

International Journal of Communication and Public Relations (IJCPR)

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EPC Disclosure concerning Epistemic Corruption and Pharmaceutical Fraud of Off-label
Medicines as Health Regulation and Policy**

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Health Regulation and Policy**

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Article History

Received 25th January 2023
Received in Revised Form 16th February 2023
Accepted 27th February 2023

Abstract

Purpose: Corporate Governance is a conceptual framework of business designs intended to illustrate the various activities of a company towards fulfilling its profit goals as private stakeholder and contributing to public interests for social obligation of sustainable development. Disclosure of corporate social responsibility is the central mechanism of corporate governance.

Methodology: Based on stakeholder theory, corporate governance strongly influences corporate social responsibility disclosure to enhance the relationship of stakeholders and its business community.

Findings: Tax aggressiveness is utilized by board director and its members to lessen tax contribution which is contrary to the government sector goals of maximizing tax impositions for public welfare and safety. Unlawful behavior on tax aggressiveness is known as tax evasion while tax avoidance is not a violation and serves as a loophole to the taxation system, although corporate fraud is apparent in off-label medicines. UNCITRAL model law is a legal arbitration concept of making “commercial” expand to other comparable jurisdiction of international trade. The European Patent Commission is the legal authority that delineates medical policies from patented products.

Unique Contribution to Theory, Practice and Policy: This paper aims to develop arbitration framework based on stakeholder theory of corporate governance to separate tax evasion from tax avoidance as organized crime sourcing treatment of policies and engineer tax planning to divide intellectual property of product design with corporate fraud concerning off-label medicines. Therefore, tax evasion and corporate fraud are business crimes in pharmaceutical industries needed to be clearly managed by institutional healthcare companies for promoting economic success.

Keywords: *Corporate Governance, Tax Aggressiveness, Corruption, Fraud, Off-Label Medicines*

INTRODUCTION

Corporate Governance is crucial in maintaining the systematic framework of a company for strengthening its authoritative liability to shareholder in terms of corporate goals in compliance with their code of conduct. It is important to discuss conceptual issues encountered within the directed organizational functions of business ethics resulting to controlled shareholders. Hence, good governance is the art of exhibiting its optimum control in executing its corporate code of conduct for troubleshooting the problems encountered by the company.

The practice of corporate governance influences company value by leading their shares to multiples of high stock price and lessening the anticipated capital expenditures of equity. It is effective to conduct harmonious alignment in management ownership associated with controlling the interest of the corporate system. Thus, corporate governance is an organizational system designed to practice business ethics related to its structural, procedural, and cultural mechanisms. Majority of countries under developing economies manifest the essence of corporate governance in relation to firm value increment. Hence, every country has their own distinct corporate value for comparison to others pertaining to their corporate governance of sustainable development [1].

The intended design of business activities strongly focuses on philanthropic concerns affecting society, investors, and their immediate community to fulfill the goals and resolving ethical issues addressed on trilogy of corporate governance. Managerial tools are integral actions made by the firm to execute their corporate code of conduct in resolving issues concerning stakeholders and management to maintain sustainable development on various resources. Hence, corporate governance serves as the key framework to address and resolve problems pertaining to company behaviors of its management and stakeholders, such as the business community, employees, and shareholders, particularly case-related issues on legal ethics of corporate crimes. Thus, research discussions pertaining to the scope of corporate governance had shown significant correlations with social responsibility of its management to their company profit.

Corporate social responsibility (CSR) is a cultural notion of company standard and principles aiming to produce an incremental interest of stakeholders resulting to positive social and economic impact of the company. Hence, its liability can be defined as fulfilling the philanthropic means of business ethics to conduct its business transactions towards economic profit of the firm and its community in majority of the time. Therefore, it establishes a strong relationship between management and its community to execute the philanthropic and trustworthy communication of business ethics to advocate sustainable development towards economic success. Hence, the integration of corporate social responsibility marks a distinction between charity and its established goal of economic success based on philanthropic compliance of global commerce. Therefore, it is a discipline of corporate governance to handle the needs of environmental authorities and organizations for compliance of philanthropic goals beyond commercial transactions and create strategic integral actions for sustainable development of innovation and advancements to promote public welfare and safety.

Based on European Commission, corporate social responsibility is the legal basis of the business community to handle unintended outcomes of business operations. Furthermore, the World

Business Council for Sustainable Development (WBCSD) and United Nations Industrial Development Organization (UNIDO) explained it as their foundational system to welcome problems concerning their consumers, community, natural resources, and corporate management and mitigate it using the core principles established by the company as its justifying ground of complying its liability to public safety of economic growth, in compliance of the Triple-Bottom-Line Approach of the CSR as the entrusted discipline to conduct and promote the sustainable development of corporate governance. Hence, CSR tremendously contributes to lessen poverty decline as observed in its economic impact of positive strategic market success as apparent to its firm value.

There are noticed threatening and novel calls being observed as health globalization impacts. Hence, global health governance is on demand of paradigm shift facilitation due to pandemic spread of communicable diseases although there are also other global advancements being authorized such as on travel, trade, and communications. In addition to that, there is a more rapid concern as systemic corruption in global healthcare adversely affects developing countries and other poor regional states, as Transparency International reports the corruption scale and its range of vast health impacts. In 2009, it is approximated that global health corruption and fraud in marketing lost billions of dollars per annum. In terms of meeting the demands of Millennium Development Goals, systematic health corruption serves as an impediment as it attenuates health delivery systems.

There are interconnected concerns being associated with business ethics compliance of pharmaceutical industries raising regulation and crime prevention. These key problems are emphasized by John Braithwaite's classic corporate criminology piece entitled, "Corporate Crime in the Pharmaceutical Industry," in 1984. After 30 years of study publication, there are observed increments in corporate crimes under pharmaceutical industries indicating "a worsening crisis" diagnosis since 1990 of revisiting these corporate gaps. Hence, Braithwaite was highly commended in resolving issues concerning abusive business ethics and regulatory authorities applied his responsive approach of displacing state criminal enforcement towards legal technology for social control and support principles in harmony with self-regulation and cooperation frameworks. Responsive regulation is marked with "enforcement pyramid" concept involving regulators to seek compliance motivation in first cases of applying self-regulatory means which are less punitive in relation to cognitive persuasion and negotiation by appealing to internal code of conduct of the company. Thus, enforcement pyramid follows procedural steps of hierarchy as necessary and if legal technology measurement fails. Hence, criminal prosecution is still a part of enforcement pyramid, however, its main design is to prevent and control the alarming elements in the context, since regulatory approach has the main purpose of crime prevention due to perception of reduced corporate crime notion in the design of pharmaceutical industry settings. Thus, the pyramidal intent is not concerned with crime treatments, rather with controlling the ethical conduct of its people.

There are sufficient studies concerning responsive regulation involving public sectors and private industries, hence, it is already proven to appeal on policymakers and regulators, especially on the state decentralization concept through application of enforcement pyramids. However, there are

encountered problems pertaining to enforcement of responsive regulation due to increasing corporate crimes in the pharmaceutical sector that controlling is deemed to be a conflict due to already existing corporate crimes that are in need to be resolved and mitigated, not prevented, due to issue of regulatory control [5].

There is an increasing global problem concerning corruption and its determinants responsible for it are consensus confirmation of universal crime, political charges and allegations that play a key role liable to corruption brought by international feeds on mass media involving unethical behavior, and it serves as an impediment to economic development process in terms of nation modernization. Thus, it is a must to pay attention prioritizing constitutional goals of the country focusing on economic success by addressing to tackle these global issues on corruption.

In developing countries, there is an immersive attention being paid to corruption issues due to implication of grave adverse economic impact involving their monetary goals for sustainable development success. A study has been published involving 150 high government officials originating from 60 countries belonging to 3rd world classification. In this survey, the respondents ranked corruption in public sector as the most serious impediment to handle their success on economic development process. Thus, Asian countries including the Pacific region are alarmed by this issue and they all construed that corruption is the important obstacle impeding the monetary goals of sustainable development [6].

Corporate Governance is facilitated by various conceptual frameworks towards fulfillment of sustainable developmental goals crucial in advocating diplomacy in dispute settlements concerning corporate crimes. Leadership and management skills must be exhibited using decision-making proficiencies governed by knowledge management of the institution harmoniously aligned with other intergovernmental agencies designed to promote public welfare and safety. Hence, this paper is designed to address issues concerning corruption and fraud in global healthcare settings in cases pertaining to universality of commercial law in terms of international trade law jurisdiction, the employment of patent products emphasizing the practice of medical professions in handling services of administrative policies and processes involving medical treatments for humans and animals, and financial dispute settlement pertaining to separate tax aggressiveness for compliance of European Patent Convention.

Authoritative Induction of Rules

The Government sector utilizes the tax contribution to facilitate sustainable development of advocating public welfare and safety. As specified in article 23A of the 3rd Amendment Act of the 1945 Constitution, the tax impositions are vital instruments for the nation to fund the improvements of its people which are deemed to be compulsory as legal regulations of enhancing economic success of its society. Hence, taxes are enforceable obligations, as well as compliance for constitutional promotion of monetary freedom, of improving the welfare of its people by functional fulfillment of revenue redistribution.

However, corporate taxes are perceived as a barrier or impediment of diminishing the income of the company. Hence, the private business sectors do not always acknowledge the levied tax of the government and tend to pay the tax sector the lowest possible revenue the public society may

receive from them. Hence, the distinct interests of the business companies caused conflicts with the goals of the government in exercising the revenue distribution with the same constitutional compliance of advocating public welfare and safety, since commercial transactions perceive taxes as a burden due to apparent net income reduction due to personal interests of the owner of welcoming prosperity in his own constitutional expense of making successful earnings per annum within his business jurisdiction.

Aggressive tax performances are exhibitions of carrying out tax savings and non-compliance behavior concerning regulations in taxes. Majority of business companies benefit from regulatory loopholes as tax burden removal to generate company savings. Hence, tax aggressiveness of companies is legally and technically considered as a lack of violation in tax regulations.

The act of tax evasion shows differences in tax liability removal of government taxes and its deferred commercial profit challenges versus public revenues as cost minimization. Thus, tax evasion must be clearly explained to draw distinction with tax avoidance as the former is an apparent performance of tax evasion and the latter is defined as tax avoidance. For legal compliance of the constitutional arrangement and its amendments, tax planning is effective to uphold the tax law as pre-emptive doctrine of the constitution. Unfortunately, tax avoidance from revenue aggressiveness has no known violative actions against the law, while tax evasion can be persecuted for criminal liabilities.

The United Nations Convention on Contracts for the International Sale of Goods (CISG) has resolved dissimilarities observed in culture, language, and legal operation for the global provision of widely recognizing contract process in relation to selling of goods. This convention highly augments the potential ability of international trade to expand the interpretation and application of contract law in harmony with its ultimate design as efficiency must be directly associated with the sale of goods.

In 1981, the Working Group created and drafted model law for International Contract Practices. Subsequently, after a 21-day diplomatic conference on 1985, United Nations Commission on International Trade Law (UNCITRAL) adopted a new model law system designed to be applied limitedly to arbitrations concerning international commercial transactions. Thus, there is a strong demand to employ commercial laws to its utmost extent beyond a particular territory. It is apparent that commercial laws vary technically per jurisdiction, thus, legal principles must be exercised to apply those mechanisms to disputed limitations since the practice of law should be made comparable to other regions.

Based on Article 1(3), international arbitration is considered in the specified matter of conditions, such as business places of parties involved, and their contract performance are not within the same jurisdiction or country. Meanwhile, Article 1(1) defines on its explanatory footnote that “commercial” in nature must be broadly interpreted to cover all aspects of transactions to emphasize the fulfillment of economic goals in relation to business ethics.

The European Patent Convention (EPC) emphasized the value of innovative research to pharmaceutical firms. Unfortunately, policy justifications removed patent protection involving mitigations based on medical research methods. Based on article 53(c) EPC 20002, its exclusion

pertains to therapeutic and surgical methods of human and animal treatment, as well as its diagnostic practices. Hence, the products used for medical treatment are not considered as exclusions to remove their patent protection, as specified in their official declaration of therapeutic compositions. Hence, these substances used to heal people has restrained its patent rights over medical treatment justified policy exclusions, in such a way that refusing to acknowledge its second-use patents would result in innovation denial against its appropriate reward. Moreover, United Kingdom, Netherlands, and Denmark expressed paragraph 2(d) replacement at Article 50 with Article 52, under paragraph 5, stating that no provisions must be deemed as removing patent protection, consisting of its declared therapeutic substance intended as a treatment design away from making policies on medical, surgical, and diagnostic practices. Hence, United Kingdom clearly draws a line between product patentability and second-use design.

In 1952, under art 28 of 1954 Hague Convention, using exercise of international law for universal jurisdiction, governmental authorities drafted the legal context of travaux preparatoires as conceptual design restricted within a framework under common criminal jurisdiction based on strict liability, thus, its purpose should not be used for a different consideration although imposed obligations are limited not to engage in universal territory of criminal offenses due to comparable incapacity of the U.S. constitution to make it an ordinary jurisdiction common to all of their federal states [12]. Hence, based on Article 1(5) of UNCITRAL Model Law, the advocacy of implementing uniformity to another territorial jurisdiction is restricted.

Meanwhile, the U.S. legislation passed Federal Food, Drug and Cosmetic Act of 1938, also known as FD&C Act or “Act”, and upon this enactment, the executive branch created U.S. Food and Drug Administration (FDA) which was given the duty and obligation to warrant with specialized function to control the handling of biologics, pharmaceuticals, and medical devices designed for human safety with ensured efficiency. Under this Act and its supplementing amendments, the FDA was assigned to supervise the official capacity of the new medicines in terms of its marketing power based on research and development of pharmaceutical industries, and the duties of prescribing physicians and their medical practices were outside the responsibility scope of FDA. The restricted function maintenance of the FDA, in terms of not controlling the medicine practice of prescribing doctors, has been complied by the administrative agency throughout its complexed and long legislative history of promoting “Practice of Medicine Exception.”

However, the U.S. legislation does not clearly stated and discussed that they exclude to oversee the medical duties and obligations of physicians in prescribing medicines in the enactment of FD&C Act of 1938 with subsequent amendments, although it is clear that FDA enforces strict compliance of authority in terms of regulating drugs in the market, and the Congress believed that the original purpose of the Act was for FDA not to cause any interference while doing medical procedures and treatments in physician-patient relationship. It is presumed for this reason that doctors, in majority of their contact with their patients, do off-label medication practice as healthcare policy.

In 1996, there are two (2) guidance documents published: (1) Guidance to Industry on Dissemination of Reprints of Certain Published, and (2) Original Data and Guidance for Industry Funded Dissemination of Reference Texts. These guidance papers were summarized as

information to appropriately explain and disseminate their purposive function on unapproved usages of approved medicines. Under Section 401 of the 1997 Food and Drug Administration Modernization Act (FDAMA), these guidance documents were subsequently incorporated to meet aggressive opposition of the pharmaceutical firms, as law would strongly demand afterwards to produce changes in their drug data dissemination practices and be obliged to provide supplemental corroborating study information concerning application of new drugs to the FDA.

Unfortunately, before the U.S. legislation passing of 1998 FDAMA, there is a conservative-leaning business advocate group named as Washington Legal Foundation (WLF), who filed a case against the authority of FDA in claim of its guidance papers and its subsequent problems in regulations attesting that it was unconstitutional based on the violating grounds pertaining to the U.S. Constitution and its First Amendment. The U.S. District Court under the jurisdiction of Columbia favored WLF and decided for a permanent order of conduct restraint in reversal of law rendering FDA's authoritative functions on WLF be invalid. After the ruling, the FDA clarified the standpoint of their regulatory agency and stated that a "safe harbor" is indicated in rendering FDAMA provisions to manufacturers under Section 401 and that the dissemination of peer-reviewed scientific and medical journal articles explaining unapproved usages of their medicines would not be perceived contrary to their office as misbranding law violation.

There is an important turn of occasions as observed in FDA ruling on an appeal in a dismissal case from the U.S. District Court of Appeals that rejected the plea of FDA and cancelled the judicial opinions and injunctions of District Court only to the degree of declaring their continuing medical education (CME) advice, and FDAMA as unconstitutional. This divided authoritative decision led to the FDA retention of its right to provide reasons in utilization of promotional aids, such as references and reprints that are distributed beyond the "safe harbor" of the FDA, serving as material of fact as proof in misbranding or enforcing the intended use of its design as action evidence. At the same instance that manufacturers maintain their rights to use the First Amendment of the U.S. Constitution to raise issues with the government in possible cases which can be filed against them.

Currently, in Section 401 of FDAMA and its supplemental regulations in FDA are no longer effective for legal actions. The FDA enforces legal compliance based on its existing statutory legal function and its accompanying authoritative guidance is primarily enforced from prosecutor tools against pharmaceutical industries who perpetrate misbranding or marketing their approved drugs as "off-label" medicines.

Lately, as settlements in marketing of off-label products are gaining immense attention in public media, it became apparent and ongoing as though its practice is widespread. The public perception, in general, among industries and media is that nothing much has caused great modifications, together with the participation of numerous famous government officials. Among other else, matter of fact as evidence suggests an increment in both violations and monetary penalties concerning unlawful off-label medicine practices in relation to marketing and promotional agendas.

Despite exhibiting efforts to comply with enforcement agencies, industries are open to be prosecuted several times together with the same or related violations. The Department of Justice cited some accused companies who committed regulatory offenses, such as the most recognized settlements of Eli Lilly and Pfizer in 2009. Although experts are in debate that this case has been greatly ineffective at practice curb of off-label marketing due to associated legal expenses and penalties which are lesser in comparison with the crime conviction of companies with apparent monetary earnings. Furthermore, as stock prices unavoidably decline after public announcements, it will not affect much, and the stock increment climbs up instantaneously. A federal prosecutor had stated, while in discussion with a reporter, his opinion regarding the takeaway of Pfizer from Bextra® settlement in 2009 that arguing with Department of Justice are perceived as expenses in running business transactions.

Federal prosecutors are concerned that their campaigns might not produce sufficient impact on this medical practice pertaining to off-label marketing even though their government, since 2006, had already acquired nearly \$4 billion for this violation alone. The government lucidly augments the pressure by controlling people, like the chief executive officers (CEOs) and other corporate executives, who are personally liable for unlawful activities, as far as going to implement the “exclusion” authority of the Inspector General.

In a recent turning point of case discovery, Marc Hermelin, the former board chairman of K-V Pharmaceutical Co., was removed from federal health care program participation, since November 18, 2010, after a fully owned K-V subsidiary, Ethex Corp., invoked guilty for two (2) felony counts of alleged marketing of misbranded and adulterated drugs. This is recorded as the first case wherein the executive of a pharmaceutical firm was officially removed without crime conviction.

From 1997 to 2004, pharmaceutical companies are being reported under federal investigation in allegation of promoting nine (9) products as “off-label” medicines. On February 28, Elan Pharmaceuticals, a U.S. company subsidiary to Elan Corporation, PLC, as Irish drugmaker, pled guilty afterwards with finalized settlement reaching \$203.5 million for agreement in December 2010 in relation with marketing Zonegran® as epilepsy drug. On March 10, Astra-Zeneca PLC has reach monetary settlement in lack of inclusion of admitting guilty. The company agreed to settle for a civil remedy of \$68.5 million involving 37 states and the jurisdiction of Columbia was able to provide solutions concerning alleged promotion of off-label prescribing of Seroquel® as schizophrenia drug. For document purposes, this is the biggest multi-state, client protection-based pharmaceutical monetary dispute agreement to record, separated from other federal settlement worth \$520 million concerning similar allegations being made to public in the previous year.

The Wall Street Journal documented that based on unknown sources federal prosecutors are in dispute to settle in an estimation of \$1 billion from a six-year legal investigation of whether there was perpetrated promotion of off-label use of Risperdal® as antipsychotic medicine with Janssen Pharmaceutical Inc., a company of Johnson & Johnson (J&J), in May 13. Based from one of its sources, prosecutors are applying the case law of 2009 Eli Lilly settlement, involving \$1.4 billion payment in relation to marketing Zyprexa® as antipsychotic drug, and this legal principle is used in resolving the case of Janssen company. Securities and Exchange Commission (SEC) filed, in April 3, and documented the subsidiary of J&J had confirmed reserve for potential monetary

settlement concerning penalties that might be involved under Food, Drug and Cosmetic Act. The attorneys general of more than 40 states already filed or waiting to charge a lawsuit against Janssen's actions demanding that the J&J subsidiary must repay them with civil penalties, Medicaid funds and other payments concerning off-label use of Risperdal® prescriptions.

The regulations being implemented and enforced in U.S. Food and Drug Administration (FDA) involving supervision of development of novel medicines are designed to be in strict compliance. To pass the strict compliance of FDA, manufacturers should demonstrate safety and efficacy data evidence as matter of fact concerning their submitted drug to the regulatory agency with requirements of conducting long and well-funded studies for facilitation of pre-clinical, non-clinical wet investigations, and animal testing, as well as clinical phases of drug research involving human as subjects also termed as clinical trials. Before granting the company its requested market approval, the FDA orders manufacturers to comply with their requirements of filing new drug application (NDA), for rendering FDA assessors with all the vital information needed to confirm whether the applied drug is effective and safe for its proposed usage and that the risks involved are very minimal to be noticed by the consumer.

The application of off-label use of medicines are indicated as employment of drugs beyond or outside the evaluation of manufacturer being submitted for FDA approval. As part of FDA review, the regulatory agency examines the documented adverse drug reactions or events that were known during the stages of clinical trials, as well as any possible and potential drug side effects. Assessors depend on this drug information to critically review whether the documented labeling language is suitable for the novel medicine, and if not, what inclusions for labelling must be added. Furthermore, it is crucial that FDA assessors evaluate this data as corroborated and consisted with the matter of fact as evidence from clinical trials to warrant issues of claims that is printed on the drug label.

Theoretical Framework for Tax Evasion

The principle of corporate governance must exhibit efficient company earnings using effective management practice in fulfilling the standards of company value as these determinants are crucial for competent monetary performance, hence, tax reductions should not be the sole focusing line on profit increment. Social responsibility is the center and plays a key role in promoting business communication to execute financial goals and public interests. Competencies involved in corporate management includes not only tax expense adjustments, but also, operational reduction costs such as administrative expenditures, extensive product designs, and expansive customer services. Hence, criminal offenses related to tax evasion are considered as violation towards inclination to tax minimization and up to the extent of net income increment. Moreover, the board director plays an important role in tax expense deceleration for corporate governance facilitation of company value, thus, the size and depth of organizational business system is associated with the mechanism efficiency of corporate governance.

Furthermore, corporate governance significantly affects tax aggressiveness based on its mechanism. Its principle is widely exercised to reduce tax expenses in a proficient means of exhibiting expertise in management, ingenuity in tax handling, and sincerity in economic purpose

resulting to monetary success of the organization while avoiding perpetrating tax evasion. According to tax law, deductibles are allowable items being applied to revenue expenses as expression of strategic tax aggressiveness. Hence, when there is tax reduction in operational costs, return of investment is higher that earnings are apparent for a fixed time duration. Thus, attacking tax aggressiveness strategically to lower down tax expenses may result to unwanted tax avoidance which can taint company image.

Corporate Governance is associated ideally with Corporate Social Responsibility Disclosure (CSR) in terms of stakeholder theory in aiming to improve the ties of stakeholders with public organizations for legitimacy of purpose as shown in Figure 1. Business relationships are not restricted within the context of private firm in which employees, investors, and members of the board must the only people to interact with, rather company reputation must be established public performance and disclosure as part of strategic means of increasing market profit. Hence, CSR must exhibit and meet public expectations as their strategic response to business community [16].

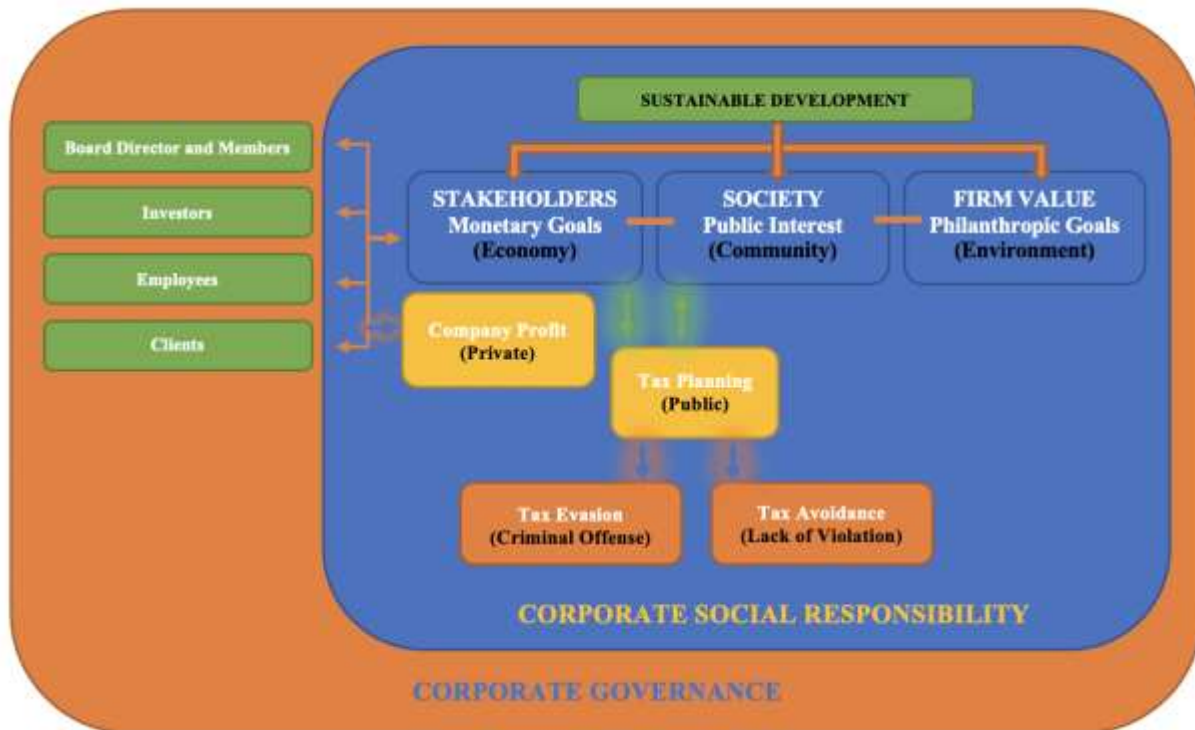


Figure 1: Business Modelling Arbitration Framework

Tax Planning Development and Fraud Separation from Patent Design

There are logical debates in favor and contrary to legal formalism approach and judicial activism arbitration. Addressing gaps on parliamentary system and its accompanied legislative amendments fulfills the formalist duty of exercising the constitutional powers of the government. The public must feel the presence of the justice system for security ties of statutory interpretation, specifically

when values are emphasized for public safety as to gain rightful intuitive outcome. Statutory interpretation is a judicial activism process of developing the right answer based on presumptions, rules, extrinsic materials, and written laws. It is illustrated as a hermeneutical circle since engineering deeper thoughts based on provisional interpretations is inclined for a different and lucid understanding of an innovative reasoning approach. Hence, using a mathematical principle, statutory interpretation [17] is expressed as the following equations to elucidate and show that medical policies must be equivalent with product designs to measure the financial transparency of tax reduction for public interests.

Based on the given statutory interpretation formula:

$$\text{ISSUE} + \text{RULES} = \text{OUTCOME} \quad (1)$$

Hence:

$$\text{RULES} = \frac{\langle \frac{\text{WORDS}}{\text{CONTEXT}} \times \text{PURPOSE} \rangle - \text{MAXIMS} + \text{PRESUMPTIONS}}{\text{EXTRINSIC MATERIALS} = \text{HISTORY} + \text{DEBATES} + \text{DICTIONARIES}} \quad (2)$$

$$\text{EXTRINSIC MATERIALS} = \frac{\langle \frac{\text{WORDS}}{\text{CONTEXT}} \times \text{PURPOSE} \rangle - \text{MAXIMS} + \text{PRESUMPTIONS}}{\text{RULES}} \quad (3)$$

$$\text{EXTRINSIC MATERIALS} = \frac{\langle \frac{\text{WORDS}}{\text{CONTEXT}} \times \text{PURPOSE} \rangle}{\text{RULES}} - \frac{\text{MAXIMS}}{\text{RULES}} + \frac{\text{PRESUMPTIONS}}{\text{RULES}} \quad (4)$$

$$\frac{\text{PRESUMPTIONS}}{\text{RULES}} - \text{EXTRINSIC MATERIALS} = \frac{\text{MAXIMS} - \langle \frac{\text{WORDS}}{\text{CONTEXT}} \times \text{PURPOSE} \rangle}{\text{RULES}} \quad (5)$$

$$\frac{\text{PRESUMPTIONS} - \text{EXTRINSIC MATERIALS}}{\text{RULES}} = \frac{\text{MAXIMS} - \langle \frac{\text{WORDS}}{\text{CONTEXT}} \times \text{PURPOSE} \rangle}{\text{RULES}} \quad (6)$$

$$\frac{\text{PRESUMPTIONS} + \langle \frac{\text{WORDS}}{\text{CONTEXT}} \times \text{PURPOSE} \rangle}{\text{RULES}} = \frac{\text{MAXIMS} + \text{EXTRINSIC MATERIALS}}{\text{RULES}} \quad (7)$$

$$\text{PRESUMPTIONS} + \langle \frac{\text{WORDS}}{\text{CONTEXT}} \times \text{PURPOSE} \rangle = \frac{\text{MAXIMS} + \text{EXTRINSIC MATERIALS}}{\text{RULES}} \quad (8)$$

Equation (9) is shown below to explain development of tax planning. The exhibition of tax aggressiveness is directly proportional with patented product as uppercase shows strong financial evidence of commercial market value, while lowercase symbols illustrate possible sources of tax avoidance as commercial interests are restricted due to limited implementation of medical policies and regulations per country, thus, not a universal rule that can be comparable to another territorial jurisdiction by means of international law.

$$\Lambda + < K \times \beta > = \frac{\tau + \alpha}{\theta} \quad (9)$$

Where:

Λ = Uppercase lambda

β = Uppercase beta

α = Lowercase alpha

θ = Lowercase theta

K = Uppercase kappa

τ = Lowercase tau

Since:

$$\Lambda = \frac{\tau + \alpha}{\beta} \frac{\partial (K)}{\partial (\theta)} \quad (10)$$

However, tax planning, in relation to statutory interpretation, did not exhibit relationship of equal ratio between medical policy and patented product. Equations (11) to (21) show that tax avoidance is generated when medical policies are used and employed in relation to patent products.

$$\text{TAX PLANNING} = \frac{\text{DISCLOSURE} + \text{EPC}}{\text{PRODUCT DESIGN}} \frac{\partial \left(\frac{\text{SUBSTANCE}}{\text{UCC}} \right)}{\partial (\text{TRAVAUX PREPARATOIRES})} \quad (11)$$

Since:

$$\Lambda = \frac{\partial (K)/\beta}{\partial (\theta)/\tau + \alpha} \quad (12)$$

$$\text{TAX PLANNING} = \frac{\partial \left(\frac{\text{SUBSTANCE}}{\text{UCC}} \right) / \text{PRODUCT DESIGN}}{\partial (\text{TRAVAUX PREPARATOIRES}) / \text{DISCLOSURE} + \text{EPC}} \quad (13)$$

Hence:

$$\Lambda = \frac{\partial \ln \beta}{\partial \ln \theta} \quad (14)$$

$$\text{TAX PLANNING} = \frac{\partial \ln \text{PRODUCT DESIGN}}{\partial \ln \text{TRAVAUX PREPARATOIRES}} \quad (15)$$

Since:

$$\text{ISSUE} + \text{RULES} = \text{OUTCOME} \quad (16)$$

$$\text{ISSUE} = \text{RULES} - \text{OUTCOME} \quad (17)$$

Thus:

$$\Delta = \Lambda - X \quad (18)$$

$$\text{POLICY} = \text{TAX PLANNING} - \text{PRODUCT DESIGN} \quad (19)$$

Where:

$X = \text{Uppercase chi}$

$\Delta = \text{Uppercase delta}$

Therefore:

$$\text{ISSUE} + \text{RULES} = \text{OUTCOME} \quad (20)$$

$$\text{TAX PLANNING} = \text{POLICY} + \text{PRODUCT DESIGN} \quad (21)$$

Conclusion

Corporate Governance is a commercial design organized to exhibit the mechanism of sustainable development created to maximize the company earnings while reducing costs of revenue distribution. Stakeholder theory illustrates a tremendous association between corporate governance and disclosure of corporate social responsibility in terms of performing its philanthropic role of making its utmost profit through establishment of business communication relationship with its stakeholders and participating to contribute towards public interests. Taxes are public funds created and maximized by the government sector for public welfare and safety, and its aggressiveness must be exercised by the company for strategic approach of profit increment away from tax avoidance while preventing corruption known as tax evasion and corporate fraud

as criminal offenses involved in healthcare policies involving off-label medicines. UNCITRAL model law is a legal product context intended to make commercial transactions comparable to any other state or country by means of universality of international law concerning patented designs, while travaux preparatoires is a legal approach to medical processes making its policy systems work within a defined and limited jurisdiction. Therefore, engineering statutory interpretation for tax planning provided means of separating revenue distribution between medical policies and regulations, and utilization of patented products, hence, tax avoidance is cleared to separate profits made from medical policy services termed as direct taxation and patented product selling known as manufacturing or indirect taxation.

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