least up to the early 1990s, relative success in setting the Commission's environmental agenda. (Lubell 2001) One major drawback distinguishing them from business lobby is their much weaker in their ability to follow an issue all the way through to the detailed drafting of policy due to of resources. This argument could explain the defeat in opposing the directive, together with „No Patents on Life" having focused on more distant issues like the impact on GMOs and designer babies. Instead, „No Patents No Cure" succeeded in

touching a most sensitive chord of public perception by drawing direct correspondence between the potential benefits of medical research and an eventual stalemate if the Directive was to be again rejected. Paradoxically, both campaigns involved working with patient interest groups, to stand out from the general population of interest groups in that they often focus on the delivery of services and research into better treatments and cures. The term was introduced by Jack Walker in 1960's. Here, I used Keller and Packle's definition of patient interest groups as „any group that is organized around a particular disease, health impairment, or disability that allows those with the disease to join as members or to engage in the organization's activities by volunteering for the organization."

In the debated case, identification and subsequent contribution brought by two main groups, namely GIG and EAGS proved vital for the outcome especially in the second round. As explained in the Corporate Newsletter Quarterly (Industry and Patents 1998), „The Genetic Interest Group" (GIG), a UK umbrella organization, and „The European Alliance of Genetic Support Groups" (EAGS), have actively lobbied against and for the Directive, respectively. Correlation is claimed between SmithKline Beecham donations to GIG and consequent aggressive lobby in favor of the Directive. In 1995 the EP rejects the Directive as a direct result of the Green Lobby Campaign in what GRAIN qualified as „a vote of Conscience over Capital." (Emmott 2002) In 1998 EP approves the directive, with minor modifications, as a result of the „most expensive" Biotech Industry Lobby Campaign. As Emmott details, the Greens and NGOs manage to amend it by retaining „the farmers' privilege", the „animal welfare" provisions and, most important, by placing outside the scope of patentability „human genes and germ-line therapies" (Emmott 2002) (the most compelling argument in the first rejection round), on three

main grounds: Philosophically, morally and religiously human beings and their genetic makeup are not commodities; furthermore they already exist, so they can be at most discovered, but not invented, which undermines the foundations of patent law itself; and last but not least granting a monopoly patent over a gene to one organization, be it company or institution, functions as an obstruction to the collective good itself in that it prevents the free usage of the respective knowledge for purposes like developing medicines or treatments.

Nodal Point: The „TRIPS Agreement" under WTO authority „requires Member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced" (Article 27.1) (TRIPS Official WebSite) The European Directive under discussion is concerned only with harmonizing patent laws of the EU member states with regard to biotechnology, outside any intended realm of creating a European Community Patent. Leskien (Leskien 1998) refers to it as a pioneer in the history of patent law, in that it establishes a set of rules allowing for „broad biotechnology patents" on „biological material", „biotechnological processes" and „products containing or consisting of genetic information". The problematic implications of these provisions are that patents over „specific characteristics shall extend to any biological material derived from the patented material, provided the patented material still possesses those same characteristics". The aim of TRIPS being to clarify the conditions setting the "social contract" between inventors and society, it is not always obvious that throughout their implementation in particular host societies such targets will be successfully accomplished. the

purpose of a patent is to strike a balance between different interests. The patent system aims to keep a balance between the inventors' interests and the interests of society, thus the "moral" claim constituttes the usual pivotal weight in striking such a sensitive balance, depending on how much it is perceived to influence "public order" inside a society.

However, intellectual property rights as synthesized by the TRIPS Agreement which entered into force in the year 2000 changed the traditional equation in that they inserted the global dimension with the purpose of fostering inter-trade relations by harmonizing extremely different national/regional standards. Intellectual property rights as applied to the domain of Biotechnology basically grant the right of inventors to explore and exploit resources of biotechnology, genetic material and knowledge for a period of twenty years based on the funding provided by private companies otherwise not interested to invest in such risky projects without a minimum warranty. However, the present debate continues to revolve around two clashing arguments. On the one hand, it is stated that patents benefit society because they add to the knowledge available through the disclosure of information contained by the patent application once it is granted. On the other hand, they implicitly confer exclusionary rights to the patentees with regard to substantial pecuniar advantages deriving from the commercial use of the actual invention and the genetic material it consists of. Therefore, although patent law has a strictly technical character by nature, it triggers broader social outlooks through setting the standards for freedom of access to benefits, use of knowledge and genetic material itself as well as through impacting upon traditional resources of life and culture. (Koopman 2003)

7 CONCLUSIONS

Throughout this paper I tested the relationship between comitology and the democratic deficit in the European Union by engaging in qualitative analysis, namely Process Tracing conducted through Within Case and Document Analysis, which allowed for the evaluation of both rival hypotheses that have crystallized in the literature along the past years. Initial attempts to understand whether comitology represents the locus of intergovernmentalism or supranationalism eventually clustered around two composed concepts: "intergovernmental bargaining" and "supranational deliberation". Therefore, disentangling these interlinked concepts emerged as necessary on the purpose of taking a stance further on and consequently converted into my primary challenge for this research project. I measured comitology as the locus of intergovernmentalism versus supranationalism by using as proxies the revealed attitudes towards EU legislative outcomes. The case I chose for hypothesis testing, namely the "Patents on Life" clause in the framework of Directive 98/44/EC of the European Parliament and of the Council", of 6 July 1998, on the legal protection of biotechnological inventions, is generalizable inside First Pillar Legislation, concerned with deepening the single market.

In the Ist chapter I identified and compared differences in morality standards as materialized in the EU and US Patent Law regulating Human Biotechnology respectively. Therefore, in the case of the US the historical concept of "moral utility" has suffered consequent transformations because there was no statutory basis for inserting such standards either by the Courts or by the USPTO up to the point where it was replaced simply by "utility", irrespective of any ethical dimensions. On the contrary, in Europe two parallel moral standards emerged, namely "abhorrence" and "unacceptability", once promoted by EPO and the other by the Court,

transmitting conflicting signals and eventually impeding or giving green-light to different interests inside the bio-industry. Furthermore, while in the US debate is still ongoing, following a rather conservative line materialized in that no piece of legislation has yet been adopted, EU regulated human biotechnology successively through Directive EC/44/98 and eventually overcame the implementation problems at the level of national states through inserting public pressured moral exclusions inside the body of the final text.

In the IInd chapter I performed hypotheses testing, which resulted in two parts. First, I operationalized the concept of "democratic deficit" in terms of accountability of the appointed regulatory agencies towards the political leaders who function as institutional appointees on behalf of the electorate they represent. This approach is complementary to the more popular understanding of "democratic deficit" in terms of legitimacy, be it input (lack of representativeness caused by insufficient public participation) or output (difficulties to justify allegedly non-representative legislative outputs for the public good), of the directly elected leaders (who function as further appointees in the democratic chain) towards the citizens electors. Needless to say, accountability is one of the volatile concepts which escapes empirical measurements. I thus checked the compatibility between expressed preferences of Member States and expressed preferences of the Commission in two crucial points along the Directive's history of implementation,2002 and 2005 respectively. According to the output of the FP6 Programme Committee Priority 1, Configuration: "Life Science, Genomics and Biotechnology for Health", the agenda was approved with no modifications and so was .

As the findings will suggest, despite comitology committees having been designed as buffer

supervisors of the Member States interest implementation against potential infringements coming from the supranational arena, as the multi-actor (consecutive enlargements) and multi-level (heavy technicalization) nature of the European policy process intensified, the center of weight re-equilibrated, depriving comitology committees of their previously considered potential (implementating CAP during the 70's) as a locus for supranational bargaining. “After the passage of legislation, a different balance of policy forces arises. Much legislation depends upon national administrations for its implementation, and some have used self-regulation as a preferred mechanism of implementation. These roles, together with the monitoring of implementation, create opportunity structures for participation by organized civil society.” (Greenwood, pp 25). The multi-level character of the European policy process refers to the multiple “routes of influence” that supra, sub and national actors alike have at their disposal once they decide to participate in European Public Affairs. Whether we are considering “national routes”, namely the use of national constacts and national governments to influence EU decision-making, or the “Brussels route”, namely the quest to exert influence by direct representation at the European institutions themselves, “experts” composing the comitology committees are lobbying pre-set decisions. I attempted to provide an overview of these mechanisms throughout Chapters III and IV.

Having agreed that, in terms of controlling the congruence between Member States' expressed preferences and its working output, comitology committees represent a locus for supranational interest representation as opposed to intergovernmental interest representation (the initial purpose of their comitology committees), I indulged further into tracing the points where the center of weigt moved away from comitology in the process of enfocing interegovernmentalism

as opposed to supranationalism. The ultimate nodal point of convergence between Member States consensus and the Commission position was during the negotiation of the TRIPS Agreement with the WTO, where the "moral clause" concerning "life patents" is introduced. Consequently, the formulation and adherent amendments upon the moral claim representating in this case the result of intergovernmentalist consensus can be traced back to the period of the directive drafting. In conclusion, comitology is defficitary from a democratic point of view withput being the the locus of the democratic deficit formation.

Conversely, I advance the hypothesis that intergovernmental bargaining takes place in "expert groups" and "consultative committees", as opposed to comitology committees. Therefore, it follows logically that in the implementation stage, those states who were active in pursuing the desired interest during drafting will perform better in adjusting the technicalities compared to those states who did not manage to articulate their interests and somehow convert the implementation stage into opportuinities to bargain what previous governments have failed to achieve by engaging in subversive behavior. This hypothesis I intend to check further on and shall it prove true, emphasis should be placed on democratizing the decision-making process inside expert groups and consultative committes. Current findings whatsoever build strictly on the "interaction effect" between "multilevel governance" and "guardianship", the latest "democratic revolutions" (Schmitter 2005). While the former misproved the assumption of bargaining overlapping intergovernmentalism as a strategy, since non-state actors, be they sub or supra national, take part in the international negotiations alike, the latter misproved deliberation as automatically attaching itself to supranationalism, since negotiations taking place at a supranational level can follow the tactics of bargaining and deliberation alike.

“The Commission's importance as a venue for interest representation stems from its powers to initiate and draft legislation, its role in policing European legislation, and from its role in representing member states in world trade negotiations. These roles create inevitable technical dependencies between it and organized civil society, with significant recent attempts to use procedural mechanisms applicable across the Commission to institutionalize relationships for wider ends of input (participative) legitimacy.” These intentions have been formalized throughout the 2001 White Paper on Governance, which asserted its intentions to “reduce the risk of policy-makers just listening to one side of the argument or of particular groups getting privilleged access.” (European Commission 2001a, p. 17) At the practical level, the intention got translated into a series of transparency enhancing measures aimed at achieving input legitimacy from the process of using expert advice through the participation of “expert groups” and “consultative committees”. It is at this particular level that further action should be taken in order to check and consequently address potential breaches in the democratic decisionmaking process.

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