Keynote speech: Innovations for clinical research

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Introduction

Thank you for inviting me to this symposium. I was wondering why it was me chosen to give the keynote speech. In fact, I received an email from my good friend Professor de Zeeuw of Groningen a few months ago. He was supposed to come to Tokyo for this occasion, and he asked me if I could spare him some time, and I said yes I would. And then a few days ago, I received an email from him telling me that his mother became ill, and he couldn't come to this meeting. So I'm very sorry but you have me as a replacement for today's programme. Thus, Honorable Minister, your Excellency, Mr. Ambassador, guest and friends, it is my privilege to speak to you on this occasion.

Innovation in the era of globalization

Now what do I talk about clinical research in this time of globalization? In recent years, everybody is talking about 'innovation' – EU, US, Japan – as if a word innovation is becoming almost like a 'mantra'. But if you look at innovation (this is taken from Handbook of Innovation by Richard Nelson and his associate), it's clear that innovation in scholarly articles in the field of social science rapidly rose since maybe 1994, 1995. So you had to wonder why. Why innovation now?

Japan's problems

Japan is facing a major challenge. More than 20 percent of the Japanese population are 65 years or older, quite an aged society. It took Japan for 26 years to reach the population demography where those aged 65 years or older captured 7% to 14% of the population, an ageing to an aged society. But this speed will be broken fairly rapidly by many rapidly industrializing countries, eg, China, Chile and many other industrialized countries. Declining birthrate and longer life span leading to an aging population, and this is one of major issues in Japan and elsewhere.

Asia's growing economies

Over the last 15 years, Asia has been rapidly growing. In fact, Japan had a tripartite negotiations since early 1990s with the US and EU for the international harmonization of clinical trials and drug approval systems. But this topic is now passé. Because of the rapidly growing economies in Asia with global economy and interconnected world via widening Internet connectivity, pharmaceuticals business models like other businesses have been changing. Moreover, other pressing issues such as climate change, energy, natural resources, poverty, global health and other issues have become more important as a global agenda.

The world in the age of globalization

If you look at the world, you will see further development of knowledge-based network society;

accelerating progress of globalization which will never go back; explosive population growth which, over the last hundred years, rose from 1.6 billion to 6.6 billion now, and which is projected to reach 9 billion by year 2050; climate change and environmental degradation which was clearly represented by the Nobel Peace Prize this year going to IPCC and Al Gore which raises public awareness on climate change.

Innovation and world issues

So what are the issues? One is the increasing threat in sustainability of humankind and the widening gap between rich and poor which is visibly seen and perceived by many in the world. Therefore, many countries try to invest in science and technology. Many pharmaceutical and biotech-venture companies invest in innovative medicine and health. But why innovation? Whatever you invest in research and technology, but you have to deliver. You have to create values, either economic or social value, that is what innovation is all about. Otherwise, the global community will demand what happens to the investments by the government or public money or through the market.

I would like to explain why globalization affects investments in innovation. What is the paradigm of new economic growth and industrial structure and socio-economic paradigm? This is the first time in the history of mankind, whatever the technological revolution and economic growth engine may be, and there are a lot of constraints. This is the first time we're faced with such constraints. And we have to face these issues.

One is climate change and climate crisis, and other include environmental deterioration and pollution, water and food and natural resources. There are a lot of insecurities in businesses because of these factors. Another factor is the perception by the greater general public of why we have those huge disparities of those how have and those how have not; the fact which raise the sense of inequity and unfairness felt by many, thus frustration and often violence.

The UN Millennium Summit

The question is – Is our society sustainable? That has become a common agenda. In fact, in 2000 the United Nations launched the Millennium Development Goals to tackle this question. Then in 2005, a group of experts led by Jeffrey Sachs at Columbia University, developed the Millennium Development Goals which is composed of the following 8 specific goals with each be halved the values of year 2000 by year 2015;

1. Eradicate extreme poverty and hunger
2. Achieve universal primary education
3. Promote gender equality and empower women
4. Reduce child mortality
5. Improve mental health
6. Combat HIV/AIDS, malaria and other diseases
7. Ensure environmental sustainability
8. Develop a global partnership for development

The Japanese government, as other major governments, made a significant contribution to these initiatives. Japan has funded 8 millennium village projects in Africa in the UN Millennium Summit of 2005. Utilizing this Japanese commitment, there are now 15 ongoing millennium village programmes in 12 countries in Africa. And I was told that these projects have been very successful – empowering children and women and improving economy and food production and self independence. With such background of the Millennium Summit, now all countries are asked to reach these 8 goals. The aim is to reduce these goals by half or 50 percent of the numbers in year 2000 by year 2015. Next year, we

will be at the mid-point of 2015, the target year. So all the countries will be asked to show what they have done to halve these millennium goals.

But in this globalize world, we need a new paradigm of industrial economy and societal reform, which is represented with such keywords like personalization, collaboration, innovation, global and human capital. Up until some 10 years ago, we often talk about "international." But now we are not using the word "international" that often, but rather we often hear the word "global." Why is that? Also, quite often, we talk about "human resource development." But over the last 10 years or so, we hear more often the word "human capital." Why is that? We also see a lot of movement of civil society, and social entrepreneurship, and also "think locally and act globally" has become a buzz word. Up until some 10 years ago, we were talking about "think globally, act locally." Not anymore. Sometimes new value could be created by "think locally, act globally." Wikinomics is another keyword for the global economy. Why?

The age of progress – industrial revolution

About 200 years ago, there was a major revolution which changed our society and industry and economic growth and the way we live and think. That is called "industrial revolution" which began in the United Kingdom in late 18th century with the invention of steam engine by James Watt. This period of economic growth primarily driven by this invention lasted for about 50 years according to an excellent analysis by Dr. Freeman, an economist in the University of Sussex. His theory indicates that since the industrial revolution, there has been a significant technological invention considered to be the "big bang" which led to significant changes in the economic growth and societal structure. The industrial revolution also broadened the range of trade and import because of boats and a number of waterways built in UK and Europe. Also during this period, we saw the replacement of horsepower and manpower or manual labor with machines.

The "age of industrial revolution" was overtaken in around 1930 by the "age of steam and railways" which saw the development of steam-powered ships and railways which are much faster than boats so the previous economic growth pattern was easily taken over. This period lasted about 50 years or so. The expansion of this big bang and technological advances during this period would change the societal way we live. It also changed employment and promoted urbanization.

But then again this period was quickly replaced by the "age of steel, electricity and heavy engineering" which was launched by Bessemar in UK, then spread out to Europe and US (Andrew Carnegie). By using steel, many big structures like bridges and buildings started to appear and flourish. The construction of those structures became possible only by using steel and heavy engineering. That was the paradigm and the engine of economic growth by that time. That obviously expanded and changed the way of communication as well as the way we commute and work, and also social infrastructure.

The paradigm we used to live in and recognize in the 20th century began, characterized by what we see now, i.e. oil, automobile and mass production. These all started in 1908, which according to their analysis marked the production of T-Ford. T-Ford is the hallmark of mass production. Automobiles were already available at that time but not in mass production line. So automobiles, like tractors and others, are very expensive. But T-Ford provided with much more affordable automobile through a new combination of available technology during that time. If you have been to a slaughterhouse, you will see a lot of cows lined up. At the

end of this line, they are knocked down by electric shock, and the carcasses of the cows are then hang on a long-chain, and this chain carries these cows to another line where workers cut up the cows. That's the production line. The T-Ford production is a combination of these processes, each part of the automobile is placed on a line, which is systematically assembled together one by one, creating this automobile. That was an innovation, ie, creation of new economic and social values. It's a new combination of technologies. That's what innovation is almost all about.

We are now in the "age of information technology and telecommunication." But we will discuss this later.

In the "age of automobile and mass production," around that time at the beginning of 20th century, new oil reserves were discovered in US and the Middle East by UK. Oil was very cheap then. This paradigm provided us (in addition to the social infrastructure, which was built on the previous paradigm) mass production, mass market and consumerism, very convenient lifestyle that we enjoy very much. Therefore, trade became international, standardization of products began, energy intensive mass production (which was mostly oil-based but which was then very cheap). Synthetic new materials appeared, dyes and plastics, medicines. Some of medicines, eg, digitalis, aspirin, have been analyzed, discovered and synthesized during this time.

This period also saw the emergence of specialized functions and hierarchy of regions and centralization, metropolitan centers and sub-urbanization. That's how we lives and worked for almost over 100 years now, and that has identified national power because that is where the economic power of a nation lies. Therefore, international agreements, confrontation and that kind of mass production and economic power led innovation – from research and development into the marketplace. The typical big pharmaceutical companies carry this model. And such industries represent national power strength, thus 'bilateral, national and international' were the common language we use. Human resource development fit into such economic and social structures.

Japan and its social values

But this paradigm suited well to the Japanese. Japan closed herself to the outside world some 400 years ago. Up to maybe 150 years ago perhaps the Dutch were the only foreigners who are allowed to come and trade with Japan through Dejima, Nagasaki. And that was the foundation of modern medicine brought into Japan. The Japanese tend to think about belonging to a certain clan and seniority-base social hierarchy has been a norm to most. When you work for Mitsubishi or Yamanouchi (which has just merged with Fujisawa to form Astellas), you stay there for life without never moving to other company or Mura. Also, the concept of seniority is commonly accepted by the Japanese since the Edo era. So this structure fit very nicely to this industrial structure which drove the economic growth since Meiji restoration through post-war Japan. The structure of the Japanese society, its social values as well as Japanese mind-set and cultural value, fit into this style of industrial and social paradigm.

Modernization and the environment

How about the current paradigm which really changed the world and innovation became a mantra since mid-1990s? This is the "age of information and telecommunications." Professor C Freeman tells us why the industrial paradigm since 1908 of T-Ford ended in 1974. The reason is that towards the end of 1973, the Yom Kippur War in the Middle East began, and oil price began to rise. So oil is not

a cheap commodity anymore.

Also, you may remember, in 1962, Rachel Carson, published a book on this paradigm, entitled "Silent Spring" which is about industrial pollution of environment. This is a clear warning to this industrial growth. The 1972, Club of Rome published a book entitled "Limits to Growth." That's again a warning to this industrial paradigm.

Age of information technology

According to the analysis by Freeman, year 1971 is a beginning of this new "age of information" which brought about a major revolutionary technology since the industrial revolution – that is the "Internet." 1971 is the year Intel was founded. Since then, computer chip became faster, better, and cheaper, based on what is known as the Moore's Law. This law is still valid at present.

However, during the 1980s, perhaps some of us began to use table-top, the laptop computers thru 1980s, but we are not really connected. Do you remember how it was 15 years ago? Are you using emails then? How about mobile phones? Not then, I'm sure. These things happened only during the last 10 years. Just think about it – the power of Internet, the mobile phone, emails - that changed your behavior, your way of thinking, how you work. In fact, the worldwide web (www) on which you are familiar, was introduced in 1992. That's just one year after the end of the Cold War. The end of the Cold War means there appeared one great market – 2-3 billion people added to the market-driven economy. That is a great opportunity. Then it was followed by the internet. And all of a sudden the world became connected.

When you saw the worldwide web, you may have thought it is sometime very difficult to understand. But many smart kids, computer hackers, came into play, creating Netscape, Yahoo, Amazon. All of these companies were founded around 1994. Bill Gates, who began MicroSoft in mid 80s followed with Windows 95, and then came Linux, an open source. Google was set up by two graduate students in 1998. Now, they are more than a hundred billion dollars worth of company. They wanted offer free web access at no charge to the consumer of well analyzed data-sets. Almost everybody use mobile phone now. Ten years ago, we used telephone card. Now there's the email, iPod, iTune and iPhone. iPod was produced by Apple of Steve Jobs. But actually Apple was not producing any part of this iPod. They are just presenting a concept which everybody liked. So it's not a manufacturing innovation. This is a competition of something new. Play Station 3 by Sony, was beaten by WII. So you have to think about what kind of things customer wants. Or what people want and need, and the processes are well open, like Wikipedia. This era became more demand-driven innovation, not necessarily market size or market, and you could pursue collections of niches where the demands are specific.

Now, if you see the economic impact of this paradigm, there's always a history of new technology – a big bang, and there's also speculative investment and always a bubble burst. It has happened for ICT in the year 2000. Do you remember the year 2000? That's when we had the so-called ICT bubble crash. During that time, Nasdaq stock prices went very low within a few months. Before this, in 1995 to 2000, in five years time, IT-producing industry contributed to a significant portion of economic productivity growth, but not IT-using industries. But after the IT bubble crash what happened? IT producing industry shrunk and became a smaller portion of the productivity growth of economy. And now the growing economy is now driven primarily on how you use IT technology into your business or emergence of new business models utilizing ICTT.

So the age of information technology is information intensity, and chip drives that, paving the way for decentralized and integration network structure. Therefore, many people of the world see your company, thus about 80 percent of corporate value is comprised of intangible asset. How much your company is contributing not only to your finance and the debts and quality of products, but how much you contribute to nurturing your own personnel, how much you contribute to global warming, CO2 emission, how much to environment and also contribution to your society.

Diverse markets are target of new economy, and heterogeneity and diversity became a very important element of innovation, that is, creation of new economic and social values. Further, segmentation as well as instant decision and communication are the key for global competition.

Innovation 25 – innovation in a global world

We now have what we call innovation in a global world. Wherever you are – in pharma industry or electronics industry – whatever you are, invest on human capital nurturing both 'out of box' thinking, and entrepreneurship. That is the message in Innovation 25. Heterogeneity is an asset and not an obstacle in this global world. Recognize on your strength, be it corporate, individual, or community. Focus on the core competence, and recognize the weakness and then collaborate to create best mix to deliver values and fast. The speed is the essence of the competition of this new world. That is the key of this message.

When we hear the strength of the Netherlands in clinical research and the strength of Japanese medical health sciences, distinction and collaboration will be complementary. Where are your best global partners? – that you have to know.

Therefore again I tell you, the keyword in global world (and this is a different paradigm) – Personalization – who you are in this flat world, and who you want to collaborate with. You want to know the best partner. And that leads to innovation; deliver value to the society, wherever the target sectors of the society maybe. International and global; human resource and civil society; think locally, but act globally.

Biotechnology and its potential

In this age of globalization, biotechnology suddenly has a big potential. Life sciences, like molecular and genetic mechanism or diseases, diagnosis, innovative drug, organ transplantation, stem cell and everything now is possible.

Agriculture in Netherlands is very strong and the country is one of the major agricultural exporters in the world today. In the agriculture, food production, farming and plant biology and others are very important. Also environment, clean and green and revitalizing natural environs and clean energy, and biofuel is a possibility. So we're going to invest your biotechnology knowledge. Capital investment in the environment has become important. For example in Silicon Valley, clean energy has become a powerful target of venture capital investment. This year 2007 alone, about 4 billion dollars of venture capital was invested in clean energy in Silicon Valley. Last year only 1 billion was invested. Two years ago, only half a billion. That's a lot of expectations and many may fail. Just for comparison, 4 billion dollars was invested in ICT in Silicon Valley, 1995.

With that I would like to end my speech. You could find more about me and my thoughts and writings, simply type my name and 'Google.' Thank you very much.