Adaptive Regulation for Industry 4.0

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Abstract— **Industry 4.0 challenges traditional regulatory mechanism. Seeking to protect the weak, the vulnerable and the uninformed, regulation must strike the right balance between sustainability, consumer safety, economic growth and innovation. Traditional regulatory mechanism is seen to be ill-suited in addressing issues raised by emerging technologies. This paper examines some legal issues raised by Industry 4.0 and the move from traditional regulatory mechanism to a more progressive approach of Adaptive Regulation.**

Keywords—adaptive regulation, legal issues, national policy, regulatory sandbox

I. INTRODUCTION

Regulation refers to rules set out in legislations and the process used to monitor them [1]. Regulation seeks to protect the weak, the vulnerable and the uninformed [2]. Sound and effective regulation strikes the right balance between sustainability, consumer safety, economic growth and innovation. The fusion of physical, digital and biological worlds [3][4] and the advancement of technologies brought by Industry 4.0 such as augmented reality [5], big data analytics [6], Internet of Things (IoT) [7][8][9], additive manufacturing [10], big data analytics [11] and smart cities [12] have disrupted manufacturing and business process. Products are now able to direct and optimize autonomously with little human intervention, with interconnectivity with information data [13] While these emerging technologies improves manufacturing process, business models and quality of life, they also raise numerous legal and regulatory concerns, putting government and regulatory authorities with the task of ensuring that law and regulations are in place to maintain a balance between fostering innovation, protecting the consumers, and addresses the potential unforeseen and unintended harm of emerging technologies [14] [3]. It is widely accepted that the biggest problem faced by innovators is regulatory and inflexible rules [14] [15] [16] [17][18]

This paper examines some legal issues raised by Industry 4.0, such as 3D printing and intellectual property, Industry 4.0 and labour laws and big data analytics and informed consent, followed by a discussion on regulatory approach for Industry 4.0.

II. SOME LEGAL ISSUES

Legal issues raised by Industry 4.0 are complex and varied. In New Scientist, a weekly magazine covering news from a scientific viewpoint highlights many innovations with potentially challenging regulatory issues. Some of these are ROBOpilot – a robot pilot [19] Worm robot wiggle its way through arteries in the brain [20] and an Artificial Leg with Sensors [21]

A. 3D Printing and Intellectual Property

There been many discussions about the interface between additive manufacturing or 3D printing with intellectual property (IP) law, particularly pertaining to IP protection and IP ownership. Although the technology has been available for more than 30 years [22], it is the availability of affordable 3D desktop printers into the consumer market that has transformed 3D printing from an expansive manufacturing technique for big corporations within reach of consumers to the domain of 'personal manufacturing' [23] for hobbyist and creative do-it-yourself (DIY) community of home users. Today, a user has ready access to the technology either through online services that print 3D designs or he may choose to `print' the objects at home using 3D desktop printers as what, when and where he needs it. The expanding use of 3D printing at the consumer level causes considerable impact on three main spectrum of IP, i.e. copyrights, trademark and patent. Daly identified identified 4 scenarios in the 3D printing process in which IP may be created (or infringed), i.e. (i) 3D printing design (CAD file) and the software which it interacts, (ii) the substance within the design file, that is the artistic creation to be printed, (iii) the final 3D printed object, and (iv) the online repository where 3D design files are uploaded and shared such as Thingiverse [10]. Nelson questioned to what extent innovators are adequately protected against IP infringement for using 3D printing techniques? [24].

3D printing patents is complex and spans across several technology domains encompassing hardware, software, AI-based automation and material science. 3D printing technology and process can be used seamlessly to copy patents and copyrighted products adding more fuel to the legal quagmire. The case for 3D patents is picking up speed within Asia-pacific region. There are reported 1,381 worldwide patent [25] references related to 3D printing.

Patent provides exclusive rights to the patent owner and allows the owner to stop, prevent anyone from copying, making, using, selling or importing or exporting the patented invention. These exclusive rights grant patent owner exclusive rights to commercialize the invention. 3D printing

can bypass patented invention in many ways. It enables the user of 3D printing to copy and "print" out an object that is protected patent. How does a patent owner stop and prevent such 'copying'? Direct infringement of patent is not difficult to identify. It arises when a person copies and create a similar physical form to the patented invention. However, with mass proliferation of 3D printers and sharing of 3D design files on online repository, policing infringement is not easy.

3D printing also raises concerns relating to copyright. Copyright protects the expression of idea rather than the idea itself. Types of works protected by copyright are literary, musical, artistic, film, sound recording, broadcast and derivative works. Copyright protection is automatic, but certain jurisdiction like Malaysia and Indonesia have a Voluntary Registration System for administrative purposes. In the US, there have been claims of copyright infringement and DMCA take down notices relating to 3D printing design files uploaded on file-sharing platforms such as Thingiverse [10]. In the United Kingdom, CAD files are protected by copyright as literary works (Daly, 2016), while in the European Union as computer program in accordance with the EU Software [26]

Another relevant IP is trademark, which is a sign used to identify the origin of a product or services. Trademark may consist of graphical sign, word, letter, numeral, brand but more recently, non-traditional marks such as scents, smells, colours and shapes. Examples of shape trademarks are KitKat bar and London Black Cab. In the context of 3D printing, trademark issues are likely to arise when a printed object incorporated a 2D trademark, or a 3D representation of a 2D trademarks being printed or a 3D object which replicates a shape trademark [10]. It is not hard to imagine that unethical use of 3D printers would allow patented products, copyrighted documents, and trademark goods to be easily reproduced, printed and duplicated. Enforcement is, nonetheless difficult.

B. Industry 4.0 and Labour Law

Industry 4.0 has a huge impact in the context of labor and work organization, it changes how human work in the workplace [27]. This scenario affects not only the low-skilled workers but also high-skilled works leading an organization. Highly skilled works have to learn to adapt to new environment by utilizing Artificial Intelligence (AI), machine learning and automation technology in their system in order to become useful. This requires significant training and lifelong education [28] [29]

By utilizing technology, companies should aim to improve business, and make it sustainable for future development. In the labor law context, a changed relationship between human and robot challenges the concept of equality and rights. Human adds value to the company by providing their time and skills in exchange for the salary, but now robot could provide better value. In the end, automation of process leads to loss of jobs [17]

C. Big Data and Informed Consent

In a data driven economy, companies rely on data and information to make better decision. The ability to analyze huge amount of data coming from many sources will have a great impact on business sustainability. According to Cisco 2018 Annual Cybersecurity report [30], 31% of organization had experienced cyber-attacks on operational technology, and most of the companies are vulnerable for real-time attacks.

In biomedical research, the continuous collection of data collected from various observational and instrumental sources such as health data, research data and health services/devices raises privacy and ethical issues [11]. Individuals can be identified from anonymized and aggregated data sets derived from smartphones apps, social networks, wearable devices or satellite images, raises concern about their potential misuse [31]. Informed consent according to the Nuremberg and Helsinki Code is complicated in the age of big data, with discussion around Digital Consent in biomedical research are taking place [31].

III. MOVING AWAY FROM TRADITIONAL REGULATION

There is a tendency among regulators to move away from traditional regulation. In the United States, the Deloitte Centre for Government Insights proposed five principles for regulating new technologies: (i) Adaptive Regulation – shift from 'regulate and forget' to a responsive, iterative approach, (ii) Regulatory Sandbox – prototype and test new approaches by creating sandbox and accelerators, (iii) Outcome-based Regulation – focus on result and performance rather than form, (iv) Risk-weight Regulation – move from one size fits all regulation to a data-driven, and (v) Collaborative Regulation – align regulation nationally and internationally by engaging a broader set of players across the ecosystem. [14]. In the United Kingdom, a similar approach was adopted in a recent White Paper [1].

The main impetus for moving away from traditional regulation lies on the belief that traditional regulation is ill-suited to address issues raised by emerging technologies. The pacing problem, i.e. the gap between technological advancement and regulatory mechanism is growing wider [18]. Law and regulation fails to respond in a timely manner to technological advancement. Dated and rigid may lead to regulatory failure and distrust in the system [2].

Traditional regulation process is known to be slow and risk-adverse. In Common Law countries such as Malaysia, regulation involves the following 4 stages [1]:

i) Agenda Setting Phase of Regulation. During this phase, the main preparatory documents are prepared, i.e. Green Paper (consultation documents produced by the government for discussing and debating policy or legislative proposals), White Paper (official policy documents produced by government that set out their proposals for future legislation)

ii) Legislation Phase. This is the decision making and adoption of primary legislation in the form of Acts of Parliament, Subsidiary Legislation. Draft of legislation are prepared by relevant government Ministries in consultation with the Attorney General Chambers. During this process, numerous public consultation and focus group discussion are also made so that feedback from all relevant stakeholders are considered.

iii) Compliance Phase sets out the set of actions and behavior that has to be put in place by targeted stakeholders in order to comply with specific rules.

iv) Enforcement Phase refers to the monitoring of compliance with the rules by national government bodies, specific agencies, local authorities or even private entities.

They perform inspection and may impose sanction for non-compliance.

A. National Policy on Industry 4.0

Malaysia has taken the first critical step of Agenda Setting by launching the National Policy on 4.0 (Industry4WRD) on 31 October 2018 [32]. The Policy will drive Malaysia to becoming a strategic partner for smart manufacturing and related services in Asia Pacific in leading the emergence of Smart Cities, Smart Grides and Smart Services [3] through 5 specific enables FIRST, i.e. Funding, Infrastructure, Regulations, Skills & Talent, and Technology [32]

B. Regulatory Sandbox

Interestingly, in the Industry4WRD, a Regulatory Sandbox Initiative was introduced to enable firms to manage regulatory risks during testing stage [33]. This progressive move, most common in the financial technology industry [34] allows innovators to test and pilot their ideas, services, business models and delivery mechanism in a live controlled environment under the supervision of a monitoring committee. During the 9 months Sandbox period, compliance with regulatory matters are relaxed. Regulatory Sandbox enables innovation and adaptive policy making to accelerate lab-to-market adoption for local technology solutions [35]. It is widely accepted that the biggest problem faced by innovators is regulatory and inflexible rules [15]. Innovation for 5G is currently being tested in the Living Lab of Putrajaya and Cyberjaya.

IV. CONCLUSION

Regulation must be sensible. In regulating emerging technologies, adaptive regulatory approach appears to be more sensible to both innovators and regulators than traditional regulatory mechanism. Regulatory Sandbox Initiative as practiced in Malaysia is attractively supported by aspiring innovators and should be replicated by other emerging economies.

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