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Regulation and innovation under Industry 4.0: Case of medical/healthcare robot, HAL by Cyberdyne

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Regulation and innovation under Industry 4.0: Case of medical/healthcare robot, HAL by Cyberdyne

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Abstract

Innovations using emerging technologies (artificial intelligence, robotics, the internet of things), are said to improve productivity and quality of life. On the other hand, the diffusion of such innovation involves risks and uncertainties regarding safety. Generally, these risks are managed by government by means of regulation. Yet it increasingly falls short on governing emerging technology due to innovations' global connectivity, commercialization and heightened risk & uncertainty. These pose challenges to firms for commercialization because emerging innovations often do not come under the existing product categories nor corresponding regulations. This study answers how product based on emerging technology commercialize, overcoming existing regulatory barriers on safety, using firm strategies and role of standards played, through an examination of the case of Cyberdyne, a successful medical/healthcare robotics company in Japan. Cyberdyne developed and commercialized the world's first product using cybernics in wearable medical/healthcare device. The case illustrates the increasing complexity of safety regulations and role of standards for firms to innovate applying emerging technologies. It concludes with an exploration of policy considerations regarding the regulation in dealing with emerging technologies under Industry 4.0.

JEL CODE:
O33, F23, I18, L15

Keywords:
Regulation, standards, Industry 4.0, emerging technology, robotics, institutional arbitration, rulemaking, Japan

1. Introduction

Innovations using emerging technologies, for example artificial intelligence (AI), robotics, and the internet of things (IoT), are generally considered to improve productivity and quality of life. On the other hand, the diffusion of emerging technologies entails risks and uncertainties regarding aspects on safety. Generally, these risks are managed by government by means of regulation. However, as the rate of change and degree of uncertainty in emerging technologies augmented with global connectivity and commercialization, the prevailing regulatory frameworks at national level may fall short in comprehensive governance of these technologies. In that regard, governments face a substantial challenge: the balancing of risks and societal and economic benefits associated with the adoption of new technologies (Borras and Edlar, 2014).

The rationale for regulation from innovation policy perspective had been given under "market failure" that market forces fail to restrict technologies which are harmful to health, safety and the environment (Nelson, 1959, Arrow 1962, Sharp and Pavitt, 1993). The progress of market liberalization in the last decades had narrowed regulatory policy space substantially, except for above mentioned areas. Further to being insular from liberalization, these are the areas where demand side policy approach is pursued (Edler and Georghiou, 2007; Nemet, 2009) with the assumption that regulatory authority has good understandings on technological potentials in meeting desirable ends.

Today, Industry 4.0 signals a rapid transformation of society via new technologies. In other words, it is expected that new technologies will rapidly replace the current technological "dominant design" and bring about near-future improvements in productivity and welfare. For the realization of such an enhanced society under Industry 4.0, it is considered necessary to have agile regulatory institutions which can flexibly oversee the adoption of emerging technology and innovation (Featherston et al., 2016). This requires a great adjustment of the systems charged with the regulation of safety (in particular health and the environment); because at present much of such systems are still with government under national jurisdiction. Moreover, these regulatory systems are considered to be path dependent, strongly influenced by history and culture, creating "misfit" with rapidly changing technology (Tate, 2001, Consoli and Mina, 2009). In this scenario, there is a need for deeper understandings on the process of commercialization of products based on emerging technology by firms and within that process, the means by which existing regulatory barriers are overcome, and the role played by standards in that process. As this requires a deep understanding of the process involving various actors, this study employ case study method (Yin, 2009) to illustrate a case in detail. This paper examines the case of Cyberdyne, a successful medical/healthcare robotics[1] company, which has developed and commercialized Hybrid Assistive Limb (HAL), wearable robotics with the use of cybernics, a frontier scientific approach, in Japan, where regulatory systems are characterized as highly risk averse (Tate, 2001).

The paper consists of following sections: an introduction; theoretical reviews concerning regulation and innovation and the changes that are arising during the transition towards Industry 4.0; a description of the methodology and research questions; examination of the case of Cyberdyne, followed by discussion and conclusions. The conclusion examines the new role of standards not only as a harmonizing reference point but also as dynamic and innovation friendly rulemaking platform enabling collaborative work towards broader societal goals.

2. Theoretical Discussions

[1] Here in this paper, we apply "medical/healthcare" to indicate an emerging sector that are not clearly defined as stated in MHRA (2016). In Japan, this includes medical and assistive devices.

2.1 Industry 4.0 and challenge to regulatory institutions

Industry 4.0 is considered to have created an innovation paradigm shift (Kodama, 2018). The key feature of Industry 4.0 is its support of the integration of cyber-physical space, effecting a reduction of sectoral and technological boundaries, which in turn enables unprecedented vertical and horizontal connectedness in collaboration, thanks to improved information exchange in support of economic activities (Szalavertz, 2018). Some studies emphasize disruption and radical aspect of innovation (Christiansen, 1997), while others emphasize cumulative aspects in the form of transformations effected by business models (Kodama, 2018). Both Christiansen and Kodama, albeit working from different perspectives, identify serving "non-consumers (of emerging innovation)" and providing unprecedented products or services as noteworthy outcomes of Industry 4.0 (Christiansen, 1997, Kodama, 2018). As these innovations are unprecedented, many of them are currently managed under potentially, "misfit", regulations.

Many studies agree that the current regulatory institutions surrounding Industry 4.0 are failing to accommodate the speed and degree of change (Shapiro and Glicksman, 2002). Several studies posit that regulatory institutions need to be more adaptive and flexible (Dietz et al., 2003). Others argue that regulations should keep pace with technological adaptation processes through collaboration among firms, institutions and users from very early stages of product development (Marchant et al., 2011). The speed and direction of technological adaptation are said to be highly path-dependent, varying by country (Tate, 2001). Variances in speed of change at different technological and institutional levels could, for strategic reasons, be grounds for institutional arbitration by firms looking overseas for more favourable institutional settings to develop their activities employing new technologies. In fact, this phenomenon was observed in the 1990s in the context of increased internationalization of firm activities, and it is expected to occur more frequently under Industry 4.0 (Hall and Soskis, 2001, Witt and Lewin, 2007).[2]

2.2. Current understandings of regulation and innovation

Regulatory institutions are said to influence both the "rate" (quantity) and "direction" (quality) of innovation, and to be closely associated with distinct stages of industrial and technological cycles, namely, fluid (embryonic), transitional and specific stages (Freeman and Soete, 1997, Utterback and Abernathy, 1975, Klepper, 1997, Anderson and Tushman, 1990). For instance, several types of regulation, applied both horizontally (across sectors) and vertically (within specific sectors)—governing trade competition and consumer protection—affect both the speed and the direction of commercialization of new products and services.

There are well established theoretical discussions of the relationship between regulation and innovation. Arguments against regulation governing innovation consider that regulation deters firms from investing in R&D due to the added cost of compliance with regulations (Eads, 1980, Milmo, 2000), and heightened perception of risk (Mansfield et al., 1971). In addition, it is argued that as regulatory control eliminated firms that were not capable of investing to meet regulations, the innovation "rate" would slow as a result of decreased competition (Davis, 1983). On the other hand, other studies hold that regulation aims to intervene in the market, addressing market failure, for socially desirable ends, (Nelson, 1959, Arrow 1962) and that well-designed regulations would induce firms to adopt social innovations (Rothwell, 1980, 1992) which could support the opening of new market opportunities in response to public needs (Ashford and Heaton, 1983, Gerstenfeld, 1977; Howes, Skea and Whelan, 1997). In fact, well designed goal-oriented regulation, rather than prescriptive regulation, would leave greater scope for innovation aimed at the achievement of societal goals, and would eventually enhance the competitiveness of firms (Porter and van der Linde,

[2] For example, the case where a firm moves some of its activities to more favourable institutional settings, e.g., Nissan relocating its design facilities to California, USA; Deutsche Bank acquiring subsidiaries in Chicago and London; and German pharmaceutical firms opening research labs in the United States (Hall and Soskice, 2001).

1995). These points have been echoed in recently revived discussion of the importance of the demand-side approach in innovation policy. The goal-oriented regulation considers governmental regulatory requirements as an important policy instrument for advancing sustainable and societal agenda (Edler and Georghiou, 2007; Nemet, 2009). Such an approach assumes that the state has a clear image of desirable ends of the potentials of innovation and technology in question (Rothwell and Zegveld, 1981).

The main regulatory areas related to sustainable and societal agenda are health, safety, and the environment (Sharp and Pavitt, 1993). In particular, innovation in health sector is highly regulated at the national level to ensure the safety of potential users/consumers (Consoli and Mina, 2009) even today; thus innovation in that sector is still greatly influenced by regulation (Nelson and Sampat, 2001).

2.3 Increasing role of standards as instruments of regulatory institutions

Standards, one tool of regulatory institutions, play an increasingly dynamic and influential role in the innovation process (Josanoff, 2004, Blind, 2010). Initially used as external points of reference in the assessment of the performance, quality, and physical characteristics of products or services, standards encourage exchange by supporting harmonization and thus promote the implementation of mass production and consumption systems (Hawkins et al., 1995, Blind and Gauch, 2009, BERR, 2008). It creates an ecology which will eventually eliminate the oligopolistic power of firms with elements of technological and market dominance (Steinmeuller, 2016, Tassey, 2017, BERR, 2008). Standards set clear technological or quality-related reference points, so they have been particularly useful for reducing information asymmetry between buyers and suppliers, and hence reducing transaction costs (Blind and Gauch, 2009). The presence of transparent reference points for quality offered clear guidance to catch-up countries working to upgrade their production capability. The frequent entry of firms would reduce product cost, in turn benefiting the consumers (Henson and Jaffee, 2007, Henson and Humphrey 2009, Iizuka, 2009). Standards also apply to the coordination and governance of globally disintegrated segments of interdependent activities along value chains (Hawkins et al., 2017, Henson and Humphrey, 2009). Such changes took place in the 1990s due to globalization, and in that context, the use of standards gradually increased, as can be seen from the increase in adoption of ISO standards since the 1990s, in terms of both areas of coverage and number of entities obtaining certificates (ISO, 2017).

With the emergence of digital technology, standards are playing a new role: serving as a platform for the coordination of firm activities (Blind, 2016, Steinmueller, 2016, Hawkins et al., 2017). Furthermore, that platform can support firm interaction with customers, buyers and sellers beyond traditional sector boundaries, hierarchies and national borders. In sum, the functions of standards have extended from the original emphasis on 1) interfaces and compatibility; 2) minimum quality/safety; 3) decreased variety; and 4) production description information (Swann 2000:12), to interoperability, a dynamic ecology platform connecting different segments of industrial activity (Steinmueller, 2016).

Table 1: General effects of standards on the innovation process

Type of standard	Positive effects	Negative effects
Compatibility/ interface	● Provides network externalities ● Avoids lock-in of old technologies ● Increases variety of systems products ● Makes global value chains more efficient	● Allows monopolistic power ● Locks in old technologies if network externalities are too strong
Minimum quality/safety	● Corrects adverse selection ● Reduces transaction costs by creating trust ● Prevents negative externalities	● Generates regulatory capture by raising rivals' costs
Harmonization/ variety reduction	● Allows economies of scale and reduces unit cost ● Builds critical mass in emerging technologies, products and services	● Reduces choices ● Generates market concentration ● Makes premature selections
Information	● Provides codified knowledge ● Reduces transaction costs, information asymmetry	● Enables regulatory capture
Interoperability/ Platform	● Enables collaboration ● Supports consumer participation ● Creates dynamic ecosystems for new business	● Leads to platform dominance ● Lacks regulatory control of consumer participation

Source: Based on Blind (2010), Hawkins et al. (2017), Steinmueller (2016)

Table 1 presents the positive and negative effects of standards on the innovation process. For instance, standards for minimum quality and safety can alert consumers to inferior products/services with lower transaction cost, thus minimizing negative externalities of inferior products. Similarly, variety reduction and information functions generate gains for firms via economies of scale. While the above examples are valid, if standards allowed existing technology/products to exert excessive dominance via regulatory capture, there would be a risk of locking in consumers or reducing selection choices at a premature stage of product development; either of those outcomes would leave society with sub-optimal choices of technology (e.g., a fossil fuel-based technological infrastructure). Under Industry 4.0, interoperability creates a common ecology where numerous firms, beyond sectoral and national boundaries, can interact to create a new business on the same platform. This, without clear regulatory institutions, could lead to platform dominance by one powerful owner (e.g. GAFA[3]). These examples point to a need for international coordination of regulatory institutions as well as governance built around transparent systems.

In general, standards can be categorized into three types: first, de-facto standards whose specifications are determined by market competition (e.g. Schilling, 2002, Suarez, 2004); second, *de jure* standards whose specifications are agreed by formal committee based institutions with stakeholder participants (e.g. ISO) (Jain 2012; Narayanan and Chen, 2012); and third, government-based standards (e.g. Buthe and Mattli, 2011), which are *de jure* standards devised and monitored by government within the nation's borders (Wiegmann et al.,2017). The third type is closer to regulation in the traditional sense, while the first and second are increasingly being employed in response to globalization of firm activities (Dan, forthcoming). Much studies were done on market competition based de-facto standards to understand firm strategy, associating with obtaining the "dominant design" and platforms (Gallagher, 2012; den Hartigh et al., 2016) with examples of competing innovations (blue-ray vs HD-DVD vs DVD, IBM vs Apple). Similarly, studies on committee based standards are also being conducted to understand its impacts on innovation, firms' strategic decision and knowledge diffusion (Manders et al., 2016), however, less attentions have been given to regulatory aspects of standards that ensure levels of safety in use of emerging technologies.

[3] The acronym GAFA refers to the big 4 tech companies: Google, Amazon.com, Facebook and Apple Inc..

2.4 Role of standards and regulation in new era

Regulatory institutions play different roles along the product life cycle (PLC) (Klepper,1997, Utterback and Abernathy, 1975, Anderson and Tushman, 1990): first, they create open and transparent regulatory platforms to reduce risks related to the use of emerging technologies while at the same time ensuring minimum standards; second, they create products and improve their quality in open access form so that diverse participants can be included and compete; and third, they ensure positive externalities by means of good governance (Edler and Georghiou, 2007).

Owing to the globalization of firm activities and interconnectivity through digital means, interoperability via standards is important for connecting actors beyond national and sectoral boundaries. In fact, standardization is increasingly considered to mediate and catalyse the innovation (Featherston et al., 2016). Nevertheless, in selective areas, including health and the environment, regulations still play dominant role as such, coordination of national regulators with other international regulatory institutions is becoming ever more necessary, to insure that individual countries do not lose out in terms of competitiveness or in terms of the potential social benefits gained from innovation with new technologies. These regulations are often highly path dependent and idiosyncratic hence coordination poses a big challenge (Tate, 2001).

Parallel to the above, it has been observed that, with the growing global interdependence of knowledge in the form of networks, the value of innovation has shifted from knowledge creation to knowledge diffusion (Blind, 2016). In this new context, standards, rather than national regulatory bodies, can provide more space for network-based coordination of technology, facilitating participation by multiple stakeholders in voluntary consensus creation (Steinmeuller, 2016)—while international standards institutions such as the International Organization for Standardization (ISO) serve as a dynamic interface (Blind, 2010, 2012, Steinmueller, 2016, Tassey, 2017). In particular, this institutional setting enables the creation of interfaces for a variety of related product producers and actors to interact beyond conventional boundaries. Moreover, under the institutions such as ISO, standards setting processes are open and transparent, offering a flexible form of technological governance (Borras and Edler, 2014, Wiegmann et al., 2017).

While the critical role of standards in the innovation process is expanding to that of interoperating platform, many safety standards are still controlled by government in a path dependent manner due to a sense of risk, reflecting cultural preferences (Blind, 2016, Blind and Gauch, 2009, Consoli and Mina, 2009). This can be one of the major barriers to commercialization for firms, particularly firms competing at the technological frontier of the rapidly changing global market.

2.5 Firm behaviour under misaligned institutions

Nowadays, firms are operating in an increasingly competitive global market characterized by rapid technological change. Firms must adapt to that rapidly changing global environment if they are to gain market access. Nevertheless, firm performance is still strongly influenced by the institutional settings of the localities where the firm operates. In “Varieties of Capitalism," Hall and Soskice (2001) maintain that firms engage in distinctive behaviours due to differences between the institutions where the firms are embedded, since firm actions are motivated not only by economic efficiency, but also by institutional advantage. In other words, some elements of institutional conditions help particular industries to grow because those elements reinforce certain actions. Conversely, certain institutional conditions prevent firms from growing because they constitute barriers. Following that logic, it is considered that firms operating under global competition tend to engage in institutional arbitration, i.e. they “...may shift particular activities to other nations in order to secure the advantages that the institutional framework of their political economies offer for pursuing those activities” (Hall and Soskice, 2001:57).

In the international business literature, institutional arbitration has been the subject of study towards an understanding of firms' outward off-shore investment (OFDI) as an additional explanatory factor complementing the existing OLI (ownership, location, and internationalization advantages) model (Dunning, 1979). Such studies maintain that firms are motivated to engage in OFDI as a strategic response to the need to escape their home countries' institutional rigidity and inflexibility, which are misaligned with firm needs such as stringency in intellectual property rights and environmental standards (Witt and Lewin, 2007). Hall and Soskis (2001) claim that such cases of institutional arbitration are more prevalent in countries where societal coordination is a prerequisite for institutional change (Witt and Lewin, 2007).

3. Research Questions, Methodology, and Case Background

3.1 Research Questions

The literature review in the previous section revealed following understandings and gaps. First, regulations and standards influence the innovation process; however, few literature refers to its relationship under industry 4.0, where technological progress in terms of speed and directions is increasingly uncertain while connectivity and global activity of firm pose new challenges for its governance. Second, although policy space had diminished with regards to national regulation in last decades of liberalization, selected areas where "market failure" occurs—namely health, safety and environmental areas—are still well regulated at national level (Mina and Consli, 2009) even under industry 4.0. Third, due to increasing firms' global operation, path-dependent and idiosyncratic regulatory institutions are acting as innovation barrier for firms operating under Industry 4.0. They require new understandings on safety regulations and innovation as well as firm strategies in dealing with such regulations.

Based on above understandings, this paper addresses following questions:

- How can a product/service based on emerging technology commercialize globally, overcoming existing regulatory barriers on safety?
- What kind of strategy can firm take to overcome regulatory barriers on safety?
- What role do standards play in above process?

This paper examines the case of Cyberdyne, which successfully commercialized medical/healthcare robotics applying emerging technology in Japan, where regulatory institutions governing the medical area are rigid and inflexible (Tate, 2001, Ikeda, 2016). Cybernics technology applied for robotics is at the embryonic stage (Utterback and Abernathy, 1975, Anderson and Tushman, 1990), extending beyond conventional sectoral boundaries. Against all odds, the firm managed to commercialize the product, by first strategically using institutional arbitration and then building regulatory institutions at the international level in collaboration with the public sector using international standards, ISO. The following sections identify the mechanism by which Cyberdyne overcame existing regulatory barriers and achieved commercialization, and examine the role played by standards in that process.

3.2 Methodology

This study applied qualitative case study methodology, which is suitable for identifying with rich insights from the case of Cyberdyne in its process of overcoming regulatory barriers (Yin, 2009). Several in-depth interviews were conducted with related stakeholders representing distinct areas: government, standardization body, review administration, certification body, insurance company, hospital/user, related firm, academics, think tank, and consulting company (see Appendix 1) during the period June 2015 to July 2016. The interviews were conducted using a semi-structured interview approach in order to allow for open-ended responses. Government policy documents and company reports were used to triangulate information obtained from interviews.

4. Case Study

4.1 About Hybrid Assistive Limb (HAL) and Cyberdyne

This case study depicts the strategic steps taken by the company, Cyberdyne, to introduce Hybrid Assistive Limb (HAL), the world's first cyborg-type medical/healthcare robot, into the market. HAL is a robot that can supplement, expand or improve on the user's physical capabilities, particularly people who have physical mobility difficulties as a result of car accidents, illness or aging. HAL supports and improves the user's physical mobility, monitoring the user's centre of gravity to infer intended body movement and direction of movement. Sensors attached to the skin pick up bio-potential signals generated in the brain immediately after the user attempts muscle movement, and operates motors incorporated in the user's joints. The technology is based on cybernics, a frontier research area whose products have no antecedent (Cyberdyne, 2017a). Cyberdyne Inc. was established in Japan as a university start-up company to introduce HAL to the market. The firm grew rapidly[4] after its establishment in 2004.[5] The current sales destination is Japan, extending to overseas markets such as the EU, the US, Saudi Arabia and South-east Asia (Cyberdyne, 2019b).

Leading to a detailed discussion of the process of commercialization of HAL, the following section summarizes characteristics of emerging medical/healthcare robots in Japan. Here, medical device is defined as "a product, such as an instrument, machine, implant or in vitro reagent that is intended for use in the diagnosis, prevention and treatment of diseases or other medical conditions."[6]. Assistive device is defined as instrument for personal care for disable or otherwise unable to care for themselves in managing bodily functions.[7]

4.2. Emergence of medical/healthcare robot sector in Japan

4.2.1 Ambiguous boundaries of emerging products and technology

Medical/healthcare robotics is an emerging strategic sector with high growth potential. Due to the sector's embryonic status, its product boundary is not clearly defined and new products can be classified under multiple categories such as medical devices and assistive devices (amongst many possible categorizations). Such ambiguous product definitions lead to ambiguity in legal status when the products are heading for commercialization. However, once a product is assigned to a specific category, the regulatory institutions influence the trajectory and the rate of innovation (MHRA, 2016). Safety standards, in particular, strongly influence the framing of a technology in the early stages of development (Delemarle, 2017). In other words, the choice of regulatory institution can influence the developmental pathway of embryonic products and technology because regulations will ultimately shape the product.

4.2.2 Product diversity

[4] This is a spinoff company of the University of Tsukuba, under the direction of Prof. Sankai. The company was established in 2004 and was listed on the High-Growth and Emerging Stock Market in 2014. The scale of consolidated net sales is about 1.7 billion dollars (exchange rate: 1 US dollar was equivalent to 109 Japanese yen as of 10 June 2018)), increasing by 30% within a few years and still growing. By March 2019, 17% of total sales are from overseas.

[5] It received the Japan Venture Grand Prize and the Prime Minister's Prize in 2017.

[6] Medical robot application of ISO are published in 2019. These are: IEC 80601-2- 77:2019, Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment; and IEC 80601-2- 78:2019, Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation.

[7] ISO defines personal care robot to include: "mobile servant robot, physical assistant robot and person carrier robot. These robots typically perform tasks to improve the quality of life of intended users, irrespective of age or capability." (ISO 13482, 2014)

The application of robotics in the field of healthcare is diverse. These robotic technologies include home automation, ambient intelligence, ubiquitous network societies, and assistive technology (Lau et al., 2009). Figure 1 presents the diversity of medical/healthcare robots, classified according to two characteristics: mechanical features (low to high tech) and intelligence (low to high). Conventional assistive technologies are located low on the intelligence scale; such devices can also be AI controlled humanoid-type, seen in the top right-hand corner of the figure. The diversity of product type again confirms the view that health robotics is still at an early, fluid stage of the product life cycle, where dominant design is not yet clearly defined and expanding product diversity makes existing regulations increasingly irrelevant.

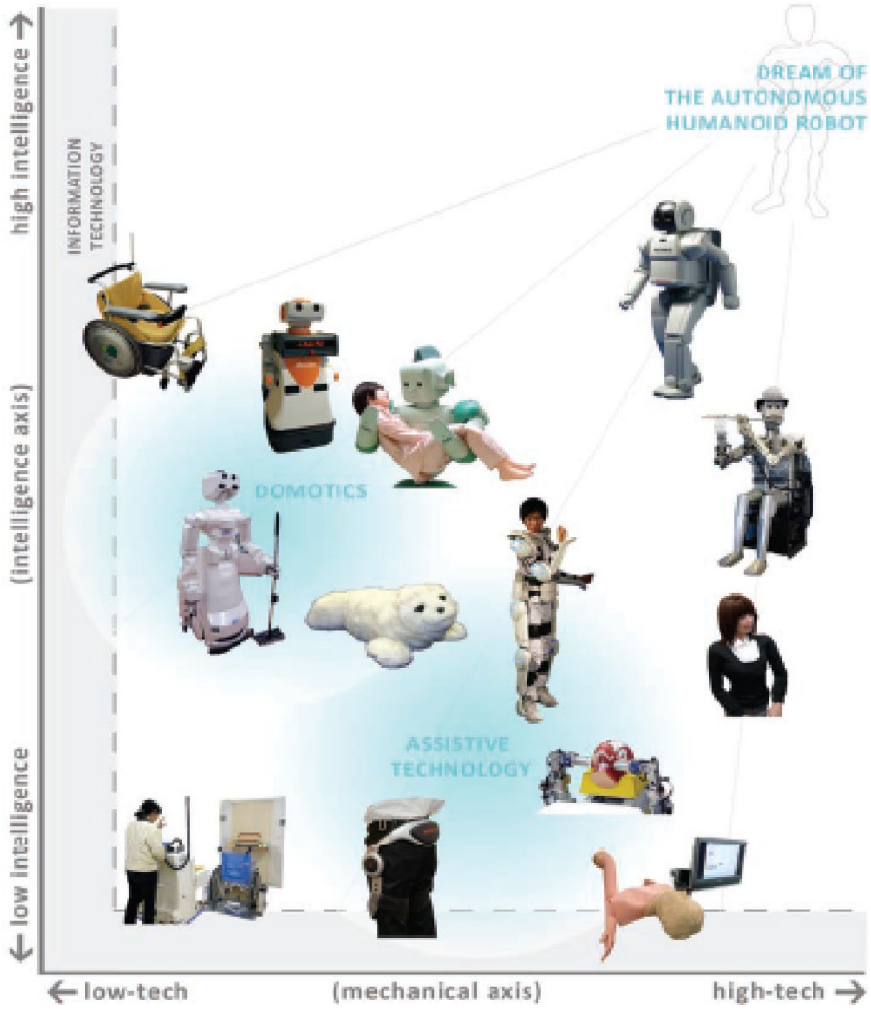

Figure1: Diversity of the emerging medical/healthcare/personal care robotics sector
Source: Lau et al. (2009)

4.3 Cyberdyne's strategy for commercialization of HAL

Cyberdyne wanted to commercialize HAL with public medical insurance coverage but for HAL, to be covered by public insurance in Japan, it had to comply with rigorous medical safety regulation with clinical trials. These posed three challenges to Cyberdyne. First, procedural challenge of collecting clinical trial data, second, time lag in commercialization; and third, creating precedent example to get government approval. In order to overcome above regulatory obstacles, Cyberdyne adopted the strategy of institutional arbitration in various forms (Hall and Soskice, 2001).

4.3.1 Product level institutional arbitration

Cyberdyne initially took advantage of the ambiguous nature of Japanese product classification. In Japan, HAL could be categorized as a medical device or as an assistive device. Each comes under different regulatory institutions.

In Japan, if a new device is categorized as a medical device, it falls under the jurisdiction of the state managed Ministry of Health, Labour and Welfare (MHLW) under the Pharmaceutical and Medical Device Act, and thus requires state-managed approval from the MHLW, based on a long scientific review at the Pharmaceuticals and Medical Devices Agency (PMDA). PMDA basically assesses the safety of products based on previously existing similar medical products, so it is almost impossible for a product like HAL, with no precedent product, to obtain a quick approval. On the other hand, if a device is categorized as an assistive device, it is not subject to review by any sector-specific regulatory authority. For assistive devices, firms usually make use of voluntary standards, such as the Japan Industrial Standard (JIS) T 9201 (safety of manually-propelled wheelchairs) and acquire certification by a private certification body to guarantee reliable business transactions, public procurement and personal purchases (Government, personal communication, May 11st, 2016). And Japan's standardization system is governed under the Japan Industrial Standardization Act (JIS-Act) by the Ministry of Economy, Trade and Industry (METI). Due to the relative ease of obtaining third-party certification under such voluntary standards, this category is often used as a loophole for commercialization of new healthcare devices, establishing a track record in the market (Asahi Research Centre, 2016).

Given the above institutional environment, Cyberdyne first opted to commercialize HAL as an assistive device.[8] Categorization as an assistive device in Japan usually requires proof of safety, certified by a third party on voluntary terms. A typical product must comply with generic standards for devices; however, for a product like HAL, there was no precedent product that could serve as a reference. Hence, Cyberdyne had to create its own proof of safety, to be certified by a third party. This means that Cyberdyne had to collect and analyse data, formulate safety standards, and establish testing methods (Weng, Sugahara and Hashimoto, 2015). This was an unprecedented undertaking for a start-up company like Cyberdyne.

In order to accumulate evidence for proof of safety, Cyberdyne sought the support of the Robot Safety Centre, a public institution located in the Tsukuba International Strategic Zone (*Tokku*). The centre was jointly established by METI and the New Energy and Industrial Technology Development Organization (NEDO), Japan's largest publicly managed organization promoting research and development and deployment of new technologies. This centre facilitated the necessary testing and collected proof of safety data. Eventually, in response to a number of such demands, METI and NEDO jointly launched the Project for Practical Application of Service Robots and in 2009 established the Robot Safety Centre, an experimentation laboratory for the verification of safety of new technology, and an international robot certification organization. This project was in place until 2013; in February 2013 HAL was certified by the Japan Quality Assurance Organization (JQA), and could then be commercialized as an assistive device. A set of evidence created during this period became basis for the evidence presented to establish ISO standards on robotics safety. In fact, the certification published by JQA is equivalent to the Draft ISO 13482 (Draft International Standard: DIS) that was published in February 2014.

4.3.2 Country level institutional arbitration

When Cyberdyne was beginning its effort to get approval for HAL, there was little chance of obtaining a quick approval from MHLW, because there are no precedent product similar to HAL. Cyberdyne would have to wait until another company (outside or large) began commercialization of

[8] Here selection of category is by self-declaration (Asahi Research Center, 2016).

a similar product in Japan. To overcome that barrier, Cyberdyne commercialized HAL as a medical device in Germany, certified to ISO13485 (Medical devices -- Quality management systems -- Requirements for regulatory purposes), which is one of harmonized standards, necessary for declaration of conformity to essential principles of EU's Medical Device Directive (MDD) [9] (93/42/EEC), Directive for In Vitro Diagnostic Medical devices (98/79/EC) and Directive for Active Implantable Medical Devices (90/385/EEC) by TÜV Rheinland, a private certification body. The clinical trial is also required for Germany; however, unlike in Japan, this comes after the approval (Ikeda and Iizuka, forthcoming). This demonstrates that Cyberdyne took advantage of differences in regulatory system to commercialize the product quickly.

Although Japan and Germany have mandatory regulatory frameworks for medical devices, set by their governmental bodies, they differ in terms of the culture of management of the regulatory environment. It can be said that Japanese regulatory institutions are more paternalistic and dependent on state authority, whereas German institutions value the concept of self-responsibility of each actor (Hospital/doctor, personal communication, March 22nd, 2016). Moreover, the system in Germany is more decentralized, and includes numerous private certification bodies, which enables a quicker certification process. At the same time, German firms are ready to take on a proactive role in the rulemaking process, preparing proof of safety for new medical/healthcare devices. In fact, some large global firms have their own regulatory affairs division to formulate global business strategies and at times to actively lobby over regulatory issues. On the other hand, in Japan, there has been a clear separation of roles: the government establishes regulations based on prior experience, and firms follow those rules (German-based certification organization, personal communication, April 28th, 2016).

In Germany, governed by the Medical Device Directive (MDD), a new health device like HAL is categorized solely as a medical device strictly by its function regardless of its risk levels on safety. The review of medical devices is always certified by a notified body (NB), a private institution, hence the procedure is codified, open and transparent. As a result, the time required for approval of new medical devices in Germany became substantially less than in Japan (PMDA, 2018)[10]. In August 2013, HAL was certified as a medical device by TÜV Rheinland (a private German certification body), and was subsequently commercialized in Germany and Europe.

4.3.3 Regulatory institutional arbitration: Creating ISO standards on safety requirements for Robots and Robotic devices (ISO 13482)

Parallel to getting HAL certified as a medical device in Germany, Cyberdyne engaged in the creation of ISO standards for safety of personal care robots, including healthcare robots, since 2009. According to the CEO of Cyberdyne, standards for emerging technology are imperative, especially "...because the world has not seen anything like these robots before, there is no legislation in place to protect users. International standards are therefore crucial for creating and showing confidence to users in these products" (ISO, 2014). Moreover, developing these new standards can guarantee Cyberdyne an early-mover advantage with global recognition of its brand (Robotics company, personal communication, April 18th, 2016). Furthermore, "...the standard levels the playing field for new companies wishing to enter the emerging industry" (ISO, 2014) because ISO sets clear general/minimum safety requirements for health robotics while leaving ample space for exploration

[9] The MDD published by the EC shows manufacturers the "essential requirements" and/or "performance levels" and "Harmonized Standards" to which the products must conform. The MDD is transposed into the German Medical Devices Act, called the Medizinproduktegesetz (MPG—"Medical Devices Act")(Ikeda, 2016)

[10] Approval of medical device in the US requires 1.9 year less than that of Japan. There is no statistic directly comparing EU and Japan but generally the time required for obtaining certification in EU is even less than in the US. (https://www.pmda.go.jp/files000222042.pdf.)

towards innovation, avoiding a lock-in effect at the early stage of product development (Standardization expert/professor, personal communication, March 23rd, 2016).

To create ISO standards of safety requirements for personal care robots, Technical committee (TC) 184/SC2/WG7, a team of more than 50 nominated experts and observers from 12 countries, was created under the ISO in 2011. In the process of negotiating the standards, Japan took the initiative and proposed measures for risk assessment at the systemic level, ranging from the product conceptualization stage to design management and development. Japan's proposal had an advantage: Cyberdyne was already developing personal care robotics and was experimenting with prototype safety measures at the Robot Safety Centre with evidence for proof of safety. Japan's proposal to the ISO was supported by METI, NEDO, and Cyberdyne among others. Furthermore, certification of safety standards by Japan Quality Assurance Organization (JQA) helped to spearhead negotiation process (Nabeshima, 2016). In reality, Cyberdyne did not wait until the publication of ISO13482 to commercialize. Cyberdyne commercialized HAL with the certification by JQA in as early as 2013 when safety standards certified by JQA became equivalent to Draft International Standards (DIS) of ISO 13482[11]. This is because that they were confident that DIS is going to be approved (Government, personal communication, May 11st, 2016). In fact, after the series of discussions among stakeholders, ISO adopted Japan's proposal and issued ISO 13482, standardization titled, "Robots and robotic devices -- Safety requirements for personal care robots," officially published in February 2014.

4.3.4 Getting national approval from PMDM

In November 2015, HAL was approved as a medical device by MHLW in line with Japanese safety regulations. Soon after getting approval from PMDM, Cyberdyne filed application to be covered by National Health Insurance. This was granted in September, 2016 (Cyberdyne, 2016)[12]. Cyberdyne then began commercialize HAL with public insurance coverage in Japan (Cyberdyne, 2016). Cyberdyne did not attempt to directly influence PMDM to change its regulatory institutions that would have been difficult for a start-up company; rather, it managed to overcome the legislative impasse by first, commercialized as assistive device; second, creating a track record in Germany and third, participating in the creation of ISO 13482, preceding a regulatory institution by arbitrating different levels of regulatory institutions –international and national—to maintain its pioneer position in cybernics-based medical/healthcare robotics.

[11] The steps for establishing International Standards (IS) are as follows: 1) A proposal or the standards is approved by relevant subcommittee(SC) or technical committee (TC); 2)Working group (WG) of experts is set up by SC/TC for the preparation of draft; 3) WG creates working draft (WD) for internal revision; 4) WD becomes committee draft (CD); 5) with positive votes of approval by WG, CD becomes final committee draft (FCD); 6) FCD becomes draft International Standards (DIS) after revision on technical contents; 7) DIS is submitted to national bodies for voting and comments within the period of 5 months for approval to be the final draft International Standards (FDIS); 8) FDIS becomes IS if a two-thirds majority of the members of the TC/SC are in favor and not more than one-quarter of the total number of votes negative (ISO, 2007). It is possible that with a strong technical leadership, it is a matter of time for DIS to become ISO.

[12] Different from medical devices, the coverage of National Long-term Care Insurance was not extended to cover HAL as assistive devices. The discussion of extending National Long-term Care Insurance to Robotics for assistive purposes only recently started in order to lessen the burden of care takers and scarcity in numbers (Cyberdyne, 2019).

Table 2: Process of institutional arbitration: The case of Cyberdyne's HAL

Date of approval	Arbitration between Chosen / Avoided		Place/ certified body	Approved as/for Market in	Type of regulatory institutions used
February 2013*	Assistive device	Medical device	Japan Quality Assurance Organization (JQA), Japan	Assistive device, in Japan	Committee-based standard agreed at national level
Same as above	Draft ISO(13482)** (ISO 13482 was published in February, 2014)	Gov't based regulation	Same as above	Same as above	Committee-based standard agreed at international level
August2013	Germany ISO13485 harmonized to EU's Medical Device Directive (MDD) (93/42/EEC) etc. ***.	Japan Pharmaceutical and Medical Device Act	TÜV, Germany	Medical device, in Germany and EU	Gov't based regulation/standard agreed at Germany and EU
November 2015			MHLW, Japan	Medical device, in Japan	Gov't based regulation agreed at national level

Source: Authors, based on Ikeda (2016)

Note: *The version certified by JQA became equivalent to Draft International Standards (DIS) 13482.

** ISO 13482 was published in February, 2014. However, as Cyberdyne did not wait and commercialized with DIS.

*** In addition to MDD, the Directive for in Vitro Diagnostic Medical devices (98/79/EC) and Directive for Active Implantable Medical Devices (90/385/EEC). (TUV website https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/medical-devices-and-ivd/quality-management-and-quality-control-for-medical-devices/iso-13485-quality-management-system-for-medical-devices) accessed Sept. 21, 2019.

As mentioned above, due to HAL's novelty, there was no precedent device to facilitate approval for commercialization in Japan under MHLW, and Cyberdyne was situated in Japan, where regulatory institutions were ill-equipped to accommodate the entry of new products into the market, especially when medical safety issues were a concern. As a result, being a start-up firm, Cyberdyne was obliged to exercise its expertise to become involved with regulatory institutions, strategically arbitrating various institutional environments and using existing domestic and global public support. Cyberdyne engaged in arbitration at several levels: (1) product domain (medical device and assistive device); (2) country (medical devices in Germany and Japan); and (3) different levels and types of regulatory institutions (International standards vs National regulation) (Table 2). In sum, Cyberdyne used institutional arbitration effectively to get ultimate approval from MHLW.

Standardization is considered beneficial to all involved parties, facilitating market entry and competition, and serving as a stepping stone to expansion of the market to global scale (Hawkins et al., 2017). As ISO offers an open and transparent platform for negotiation, its standards can allow related product actors to experiment with emerging technologies while negotiating within the context of overarching societal goals. In other words, these may enable better balance between productivity, welfare and risk caused from uncertainties. It also has signalling power to the authorities which are slow to change in the era when institutional arbitration will accelerate.

5. Policy implications for regulatory institutions for innovation with emerging technology

Due to HAL's novelty, its quick commercialization was difficult in Japan. As a result, Cyberdyne was obliged to take strong initiatives, first strategically arbitrating various institutional environments, and later taking on a rule-making role using existing both domestic and global institutional support.

This case demonstrates that standards support the following: (1) provision of an interoperative platform at the systemic level extending, beyond national and sectoral boundaries; (2) experimentation at the design phase of technology development to facilitate smooth commercialization of products and services; (3) facilitation of interaction among a diverse set of stakeholders; and (4) collaboration between public and private sectors towards early stage commercialization of products while safeguarding public interests. The following sections discuss broader issues in light of the findings of the case study.

5.1 Standards as system level platform

"Robots and robotic devices -- Safety requirements for personal care robots" (ISO 13482) was established to set an overarching safety standard. The standard is not limited to a single device but serves as a reference for the general safety of a device related to health robotics systems.

Systems level standardization is increasingly common globally. According to ISO Survey (2017), the use of ISO management system standards (in terms of number of valid certifications) continues to rise; in 2016 it increased by 8% across all industry sectors. New management system standards are not product- or sector-specific; they are broader, covering inter-related areas of business to facilitate integrated solutions. For example, standards for "Sustainable cities and communities" (ISO/TC 268) was set up through the participation of more than 50 countries around the world. Similarly, ISO/IEC 27001 and ISO/IEC 27002, information security management system standards to help organizations address security and privacy issues, are now being set up. In sum, standards are increasingly covering issues at the systems level (e.g. safety, sustainability, IT security) rather at product and technology levels.

In Japan, the systems approach is considered important for the following reasons: (1) more value is created by systems than by individual devices (c.f. "think systems not technologies") (Aikman, 2017, WEF, 2018); (2) strategic importance is attached to achieve a dominant platform through supporting holders of leading technology, so as to maintain industrial competitiveness (METI, 2016); and (3) faster, more open, participatory markets based de facto standards are seen as the next generation of regulatory institutions, along with existing committee based *de jure* (ISO/IEC/ITU) standards. Based on above thinking, the Japanese Industrial Standardization Act, which was revised in 2018 (and came into force in July, 2019), covers management, service and social systems. Those regulatory institutions are expected to adapt to technological change via private-public collaboration in the context of international standardization (METI, 2018)[13].

5.2 Early stage experimentation: Regulatory mechanisms for testing new technology

As seen in the example of Cyberdyne, several other high tech firms are using institutional arbitration to speed up commercialization via experimentation, and to overcome legislative barriers. For emerging technologies, the experimentation phase is crucial, as some products and services are unprecedented in the market, or even disruptive. Hence, firms require institutional facilities for experimentation. Some countries strategically respond to such needs by providing venues for experimentation. For instance, Singapore and the United Arab Emirates are providing demonstration test sites for development of flying cars, autonomous vehicles that can take off and land vertically.

[13] This case study predates that reform.

Moreover, Singapore is working to become a prime testing location for identifying means by which developed nations can best manage disruptive technologies such as advanced robotics and AI. Furthermore, to attract multinational firms working on autonomous vehicles, Singapore created one of the most permissive regulatory regimes for the testing of driverless cars, even opening up public roads for experimentation.

Similarly, developing countries are strategically inviting high tech start-up firms and offering them a lightly regulated environment to exploit the potential for social impacts generated by emerging technologies. Those firms are attracted by the opportunity to experiment around the use of their products, and to accumulate experience while responding to societal challenges. For example, a Silicon Valley start-up, Zipline,[14] has been using its drones to deliver life-saving blood in Rwanda within 30 minutes of receiving emergency calls, using advanced logistic services connected to satellite systems. Also, the Japanese start-up drone company CLUE, Inc. has collaborated with the Ghana Highways Authority (GHPA) to provide inspection services for major infrastructural works in Ghana. These firms arbitrate institutionally to operate in countries where social needs overshadow risk, which allows for more flexible regulatory institutions.

The Japanese government provided restricted zones for experimentation with new initiatives by firms employing new technologies. For instance, the National Strategic Special Zone in the Kansai region promotes deregulation of the medical field, in instances such as the effective use of iPS cells (induced pluripotent stem cells). Other examples are agricultural reforms in Niigata City and Yabu City, deregulation of employment to support business formation in Fukuoka City, and deregulation supporting the promotion of international tourism in Okinawa. These Special Zones (*Tokku*) are areas deregulated to support experimentation towards new innovation and verification of effects and issues for the establishment of appropriate regulatory regimes prior to scaling up.

Furthermore, to allow progress beyond special zone work, a regulatory sandbox is implemented in Japan to promote and experiment with new technology such as fintech (financial technology) and the sharing economy. This approach balances innovation and regulations by providing firms with limited-time use of "free space" for testing products, services and business models based on emerging technology, without conventional regulatory requirements, to enable commercialization while government collects the data and experience needed to frame appropriate regulations (FCA, 2017). Regulatory sandboxes are seen as more flexible than special zones, since they take into account the uncertainty of technological transformation.

The above examples confirm that under Industry 4.0, faster, more agile regulatory institutions are needed to keep pace with rapid technological change by enabling experimentation (WEF, 2018, Marchant et al., 2011). The examples also indicate that the important factors of competitiveness are shifting from competitive products to competitive regulatory systems that enable effective governance of emerging technologies, speeding up commercialization while ensuring public well-being. With rapid changes in technology, experimentation in the early stages of the product cycle is critical for both firms and government. Under those circumstances, standards would provide an open, flexible arena for experimentation towards more collaborative shaping of regulatory institutions.

5.3 Platform for interaction among a diverse set of stakeholders

[14] Zipline is also operating in Ghana from May, 2018. The company was participating the U.S. Department of Transportation's Unmanned Aircraft Systems Integration Pilot Programme, out of 149 applicants. (Bright, 2019) https://techcrunch.com/2019/04/24/drone-delivery-startup-zipline-launches-uav-medical-programme-in-ghana/ Accessed June 15, 2019.

"Robots and robotic devices – Safety requirements for personal care robots" (ISO 13482) was established through collaborative efforts involving more than 50 nominated experts and observers from 12 countries, under ISO. Standards can bring diverse stakeholders together to work towards one purpose. This is important because frontier technologies (e.g. medical/health robotics) require the collaboration of persons with diverse technological backgrounds, so as to make optimum use of their potential.

For instance, in Japan, medical/healthcare robotics development brought together diverse actors: automotive companies (e.g. Toyota, Honda); hospital management electronics corporations (e.g. Panasonic), university start-ups (e.g. Cyberdyne), telecommunication companies (e.g. NTT Docomo), home construction companies (e.g. Daiwa House). Since these firms do not fall under any existing sectoral category, there has been no venue where all of these actors can interact and discuss effective regulatory institutions related to their new products. Standardization related entities, in particular committee-based standards, can provide a common space where a diverse set of stakeholders can shape an effective regulatory regime, to ensure that technological potential is not limited to catering to current consumers and markets. In the case of international standards, the standardization process can involve an even broader spectrum of stakeholders, coming from beyond national and sectoral boundaries.

5.4 Collaboration between private and public sector

Globalization and technological connectivity of products and services diminish the policy space of national regulatory institutions. This means that with the widespread implementation of standards, government will increasingly need collaboration with the private sector to identify the appropriate regulatory measures and institutions. In that context, one crucial policy area for government attention is the provision of a sound ecosystem to encourage commercialization and standardization. For example, in the case of Cyberdyne the number of private certification bodies in Germany was about five times that in Japan (German-based certification body, personal communication, April 28th, 2016). Such institutional differences in certification bodies would certainly restrict the speed with which standardization spread among firms. Hence providing support in an innovation-friendly ecosystem would become an increasingly important task for the government.

On the other hand, firms will also need to participate in standard setting processes to ensure their future competitiveness under Industry 4.0. Participation in negotiations for international standards requires human resources with a wide range of skills: technical knowledge, negotiation capability, communication and familiarity with regulatory frameworks. Considering that the whole process would normally last 2-3 years, such engagement would be difficult for firms, especially start-ups, due to shortages of human resources and finances. These firms would have a strong need for public support in capacity building and financial resources.

It can be seen from the above discussion that an open and transparent standards setting process requires closer collaboration between private and public sectors. The government is responsible for providing a sound institutional environment—by providing flexible regulatory institutions, research and experimentation labs, and supportive measures to enable firms to participate in standard setting activities—so that firms can swiftly commercialize their products and rapidly create positive network externalities at an early phase of the product life cycle. The government should also work in a collaborative manner to ensure public safety within its own overarching social agenda.

6. Conclusion

The case of Cyberdyne demonstrates that firms can overcome the barrier of regulatory institutions through institutional arbitration and by participating in the establishment of international standards,

eventually achieving the commercialization of their product. The case illustrates the increasing need for reflexive and agile regulatory institutions governing emerging technologies and the strategic use of international standards. In other words, there is a demand for an open, transparent, interactive and dynamic platform where multiple stakeholders can participate in experimentation, negotiation and interaction to ensure that innovative potentials are not being restricted at the emergent phase, while at the same time ensuring user safety. Furthermore, findings of this case study indicate that favourable institutional infrastructure and policy support are needed at the national level to ensure that competitiveness and prosperity will arise from innovation.

Standards offer a neutral platform for experimentation, interaction, negotiation and collaboration among a diverse set of stakeholders, at both the domestic and international levels. With rapid technological progress characterized by broad connectivity beyond boundaries, innovation entails increased risk and uncertainty. It is expected that standards will be even more crucial as a dynamic interoperative platform where diverse stakeholders can interact, negotiate and engage in societal agenda-setting via rulemaking activities under Industry4.0.

This paper, by examining the case of Cyberdyne, demonstrate commercialization process of disruptive product--HAL-- overcoming existing safety regulations, utilizing institutional arbitration strategy and standardization. The case demonstrates potential of standards playing a critical role in industry 4.0, especially commercializing and governing the products and services that are disruptive. The authors are aware that there are limitations inherent in drawing a generic understanding from a single case. Further exploration of similar studies (of cases such as self-driving vehicle, flying car and artificial intelligence) are needed to confirm the observations presented here.

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Appendix: list of interview/personal communication
Questioned items
-Current status on healthcare/medical robotics and medical device
-Specific definition of healthcare/medical robotics and medical device
-Certification schemes and main stakeholders
-Philosophy and Concept behind the Certification
-Balancing commercialization of frontier technology and regulatory mechanism
-Potential policy supports as well as direction of future private and public collaborations

Stakeholders	Data when interview was conducted
Government	Person1: February 16, 2016 Person2: May 11, 2016
Standardization body	March 9, 10, 2016 (lecture)
Review administration	March 15, 2016
Certification Body	April 28, 2016
Insurance company	June 30, 2016
Robotics company	April 18, 2016
Hospital/User	March 22, 2016
Academia	March 23, 2016
Think tank Consulting company	May 12, 2016

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