BIOPOLITICAL FORM OF GOVERNANCE AND IDEOLOGICAL ISSUES IN MEDICINAL PATENTS: CRITICAL STUDY OF CORPORATE PREROGATIVE

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Abstract

A new biopolitical form of governance, in today's late-stage capitalism, has essentially extinguished the inventor's exclusive rights at the point of discovery, as the inventors or patent holders are a mere subjugated lifeworld. The general research objective of this article is to analyse critically the ideological issues in medicinal patents. The research question asked about meaning of the progress of medicinal science and its useful arts, arising from medicinal inventions and discoveries. The rhetoric of property in patent law has become a Darwinian struggle for survival of the most dominant corporate actors, through ownership of medicines to maintain life. Discussion seeks to sustain the view that progress of both medicinal science and its useful arts represents a wholly unreasoned mental concept that is really dominant through a corporate prerogative to own the molecules of medicines that maintain life, thereby extinguishing the inventor's exclusive rights. Thus, the article critically analyses the legal narrative, through the lens of ideology in times of late-stage capitalism.

Keywords: medicinal patents; private monopoly; corporate prerogatives; inventor's exclusive rights; ideology; biopolitical governance.

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Introduction

In the United States, the first medicinal patent was granted in 1796, for "Dr Lee's Windham Bilious Pills," used for treating digestive problems (Gabriel, 2021). Patent medicines were contentious then, with physicians denouncing them for false and misleading advertising claims. Physicians also rejected efforts to create monopolies with such products, believing that medical science should benefit their patients freely, and not be a private monopoly for corporate commercial interests (Gabriel, 2021). In 1849, medical leaders tried to get a new law enacted to prohibit drug patents (Gabriel, 2021). These developments created the first market for generic drugs, a small number of companies beginning to manufacture standard preparations without the use of patents and the law of trade secrets. Following the Second World War, these very same companies became huge corporate enterprises and formed today's monopolistic American pharmaceutical industry (Gabriel, 2021), the largest of which are now Johnson & Johnson, Roche, Pfizer, Eli Lilly, and Novartis. With the general significance of this field, and this article, now articulated as both ideological and rhetorical within the law, the general research objective of this article is to analyse critically any ideological meanings in the rhetoric surrounding medicinal patents.

Apparently signified by some kind of fundamental phantasy of public reciprocity, today's version of the patent system is articulated as fostering knowledge creation, while advancing knowledge diffusion for public benefit (Osenga, 2012, pp. 312-13). A patent is said to be a document issued by the state, conferring exclusive rights onto the person who invented the subject of the patent. These rights are granted by the state for an apparently limited time, in exchange for

the inventor's detailed public disclosure to society of the invention's inherent intellectual property. These exclusive rights are conferred by the statutory patent law of a legislature, with the stated purpose of promoting the progress of both science and the useful arts arising from inventions and discoveries therein (US Constitution). However, research science observers diverge on the meaning of exclusive rights conferred by a patent, suggesting some kind of an ideological conflict. A group of them state that when all enjoy free access to new discoveries, this expedites scientific progress (Merton, 1973, pp. 273-75; Osenga, 2012, pp. 90-93). This assertion makes the idea counterintuitive that an inventor's exclusive rights in new knowledge will foster scientific progress, because initially, inventors tend to proceed with undertaking their tasks of invention, as a moment of insight and discovery, without much concern for later incentives (Eisenberg, 1989, p. 1017). In order to be eligible for patent protection, an invention must fall within the patent law's stated scope of patentable subject matter. Conditions of patentability are: Novelty, inventive step (nonobvious) and capability of industrial application, that is, being industrially useful (TRIPS). This usefulness turns out to be the exact same formula as the well-known corporate labour argument, where labour is merely a subsidiary economic input to profitable industrial production. In the light of this brief review of the field, the question arises as to meaning of the progress of medicinal science and its useful arts, arising from medicinal inventions and discoveries. Argument seeks to sustain the view that progress of both medicinal science and its useful arts represents a wholly unreasoned mental concept that is really dominance through a corporate prerogative to own the molecules of medicines that maintain life, thereby extinguishing the inventor's exclusive rights.

The research paradigm is development of ideological significations in medicinal patents. Therefore, the article's research methodology is library research, based on the most relevant evidence, rather than necessarily chronologically recent evidence, to form a critical legal narrative analysis through the lens of ideology in times of late-stage capitalism. This is diachronic argument, where a diachronic approach considers the development and evolution of a language, or a conception, through the course of its history, regardless of where that history ends (Ramat, et al., 2013, pp. 17, 18). The article is structured as follows. In the first section, on 'Ideology', argument builds a conception of ideology during late-stage capitalism. The section on 'The Ideological Structure of Late Capitalism' emphasises the further ideological subjugation of the working class. This is followed by 'Foucault's' scholarship on top-down instructions, constituting ideological bio-policing of lifeworlds. In 'Pharmaceutical Patents, Intellectual Property and Public Health in International Law', argument explores biopolitical policing at the moment of invention. In 'International Intellectual Property Treaties', argument builds on the conception of corporate prerogatives transforming now subjugated private invention into an internationally tradable commodity. The 'Developing Rhetoric of Property' examines how a new dominant ideology consolidation might be in progress. In 'Competition law, Intellectual Property and Pharmaceuticals', argument investigates how this rhetoric of property represents conflicts among the dominant corporate actors. Thus, 'Bias in the Patent System' discovers apparent administrative bias in the Patents Office, and its consequences. With all this scaffolding now in place, 'Genome Patenting and Innovation' discovers how genomic patents can "game" the patent system. Finally, 'Oke and the Relationship between Patent Rights and the Right to Health'

revisits certain parts of the TRIPS Agreement and develops its findings of the ephemeral character of intellectual property rights, as less universal than human rights.

Argument will conclude that ideology is a process resulting in unreasoned mental concepts. Late-stage capitalism's dominant ideology is one of dominance through unpoliced corporate prerogative. There has been rhetorical reframing of inventors' rights, arising at the point of discovery, into a new and freely alienable commodity, an unfettered corporate prerogative. The rhetoric of property in patent law has become a Darwinian struggle for survival of the most dominant corporate actors, through ownership of medicines to maintain life. This evolving patent regime sets up a patent with little resemblance to the original rhetoric of protecting an inventor's moment of discovery. This new biopolitical form of governance, in today's late-stage capitalism, has essentially extinguished the inventor's exclusive rights at the point of discovery, as the inventor is now a mere subjugated lifeworld.

Ideology

First, argument begins to build a conception of ideology in current times of late-stage capitalism. According to Engels' originary formulation of the term, 'ideology' could be described in detail as follows.

> Ideology is a process accomplished by the so-called thinker consciously . . . but with a false consciousness. The real motive forces impelling him remain unknown to him; otherwise, it simply would not be an ideological process. Hence, he imagines false or seeming motive forces. Because it is a process of thought, he derives its form as well as its content from pure thought, either his own or that of his predecessors.

> He works with mere thought material, which he accepts without examination as the product of thought and does not investigate further for a more remote source independent of thought; indeed, that is a matter of course for him, because, as all action is mediated by thought, it appears to him to be ultimately based upon thought (Marx, nd., p. 541).

Thus, this ideological thinker constructs arguments from thought materials unverified in social fact. The divergence between 'objective' and 'ideological' thinking is that the objective thinker understands the social bases of his or her thinking, while the ideologue cannot. According to Žižek, ideology can symbolically structure a particular image of social reality by the use of what he called 'fantasy' (Žižek, 1997; Porter, 2006, p. 52). Therefore, the objective thinker brings into the conscious that which stays both fundamental and unconscious in the ideologist's thought, thereby generating false knowledge, where knowledge consists in the correct understanding of one's condition, as an image grounded in social fact (McCarthy, 1979; Doha Declaration, 2001).

Habermas' conception of ideology was that it was differentiated from the real, through a communicative action, that kind of discourse directed towards mutual understanding, the inference being that reasoned communication is differentiated from the ideological (Porter, 2006, pp.18, 23). In this context, reason is universal through its own necessity (Lilienthal, 2018, p. 355). When communicating actors join in dialogue they, according to Habermas, reason with one another by asserting claims and presenting arguments seeking to convince others of their view's efficacy (Habermas, 2015, p. 2). Thus, making a bare

claim, but without any likely substantiating argument, raises a presumption of ideology.

The French psychoanalyst Jacques Lacan had held that, beyond all the myriad images, which might appear in dreams and everyday life, there is always one 'fundamental fantasy', which is necessarily unconscious (Lacan, 1977, p. 127). Although Lacan recognized the role of the image in the formation of fantasy, he insisted that this was not because of any inherent quality of the image, but rather, was due to the place, which it occupied in a symbolic structure. He observed that the fantasy was always 'an image set to work in a signifying structure' (Lacan, 1991, p. 272) explaining the structural relationship between mental images and how they are sourced back to 'fundamental fantasy' (Laplanche and Pontalis, 1988), rather than a socially based fact.

Thus, any society is organized around its preferred self-images, as the way in which its dominant groups envision the society. It is this very societal self-image, which unites it, and makes it into a unity. Any society undergoing a crisis, such as a crisis about which groups ought to be dominant, will project competing self-images, before one is accepted as the dominant image for the society's continued coherence. These self-images form the framework of intermeshing ideological concepts, such as liberty, democracy, morality, race, justice, gender, nationality, religion, and more, essentially grounded in fantasy. These concepts generate linguistic and social practices, so that members of that society can communicate with each other. Their language is spoken in such specific social contexts. The interaction between their symbolic system, which is the spoken language, and their social system, the matrix in which their speech occurs, produces their agreed meanings, marking their limits of acceptable debate. If members of society move outside their ideological framework, they

could well lose their audience (Cormack, 1992, p. 12), because communication will be defective for lack of consciously discernible meaning.

In the light of this argument, ideology is a process linking socio-economic reality to individual consciousness, by establishing a conceptual framework, which results in specific uses of agreed, but unreasoned, mental concepts. The structure of people's thinking about their social world, and their roles within that world, is linked by ideology's fantasies about socio-economic conditions (Cormack, 1992, p. 13).

The Ideological Structure of Late Capitalism

In the current late stage of capitalism, the working class does not adopt any so-called dominant ideology. At best, there is some working-class accommodation with perceived dominant ideology, formed mainly through a greater efficiency in transmitting dominant beliefs. The resultant splintering variety of dominant ideologies may suggest that there is no unitary dominant ideology in modern capitalist societies (Abercrombie and Turner, 1978, p. 161). While moral values were primary in capitalism's early ideology, the moral facet of ideology now approaches irrelevance in late-stage capitalism, as it filters out everything except support for the political and economic position of the dominant class. Stated more accurately, a very weakly defined dominant ideology has led to 'pluralization of life-worlds' (Schutz and Luckmann, 1974). Husserl introduced this concept of the lifeworld, in 1936, thus:

> In whatever way we may be conscious of the world as universal horizon, as coherent universe of existing objects, we, each "I-the-man" and all of us together,

> belong to the world as living with one another in the world; and the world is our world, valid for our consciousness as existing precisely through this "living together". We, as living in wakeful world-consciousness, are constantly active on the basis of our passive having of the world .... Obviously, this is true not only for me, the individual ego; rather we, in living together, have the world pre-given in this together, belong, the world as world for all, pre-given with this ontic meaning ... The we-subjectivity ... (is) constantly functioning (Husserl, 1970, pp. 108-109).

Husserl could well have suggested here that our passivity to domination, or otherwise stated as our subjugation, creates a separate 'life-world'. This pluralization of life-worlds means there is less ideological coherence in late-stage capitalist societies than in the other social contexts. There have been two critical propositions deriving from this view, often considered as discredited, specifically, the 'End of Ideology' thesis, and also, the view that the variety of opinion and beliefs, in modern times, is sociologically significant.

In the 1950s, the field of political sociology stated that advanced capitalism coincided with an end of ideology (MacIntyre, 1971). The western liberal ideologies had apparently resolved their major institutional conflicts of political involvement. The result was that the Left ideologies, presupposing class struggle, became irrelevant in public discourse. Bell proposed that the older, humanistic ideologies from the 19th and early 20th centuries were now exhausted, and that newer and localised ideologies would soon develop. He posited that political ideology was now immaterial to "sensible" people. From this, he deduced that the working classes would no longer engage in revolutionary movements to overthrow liberal democracy (Bell, 1962).

The rebuttal to this thesis was by evidence of the social facts of subsisting class struggle, social inequalities and ideological hostility. Bronstein and Miliband observed the key role of the legitimising institutions of family, school, church, school and mass media, in preserving capitalist class inequality (Bronstein and Miliband, 2009). Westergaard and Resler later argued that the ideology of individualism, private property and personal achievement was connected causally with social inequalities (Westergaard and Resler, 1976). This kind of response ignored major changes in capitalism, such as developments in kinds of ownership, possession and control, and developments in the character of the class of capitalists. The ideology of small private capitalist firms was frequently opposed to that of larger capitalist enterprises, multinational corporations, and the state-owned enterprises. Since early and late capitalism are still grounded in a socio-economic structure, in which profit is appropriated privately, ideologies of private property might continue within the ideology of capitalism. However, this view has been difficult to sustain. The end of ideology thesis, rather, has preferred to deal with the issue of whether lower classes were still committed to alternative politics (Abercrombie and Turner, 1978, p. 162).

The dominant class could well have been characterized by an ‘end of ideology’, during the 1950s and early 1960s, while the dominant class unified on a common political platform, of welfare (Gamble, 1974). The so-called 'dominant ideology' in late-stage capitalism is now a non-uniform set of assumptions about private property, ownership and state intervention, in the economy, inferring a pluralization of beliefs, worldviews and their consonant ideologies (Berger and Luckmann, 1967, p. 85; Wilson, 1976; Haug, 1967). One indicium of the end of any unified moral ideology is the disintegration of duty or responsibility.

Moral philosophy, from Moore to Ayer, outlines the various transitions within capitalist production (MacIntyre, 1967).

Moore saw in the utility principle the articulation of ethical reasoning, relating ethics to conduct. He stated "that 'right' does and can mean nothing but 'cause of a good result,' and is thus identical with 'useful'" (Moore, 2004, p. 147). Ayer's view was that ethical expressions were merely emotive. For example, the saying 'stealing money is wrong', is merely an expression of feelings. This could have been expressed without the ethical term "stealing money", removing the adverse conception of stealing from the appropriation of money. The 'good result' of Moore remains as an emotively good result (Ayer, 2012, p. 108).

Finally, Berger and Luckmann argued that, in this pluralistic world, there was a shared constructed discourse, allowing different partial universes to coexist in a state of mutual accommodation. Conflict between ideologies had been replaced, in late-stage capitalism, by degrees of tolerance of crumbling forms of ethical deliberation, resulting in tacitly agreed common top-down instructions (Berger and Luckmann, 1967, p. 142; Abercrombie and Turner, 1978, p. 163). This set of top-down instructions, according to Foucault, constituted a system of ideological policing of those in subjugated lifeworlds.

Foucault

In his History of Madness (2006), Foucault opined that excluding the insane from society was a mere pretext for enclosing all unproductive parts of the population, thereby forcing beggars either to sell their labour or risk being taken into custody (Foucault, 2006). In his Discipline and Punish: The Birth of the Prison (Foucault, 1977), Foucault posited that the humanistic justification for prisons indicated a

deliberate drive to subjugate paupers. The development of prisons proves systematic class bias. While the law applies equally to everyone, it is selectively and deliberately enforced on the uneducated majority.

Although prison has failed to eliminate crime, one might hypothesise that prison has succeeded in producing a politically and economically less dangerous delinquency, occasionally manifesting as a usable kind of illegality. It produces delinquents in its supervised environment (Foucault, 1977, p. 277). This modernising neoliberal State permits and disregards those criminal contraventions of rich and powerful people, through its top-down rules generation, while over-regulating insufficiently productive sectors of the masses. This produces the systemic racism in mass policing and jailing of minorities, such as among African American and Hispanic populations in the United States (Rios, 2006). Corporate profiteering is prioritised above the citizens' welfare, by defective ethical deliberation combined with top-down rules, thus coupling capitalism with biopower, in which people are treated little differently to farm animals. This implies a systematic malevolence, as this severe oppression of today's America constitutes an intended economic stratification of society (Johnson, 2014, p. 21), into the moneyed class and the sub-proletariat.

Foucault's analyses of power and history expose dynamic control systems. The modern policing institutions utilise a range of techniques, such as legal exemptions, disciplinary tactics, normalising methodologies, biopolitical management and regulatory economics (Deleuze, 1992), where the term "biopolitics" indicates that style of government regulating populations through political power over all features of human life.

Neocleous opines that: 'Foucault is undoubtedly the thinker who had done the most to put a broad concept of "police" back in the centre of political thinking' (Neoclaus, 2014, p. 11). He continued with the view that: 'Foucauldians use the police concept so abstractly that it comes to look as though it is yet one more synonym for "power", "discipline" and "governmentality"' (Neoclaus, 2000, p. ix). Harcourt conducted a Foucauldian analysis of both the Paris market and the Chicago Board of Trade, stating 'although this project shares a methodological sensibility with Foucault, it breaks sharply from his analysis' (Harcourt, 2011, p. 46). Accumulating together all these views, Rancière regarded as mere bare claims, or prerogatives, all reasoning emanating from the state as 'the Police' (Rancière, 1998, p. 29; Johnson, 2014, p. 22), inferring late-stage capitalism's dominant ideology as an ideology of dominance.

Pharmaceutical Patents, Intellectual Property and Public Health in International Law

Having now viewed dominant ideology operating in late-stage capitalism, argument now examines critically the possibility of biopolitical policing of the very moment of invention. Apparently premised on reciprocity, the patent system is said to foster new knowledge creation on the one hand, and advance knowledge diffusion on the other (Osenga, 2012, pp. 312-313). A patent is a document issued by the state, conferring exclusive rights to an inventor. The rights are granted by the state for a limited time, in exchange for the inventor's detailed public disclosure of the invention's inherent intellectual property. These exclusive rights are conferred by patent law, with the stated purpose of promoting the progress of both science and the useful arts arising from inventions and discoveries therein (US Constitution), although the truth seems to be that progress means a prerogative for rapacious corporate profits.

Research science observers diverge on the meaning of exclusive rights, suggesting an ideological conflict. A group of them state that it is free access to new discoveries, which expedites scientific advances, suggesting a meaning to the term "progress" (Merton, 1973, pp. 273-275; Ravetz, 1971, pp. 90-93). This assertion makes the idea counterintuitive that exclusive rights in new knowledge will foster scientific progress (Eienberg, 1989, p. 1017), because initially, inventors tend to proceed with undertaking their tasks at the moment of invention and discovery without much concern for later incentives.

In order to be eligible for patent protection, an invention must fall within the patent law's stated scope of patentable subject matter. Conditions of patentability are: Novelty, inventive step (nonobvious) and capability of industrial application, that is, being useful (TRIPS). This usefulness is, of course, also a labour argument, where labour is an economic input to profitable industrial production. Development of a new drug is a convoluted process making the research and development costs very high in the pharmaceutical sector. Therefore, adequate remuneration for the corporate inventor, arguably a term of legal fiction, and incentivizing the corporation to pay the actual inventors of the new drug, are the main focus of patent protection given for the production of new medicines (Maskus and Penubarti, 1995, p. 242).

Concurrently, the rhetorical formulation 'access to medicines' fundamentally defines the public health policies of states (Pogge and et al., 2010), also having human rights inferences (89, p. 98). This implies that patent rights may not always be absolute, as the identities of the rights holders may be contentious and ambiguous. Patent protection is limited in scope and time by virtue of restrictions like compulsory

licenses and limiting exceptions (Vadi, 2015, p. 151; Haugen, 2007, p. 108). Patent protection in the pharmaceutical sector thus assimilates both private and public interests. Awarding exclusive rights to the corporate patent owner recognizes a kind of private interest, albeit derived from a legal fiction. The public interest is served in a binary approach. First, the developed drug may be life saving for patients, and second, other firms may draw from the existing invention once it enters the public domain (McCarthy, 1995; Garner, 1999), after expiry of the patents. This paves the way for later and cheaper generic versions, possibly unavailable to the detriment of those who might have needed the drug during its more expensive patent period.

Certain provisions factor in: limited exceptions; use of patent matter may be permitted without the consent of the patent owner; and limits to patentability (Haugen, 2007, pp. 108-109), making the patent owner's right 'not absolute'. These rules seem to be arranged in the public interest. However legislative expansion of patent holders' rights, in recent years, has led to common criticism of their being to the detriment of the public interest (Maskus and Penubarti, 1995, p. 315), suggesting the addition of late-stage capitalism's top-down rules, inevitably attended by biopolitical policing. This extension of inventors' rights had led to the creation of antinomies between the protection of patents and access to medicines, inferring that patent monopolies have an oppressive public interest conflict (Weiss, 1999, p. 60).

Public well-being conflict arises when pharmaceutical patents engage in monopoly rights, by increasing drug prices and making them inaccessible to the poor (Maskus and Penubarti, 1995, pp. 312, 315). Access to medicine for the poor is also threatened by the corporate practices of using

top-down regulatory processes to prolong their monopoly rights. These practices are often termed as "evergreening", and are prevalent particularly for highly profitable medicines, suggesting that the emotive objectives of private monopolists and corporate profiteers can breach normative public ethics. States then resort to emergency measures to facilitate access to medicines and curb corporate profits, while state adherence to treaty commitments in intellectual property protection may become contentious (Maskus and Penubarti, 1995, p. 317). Pharmaceutical patents create both welfare and costs, depending on the state of affairs of a country (Drahos, 2002, pp. 1, 4). The extent of resources deployed to develop intellectual assets by a country defines the role of pharmaceutical patents in stimulating research and development of new medicines (Braga et al., 2004, p. 254), dependent upon the proportion of knowledge possessed and knowledge required by a country to advance its pharmaceutical sector (Gould and Gruben, 19963, pp. 323, 324).

Imperative public policy concerns render regulation of pharmaceuticals a critical field in developed countries as well. Recently, vaccines that help to develop disease-fighting mechanisms in the body, have been subject to patentability, which had not been applicable earlier in many countries (Rosenthal, 2014). It is evident that during the term of patents, the rights holder has monopoly rights of a sort (Vadi, 2015, p. 152), which cause rises in vaccines prices (Rosenthal, 2014). This price rise taints public health budgets and also brings into question the apparently agreed ideology of patents, premised on reciprocity, that knowledge creation promotes societal welfare (Rosenthal, 2014).

A grant of intellectual property monopoly rights is grounded in a theory of social contract, in which a specified

monopoly lasts for a fixed time, after which the knowledge is released to society (O'Brien, 1974, p. 32). It implies a balance between the monopoly holder's gains and those of society. If fast dispersal of the new technology by mimesis would maximize consumer welfare, there are those who say it would also act as an impediment to innovation investment, and a grant of fixed-term exclusive patent rights would permit the intellectual property holders to supply the market above marginal cost, thereby promoting research and development investment (Braga et al., 1998; Deardorff, 1990, p. 497; Wallerstein et al., 1993). The so-called disclosure theory states that this would inspire inventors to release their secrets as public goods, which would otherwise never benefit society (Stewart, 2000, p. 17), but also becomes an ideological premise for monopoly ownership of the very moment of invention.

Public goods are defined in international law in terms of their economic elements. For example: Cafaggi and Caron defined a public good 'as one that is characterized by non-rivalry (anyone can use a good without diminishing its availability to others) and non-excludability (no one can be excluded from using the good)' (Cafaggi and caron, 2012, p. 644). Samuelson regarded this as a concise articulation of the economic principle (Samuelson, 1954, p. 387). Public goods like knowledge, governance, and public health, are much in use in pharmaceuticals and they are administered by diverse international laws like: human rights law, international intellectual property law, and international health law. This makes pharmaceutical regulation a complex regime characterized by institutional density (Keohane and Victor, 2010, pp. 7-8), the complexity itself giving rise to exercising corporate prerogatives.

International Intellectual Property Treaties

Following the above-stated conception of corporate prerogatives arising from perceived complexity, argument now looks into the rhetoric transforming intellectual property into an internationally tradable commodity.

The following is a bird's eye view of the four main facets of this regime complex: a) human rights treaties; b) international intellectual property treaties; c) investment treaties and d) international health law (Anderson and Razavi, 2010, pp. 265, 269). The International Covenant on Economic, Social and Cultural Rights (ICESCR) (Holbrook, 2016) has provided the human rights component of the pharmaceutical regime by a series of its provisions. Article 15 of the covenant, without explanation, asserts protection of public and private interests in knowledge creation and knowledge dissemination (ICESCR, Article 15). The right to access the highest attainable standard of physical and mental health is in Article 12 (ICESCR, Article 12). Conceptualized after World War II, this right to health encompasses access to medicine (Vadi, 2013), but for political reasons it has remained under-theorized. After the fall of the Berlin Wall, economic, social, cultural, civil and political rights have been better understood (Vadi, 2013). The realization of the international right to health (UDHR), and its international, regional and national recognition, depends on its reduction into the various municipal laws of state authorities (Vadi, 2015, pp.149, 153). Also, access to medicines has been considered to be a constituent component of the right to life (Hestermeyer, 2007; Dreyfuss and Frankel, 2014). Thus far, states' opposition to creating a global human rights court, in the fractious landscape of international human rights institutions, has truncated the development of this right to health and also the right to life (Helfer, 2014, pp. 311, 317).

The International Commission of Jurists has stated that an international judicial body will be required, if the goal of universal realization of human rights is ever to be achieved (Human Dignity, 2011, p. 8), by effective judicial remedies to strengthen human rights (Devereux, 2003). Any right to judicial remedies for human rights violations is the principal responsibility of states. Since effective remedies are often not available in municipal laws, a global human rights court could provide more predictable outcomes for those victims of human rights violations, making the international right to health and life more substantial (Human Dignity, 2012, p. 9). International intellectual property treaties had been formed as long ago as the 19th century of the common era, with the Paris Convention being the earliest treaty regulating the various facets of patent schemes (Paris Convention, 1883). It conceived of intellectual property as an enticement to innovate (Dreyfuss and Frankel, 2015). Also, it introduced regulatory schema for harmonizing the adjectival rules of licensing, priority and procedures for registration. It mandated local national protection for proprietors of foreign patents (Helfer, 2002, p. 314), and thus it became a long-arm extra-jurisdictional international regulatory law. Although a member failing to comply with its Paris Convention obligations might be sued in the International Court of Justice (Paris Convention, 1883), no such cases have ever been litigated, as at 2015 (Dreyfuss and Frankel, 2015), raising the issue of the real effectiveness of its stated premises.

A further development in intellectual property treaty-making was the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement), under the regulatory framework of the World Trade Organization (WTO) (TRIPS). It is arguably a more all-inclusive international instrument for the governance of world standards of medical knowledge (Convention of

Rights and Duties of States, 1933; Gervais, 2012), making it likely it had been subjected to the force of corporate pharmaceutical interests. It created statutory interests in pharmaceuticals as patentable rights, mandating that patents be accessible in WTO member states 'for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application' (TRIPS). Thus, exclusive rights in the managerial area of technological processes, rather than in substantive inventions, became the subject of monopoly protection, for the first time internationally protecting process managers, as if they were inventors. Patent owners were given restricted monopoly rights for a period of 20 years, after which date of patent expiry their competitors might duplicate the subject matter of the patent (Vadi, 2015, p. 154). The fact that it created a monopoly against the interests of competitors, suggested the 20-year period was sufficient to dampen long-term competition, or to allow for erstwhile product improvement, to the detriment of competitors. The monopoly was therefore really of longer duration that was apparent in the treaty.

The process of states-parties' adoption of the TRIPS Agreement was contentious. Many developing states opposed adoption of the instrument, out of concern that its high levels of intellectual property protection would limit accessibility to a large range of products, including life-saving pharmaceutical commodities (Reichmann, 2000, p. 443). Some scholars expressed concerns that intellectual property ought not be permitted to generate monopoly-based trade regimes, because it was really a device for restraining trade in the market (Spence, 2001, pp. 263–285). These concerns indicated that healthcare and access to medicines were exceptions to any private monopoly grant and needed to be arranged more in the public interest. States-parties'

required broader discretion to manage public health concerns and the intellectual property protection of the TRIPS Agreement ought not outweigh the public interest (Spence, 2001, pp. 263–285).

Apparently deliberately, and in response to these contentions, an early locus referencing intellectual property is in the General Agreement on Tariffs and Trade (GATT), among its negotiated exceptions (GATT). Despite this exception, "linkage bargaining", that is, linking negotiations on intellectual property to those negotiations taking place at the same time in alternate but unrelated fields, such as in agriculture, the TRIPS Agreement was concluded and signed in 1994 at the Marrakesh Ministerial conference, as an integral part of a composite agreement with the other Uruguay Round Agreements. It entered into effect in January of 1995, including intellectual property, but not as an exception (Alvarez, 2002, pp.146, 147). This adoption of the TRIPS Agreement had repositioned the framing of intellectual property away from the trope of "hindrance to trade" into reframing it as a "freely alienable commodity", this reframing now based in "facilitating trade" and further emphasizing the rhetorical trope of irony, by facilitating a prerogative, (a bare claim), of the rights holder to alienate the rights from the inventor (Dreyfuss and Frankel, 2015).

The TRIPS Agreement includes minimum international protocols for intellectual property protections, from which members may not diverge with lower levels of protection (TRIPS). States-parties may enforce the tenets of the TRIPS Agreement through the dispute settlement mechanism of the WTO, providing for mandatory jurisdiction over any TRIPS-related contentious matter (TRIPS; Dreyfuss and Lowenfeld, 1997, p. 282). WTO members retain a right to legislate for more wide-reaching protections than the agreement requires, provided they apply

the general principles of the agreement's most-favoured-nation clause, as well as national treatment (TRIPS). Any such intellectual property agreement negotiated by WTO members after TRIPS may only provide for either similar or higher-level standards (Vadi, 2015, p. 155). This is generally known as "TRIPS-plus" (Okediji, 2003, p. 141). Arguably, this prevents the removal of intellectual property, from the international law, and establishes it as an internationally tradable commodity. From this point, the movement into the international arena of municipal investment law now implies 'the last wave of IPR protection', as it treats intellectual property as a form of investment, this outcome being one more product of rhetorical re-framing (Vadi, 2015, pp. 1, 16). Thus, this rhetorical reframing of inventors' rights arising at the point of discovery into a freely alienable commodity generates a corporate prerogative, whether or not backed up by municipally enforced rights.

The Developing Rhetoric of Property

Shifting regimes in international intellectual property have created a different qualitative vision of intellectual property (Teitel and Howse, 2008, pp. 962-968), initiating fundamental reconceptualization, and suggesting a dominant ideology consolidation in progress. Under the pretext of trade facilitation, the comparison of the original General Agreement on Tariffs and Trade (GATT) and the WTO's TRIPS Agreement changed the conceptualizing of intellectual property from a mere trade barrier into a tradable and investable commodity (78). While this ideologized the rhetoric of rights, the shift from TRIPS to free trade agreements and bilateral investment treaties was correspondingly radical. These measures, although apparently directed at enhancing the level of protection, changed intellectual property into an investment asset,

subject to claim by third parties (Dreyfuss and Frankel, 2014, pp. 557, 559). The protection was no doubt of corporate monopolies and their biopolitical procedures. The conversion of intellectual property to an investment asset is considered as emphasizing a rhetoric of property (Dreyfuss and Frankel, 2014). A relevant question is whether this amalgamation of a series of norms and regulations has led to the creation of a strong system of intellectual property protection, to the detriment of public goods and public health. The international laws of health and pharmaceuticals are currently not as well developed as the law of intellectual property protection (Fidler, 2000; Harmon, 2009; Ruger, 2008, p. 424).

The 1948 advent of the World Health Organization brought about a change in the number of binding international conventions dealing with facets of public health (WHO Constitution, 2006). The World Health Organization is said to have preferred non-legal approaches to health issues (Fidler, 1999, p. 22). Recognizing itself as a kind of "transnational Hippocratic society" (Fidler, 1999, p. 23), mainly comprising health specialists, the WHO has primarily, if not solely, established medical guidelines and other tools promoted as nonbinding (Fidler, 1999, p. 22). Interestingly, a body of applied medical knowledge is not seen in dominant ideology as a body of laws.

The WHO, in its actions, reflected that it was a centre of a transnational Hippocratic society, comprising physicians, medical scientists, and public health experts. This was contrary to the usual dynamics of its non-governmental core and suggested the absence of any legal strategy in its approach to public health, whereas the era prior to the WHO was characterized by extensive use of international law in public health matters (Fidler, 1999, p. 15). The nature of this kind of transnational Hippocratic

society that formed after creation of the WHO sounded like it had rejected its previous legal powers (Fidler, 1999, p. 16), and instead, chose a path of regulation by the power of professional advice, a path excluding the prerogatives of corporate business ideologues.

WHO established a view of resolving global health problems, as if they were medical- technical matters, by applying the healing arts (Fidler, 1998). This approach has led to labelling the WHO's tools as "restricted in scope and usage", and also as 'historically, politically and structurally insufficient to do what is required' (Wilkinson and Vookman, 1975, p. 251). Such tools have also lacked the coordination and application of instruments of governance. This system of international health law can be attributed to several factors, such as their reframing as a non-legal approach, lack of firm controls and failure to ensure states adhering to international rules (Vadi, 2015, p. 156; Samuelson, 2002, pp. 423, 438). The WHO has rarely participated forcefully in trade negotiations or international dispute settlements, even in those associated with public health (Harmon, 2009, p. 251).

WHO adopted a binding tobacco control convention in the past decade (202), and only recently had amicus curiae participation in investment treaty negotiations (Trevino and Peterson, 2015; Vadi, 2012, p. 93). Nonexistence of a well-drafted international health law regime has allowed public health protection to remain as a vital state power, with public health protection as a right and a duty of the state. On the one hand, statehood requires having a population as one of the three elements of sovereignty, along with territory and government (Convention on the Rights and Duties of States, 1883). On the other hand, 'as a result of the social contract (Loewe, et al., 2020, pp. 1, 3; Meurer and Strandburg, 2008)

between it and its subjects/citizens' (Harmon, 2009, p. 247), public health protection duties are to be undertaken by the state. Components of public health governance have been delegated to many such organizations 'whose principal issues and objects are not health' (Harmon, 2009, p. 251). This raises the concept of 'issue linkage', indicating trading health for other global issues, including foreign investment and trade (Taylor, 2002, p. 976), and suggesting an overt operation of biopolitics. Thus, it is also evident that without a World Health Court, there is a plethora of international courts, together with investment treaty arbitral tribunals, increasingly governing and restricting issues of public health (Vadi, 2013, p. 157), apparently without heeding any expert medical evidence or contentions, in the result suggesting biopolitical governance.

Competition Law, Intellectual Property and Pharmaceuticals

Biopolitical policing, by default, by the international court system infers a need to examine what conflicts happen among the dominant corporate actors. Manufacture of generic pharmaceuticals is often restricted due to patents (Vondeling, et al., 2018, p. 654; 33; 121). The inventor of a new drug files a product patent even before the commencement of clinical development and years before the drug actually reaches the market. The product patent is referred to as the primary patent and it protects the molecule itself. Almost half of the 20-year restricted monopoly period is exhausted in the process, between filing of the product patent application and the ultimate launch of the product. This leaves only half of the patent term of 10 years, in which the fictional corporate inventor seeks to recover research and development costs (Kyle, 2016, p. 4). This development cycle is bound to exert influence on the level and nature of research and development investment (Budish, et al., 2015,

p. 2050). Thus, pharmaceutical firms often protect innovation by applying for an extension.

The Hatch-Waxman Act, in the United States, provides that producers of generic drugs must file an abbreviated new drug application and need not file a new drug application. The abbreviated new drug application banks on prior Food and Drug Administration approval of a previously approved drug with the same active ingredients. This helps to ensure that it is safe and effective (21 C.F.R. § 314.3; 21 C.F.R. §§ 314.94, 320.21; 21 U.S.C. § 355(j)(2)(A)), suggesting that generics may not be safe and effective. This provision of the Hatch-Waxman Act has simplified the process and saved the generic drug firms from cumbersome repetitions of clinical trials (21 U.S.C. 355). They are only required to authenticate the generic drug's bioequivalence to the 'reference listed drug, if they can (21 C.F.R. 314.92). This mechanism facilitates competition and results in reducing the drug prices (Richards, et al., 2020, pp. 1-45).

The Hatch-Waxman Act also allows a patent holder to apply for a five-year extension if the time between regulatory approval and expiry of the patent does not exceed 14 years (21 U.S.C. 355). The European Union grants a 'supplementary protection certificate' to a patent holder, equal to the number of years elapsed between the first patent application, and first marketing authorization, up to a maximum of five years beyond the first expiration date. It is the national Member State Authority, which approves the supplementary protection certificate to become a national patent, even though the validity dates from the initial European Union marketing approval. Other aspects like pricing and reimbursement negotiations after marketing authorization delay the launch of the product.

'Patent Linkage' entails creating an administrative trail for regulatory approval of the generic drug, considering the status of the original product's patent. There are variations between these approvals in the United States and in the European Union. In America, applications for manufacturer certification of generic pharmaceuticals must name the applicable patents. These are available in the so-called "Orange Book" of the Food and Drug Administration (21 U.S.C. 355). The Food and Drug Administration takes into account the patent status of the original drug while scrutinizing generics applications. The approaches to generics approvals under the Hatch-Waxman Act are contained in paragraphs I-IV. The applicant under these paragraphs makes a statement to the effect that patent information has not been filed with the Food and Drug Administration, I–III. The patent has or will expire, before the launch of the generic version. Paragraph IV requires a declaration by the generic applicant that the Orange Book Patent is either invalid or not infringed. Typically, a patent holder instantaneously files an infringement suit in response to Paragraph IV trials. He is granted a 30-month injunction. During this time, the Food and Drug Administration will not approve the generic (21 U.S.C. 355).

In America the national regulators, and in Europe the European Medicines Agency, evaluate the generic application without assessing the validity of patents. A basic variation is that European regulations exclude patent linkage (Directive, 2001), making patent information opaque in the region. There is no Orange Book listing vital patents. Generic applications may be reviewed even when the original drug patent is remaining, in other words, regulators may review generic applications even if the originating product has some remaining patents, while they must adhere to the data exclusivity rules (Kyle, 2016).

Policymakers have resolved those instruments, like patent extensions and 5-year supplementary protection certificates, are meant to strengthen research and development incentives required developing a new drug. Theoretically, these extensions are applicable to the primary patent protecting the new molecule and the novel drug. Using follow-on patents, instead of the primary patent, to extend market exclusivity may not be equivalent. Not undermining their significance (Frakes and Wasserman, 2017), the nature of protection that secondary patents provide, is more uncertain than the claim for protection of the chemical compound (Kapczynski, et al., 2005, p. 1). These secondary patents, prior to generic entry, may extend the market exclusivity period of the original inventor (Kyle, 2016, p. 6). If it causes disequilibrium between incentivizing innovation and societal welfare, then it is a cause of concern for the competition authorities. A generic competitor entering prior to original patent expiration is close to infringement, making product patent invention a difficult one. Secondary patents are technically or legally weaker than a product patent. A competitor may find the means to invent around a patent on a manufacturing process for a particular molecule. A secondary patent may become invalid in the presence of prior art (Holbrook, 2016, p. 987; Holbrook, 2018, p. 127), more so if replication of a patent idea is present. These are suggestive that secondary patents present imperfect barriers to generic entry.

Commencements of litigation in relation to secondary patents are much more numerous than for primary patents (Hemphill and Sampat, 2012, p. 346). The provisions of the Hatch-Waxman Act provide more incentives for patent lawsuits in America, with the explicit objective of rewards for ‘challenging a weak pharmaceutical patent’, the Hatch-Waxman Act provides for 180-day exclusivity. As a

Paragraph IV challenge, generic firms may challenge a patent. The first among the generic challengers, who is able to successfully prove that it is invalid or not infringed, is rewarded with the 180-day exclusivity prize. In the absence of such a prize, challenging a patent becomes expensive for a generic firm. Proving a patent invalid generates public goods for other generic firms as well.

Challenging a patent in the European Union is not easy. The EU patent system is disjointed and does not contain anything parallel to the Hatch-Waxman Act's incentivizing generic firms to challenge brand-name patents. In Europe, patent enforcement is done at a national level. If a challenger launches litigation in different countries, she or he may end up fighting multiple infringement suits. While 2004/48/EC Directive tries to harmonize intellectual property enforcement and protection throughout member states (Directive, 2004), matters like patent validity in the courts of different countries may be seen through the lenses of differing state policies (Kyle, 2016, p. 37). Thus, medicinal patents in these jurisdictions become a Darwinian struggle for survival of the most dominant corporate actors.

Bias in the Patent System

The argument now delves into the apparent administrative bias in the Patents Office, with a view to a later assessment of its effect on patent applications for complex medicines. Patents are simple to acquire initially, tough to cancel later on, and difficult to apply in uncertain conditions (Mazzoleni and Nelson, 1998; Burstein, 2015, pp. 538–542; Ford, 2016, pp. 837–839, 858–863). Recently, the United States Congress and the Supreme Court of the United States have adopted measures to weaken the control of those patents with suspect validity (Yelderman, 2017, p. 1218; *eBay v MercExchange*; Bilski v Kappos; AIA, 2011). A multitude

of proposals focused on restricting the grant and execution of undeserved patent rights. However, there was little basis to conclude that the existing state of affairs was optimal. In the present system, patent rights have been granted, in certain cases, in which the black-letter patentability requirements had not been fulfilled. To state that the system ought to make a mistake inversely, that is, unclear cases should be decided *against* patent protection, there should be a mechanism of comparing the costs of an error in either direction. If the costs of mistaken denial of patent protection are bigger than the costs of mistaken grant of patent protection, then the current balance of errors needs no amendment. If it is altered it could create more harm, as the overall error cost would be more (Golden, 2011, p. 1068).

The conventional understanding of the existing theory of error costs of patents is not conclusive. A mistaken grant of patent rights generates a 'false positive' and a mistaken denial generates a 'false negative', both accounting for error cost. The cost of an erroneous grant is higher than an erroneous denial (Miller, 2014, p. 182). This is because it effectively creates a new property right. The result is a restriction of action, and the freedom of others, in the public domain. Any legislative amendment would now require removal of an established property right, which is costly to correct (Miller, 2014, p. 175).

Undeserved patents create cost burdens, which are sometimes incurred at the expense of public benefits (*Lear Inc. v Adkins*, pp. 670–671; Lemley and Shapiro, 2005, p. 77; Bock, 2015, p. 449; Mandel, 2007, pp. 31–32; Beard, 2010, pp. 243–245; Dreyfuss, 2008, pp. 434–435; Ghosh and Kesan, 2004, pp. 1228, 1244–1245; Ghosh, 2015, p. 801; Meurer and Strandburg, 2008). A mistaken denial chills private incentives to invent (Yelderman, 2017, p. 1219),

which is said to be the fundamental reason for having a patent system (Sawicki, 2012, p. 760; Wagner, 2009, p. 2141; Bock, 2015, p. 449; Lemley, 2001, p. 1521). Nevertheless, the theory is that inventors, meaning corporate employers of inventors, will invest in research and development anticipating a grant of patent rights. This appears to be an ideological conflict as inventors invent, it is the corporations that position the use of these inventions subject to private gain.

A capitalist corporation would deny society of benefits of an invention, unless it reaped profit. Common judgment dictates that a lesser marginal cost of patents, versus greater marginal benefits of patent-induced innovation, would make the grant of patents more desirable (Lunney, 2001, pp. 385–386; Sawicki, 2012, p. 744). However, if a patent grant imposes more marginal cost than marginal benefits, then patent rights may be granted only sparingly. The conventional approach does not provide a clear path, one way or the other (Mandel, 2007, pp. 31–32; Bock, 2015, pp. 448-449), and fundamental questions still need to be addressed (Liivak, 2013, pp. 1337–1338; Ouellette, 2015, pp. 75–84). Perplexed scholars have either overtly reserved judgment on the issue of how the patent system ought to be refined (Ouellette, 2015; Mandel, 2007, pp. 31–32; Bock, 2015, p. 449; Ghosh and Kesan, 2004, pp.1227–1229), or simply followed prior litigation on the costs and benefits of patent protection (Meurer and Standburg, 2008; Yelderman, 2017, p. 1221).

The patent trademark officer initiates preferences for patent rights as soon as an application is received. Established regulations suggest patent applications are scrutinized with a presupposition of patentability, unless an examiner is able to justify why a patent should not be granted (35 USC 102; *In re Oetiker*). This often burdens the

examiner, tilting the bar in favour of patentability (*In re Oetiker*; Seymore, 2013). This presumption indicates that, in close cases, patents are granted even if the patent trademark officer had imperfect information. However, this has compounding effects, as the information available at the examination stage is limited (Meurer and Strandburg, 2008, p. 143; Seymore, 2013; Frakes and Wasserman, 2017, pp. 8–9; 42). Prior art ceases to exist because of patentability (Frakes, et al., 2017; Holbrook, 2016, p. 987; Holbrook, 2018, p. 127; Yelderman, 2017, p. 1233). Any deficit in information tends to benefit a patent applicant, causing non-patentable inventions to appear patentable. In less than twenty hours, a patent examiner is required to scrutinize a patent application, examine the prior art, and provide a written decision (Frakes and Wasserman, 2017, pp. 8-9; *In re Oetiker*; Ford, 2016, p. 860; Yelderman, 2017, p. 1233).

Inadequate incentives at the Patent and Trademark Office further narrow the gateway to patentability, in practice, with financial motives for granting rather than rejecting a patent. Grant of a patent ensures substantial future renewal or "maintenance" fees remitted to the Patent and Trademark Office (Frakes and Wasserman, 2013, pp. 70, 78). The maintenance fee contributes to revenue for the agency and is remitted to the Patent and Trademark Office, which incurs only minimal costs in the process (Frakes and Wasserman, 2013, pp. 79-80; Frakes and Wasserman, 2015, pp. 629–630). If a patent and trademark officer decides not to grant a patent, there may be a swift appeal in the court (Yelderman, 2017, p. 1234). In case a patent is granted, the agency need not defend its decision (Masur, 2011, p. 487; 35 USC 102; Alvarez, 2002; Dolin, 2015, pp. 914–920). This makes the agency err in favour of granting a patent, in unclear cases, so as to ward off appeals, in general, and reversals in particular (Masur, 2011, pp. 489–499, 505–507).

The examiner is evaluated using a points system, where the Patent and Trademark Office determines every two weeks that the required number of work units has been duly completed (Long, 2009; Jaffe and Lerner, 2004, pp. 133–38). Rejections or allowances are counted as equal for productivity measurement purposes, although an allowance is accounted for as less work than a rejection (Jaffe and Lerner, 2004, pp. 133–138; Rohde and Sag, 2007; Lemley, 2001, p. 1496; 37 C.F.R.; *In re Oetiker*; Merges and farrell, 2004, p. 590). This prompts examiners to grant rather than reject patents, in marginal cases. The decision of the examiner is not final, and filing a lawsuit in a federal district court may challenge a patent granted by the Patent and Trademark Office. If in the final judgment the patent is declared invalid, it will prevent any further claim on the patent. Litigation burdens, and fundamental incentives, still work to the advantage of patent rights, in cases of uncertainty. A patent once granted enjoys a legislative presumption of validity (35 USC 355; *Blonder-Tongue Laboratories, Inc v University of Illinois Foundation*).

To challenge an erroneous grant by the Patent and Trademark Office, a standard of civil litigation, whereby 'clear and convincing evidence', stronger than 'preponderance of the evidence', is required to prove that the patent is invalid (35 USC 282; *Microsoft Corp v i4i Limited Partnership*, pp. 95, 99). This may be the case even if there is evidence of laxity at the time and stage of examination by the Patent and Trademark Office (*Microsoft Corp v i4i Limited Partnership*; *Dow Chemical Co v Nova Chemicals Corp (Canada)*; Yelderman, 2017, p. 1235). In the result, a corporation able to sustain the high cost of a patent application is likely to be granted the patent.

Genome Patenting and Innovation

In the cases involving patenting of medicines, the patent application can be very complex, and could be very expensive applications of difficult concepts. This section investigates critically what kinds of patent these really are. Challenging a court's ability to view probative evidence, the long molecules of deoxyribonucleic acid (DNA) contain the fundamental information required to produce the machinery and structure of life in every living organism. Proteins are building block molecules, assembled on the basis of information in the DNA. The unique characteristics of an individual are determined by differences in these proteins. The malfunctioning of these proteins causes certain diseases. The centre of gene patenting considers the sequence of letters in a genome as a subject matter of for intellectual property. This sequence may be in normally functioning genes, or in cases of defective genes, in those causing disease (Jackson, 2003, p. 9).

Genomic information is extremely vital and is useful for developing varied products, like tests for gene-based disease, gene therapies, finding new target drugs using sequence data, use of proteins as drugs, use of genes of other creatures or plants for human benefit, and many more. These products have huge potential and therefore attract the attention of corporate investors. The innovation in these products implies substantial research and development investment. Firms in biomedical and biotechnology industries resort to intellectual property protection for their research investment (Jackson, 2003, p. 9).

Monopoly rights granted on genes have a broad coverage, because there is a distinctive element of 'information character' to a 'genomic invention'. A gene

patent is not just a patent on the invention, but also a claim on a piece of information that has several potential uses (Jackson, 2003, p. 10). The same gene sequence may have many applications in pharmaceuticals, being a part of a diagnostic test, a subject of bioengineering, or else for other kinds of gene therapy target. Knowledge of gene sequences may be helpful for forming the bases for many discoveries and innovations. The patenting of individual molecules of DNA, covering gene sequences, suggests both the 'information character' and potential scope for monopolies grounded solely on gene sequences (Dreyfuss and Frankel, 2014; Kinter and Lahr, 1982, pp. 18-22), or the rhetorical overreach of the biopolitical patenting of the structure of life itself.

Intellectual property protection is said to be imperative for discoveries of genomics, according to the principal corporate argument advocating gene patenting that private firms may not invest the required resources to translate "inventions" into commercial innovation, in the absence of protection of intellectual property ownership. This apparent argument posits that if a gene sequence is to be used for development of other products the proteins' functions and interactions have to be further understood. Such study requires substantial investment and firms may hesitate to make such investments without intellectual property protection. For example, development of gene sequences into a new drug could involve hundreds of millions of dollars (Lisagor, 2000, p. 2316). The scientists and firms fear that, in the absence of intellectual property protection, a sort of reverse tragedy of the commons may occur vis-a-vis genomic innovations. There may be a common loss, if the data in public domain is not utilized optimally (Boyd, 1997; Jackson, 2003, p. 13).

Hardin gives a theoretical proposition of the tragedy of the commons, such that in the short term, individual incentives cause a surge in the exploitation of an 'unmanaged' common (Garrett, 1998), suggesting that assets not controlled by managers are in a state of tragedy. Thus, according to Hardin, over-exploitation depletes the resource until consumption becomes unsustainable (Garrett, 1968), suggesting some kind of standard by which exploitation can be measured, such as a managerial standard. Public goods are said to be subject to over-exploitation, because while the adverse influence of exploitation is jointly borne by all stakeholders, only individual exploiters reap benefits (Samuelson, 1954), which really argues for state control of the resources, not corporate control. Feeny advocates that such a tragedy is not a foregone conclusion and that commons may also be subject to being 'under-exploited' (Feeny, et al., 1990). When stakeholders under-exploit a common resource, the 'reverse tragedy of the commons' occurs. Under-exploitation is constituted by both the properties of public goods and the incentives for commercialization (Piirainen, et al., 2018).

Discoveries in the area of individual genes are said to open up several possibilities for subsequent innovations, suggesting protection of a future interest in present intellectual property protection. This advocates for a broad initial patent, considering the future opportunities in genomic inventions. It would streamline how firms undertake potential follow-on inventions and avoid duplication of efforts and work (Mazzoleni and Nelson, 1998). A firm or organization is thus able to regulate the potential uses, by private ordering, when the patent is granted to the discoverer of a gene. However, use of a given gene is subject to numerous scientific and market uncertainties (Jackson, 2003, p. 15).

The term "private ordering" denotes the use of rules systems that private parties conceive, observe, and often enforce by extra-legal means (Koren, 2001, pp. 191, 192). Generally, use of private ordering mechanisms has been a way to expand the monopoly granted by the law and to constrain or restrict the free use of resources by the public. However, private ordering is really regulation solely in the interests of corporate advantage, and it is hard to imagine it being performed in accordance with normative public ethics. The setting up of contracts and technological measures to follow this objective has been exhaustively considered in copyright doctrine (Benkler, 2000; Cohen, 1998, p. 1090; Lemley, 1995, p. 319; Radin and Wagner, 1998; Samuelson, 2002, pp. 63, 72; Burk, 2004), but less in the field of patent law (Burk, 2004; Severine, 2007). Thus, a patent with broad application, conferring exclusive rights in future interests, concerned with private ordering of corporations' internal management systems, sets up a patent with little resemblance to an inventor's moment of discovery.

Oke and the Relationship between Patent Rights and the Right to Health

As the final link in the chain of argument, the research will now examine the more recent scholarship of Oke.

The TRIPS Agreement and the Right to Health

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) appears allow member states to ensure that their protection of intellectual property rights will not derogate from public health (Bazzle, 2011, p. 795). The TRIPS Agreement provides that protecting and enforcing intellectual property rights should be consonant with social and economic welfare (TRIPS, Article 7). States may also adopt protections to public health and nutrition if

consistent with the TRIPS agreement (TRIPS, Article 8(1)), suggesting that the TRIPS Agreement protects intellectual property rights while advancing economic and social welfare (UNCTAD, p.126; Correa, 2007, p. 103). However, a developing country may not decline patent protection for pharmaceutical products, even when necessary for facilitating local production of life-saving medicines (TRIPS, p. 133). Also, the Doha Declaration amends article 8(1) of the TRIPS Agreement so that it could not prevent the addressing of public health (205, para 4). States may, nevertheless, grant a compulsory government license to exploit a patented discovery without the owner's consent (TRIPS, Article 31).

The TRIPS Agreement also offers certain flexibilities, including a freedom to exclude new versions of drugs from patent protection, the principle of international exhaustion of patent rights to allow parallel importing of drugs, an exemption from regulatory review for generic drugs, a research exception, and severing marketing approval for generics from that of branded drugs (TRIPS, Article 6). Yet, many countries cannot derive benefit from these flexibilities, due to pressures from more industrialized countries (Hermann, 2011). In this way, the TRIPS Agreement's human protections may be neutralised by pressure from industrial groupings, namely nations whose dominant ideologies are dictated by monopoly corporations.

Are Patent Rights Human Rights?

The International Covenant on Economic, Social and Cultural Rights states a right of everyone to "benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author" (ICESCR, Article 15(1)(c)). Similarly, the

Universal Declaration of Human Rights appears to provide the same right (ICESCR, Article 27(2)). This apparent similarity has inferred a basis in human rights for patent rights (Marks, 2009, p. 87; Millum, 2008, p. e25; Oke, 2013, p. 99).

Despite this, the Committee on Economic Social and Cultural Rights stated that human rights and intellectual property rights were not the same. They held that Article 15(1)(c) only 'safeguards the personal link between authors and their creations … as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living', whereas 'intellectual property regimes primarily protect business and corporate interests and investments' (Committee on Economic Social and Cultural Rights, para 2). In their analysis, the Committee on Economic Social and Cultural Rights stated:

> In contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person (Committee on Economic Social and Cultural Rights, para. 2).

The view of the Constitutional Court of South Africa in *Re Certification of the Constitution of the Republic of South Africa, 1996*, after an objection that a right to intellectual property was a 'universally accepted fundamental right', was that any right in intellectual property 'cannot be characterised as a trend which is universally accepted' (Certification Constitution South Africa, para. 75).

Thus, intellectual property rights are more ephemeral than human rights, and cannot be universal. Nevertheless, they are far better enforced by states, further implying biopolitical forms of governance in today's late-stage capitalism.

Conclusion

The research question asked about meaning of the progress of medicinal science and its useful arts, arising from medicinal inventions and discoveries. Argument sought to sustain the view that progress of both medicinal science and its useful arts represented a wholly unreasoned mental conception, really a form of dominance through unfettered exercise of corporate prerogatives to own the molecules of medicines that maintain life, thereby extinguishing the inventor's exclusive rights.

Ideology is a process linking socio-economic reality to individual consciousness, by establishing a conceptual framework, which results in specific uses of agreed, but unreasoned, mental concepts. The structure of people's thinking about their social world, and their roles within that world, is linked by ideology's fantasies about socio-economic conditions. Conflict between ideologies had been replaced, in late-stage capitalism, by degrees of tolerance of crumbling forms of ethical deliberation, resulting in tacitly agreed common top-down instructions. This set of top-down instructions, according to Foucault, constituted a system of ideological policing of those in subjugated lifeworlds, indicating a consolidated dominant ideology. Accumulating together all these views, Rancière regarded as mere bare claims, or prerogatives, all reasoning emanating from the state as 'the Police', inferring late-stage capitalism's dominant ideology as an ideology of dominance by corporate prerogative.

Pharmaceutical regulation is a complex regime characterized by institutional density, the complexity itself facilitating the unpoliced exercise of corporate prerogatives. In this ideology of prerogatives, the rhetorical reframing of inventors' rights arising at the point of discovery into a freely alienable commodity generates a new corporate prerogative, whether or not backed up by municipally enforced rights. Without any World Health Court, there is a plethora of international courts, together with investment treaty arbitral tribunals, increasingly governing and restricting issues of public health, apparently without heeding any expert medical evidence or contentions, in the result suggesting biopolitical governance by private ordering.

For medicinal patents, the rhetoric of property has become a Darwinian struggle for survival of the most dominant corporate actors. To challenge any erroneous grant by the Patent and Trademark Office, a standard of civil litigation, whereby 'clear and convincing evidence', stronger than 'preponderance of the evidence', is required to prove that the patent is invalid. This may be the case even if there is evidence of laxity at the time and stage of examination by the Patent and Trademark Office. In the result, a corporation able to sustain the high cost of a patent application is likely to be granted and to maintain the patent. This patent regime, with broad prerogative application, conferring exclusive corporate rights in future interests, concerned with exclusive rights by private ordering of corporations' internal management systems, sets up a patent with little resemblance to protecting an inventor's moment of discovery.

The TRIPS Agreement's human protections may be neutralised by pressure from industrial groupings, namely nations whose dominant ideologies are dictated by monopoly corporations. Despite a corporate desire,

expressed in late-stage capitalism ideologies, to raise intellectual property rights to the level of universal rights, such as human rights, intellectual property rights remain more ephemeral than human rights, and cannot be universal. Nevertheless, they are far better enforced by states, than any effort to enforce human rights, further implying that this biopolitical form of governance in today's late-stage capitalism has extinguished the inventor's exclusive rights at the point of discovery, as the inventor is now a mere subjugated lifeworld.

Ideology is a process resulting in unreasoned mental concepts. Late-stage capitalism's dominant ideology is an ideology of dominance by corporate prerogative. There has been rhetorical reframing of inventors' rights arising at the point of discovery into a freely alienable commodity. This generates a new and unpoliced corporate prerogative. The rhetoric of property in patent law has become a Darwinian struggle for survival of the most dominant corporate actors to control medicines that maintain life. This evolving patent regime sets up a patent with little resemblance to the original rhetoric of protecting an inventor's moment of discovery. This new biopolitical form of governance, in today's late-stage capitalism, has essentially extinguished the inventor's exclusive rights at the point of discovery, as the inventor is now a mere subjugated lifeworld.

References

21 C.F.R. § 314.3.

21 C.F.R. §§ 314.92, 314.94.

21 C.F.R. §§ 314.94, 320.21.

21 U.S.C. § 355(j)(2)(A).

35 USC § 102(a).

35 USC § 282(a).

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